

THERAVANCE INC  
Form 10-Q  
August 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 June 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 July 24, 2013 was 107,238,079.



Table of Contents

**TABLE OF CONTENTS**

**PART I FINANCIAL INFORMATION**

<u>Item 1. Financial Statements</u>	
<u>Condensed Consolidated Balance Sheets as of June 30, 2013 and December 31, 2012</u>	3
<u>Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2013 and 2012</u>	4
<u>Condensed Consolidated Statements of Comprehensive Income (Loss) for the three and six months ended June 30, 2013 and 2012</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2013 and 2012</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	21
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	33
<u>Item 4. Controls and Procedures</u>	33
<b><u>PART II. OTHER INFORMATION</u></b>	
<u>Item 1A. Risk Factors</u>	34
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	49
<u>Item 6. Exhibits</u>	50
<u>Signatures</u>	51

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

(In thousands, except per share data)

	June 30, 2013 (Unaudited)	December 31, 2012 *
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 199,243	\$ 94,849
Short-term investments	243,768	153,640
Receivables from collaborative arrangements (including amounts from a related party of \$337 at June 30, 2013 and \$123 at December 31, 2012)	2,233	1,064
Notes receivable, current	140	100
Prepaid expenses and other current assets	3,609	3,966
Inventories	8,240	7,514
Total current assets	457,233	261,133
Marketable securities	90,314	95,194
Restricted cash	833	833
Property and equipment, net	8,952	9,154
Intangible asset	30,000	
Other assets, non-current	7,372	2,268
Total assets	\$ 594,704	\$ 368,582
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 4,834	\$ 5,377
Accrued personnel-related expenses	6,001	9,002
Accrued clinical and development expenses	9,222	6,550
Other accrued liabilities	4,703	2,072
Accrued interest on convertible subordinated notes	4,912	2,372
Deferred revenue, current	8,974	4,593
Total current liabilities	38,646	29,966
Convertible subordinated notes	459,960	172,500
Deferred rent	4,698	5,074
Deferred revenue, non-current	5,753	6,014
Commitments and contingencies (Notes 3, 8 and 10)		
Stockholders equity:		
Common stock, \$0.01 par value; authorized: 200,000 shares; outstanding: 100,766 at June 30, 2013 and 98,379 at December 31, 2012	1,008	984
Additional paid-in capital	1,492,945	1,488,447
Accumulated other comprehensive income (loss)	(15)	99

Edgar Filing: THERAVANCE INC - Form 10-Q

Accumulated deficit	(1,408,291)	(1,334,502)
Total stockholders' equity	85,647	155,028
Total liabilities and stockholders' equity	\$ 594,704	\$ 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 June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Revenue from collaborative arrangements (including amounts from a related party: three months 2013-\$1,322; 2012-\$1,430; six months 2013-\$2,644; 2012-\$2,860)	\$ 1,327	\$ 1,430	\$ 2,671	\$ 128,529
Operating expenses:				
Research and development	31,739	29,549	58,155	62,751
General and administrative	11,374	7,590	19,689	15,447
Total operating expenses	43,113	37,139	77,844	78,198
Income (loss) from operations	(41,786)	(35,709)	(75,173)	50,331
Other income (expense), net	8,192		6,770	
Interest income	189	90	375	145
Interest expense	(3,024)	(1,501)	(5,761)	(3,002)
Net income (loss)	\$ (36,429)	\$ (37,120)	\$ (73,789)	\$ 47,474
Net income (loss) per share:				
Basic net income (loss) per share	\$ (0.37)	\$ (0.42)	\$ (0.76)	\$ 0.55
Diluted net income (loss) per share	\$ (0.37)	\$ (0.42)	\$ (0.76)	\$ 0.53
Shares used to compute basic earnings per share	97,603	89,169	96,964	86,379
Shares used to compute diluted earnings per share	97,603	89,169	96,964	95,044

*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 June 30,</b>		<b>Six Months Ended June 30,</b>		
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>	
Net income (loss)	\$ (36,429)	\$ (37,120)	\$ (73,789)	\$ 47,474	
<b>Other comprehensive loss:</b>					
Net unrealized loss on available-for-sale securities, net of tax	(107)	(100)	(114)	(125)	
Comprehensive income (loss)	\$ (36,536)	\$ (37,220)	\$ (73,903)	\$ 47,349	

*See accompanying notes to condensed consolidated financial statements.*



Table of Contents

## THERAVANCE, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2013	2012
<b>Cash flows from operating activities</b>		
Net income (loss)	\$ (73,789)	\$ 47,474
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	3,890	3,572
Stock-based compensation	13,257	12,214
Gain on marketable securities	(3)	(2)
Change in capped-call option valuation	1,422	
Changes in operating assets and liabilities:		
Receivables from collaborative arrangements	(1,169)	129
Prepaid expenses and other current assets	357	127
Inventories	(2,533)	(4,299)
Accounts payable	1,026	(81)
Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued liabilities	2,941	(5,956)
Accrued interest on convertible subordinated notes	2,540	
Deferred rent	(376)	(344)
Deferred revenue	4,120	(128,530)
Net cash used in operating activities	(48,317)	(75,696)
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(1,431)	(1,762)
Purchases of available-for-sale securities	(211,797)	(185,456)
Maturities of available-for-sale securities	106,983	153,921
Sales of available-for-sale securities	17,600	8,520
Intangible asset	(30,000)	
Release of restricted cash		60
Payments received on notes receivable	100	
Net cash used in investing activities	(118,545)	(24,717)
<b>Cash flows from financing activities</b>		
Payments on note payable and capital lease		(69)
Proceeds from issuances of common stock, net	26,433	216,800
Payment for capped calls	(36,800)	
Proceeds from issuances of convertible subordinated notes, net	281,623	
Net cash provided by financing activities	271,256	216,731
Net increase in cash and cash equivalents	104,394	116,318
Cash and cash equivalents at beginning of period	94,849	44,778
Cash and cash equivalents at end of period	\$ 199,243	\$ 161,096

*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. On August 1, 2013, the company to be spun-off, Theravance Biopharma, Inc., filed a preliminary Form 10 with the SEC. Theravance will focus on managing all development and commercial responsibilities under the LABA collaboration with Glaxo Group Limited 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 its stockholders. Theravance Biopharma, Inc. will be a biopharmaceutical company

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

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. Revenue has been generated primarily from the Company's collaborative arrangements with GSK, located in the United Kingdom and Astellas Pharma Inc. (Astellas) (through January 6, 2012), located in Japan. All long-lived assets, which were comprised of property and equipment, are maintained in the United States.

