

THERAVANCE INC  
Form 10-Q  
August 07, 2008  
[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, 2008**



OR



**o 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.**

Edgar Filing: THERAVANCE INC - Form 10-Q

(Exact Name of Registrant as Specified in its Charter)

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

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

**901 Gateway Boulevard**

South San Francisco, CA 94080

Edgar Filing: THERAVANCE INC - Form 10-Q

(Address of Principal Executive Offices including Zip Code)

**(650) 808-6000**



Edgar Filing: THERAVANCE INC - Form 10-Q

(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 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 31, 2008 was 52,128,451.

The number of shares of registrant's Class A common stock outstanding on July 31, 2008 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, 2008 and December 31, 2007 3

Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2008 and 2007 4

Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2008 and 2007 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 24

Item 4. Controls and Procedures 25

**PART II. OTHER INFORMATION**

Item 1A. Risk Factors 26

Item 4. Submission of Matters to a Vote of Security Holders 38

Item 5. Other Information 39

Item 6. Exhibits 40

Signatures 41

Exhibit Index 42

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, 2008 (Unaudited)	December 31, 2007 *
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 87,610	\$ 86,433
Marketable securities	144,737	40,383
Receivable from related party	10,030	316
Notes receivable	503	223
Prepaid and other current assets	9,611	6,732
Total current assets	252,491	134,087
Marketable securities		2,456
Restricted cash	3,810	3,810
Property and equipment, net	18,481	20,091
Notes receivable	1,201	1,539
Other long-term assets	5,407	
Total assets	\$ 281,390	\$ 161,983
<b>Liabilities and stockholders equity (net capital deficiency)</b>		
Current liabilities:		
Accounts payable	\$ 3,068	\$ 6,957
Accrued personnel-related expenses	9,898	11,841
Accrued clinical and development expenses	6,618	11,318
Other accrued liabilities	6,483	2,797
Current portion of note payable	109	101
Current portion of deferred revenue	23,996	22,519
Total current liabilities	50,172	55,533
Convertible subordinated notes	172,500	
Deferred rent	1,801	2,003
Notes payable	379	435
Deferred revenue	164,509	166,136
Other long-term liabilities	3,655	4,140
Commitments and contingencies		
Stockholders equity (net capital deficiency):		
Preferred stock, \$0.01 par value, 230 shares authorized, no shares issued and outstanding		

Edgar Filing: THERAVANCE INC - Form 10-Q

Common stock, \$0.01 par value; 200,000 shares authorized, issuable in series; 52,054 and 51,684 shares issued and outstanding at June 30, 2008 and December 31, 2007, respectively	520	516
Class A Common Stock, \$0.01 par value, 30,000 shares authorized, 9,402 issued and outstanding at June 30, 2008 and December 31, 2007	94	94
Additional paid-in capital	882,369	870,878
Accumulated other comprehensive income (loss)	(10)	57
Accumulated deficit	(994,599)	(937,809)
Total stockholders' equity (net capital deficiency)	(111,626)	(66,264)
Total liabilities and stockholders' equity (net capital deficiency)	\$ 281,390	\$ 161,983

---

\* Condensed consolidated balance sheet at December 31, 2007 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,	
	2008	2007	2008	2007
Revenue (1)	\$ 5,505	\$ 5,305	\$ 11,150	\$ 10,703
Operating expenses:				
Research and development	19,996	43,497	46,775	92,355
General and administrative	7,256	9,512	16,422	18,310
Restructuring charges	5,063		5,063	
Total operating expenses	32,315	53,009	68,260	110,665
Loss from operations	(26,810)	(47,704)	(57,110)	(99,962)
Interest and other income	1,295	2,603	2,967	5,441
Interest expense	(1,511)	(24)	(2,647)	(54)
Net loss	\$ (27,026)	\$ (45,125)	\$ (56,790)	\$ (94,575)
Basic and diluted net loss per common share	\$ (0.44)	\$ (0.75)	\$ (0.93)	\$ (1.57)
Shares used in computing net loss per common share	61,192	60,341	61,098	60,222

(1) Revenue includes amounts from GSK, a related party, of \$2,830 and \$5,654 for the three and six months ended June 30, 2008, respectively, and \$2,824 and \$5,649 for the three and six months ended June 30, 2007, 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,	
	2008	2007
<b>Cash flows from operating activities</b>		
Net loss	\$ (56,790)	\$ (94,575)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,156	1,691
Stock-based compensation	8,646	11,293
Forgiveness of notes receivable	3	(17)
Changes in operating assets and liabilities:		
Receivables, prepaid and other current assets	(3,572)	743
Accounts payable and accrued liabilities	(3,799)	(5,334)
Accrued personnel-related expenses	(1,943)	947
Deferred rent	(202)	(149)
Deferred revenue	(10,150)	21,298
Other long-term liabilities	(485)	5,361
Net cash used in operating activities	(64,136)	(58,742)
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(791)	(4,761)
Purchases of marketable securities	(241,292)	(62,331)
Maturities of marketable securities	124,002	38,494
Sales of marketable securities	13,804	55,309
Release of restricted cash		30
Additions to notes receivable	(100)	(150)
Payments received on notes receivable	160	1,165
Net cash provided by (used in) investing activities	(104,217)	27,756
<b>Cash flows from financing activities</b>		
Payments on notes payable	(48)	(43)
Net proceeds from issuances of common stock	2,845	4,186
Proceeds from issuance of convertible subordinated notes, net of issuance costs	166,733	
Net cash provided by financing activities	169,530	4,143
Net increase (decrease) in cash and cash equivalents	1,177	(26,843)
Cash and cash equivalents at beginning of period	86,433	72,388
Cash and cash equivalents at end of period	\$ 87,610	\$ 45,545

