

THERAVANCE INC  
Form 10-Q  
May 02, 2012  
[Table of Contents](#)

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

WASHINGTON, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2012

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 including Zip Code)

**(650) 808-6000**

(Registrant's Telephone Number, Including Area Code)

---

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer   
Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

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

The number of shares of registrant's common stock outstanding on April 25, 2012 was 86,542,315.



Table of Contents

TABLE OF CONTENTS

<b><u>PART I. FINANCIAL INFORMATION</u></b>	3
<u>Item 1. Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets as of March 31, 2012 and December 31, 2011</u>	3
<u>Condensed Consolidated Statements of Operations for the three months ended March 31, 2012 and 2011</u>	4
<u>Condensed Consolidated Statements of Comprehensive Income (Loss) for the three months ended March 31, 2012 and 2011</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2012 and 2011</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	17
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	25
<u>Item 4. Controls and Procedures</u>	25
<b><u>PART II. OTHER INFORMATION</u></b>	25
<u>Item 1A. Risk Factors</u>	25
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	40
<u>Item 6. Exhibits</u>	40
<u>Signatures</u>	41

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

(In thousands, except per share data)

	March 31, 2012 (Unaudited)	December 31, 2011 *
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 14,310	\$ 44,778
Marketable securities	185,854	196,137
Receivable from related party	63	223
Notes receivable, current	200	100
Prepaid and other current assets	3,900	3,525
Total current assets	204,327	244,763
Restricted cash	893	893
Property and equipment, net	10,059	10,372
Notes receivable, non-current	140	240
Other assets, non-current	2,308	2,514
Total assets	\$ 217,727	\$ 258,782
<b>Liabilities and stockholders equity (net capital deficiency)</b>		
Current liabilities:		
Accounts payable	\$ 5,308	\$ 5,813
Accrued personnel related expenses	4,884	9,643
Accrued clinical and development expenses	6,547	6,956
Accrued interest on convertible subordinated notes	1,078	2,372
Other accrued liabilities	1,974	1,946
Note payable and capital lease, current	13	69
Deferred revenue, current	5,771	18,697
Total current liabilities	25,575	45,496
Convertible subordinated notes	172,500	172,500
Deferred rent	5,678	5,821
Deferred revenue, non-current	7,843	122,017
Commitments and contingencies (Notes 3 and 7)		
Stockholders equity (net capital deficiency):		
Common stock, \$0.01 par value; authorized: 200,000 shares; outstanding: 86,470 at March 31, 2012 and 85,543 at December 31, 2011	865	855
Additional paid-in capital	1,236,641	1,228,037
Accumulated other comprehensive income (loss)	(9)	16
Accumulated deficit	(1,231,366)	(1,315,960)
Total stockholders equity (net capital deficiency)	6,131	(87,052)

Edgar Filing: THERAVANCE INC - Form 10-Q

Total liabilities and stockholders' equity (net capital deficiency) \$ 217,727 \$ 258,782

---

\* Condensed consolidated balance sheet at December 31, 2011 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)

	<b>Three Months Ended March 31,</b>	
	<b>2012</b>	<b>2011</b>
Revenue (including amounts from a related party of \$1,430 in the three months ended March 31, 2012, and \$2,456 in the three months ended March 31, 2011)	\$ 127,099	\$ 6,331
Operating expenses:		
Research and development	33,202	20,464
General and administrative	7,857	7,169
Total operating expenses	41,059	27,633
Income (loss) from operations	86,040	(21,302)
Interest income	56	145
Interest expense	(1,502)	(1,510)
Net income (loss)	\$ 84,594	\$ (22,667)
Net income (loss) per share:		
Basic	\$ 1.01	\$ (0.28)
Diluted	\$ 0.93	\$ (0.28)
Weighted-average number of shares used in per share calculations:		
Basic	83,590	80,854
Diluted	92,080	80,854

*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</b>		
	<b>March 31,</b>		
	<b>2012</b>		<b>2011</b>
Net income (loss)	\$	84,594	\$ (22,667)
Other comprehensive income:			
Net unrealized loss on available-for-sale securities, net of tax		(25)	(5)
Comprehensive income (loss)	\$	84,569	\$ (22,672)

*See accompanying notes to condensed consolidated financial statements.*



Table of Contents

## THERAVANCE, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2012	2011
<b>Cash flows from operating activities</b>		
Net income (loss)	\$ 84,594	\$ (22,667)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	1,910	1,650
Stock-based compensation	6,235	5,541
Forgiveness of notes receivable		1
Changes in operating assets and liabilities:		
Receivables	160	268
Prepaid expenses and other current assets	(375)	73
Accounts payable	48	198
Accrued personnel-related expenses, accrued interest on convertible subordinated notes and other current liabilities	(6,657)	(6,031)
Deferred rent	(143)	776
Deferred revenue	(127,100)	(5,700)
Net cash used in operating activities	(41,328)	(25,891)
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(1,103)	(1,381)
Purchases of marketable securities	(35,671)	(76,408)
Sales of marketable securities		5,000
Maturities of marketable securities	45,158	71,250
Payments received on notes receivable		300
Net cash provided by (used in) investing activities	8,384	(1,239)
<b>Cash flows from financing activities</b>		
Payments on note payable and capital lease	(56)	(62)
Proceeds from issuances of common stock, net	2,532	11,733
Net cash provided by financing activities	2,476	11,671
Net decrease in cash and cash equivalents	(30,468)	(15,459)
Cash and cash equivalents at beginning of period	44,778	163,333
Cash and cash equivalents at end of period	\$ 14,310	\$ 147,874

*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. By leveraging the Company's proprietary insight of multivalency to drug discovery, Theravance is pursuing a best-in-class strategy designed to discover superior medicines in areas of significant unmet medical need.

*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, 2012 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, 2011 filed with the Securities and Exchange Commission (SEC) on February 27, 2012.

*Principles of Consolidation*

The 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 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 research and development of human therapeutics. Revenues are generated primarily from the Company's collaborations with GlaxoSmithKline plc (GSK), located in the United Kingdom and, through January 6, 2012, Astellas Pharma Inc. (Astellas), located in Japan. All long-lived assets are maintained in the United States.

*Marketable Securities*

The Company determines the appropriate classification of its marketable securities, which consist of debt securities, at the time of purchase and reevaluates such designation at each balance sheet date. All of the marketable securities are classified as available-for-sale and carried at estimated fair values and reported in either cash equivalents or marketable securities. Unrealized gains and losses on available-for-sale securities are reported in accumulated other comprehensive income (loss) as a separate component of stockholders' equity (net capital deficiency). Interest, amortization of purchase premiums and discounts, and realized gains and losses on sales of securities are included in interest. The cost of securities sold is based on the specific identification method.

Table of Contents

The Company regularly reviews all of its investments for other-than-temporary declines in 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 determines that the decline in 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.

*Research and Development Costs*

Research and development costs are expensed in the period that services are rendered or goods are received. Research and development costs consist of salaries and benefits, laboratory supplies and facility costs, as well as fees paid to third parties that conduct certain research and development activities on behalf of the Company, net of certain external research costs reimbursed by GSK and, through 2011, Astellas.

*Fair Value of Stock-Based Compensation Awards*

Stock-based compensation arrangements currently include the following awards granted under the 2004 Equity Incentive Plan (2004 Plan) and the 2008 New Employee Equity Incentive Plan (2008 Plan): stock options, restricted stock unit awards (RSUs), performance-contingent RSUs, restricted stock awards (RSAs), and performance-contingent RSAs. In addition, stock-based compensation arrangements include purchases of common stock by the Company's employees at a discount to the market price during offering periods under the Company's Employee Stock Purchase Plan (ESPP). Under the 2004 Plan and 2008 Plan, stock options are to be granted at an exercise price not less than the fair market value per share on the grant date for incentive options and are generally granted with terms of up to ten years and vest over a period of four years. Following the approval by stockholders of the amendment and restatement of the 2004 Plan on April 27, 2010, no additional awards have been made or will be made in the future under the 2008 Plan.

The Company uses the Black Scholes 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. The Black Scholes 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 for the expected option term because the usage of its historical 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. RSUs and 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 has been reduced for estimated forfeitures at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ 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 fair value of performance-contingent RSUs and RSAs is expensed during the term of the award when the Company determines that it is probable

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

that certain performance milestones will be achieved. Compensation expense for purchases under the ESPP is recognized based on the estimated fair value of the common stock during each offering period and purchase discount percentage.

The Company has not recognized, and does not expect to recognize in the near future, any tax benefit related to employee stock-based compensation costs 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.

### *Recently Adopted Accounting Updates*

On January 1, 2012, the Company adopted Accounting Standards Update (ASU) No. 2011-05, Presentation of Comprehensive Income—an update to Accounting Standards Codification (ASC) Topic 220, Comprehensive Income. This update requires that all nonowner changes in stockholders equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This update is to be applied retrospectively and is effective for financial statements issued for fiscal years, and interim periods within those years, beginning after December 15, 2011, and interim and annual periods thereafter. This update was effective for the Company January 1, 2012. The Company elected the two separate but consecutive statements approach.

Table of Contents**2. Net Income (Loss) per Share**

Basic net income (loss) per share amounts for each period presented were 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 months ended March 31, 2012, diluted net income per share was computed by dividing net income plus interest on dilutive convertible notes by the weighted-average number of shares of common stock outstanding during each 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 6) and other dilutive securities.