Table of Contents**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 raw materials and work-in-process 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 stated at the lower of cost or market value. If information becomes available that suggests the inventories may not be realizable, the Company may be required to expense a portion or all of the previously capitalized inventories. Inventories are summarized as follows:

(in thousands)	June 30, 2013	December 31, 2012
Raw materials	\$ 3,531	\$ 5,668
Work-in-process	4,709	1,846
Total inventory	\$ 8,240	\$ 7,514

**Intangible Assets**

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

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. 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 on an annual basis or when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. The recoverability of finite 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 sales and long-term projected sales in the corresponding market.

Table of Contents

**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 used 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 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 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 expense is comprised of third party expenses related to

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

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 six months ended June 30, 2013, and the three months ended June 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 six months ended June 30, 2012, diluted net income per share was computed by dividing net income plus interest on dilutive convertible subordinated notes 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 dilutive convertible notes (see Note 7) and other dilutive securities.

Dilutive potential common shares were calculated based on the if-converted method. Under the if-converted method, when computing the dilutive effect of convertible notes, net income is adjusted to add back the amount of interest and debt issuance costs recognized in the period and the denominator is adjusted to add back the number of shares that would be issued if the convertible notes were settled in shares.



Table of Contents

Dilutive potential common shares also 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:

(in thousands, except for per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
<b>Numerator:</b>				
Net income (loss) basic	\$ (36,429)	\$ (37,120)	\$ (73,789)	\$ 47,474
Add: interest and issuance costs related to convertible notes				3,002
Net income (loss) diluted	(36,429)	(37,120)	(73,789)	50,476
<b>Denominator:</b>				
Weighted-average common shares outstanding	100,316	91,809	99,677	89,019
Less: unvested RSAs	(2,713)	(2,640)	(2,713)	(2,640)
Weighted-average common shares outstanding basic	97,603	89,169	96,964	86,379
Dilutive effect of equity incentive plans and ESPP				1,997
Dilutive effect of convertible subordinated notes				6,668
Weighted-average common shares outstanding and dilutive potential common shares - diluted	97,603	89,169	96,964	95,044

*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 June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Shares issuable under equity incentive plans and ESPP	3,848	6,348	4,519	3,801
Shares issuable upon the conversion of convertible subordinated notes	17,015	6,668	15,643	
Total anti-dilutive securities	20,863	13,016	20,162	3,801

**3. COLLABORATIVE ARRANGEMENTS**

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

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

(in thousands)	Three months Ended June 30,		Six months Ended June 30,	
	2013	2012	2013	2012
Collaborative arrangements				
GSK Collaborative arrangement	\$ 1,322	\$ 1,430	\$ 2,644	\$ 2,860
Astellas Collaborative arrangement				125,669
Other Collaborative arrangements	5		27	
<b>Total Revenue</b>	<b>\$ 1,327</b>	<b>\$ 1,430</b>	<b>\$ 2,671</b>	<b>\$ 128,529</b>

Table of Contents

**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), an investigational 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 milestone payments to GSK which could total as much as \$190.0 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, the Company estimates up to \$110.0 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. As a result of this approval the Company paid GSK a \$30.0 million registrational milestone fee in the second quarter of 2013. These milestone payments to GSK will be capitalized as finite-lived intangible assets and amortized over their estimated useful life.

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.

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

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.

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

During the first six months of 2013, the Company issued and Glaxo Group Limited, an affiliate of GSK, purchased 310,090 shares of the Company's common stock, for an aggregate purchase price of approximately \$9.3 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 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			Six Months Ended				
	2013	June 30, 2012	2012	2013	June 30, 2012	2012		
LABA collaboration	\$	907	\$	907	\$	1,814	\$	1,814
Strategic alliance MABA program license		415		523		830		1,046
Total revenue	\$	1,322	\$	1,430	\$	2,644	\$	2,860

Under the GSK collaborative arrangements, the Company is reimbursed for R&D expenses. These reimbursements have been reflected as a reduction of R&D expense. Reduction of R&D expense was \$165,000 for the three months and \$337,000 for the six months ended June 30, 2013. Reduction of R&D expense was \$31,000 for the three months and \$77,000 for the six months ended June 30, 2012.

**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 will receive funding for research and be 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 is twelve months, with optional extensions by mutual agreement, and Merck can terminate the agreement at any time.

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 as the license, which includes rights to the Company's underlying technologies for its therapeutic candidates, has standalone value because the rights conveyed 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 based 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 is being 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.

Table of Contents

Revenue recognized from Merck under the collaboration agreement was \$5,000 for the three months and \$10,000 for the six months ended June 30, 2013. Amounts reflected as a reduction of research and development expense were \$1.8 million for the three months and \$3.3 million for the six months ended June 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 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 and the Company based the best estimate of selling price for the license based 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 based the best estimate of selling price of the committee participation based on the nature and timing of the services to be performed. The Company determined the best estimate of selling price for the manufacturing supply based on a fully burdened cost to purchase and transfer the underlying API and finished goods from 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 June 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 to be received related to supply of API and finished goods supply, which will be manufactured by the Company's third party contract manufacturers, will be subject to a separate arrangement and 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.



Table of Contents

*TD-1792*

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 based on its fully burdened cost to manufacture the underlying API.

The \$1.1 million upfront payment for the TD-1792 agreement was allocated to the license and committee participation 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. 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.

Reduction of R&D expense was \$50,000 for the three months and \$86,000 for the six months ended June 30, 2013.