*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*



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

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 the 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 at June 30, 2008, the results of operations for the three and six months ended June 30, 2008 and 2007 and the cash flows for the six months ended June 30, 2008 and 2007. The results for the three and six months ended June 30, 2008 are not necessarily indicative of the results of operations to be expected for the year ending December 31, 2008 or any other period.

The condensed consolidated balance sheet at December 31, 2007 has been derived from audited consolidated financial statements, which are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2007 filed with the Securities and Exchange Commission (SEC) on February 26, 2008 (2007 10-K). The accompanying condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the 2007 10-K.

### *Use of Management's Estimates*

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates based upon current assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual conditions may differ materially from the Company's current assumptions. This may result in the Company's estimates being incorrect and may require it to record adjustments to its financial position, results of operations or cash flows.

### *Segment Reporting*



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

The Company has determined that it operates in only one segment, which is the research and development of human therapeutics. Revenues are primarily generated from collaborations with the Company's partners located in the United Kingdom and Japan. All long-lived assets are maintained in the United States.

### *Inventory*





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

Inventory is stated at the lower of cost or market and is included with prepaid and other current assets. Inventory consists of \$5.5 million of commercial launch supplies of the Company's product candidate telavancin which is currently under regulatory review. Under the Company's 2005 License, Development and Commercialization Agreement with Astellas Pharma Inc. (Astellas), the Company is responsible to deliver to Astellas approximately six months of first commercial sale stock (as defined) in preparation for the regulatory approval and commercialization of telavancin in the United States. If the Company's product candidate is approved by the U.S. Food and Drug Administration (FDA), the inventory costs would be reimbursed through a milestone payment.

If the regulatory approval of telavancin is substantially further delayed or denied by the necessary regulatory bodies, or if new information becomes available that suggests that the telavancin inventory will not be realizable, the Company may be required to expense a portion or all of the capitalized inventory costs. A portion of the amount that may be expensed would be eligible for reimbursement through alternative arrangements with Astellas under terms of the Company's collaboration agreement.

### *Bonus Accruals*



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

The Company has short- and long-term bonus programs. Bonuses are determined based on various criteria, including the achievement of corporate, departmental and individual goals. Bonus accruals are estimated based on various factors, including target bonus percentages per level of employee and probability of achieving the goals upon which bonuses are based. The Company's management periodically reviews the progress made towards the goals under the bonus programs. As bonus accruals are dependent upon management's judgments of the likelihood of achieving the various goals, in some cases over a period of time in excess of twelve months, it is possible for bonus expense to vary significantly in future periods

Table of Contents

if changes occur in those management estimates. During the three months ended June 30, 2008, the Company reduced the accrual balances by \$0.7 million for its non-officer long-term bonus program established in 2004 due to the reduction in force which was announced in April 2008. As of June 30, 2008, the Company had approximately \$7.3 million remaining to be paid under its non-officer long-term bonus program. These payments are scheduled to be made in December of 2008 and 2009.

*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 ability and intent to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. If the Company determines that an investment impairment is other-than-temporary, the investment is written down with a charge recorded in interest and other income, net.

*Fair Value of Share-based Payment Awards*

The Company uses the fair value method of accounting for share-based compensation arrangements in accordance with Financial Accounting Standards Board (FASB) Statement No. 123(R), Share-based Payment (SFAS 123(R)). The Company adopted SFAS 123(R) on January 1, 2006 using the modified prospective method of transition. Under this method, compensation expense is recognized beginning with the effective date of adoption of SFAS 123(R) for all share-based payments (i) granted after the effective date of adoption and (ii) granted prior to the effective date of adoption and that remain unvested on the date of adoption. Share-based compensation arrangements covered by SFAS 123(R) currently include stock options granted, restricted shares issued and restricted stock unit awards (RSUs) granted under the 2004 Equity Incentive Plan, as amended, 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, as amended (ESPP). The estimated fair value of stock options, restricted shares and RSUs (excluding performance-contingent RSUs) is expensed on a straight-line basis over the expected term of the grant. 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 conditions 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.

