

THERAVANCE INC  
Form 10-Q  
August 04, 2010  
Table of Contents

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

WASHINGTON, D.C. 20549

**FORM 10-Q**

**(Mark One)**

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

**For the quarterly period ended June 30, 2010**

**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)

Edgar Filing: THERAVANCE INC - Form 10-Q

**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 July 30, 2010 was 64,258,295

The number of shares of registrant's Class A common stock outstanding on July 30, 2010 was 9,401,499.



Table of Contents

**TABLE OF CONTENTS**

**PART I. FINANCIAL INFORMATION**

Item 1. Financial Statements

Condensed Consolidated Balance Sheets as of June 30, 2010 and December 31, 2009 3

Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2010 and 2009 4

Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2010 and 2009 5

Notes to Condensed Consolidated Financial Statements 6

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations 15

Item 3. Quantitative and Qualitative Disclosures About Market Risk 21

Item 4. Controls and Procedures 21

**PART II. OTHER INFORMATION**

Item 1A. Risk Factors 22

Item 6. Exhibits 36

Signatures 37

Exhibit Index 38

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

(In thousands, except per share data)

	June 30, 2010 (Unaudited)	December 31, 2009 *
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 69,721	\$ 47,544
Marketable securities	140,972	107,846
Receivable from related party	33	274
Notes receivable	434	144
Prepaid and other current assets	5,063	6,234
Total current assets	216,223	162,042
Restricted cash	893	1,310
Property and equipment, net	11,049	12,927
Notes receivable	530	947
Other long-term assets	3,754	4,167
Total assets	\$ 232,449	\$ 181,393
<b>Liabilities and stockholders' net capital deficiency</b>		
Current liabilities:		
Accounts payable	\$ 1,749	\$ 1,792
Accrued personnel-related expenses	4,692	6,314
Accrued clinical and development expenses	2,231	1,805
Other accrued liabilities	4,335	5,129
Current portion of note payable and capital lease	195	184
Current portion of deferred revenue	22,802	23,722
Total current liabilities	36,004	38,946
Convertible subordinated notes	172,500	172,500
Deferred rent	1,782	851
Notes payable and capital lease	175	275
Deferred revenue	147,946	157,426
Other long-term liabilities		389
Commitments and contingencies		
Stockholders' net capital deficiency:		
Common stock, \$0.01 par value; 200,000 shares authorized; 64,242 and 54,830 shares issued and outstanding at June 30, 2010 and December 31, 2009, respectively	642	549

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

Class A Common Stock, \$0.01 par value, 30,000 shares authorized, 9,402 issued and outstanding at June 30, 2010 and December 31, 2009	94	94
Additional paid-in capital	1,033,427	927,082
Accumulated other comprehensive (loss) income	(26)	35
Accumulated deficit	(1,160,095)	(1,116,754)
Total stockholders' net capital deficiency	(125,958)	(188,994)
Total liabilities and stockholders' net capital deficiency	\$ 232,449	\$ 181,393

---

\* Condensed consolidated balance sheet at December 31, 2009 has been derived from audited consolidated financial statements.

*See accompanying notes to condensed consolidated financial statements.*

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

(In thousands, except per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Revenue (1)	\$ 6,264	\$ 5,493	\$ 11,979	\$ 15,037
Operating expenses:				
Research and development	18,705	20,020	39,057	39,577
General and administrative	6,991	6,796	13,467	13,848
Restructuring charges		30		1,313
Total operating expenses	25,696	26,846	52,524	54,738
Loss from operations	(19,432)	(21,353)	(40,545)	(39,701)
Interest and other income	134	1,172	229	1,819
Interest expense	(1,508)	(1,511)	(3,025)	(3,027)
Net loss	\$ (20,806)	\$ (21,692)	\$ (43,341)	\$ (40,909)
Basic and diluted net loss per share	\$ (0.28)	\$ (0.35)	\$ (0.63)	\$ (0.65)
Shares used in computing net loss per share	73,282	62,842	69,124	62,567

(1) Revenue includes amounts from GSK, a related party, of \$2,457 and \$2,708 for the three months ended June 30, 2010 and 2009, respectively, and \$4,913 and \$9,656 for the six months ended June 30, 2010 and 2009, respectively.

*See accompanying notes to condensed consolidated financial statements.*

Table of Contents

## THERAVANCE, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2010	2009
<b>Cash flows from operating activities</b>		
Net loss	\$ (43,341)	\$ (40,909)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,137	2,529
Stock-based compensation	9,820	10,387
Notes receivable	4	(23)
Changes in operating assets and liabilities:		
Receivables, prepaid and other current assets	1,205	545
Accounts payable and accrued liabilities	(232)	(1,092)
Accrued personnel-related expenses	(1,622)	(974)
Deferred rent	931	(280)
Deferred revenue	(10,400)	(4,038)
Other long-term liabilities	(389)	543
Net cash used in operating activities	(40,887)	(33,312)
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(133)	(359)
Purchases of marketable securities	(103,861)	(54,570)
Maturities of marketable securities	70,000	48,065
Release of restricted cash	417	2,500
Payments received on notes receivable	110	238
Net cash used in investing activities	(33,467)	(4,126)
<b>Cash flows from financing activities</b>		
Payments on notes payable and capital lease	(89)	(57)
Proceeds from issuances of common stock	96,620	6,313
Net cash provided by financing activities	96,531	6,256
Net increase (decrease) in cash and cash equivalents	22,177	(31,182)
Cash and cash equivalents at beginning of period	47,544	92,280
Cash and cash equivalents at end of period	\$ 69,721	\$ 61,098

*See accompanying notes to condensed consolidated financial statements.*



Table of Contents

**Theravance, Inc.**

**Notes to Condensed Consolidated Financial Statements**

**(Unaudited)**

**1. Basis of Presentation and Significant Accounting Policies**

*Basis of Presentation*

The accompanying unaudited condensed consolidated financial statements of Theravance, Inc. (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 and cash flows. The interim results are not necessarily indicative of the results of operations to be expected for the year ending December 31, 2010 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, 2009 filed with the Securities and Exchange Commission (SEC) on February 26, 2010.

*Use of Management's Estimates*

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

*Inventory*

Inventory is stated at the lower of cost or market and is included in prepaid and other current assets in the accompanying condensed consolidated balance sheets. Inventory consisted of \$2.5 million and \$3.4 million of VIBATIV finished goods, active pharmaceutical ingredient, or other commercial launch supplies as of June 30, 2010 and December 31, 2009, respectively. If Astellas Pharma Inc. (Astellas) decides not to purchase some or any of the remaining VIBATIV inventory, the Company will be required to expense a portion of or the entire remaining capitalized inventory.

*Other-than-Temporary Impairment Assessment*

The Company reviews its investment portfolio to identify and evaluate investments that have indications of possible impairment. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, credit quality and the Company's conclusion that it does not intend to sell an impaired investment and is not more likely than not to be required to sell the security before it recovers its amortized cost basis. If the Company determines that the impairment of an investment is other-than-temporary, the investment is written down with a charge recorded in interest and other income.

*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 development costs reimbursed by GlaxoSmithKline plc (GSK) and Astellas.

*Fair Value of Stock-based Compensation Awards*

The Company uses the fair value method of accounting for stock-based compensation arrangements. Stock-based compensation arrangements currently include stock options granted, restricted shares issued, restricted stock unit awards (RSUs) granted and performance-contingent RSUs granted under the 2004 Equity Incentive Plan and the 2008 New Employee Equity Incentive Plan and 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). The estimated fair value of stock options, restricted shares and RSUs is expensed on a straight-line basis over the expected term of the grant and the fair value of performance-contingent RSUs is expensed during the term of the award when the Company determines that it is probable that certain performance milestones will be met. Compensation expense for purchases under the ESPP is recognized based on the estimated fair value of the common stock during each offering period and the percentage of the purchase discount.

Table of Contents

Stock-based compensation expense for stock options and RSUs has been reduced for estimated forfeitures so that compensation expense is based on options and RSUs ultimately expected to vest. The Company's estimated annual forfeiture rates for stock options and RSUs are based on its historical forfeiture experience.

*Recent Accounting Pronouncements*

In January 2010, the Financial Accounting Standards Board issued guidance to amend the disclosure requirements related to recurring and nonrecurring fair value measurements. The guidance requires new disclosures on the transfers of assets and liabilities between Level 1 (quoted prices in active market for identical instruments) and Level 2 (significant other observable inputs) of the fair value measurement hierarchy, including the reasons and the timing of the transfers. Additionally, the guidance requires a roll forward of activities on purchases, sales, issuance, and settlements of the assets and liabilities measured using significant unobservable inputs (Level 3 fair value measurements). The guidance became effective for the Company with the reporting period beginning January 1, 2010, except for the disclosure on the roll forward activities for Level 3 fair value measurements, which will become effective for the Company with the reporting period beginning July 1, 2011. Adoption of this new guidance did not have a material impact on the Company's condensed consolidated financial statements.

**2. Net Loss per Share**

Basic net loss per share (basic EPS) is computed by dividing net loss by the weighted-average number of common shares outstanding during the period, less shares subject to repurchase. Diluted net loss per share (diluted EPS) is computed by dividing net loss by the weighted-average number of common shares outstanding during the period, less shares subject to repurchase, plus any dilutive potential common shares. Diluted EPS is identical to basic EPS for all periods presented since potential common shares are excluded from the calculation, as their effect is anti-dilutive.