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

Dilutive potential common shares also include the dilutive effect of the common stock underlying in-the-money stock options 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.

For the three months ended March 31, 2011, diluted net loss per share was identical to basic EPS since potential common shares were excluded from the calculation, as their effect was anti-dilutive.

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

(in thousands, except for per share amounts)	Three Months Ended	
	2012	March 31, 2011
<b>Numerator:</b>		
Net income (loss) basic	\$ 84,594	\$ (22,667)
Add: interest and issuance costs related to convertible notes	1,500	
Net income (loss) diluted	86,094	(22,667)
<b>Denominator:</b>		
Weighted-average common shares outstanding	86,292	83,325
Less: unvested RSAs	(2,702)	(2,471)
Weighted-average common shares outstanding basic	83,590	80,854
Dilutive effect of equity incentive plans and ESPP	1,822	

Edgar Filing: THERAVANCE INC - Form 10-Q

Dilutive effect of convertible subordinated notes	6,668	
Weighted-average common shares outstanding and dilutive potential common shares diluted	92,080	80,854

*Anti-dilutive securities*

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

(in thousands)	Three Months Ended	
	2012	March 31, 2011
Shares issuable under Equity Incentive Plans and ESPP	4,641	6,673
Shares issuable upon the conversion of convertible debt		6,668
Total anti-dilutive securities	4,641	13,341

Table of Contents

**3. Collaboration Arrangements**

**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 combination products, RELOVAIR and the LAMA/LABA (GSK573719/vilanterol or 719/VI). For the treatment of asthma, the collaboration is developing RELOVAIR. RELOVAIR is an investigational once-daily combination medicine consisting of a LABA, VI, previously referred to as GW642444 or 444, and an inhaled corticosteroid (ICS), fluticasone furoate (FF). The LAMA/LABA, 719/VI, is an investigational once-daily combination medicine consisting of the long-acting muscarinic antagonist (LAMA) 719, and the LABA, VI.

The current lead product candidates in the LABA collaboration, VI and FF, were discovered by GSK. In the event that VI is successfully developed and commercialized, the Company will be obligated to make milestone payments to GSK which could total as much as \$220.0 million if both a single-agent and a combination product or two different combination products are launched in multiple regions of the world. If global regulatory authorities accept the applications for RELOVAIR, which the Company anticipates will be filed by GSK beginning in mid-2012, a portion of these potential milestone payments could be payable to GSK within the next two years. The Company is entitled to 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 719/VI, royalties are upward tiering and range from the mid-single digits to 10%. However, if GSK is not selling a LABA/ICS combination product at the time that the first other LABA combination is launched, then the royalties described above for the LABA/ICS combination medicine would be applicable.

*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.



## 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 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 a MABA/ICS, 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, 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 milestone payments 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 milestone payments up to \$129.0 million.

Table of Contents

In connection with the expansion of the MABA program, GSK relinquished its option right on the Company's MonoAmine Reuptake Inhibitor (MARIN) program and Angiotensin Receptor-NEP Inhibitor (ARNI) program. GSK has no further option rights on any of the Company's research or development programs under the strategic alliance.

In May 2004, GlaxoSmithKline LLC, an affiliate of GSK, purchased 6,387,096 shares of the Company's Class A common stock for an aggregate purchase price of \$108.9 million and, upon the closing of the Company's initial public offering on October 8, 2004, GlaxoSmithKline LLC purchased an additional 433,757 shares of Class A common stock for an aggregate purchase price of \$6.9 million. In November 2010, Glaxo Group Limited, an affiliate of GSK, purchased 5,750,000 shares of the Company's common stock for an aggregate purchase price of \$129.4 million.

*GSK Conversion of the Company's Class A Common Stock and Purchases of Common Stock under the Company's Governance Agreement with GSK*

In July 2011, GSK converted all of the shares of the Company's Class A common stock held by its affiliates into 9,401,499 shares of the Company's common stock on a one share-for-one share basis in accordance with the terms of the Company's restated certificate of incorporation. In addition, Glaxo Group Limited purchased shares of the Company's common stock pursuant to its periodic top-up rights under the Company's governance agreement with GSK dated June 4, 2004, as amended, as follows:

<i>Purchase dates</i>	<b>Through March 31, 2012</b>	
	<b>Common Stock Shares Purchased</b>	<b>Aggregate Amounts (in thousands)</b>
February 24, 2011	152,278	\$ 3,609
May 3, 2011	261,299	\$ 6,689
August 2, 2011	102,466	\$ 2,020
November 1, 2011	58,411	\$ 1,298
February 14, 2012	88,468	\$ 1,603

See Note 10 for subsequent event.

*GSK Upfront License Fees, Milestone Payments and Revenue*

Upfront license fees and milestone payments received from GSK under the LABA collaboration and strategic alliance agreements were as follows:

<b>(in thousands)</b>	<b>Through March 31, 2012</b>		<b>Total</b>
	<b>Upfront Fees</b>	<b>Milestone Payments</b>	
<i>GSK Collaborations</i>			

Edgar Filing: THERAVANCE INC - Form 10-Q

LABA/RELOVAIR collaboration(1)	\$	10,000	\$	50,000	\$	60,000
Strategic alliance agreement		20,000				20,000
Strategic alliance LAMA license(2)		5,000		3,000		8,000
Strategic alliance MABA program license		6,000		16,000		22,000
Total	\$	41,000	\$	69,000	\$	110,000

---

(1) The Company does not currently expect to be eligible for any additional milestones under this collaboration.

(2) In August 2004, GSK exercised its right to license the Company's LAMA program pursuant to the terms of the strategic alliance. In 2009, GSK returned the program to the Company.

The eligible potential contingent payments related to the MABA program, which includes the Additional MABAs, are not deemed substantive 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.

Table of Contents

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

(in thousands)	Three Months Ended	
	2012	2011
<b>March 31,</b>		
<i>GSK Collaborations</i>		
LABA/RELOVAIR collaboration	\$ 907	\$ 1,270
Strategic alliance agreement		684
Strategic alliance MABA program license	523	502
<b>Total</b>	<b>\$ 1,430</b>	<b>\$ 2,456</b>

*Astellas*

*License, Development and Commercialization Agreement with Astellas*

In November 2005, the Company entered into a global collaboration arrangement with Astellas for the development and commercialization of VIBATIV®. On January 6, 2012, Astellas exercised its right to terminate this 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®. In March 2012, the Company entered into a series of agreements with Astellas for the purchase of VIBATIV® active pharmaceutical ingredient and raw materials of up to \$6.2 million and VIBATIV® finished goods inventory of up to \$4.2 million, which is subject to release by a third party manufacturer.

In addition, beginning July 1, 2012, the Company is responsible to fund governmental rebate and governmental chargeback claims for Astellas-labeled product sales. As a result of the termination agreement, the Company recorded a liability of \$150,000 at March 31, 2012. The Company is evaluating global commercialization alternatives for VIBATIV® either with partners or alone.

Through January 6, 2012, the Company had received \$191.0 million in upfront license, milestone and other fees from Astellas. The Company previously recorded these payments as deferred revenue and amortized them ratably over its estimated performance period (development and commercialization period). As a result of the termination of the collaboration agreement, the Company has no remaining performance obligations. Therefore the development and commercialization period ended on January 6, 2012. As such, the Company recognized into revenue \$125.8 million of deferred revenue related to Astellas in the three months ended March 31, 2012, and it is no longer eligible to receive any further milestone payments.

Net revenue recognized under this collaboration agreement was as follows:

(in thousands)	Three Months Ended	
	2012	2011
<b>March 31,</b>		

Edgar Filing: THERAVANCE INC - Form 10-Q

Recognition of deferred revenue	\$	125,819	\$	3,244
Royalties from net sales of VIBATIV®				631
Astellas-labeled product sales allowance		(150)		
Total net revenue	\$	125,669	\$	3,875

4. Marketable Securities

Available-for-sale money market funds and debt securities were recorded in cash equivalents or marketable securities in the Company's consolidated balance sheets at their estimated fair value based on prices obtained from commercial pricing services. The Company's marketable securities were as follows:

(in thousands)	Amortized Cost	March 31, 2012			Amortized Cost	December 31, 2011		
		Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value		Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. government securities	\$ 61,028	\$ 5	\$ (2)	\$ 61,031	\$ 66,150	\$ 24	\$	\$ 66,174
U.S. government agencies	82,942	2	(15)	82,929	93,183	9	(17)	93,175
U.S. corporate notes	550			550	2,707		(2)	2,705
U.S. commercial paper	45,736	1		45,737	34,973	3		34,976
Money market funds	6,213			6,213	38,721			38,721
Total	196,469	8	(17)	196,460	235,734	36	(19)	235,751
Less amounts classified as cash equivalents	(9,713)			(9,713)	(38,721)			(38,721)
Less amounts classified as restricted cash	(893)			(893)	(893)			(893)
Amounts classified as marketable securities	\$ 185,863	\$ 8	\$ (17)	\$ 185,854	\$ 196,120	\$ 36	\$ (19)	\$ 196,137

Table of Contents

At March 31, 2012, all of the marketable securities have contractual maturities within twelve months and the average duration of marketable securities was approximately five 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 March 31, 2012, 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 estimated fair values of the Company's financial assets were as follows:

March 31, 2012 (in thousands)	Fair Value Measurements at Reporting Date Using			
	Quoted Prices in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Total
U.S. government securities	\$ 25,998	\$ 35,033	\$	\$ 61,031
U.S. government agency securities	34,441	48,488		82,929
U.S. corporate notes		550		550
U.S. commercial paper		45,737		45,737
Money market funds	6,213			6,213
Total	\$ 66,652	\$ 129,808	\$	\$ 196,460

Edgar Filing: THERAVANCE INC - Form 10-Q

Fair Value Measurements at Reporting Date Using

December 31, 2011 (in thousands)	Quoted Prices in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Total
U.S. government securities	\$ 66,174	\$	\$	\$ 66,174
U.S. government agency securities	55,901	37,274		93,175
U.S. corporate notes	2,705			2,705
U.S. commercial paper		34,976		34,976
Money market funds	38,721			38,721
Total	\$ 163,501	\$ 72,250	\$	\$ 235,751

Table of Contents

At March 31, 2012, securities with a total fair value of \$19.6 million were measured using Level 1 inputs in comparison to December 31, 2011, at which time the securities had a fair value of \$19.7 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 March 31, 2012, compared to December 31, 2011.