*VIBATIV®*

Under the VIBATIV® Development and Commercialization Agreement, the significant deliverables were determined to be the license and 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 and the Company based the best estimate of selling price for the license based 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.

**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

**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 US, 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%.

Reduction of R&D expense was \$0.2 million for the three months and \$0.5 million for the six months ended June 30, 2013.

**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**

Securities classified as available-for-sale at June 30, 2013 and December 31, 2012 are summarized below. Estimated fair value is based on quoted market prices for these or similar investments that were based on prices obtained from a commercial pricing service:

June 30, 2013

Edgar Filing: THERAVANCE INC - Form 10-Q

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. government securities	\$ 27,101	\$ 15	\$	\$ 27,116
U.S. government agencies	157,932	48	(51)	157,929
U.S. corporate notes	104,098	15	(42)	104,071
U.S. commercial paper	44,967			44,967
Money market funds	192,694			192,694
Total	\$ 526,792	\$ 78	\$ (93)	\$ 526,777

(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

Table of Contents

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

(in thousands)	June 31, 2013		December 31, 2012	
Cash and cash equivalents	\$	191,862	\$	86,298
Short-term investments		243,768		153,640
Long-term marketable securities		90,314		95,194
Restricted cash		833		833
Total	\$	526,777	\$	335,965

At June 30, 2013, all of the marketable securities have contractual maturities within two years and the average duration of marketable securities was approximately nine 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 June 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.

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 Inputs* Quoted prices for identical instruments in active markets.

*Level 2 Inputs* 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 Inputs* 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:

Edgar Filing: THERAVANCE INC - Form 10-Q

Estimated Fair Value Measurements at Reporting Date Using

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 June 30, 2013:</i>				
U.S. government securities	\$ 27,116	\$	\$	\$ 27,116
U.S. government agency securities	113,583	44,346		157,929
U.S. corporate notes	91,871	12,200		104,071
U.S. commercial paper	4,989	39,978		44,967
Money market funds	192,694			192,694
Total assets measured at estimated fair value	\$ 430,253	\$ 96,524	\$	\$ 526,777
<i>Liabilities at June 30, 2013:</i>				
Convertible subordinated notes due 2015	\$ 268,596	\$	\$	\$ 268,596
Convertible subordinated notes due 2023	443,920			443,920
Total convertible subordinated notes	\$ 712,516	\$	\$	\$ 712,516

Table of Contents

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
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 June 30, 2013, securities with a total fair value of \$11.9 million were measured using Level 1 inputs in comparison to December 31, 2012, at which time the securities had a fair value of \$12.0 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 June 30, 2013, compared to December 31, 2012.

At June 30, 2013, convertible subordinated notes with a total fair value of \$268.6 million were measured using Level 1 inputs in comparison to December 31, 2012, at which time the convertible subordinated notes had a fair value of \$194.1 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 June 30, 2013, compared to December 31, 2012.

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. INTANGIBLE ASSETS**

The Company's intangible assets at June 30, 2013 consist of the \$30.0 million registrational milestone fee paid to GSK (see Note 3 Collaborative Arrangements above for more information) and are considered finite-lived intangible assets 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 \$10.0 million. There was no amortization expense for the three months and six months ended June 30, 2013.

**7. LONG-TERM DEBT**

Long-term obligations are as follows:

Edgar Filing: THERAVANCE INC - Form 10-Q

(in thousands)	June 30, 2013		December 31, 2012	
Convertible Subordinated Notes Due 2015	\$	172,460	172,500	
Convertible Subordinated Notes Due 2023		287,500		
<b>Total</b>	<b>\$</b>	<b>459,960</b>	<b>\$</b>	<b>172,500</b>

*Convertible Subordinated Notes Due 2015*

In January 2008, the Company completed an underwritten public offering of \$172.5 million aggregate principal amount of unsecured convertible subordinated notes which will mature on January 15, 2015 (2015 Notes). The financing raised proceeds, net of issuance costs, of \$166.7 million. The notes bear interest at the rate of 3.0% per year, that is payable semi-annually in arrears in cash on January 15 and July 15 of each year, beginning on July 15, 2008. The issuance costs, which are included in other long-term assets, are being amortized over the life of the notes. Unamortized issuance costs totaled \$1.3 million as of June 30, 2013. Amortization expense was \$0.2 million in both the three months ended June 30, 2013 and 2012, and \$0.4 million in both the six months ended June 30, 2013 and 2012.



Table of Contents

The notes are convertible, at the option of the holder, into shares of the Company's common stock at an initial conversion rate of 38.6548 shares per \$1,000 principal amount of the notes, subject to adjustment in certain circumstances, which represents an initial conversion price of approximately \$25.87 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. On or after January 15, 2012 and prior to the maturity date, the Company, upon notice of redemption, may redeem for cash all or part of the notes if the last reported sale price of its common stock has been greater than or equal to 130% of the conversion price then in effect for at least 20 trading days during any 30 consecutive trading day period prior to the date on which it provides notice of redemption. The redemption price will equal 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest up to but excluding the redemption date.

On June 4, 2013, the Company called for redemption all of its outstanding 3% Convertible Subordinated Notes due 2015, pursuant to the redemption right in the indenture governing the 2015 Notes. 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). As of June 30, 2013, \$40,000 principal amount of the 2015 Notes was converted into 1,546 shares of the Company's common stock. See Note 11, "Subsequent Events" below for more information.

*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 \$6.0 million as of June 30, 2013. Amortization expense was \$0.2 million for the three months and \$0.3 million for the six months ended June 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.

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

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.

Table of Contents

**8. 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 June 30, 2013, total shares remaining available for issuance under the 2012 Plan were 3,514,872.