Using the treasury stock method, potential common shares that were excluded from the calculation of net loss per share are as follows:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Shares issuable upon the exercise of stock options	1,716	2,112	1,558	2,157
Shares issuable under restricted stock unit awards	466	305	324	291
Shares issuable upon the conversion of convertible debt	6,668	6,668	6,668	6,668

The calculation of basic and diluted EPS is as follows:

(in thousands, except for per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Basic and diluted:				
Net loss	\$ (20,806)	\$ (21,692)	\$ (43,341)	\$ (40,909)

Edgar Filing: THERAVANCE INC - Form 10-Q

Weighted average shares of common stock outstanding	73,339	62,919	69,181	62,644
Less: unvested restricted shares	(57)	(77)	(57)	(77)
Weighted average shares used in computing basic and diluted net loss per common share	73,282	62,842	69,124	62,567
Basic and diluted net loss per share	\$ (0.28)	\$ (0.35)	\$ (0.63)	\$ (0.65)

Table of Contents**3. Comprehensive Loss**

Comprehensive loss is comprised of net loss and changes in other comprehensive (loss) income, which consists of unrealized gains and losses on the Company's marketable securities. Comprehensive loss is as follows:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Net loss	\$ (20,806)	\$ (21,692)	\$ (43,341)	\$ (40,909)
Other comprehensive loss:				
Net unrealized loss on available-for-sale securities	(8)	(129)	(61)	(303)
Comprehensive loss	\$ (20,814)	\$ (21,821)	\$ (42,402)	\$ (41,212)

**4. Restructuring Charges**

In April 2008, in response to the completion of its Phase 3 telavancin development activities and to reduce its overall cash burn rate, the Company announced a plan to reduce its workforce by approximately 40% through layoffs from all departments throughout the organization. The Company incurred adjusted restructuring charges totaling \$5.4 million through 2008 and 2009 related to this reduction in force.

In February 2009, the Company entered into a sublease agreement with a third party to sublease excess space in a portion of one of its South San Francisco, CA buildings. The sublease has a 37 month term that began March 2009. For the six months ended June 30, 2009, the Company recorded a restructuring charge of \$1.3 million of which \$1.1 million represents the fair value of the Company's lease payments and expenses less sublease income through March 2012. As further described in Note 9, the Company entered into amendments to its South San Francisco, CA facility leases in June 2010. The amendments enabled the Company to reduce the accrual related to the sublet facilities by \$0.5 million for the three months ended June 30, 2010. The restructuring accrual related to excess facilities is recorded within other accrued liabilities on the Company's condensed consolidated balance sheets.

The following table summarizes the accrual balance and utilization by cost type for the restructuring for the six months ended June 30, 2010:

(in thousands)	Employee Severance and Benefits		Excess Facilities	
<b>Balance as of December 31, 2009</b>	\$	116	\$	694
Cash payments		(116)		(136)*
Adjustment				(504)
<b>Balance as of June 30, 2010</b>	\$		\$	54

\* Includes cash payments less sublease payments received

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

To date, the Company has incurred cumulative adjusted restructuring charges of \$6.7 million relating to the actions taken in April 2008 and February 2009. The Company does not anticipate incurring additional restructuring charges from these actions.

### 5. Collaboration and Licensing Agreements

#### *2005 License, Development and Commercialization Agreement with Astellas*

In November 2005, the Company entered into a collaboration arrangement with Astellas for the development and commercialization of telavancin. In July 2006, Japan was added to the collaboration, thereby giving Astellas worldwide rights to this medicine. Through June 30, 2010, the Company has received \$191.0 million in upfront, milestone and other fees from Astellas. The Company is eligible to receive up to an additional \$30.0 million in remaining milestone payments related to regulatory approvals in various regions of the world. The Company records these payments as deferred revenue and is amortizing them ratably over its estimated period of performance (development and commercialization period).

Table of Contents

Under this arrangement, the Company is responsible for substantially all costs to develop and obtain U.S. regulatory approval for telavancin for complicated skin and skin structure infections (cSSSI) and nosocomial pneumonia (NP) and Astellas is responsible for substantially all other costs associated with commercialization and further development of telavancin. The Company is entitled to receive royalties on global net sales of VIBATIV by Astellas that, on a percentage basis, range from the high teens to the upper twenties depending on sales volume. The following table discloses net revenue under this collaboration agreement:

(in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2010	2009	2009	2010	2009	2009
Amortization of deferred revenue	\$ 3,244	\$ 2,785	\$ 2,785	\$ 6,487	\$ 5,380	\$ 5,380
Royalties from net sales of VIBATIV	114			124		
Proceeds from VIBATIV delivered to Astellas	1,393			1,393		
Cost of VIBATIV delivered to Astellas	(943)			(943)		
Net Astellas collaboration revenue	\$ 3,808	\$ 2,785	\$ 2,785	\$ 7,061	\$ 5,380	\$ 5,380

*RELOVAIR™ Program with GSK*

In November 2002, the Company entered into its long-acting beta2 agonist (LABA) collaboration with GSK (the RELOVAIR program) to develop and commercialize a LABA product candidate both as a single-agent new medicine for the treatment of chronic obstructive pulmonary disease (COPD) and as part of a new combination medicine with an inhaled corticosteroid (ICS) for the treatment of asthma and/or a long-acting muscarinic antagonist (LAMA) for COPD.

In connection with the RELOVAIR program, in 2002 the Company received from GSK an upfront payment of \$10.0 million and sold to an affiliate of GSK shares of the Company's Series E Preferred Stock for an aggregate purchase price of \$40.0 million. In addition, the Company was eligible to receive up to \$495.0 million in development, approval, launch and sales milestones and royalties on the sales of any product resulting from this program. Through June 30, 2010, the Company has received a total of \$60.0 million in upfront and development milestone payments. GSK has determined to focus the collaboration's resources on the development of the lead LABA, GW642444, a GSK-discovered compound, together with GSK's ICS, fluticasone furoate. Accordingly, the Company does not expect to receive any further milestone payments from the RELOVAIR program. In the event that a LABA product candidate discovered by GSK is successfully developed and commercialized, the Company would 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 were launched in multiple regions of the world. Based on available information, the Company does not estimate that a significant portion of these potential milestone payments to GSK are likely to be made in the next two years. Moreover, the Company is entitled to receive the same royalties on sales of medicines from the RELOVAIR program, regardless of whether the product candidate originated with Theravance or with GSK. The Company is entitled to receive royalties of 15% on the first \$3.0 billion of annual global net sales, and 5% on annual global net sales above \$3.0 billion, for approved single-agent LABA and combination LABA-ICS medicines. 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 RELOVAIR program, such as a combination LABA/LAMA medicine, which are launched after a LABA/ICS combination medicine, 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 are applicable.

The Company recorded the initial cash payment and subsequent milestone payments as deferred revenue and is amortizing them ratably over its estimated period of performance (the product development period). Collaboration revenue from GSK under this agreement was \$1.3 million in each of the three months ended June 30, 2010 and 2009 and \$2.5 million in each of the six months ended June 30, 2010 and 2009, respectively.

*2004 Strategic Alliance with GSK*

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 all of the Company's full drug discovery programs initiated prior to September 1, 2007, on pre-determined terms and on an exclusive, worldwide basis. Under the terms of the strategic alliance, GSK has only one opportunity to license each of the Company's programs. 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. Consistent with the Company's strategy, it is obligated at its sole cost to discover two structurally different product candidates for any programs that are licensed by GSK under the alliance. If these programs are 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 these programs. For product candidates licensed to date under this agreement, the royalty structure for a product containing one of its compounds as a single active ingredient would result in an average percentage royalty rate in the low double digits. If a product is successfully commercialized, in addition to any royalty revenue that the Company receives, the total upfront and milestone payments that it could receive in any given program that GSK licenses range from \$130.0 million to \$162.0 million for programs with single-agent medicines and up to \$252.0 million for programs with both a single-agent and a combination medicine. If GSK chooses not to license a program, the Company retains all rights to the program and may



Table of Contents

continue the program alone or with a third party. To date, GSK has licensed the Company's two COPD programs: long-acting muscarinic antagonist (LAMA) and bifunctional muscarinic antagonist-beta2 agonist (MABA). The Company received \$5.0 million payments from GSK in connection with its license of each of the Company's LAMA and MABA programs in August 2004 and March 2005, respectively. GSK has chosen not to license the Company's bacterial infections program, anesthesia program or 5-HT4 program.

In connection with the strategic alliance with GSK, the Company received from GSK a payment of \$20.0 million. This payment is being amortized over the initial performance period during which GSK may exercise its right to license certain of the Company's programs under the agreement. In connection with the strategic alliance, the Company recognized \$0.7 million in revenue for each of the three months ended June 30, 2010 and 2009 and \$1.4 million for each of the six months ended June 30, 2010 and 2009. In addition, in May 2004, GSK purchased through an affiliate 6,387,096 shares of the Company's Class A common stock for an aggregate purchase price of \$108.9 million.

Through June 30, 2010, the Company has received \$46.0 million in upfront and milestone payments from GSK relating to the strategic alliance agreement. In addition, pursuant to a partial exercise of its rights under the governance agreement, upon the closing of the Company's initial public offering on October 8, 2004, GSK purchased through an affiliate an additional 433,757 shares of Class A common stock for \$6.9 million.