At March 31, 2012, securities with a total fair value of \$56.2 million were measured using Level 2 inputs in comparison to December 31, 2011, at which time the securities had a fair value of \$56.5 million and were measured using Level 1 inputs. The transfer to Level 2 from Level 1 was primarily the result of decreased trading volume of the securities at and around March 31, 2012, compared to December 31, 2011.

**6. Long-Term Debt**

The fair value of debt was estimated based on the quoted price of the instrument as of March 31, 2012 and December 31, 2011. The carrying values and estimated fair values for the notes were as follows:

(in thousands)	March 31, 2012		December 31, 2011	
	Carrying Value	Estimated Fair Value Level 2	Carrying Value	Estimated Fair Value Level 2
Convertible subordinated notes	\$ 172,500	\$ 178,436	\$ 172,500	\$ 189,588

*Convertible Subordinated Notes*

In January 2008, the Company closed an underwritten public offering of \$172.5 million aggregate principal amount of unsecured convertible subordinated notes which will mature on January 15, 2015. 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 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. The debt issuance costs, which are included in other long-term assets, are being amortized on a straight-line basis over the life of the notes. Unamortized debt issuance costs totaled \$2.3 million as of March 31, 2012. Amortization expense was \$0.2 million in both the three months ended March 31, 2012 and 2011.

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 (as defined) 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 January 15, 2012. 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. As of March 31, 2012, the Company did not provide notice of redemption or redeem any of the notes.

## **7. Commitments and Contingencies**

### *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 March 31, 2012.

Table of Contents*Purchase Obligation*

On January 6, 2012, Astellas exercised its right to terminate the Company's collaboration agreement for VIBATIV®. In March 2012, the Company entered into a series of purchase agreements for VIBATIV® active pharmaceutical ingredient and raw materials of up to \$6.2 million and VIBATIV® finished goods inventory of up to \$4.2 million, which is subject to release by a third party manufacturer.

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

The 2004 Plan provides for the granting of stock options, restricted stock awards, stock appreciation rights and RSUs to employees, officers, directors and consultants of the Company. On April 27, 2010, an amendment and restatement of the 2004 Plan was approved by the Company's stockholders to, among other things, reserve additional shares of common stock for issuance thereunder. As of March 31, 2012, total shares remaining available for issuance under the 2004 Plan were 720,587.

*Employee Stock Purchase Plan*

As of March 31, 2012, a total of 2,025,000 shares of common stock were approved and authorized for issuance under the ESPP. Through March 31, 2012, the Company issued 1,468,454 shares under the ESPP at an average price of \$10.15 per share. Total shares remaining available for issuance under the ESPP were 556,546 as of March 31, 2012.

*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			
	2012		2011	
		March 31,		March 31,
Research and development	\$	3,529	\$	3,132
General and administrative		2,706		2,409
Total stock-based compensation expense	\$	6,235	\$	5,541

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

As of March 31, 2012, unrecognized compensation expense, net of expected forfeitures, was as follows: \$7.0 million related to unvested stock options; \$21.9 million related to unvested RSUs; and \$29.1 million related to unvested RSAs (excludes performance-contingent RSAs).

### *Compensation Awards*

The Company granted the following compensation awards:

	Three Months Ended March 31, 2012		Three Months Ended March 31, 2011	
	Number of Compensation	Weighted- Average Exercise Price/Fair Value	Number of Compensation Awards Granted	Weighted- Average Exercise Price/Fair Value
	Awards Granted		Awards Granted	
2004 Plan				
Stock options	118,000	\$ 19.05	94,000	\$ 22.12
RSUs time-based	468,541	18.12	394,580	24.59
RSAs time-based	402,500	18.11	1,148,000	24.70
RSAs performance-contingent(1)	44,500	18.11	1,290,000	24.73

Table of Contents

(1) In 2011, the Compensation Committee of the Company's Board of Directors approved the grant of 1,290,000 performance-contingent RSAs to senior management. These grants 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 March 31, 2012, 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. 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 grants are subject to forfeiture unless one of three possible performance goals is achieved by December 31, 2013.

*Valuation Assumptions*

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

	Three Months Ended March 31,	
	2012	2011
<b><i>Employee stock options</i></b>		
Risk-free interest rate	1.00%-1.17%	2.38%-2.46%
Expected life (in years)	6	6
Volatility	0.55	0.49
Dividend yield	%	%
Weighted-average estimated fair value of stock options granted	\$ 9.88	\$ 10.86

*Stockholders' Equity*

For the three months ended March 31, 2012, approximately 247,818 shares were exercised at a weighted-average exercise price of \$8.13 per share, for total cash proceeds of approximately \$2,015,000.

**9. Income Taxes**

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

**10. Subsequent Event**

*Sale of Stock*

On April 2, 2012, the Company and GSK entered into a common stock purchase agreement, under which the Company will issue, and GSK will acquire, through an affiliate, 10,000,000 shares of the Company's common stock at a price of \$21.2887 per share, for a total investment of \$212,887,000. This transaction is subject to certain closing conditions, including approval of the Company's stockholders at the annual meeting of stockholders scheduled for May 15, 2012, and expiration of the waiting period under the Hart-Scott-Rodino Act. The agreement may be terminated (i) by GSK if, on any day before the closing of the private placement, the closing S&P 500 index is more than thirty percent (30%) less than the closing S&P 500 index on March 30, 2012, or the Company's Board of Directors changes its recommendation to stockholders to vote in favor of the private placement or (ii) by either of the parties if a vote of the Company's stockholders does not approve the private placement or if the private placement has not closed by July 15, 2012.

Table of Contents

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

**Forward-Looking Statements**

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

**OVERVIEW**

**Executive Summary**

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. We are focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections, and central nervous system (CNS)/pain. Our key programs include: RELOVAIR, LAMA/LABA (719/vilanterol (VI)) and MABA (Bifunctional Muscarinic Antagonist-Beta2 Agonist), each partnered with GlaxoSmithKline plc (GSK), and our oral Peripheral Mu Opioid Receptor Antagonist (PμMA) 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.

Our net income was \$84.6 million in the first quarter of 2012, compared with our net loss of \$22.7 million for the same period in 2011. Net income in the three months ended March 31, 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. Research and development expenses were \$33.2 million for the three months ended March 31, 2012, compared with \$20.5 million for the same period in 2011. This increase was driven primarily by higher external costs relating to ongoing clinical trials. Cash, cash equivalents, and short-term investments totaled \$200.2 million at March 31, 2012, a decrease of \$40.7 million since December 31, 2011. The decrease was due primarily to cash used in operations, partially offset by net proceeds of \$2.0 million received from exercises of employee stock options and \$1.6 million received from the sale of our common stock to an affiliate of GSK.

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

On April 2, 2012, we and GSK entered into a common stock purchase agreement, under which we will issue, and GSK will acquire, through an affiliate, 10,000,000 shares of our common stock at a price of \$21.2887 per share, for a total investment of \$212,887,000. This transaction is subject to certain closing conditions, including approval of our stockholders at the annual meeting of stockholders scheduled for May 15, 2012, and expiration of the waiting period under the Hart-Scott-Rodino Act.

### **Programs**

#### *Respiratory Programs with GSK*

##### *RELOVAIR*

RELOVAIR is an investigational once-daily inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) combination treatment, comprising fluticasone furoate and vilanterol (FF/VI), currently in development for the treatment of patients with chronic obstructive pulmonary disease (COPD) and patients with asthma.

Table of Contents

During the first quarter of 2012, we and GSK announced the completion of the overall registrational program for RELOVAIR in COPD and asthma. In addition, results from two non-pivotal Phase 3 studies of RELOVAIR compared with twice-daily Advair® (fluticasone propionate (FP)/salmeterol (SAL) (FP/SAL)) in patients with COPD and results from a pivotal Phase 3 study evaluating the efficacy and safety of FF and FP compared to placebo in the treatment of persistent asthma in adults and adolescents were announced. For COPD, GSK continues with its plans to submit regulatory applications for RELOVAIR in the U.S. and Europe in mid-2012. For asthma, GSK plans to submit an application in Europe in mid-2012 and GSK and we are reviewing the strategy for a future U.S. filing. In March 2012, the Salford Lung Study, the first real-world effectiveness study to investigate the potential effects of RELOVAIR versus the standards of care in Europe, was initiated in patients with COPD.