*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 June 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 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 of \$217,000 was recognized for the three months ended June 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 \$59,000 for the three months and \$146,000 for the six months ended June 30, 2013. 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 \$31.9 million (allocated as \$6.3 million for research and development expense and \$25.6 million for general and administrative expense) if all of the performance conditions are achieved on time. As of June 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 \$7.6 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 of \$367,000 was recognized for the three months ended June 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 \$32,000 for the three months and \$72,000 for the six months ended June 30, 2013 and was \$80,000 for the three months and \$177,000 for the six months ended June 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 June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Research and development	\$ 4,508	\$ 3,541	\$ 8,305	\$ 7,070
General and administrative	2,654	2,438	4,952	5,144
Total stock-based compensation expense	\$ 7,162	\$ 5,979	\$ 13,257	\$ 12,214

Total stock-based compensation expense capitalized to inventory was \$28,000 for the three months and \$170,000 for the six months ended June 30, 2013. No stock-based compensation expense was capitalized to inventory for the three months and six months ended June 30, 2012.

As of June 30, 2013, unrecognized compensation expense, net of expected forfeitures, was as follows: \$6.9 million related to unvested stock options; \$20.4 million related to unvested RSUs; and \$28.9 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 June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
<b>Employee stock options</b>				
Risk-free interest rate	0.76%-1.30%	0.74%-1.10%	0.76%-1.30%	0.74%-1.17%
Expected term (in years)	5-6	5-6	5-6	5-6
Volatility	59%-60%	55%-60%	58%-60%	55%-60%
Dividend yield	%	%	%	%
Weighted-average estimated fair value of stock options granted	\$ 17.64	\$ 11.11	\$ 15.43	\$ 10.37

The range of weighted-average assumptions used to estimate the fair value of employee stock purchase plan awards was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
<b>Employee stock purchase plan issuances</b>				

Edgar Filing: THERAVANCE INC - Form 10-Q

Risk-free interest rate	0.09%-0.26%	0.15%-0.29%	0.09%-0.26%	0.15%-0.29%
Expected term (in years)	0.5-2.0	0.5-2.0	0.5-2.0	0.5-2.0
Volatility	56%-61%	55%-64%	56%-61%	55%-64%
Dividend yield	%	%	%	%
Weighted-average estimated fair value of ESPP issuances	\$ 16.44	\$ 9.00	\$ 16.44	\$ 9.00

*Stockholders Equity*

For the six months ended June 30, 2013, approximately 1,158,057 shares were exercised at a weighted-average exercise price of \$14.95 per share, for total cash proceeds of approximately \$17,315,980.

Table of Contents

**9. INCOME TAXES**

The Company did not record a provision for income taxes for both of the three months and six months ended June 30, 2013 and June 30, 2012, because it expected to generate a taxable net operating loss for the fiscal year ending December 31, 2013 and 2012. In addition, the deferred tax assets continue to be treated as having no current value and remain fully reserved.

**10. 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 June 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 June 30, 2013.

**11. SUBSEQUENT EVENTS**

*Conversion of Convertible Subordinated Notes Due 2015*

On June 4, 2013, the Company called for redemption all of its 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). As of June 30, 2013, \$40,000 principal amount of the 2015 Notes was converted into 1,546 shares of the Company's common stock and between July 1, 2013 and through July 3, 2013, all of the

remaining 2015 notes were converted into 6,666,386 of the Company's common stock. All of convertible subordinated notes, \$172.5 million principal amount, were converted into 6,667,932 of the Company's common stock and none were redeemed for cash. As a result of the conversion, unamortized debt issuance costs of \$1.3 million will be included in additional paid-in capital in the third quarter of 2013.

*Sale of Stock*

On July 30, 2013, the Company and Glaxo Group Limited, an affiliate of GSK, entered into an agreement to purchase 3,064,407 shares of the Company's common stock at \$36.50 per share, for an aggregate purchase price of approximately \$111.9 million, pursuant to its rights under the Company's governance agreement with GSK dated June 4, 2004, as amended.

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

**Forward-Looking Statements**

The information in this discussion contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements involve substantial risks, uncertainties and assumptions. All statements contained herein that are not of historical fact, including, without limitation, statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, intentions, expectations, goals and objectives, may be forward-looking statements. The words anticipates, believes, could, designed, estimates, expect, goal, intends, may, objective, plans, projects, pursue, will, would and similar expressions (including the negatives thereof) are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions, expectations or objectives disclosed in our forward-looking statements and the assumptions underlying our forward-looking statements may prove incorrect. Therefore, you should not place undue reliance on our forward-looking statements. Actual results or events could materially differ from the plans, intentions, expectations and objectives disclosed in the forward-looking statements that we make. Factors that we believe could cause actual results or events to differ materially from our forward-looking statements include, but are not limited, to those discussed below in Risk Factors in Item 1A of Part II and in Management's Discussion and Analysis of Financial Condition and Results of Operations in this Item 2 of Part I. All forward-looking statements in this document are based on information available to us as of the date hereof and we assume no obligation to update any such forward-looking statements.



Table of Contents

**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 second quarter of 2013, our net loss was \$36.4 million, a decrease of 2% from \$37.1 million in the second quarter of 2012. In the first six months of 2013, our net loss was \$73.8 million, compared with net income of \$47.5 million in the first six months of 2012. Net income in the six months ended June 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 second quarter of 2013, our research and development expenses were \$31.7 million, an increase of 7% from \$29.5 million in the second quarter of 2012. In the first six months of 2013, our research and development expenses were \$58.2 million, a decrease of 7% from \$62.8 million in the first six months of 2012. Cash, cash equivalents, short-term investments, and long-term marketable securities totaled \$533.3 million at June 30, 2013, an increase of \$189.6 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, less \$36.8 million of payments on privately-negotiated capped call option transactions in connection with the issuance of the 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. On August 1, 2013, the company to be spun off, Theravance Biopharma, Inc., filed a preliminary Form 10 with the SEC. Theravance will focus on managing all development and commercial responsibilities under the LABA 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 redemption 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 convertible subordinated notes, \$172.5 million principal amount, were converted into 6,667,932 of our common stock and none were redeemed for cash.