In August 2004, GSK exercised its right to license the Company's LAMA program pursuant to the terms of the strategic alliance. The Company received a \$5.0 million payment from GSK in connection with its licensing of the Company's LAMA program. In June 2005, the Company received a milestone payment from GSK of \$3.0 million related to clinical progress of the Company's product candidate. These payments were amortized ratably over the estimated period of performance (the product development period) until March 2009, when the Company recognized the remaining \$4.2 million of deferred revenue related to the LAMA program as a result of the program being returned to the Company from GSK.

In March 2005, GSK exercised its right to license the Company's MABA program pursuant to the terms of the strategic alliance. The Company received a \$5.0 million payment from GSK in connection with the license of the Company's MABA program. Through June 30, 2010, the Company received milestone payments from GSK of \$13.0 million related to clinical progress of the Company's product candidate. These payments are being amortized ratably over the estimated period of performance (the product development period). The Company recognized \$0.5 million and \$0.8 million in revenue related to the MABA program for the three months ended June 30, 2010 and 2009, respectively, and \$1.0 million and \$1.5 million for the six months ended June 30, 2010 and 2009, respectively.

**6. Marketable Securities**

The Company manages, monitors and measures its investments in highly liquid investment-grade securities by major security type. The following is a summary of the Company's cash equivalents, marketable securities and restricted cash by major security type at June 30, 2010 and December 31, 2009:

(in thousands)	June 30, 2010			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. government securities	\$ 39,986	\$ 29	\$	\$ 40,015

Edgar Filing: THERAVANCE INC - Form 10-Q

U.S. government agency securities	49,832	22	(1)	49,853
U.S. corporate notes	28,701	2	(78)	28,625
U.S. commercial paper	39,813			39,813
Money market funds	49,664			49,664
Total	207,996	53	(79)	207,970
Less amounts classified as cash equivalents	(66,105)			(66,105)
Less amounts classified as restricted cash	(893)			(893)
Amounts classified as marketable securities	\$ 140,998	\$ 53	\$ (79)	\$ 140,972

Table of Contents

(in thousands)	December 31, 2009			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. government securities	\$ 45,123	\$ 27	\$ (5)	\$ 45,145
U.S. government agency securities	18,032	10		18,042
U.S. corporate notes	11,181	8	(5)	11,184
U.S. commercial paper	43,473	1		43,474
Money market funds	35,425			35,425
Total	153,234	46	(10)	153,270
Less amounts classified as cash equivalents	(44,114)			(44,114)
Less amounts classified as restricted cash	(1,310)			(1,310)
Amounts classified as marketable securities	\$ 107,810	\$ 46	\$ (10)	\$ 107,846

The estimated fair value amounts were determined using available market information. At June 30, 2010, 100% of marketable securities have contractual maturities within twelve months and the average duration of marketable securities was approximately six months. The Company does not intend to sell the investments which are in an unrealized loss position and it is unlikely that the Company will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. The Company has determined that the gross unrealized losses on its marketable securities at June 30, 2010 were temporary in nature. All marketable securities with unrealized losses have been in a loss position for less than twelve months.

**7. 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

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

The Company's assets and liabilities that are measured at fair value are based on one or more of the three following valuation techniques:

*Market approach* Prices and other relevant information generated by market transactions involving identical or comparable assets

*Cost approach* Amount that would be required to replace the service capacity of an asset

*Income approach* Techniques to convert future amounts to a single present amount based on expectations

Table of Contents

The fair values of the Company's financial assets were as follows at June 30, 2010 and December 31, 2009:

(in thousands)	Fair Value Measurements at Reporting Date Using				Total
	Quoted Prices in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3		
U.S. government securities	\$ 35,015	\$ 5,000	\$	\$	40,015
U.S. government agency securities	41,241	8,612			49,853
U.S. corporate notes	24,869	3,756			28,625
U.S. commercial paper		39,813			39,813
Money market funds	49,664				49,664
Total	\$ 150,789	\$ 57,181	\$	\$	207,970

(in thousands)	December 31, 2009 Fair Value Measurements at Reporting Date Using				Total
	Quoted Prices in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3		
U.S. government securities	\$ 45,145	\$	\$	\$	45,145
U.S. government agency securities	18,042				18,042
U.S. corporate notes	1,020	10,164			11,184
U.S. commercial paper		43,474			43,474
Money market funds	35,425				35,425
Total	\$ 99,632	\$ 53,638	\$	\$	153,270

## 8. Convertible Subordinated Notes

On January 23, 2008, the Company closed an underwritten public offering of \$172.5 million aggregate principal amount of unsecured convertible subordinated notes that 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, which 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.

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.

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

The following table presents the carrying values and estimated fair values for the notes as of June 30, 2010 and December 31, 2009. The estimated fair value amounts were determined using available market information.

(in thousands)	June 30, 2010		December 31, 2009	
	Carrying value	Estimated fair value	Carrying value	Estimated fair value
Convertible subordinated notes	\$ 172,500	\$ 147,327	\$ 172,500	\$ 137,784

### 9. Operating Lease and Sublease

The Company entered into amendments to its South San Francisco, CA facility leases in June 2010. These amendments extend the lease terms through May 2020 and the Company may extend the terms for two additional five-year periods. The leases are for two buildings of approximately 110,000 and 60,000 square feet.

Table of Contents

Under the amendments, unused portions of a tenant improvement allowance can be used to reduce base rent up to a limit. Without considering such reductions, at June 30, 2010, future commitments under the amended noncancelable operating leases are as follows:

(in thousands)

Years ending December 31:		
Remainder of 2010	\$	2,312
2011		4,466
2012		5,429
2013		5,029
2014		4,860
Thereafter		28,966
Total	\$	51,062

**10. Stock-Based Compensation***2008 New Employee Equity Incentive Plan*

For the six months ended June 30, 2010, the Company granted stock options to purchase 110,000 shares at a weighted average exercise price of \$10.95 per share under the 2008 Plan. For the six months ended June 30, 2009, the Company granted stock options to purchase 133,000 shares at a weighted average exercise price of \$14.83 per share and granted 10,000 RSUs with a weighted-average fair value of \$14.31 per share under the 2008 Plan. With stockholders' approval of the amendment and restatement of the 2004 Plan in April 2010, no further equity awards will be issued under the 2008 Plan.

*2004 Equity Incentive Plan*

For the six months ended June 30, 2010, the Company granted stock options to purchase 143,750 shares at a weighted average exercise price of \$16.37 per share and granted 940,042 RSUs and 210,000 performance RSUs with a weighted-average fair value of \$10.47 per share and \$10.12 per share, respectively, under the 2004 Plan. For the six months ended June 30, 2009, the Company granted 928,911 RSUs with a weighted-average fair value of \$14.66 per share and 42,000 stock options with a weighted-average exercise price of \$14.98 per share under the 2004 Plan. As of June 30, 2010, there were 6,667,142 shares remaining available for issuance under the 2004 Plan. 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.

The following table summarizes equity award activity under the 2008 Plan and the 2004 Plan and related information:

(in thousands, except per share data)	Number of Shares Subject to Outstanding	Weighted-Average Exercise Price per Share	Number of Shares Subject to Outstanding	Weighted-Average Fair Value per Share
---------------------------------------	---	---	---	---------------------------------------

Edgar Filing: THERAVANCE INC - Form 10-Q

	Options		RSUs		
Balance at December 31, 2009	8,414	\$	16.63	2,042	\$ 14.15
Granted	110		10.95	1,087	10.15
Exercised	(86)		7.68		
Released				(122)	14.37
Forfeited	(72)		29.39	(7)	14.24
Balance at March 31, 2010	8,366		16.54	3,000	15.72
Granted	144		16.37	63	14.79
Exercised	(225)		7.23		
Released				(174)	13.04
Forfeited	(82)		21.35	(569)	28.40
Balance at June 30, 2010	8,203	\$	16.75	2,320	\$ 12.46



Table of Contents*Valuation Assumptions*

The assumptions used to value employee stock-based compensation expense for stock options granted were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
<b>Employee stock options</b>				
Risk-free interest rate	2.42%-2.82%	1.65%-2.92%	2.42%-2.82%	1.55%-3.07%
Expected life (in years)	5-6	5-6	5-6	6
Volatility	0.52	0.51	0.48-0.52	0.49-0.57
Dividend yield	%	%	%	%
Weighted average estimated fair value of stock options granted	\$ 8.41	\$ 7.58	\$ 7.07	\$ 7.79
<b>Employee stock purchase plan issuances</b>				
Risk-free interest rate	0.22%-0.79%	0.29%-0.88%	0.22%-0.79%	0.29%-0.88%
Expected life (in years)	0.5-2.0	0.5-2.0	0.5-2.0	0.5-2.0
Volatility	0.50-0.69	0.71-0.84	0.50-0.69	0.71-0.84
Dividend yield	%	%	%	%
Weighted average estimated fair value of ESPP issuances	\$ 5.86	\$ 6.46	\$ 5.86	\$ 6.46

Stock-based compensation expense consists of the compensation cost for employee share-based awards, including employee stock options, the employee stock purchase plan, RSUs and restricted stock, and the value of options and RSUs issued to non-employees for services rendered. In connection with the retirement of the Company's former chairman of the Board of Directors in April 2010, the Company entered into a consulting agreement that provided for, among other things, the acceleration of an RSU that was scheduled to vest through April 2012 and an extension of the period of time in which vested stock options may be exercised until to the stated expiration date of the stock options. As a result of the stock option modification, the Company recorded an expense of \$0.9 million during the three months ended June 30, 2010. The following table discloses the allocation of stock-based compensation expense included in the unaudited condensed consolidated statements of operations:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Research and development	\$ 2,618	\$ 3,055	\$ 5,145	\$ 6,062
General and administrative	2,704	2,219	4,675	4,325
Total	\$ 5,322	\$ 5,274	\$ 9,820	\$ 10,387

As of June 30, 2010, there was \$8.0 million, \$22.5 million and \$0.6 million of total unrecognized compensation cost related to unvested stock options, RSUs and restricted stock awards, respectively. 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 net deferred tax assets including deferred tax assets related to its net operating loss carryforwards.