*LAMA/LABA Combination (GSK573719/Vilanterol or 719/VI)*

The Phase 3a program for the once-daily LAMA/LABA dual bronchodilator 719/VI is progressing well. We and GSK expect to report Phase 3a results from the LAMA/LABA program in 2012. 719/VI combines two bronchodilators currently under development: 719, a long-acting muscarinic antagonist (LAMA) and VI, a LABA. These molecules act through antagonism of acetylcholine muscarinic receptors and agonism of beta2 adrenoreceptors.

The LAMA/LABA Phase 3a program, which has enrolled over 5,000 patients with COPD globally, consists of a 52-week study to evaluate the long term safety and tolerability of 719 (125mcg) alone as well as the combination 719/VI (125/25mcg), two large 6-month pivotal studies that will compare improvements in lung function among 719/VI, its components and placebo, two 6-month studies to compare the combination with its components and tiotropium and two studies to assess the effect of 719/VI on exercise endurance. The Phase 3a program will investigate two doses of 719 (125mcg and 62.5mcg) and two doses of the combination 719/VI (125/25mcg and 62.5/25mcg).

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

GSK961081 (081) is a single molecule bifunctional bronchodilator with both muscarinic antagonist and beta2 receptor agonist activity. In February 2012, we presented at Leerink Swann Healthcare Conference topline results from a Phase 2b efficacy and safety study of 081 administered once-daily (QD) or twice-daily (BID) to 436 patients with moderate to severe COPD for 28 days. The results of the Phase 2b study and a number of ongoing non-clinical enabling studies will inform the selection of the most appropriate dose and dosing interval for 081 and progression to Phase 3 will be dependent upon successful completion of these enabling studies.

*Central Nervous System (CNS)/Pain Program*

*Oral Peripheral Mu Opioid Receptor Antagonist (PμMA) TD-1211*

Enrollment is complete in two of the three studies in the Phase 2b program, which will assess the safety, tolerability and clinical activity of TD-1211 in patients with opioid-induced constipation (OIC). This program is evaluating several doses and dosing regimens to provide



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

information for the design of the Phase 3 program. TD-1211 is an investigational once-daily, orally-administered, peripherally selective, multivalent inhibitor of the mu opioid receptor designed to alleviate gastrointestinal side effects of opioid therapy without affecting analgesia.

### *MonoAmine Reuptake INhibitor (MARIN) TD-9855*

Enrollment is progressing in the Phase 2 proof-of-concept study with TD-9855 in patients with Attention-Deficit/Hyperactivity Disorder (ADHD), the lead compound in our MARIN program. This Phase 2 study will evaluate the safety and efficacy of two different doses of TD-9855 in adults with ADHD. TD-9855 is an investigational norepinephrine and serotonin reuptake inhibitor (NSRI) discovered by Theravance for the treatment of central nervous system (CNS) conditions such as ADHD and chronic pain.

### **Collaboration Arrangements**

#### **GSK**

#### *LABA collaboration*

In November 2002, we entered into our LABA collaboration with GSK to develop and commercialize once-daily LABA products for the treatment of COPD and asthma. For the treatment of COPD, the collaboration is developing combination products, RELOVAIR and the LAMA/LABA 719/VI. For the treatment of asthma, the collaboration is developing RELOVAIR .

Table of Contents

RELOVAIR is an investigational once-daily combination medicine consisting of a LABA, VI, previously referred to as GW642444 or 444, and an ICS, fluticasone furoate (FF). The LAMA/LABA, 719/VI, is an investigational once-daily combination medicine consisting of the LAMA, 719, and the LABA, VI. The RELOVAIR 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 2011 sales of approximately \$8.1 billion, and to compete with Symbicort® (formoterol and budesonide as a combination), which had reported 2011 sales of approximately \$3.1 billion. 719/VI, 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 2011 sales of approximately \$4.2 billion.

The current lead product candidates in the LABA collaboration, VI and FF, were discovered by GSK. In the event that VI is successfully developed and commercialized, we will be obligated to make milestone payments to GSK which could total as much as \$220.0 million if both a single-agent and a combination product or two different combination products are launched in multiple regions of the world. If global regulatory authorities accept the applications for RELOVAIR, which we anticipate will be filed by GSK beginning in mid-2012, a portion of these potential milestone payments could be payable to GSK within the next two years. We are entitled to 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 719/VI, royalties are upward tiering and range from the mid-single digits to 10%. However, if GSK is not selling a LABA/ICS combination product at the time that the first other LABA combination is launched, then the royalties described above for the LABA/ICS combination medicine would be applicable.

*2004 Strategic Alliance with GSK*

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.

In 2005, GSK licensed our MABA program for the treatment of COPD, and in October 2011, we and GSK expanded the MABA program by adding six additional Theravance-discovered preclinical MABA compounds (the Additional MABAs). GSK's development, commercialization, milestone and royalty obligations under the strategic alliance remain the same with respect to 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 a MABA/ICS, 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, 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 milestone payments 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 milestone payments up to \$129.0 million.

In connection with the expansion of the MABA program, GSK relinquished its option right on our MonoAmine Reuptake Inhibitor (MARIN) program and Angiotensin Receptor-NEP Inhibitor (ARNI) program. GSK has no further option rights on any of our research or development programs under the strategic alliance.

In May 2004, GlaxoSmithKline LLC, an affiliate of GSK, purchased 6,387,096 shares of our Class A common stock for an aggregate purchase price of \$108.9 million and, upon the closing of our initial public offering on October 8, 2004, GlaxoSmithKline LLC purchased an additional 433,757 shares of Class A common stock for an aggregate purchase price of \$6.9 million. In November 2010 Glaxo Group Limited, an affiliate of GSK, purchased 5,750,000 shares of our common stock for an aggregate purchase price of \$129.4 million.

Table of Contents

*Common Stock Purchase Agreement, Purchases of Common Stock under our Governance Agreement and Conversion of our Class A Common Stock*

On April 2, 2012, we and GSK entered into a stock purchase agreement, under which we will issue, and GSK will acquire, through an affiliate, 10,000,000 shares of our common stock at a price of \$21.2887 per share, for a total investment of \$212,887,000. This transaction is subject to certain closing conditions, including approval of our stockholders at the annual meeting of stockholders scheduled for May 15, 2012, and expiration of the waiting period under the Hart-Scott-Rodino Act. The agreement may be terminated (i) by GSK if, on any day before the closing of the private placement, the closing S&P 500 index is more than thirty percent (30%) less than the closing S&P 500 index on March 30, 2012, or our Board of Directors changes its recommendation to stockholders to vote in favor of the private placement or (ii) by either of the parties if a vote of our stockholders does not approve the private placement or if the private placement has not closed by July 15, 2012.

In addition, Glaxo Group Limited purchased shares of our common stock pursuant to its periodic top-up rights under our governance agreement with GSK dated June 4, 2004, as amended, as follows:

<i>Purchase dates</i>	<b>Through March 31, 2012</b>	
	<b>Common Stock Shares Purchased</b>	<b>Aggregate Amounts (in millions)</b>
February 24, 2011	152,278	\$ 3.6
May 3, 2011	261,299	\$ 6.7
August 2, 2011	102,466	\$ 2.0
November 1, 2011	58,411	\$ 1.3
February 14, 2012	88,468	\$ 1.6

In July 2011, GSK converted all of the shares of our Class A common stock held by its affiliates into 9,401,499 shares of our common stock on a one share-for-one share basis in accordance with the terms of our restated certificate of incorporation.

*GSK Upfront License Fees, Milestone Payments and Revenue*

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

<b>(in millions)</b>	<b>Three Months Ended March 31,</b>	
	<b>2012</b>	<b>2011</b>
LABA/RELOVAIR collaboration	\$ 0.9	\$ 1.3
Strategic alliance agreement		0.7
Strategic alliance MABA program license	0.5	0.5
Total revenue	\$ 1.4	\$ 2.5

*Astellas*

*License, Development and Commercialization Agreement with Astellas*

In November 2005, we entered into a global collaboration arrangement with Astellas for the development and commercialization of VIBATIV®. On January 6, 2012, Astellas exercised its right to terminate this 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®. In March 2012, we entered into a series of agreements with Astellas for the purchase of VIBATIV® active pharmaceutical ingredient and raw materials of up to \$6.2 million and VIBATIV® finished goods inventory of up to \$4.2 million, which is subject to release by a third party manufacturer. In addition, beginning July 1, 2012, we are responsible to fund governmental rebate and governmental chargeback claims for Astellas-labeled product sales. As a result of the termination agreement, we recorded a liability of \$150,000 at March 31, 2012, which is included in the condensed consolidated balance sheets. We are evaluating global commercialization alternatives for VIBATIV® either with partners or alone.