Table of Contents

***Hikma Pharmaceuticals LLC***

In May 2013, we 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. Under the agreement, we 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. We received a \$0.5 million upfront payment in June 2013. Also, we are eligible to receive contingent payments of up to \$0.5 million related to the successful commercialization of telavancin. We are responsible, either directly or through our vendors or contractors, for supplying drug product for Hikma's commercialization activities for 15 years.

***Royalty Participation Agreement***

In May 2013, we 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, we terminated the agreement and as a result, Elan paid us a \$10.0 million termination fee in June 2013, which is reflected in other income.

**Programs**

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

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

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. Following FDA approval, it is anticipated that BREO ELLIPTA will be made available in the U.S. by GSK during the third or fourth quarter of 2013. BREO ELLIPTA is a combination of the inhaled corticosteroid (ICS), FF, and the long-acting beta2 agonist (LABA), VI. Combination treatment FF/VI (BREO in the U.S. and proposed brand name, RELVAR, in the EU) is administered by a new dry powder inhaler called ELLIPTA. The Marketing Authorization Application for RELVAR ELLIPTA for COPD and asthma is currently under review by the European Medicines Agency.

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. Following its authorization for use in the treatment of COPD, it is anticipated BREO ELLIPTA 100/25 mcg will be made available in Canada by GSK by the end of 2013.

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

In July 2013, the license application for the use of RELVAR ELLIPTA in patients with COPD was withdrawn from the current Japanese New Drug Application (JNDA). The review of FF/VI for use in patients with asthma is continuing to progress through the normal Japanese regulatory process as part of this JNDA. GSK and Theravance are currently determining next steps and possible clinical studies of FF/VI for the treatment of Japanese patients with COPD to support the resubmission.

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

UMEC/VI (proposed brand name ANORO ) is a once-daily investigational medicine, combining a long-acting muscarinic antagonist (LAMA), UMEC, and a LABA, VI, for the maintenance treatment of patients with COPD. UMEC/VI is administered by the ELLIPTA dry powder inhaler.

UMEC/VI is under regulatory review by the FDA, European Medicines Agency and the Japanese Ministry of Health, Labor and Welfare. The Prescription Drug User Fee Act goal date is December 18, 2013 and the FDA Pulmonary-Allergy Drugs Advisory Committee is scheduled to discuss the NDA for ANOROTM ELLIPTATM at a meeting on September 10, 2013. Regulatory submissions for UMEC/VI have 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. GSK recently initiated preclinical Phase 3 enabling studies in the combination 081/FF program. For 081 monotherapy, we were recently informed by GSK that the Phase 3 study will not be initiated in 2013.

Table of Contents

***Bacterial Infections Program***

*VIBATIV® (telavancin)*

In June 2013, the FDA approved VIBATIV® for the treatment of adult patients with hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Staphylococcus aureus* when alternative treatments are not suitable. VIBATIV® is a bactericidal, once-daily, injectable lipoglycopeptide antibiotic also approved in the U.S. and Canada for the treatment of adult patients with complicated skin and skin structure infections (cSSSI) caused by susceptible Gram-positive bacteria, including *Staphylococcus aureus*, both methicillin-resistant (MRSA) and methicillin-susceptible (MSSA) strains. We intend to reintroduce VIBATIV® into the U.S. market with the product available for order from pharmaceutical wholesalers. We continue to evaluate commercialization alternatives in the U.S.

***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*

TD-4208, an investigational LAMA for the treatment of COPD, is being evaluated in an ongoing randomized, double-blind, multiple-dose Phase 2b study to examine pharmacodynamics, safety and tolerability, and pharmacokinetics. Enrollment is progressing well and results from the Phase 2b study are anticipated to be reported in the second half of 2013.

**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), an investigational 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 milestone payments to GSK which could total as much as \$190.0 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 estimate up to \$110.0 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. As a result of this approval we paid GSK a \$30.0 million registrational milestone fee in the second quarter of 2013. These milestone payments to GSK will be capitalized as finite-lived intangible assets and 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%.

Table of Contents

*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 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 six months of 2013, we issued and Glaxo Group Limited, an affiliate of GSK, purchased 310,090 shares of our common stock for an aggregate purchase price of approximately \$9.3 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.

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

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

(in millions)	Three Months Ended June 30,			Six Months Ended June 30,		
	2013	2012	2012	2013	2012	2012
<i>GSK Collaborations</i>						
LABA collaboration	\$ 0.9	\$ 0.9	\$ 0.9	\$ 1.8	\$ 1.8	\$ 1.8
Strategic alliance MABA program license	0.4	0.5	0.5	0.8	0.8	1.1
Total revenue	\$ 1.3	\$ 1.4	\$ 1.4	\$ 2.6	\$ 2.6	\$ 2.9

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 \$0.3 million for the six months ended June 30, 2013. Reduction of R&D expense was \$31,000 for the three months and \$77,000 for the six months ended June 30, 2012.



Table of Contents

**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 United States generally accepted accounting principles, or U.S. 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***

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 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.

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

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 June 30, 2013 is \$8.1 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

Table of Contents

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 \$2.6 million in the six months ended June 30, 2013 and \$2.9 million in the six months ended June 30, 2012. The remaining deferred revenue under the GSK strategic alliance agreement is \$6.6 million at June 30, 2013. Any change in the estimated performance period 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 six months ended June 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 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 Merck, R-Pharm and Hikma were \$158.5 million at June 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 six months ended June 30, 2013, we recorded a reduction in our research and development expenses of \$4.2 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.

Table of Contents

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 used 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 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.

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 \$31.9 million, which would be recognized in increments based on achievement of the performance conditions. As of June 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 \$7.6 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 \$3.5 million and work-in-process of \$4.7 million at June 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. 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 Asset***

We review the intangible asset for impairment on a quarterly basis. The recoverability of finite 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 sales and long-term projected sales in the corresponding market.

At June 30, 2013, the net book value of our finite-lived intangible asset was \$30.0 million. This intangible asset is related to the registration milestone payment to GSK for the approval of BREO ELLIPTA, which is being amortized over its estimated useful life of 15 years using the straight-line method.