**11. Stockholders Net Capital Deficiency**

In March 2010, the Company completed a public offering of approximately 8.6 million shares of common stock, at a price of \$11.50 per share. The Company received net proceeds of approximately \$93.5 million, after deducting underwriting fees and other related expenses of \$5.7 million.

**12. Guarantees and Indemnifications**

The Company indemnifies its officers and directors for certain events or occurrences, subject to certain limits. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recognized any liabilities relating to these agreements as of June 30, 2010.

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.

**Executive Summary**

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates. 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 gastrointestinal motility dysfunction. Our key programs include: VIBATIV™ (telavancin) with Astellas Pharma Inc. (Astellas) and the RELOVAIR™ program and the bifunctional muscarinic antagonist-beta2 agonist (MABA) program with GlaxoSmithKline plc (GSK). By leveraging our proprietary insight of multivalency to drug discovery focused primarily on validated targets, we are pursuing a best-in-class strategy designed to discover superior medicines in areas of significant unmet medical need.

Our net loss was \$20.8 million and \$21.7 million for the three months ended June 30, 2010 and 2009, respectively, and \$43.3 million and \$40.9 million for the six months ended June 30, 2010 and 2009, respectively. Total operating expenses were \$25.7 million and \$26.8 million for the three months ended June 30, 2010 and 2009, respectively, and \$52.5 million and \$54.7 million for the six months ended June 30, 2010 and 2009, respectively. Cash, cash equivalents and marketable securities totaled \$210.7 million at June 30, 2010, an increase of \$55.3 million since December 31, 2009. The increase was primarily due to net proceeds of \$93.5 million received from our public offering of common stock in March 2010, partially offset by cash used in operations.

Following are updates on the progress of our programs:

RELOVAIR (previously Horizon) Asthma

Enrollment is progressing in the Phase 3 asthma program. In March 2010, GSK and Theravance announced that the first asthma patient commenced treatment with RELOVAIR (fluticasone furoate/vilanterol trifenate) in an asthma exacerbation study, marking the start of the Phase 3 asthma clinical development program with this once-daily therapy.

The Phase 3 asthma program consists of eight studies, five of which are underway, to determine the safety and efficacy of RELOVAIR in asthma patients who remain uncontrolled on current treatment. These studies include an exacerbation study, a 12-month safety study (which also supports the chronic obstructive pulmonary disease (COPD) program), a 12-week low-dose combination and a 24-week high-dose combination efficacy study, a 24-week head-to-head study of RELOVAIR versus Advair/Seretide, a 24-week study of fluticasone furoate versus fluticasone propionate, a 12-week study of vilanterol trifenate versus salmeterol, and a hypothalamic-pituitary-adrenal (HPA) axis study.

In the Phase 3 asthma program, four studies are currently recruiting patients:

- Exacerbation Study ~2,000 patients
- 24-Week High Dose Combination Efficacy Study ~1,000 patients
- 24-Week Head-to-Head Study of RELOVAIR versus Advair®/Seretide ~100 patients
- Hypothalamic-Pituitary-Adrenal (HPA) Axis Study ~200 patients

Table of Contents

Enrollment of approximately 500 patients in the 12-month safety study has been completed and treatments are currently ongoing.

RELOVAIR (previously Horizon) Chronic Obstructive Pulmonary Disease (COPD)

The Phase 3 program in COPD was initiated in October 2009 and enrollment is progressing. The overall program, which is comprised of five studies encompassing more than 6,000 patients, includes two 12-month exacerbation studies, two 6-month efficacy and safety studies, a detailed lung function profile study, and studies to assess the potential for superiority of the fixed combination of vilanterol trifenate and fluticasone furoate versus other treatments for COPD.

All five Phase 3 studies in COPD are underway. Four of the five studies are currently recruiting patients; one has fully enrolled and is ongoing.

Patients across all of the RELOVAIR programs will be dosed using a unique single-step activation inhaler. This novel delivery device was developed utilizing GSK's expertise in device development and valuable patient input.

VIBATIV (telavancin)

VIBATIV™ was launched in the United States (U.S.) in the fourth quarter of 2009 for the treatment of adult patients with complicated skin and skin structure infections (cSSSI) caused by susceptible Gram-positive bacteria, including *Staphylococcus aureus*, both methicillin-resistant (MRSA) and methicillin-susceptible (MSSA) strains. The VIBATIV™ launch is progressing in the U.S. and VIBATIV™ is under review by the European Medicines Agency (EMA) for the treatment of nosocomial pneumonia (NP) and complicated skin and soft tissue infections in adults.

Peripheral Mu Opioid Receptor Antagonist (PUMA) TD-1211

Enrollment is progressing in the Phase 2 clinical study with TD-1211, an orally-administered peripherally selective mu opioid receptor antagonist (PUMA), for the treatment of opioid-induced constipation (OIC). TD-1211 is a potent, multivalent inhibitor of the mu opioid receptor designed to alleviate gastrointestinal side effects of opioid analgesic therapy without affecting analgesia. This proof of concept study is designed to assess the efficacy, tolerability and safety of TD-1211 in patients with OIC. We expect to report top-line data from this study toward the end of 2010.

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

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

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 and six months ended June 30, 2010 compared to those discussed in our 2009 Annual Report on Form 10-K filed on February 26, 2010.

### **Collaboration and Licensing Agreements**

#### *2005 License, Development and Commercialization Agreement with Astellas*

In November 2005, we entered into a collaboration arrangement with Astellas for the development and commercialization of telavancin. In July 2006, Japan was added to the collaboration, thereby giving Astellas worldwide rights to this medicine. Through June 30, 2010, we have received \$191.0 million in upfront, milestone and other fees from Astellas. We are eligible to receive up to an additional \$30.0 million in remaining milestone payments related to regulatory approvals in various regions of the world. We record these payments as deferred revenue and are amortizing them ratably over our estimated period of performance (development and commercialization period).

Table of Contents

Under this arrangement, we are responsible for substantially all costs to develop and obtain U.S. regulatory approval for telavancin for cSSSI and NP and Astellas is responsible for substantially all other costs associated with commercialization and further development of telavancin. We are entitled to receive royalties on global net sales of VIBATIV by Astellas that, on a percentage basis, range from the high teens to the upper twenties depending on sales volume. The following table discloses net revenue under this collaboration agreement:

(in millions)	Three Months Ended June 30,			Six Months Ended June 30,		
	2010	2009	2009	2010	2009	2009
Amortization of deferred revenue	\$ 3.2	\$ 2.8	\$ 2.8	\$ 6.5	\$ 5.4	\$ 5.4
Royalties from net sales of VIBATIV	0.1			0.1		
Proceeds from VIBATIV delivered to Astellas	1.4			1.4		
Cost of VIBATIV delivered to Astellas	(0.9)			(0.9)		
Net Astellas collaboration revenue	\$ 3.8	\$ 2.8	\$ 2.8	\$ 7.1	\$ 5.4	\$ 5.4

*RELOVAIR Program with GSK*

In November 2002, we entered into our long-acting beta2 agonist (LABA) collaboration with GSK (the RELOVAIR program) to develop and commercialize a LABA product candidate both as a single-agent new medicine for the treatment of COPD and as part of a new combination medicine with an ICS for the treatment of asthma and/or a long-acting muscarinic antagonist (LAMA) for COPD.

In connection with the RELOVAIR program, in 2002 we received from GSK an upfront payment of \$10.0 million and sold to an affiliate of GSK shares of our Series E Preferred Stock for an aggregate purchase price of \$40.0 million. In addition, we were eligible to receive up to \$495.0 million in development, approval, launch and sales milestones and royalties on the sales of any product resulting from this program. Through June 30, 2010, we have received a total of \$60.0 million in upfront and development milestone payments. GSK has determined to focus the collaboration's resources on the development of the lead LABA, GW642444, a GSK-discovered compound, together with GSK's ICS, fluticasone furoate. Accordingly, we do not expect to receive any further milestone payments from the RELOVAIR program. In the event that a LABA product candidate discovered by GSK is successfully developed and commercialized, we would 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 were launched in multiple regions of the world. Based on available information, we do not estimate that a significant portion of these potential milestone payments to GSK are likely to be made in the next two years. Moreover, we are entitled to receive the same royalties on sales of medicines from the RELOVAIR program, regardless of whether the product candidate originated with Theravance or with GSK. We are entitled to receive royalties of 15% on the first \$3.0 billion of annual global net sales, and 5% on annual global net sales above \$3.0 billion, for approved single-agent LABA and combination LABA-ICS medicines. 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 RELOVAIR program, such as a combination LABA/LAMA medicine, which are launched after a LABA/ICS combination medicine, 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 are applicable.