In conjunction with the adoption of SFAS 123(R), the Company changed its method of expensing the value of stock-based compensation from the accelerated method to the straight-line single-option method. Compensation expense for all share-based payment awards granted prior to January 1, 2006 will continue to be recognized using the accelerated method over the vesting period, while compensation expense for all share-based payment awards granted on or subsequent to January 1, 2006 is recognized using the straight-line single-option method. Stock-based compensation expense for stock options has been reduced for estimated forfeitures so that compensation expense is based on options ultimately expected to vest. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company's estimated annual forfeiture rate for stock options remained unchanged at 4% for the three months ended June 30, 2008 based on its historical forfeiture experience. The effect of the reduction in force announced in April 2008 was excluded from the Company's estimated forfeiture rate as it was deemed to be a deviation from historical trends.

*Recent Accounting Pronouncements*

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

In June 2007, the Emerging Issues Task Force (EITF) ratified a consensus on EITF Issue No. 07-3 (EITF 07-3), *Accounting for Non-Refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, which concluded that non-refundable advance payments for goods or services for use in research and development activities should be deferred and capitalized. EITF 07-3 is effective for the Company beginning in the first quarter of fiscal year 2008. The Company adopted EITF 07-3 effective January 1, 2008 and has determined that the adoption had no material impact on its financial position, results of operations and cash flows.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with GAAP and expands disclosures about fair value measurements. SFAS 157 is effective for the Company beginning in the first quarter of fiscal year 2008. In February 2008, the FASB issued Statement of Financial Position No. 157-2, which delays the effective date of SFAS 157 for non-financial assets and non-financial liabilities and is effective for fiscal years beginning after November 15, 2008. The Company adopted SFAS 157 effective January 1, 2008 for financial assets and liabilities and has determined that the adoption had no material impact on our financial position, results of operations and cash flows.

*Table of Contents*



*Reclassification of Prior Period Amounts*





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

Certain prior period amounts related to the classification of interest and other income, net, and interest expense in the condensed consolidated statements of operations have been reclassified to conform to the current period's presentation. These reclassifications had no impact on previously reported results of operations or stockholders' equity (net capital deficiency).

### 2. Net Loss per Share

Basic net loss per common 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 common 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 dilutive potential common shares and shares subject to repurchase. 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. The Company's potentially dilutive common shares include outstanding options to purchase shares of common stock, outstanding restricted stock unit awards and common shares issuable upon the conversion of convertible debt.

At June 30, 2008, potential common shares consist of approximately 10,723,000 shares issuable upon the exercise of stock options, approximately 1,607,000 shares issuable under performance-contingent restricted stock unit awards and approximately 460,000 shares issuable under restricted stock unit awards. At June 30, 2007, potential common shares consist of approximately 11,283,000 shares issuable upon the exercise of stock options, 1,826,000 shares issuable under performance-contingent restricted stock unit awards and approximately 18,000 shares issuable upon the exercise of warrants. (The outstanding warrant subsequently expired on October 5, 2007 without being exercised and as a result, no stock was issued under the warrant).

(in thousands, except for per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Basic and diluted:				
Net loss	\$ (27,026)	\$ (45,125)	\$ (56,790)	\$ (94,575)
Weighted average shares of common stock outstanding	61,285	60,437	61,191	60,320
Less: unvested restricted shares	(93)	(96)	(93)	(98)
Weighted average shares used in computing basic and diluted net loss per common share	61,192	60,341	61,098	60,222
Basic and diluted net loss per common share	\$ (0.44)	\$ (0.75)	\$ (0.93)	\$ (1.57)

### 3. Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income (loss), which consists of net unrealized gains and losses on the Company's available-for-sale securities. The components of comprehensive loss are as follows:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Net loss	\$ (27,026)	\$ (45,125)	\$ (56,790)	\$ (94,575)
Other comprehensive income:				
Net unrealized gain (loss) on available-for-sale securities	(372)	(47)	(67)	8
Comprehensive loss	\$ (27,398)	\$ (45,172)	\$ (56,857)	\$ (94,567)

### 4. Restructuring Charges

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

In response to the completion of its Phase 3 development activities with telavancin and to reduce its overall cash burn rate, the Company announced on April 21, 2008 a plan to reduce its workforce by approximately 40% through layoffs from all departments throughout the organization. On April 23, 2008, the Company notified the employees impacted by the plan. For the three months ended June 30, 2008, the Company recorded charges totaling \$5.1 million related to severance, other termination benefits and outplacement services.

Table of Contents

The following table summarizes the accrual balance and utilization by cost type for the restructuring for the three months ended June 30, 2008:

(in thousands)	<b>Employee Severance and Benefits</b>	
Restructuring charges accrued	\$	5,063
Cash payments		(2,816)
Adjustments		
<b>Balance as of June 30, 2008</b>	<b>\$</b>	<b>2,247</b>

The remaining accrual as of June 30, 2008 is primarily related to employee severance and related benefits that are expected to be paid within the next six months. As such, the restructuring accrual is recorded as a current liability within accrued personnel-related expenses. Several of the Company's employees impacted by the plan have future service requirements extending beyond June 30, 2008. As a result, the Company anticipates that approximately \$0.7 million of additional severance and other termination benefits will be recognized over their service periods during the second half of 2008. The execution of the restructuring plan is expected to be completed by December 31, 2008.