Table of Contents**RESULTS OF OPERATIONS***Revenue*

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

(in millions, except percentages)	Three months Ended				Six months Ended			
	June 30,		Change		June 30,		Change	
	2013	2012	\$	%	2013	2012	\$	%
Collaborative arrangements GSK Collaborative arrangement	\$ 1.3	\$ 1.4	\$ (0.1)	(7)%	\$ 2.6	\$ 2.9	\$ (0.3)	(10)%
Astellas Collaborative arrangement				%		125.7	(125.7)	(100)%
Other Collaborative arrangements	*		*	**	*		*	**
Total Revenue	\$ 1.3	\$ 1.4	\$ (0.1)	(7)%	\$ 2.6	\$ 128.6	\$ (126.0)	(98)%

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

\*\* Calculation not meaningful.

Revenue decreased 7% to \$1.3 million in the second quarter of 2013 and decreased 98% to \$2.6 million in the first six month of 2013, from the comparable periods in 2012. The decreases in 2013 were primarily related to the revenue recognized in the first quarter of 2012 which reflect the accelerated recognition of deferred revenue of \$125.7 million from our global collaboration arrangement with Astellas for the development and commercialization of VIBATIV® in the first quarter of 2012. This accelerated recognition was the result of the termination of the Astellas agreement on January 6, 2012.

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*

Research and development expenses, as compared to the prior year periods, were as follows:

Edgar Filing: THERAVANCE INC - Form 10-Q

(in millions, except percentages)	Three months Ended					Six months Ended				
	June 30,		Change		June 30,		Change			
	2013	2012	\$	%	2013	2012	\$	%		
Employee-related	\$ 8.6	\$ 9.4	\$ (0.8)	(9)%	\$ 17.9	\$ 19.6	\$ (1.7)	(9)%		
External-related	12.6	11.0	1.6	15%	19.8	24.1	(4.3)	(18)%		
Stock-based compensation	4.5	3.5	1.0	29%	8.3	7.1	1.2	17%		
Facilities, depreciation and other allocated	6.0	5.6	0.4	7%	12.2	12.0	0.2	2%		
Total expenses	\$ 31.7	\$ 29.5	\$ 2.2	7%	\$ 58.2	\$ 62.8	\$ (4.6)	(7)%		

R&D expenses increased 7% to \$31.7 million in the second quarter and decreased 7% to \$58.2 million in the first six months of 2013 from the comparable periods in 2012. The increase in the second quarter of 2013 was primarily due to higher external R&D costs resulting from ongoing enrollment of Phase 2 clinical studies of TD-9855 in fibromyalgia and attention-deficit/hyperactivity disorder (ADHD), the Phase 2b study of TD-4208 in COPD, as well as costs associated with our preclinical and late-stage discovery programs. The decrease in the first six months is primarily due to lower external R&D costs resulting from the completion of our Phase 2 studies in opioid-induced constipation with TD-1211 in 2012 and, to a lesser extent, from an increase in collaborative partner R&D reimbursements.

*General and administrative*

General and administrative expenses, as compared to the prior year periods, were as follows:

(in millions, except percentages)	Three months Ended					Six months Ended				
	June 30,		Change		June 30,		Change			
	2013	2012	\$	%	2013	2012	\$	%		
General and administrative expense	\$ 11.4	\$ 7.6	\$ 3.8	50%	\$ 19.7	\$ 15.4	4.3	28%		



Table of Contents

G&A expenses increased 50% to \$11.4 million in the second quarter and 28% to \$19.7 million in the first six months of 2013 from the comparable periods in 2012. The increases in 2013 were primarily due to an increase in external legal and accounting fees in connection with our strategic initiatives as well as an increase in external costs in connection with commercialization activities related to VIBATIV®. Stock-based compensation expense was \$2.7 million in the second quarter of 2013, compared to \$2.4 million in the same period of 2012 and \$5.0 million in the six months ended June 30, 2013, compared to \$5.1 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				Six months Ended			
	June 30,		Change		June 30,		Change	
	2013	2012	\$	%	2013	2012	\$	%
Interest income	\$ 0.2	\$ 0.1	\$ 0.1	100%	\$ 0.4	\$ 0.1	\$ 0.3	300%
Other income (expense), net	8.2		8.2	*	6.7		6.7	*
Interest and other income (expense), net	\$ 8.4	\$ 0.1	\$ 8.3	*	\$ 7.1	\$ 0.1	\$ 7.0	*

\* Calculation not meaningful.

Interest and other income (expense), net increased \$8.3 million to \$8.4 million in the second quarter and \$7.0 million to \$7.1 million in the first six months of 2013, compared to the same periods in 2012. The increases in 2013 were 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:

Interest expense	\$ 3.0	\$ 1.5	\$ 1.5	100%	\$ 5.8	\$ 3.0	\$ 2.8	93%
------------------	--------	--------	--------	------	--------	--------	--------	-----

Interest expense increased 100% to \$3.0 million in the second quarter of 2013 and increased 93% in the first six 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 June 30, 2013, we had \$533.3 million in cash, cash equivalents 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 six months of 2013, we issued and Glaxo Group Limited, an affiliate of GSK, purchased 310,090 shares of our common stock for an aggregate purchase price of approximately \$9.3 million pursuant to its periodic top-up rights under our governance agreement with GSK dated June 4, 2004, as amended. In addition, on July 30, 2013, we entered into a common stock purchase agreement with Glaxo Group Limited in which we agreed to sell 3,064,407 shares of our common stock at a price of \$36.50 per share for an aggregate purchase price of approximately \$111.9 million pursuant to its periodic top-up rights under our governance agreement with GSK dated June 4, 2004, as amended. The closing of the purchase and sale of the shares is expected to occur on August 2, 2013.

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 commenced a Phase 2b study in December 2012. 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,

Table of Contents

we may choose to progress TD-1211 into Phase 3 studies by ourselves, which would increase our operating expenses substantially. In addition, we intend to reintroduce VIBATIV® in the U.S. during the third quarter of 2013, which will involve outside services costs associated with manufacturing and distribution capabilities. Furthermore, should we decide 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 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 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.