We recorded the initial cash payment and subsequent milestone payments as deferred revenue and are amortizing them ratably over our estimated period of performance (the product development period). Collaboration revenue from GSK under this agreement was \$1.3 million in each of the three months ended June 30, 2010 and 2009 and \$2.5 million in each of the six months ended June 30, 2010 and 2009, respectively.

*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 all of our full drug discovery programs initiated prior to September 1, 2007, on pre-determined terms and on an exclusive, worldwide basis. Under the terms of the strategic alliance, GSK has only one opportunity to license each of our programs. 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. Consistent with our strategy, we are obligated at our sole cost to discover two structurally different product candidates for any programs that are licensed by GSK under the alliance. If these programs are 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 these programs. For product candidates licensed to date under this agreement, the royalty structure for a product containing one of our compounds as a single active ingredient would result in an average percentage royalty rate in the low double digits. If a product is successfully commercialized, in addition to any royalty revenue that we receive, the total upfront and milestone payments that we could receive in any given program that GSK licenses range from \$130.0 million to \$162.0 million for programs with single-agent medicines and up to \$252.0 million for programs with both a single-agent and a combination medicine. 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. To date, GSK has licensed our two COPD programs: long-acting muscarinic antagonist (LAMA) and bifunctional muscarinic antagonist-beta2 agonist (MABA). We received \$5.0 million payments from GSK in connection with its license of each of our LAMA and MABA programs in



Table of Contents

August 2004 and March 2005, respectively. GSK has chosen not to license our bacterial infections program, anesthesia program or 5-HT4 program.

In connection with the strategic alliance with GSK, we received from GSK a payment of \$20.0 million. This payment is being amortized over the initial performance period during which GSK may exercise its right to license certain of our programs under the agreement. In connection with the strategic alliance, we recognized \$0.7 million in revenue for each of the three months ended June 30, 2010 and 2009 and \$1.4 million for each of the six months ended June 30, 2010 and 2009. In addition, in May 2004, GSK purchased through an affiliate 6,387,096 shares of our Class A common stock for an aggregate purchase price of \$108.9 million.

Through June 30, 2010, we have received \$46.0 million in upfront and milestone payments from GSK relating to the strategic alliance agreement. In addition, pursuant to a partial exercise of its rights under the governance agreement, upon the closing of our initial public offering on October 8, 2004, GSK purchased through an affiliate an additional 433,757 shares of Class A common stock for \$6.9 million.

In August 2004, GSK exercised its right to license our LAMA program pursuant to the terms of the strategic alliance. We received a \$5.0 million payment from GSK in connection with its licensing of our LAMA program. In June 2005, we received a milestone payment from GSK of \$3.0 million related to clinical progress of our product candidate. These payments were amortized ratably over the estimated period of performance (the product development period) until March 2009, when we recognized the remaining \$4.2 million of deferred revenue related to the LAMA program as a result of the program being returned to us from GSK.

In March 2005, GSK exercised its right to license our MABA program pursuant to the terms of the strategic alliance. We received a \$5.0 million payment from GSK in connection with the license of our MABA program. Through June 30, 2010, we received milestone payments from GSK of \$13.0 million related to clinical progress of our product candidate. These payments are being amortized ratably over the estimated period of performance (the product development period). We recognized \$0.5 million and \$0.8 million in revenue related to the MABA program for the three months ended June 30, 2010 and 2009, respectively, and \$1.0 million and \$1.5 million for the six months ended June 30, 2010 and 2009, respectively.

**RESULTS OF OPERATIONS**

*Revenue*

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

(in millions, except percentages)	Three months Ended		Change		Six months Ended		Change	
	2010	2009	\$	%	2010	2009	\$	%
Revenue	\$ 6.3	\$ 5.5	\$ 0.8	15%	\$ 12.0	\$ 15.0	\$ (3.0)	(20)%

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

Revenue increased for the three months ended June 30, 2010 compared to the same period in 2009 primarily due to the sale of VIBATIV inventory to Astellas and VIBATIV royalties earned. Revenue decreased for the six months ended June 30, 2010 compared to the same period in 2009 primarily due to a one-time non-cash recognition of deferred revenue of \$4.2 million as a result of the LAMA program being returned to us by GSK in the three months ended March 31, 2009, partially offset by revenues relating to the sale of VIBATIV<sup>TM</sup> inventory to Astellas and VIBATIV<sup>TM</sup> royalties earned. From GSK, we recognize revenue from the amortization of upfront and milestone payments related to our RELOVAIR program and strategic alliance agreements. From Astellas, we recognize revenue from the amortization of upfront and milestone payments related to our telavancin collaboration, royalties from net sales of VIBATIV and the impact of VIBATIV inventory transfers or dispositions.

### *Research & Development*

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

(in millions, except percentages)	Three months Ended June 30,				Six months Ended June 30,			
	2010	2009	Change		2010	2009	Change	
			\$	%			\$	%
External research and development	\$ 3.3	\$ 4.0	\$ (0.7)	(18)%	\$ 7.4	\$ 6.7	\$ 0.7	10%
Employee-related	7.3	7.1	0.2	3%	15.3	15.3		%
Stock-based compensation	2.6	3.1	(0.5)	(16)%	5.1	6.1	(1.0)	(16)%
Facilities, depreciation and other allocated	5.5	5.8	(0.3)	(5)%	11.3	11.5	(0.2)	(2)%
Total research and development expenses	\$ 18.7	\$ 20.0	\$ (1.3)	(7)%	\$ 39.1	\$ 39.6	\$ (0.5)	(1)%

Table of Contents

Research and development expenses decreased for the three and six months ended June 30, 2010 compared to the same periods in 2009 primarily due to lower external costs from our drug discovery programs, lower stock-based compensation expenses and lower facilities and related expenses. The results for the three and six months ended June 30, 2009 include \$1.0 million and \$3.6 million of reimbursements of development expenses from Astellas, respectively.

Research and development expenses for the remainder of 2010 are expected to be driven largely by employee related expenses, costs associated with our continued development efforts in our oral peripherally selective mu opioid receptor antagonist, or PUMA, program for opioid-induced constipation with TD-1211, our MonoAmine Reuptake Inhibitor, or MARIN, program for chronic pain with TD-9855 and costs associated with 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 periods, were as follows:

(in millions, except percentages)	Three months Ended				Six months Ended			
	June 30,		Change		June 30,		Change	
	2010	2009	\$	%	2010	2009	\$	%
General and administrative	\$ 7.0	\$ 6.8	\$ 0.2	3%	\$ 13.5	\$ 13.8	(0.3)	(2)%

General and administrative expenses increased for the three months ended June 30, 2010 compared to the same period in 2009 primarily due to higher stock compensation expenses. General and administrative expenses decreased for the six months ended June 30, 2010 compared to the same period in 2009 primarily due to lower external costs that were partially offset by higher stock compensation expenses. In connection with the retirement of our former chairman of the Board of Directors in April 2010, we entered into a consulting agreement that provided for, among other things, the acceleration of a restricted stock unit award that was scheduled to vest through April 2012 and an extension of the period of time in which vested stock options may be exercised until the stated expiration date of the stock options. As a result of the stock option modification, we recorded an expense of \$0.9 million during the three months ended June 30, 2010.

We anticipate general and administrative expenses for the remainder of 2010 to be at a similar level to the first half of the year.

***Restructuring charges***

Restructuring charges, as compared to the prior year periods, were as follows:

Edgar Filing: THERAVANCE INC - Form 10-Q

(in millions, except percentages)	Three months Ended				Six months Ended			
	June 30,		Change		June 30,		Change	
	2010	2009	\$	%	2010	2009	\$	%
Restructuring charges	\$	\$	\$	NA	\$	\$ 1.3	\$ (1.3)	(100)%

The expense in 2009 relates to the sublease of excess space in a portion of one of our South San Francisco, CA buildings.

***Interest and other income***

Interest and other income, as compared to the prior year periods, were as follows:

(in millions, except percentages)	Three months Ended				Six months Ended			
	June 30,		Change		June 30,		Change	
	2010	2009	\$	%	2010	2009	\$	%
Interest and other income, net	\$ 0.1	\$ 1.2	\$ (1.1)	(92)%	\$ 0.2	\$ 1.8	\$ (1.6)	(89)%

Interest and other income decreased for the three and six months ended June 30, 2010 compared to the same period in 2009 primarily due to lower average market rates of return during 2010.

We expect interest and other income to fluctuate in the future due to changes in average cash, cash equivalents and marketable securities balances and market interest rates.

Table of Contents**LIQUIDITY AND CAPITAL RESOURCES**

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 agreements. As of June 30, 2010, we had \$210.7 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. In March 2010, we completed a public offering of approximately 8.6 million shares of common stock, at a price of \$11.50 per share. We received net proceeds of approximately \$93.5 million after deducting underwriting fees and other related expenses of \$5.7 million.

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. 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. We will require additional capital to fund operating needs thereafter. If our current operating plans, milestone and royalty forecasts or spending assumptions change, we may require additional funding sooner in the form of public or private equity offerings or debt financings. Furthermore, if favorable financing opportunities arise, we may seek additional funding sooner. 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 future operations.

**Cash Flows**

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

(in millions)	Six Months Ended		
	2010	June,	2009
Net cash used in operating activities	\$	(40.9)	\$ (33.3)
Net cash used in investing activities	\$	(33.5)	\$ (4.1)
Net cash provided by financing activities	\$	96.5	\$ 6.3

The increase in cash used in operating activities for the six months ended June 30, 2010 compared to the same period in 2009 was primarily due to higher milestones received in 2009 and a higher net loss in 2010.