## 5. Collaboration and Licensing

*2005 License, Development and Commercialization Agreement with Astellas*



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

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 telavancin collaboration, thereby giving Astellas worldwide rights to this potential medicine. Through June 30, 2008, the Company had received \$159.0 million in upfront, milestone and other fees from Astellas, which are being amortized ratably over the estimated period of performance (the estimated development and commercialization period). The Company recognized \$2.7 million and \$2.5 million in revenue for the three months ended June 30, 2008 and 2007, respectively, and \$5.5 million and \$4.6 million in revenue for the six months ended June 30, 2008 and 2007, respectively. As of June 30, 2008, the Company was eligible to receive up to \$60.0 million in remaining milestone payments related to regulatory filings and approvals in various regions of the world.

If telavancin is commercialized, the Company will be entitled to receive royalties on global sales of telavancin by Astellas that, on a percentage basis, range from the high teens to the upper twenties depending on sales volume. Under this arrangement, the Company will be responsible for substantially all costs to develop and obtain U.S. regulatory approval for telavancin for complicated skin and skin structure infections (cSSSI) and hospital-acquired pneumonia (HAP), and Astellas will be responsible for substantially all costs associated with commercialization and further development of telavancin.

### *Horizon Program with GSK*

In November 2002, the Company entered into its Horizon collaboration agreement with GlaxoSmithKline plc (GSK) to develop and commercialize a long-acting beta<sub>2</sub> agonist (LABA) product candidate for the treatment of asthma and chronic obstructive pulmonary disease (COPD). Each company contributed four LABA product candidates to the collaboration. Four large Phase 2b asthma studies commenced in December 2007, one with the lead LABA, GW642444 ( 444), and three with the lead inhaled corticosteroid (ICS) GW685698 ( 698), and in February 2008 a large Phase 2b COPD study with 444 was initiated.

The Company is entitled to receive the same royalties on product sales of medicines from the Horizon collaboration, regardless of whether the product candidate originated with Theravance or with GSK. The royalty structure is downward tiering and would result in an average percentage royalty rate in the low- to mid-teens at annual net sales of up to approximately \$4.0 billion and the average royalty rate would decline to single digits at annual net sales of more than \$6.0 billion for sales of single-agent LABA medicines and combination LABA/ICS medicines, which would be combined for the purposes of this royalty calculation. For other products combined with a LABA from the Horizon collaboration, 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.

As of June 30, 2008, the Company had received upfront and milestone payments from GSK of \$60.0 million related to the clinical progress of its candidates. GSK has determined to focus the collaboration's resources on the development of the lead LABA, 444, a GSK-discovered compound, together with the lead ICS. Accordingly, the Company does not expect to receive any further milestone payments from the Horizon program. In the event that a LABA product candidate discovered by GSK is successfully developed and commercially launched in multiple locations of the world, the Company will be

Table of Contents

obligated to make payments to GSK of up to \$220.0 million. Based on available information, the Company does not estimate that a significant portion of these potential milestone payments to GSK is likely to be made in the next three years.

**The Company recorded the upfront and milestone payments as deferred revenue and they are being amortized ratably over the Company's estimated period of performance. Collaboration revenue was \$1.7 million for each of the three months ended June 30, 2008 and 2007, and \$3.4 million for each of the six months ended June 30, 2008 and 2007. Subsequent development milestones, if any, will be recorded as deferred revenue when received and amortized over the remaining period of performance. Additionally, certain costs related to the collaboration are reimbursable by GSK as an offset to research and development expense. For each of the three and six months ended June 30, 2008 and 2007, reimbursable costs related to the collaboration were not material.**

*2004 Strategic Alliance with GSK*

In March 2004, the Company entered into its strategic alliance with GSK for the development and commercialization of product candidates in a variety of therapeutic areas. In connection with the strategic alliance, the Company received a \$20.0 million payment from GSK in May 2004. This payment is being amortized over the initial period during which GSK may exercise its right to license certain of its programs under the agreement, which the Company currently estimates to be through September 2011.

The alliance provides GSK with 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. The remaining programs that GSK has the right to license are (i) a peripheral Opioid-Induced Bowel Dysfunction (PUMA) program, (ii) a AT1 Receptor Neprilysin Inhibitor hypertension (ARNI) program and (iii) a MonoAmine Reuptake Inhibitor chronic pain (MARIN) program. Upon licensing 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 based on performance 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 the Company's 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 it 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 continue the program alone or with a third party. To date, GSK has licensed two of its COPD programs under the terms of the strategic alliance: LAMA and MABA. GSK has chosen not to license the Company's bacterial infections program, anesthesia program and Gastrointestinal Motility Dysfunction program. There can be no assurance that GSK will license any other programs under the terms of the alliance agreement or at all, which could have an adverse effect on the Company's business and financial condition.