Table of Contents

VIBATIV® (telavancin) is a bactericidal, once-daily injectable antibiotic developed by us for the treatment of Gram-positive infections. The FDA has approved VIBATIV® for the treatment of complicated skin and skin structure infections (cSSSI) caused by susceptible Gram-positive bacteria including both methicillin-resistant (MRSA) and methicillin-susceptible strains of *Staphylococcus aureus* in adult patients. VIBATIV® is also approved in Canada for the treatment of cSSSI in adult patients. In September 2011, the European Commission granted marketing authorization for VIBATIV® for the treatment of adults with nosocomial pneumonia, including ventilator-associated pneumonia, known or suspected to be caused by MRSA when other alternatives are not suitable. However, in February 2012, the Committee for Medicinal Products for Human Use (CHMP) recommended to the European Commission that it suspend this marketing authorization because the single-source drug product supplier does not meet the Good Manufacturing Practice (GMP) requirements to allow the manufacture of VIBATIV®.

Due to manufacturing issues at the single-source supplier of VIBATIV® drug product, VIBATIV® is currently subject to critical product shortages and regional supply outages in the U.S. We have begun identifying possible alternative manufacturers for VIBATIV® drug product. The process of identifying and qualifying an alternative manufacturer could take 12 to 24 months.

Through January 6, 2012, we had received \$191.0 million in upfront license, milestone and other fees from Astellas. We previously recorded these payments as deferred revenue and amortized them ratably over the estimated performance period (development and commercialization period). As a result of the termination of the VIBATIV® collaboration agreement, the development and commercialization period ended on January 6, 2012. As such, we recognized into revenue \$125.8 million of deferred revenue related to Astellas in the three months ended March 31, 2012, and we are no longer eligible to receive any further milestone payments from Astellas.

Net revenue recognized under this collaboration agreement was as follows:

(in millions)	Three Months Ended				
	2012		March 31,		2011
Recognition of deferred revenue	\$	125.8	\$	3.2	
Royalties from net sales of VIBATIV®				0.6	
Astellas-labeled product sales allowance		(0.1)			
Total net revenue	\$	125.7	\$	3.8	

**Critical Accounting Policies and the Use of Estimates**

As of the date of the filing of this quarterly report, we believe there have been no material changes or additions to our critical accounting policies and estimates during the three months ended March 31, 2012 compared to those discussed in our 2011 Annual Report on Form 10-K filed on February 27, 2012.

**RESULTS OF OPERATIONS**

**Revenue**

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

(in millions, except percentages)	Three Months Ended				Change		
	2012	March 31,	2011		\$	%	
Revenue	\$	127.1	\$	6.3	\$	120.8	1917%

We recognized revenue from the amortization of upfront license fees and milestone payments related to our GSK LABA collaboration and strategic alliance agreements and our Astellas telavancin collaboration, which was terminated on January 6, 2012. In addition, we recognized revenue related to our Astellas telavancin collaboration from royalties from net sales of VIBATIV® and from the impact of VIBATIV® inventory transfers or dispositions.

Revenue increased to \$127.1 million in the first quarter of 2012, from the comparable period in 2011. This increase reflects the accelerated recognition of deferred revenue of \$125.7 million from our global collaboration arrangement with Astellas for the development and commercialization of VIBATIV®. This recognition resulted from Astellas' January 6, 2012 termination of our agreement with them. This increase was partially offset by a decrease in revenue related to our GSK strategic alliance agreement of \$0.7 million resulting from the deferred revenue being fully amortized in the third quarter of 2011.

Table of Contents

Upfront license fees and milestone payments received from GSK under the LABA collaboration and strategic alliance agreements and from Astellas under the telavancin collaboration were as follows:

(in millions)	Through March 31, 2012		
	Upfront License and Other Fees	Milestone Payments	Total
<i>GSK Collaborations</i>			
LABA/RELOVAIR collaboration(1)	\$ 10.0	\$ 50.0	\$ 60.0
Strategic alliance agreement	20.0		20.0
Strategic alliance LAMA license(2)	5.0	3.0	8.0
Strategic alliance MABA program license	6.0	16.0	22.0
<i>Astellas License agreement(3)</i>	70.0	121.0	191.0
<b>Total</b>	<b>\$ 111.0</b>	<b>\$ 190.0</b>	<b>\$ 301.0</b>

(1) We do not currently expect to be eligible for any additional milestones under this collaboration.

(2) In August 2004, GSK exercised its right to license our LAMA program pursuant to the terms of the strategic alliance. In 2009, GSK returned the program to us.

(3) This agreement was terminated on January 6, 2012.

Upfront fees and certain milestone payments received from GSK have been deferred and are being amortized ratably into revenue over the estimated performance period. Future revenue will include the ongoing amortization of upfront and milestone 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 period, were as follows:

(in millions, except percentages)	Three Months Ended		Change	
	2012	March 31, 2011		
Employee-related	\$ 10.2	\$ 8.3	\$ 1.9	23%
External research and development	13.2	3.2	10.0	313%
Stock-based compensation	3.5	3.1	0.4	13%
Facilities, depreciation and other allocated	6.3	5.9	0.4	7%



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

Total research and development expenses	\$	33.2	\$	20.5	\$	12.7	62%
---	----	------	----	------	----	------	-----

R&D expenses increased in the first quarter of 2012, compared to the same period in 2011. The increase in the first quarter of 2012 was due primarily to Phase 2 clinical costs related to our PμMA and MARIN programs, costs related to our preclinical and late-stage discovery programs, and higher employee-related expenses.

We anticipate R&D expenses for 2012 to increase relative to 2011. R&D expenses in 2012 will be driven largely by employee-related expenses, costs associated with our continued development efforts in our PμMA program for opioid-induced constipation with TD-1211, our MARIN program with TD-9855, and costs associated with our earlier stage clinical programs, preclinical and late-stage discovery as well as new drug discovery programs. We have not provided program costs in detail because we do not track, and have not tracked, all of the individual components (specifically the internal cost components) of our research and development expenses on a program basis. We do not have the systems and processes in place to accurately capture these costs on a program basis.

### *General and administrative*

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

(in millions, except percentages)	Three Months Ended March 31,				Change	
	2012	2011	2012	2011	\$	%
General and administrative	\$ 7.9	\$ 7.2	\$ 0.7	\$ 0.7	10%	

Table of Contents

G&A expenses increased in the first quarter of 2012, compared to same period in 2011. The increase in the first quarter of 2012 was due primarily to higher external legal and professional services costs in connection with the evaluation of global commercialization alternatives related to VIBATIV® and higher employee-related expenses, including stock-based compensation expense, partially offset by lower facilities-related costs. Stock-based compensation expense for the first quarter of 2012 was \$2.7 million compared with \$2.4 million for the same period in 2011.

We anticipate G&A expenses for 2012 to increase slightly relative to 2011, due to the transfer of certain ongoing VIBATIV® related activities following the termination by Astellas of the collaboration agreement in January 2012.

***Interest income***

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

(in millions, except percentages)	Three Months Ended March 31,		Change	
	2012	2011	\$	%
Interest income	\$ 0.1	\$ 0.1	\$	%

Interest income remained flat in the first quarter of 2012, compared to the same period in 2011.

***Interest expense***

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

(in millions, except percentages)	Three Months Ended March 31,		Change	
	2012	2011	\$	%
Interest expense	\$ 1.5	\$ 1.5	\$	%

Interest expense is primarily comprised of interest expense and amortization of debt issuance costs from our convertible subordinated notes issued in January 2008.

**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 collaboration arrangements. As of March 31, 2012, we had \$200.2 million in cash, cash equivalents and marketable securities, excluding \$0.9 million in restricted cash that was pledged as collateral for certain of our leases. On April 2, 2012, we and GSK entered into a stock purchase agreement, under which we will issue, and GSK will acquire, through an affiliate, 10,000,000 shares of our common stock at a price of \$21.2887 per share, for a total investment of \$212,887,000. This stock purchase is subject to certain closing conditions, including approval of our stockholders at the annual meeting of stockholders scheduled for May 15, 2012, and expiration of the waiting period under the Hart-Scott-Rodino Act. Further, if the closing S&P 500 index is more than thirty percent (30%) less than the closing S&P 500 index on March 30, 2012, then GSK will have the option not to consummate the private placement.

We expect to incur substantial expenses as we continue our discovery and development efforts; particularly to the extent we advance our product candidates into clinical studies, which are very expensive. A Phase 2b program is underway in our PuMA program and we initiated a Phase 2 study for MARIN in late 2011. We also intend to invest in other assets in our pipeline, including programs in earlier-stage clinical development and late-stage discovery. On January 6, 2012, Astellas exercised its right to terminate our collaboration agreement for VIBATIV®. In March 2012, we entered into a series of purchase agreements for VIBATIV® active pharmaceutical ingredient and raw materials of up to \$6.2 million and VIBATIV® finished goods inventory of up to \$4.2 million, which is subject to release of the inventory by a third party manufacturer.

Table of Contents

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, milestone and royalty forecasts and spending assumptions. If our current operating plans, milestone and royalty forecasts or spending assumptions change or if the proposed private placement to GSK is not completed, 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 presently conducted. In addition, we regularly explore debt restructuring and/or reduction alternatives, including through tender offers, redemptions, repurchases or otherwise, all consistent with the terms of our debt agreements.

*Cash Flows*

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

(in millions)	Three Months Ended	
	2012	March 31, 2011
Net cash used in operating activities	\$ (41.3)	\$ (25.9)
Net cash provided by (used in) investing activities	\$ 8.4	\$ (1.2)
Net cash provided by financing activities	\$ 2.5	\$ 11.7

Cash used in operations increased \$15.4 million for the three months ended March 31, 2012, compared to the same period in 2011, due primarily to higher uses of cash for operating liabilities.