The increase in cash used in investing activities for the six months ended June 30, 2010 compared to the same period in 2009 was primarily due to higher purchases of marketable securities as a result of investing the net proceeds of our public offering of common stock that closed in March 2010. These purchases were partially offset by higher maturities of marketable securities in 2010.

The increase in cash provided by financing activities for the six months ended June 30, 2010 compared to the same period in 2009 was primarily due to net proceeds of \$93.5 million received from our public offering of common stock that closed in March 2010.

**Contractual Obligations and Commitments**

We entered into amendments to our South San Francisco, CA facility leases in June 2010. These amendments extend the lease terms through May 2020 and we may extend the terms for two additional five-year periods. The leases are for two buildings of approximately 110,000 and 60,000 square feet. As security for performance of certain obligations under the operating leases for our headquarters, we have issued letters of credit in the aggregate of approximately \$0.8 million, collateralized by an equal amount of restricted cash.

Under the amendments, unused portions of a tenant improvement allowance can be used to reduce base rent up to a limit. Without considering such reductions, at June 30, 2010, future commitments under the amended noncancelable operating leases are as follows:

(in millions)	Remainder of		2011 to 2013		2014 to 2015		After 2015		Total	
Years ending December 31:	2010									
Operating leases	\$	2.3	\$	14.9	\$	9.9	\$	24.0	\$	51.1

In January 2008, we closed an underwritten public offering of \$172.5 million aggregate principal amount of unsecured convertible subordinated notes that will mature on January 15, 2015. The financing raised proceeds, net of issuance costs, of

Table of Contents

\$166.7 million that is being used for general corporate purposes. The notes bear interest at the rate of 3.0% per year, which 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 our 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.

In addition to our debt commitment and facility leases mentioned above, our other outstanding contractual obligations relate to fixed purchase commitments under contract research, development and clinical supply agreements and a note payable.

Pursuant to our RELOVAIR™ collaboration with GSK, in the event that a LABA product candidate discovered by GSK is successfully developed and commercialized, we will be obligated to make milestone payments to GSK that could total as much as \$220.0 million if both a single agent and a combination product were launched in multiple regions of the world. The current lead LABA candidate, GW642444, is a GSK-discovered compound. Based on available information, we do not estimate that any significant portion of these potential milestone payments to GSK is likely to be made in the next two years.

**Effect of Recent Accounting Pronouncements**

In January 2010, the Financial Accounting Standards Board issued guidance to amend the disclosure requirements related to recurring and nonrecurring fair value measurements. The guidance requires new disclosures on the transfers of assets and liabilities between Level 1 (quoted prices in active market for identical instruments) and Level 2 (significant other observable inputs) of the fair value measurement hierarchy, including the reasons and the timing of the transfers. Additionally, the guidance requires a roll forward of activities on purchases, sales, issuance, and settlements of the assets and liabilities measured using significant unobservable inputs (Level 3 fair value measurements). The guidance became effective for us with the reporting period beginning January 1, 2010, except for the disclosure on the roll forward activities for Level 3 fair value measurements, which will become effective for us with the reporting period beginning July 1, 2011. Adoption of this new guidance did not have a material impact on our condensed consolidated financial statements.

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

There have been no significant changes in our market risk or how our market risk is managed compared to the disclosures in Item 7A of our 2009 10-K.

**Item 4. Controls and Procedures**

Evaluation of Disclosure Controls and Procedures

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

We conducted an evaluation as of June 30, 2010, 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. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

### Changes in Internal Control over Financial Reporting

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



Table of Contents

**PART II. OTHER INFORMATION**

**Item 1A. Risk Factors**

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 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.*

In late 2008 and early 2009, we announced results from multiple RELOVAIR program Phase 2b asthma studies and a COPD study; the Phase 3 program for COPD commenced in October 2009 and the Phase 3 program for asthma commenced in March 2010. 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:

- the U.S. Food and Drug Administration (FDA) determining that additional clinical studies are required with respect to the Phase 3 program in asthma or COPD;
- safety or other concerns arising from ongoing preclinical or clinical studies in this program;
- the Phase 3 program in asthma or COPD raising safety concerns or not demonstrating efficacy; or
- any change in FDA policy or guidance regarding the use of long-acting beta2 agonists (LABAs) to treat asthma or COPD.

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 will now require 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

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

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. It is unknown at this time what, if any, effect these or future FDA actions will have on the development of the RELOVAIR program. 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 may increase the overall risk of the RELOVAIR asthma program in the United States.

***With regard to our telavancin nosocomial pneumonia (NP) NDA, we believe that the FDA's current position is that it will require data from an additional clinical study or studies before it will consider the NP NDA for approval and we do not currently intend to conduct any such studies.***

Our first New Drug Application (NDA) for telavancin was submitted in late 2006 and on September 11, 2009 the FDA approved VIBATIV (telavancin) for the treatment of adults with complicated skin and skin structure infections (cSSSI) caused by susceptible Gram-positive bacteria. In January 2009 we submitted a second telavancin NDA to the FDA for the NP indication and we received a Complete Response letter from the FDA in late November 2009. The Complete Response instructed us that submission of additional data and analyses for the NP patient population to support an evaluation of all-cause mortality as the primary efficacy endpoint is necessary to demonstrate the safety and efficacy of telavancin. The Phase 3 NP clinical program included clinical response as the primary efficacy endpoint, consistent with current draft FDA guidelines for antibacterial clinical trial design in NP, and all-cause mortality as a secondary endpoint. The Complete Response did not specify the time point at which the FDA will measure the all-cause mortality data, nor did it indicate the populations in which these analyses will be considered. The Complete Response letter also requested a scientific rationale for pooling the all-cause mortality data from the two studies as they may individually be of insufficient size and statistical power to support the evaluation of all-cause mortality as the primary efficacy endpoint.

We responded to the Complete Response letter in December 2009. The key elements of our response included a rationale for pooling the two Phase 3 NP studies to evaluate all-cause mortality as the primary efficacy endpoint and all available all-cause mortality data which was analyzed using Kaplan-Meier survival estimates. In January 2010 the FDA sent us a letter notifying us that it

Table of Contents

considered our response incomplete, and stating that even if pooling of the two studies is acceptable for analyzing mortality, the two pooled studies would then equate to only one adequate and well-controlled trial and therefore would not constitute the substantial evidence of efficacy required for approval. In addition, the FDA noted that the adequacy and similarity of populations across the studies for the purposes of pooling had not yet been determined, and is still a review issue. Finally, the FDA also suggested several design criteria that should be taken into account in the design of new clinical trials. These design criteria do not include a specific primary endpoint for the evaluation of efficacy, the size or number of studies required, or what the appropriate statistical analysis might be. As a result, the design, size and scope of any additional studies required by the FDA are unclear at this time. With regard to our telavancin NP NDA, we believe that the FDA's current position is that it will require data from an additional clinical study or studies before it will consider the NP NDA for approval and we do not currently intend to conduct any such studies. Any further adverse developments or perceived adverse developments with respect to telavancin for the NP indication could harm our business and cause the price of our securities to fall.

***If telavancin is not approved by the European Medicines Agency (EMA) or if the EMA requires data from additional clinical studies of telavancin, our business will be adversely affected and the price of our securities could fall.***

On October 28, 2009, Astellas Pharma Europe B.V., a subsidiary of our telavancin partner, Astellas Pharma Inc. (Astellas), announced that it submitted a new European marketing authorization application (MAA) for telavancin to the EMA for the treatment of complicated skin and soft tissue infections (cSSTI) and NP. On November 30, 2009 we announced that the EMA had completed the validation phase for the MAA and the EMA's scientific review process had begun. In October 2008, we announced that Astellas Pharma Europe B.V. voluntarily withdrew a previously filed MAA for telavancin for the treatment of cSSTI from the EMA based on communications from the Committee for Medicinal Products for Human Use (CHMP) of the EMA that the data provided were not sufficient to allow the CHMP to conclude a positive benefit-risk balance for telavancin for the sole indication of cSSTI at that time.

If the EMA does not approve our application, requires data from additional clinical studies regarding telavancin, or if telavancin is ultimately approved by the EMA but with restrictions, including labeling that may limit the targeted patient population, our business will be harmed and the price of our securities could fall.

***If our product candidates, in particular the lead compounds in the RELOVAIR program with GSK that are currently progressing in Phase 3 clinical programs for asthma and COPD and telavancin for the treatment of NP, 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 approved product, VIBATIV, was commercially launched in the U.S. by our partner Astellas in November 2009, we have not yet commercialized any of our other product candidates. 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 initial Phase 1 studies. The data supporting our drug discovery and development programs is derived solely from laboratory experiments, preclinical 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 approvable and 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 few years, as well as growing public and governmental scrutiny of safety issues, have created an increasingly conservative regulatory environment. The implementation of

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

new laws and regulations, and revisions to FDA clinical trial design guidelines, have increased uncertainty regarding the approvability of a new drug. In addition, 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.