In August 2004, GSK exercised its right to license the Company's long-acting muscarinic antagonist program (LAMA) pursuant to the terms of the strategic alliance. The Company received a \$5.0 million payment from GSK in connection with the licensing of this program. Through June 30, 2008, the Company received a milestone payment of \$3.0 million from GSK related to clinical progress of its candidate. These payments are amortized ratably over the estimated period of performance (the product development period). The Company recognized \$0.2 million for each of the three months ended June 30, 2008 and 2007, and \$0.4 million for each of the six months ended June 30, 2008 and 2007 in revenue related to the LAMA program. Additionally, the Company has been reimbursed by GSK for certain costs related to the LAMA program as an offset to research and development expense. For the three and six months ended June 30, 2008 and 2007, reimbursable costs were not

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

material. We recently announced that GSK had informed us it intends to return the LAMA program to Theravance because the current formulation of the lead product candidate, TD-4208, is incompatible with GSK's proprietary inhaler device. Deferred revenue related to the LAMA license with GSK was \$4.6 million at June 30, 2008. The Company and GSK are currently discussing the transfer of information and materials to the Company and the Company intends to explore partnerships with other companies for the further development of TD-4208.

In March 2005, GSK exercised its right to license the Company's bifunctional muscarinic antagonist-betaagonist (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, 2008, the Company received a milestone payment of \$3.0 million from GSK related to clinical progress of its candidate and has earned a \$10.0 million milestone payment for the successful achievement of proof-of-concept in the MABA Phase 2 study. The Company received the \$10.0 million milestone payment from GSK in July 2008. These amounts are being amortized ratably over the estimated period of



Table of Contents

performance (the product development period). Collaboration revenue related to the MABA program was \$0.3 million for each of the three months ended June 30, 2008 and 2007, and \$0.5 million for each the six months ended June 30, 2008 and 2007. Additionally, the Company is reimbursed by GSK for certain costs related to the MABA program as an offset to research and development expense. Reimbursements for the three and six months ended June 30, 2008 and 2007 were not material.

**6. Marketable Securities**

The Company invests in a variety of highly liquid investment-grade securities. The following is a summary of the Company's available-for-sale securities at June 30, 2008:

(in thousands)	June 30, 2008			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. government securities	\$ 147,974	\$ 32	\$ (61)	\$ 147,945
U.S. corporate notes	6,767	19		6,786
Certificates of deposit	60			60
Money market funds	81,366			81,366
Total	236,167	51	(61)	236,157
Less amounts classified as cash and cash equivalents	(87,610)			(87,610)
Less amounts classified as restricted cash	(3,810)			(3,810)
Amounts classified as marketable securities	\$ 144,747	\$ 51	\$ (61)	\$ 144,737

The estimated fair value amounts have been determined by the Company using available market information. At June 30, 2008, 100% of marketable securities have contractual maturities within twelve months. Average duration of available-for-sale securities was approximately two months at June 30, 2008. The Company has determined that the gross unrealized losses on its marketable securities at June 30, 2008 were temporary in nature.

**7. Fair Value Measurements**

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" (SFAS 157). SFAS 157 defines fair value, provides a consistent framework for measuring fair value GAAP and expands fair value financial statement disclosure requirements. SFAS 157 does not require any new fair value measurements. It only applies to accounting pronouncements that already require or permit fair value measures, except for standards that relate to share-based payments (SFAS 123(R)). The Company adopted SFAS 157 effective January 1, 2008.

SFAS 157's valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect our market assumptions. SFAS 157 classifies these inputs into the following hierarchy:

Edgar Filing: THERAVANCE INC - Form 10-Q

*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.

Table of Contents

The fair value of these financial assets was determined using the following inputs at June 30, 2008:

(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	\$ 144,981	\$ 2,964	\$	\$ 147,945
U.S. corporate notes	4,483	2,303		6,786
Certificates of deposit	60			60
Money market funds	81,366			81,366
Total	\$ 230,890	\$ 5,267	\$	\$ 236,157

SFAS 157 requires separate disclosure of assets and liabilities measured at fair value on a recurring basis from those measured at fair value on a nonrecurring basis.

**8. Commitments***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, 2008.

*Purchase Obligations*

At June 30, 2008, the Company had outstanding purchase obligations, primarily for services from contract research and manufacturing organizations, totaling \$3.5 million.

**9. 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 which will mature on January 15, 2015. The financing raised proceeds, net of issuance costs, of \$166.7 million. The notes bear interest at the rate of 3.0% per year, which is payable semi-annually in arrears in cash on January 15 and July 15 of each year,

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

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.

Holder 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 interest 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.