Pursuant to our LABA collaboration with GSK, we will be obligated to make milestone payments to GSK which could total as much as \$190.0 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 estimate up to \$110.0 million could be payable during the remainder of 2013, and all the 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 June 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 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:

Edgar Filing: THERAVANCE INC - Form 10-Q

(in millions)	Six Months Ended				
	2013		June 30,		2012
Net cash used in operating activities	\$	(48.3)	\$	(75.7)	
Net cash used in investing activities	\$	(118.5)	\$	(24.7)	
Net cash provided by financing activities	\$	271.3	\$	216.7	

*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 six-months ended June 30, 2013 was \$48.3 million, which was primarily due to:

- \$61.1 million used in operating expenses, after adjusting for non-cash related items of \$16.8 million consisting primarily of stock-based compensation expense of \$13.3 million, depreciation and amortization expenses of \$3.9 million, and rent expense of \$0.4 million;

Table of Contents

- \$2.6 million use for interest payments on convertible subordinated notes payable;
- \$2.5 million used to increase work-in-process inventory;
- \$1.2 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 received in upfront fees from collaboration agreements with Clinigen, R-Pharm and Hikma; and
- \$4.0 million increase in accrued liabilities due to \$3.0 million increase in accrued personnel-related expenses pay out of the 2011 bonus plan, accrued clinical and development expense, and other accrued liabilities, and \$1.0 million increase in accounts payable primarily due to the timing of payments.

Net cash used in operating activities in the six-months ended June 30, 2012 was \$75.7 million, which was primarily due to:

- \$62.8 million used in operating expenses, after adjusting for non-cash related items of \$15.4 million consisting primarily of stock-based compensation expense of \$12.2 million, depreciation and amortization expenses of \$3.6 million, partially offset by a reduction of rent expense of \$0.3 million;
- \$6.0 million used to decrease accrued liabilities due to a \$6.0 million decrease in accrued personnel-related expenses, accrued clinical and development expense primarily due to timing of payments; and
- \$4.3 million used to increase work-in-process inventory.

*Cash Flows from Investing Activities*

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

Net cash used in investing activities in the six-months ended June 30, 2013 was \$118.5 million, which was primarily due to \$87.2 million in cash balances being invested in short-term investments and long-term marketable securities and \$30.0 million used for a registrational milestone payment to GSK for approval of BREO ELLIPTA .

Net cash used in investing activities in the six months ended June 30, 2012 was \$24.7 million, which was primarily due to cash balances being invested in short-term investments and long-term marketable securities.

### *Cash Flows from Financing Activities*

Net cash provided by financing activities in the six months ended June 30, 2013 was \$271.3 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 \$26.4 million, less \$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 six months ended June 30, 2012 was \$216.7 million, which was primarily due to \$212.5, 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 June 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



Table of Contents

maximum potential expense associated with this program is \$31.9 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 June 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 \$7.6 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 \$190.0 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 estimate up to \$110.0 million could be 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 June 30, 2013.

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

During the first six 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.

**Item 4. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures.*

We conducted an evaluation as of June 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.

Table of Contents

**PART II. OTHER INFORMATION**

**Item 1A. Risk Factors**

**Risks Related to our Business**

*If the commercialization of BREO ELLIPTA in the countries in which it has received regulatory approval encounter any delays or adverse developments, or perceived delays or adverse developments, or if sales 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 addition, 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. Under our agreements with our collaborative partner GSK, GSK has full responsibility for commercialization of BREO ELLIPTA. Following the FDA and Health Canada approvals, it is anticipated that BREO ELLIPTA will be made available by GSK in the U.S. during the third quarter of 2013 and in Canada in the fall 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, including if sales do not meet investor expectations, will significantly harm our business and could cause the price of our securities to fall.

*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. 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;

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

- inability to gain, or delay in gaining, regulatory approval outside the U.S. 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.

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

Table of Contents

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.

***If UMEC/VI receives an unfavorable outcome at the FDA's Pulmonary-Allergy Drugs Advisory Committee in September 2013, 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. GSK plans to make regulatory submissions in other countries during the course of 2013. 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:

- 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;

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

- any unfavorable announcements made, or comments emanating from, the FDA's Pulmonary-Allergy Drugs Advisory Committee meeting in September 2013; 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/FP program. For 081 monotherapy, we were recently informed by GSK that the Phase 3 study will not be initiated in 2013. Any 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:

Table of Contents

- 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;
- 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., filed a preliminary Form 10 with the SEC. 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, Inc., 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

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

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.

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.

We have not yet determined whether the planned business separation can or will be effected on a tax-free basis. If it is not effected on a tax-free basis, the business separation is expected to result in use of the Company's current net operating losses and could also result in taxation for the Company. The dividend to effect the business separation may also result in tax liability for the Company's stockholders.

Table of Contents

***If we cannot identify a suitable commercialization partner for VIBATIV® in the U.S. we will need to develop 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, and if a suitable commercialization partner in the U.S. cannot be identified for this product, we intend to reintroduce it in the U.S. in 2013 ourselves. At present, we have no sales or distribution personnel and a limited number of marketing personnel. 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.



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

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;
- 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;

Table of Contents

- 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, 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 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

Table of Contents

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®. 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. will continue to 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.***

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:

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

- because of the complex nature of many of our compounds, our manufacturers may not be able to successfully manufacture our APIs and/or drug products in a cost effective and/or timely manner and changing manufacturers for our APIs or drug products could involve lengthy technology transfer, validation and regulatory qualification activities for the new manufacturer;
- the processes required to manufacture certain of our APIs and drug products are specialized and available only from a limited number of third-party manufacturers;
- 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.

Table of Contents

***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.

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

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

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 June 30, 2013, we had an accumulated deficit of approximately \$1.4 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 (ADHD) and fibromyalgia and our LAMA compound TD-4208 commenced a Phase 2b study in December 2012. 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 this program, we may choose to progress TD-1211 into Phase 3 studies by ourselves, which would increase our anticipated operating expenses substantially. Furthermore, should we decide 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.