*With regard to all of our programs, any delay in commencing or completing clinical studies for product candidates, as we are currently experiencing in our bifunctional muscarinic antagonist-beta2 agonist (MABA) program with GSK, and any adverse results from clinical or preclinical 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 preclinical and clinical studies as a condition to regulatory approval. Preclinical 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 Phase 2b clinical studies in our MABA program with GSK in 2009, but we are awaiting the analysis of data from several preclinical studies. These key studies, which we have also referred to as Phase 2b enabling studies, will likely determine whether or not Phase 2b clinical studies in this program proceed as planned. If

Table of Contents

the analysis of the results of these studies leads to a decision not to proceed, GSK may need to conduct additional work that could significantly delay the MABA program, or GSK may decide to terminate the entire program.

The commencement and completion of clinical studies for our product candidates may be delayed by many factors, including:

- lack of effectiveness of product candidates during clinical studies;
- adverse events, safety issues or side effects relating to the product candidates or their formulation into medicines;
- inability to raise additional capital in sufficient amounts to continue our development programs, which are very expensive;
- the need to sequence clinical studies as opposed to conducting them concomitantly in order to conserve resources;
- our inability to enter into partnering arrangements relating to the development and commercialization of our programs and product candidates;
- our inability or the inability of our collaborators or licensees to manufacture or obtain from third parties materials sufficient for use in preclinical 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, which we experienced in our Phase 3 NP program for telavancin, 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;

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

- a regional disturbance where we or our collaborative partners are enrolling patients in our clinical trials, such as a pandemic, terrorist activities or war, or a natural disaster; and
- varying interpretations of data by the FDA and similar foreign regulatory agencies.

***If our product candidates that we develop on our own or through collaborative partners are not approved by regulatory agencies, 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 studies. In addition, clinical studies of potential products often reveal that it is not possible or practical to continue development efforts for these product candidates. If our clinical 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.

Table of Contents

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

The commercial success of VIBATIV will depend 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, a number of existing anti-infectives manufactured and marketed by major pharmaceutical companies and others, and potentially against new anti-infectives 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 choose to restrict the use of VIBATIV. If we and our partner, Astellas, 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 existing or subsequently-developed anti-infective drugs, we may never generate meaningful revenue from VIBATIV. 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 approved cSSSI labeling for VIBATIV in the U.S.;
  
- whether or not VIBATIV is approved for the NP indication and the labeling associated therewith;
  
- whether or not VIBATIV is approved by regulatory authorities in Europe;
  
- the advantages and disadvantages of VIBATIV compared to alternative therapies;
  
- potential negative perceptions, if any, of physicians related to the uncertainty surrounding our NP NDA;
  
- our and Astellas' 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.

*Even if our product candidates receive regulatory approval, such as VIBATIV , 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 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. These restrictions could make it more difficult to market VIBATIV effectively. Further, now that VIBATIV is approved, we remain 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 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 agency 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. In addition, we may experience a significant drop in the sales of the product, our royalties on product revenues and reputation in the marketplace may suffer, and we could face lawsuits.

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 preclinical 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



Table of Contents

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.

***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 modest revenues and royalties. Since the commercial launch through June 30, 2010, Astellas recorded VIBATIV net sales of \$4.9 million, a substantial portion of which was related to initial wholesaler stocking. We recognize royalty revenue from Astellas in the period the royalties are earned based on net sales of VIBATIV by Astellas as reported to us by Astellas. We may never generate sufficient revenue from selling medicines to achieve profitability. As of June 30, 2010, 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 and we could be forced to share our rights to commercialize our product candidates with third parties on terms that may not be favorable to us.***

We need large amounts of capital to support our research and development efforts. If we are unable to secure capital to fund our operations we will not be able to continue our discovery and development efforts and we might have to enter into strategic collaborations that could require us to share commercial rights to our medicines to a greater extent than we currently intend. Based on our current operating plans, milestone 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. We are likely to require additional capital to fund operating needs thereafter. While we have no current intention to do so, if we were to conduct additional studies to support the telavancin NP NDA and we were required to fund such studies, our capital needs could increase substantially. In addition, under our RELOVAIR program with GSK, in the event that a LABA product candidate discovered by GSK is successfully developed and commercialized, we will be obligated to pay GSK milestone payments that could total as much as \$220.0 million if both a single-agent and a combination product were launched in multiple regions of the world. The current lead LABA candidate, GW642444, is a GSK-discovered compound and GSK has determined to focus the collaboration's LABA development resources on the development of this compound only. If this GSK-discovered compound, which is progressing through Phase 3 programs in asthma and COPD, is advanced through regulatory approval and commercialization, we would not be entitled to receive any further milestone payments from GSK with regard to the RELOVAIR program and we would have to pay GSK the milestones noted above. We cannot guarantee that future financing will 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 additional 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.

***Global financial and economic conditions have had an impact on our industry, may adversely affect our business and financial condition in ways that we currently cannot predict, and may limit our ability to raise additional funds.***

Global financial conditions and general economic conditions, including the decreased availability of credit, have had an impact on our industry, and may adversely affect our business and our financial condition. Our ability to access the capital or debt markets and raise funds required for our operations may be severely restricted at a time when we would like, or need, to do so, which would have an adverse effect on our ability to fund our operations as planned. In addition, many biotechnology and biopharmaceutical companies with limited funds have been unable to raise capital during the recent period of financial and economic uncertainty and volatility, and they are left with limited alternatives including merging with other companies or out-licensing their assets. The large number of companies in this situation has led to an increase in supply of biotechnology and biopharmaceutical assets available for license or sale, which disadvantages companies like us that intend to partner certain of their assets.

Table of Contents

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

We entered into our collaboration agreement for the RELOVAIR program with GSK in November 2002, our strategic alliance agreement with GSK in March 2004, and our telavancin development and commercialization 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 any product candidates in the programs that it has in-licensed, including RELOVAIR and MABA. 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 commercial launch. In connection with our license, development and commercialization agreement with Astellas, Astellas is responsible for the commercialization of VIBATIV and any royalties to us from net sales of VIBATIV will depend upon Astellas ability to commercialize the medicine.

Our partners might not fulfill all of their obligations under these agreements, and, in certain circumstances, they may terminate our partnership with them. 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 RELOVAIR program, 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 our product candidates would be materially and adversely affected. For example, under the terms of our telavancin license, development and commercialization agreement, Astellas has the right to terminate the agreement since VIBATIV was not approved by December 31, 2008. If Astellas chooses to terminate the agreement, the further commercialization of VIBATIV would be delayed, our business would be harmed and the price of our securities could fall.

In addition, while our strategic alliance with GSK sets forth pre-agreed upfront payments, development obligations, milestone payments and royalty rates under which GSK may obtain exclusive rights to develop and commercialize certain of our product candidates, GSK may in the future seek to negotiate more favorable terms on a project-by-project basis. To date, GSK has licensed our LAMA program and our MABA program under the terms of the strategic alliance agreement and has chosen not to license our bacterial infections program, our anesthesia program and our 5-HT4 program. In February 2009, GSK returned the LAMA program to us because the current formulation of the lead product candidate is incompatible with GSK's proprietary inhaler device. There can be no assurance that GSK will license any other development program under the terms of the strategic alliance agreement, or at all. GSK's failure to license our development programs or its return of programs to us could adversely affect the perceived prospects of the product candidates that are the subject of these development programs, which could negatively affect both our ability to enter into collaborations for these product candidates with third parties and the price of our securities.

***We rely on a limited number of manufacturers for our product candidates, and our business will be harmed if these manufacturers are not able to satisfy our demand and alternative sources are not available or if manufactured drug product is not purchased.***

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

We have limited in-house active pharmaceutical ingredient (API) production capabilities 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 favorable 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 and adversely affect the commercial introduction of any approved products. In addition, manufacturers of our API and drug product are subject to the FDA's current good manufacturing practice (cGMP) regulations and similar foreign standards and we do not have control over compliance with these regulations by our manufacturers.

We have had manufactured sufficient telavancin API and drug product for the six-month commercial launch supply of VIBATIV and this inventory has been delivered to our collaboration partner. Capitalized inventory in the amount of \$2.5 million remains on our balance sheet as of June 30, 2010. Since our collaboration partner is not obligated to purchase any of the remaining VIBATIV inventory from us and the drug product has a limited shelf life, we may be required to write off and expense a portion or all of the remaining inventory. All further manufacture of VIBATIV API and drug product is now our collaboration partner's responsibility. For the foreseeable future, we anticipate that our collaboration partner will rely on third parties for the manufacture of VIBATIV API and drug product. If, for any reason, these third parties are unable or unwilling to perform, or if their performance does not meet regulatory requirements, including maintaining cGMP compliance, our collaboration partner may not be able to locate alternative manufacturers or enter into favorable agreements with them. Any inability to acquire sufficient quantities of API and drug

Table of Contents

product in a timely manner from these third parties could delay further telavancin studies and development, and adversely affect the commercialization of VIBATIV and any other telavancin products, if approved.

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 and validation 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.

***Our relationship with GSK may have a negative effect on our ability to enter into relationships with third parties.***

As of July 30, 2010, GSK beneficially owned approximately 12.8% of our outstanding capital stock. Pursuant to our strategic alliance with GSK, GSK has the right to license exclusive development and commercialization rights to our product candidates arising from (i) our oral peripherally selective mu opioid receptor antagonist (PUMA) program for opioid-induced constipation, (ii) our AT1 Receptor Neprilysin Inhibitor (ARNI) program for cardiovascular disease and (iii) our MonoAmine Reuptake Inhibitor (MARIN) program for chronic pain. Because GSK is not required to decide whether to license these three development programs until after they have successfully completed a Phase 2 proof-of-concept study, we may be unable to collaborate with other partners with respect to these programs until we have expended substantial resources to advance them through clinical studies. We may not have sufficient funds to pursue such programs in the event GSK does not license them at an early stage. Pharmaceutical companies other than GSK that may be interested in developing products with us may be less inclined to do so because of our relationship with GSK, or because of the perception that development programs that GSK does not license, or returns to us, pursuant to our strategic alliance agreement are not promising programs. If our ability to work with present or future strategic partners or collaborators is adversely affected as a result of our strategic alliance with GSK, our business prospects may be limited and our financial condition may be adversely affected.