Table of Contents

**10. Stock-Based Compensation**

*Valuation Assumptions*



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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
<b>Employee stock options</b>				
Risk-free interest rate	3.50%-3.50%	4.56%-5.03%	2.74%-3.50%	4.48%-5.03%
Expected life (in years)	6	5-6	6	5-6
Volatility	0.49	0.48	0.49	0.48
Dividend yield	%	%	%	%
Weighted average estimated fair value of stock options granted	\$ 6.60	\$ 17.04	\$ 9.75	\$ 17.46
<b>Employee stock purchase plan issuances</b>				
Risk-free interest rate	2.21%-2.80%	4.95%-4.98%	2.21%-2.80%	4.95%-4.98%
Expected life (in years)	0.5-2.0	0.5-2.0	0.5-2.0	0.5-2.0
Volatility	0.45-0.70	0.26-0.30	0.45-0.70	0.26-0.30
Dividend yield	%	%	%	%
Weighted average estimated fair value of ESPP issuances	\$ 5.42	\$ 9.96	\$ 5.42	\$ 9.96

Stock-based compensation expense consists of the compensation cost for employee share-based awards, including employee stock options, RSUs and restricted stock, and the value of options and RSUs issued to non-employees for services rendered. 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,	
	2008	2007	2008	2007
Research and development	\$ 1,870	\$ 3,196	\$ 4,592	\$ 6,564
General and administrative	1,862	2,309	4,054	4,729
Total	\$ 3,732	\$ 5,505	\$ 8,646	\$ 11,293

As of June 30, 2008, there was \$26.3 million and \$6.5 million of total unrecognized compensation cost related to unvested stock options and RSUs (excluding performance-contingent RSUs), respectively. This cost is expected to be recognized over a weighted-average period of approximately 2.47 years and 3.42 years, 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.

### Equity Incentive Plans





2008 New Employee Equity Incentive Plan

In January 2008, the Company adopted the 2008 New Employee Equity Incentive Plan (the 2008 Plan) and reserved 500,000 shares of common stock for issuance under the 2008 Plan. The 2008 Plan provides for the granting of non-qualified stock options, restricted stock awards and RSUs to newly hired employees. As of June 30, 2008, no options, restricted stock or RSUs were issued and outstanding under the 2008 Plan.

2004 Equity Incentive Plan

During the six months ended June 30, 2008, the Company granted stock options to purchase 1,500 shares at an average exercise price of \$12.97 per share and granted 89,394 RSUs that vest over time which have a weighted-average fair value of \$12.98 per share under the 2004 Equity Incentive Plan, as amended (the 2004 Plan). As of June 30, 2008, total shares remaining available for issuance under the 2004 Plan were 1,041,354.

The performance-contingent RSUs granted to date have dual triggers of vesting based upon the successful achievement of certain corporate operating milestones, as well as a requirement for continued employment through certain dates in late 2009 and early 2010. The issuance of shares underlying the RSUs would occur, if at all, on the respective dates in 2009 and 2010. Expense associated with these RSUs would be recognized in increments, if at all, during 2008 through

Table of Contents

2009, depending on the probability of meeting the performance conditions. During the three months ended March 31, 2008, the Compensation Committee of the Company's Board of Directors approved management's recommendation to modify certain performance milestones and cancel 25% of the performance-contingent RSUs held by senior management. Accordingly, the maximum potential expense associated with the RSUs if all of the milestones are successfully achieved on time could be up to approximately \$59.6 million, which decreased \$6.7 million from December 31, 2007 (allocated as \$37.8 million for research and development expense and \$21.8 million for general and administrative expense). During the three months ended June 30, 2008, due to the reduction in force announced in April 2008, the maximum potential expense associated with the performance-contingent RSUs if all of the milestones are successfully achieved on time was further reduced to approximately \$53.4 million, which decreased \$6.2 million from March 31, 2008 (allocated as \$33.1 million for research and development expense and \$20.3 million for general and administrative expense). As of June 30, 2008, the Company had determined that none of the requisite performance conditions were probable and as a result, no compensation expense has been recognized. As vesting of these RSUs is dependent upon the successful achievement of the performance conditions, the expense associated with these RSUs may vary significantly from period to period.

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

(in thousands, except for per share amounts)	Number of Shares Available for Grant	Number of Shares Subject to Outstanding Options and Other Awards	Weighted-Average Exercise Price of Outstanding Options and Fair Value of Other Awards per Share
Balance at December 31, 2007	593	13,481	\$ 19.03
Additional shares 2008 Plan	500		
Options granted	(100)	100	\$ 19.80
RSUs granted	(560)	560	\$ 19.80
Options exercised		(29)	\$ 7.53
Options and RSUs forfeited	379	(379)	\$ 31.24
Balance at March 31, 2008	812	13,733	\$ 18.75
Additional shares authorized			
Options granted	(2)	2	\$ 12.97
RSUs granted	(89)	89	\$ 12.98
Options exercised		(214)	\$ 5.59
Options and RSUs forfeited	820	(820)	\$ 29.43
Balance at June 30, 2008	1,541	12,790	\$ 18.25

No options were granted with exercise prices less than fair value of common stock on the date of grant during the six months ended June 30, 2008 or the year ended December 31, 2007.

The total intrinsic value of the options exercised for the three months ended June 30, 2008 and 2007 was \$1.6 million and \$9.1 million, respectively, and the total fair value of options vested is \$4.1 million and \$0.5 million for the three months ended June 30, 2008 and 2007, respectively. The total intrinsic value of the options exercised during the six months ended June 30, 2008 and 2007 was \$1.8 million and \$12.1 million, respectively, and the total fair value of options vested was \$12.4 million and \$1.2 million for the six months ended June 30, 2008 and 2007, respectively.