Cash provided by investing activities increased \$9.6 million for the three months ended March 31, 2012, compared to the same period in 2011, resulting primarily from lower cash balances being invested in short-term investments during the first quarter of 2012, compared to the same period in 2011.

Cash provided by financing activities decreased \$9.2 million for the three months ended March 31, 2012, compared to the same period in 2011, due primarily to lower proceeds received from exercises of employee stock options in the first quarter of 2012, compared to the same period in 2011.

*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.

**Contractual Obligations and Commercial Commitments**

During the first three months of 2012, 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, 2011, except that we entered into a series of agreements with Astellas for the purchase of VIBATIV® active pharmaceutical ingredient and raw materials of up to \$6.2 million and VIBATIV® finished goods inventory of up to \$4.2 million, which is subject to release by a third party manufacturer.

We indemnify our officers and directors for certain events or occurrences, subject to certain limits. We may be subject to contingencies that may arise from matters such as product liability claims, legal proceedings, shareholder suits and tax matters, as such, we are unable to estimate the potential exposure related to these indemnification agreements. We have not recognized any liabilities relating to these agreements as of March 31, 2012.

Pursuant to our LABA collaboration with GSK, we will be obligated to make milestone payments to GSK which could total as much as \$220.0 million if both a single-agent and a combination product or two different combination products are launched in multiple regions of the world with the current lead LABA, VI. If global regulatory authorities accept the applications for RELOVAIR , which we anticipate will be filed by GSK beginning in mid-2012, a portion of these potential milestone payments could be payable to GSK within the next two years. We have not recognized any liabilities relating to this agreement as of March 31, 2012.

Table of Contents

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

During the first three months of 2012, 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, 2011.

**Item 4. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures.*

We conducted an evaluation as of March 31, 2012, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, which are defined under SEC rules as controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Securities Exchange Act of 1934 (Exchange Act) is recorded, processed, summarized and reported within required time periods. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

*Limitations on the Effectiveness of Controls*

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefit of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within Theravance have been detected. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

*Changes in Internal Control over Financial Reporting*

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

**PART II. OTHER INFORMATION**

**Item 1A. Risk Factors**

In addition to the other information in this Quarterly Report on Form 10-Q, the following risk factors should be considered carefully in evaluating our business and us.

**Risks Related to our Business**

*If regulatory authorities determine that the RELOVAIR Phase 3 program in asthma or chronic obstructive pulmonary disease (COPD) does not demonstrate safety and efficacy, the RELOVAIR program will be significantly delayed or terminated, our business will be harmed, 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 RELOVAIR Phase 3 registrational program for COPD and asthma. For COPD, GSK continues with its plans to submit regulatory applications for RELOVAIR in the U.S. and Europe in mid-2012. For asthma, GSK plans to submit an application in Europe in mid-2012 and GSK and we are reviewing asthma filing strategy in the U.S. The RELOVAIR Phase 3b program for COPD commenced in February 2011. Any adverse developments or results or perceived adverse developments or results with respect to the RELOVAIR 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 in the Phase 3 programs with RELOVAIR achieved its primary endpoint, and the FDA and/or other regulatory authorities may determine that additional clinical studies are required;
- inability to gain, or delay in gaining, regulatory approval for the new delivery device used in these programs;

Table of Contents

- safety or other concerns arising from non-clinical or clinical studies in these programs. For example, GSK is investigating reports of fatal pneumonia with RELOVAIR primarily at the highest dose;
- safety or other concerns arising from the ongoing long-acting muscarinic antagonist (LAMA)/long-acting beta2 agonist (LABA) Phase 3 program having to do with the LABA vilanterol, or VI, which is also a component of RELOVAIR ;
- regulatory authorities determining that the Phase 3 program in asthma or COPD raises safety concerns or does not demonstrate 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 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 development of RELOVAIR. 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 increased time and cost of the asthma clinical trials in the United States for RELOVAIR and increase the overall risk of the RELOVAIR asthma program in the United States.

***If the 719/VI Phase 3 program for the treatment of COPD does not demonstrate safety and efficacy, the 719/VI program will be significantly delayed or terminated, our business will be harmed, and the price of our securities could fall.***

The 719/VI Phase 3 program with the combination of the LABA, VI, and the LAMA GSK573719, or 719, for the treatment of COPD commenced in February 2011. Any adverse developments or results or perceived adverse developments or results with respect to the 719/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 for the new delivery device used in the program;
- safety or other concerns arising from ongoing non-clinical or clinical studies in this program;
- safety or other concerns arising from the RELOVAIR Phase 3 programs having to do with the LABA, VI, which is also a component of 719/VI;
- the Phase 3 program in COPD raising safety concerns or not demonstrating efficacy; or
- any change in FDA policy or guidance regarding the use of LABAs combined with a LAMA to treat COPD.

***If the MABA program for the treatment of COPD does not demonstrate safety and efficacy, the MABA program will be significantly delayed or 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 recently completed a Phase 2b study and a Phase 1 study in combination with fluticasone propionate (FP), an inhaled corticosteroid (ICS), and a number of Phase 3-enabling non-clinical studies are ongoing. We announced topline results from the Phase 2b COPD study in February 2012 and progression into Phase 3 is dependent upon successful completion of the Phase 3-enabling studies. Any adverse developments or results or perceived adverse developments or results with respect to these studies 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;
- inability to gain, or delay in gaining, regulatory approval for the delivery device used in the program;
- safety or other concerns arising from the Phase 3-enabling non-clinical studies; or
- any change in FDA policy or guidance regarding the use of MABAs to treat COPD.

*Our collaboration agreement for VIBATIV® was terminated in early 2012, VIBATIV® was returned to us, and we have no experience selling or distributing products and no internal capability to do so.*

Generally, our 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. With VIBATIV®, which was returned to us by Astellas in January 2012, and any of our product candidates that receive regulatory approval in the future and are not covered by our current agreements with GSK, we will need a partner in order to commercialize such products unless we establish a sales and marketing organization with appropriate technical expertise and supporting infrastructure and distribution capability. At present, we have no sales personnel and a limited number of marketing personnel. Factors that may inhibit our efforts to commercialize our products without strategic partners or licensees include:

- significant costs and expenses associated with creating an independent sales and marketing organization with appropriate technical expertise and supporting infrastructure and distribution capability;
- 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 persuade adequate numbers of physicians to prescribe our products; 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.

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

If we are not able to partner with a third party and are not successful in recruiting sales and marketing personnel or in building a sales and marketing organization with appropriate technical expertise and supporting infrastructure and distribution capability, we will have difficulty commercializing VIBATIV® and other product candidates, 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. For example, we had planned to commence the Phase 2b study in our MABA program with GSK in 2009, but the program was delayed until late 2010.

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;

Table of Contents

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

***If our product candidates that we develop on our own or through 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 telavancin is not approved for nosocomial pneumonia (NP) in the United States, the commercialization of VIBATIV® in the U.S. will continue to be adversely affected and the price of our securities could fall.***

Our first New Drug Application (NDA), for VIBATIV® (telavancin) for the treatment of complicated skin and skin structure infections (cSSSI) caused by susceptible Gram-positive bacteria in adult patients, was approved by the FDA in September 2009. In January 2009, we submitted a second telavancin NDA to the FDA for the NP indication based on data from our two Phase 3 studies referred to as the ATTAIN studies. These studies were conducted in accordance with the then current draft FDA guidelines and met their primary efficacy endpoint of clinical cure. During the fourth quarter of 2010 the FDA issued new draft guidance for antibacterial clinical trial design for the treatment of NP with a focus on mortality as the primary efficacy endpoint. In late 2010, we received a Complete Response Letter from the FDA indicating that the ATTAIN studies do not meet the new draft guidance and that additional clinical studies will be required for approval. We do not plan to conduct additional clinical studies for NP, but we do intend to continue to engage with FDA concerning the NP NDA. Lack of FDA approval for use of telavancin to treat NP has adversely affected and may continue to adversely affect commercialization of this medicine in the United States.

Table of Contents

***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 our first product, VIBATIV®, 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 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. 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 an increasingly conservative regulatory environment. The implementation of new laws and regulations, and revisions to FDA clinical trial design guidance, have increased uncertainty regarding the approvability of a new drug. Further, there are additional requirements for approval of new drugs, including advisory committee meetings for new chemical entities, and formal risk evaluation and mitigation strategy (REMS) at the FDA's discretion. These new laws, regulations, additional requirements and changes in interpretation could cause non-approval or further delays in the FDA's review and approval of our product candidates.