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

We have active collaborations with GSK for the RELOVAIR and MABA programs and with Astellas for telavancin, 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 agencies. Each of TD-5108, our lead compound in the 5-HT4 program, and TD-1792, our investigational antibiotic, has successfully completed a Phase 2 proof-of-concept study, and TD-4208, our LAMA compound that GSK returned to us in February 2009 under the terms of the strategic alliance agreement, has completed a Phase 1 study. We currently intend to pursue collaboration arrangements for the development and commercialization of these compounds. 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 weak 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.

Table of Contents

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

We depend on independent clinical investigators, contract research organizations and other third party service providers in the conduct of our preclinical and clinical studies for our product candidates. We rely heavily on these parties for execution of our preclinical 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 agencies, 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 and could result in significant additional costs.

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

Our ability to succeed in the future depends on our ability to demonstrate and maintain a competitive advantage with respect to our approach to the discovery and development of medicines. Our objective is to discover, develop and commercialize new small molecule medicines with superior efficacy, convenience, tolerability and/or safety. Because our strategy is to develop new product candidates primarily for biological targets that have been validated by existing medicines or potential medicines in late stage clinical studies, to the extent that we are able to develop medicines, they are likely to compete with existing drugs that have long histories of effective and safe use. We expect that any medicines that we commercialize with our collaborative partners will compete with existing or future market-leading medicines.

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

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

- obtain required regulatory approvals; and
  
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicines.

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

Any new medicine that competes with a generic or proprietary market leading medicine must demonstrate compelling advantages in efficacy, convenience, tolerability and/or safety in order to overcome severe price competition and be commercially successful. VIBATIV must demonstrate these advantages, as it competes with vancomycin, a relatively inexpensive generic drug that is manufactured by a number of companies, and a number of existing anti-infectives 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 and our financial condition and operations will suffer.

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



Table of Contents

*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. If we receive regulatory approval to commence commercial sales of any of our product candidates that are not covered by our current agreements with GSK, Astellas or AstraZeneca, 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 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:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products;
- 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; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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 infrastructure, we will have difficulty commercializing our product candidates, which would adversely affect our business and financial condition.

*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. We have become even more dependent on existing personnel since the significant workforce restructuring announced in April 2008, which involved the elimination of approximately 40% of our positions through layoffs from all departments throughout our organization, including senior management. While we planned our restructuring with the purpose of focusing on our key clinical programs while maintaining core research and exploratory development capability, the restructuring has adversely affected the pace and breadth of our research and development efforts. While the remaining scientific team has expertise in many different aspects of drug discovery and exploratory development, there is less depth to the team and we are more susceptible to remaining team members voluntarily leaving employment with us. 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 may leave our employment at will.

If we fail to retain our remaining qualified personnel or replace them when they leave, we may be unable to continue our development and commercialization activities.

***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 such 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 and the further development of our product candidates could be delayed.

***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

Table of Contents

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.

**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 July 30, 2010, GSK beneficially owned approximately 12.8% 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 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 provisions of the governance agreement on the same basis as the shares of GSK's Class A common stock.

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

***GSK's rights under the strategic alliance and governance agreements 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. In addition, pursuant to our strategic alliance agreement with GSK, GSK has the right to license (i) our PUMA program, (ii) our ARNI program and (iii) our MARIN program. 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.***

GSK may sell or transfer our common stock either pursuant to a public offering registered under the Securities Act of 1933, as amended (the 1933 Act), or pursuant to Rule 144 of the 1933 Act. In addition, beginning in September 2012, GSK will have no 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.

Table of Contents

**Risks Related to Legal and Regulatory Uncertainty**

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

We rely upon a combination of patents, patent applications, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any involuntary disclosure to or misappropriation by third parties of this proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. The status of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and is very uncertain. As of June 30, 2010, we owned 203 issued United States patents and 663 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.

*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. For example, an action has been filed in the United States Patent and Trademark office opposing registration of the trademark VIBATIV . Failure to register this trademark may have an adverse impact on sales of VIBATIV , which could adversely affect our business. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties or pay royalties. In addition, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our

business significantly. In addition, in the future we could be required to initiate litigation to enforce our proprietary rights against infringement by third parties. Prosecution of these claims to enforce our rights against others would involve substantial litigation expenses and divert substantial employee resources from our business. If we fail to effectively enforce our proprietary rights against others, our business will be harmed.

*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. Our partner Astellas launched VIBATIV<sup>®</sup>, our first approved product, in the U.S. in November 2009. 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

Table of Contents

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.

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

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

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

The recently enacted 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.

***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.

#### **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 operating performance of particular companies, 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 RELOVAIR program with GSK, including, without limitation, any difficulties or delays encountered with regard to the regulatory path for the RELOVAIR program or delays in initiating or completing the various Phase 3 studies;



Table of Contents

- any further adverse developments or perceived adverse developments with respect to the FDA's review of the telavancin NP NDA, which could include, without limitation, non-approval of the NDA;
- any adverse developments or perceived adverse developments with respect to the commercial launch of VIBATIV, including any failure to meet market expectations with respect to the timing and volume of sales of VIBATIV;
- any adverse developments or perceived adverse developments with respect to regulatory matters concerning telavancin in any foreign jurisdiction, in particular the MAA that our partner Astellas submitted to the EMEA in October 2009 and of which the EMEA commenced scientific review in November 2009;
- any adverse developments or results or perceived adverse developments or results with respect to the MABA program with GSK, including, without limitation, the possibility that the analysis of results from key preclinical studies may lead to significant delay of the MABA program or perhaps a decision to terminate the entire program;
- 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 or the impact of the March 2010 FDA Advisory Committee discussing LABA clinical trial design to evaluate serious asthma outcomes);
- any announcements of developments with, or comments by, the FDA with respect to products we or our partners have under development or have commercialized;
- our incurrence of expenses in any particular quarter in excess of market expectations;
- our workforce restructuring commenced in April 2008 and uncertainties or perceived uncertainties related to the restructuring, including, without limitation, concerns regarding our ability to retain key employees and the possibility that we will have to implement further workforce reductions;
- the extent to which GSK advances (or does not advance) our product candidates through development into commercialization;
- any adverse developments or perceived adverse developments with respect to our relationship with GSK;

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

- any adverse developments or perceived adverse developments with respect to our relationship with Astellas, including without limitation, disagreements that may arise between us and Astellas concerning regulatory strategy or further development of telavancin, or Astellas termination of our telavancin license, development and commercialization agreement, which it now has the right to do;
- any adverse developments or perceived adverse developments with respect to our partnering efforts with our 5-HT4 program, TD-1792 or TD-4208;
- announcements regarding GSK's decisions whether or not to license any of our development programs or to return to us any previously licensed program, such as our experience with our LAMA program licensed from us by GSK in 2004 under the strategic alliance agreement and then returned to us by GSK in February 2009;
- announcements regarding GSK or Astellas generally;
- announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors;
- developments concerning any collaboration we may undertake with companies other than GSK or Astellas;
- 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;

Table of Contents

- sales of stock by us or by our stockholders, including sales by certain of our employees and directors whether or not pursuant to written pre-determined selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, some of which plans are currently in effect, such as plans adopted by our employees to sell shares to cover taxes due upon the quarterly vesting of restricted stock units, and other plans that may be entered into; and
- potential sales or purchases of our capital stock by GSK.

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

As of July 30, 2010, GSK beneficially owned approximately 12.8% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 9.6% of our outstanding capital stock. Based on our review of publicly available filings as of July 30, 2010, our six largest stockholders other than GSK collectively owned approximately 46.6% 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 6. 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
10.4	Employee Stock Purchase Plan, as amended April 27, 2010		
10.49	Consulting Agreement effective as of April 27, 2010 between the registrant and P. Roy Vagelos, M.D.		
10.50	First Amendment to Lease for 901 Gateway Boulevard effective as of June 1, 2010 between ARE-901/951 Gateway Boulevard, LLC and Theravance, Inc.		
10.51	First Amendment to Lease for 951 Gateway Boulevard effective as of June 1, 2010 between ARE-901/951 Gateway Boulevard, LLC and Theravance, Inc.		
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		

Table of Contents

**SIGNATURES**

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

Theravance, Inc.  
(Registrant)

August 4, 2010  
Date

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

August 4, 2010  
Date

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

Table of Contents**EXHIBIT INDEX**

<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
10.4	Employee Stock Purchase Plan, as amended April 27, 2010		
10.49	Consulting Agreement effective as of April 27, 2010 between the registrant and P. Roy Vagelos, M.D.		
10.50	First Amendment to Lease for 901 Gateway Boulevard effective as of June 1, 2010 between ARE-901/951 Gateway Boulevard, LLC and Theravance, Inc.		
10.51	First Amendment to Lease for 951 Gateway Boulevard effective as of June 1, 2010 between ARE-901/951 Gateway Boulevard, LLC and Theravance, Inc.		
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		