Employee Stock Purchase Plan

On April 22, 2008, the Company's stockholders approved an amendment to the ESPP which increased the number of shares authorized for issuance under the ESPP from 625,000 to 925,000 shares. The total number of remaining shares available for issuance under the ESPP at June 30, 2008 was 354,206. The total stock-based compensation expense recognized related to the ESPP under SFAS 123(R) for the three and six months ended June 30, 2008 was \$35,000 and \$0.4 million, respectively, and \$0.4 million and \$0.8 million for the three and six months ended June 30, 2007, respectively.

Table of Contents

Reserved Shares

The Company has reserved shares of common stock for future issuance under the 2008 Plan, the 2004 Plan and the ESPP as follows (shares in thousands):

	<b>June 30, 2008</b>
Stock option plans:	
Subject to outstanding options and RSUs	12,790
Available for future grants	1,541
Available for future ESPP purchases	354
<b>Total</b>	<b>14,685</b>

**11. Related Party Transactions**

*Related Parties*



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

The Company's related parties include its directors, executive officers and GSK. Transactions with executive officers and directors include notes receivable, described below. Transactions with GSK are described in Note 5.

Robert V. Gunderson, Jr. is a director of the Company. The Company has engaged Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, of which Mr. Gunderson is a partner, as its primary legal counsel. Fees totaling \$0.3 million were incurred in the ordinary course of business for each of the six months ended June 30, 2008 and 2007, respectively.

### *Notes Receivable*

The Company has provided loans to certain of its employees primarily to assist them with the purchase of a primary residence, which collateralizes the resulting loans. Interest receivable was approximately \$29,000 and \$26,000 as of June 30, 2008 and December 31, 2007, respectively, and is included in prepaid and other current assets. The Company accrues interest on the notes at rates of up to 8.0%. The outstanding loans at June 30, 2008 had maturity dates ranging from July 2008 to January 2013.

## **12. Income Taxes**

**The Company adopted Financial Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48) effective January 1, 2007. The adoption of FIN 48 did not result in an adjustment to the beginning balance of the Company's accumulated deficit.**

**Under FIN 48, the Company has unrecognized tax benefits of \$33.2 million as of January 1, 2008. If the Company is eventually able to recognize these uncertain positions, \$33.2 million of the unrecognized benefit would reduce its effective tax rate. The Company currently has a full valuation allowance against its net deferred tax asset which would impact the timing of the effective tax rate benefit should any of these uncertain tax positions be favorably settled in the future.**

**The Company is subject to federal and state examination for years 1996 and forward, by virtue of the tax attributes carrying forward from those years. There are no tax examinations currently in progress.**

## **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,

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

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

Table of Contents

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 the subsection entitled Liquidity and Capital Resources in this Item 2. 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: telavancin for the treatment of serious Gram-positive bacterial infections with Astellas Pharma Inc., the Horizon program with GlaxoSmithKline plc, and the Gastrointestinal Motility Dysfunction program. By leveraging our proprietary insight of multivalency to drug discovery focused primarily on validated targets, we are pursuing a next generation strategy designed to discover superior medicines in areas of significant unmet medical need.

Our net loss for the three months ended June 30, 2008 was \$27.0 million compared to \$45.1 million during the same period of 2007, or a 40% decrease. Revenue recognized under our collaboration agreements for the three months ended June 30, 2008 increased by 4% when compared to the same period of 2007. For the three months ended June 30, 2008, research and development costs decreased by 54% while general and administrative costs decreased by 23% when compared to the same period of 2007. For the three months ended June 30, 2008, we recorded restructuring charges totaling \$5.1 million for reducing our workforce by approximately 40% in response to the completion of our Phase 3 development activities with telavancin and to reduce our overall cash burn rate. Cash, cash equivalents and marketable securities totaled \$232.3 million at June 30, 2008, an increase of \$103.1 million since December 31, 2007. This increase was primarily due to the net proceeds of \$166.7 million received from our convertible subordinated notes offering in January 2008, offset by the net usage of cash in operations.

Following are updates on the progress of our clinical programs:

*Respiratory Programs*

Horizon

We expect completion of enrollment in the Phase 2b asthma dose-ranging study with GW642444 ( 444) in the third quarter 2008. The Phase 2b dose-ranging studies with the lead inhaled corticosteroid (ICS) GW685698 ( 698) for patients with mild asthma and for patients with severe asthma have recently completed enrollment. The Phase 2b study with 698 for patients with moderate asthma continues to enroll patients with results now expected in early 2009.



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

Enrollment remains on track for the large Phase 2b chronic obstructive pulmonary disease (COPD) dose-ranging study with the lead long-acting beta<sub>2</sub> agonist (LABA), 444. We expect to report top-line data from this study in the first half of 2009.