***There currently is no reliable manufacturer for VIBATIV® drug product supply and we rely on a single source of supply for a number of our product candidates; accordingly, our business will be harmed if a reliable source of VIBATIV® drug product is not qualified and engaged on a timely basis or the single-source manufacturers are not able to satisfy demand and alternative sources are not available.***

During the fourth quarter of 2011, the third party manufacturer of VIBATIV® drug product notified the FDA of an ongoing investigation related to its production equipment and processes. The notification included all products manufactured at the third party manufacturer's facility which remain within expiry, including batches of manufactured but unreleased VIBATIV®. In November 2011, Astellas (our former VIBATIV® collaboration partner) voluntarily placed a hold on distribution of VIBATIV® to wholesalers, and cancelled pending orders for VIBATIV® with this manufacturer. VIBATIV® drug product previously manufactured by, and still on-site at, this manufacturer will not become available for sale in the U.S. unless and until the batches are released. Similarly, our purchase orders for this inventory cannot be fulfilled unless and until the batches are released. We cannot predict when or if the manufactured batches of VIBATIV® will be released. In addition, in August 2011 the third party manufacturer of VIBATIV® drug product announced its intention to transition out of the contract manufacturing services business over the next several years. Additional VIBATIV® drug product will need to be manufactured to meet longer-term U.S. demand as well as demand from the E.U. and Canada. In February 2012 the Committee for Medicinal Products for Human Use (CHMP) recommended to the European Commission that it suspend marketing authorization for VIBATIV® because the single-source VIBATIV® drug product supplier does not meet the good manufacturing practice (GMP) requirements to allow the manufacture of VIBATIV®. No VIBATIV® drug product intended to meet E.U. specifications has as yet been manufactured. We have begun identifying possible alternative manufacturers for VIBATIV® drug product. The process of identifying and qualifying an alternative manufacturer for VIBATIV® drug product may take 12 to 24 months.

If the VIBATIV® drug product on-site at the third party manufacturer is not released in the near future, the commercialization of VIBATIV® in the U.S. will continue to be adversely affected, and if supplemental or alternative commercial manufacture of VIBATIV® drug product cannot be arranged on a timely basis, the commercial introduction of VIBATIV® in the E.U. and Canada will be materially delayed. In each such case, our business will be harmed and the price of our securities could fall.

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

With respect to our programs other than VIBATIV®, we have limited in-house production capabilities for non-clinical and early 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 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.

Table of Contents

Our manufacturing strategy presents the following additional risks:

- because of the complex nature 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.

***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, VIBATIV®'s U.S. labeling contains a boxed warning regarding the risks of use of VIBATIV® during pregnancy. Products with boxed warnings are subject to more restrictive advertising regulations than products without such warnings. In addition, the VIBATIV® labeling that was approved for the E.U. in 2011 specifies that VIBATIV® should be used only in situations where it is known or suspected that other alternatives are not suitable. These restrictions could make it more difficult to market VIBATIV®. Further, in February 2012 the CHMP recommended to the European Commission that it suspend marketing authorization for VIBATIV® because the single-source VIBATIV® drug product supplier does not meet the GMP requirements to allow the manufacture of 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 notified the FDA of an ongoing investigation related to its production equipment and processes. The notification included all products manufactured at the third party manufacturer's facility which remain within



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

expiry, including batches of manufactured but unreleased VIBATIV®. Astellas (our former VIBATIV® collaboration partner) subsequently placed a voluntary hold on distribution of VIBATIV® to wholesalers and cancelled pending orders for VIBATIV® with this manufacturer. With this supply interruption and the termination of our VIBATIV® collaboration agreement with Astellas, commercialization of VIBATIV® has essentially stopped, we have experienced a significant drop in the sales of the product and the reputation of VIBATIV® in the marketplace may suffer.

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 our stock price to decline.

Table of Contents

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

We have been engaged in discovering and developing compounds and product candidates since mid-1997. Our first approved product, VIBATIV®, was launched by our partner Astellas in the U.S. in November 2009, and to date we have received only modest revenues from VIBATIV® sales. We may never generate sufficient revenue from the sale of medicines or royalties on sales by our partners to achieve profitability. As of March 31, 2012, we had an accumulated deficit of approximately \$1.2 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. As a result, we expect to continue to incur substantial losses for the foreseeable future. We are uncertain when or if we will be able to achieve or sustain profitability. Failure to become and remain profitable would adversely affect the price of our securities and our ability to raise capital and continue operations.

***If we fail to 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. In April 2012 we entered into a common stock purchase agreement with GSK pursuant to which we agreed to sell 10,000,000 shares of our common stock to GSK in a private placement for \$21.2887 per share, or a total investment of approximately \$212.9 million. This private placement is subject to certain closing conditions, including approval by our stockholders at our annual meeting in May 2012 and expiration of the waiting period under the Hart-Scott Rodino Act. Further, if the closing S&P 500 index is more than thirty percent (30%) less than the closing S&P 500 index on March 30, 2012, then GSK will have the option not to consummate the private placement. If any of the conditions to closing the private placement do not occur, or if the S&P 500 index drops significantly such that GSK obtains the right and decides to terminate the agreement, our business and financial condition will be harmed and the price of our securities could fall. Based on our current operating plans, milestone and royalty forecasts and spending assumptions, 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, milestone and royalty forecasts or spending assumptions change or if the proposed private placement to GSK is not completed, we may require additional funding sooner in the form of public or private equity offerings or debt financings. Although we have no current intention to do so, if we were to conduct additional studies to support the telavancin NP NDA, or if we were to build the sales and marketing, distribution and compliance infrastructure to commercialize VIBATIV® without a partner, our capital needs would increase substantially. We intend to continue development of our pipeline. A Phase 2b program is underway in our PuMA program and we initiated a Phase 2 study for MARIN in late 2011. We also intend to invest in other assets in our pipeline, including programs in earlier-stage clinical development and late-stage discovery. Further, in connection with the recent termination of our collaboration agreement with Astellas, we entered into purchase agreements for VIBATIV® active pharmaceutical ingredient and raw materials of up to \$6.2 million and VIBATIV® finished goods inventory of up to \$4.2 million, which is subject to release of the inventory by a third party manufacturer. In addition, under our LABA collaboration with GSK, in the event that vilanterol (VI), which is the current lead LABA product candidate in RELOVAIR and LAMA/LABA ( 719/VI) and which was discovered by GSK, is approved and launched 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 \$220.0 million and we would not be entitled to receive any further milestone payments from GSK. 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, and this risk is aggravated by the current critical product shortages and regional supply outages.*

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

Table of Contents

antibacterials manufactured and marketed by major pharmaceutical companies and others, and may compete against new antibacterials that are not yet on the market. Even if the medical community accepts that VIBATIV® is safe and efficacious for its indicated use, physicians may restrict the use of VIBATIV® due to the current product shortages stemming from the manufacturing issues at the drug product supplier, the recent termination of our VIBATIV® collaboration agreement with Astellas, or otherwise. If we are unable to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, VIBATIV® is preferable to vancomycin and other antibacterial drugs, 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.;
- potential negative perceptions of physicians related to our inability to obtain FDA approval of our NP NDA, the product shortages stemming from the manufacturing issues at the drug product supplier or the recent termination of our VIBATIV® collaboration agreement with Astellas;
- potential negative perceptions of physicians related to the recent CHMP recommendation to the European Commission that it suspend marketing authorization for VIBATIV® because the single-source VIBATIV® drug product supplier does not meet the GMP requirements to allow the manufacture of VIBATIV®;
- the advantages and disadvantages of VIBATIV® compared to alternative therapies;
- our ability to educate the medical community about the safety and effectiveness of VIBATIV®;
- the reimbursement policies of government and third party payors; and
- the market price of VIBATIV® relative to competing therapies.

*If our partners do not satisfy their obligations under our agreements with them, or if they terminate our partnerships with them, as Astellas did with our VIBATIV® collaboration agreement in January 2012, 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. 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 RELOVAIR , LAMA/LABA ( 719/VI) 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. Astellas terminated the VIBATIV® agreement in January 2012.

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. 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. In addition, with the exception of product candidates in our LABA collaboration and the MABA program under the strategic alliance, our partners generally are not restricted from developing and commercializing their own products and product candidates that compete with those licensed from us. 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 the partner. 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 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. For example, Astellas terminated the VIBATIV® collaboration agreement in January 2012, and both due to the termination and the current product shortages and regional supply outages stemming from the manufacturing issues at the third party VIBATIV® drug product supplier, the commercialization of VIBATIV® in the U.S. has essentially stopped and the commercial introduction of VIBATIV® in the E.U. and Canada has been delayed.

Table of Contents

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

We have active collaborations with GSK for RELOVAIR, LAMA/LABA (719/VI) and the MABA program and we have licensed our anesthesia compound to AstraZeneca AB (AstraZeneca). Additional collaborations will be needed to fund later-stage development of our product candidates that have not been licensed to a collaborator, and to commercialize these product candidates if approved by the necessary regulatory authorities. Each of TD-5108, our lead compound in the 5-HT4 program, TD-1792, our investigational antibiotic, TD-1211, the lead compound in our PuMA program for opioid-induced constipation and TD-4208, our LAMA compound, has successfully completed a Phase 2 proof-of-concept study. 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 and ARNI programs. Also, we now have full rights to VIBATIV® as a result of the termination of our collaboration agreement with Astellas in January 2012. We currently intend to seek third parties with which to pursue collaboration arrangements for the development and commercialization of our development programs and for the future commercialization of VIBATIV®. 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, especially in the current uncertain economy, which is driving many biotechnology and biopharmaceutical companies to seek to sell or license their assets. 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 our stock price to decline.

***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 good clinical practices and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators and trial sites. For example, in connection with the FDA's review of our telavancin NDAs, the FDA conducted inspections of Theravance and certain of our study sites, clinical investigators and CROs. 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.***

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

Our ability to succeed in the future depends on our ability to demonstrate and maintain a competitive advantage with respect to our approach to the discovery and development of medicines. Our objective is to discover, develop and commercialize new small molecule medicines with superior efficacy, convenience, tolerability and/or safety. 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.