Table of Contents

***If we fail to 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 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 by ourselves our capital needs would increase substantially. In addition, we initiated two Phase 2 studies with TD-9855 in the MARIN program and a Phase 2b study with our LAMA compound, TD-4208. 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 (or the Closed Triple) 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 milestone payments that could total as much as \$190.0 million. Of these potential milestone payments, we estimate that up to \$110.0 million could be 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.;



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

- 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.

Table of Contents

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

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 (or the Closed Triple), 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.

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. 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 (or the Closed Triple), VI monotherapy and the MABA program, with Alfa Wassermann for velusetrag, with Merck for novel small molecule therapeutics for the treatment of cardiovascular disease, 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. Each of velusetrag, our lead compound in the 5-HT4 program, TD-1792, our investigational antibiotic and TD-4208, our LAMA compound, has successfully completed a Phase 2 proof-of-concept study, and 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 for opioid-induced constipation. 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 pursue alternative products. 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.

Table of Contents

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

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

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

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

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

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

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

- obtain required regulatory approvals; and
- 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.

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.

Table of Contents

***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**

***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.***

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

As of June 30, 2013, GSK beneficially owned approximately 26.5% 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.

Table of Contents

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.

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 June 30, 2013, GSK beneficially owned approximately 26.5% of our outstanding capital stock. GSK may vote at its sole discretion on any proposal to effect a change of control of us or for us to issue equity securities to one or more parties that would result in that party or parties beneficially owning more than 20% of our outstanding capital stock. Our governance agreement with GSK requires us to exempt GSK from our stockholder rights plan, affords GSK certain rights to offer to acquire us in the event third parties seek to acquire our stock and contains other provisions that could deter or prevent another company from seeking to acquire us. For example, GSK may offer to acquire 100% of our outstanding stock from stockholders in certain circumstances, such as if we are faced with a hostile acquisition offer or if our board of directors acts in a manner to facilitate a change in control of us with a party other than GSK. As a result of GSK's significant ownership and its rights under the governance agreement, other companies may be less inclined to pursue an acquisition of us and therefore we may not have the opportunity to be acquired in a transaction that stockholders might otherwise deem favorable, including transactions in which our stockholders might realize a substantial premium for their shares.

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

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



**Risks Related to Legal and Regulatory Uncertainty**

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

We rely upon a combination of patents, patent applications, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any involuntary disclosure to or misappropriation by third parties of this proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. The status of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and is very uncertain. As of June 30, 2013, we owned 346 issued United States patents and 1323 granted foreign patents, as well as additional pending United States and foreign patent applications. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be invalidated or be too narrow to prevent third parties from developing or designing around these patents. If the sufficiency of the breadth or strength of protection provided by our patents with respect to a product candidate is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, the product candidate. Further, if we encounter delays in our clinical trials or in obtaining regulatory approval of our product candidates, the patent lives of the related product candidates would be reduced.

Table of Contents

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

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

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

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

***If the efforts of our 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 will be increased upon 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.

Table of Contents

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

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

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

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

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

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

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

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

#### **Risks 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;

Table of Contents

- 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 any unfavorable outcome from the FDA's Pulmonary-Allergy Drugs Advisory Committee meeting in September 2013;
  
- 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, 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;
  
- 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;
  
- the extent to which GSK advances (or does not advance) FF/VI, UMEC/VI, UMEC/VI/FF (or the Closed Triple), VI monotherapy and the MABA program through development into commercialization in all indications in all major markets;
  
- any adverse developments or perceived adverse developments with respect to our relationship with GSK, including, without limitation, disagreements that may arise between us and GSK;

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

- 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 ARNI 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;

Table of Contents

- regulatory developments in the United States and foreign countries;
- economic and other external factors beyond our control;
- sales of stock by us or by our stockholders, including sales by certain of our employees and directors whether or not pursuant to selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934;
- relative illiquidity in the public market for our common stock (our three largest stockholders other than GSK collectively owned approximately 33.9% of our outstanding capital stock as of June 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 June 30, 2013, GSK beneficially owned approximately 26.5% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 5.0% of our outstanding capital stock. Based on our review of publicly available filings as of June 30, 2013, our three largest stockholders other than GSK collectively owned approximately 33.9% 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.

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

On May 3, 2013, we completed the sale of 193,563 shares of our common stock to Glaxo Group Limited, an affiliate of GSK, at a price of \$34.61 per share, resulting in aggregate gross proceeds of \$6.7 million before deducting transaction expenses. Neither we nor the affiliate of GSK engaged any investment advisors with respect to the sale and no underwriting discounts or commissions were paid or will be paid to any party in connection with the sale. We issued and sold the shares in reliance upon an exemption from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended.

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

<b>Exhibit Number</b>	<b>Description</b>	<b>Form</b>	<b>Incorporated by Reference Filing Date/Period End Date</b>
3.3	Amended and Restated Certificate of Incorporation	S-1	7/26/04
3.4	Certificate of Amendment of Restated Certificate of Incorporation	10-Q	3/31/07
3.5	Amended and Restated Bylaws (as amended by the board of directors April 25, 2007)	10-Q	9/30/08
4.1	Specimen certificate representing the common stock of the registrant	10-K	12/31/06
4.2	Amended and Restated Rights Agreement between Theravance, Inc. and The Bank of New York, as Rights Agent, dated as of June 22, 2007	10-Q	6/30/07
4.3	Indenture dated as of January 23, 2008 by and between Theravance, Inc. and The Bank of New York Trust Company, N.A., as trustee	8-K	1/23/08
4.4	Form of 3.0% Convertible Subordinated Note Due 2015 (included in Exhibit 4.3)		
4.5	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
10.1	Royalty Participation Agreement between Theravance, Inc. and Elan Corporation, PLC dated May 12, 2013	8-K	5/16/13
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 two quarters ended June 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)

August 1, 2013  
Date

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

August 1, 2013  
Date

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