Table of Contents

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, as it competes with vancomycin, a relatively inexpensive generic drug that is manufactured by a number of companies, and a number of existing antibacterial drugs marketed by major and other pharmaceutical companies. If we are not able to compete effectively against our current and future competitors, our business will not grow, our financial condition and operations will suffer and the price of our securities could fall.

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

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

We are highly dependent on principal members of our management team and scientific staff to operate our business. Our company is located in northern California, which is headquarters to many other biotechnology and biopharmaceutical companies and many academic and research institutions. As a result, competition for certain skilled personnel in our market remains intense. None of our employees have employment commitments for any fixed period of time and they all may leave our employment at will. If we fail to retain our qualified personnel or replace them when they leave, we may be unable to continue our development and commercialization activities, which may cause our stock price to decline.

***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. We have not experienced any material system failure, accident or security breach to date, but if such an event were to occur, it 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.

Table of Contents

**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.*

As of April 25, 2012, GSK beneficially owned approximately 18.3% of our outstanding capital stock, and GSK has the right to acquire stock from us to maintain its percentage ownership of our capital stock. 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 April 2012 we entered into a common stock purchase agreement with GSK pursuant to which we agreed to sell 10,000,000 shares of our common stock to GSK in a private placement for \$21.2887 per share, or a total investment of approximately \$212.9 million. This private placement is subject to certain closing conditions and termination rights described above. If the private placement is completed after the annual meeting of stockholders in mid-May as planned, then GSK's ownership interest will increase to approximately 26.8%.

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

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

If pursuant to the provision described above GSK's ownership of us becomes greater than 50.1%, then *on or prior* to September 1, 2012 GSK is allowed to make an offer to our stockholders to merge with us or otherwise 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;
- 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 offer is for the greater of (a) the fair market value per share on the date immediately preceding the date of the first public announcement of the offer or (b) \$162.75 per share (as adjusted to take into account stock dividends, stock splits, recapitalizations and the like).

Furthermore, if pursuant to the provision described above GSK's ownership of us is greater than 50.1%, then *after* September 1, 2012, 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.

Table of Contents

***GSK's 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.***

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 these rights, 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 currently may 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. Beginning in September 2012, GSK will have no 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 March 31, 2012, we owned 287 issued United States patents and 919 granted foreign patents, as well as additional pending United States and foreign patent applications. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be invalidated or be too narrow to prevent third parties from developing or designing around these patents. If the sufficiency of the breadth or strength of protection provided by our patents with respect to a product candidate is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, the product candidate. Further, if we encounter delays in our clinical trials or in obtaining regulatory approval of our product candidates, the patent lives of the related product candidates would be reduced.

In addition, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, for processes for which patents are difficult to enforce and for any other elements of our drug discovery and development processes that involve proprietary know-how, information and technology that is not covered by patent applications. Although we require our employees, consultants,

advisors and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or, if established, maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition and results of operations, which could cause the price of our securities to fall.

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

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

Table of Contents

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

***If the efforts of our partner, GSK, to protect the proprietary nature of the intellectual property related to the assets in the LABA collaboration, including RELOVAIR and LAMA/LABA ( 719/VI), 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. 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. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forgo further commercialization of the applicable products.

Although we maintain general liability and product liability insurance, this insurance may not fully cover potential liabilities. 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. 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.***

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

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 our stock price to decline.

Table of Contents

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

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

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

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

The price of our securities has been extremely volatile and may continue to be so. The stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the companies' operating performance, in particular during the last few 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 of RELOVAIR with GSK, including, without limitation, any difficulties or delays encountered with regard to the regulatory path for RELOVAIR or any indication from the Phase 3 programs that RELOVAIR is not safe or efficacious (for example, the investor reaction to the topline results from the RELOVAIR Phase 3 registrational programs announced in early 2012);
- any adverse developments or results or perceived adverse developments or results with respect to the LAMA/LABA ( 719/VI) program with GSK, including, without limitation, any difficulties or delays encountered with regard to the regulatory path for 719/VI, delays in completing the Phase 3 studies or any indication from these studies that 719/VI is not safe or efficacious;
- any adverse developments or results or perceived adverse developments or results with respect to the MABA program with GSK, including, without limitation, any difficulties or delays encountered with regard to the regulatory path for 081 or any indication from ongoing non-clinical studies of 081 that the compound is not safe or efficacious;



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

- if any of the conditions to closing the proposed private placement of 10,000,000 shares of our common stock to GSK for approximately \$212.9 million are not met, including stockholder approval and/or expiration of the waiting period under the Hart-Scott Rodino Act, or if the closing S&P 500 index is more than thirty percent (30%) less than the closing S&P 500 index on March 30, 2012 and GSK chooses not to consummate the private placement;
- any further adverse developments with respect to the commercialization of VIBATIV®, including, without limitation, the uncertainties surrounding drug product manufacture and supply and how, when and where VIBATIV® will be commercialized;
- any further adverse developments or perceived adverse developments with respect to our telavancin NP NDA, which the FDA has determined cannot be approved without data from additional clinical studies;
- 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 from us, on a quarterly basis, sufficient shares of common stock to maintain its ownership percentage taking into account our preceding quarter's option exercise and equity vesting 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, such as the cGMP compliance issues that the single-source drug product supplier for VIBATIV® is facing with U.S. and foreign regulatory authorities;

Table of Contents

- our incurrence of expenses in any particular quarter that are different than market expectations;
- the extent to which GSK advances (or does not advance) RELOVAIR, the LAMA/LABA program and the MABA program through development into commercialization;
- 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 concerning the public announcement of data (both timing and content) from the Phase 3 programs with RELOVAIR and 719/VI and the MABA program or commercialization planning matters;
- any adverse developments or perceived adverse developments with respect to our partnering efforts with VIBATIV®, our 5-HT4, PμMA, MARIN and ARNI programs, TD-1792 or TD-4208;
- announcements regarding GSK generally;
- announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors;
- developments concerning any collaboration we undertake with companies other than GSK;
- publicity regarding actual or potential study results or the outcome of regulatory review relating to products under development by us, our partners or our competitors;
- regulatory developments in the United States and foreign countries;
- economic and other external factors beyond our control;
- sales of stock by us or by our stockholders, including sales by certain of our employees and directors whether or not pursuant to selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934;

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

- relative illiquidity in the public market for our common stock (our six largest stockholders other than GSK collectively owned approximately 50.6% of our outstanding capital stock as of April 25, 2012 based on our review of publicly available filings); and
- potential sales or purchases of our capital stock by GSK.

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

As of April 25, 2012, GSK beneficially owned approximately 18.3% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 6.6% of our outstanding capital stock. Based on our review of publicly available filings as of April 25, 2012, our six largest stockholders other than GSK collectively owned approximately 50.6% 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 stockholder meetings.

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

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

On February 14, 2012, we completed the sale of 88,468 shares of our common stock to an affiliate of GSK at a price of \$18.12 per share, resulting in aggregate gross proceeds of \$1.6 million before deducting transaction expenses. Neither we nor the affiliate of GSK engaged any investment advisors with respect to the sale and no finders' fees were paid or will be paid to any party in connection with the sale. We issued and sold the shares in reliance upon an exemption from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended.

**Item 6. Exhibits****(a) Index to Exhibits**

<b>Exhibit Number</b>	<b>Description</b>	<b>Form</b>	<b>Incorporated by Reference Filing Date/Period End Date</b>
3.3	Amended and Restated Certificate of Incorporation	S-1	7/26/04
3.4	Certificate of Amendment of Restated Certificate of Incorporation	10-Q	3/31/07
3.5	Amended and Restated Bylaws (as amended by the board of directors April 25, 2007)	10-Q	9/30/08
4.1	Specimen certificate representing the common stock of the registrant	10-K	12/31/06
4.2	Amended and Restated Rights Agreement between Theravance, Inc. and The Bank of New York, as Rights Agent, dated as of June 22, 2007	10-Q	6/30/07
4.3	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
10.9	Form of Indemnification Agreement for directors and officers of the registrant		
10.35	Common Stock Purchase Agreement, dated April 2, 2012, by and among Registrant, Glaxo Group Limited and GlaxoSmithKline LLC	8-K	4/2/12
10.36	Form Notice of Performance-Contingent Restricted Stock Award and Restricted Stock Award Agreement under 2004 Equity Incentive Plan (executive officer form)		
10.37	Form of Notice of Performance-Contingent Restricted Stock Award and Restricted Stock Award Agreement under 2004 Equity Incentive Plan		
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*	The following from the registrant's Quarterly Report on Form 10-Q for the period ended March 30, 2012, formatted in Extensible Business Reporting Language (XBRL) includes: (i) the Condensed Consolidated Statements of Operations for the three months ended March 30, 2012 and 2011, (ii) the Condensed Consolidated		

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

Balance Sheets as of March 30, 2012 and December 31, 2011, (iii) the Condensed Consolidated Statements of Cash Flows for the three months ended March 30, 2012 and 2011, and (iv) Notes to Condensed Consolidated Financial Statements.

---

\* XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Exchange Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

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)

May 2, 2012  
Date

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

May 2, 2012  
Date

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