### Inhaled Bifunctional Muscarinic Antagonist-Beta<sub>2</sub> Agonist (MABA) Program

We recently reported positive clinical results from our Phase 2 study in the MABA program with our lead investigational compound, GSK961081 ( 081), for the treatment of COPD. 081 administered once daily to COPD patients demonstrated 24-hour bronchodilation on day 14 that was statistically greater than placebo, and comparable to a combination therapy active control of salmeterol dosed twice daily plus tiotropium dosed once daily. 081 was generally well tolerated throughout the 14-day study. In conjunction with the successful achievement of proof-of-concept in this Phase 2 clinical study, we earned a milestone payment of \$10.0 million from GlaxoSmithKline plc (GSK).

### Inhaled Long-Acting Muscarinic Antagonist (LAMA) Program

We recently reported clinical results from our Phase 1 study in the LAMA program with our lead investigational compound, GSK1160724 (TD-4208), for the treatment of COPD. TD-4208 administered as a single dose to healthy volunteers was generally well tolerated, with a similar incidence of adverse events to placebo. In addition, TD-4208 demonstrated evidence of bronchodilation in volunteers sensitive to muscarinic antagonists. We also announced GSK's intent to return the LAMA program to us because the current formulation of the compound is incompatible with GSK's proprietary inhaler device. Both parties are currently discussing the transfer of information and materials back to us.

Table of Contents

*Bacterial Infections Programs*

Telavancin

We plan on submitting to the U.S. Food and Drug Administration (FDA) a New Drug Application (NDA) for telavancin in the treatment of hospital-acquired pneumonia (HAP) caused by Gram-positive bacteria including resistant pathogens such as methicillin-resistant *Staphylococcus aureus* (MRSA) in the fourth quarter 2008.

On July 24, 2008, we announced that the FDA had not yet made a decision regarding the NDA for telavancin for the treatment of complicated skin and skin structure infections (cSSSI). The Prescription Drug User Fee Act (PDUFA) date for action by the FDA was July 21, 2008, and as of August 6, 2008, we had not received an action letter from the FDA.

As previously announced, the FDA had indicated that it did not expect to take final action on the telavancin cSSSI NDA prior to completing its further evaluation of study site monitoring and study conduct in the ATLAS Phase 3 program, nor prior to resolution of the manufacturing issues not specifically related to telavancin that were cited in the approvable letter received in October 2007.

Telavancin is also under review for its safety and efficacy by regulatory authorities in Europe for the treatment of complicated skin and soft tissue infections and in Canada for the treatment of cSSSI.

*Gastrointestinal (GI) Motility Dysfunction Program*

We continue to evaluate the data and the study site audit from a previously conducted thorough QTc study of TD-5108, our lead compound, which evaluated the potential for QT prolongation. We currently anticipate initiating a drug-drug interaction (DDI) study later in 2008. We intend to meet with the FDA later in 2008 to discuss the thorough QTc study and appropriate next steps, including conducting another thorough QTc study if necessary. If we conduct another thorough QTc study, it likely would occur in the first half of 2009. We continue to evaluate the potential of this compound in chronic constipation, constipation-predominant irritable bowel syndrome and other indications.

**Critical Accounting Policies**

*Restructuring Charges*

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

As defined in Statement of Financial Accounting Standards No.146, Accounting for Costs Associated with Exit or Disposal Activities (SFAS 146), we record costs and liabilities associated with exit and disposal activities at fair value in the period the liability is incurred. Restructuring charges consist of charges related to employee severance and benefits. Charges related to employee severance and benefits are determined based on the estimated severance and fringe benefit charge for identified employees. Our estimates of future liabilities may change, requiring us to record additional restructuring charges or reduce the amount of liabilities recorded. We will reassess restructuring accruals on a quarterly basis to reflect changes in the costs of the restructuring activities and we will record new restructuring accruals as liabilities are incurred.

As of the date of the filing of this quarterly report, we believe there have been no other material changes or additions, aside from the application of SFAS 146, to our critical accounting policies and estimates during the three and six months ended June 30, 2008 compared to those discussed in our Annual Report on Form 10-K filed on February 26, 2008 (2007 10-K).

### **Collaboration and Licensing Agreements**

*2005 License, Development and Commercialization Agreement with Astellas*



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

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 our telavancin collaboration, thereby giving Astellas worldwide rights to this potential medicine. Through June 30, 2008, we had received \$159.0 million in upfront, milestone and other fees from Astellas, which are being amortized ratably over the estimated period of performance (the estimated development and commercialization period). We recognized \$2.7 million and \$2.5 million in revenue for the three months ended June 30, 2008 and 2007, respectively, and \$5.5 million and \$4.6 million in revenue for the six months ended June 30, 2008 and 2007, respectively. As of June 30, 2008, we were eligible to receive up to \$60.0 million in remaining milestone payments related to regulatory filings and approvals in various regions of the world.

If telavancin is commercialized, we will be entitled to receive royalties on global sales of telavancin by Astellas that, on a percentage basis, range from the high teens to the upper twenties depending on sales volume. Under this arrangement, we will be responsible for substantially all costs to develop and obtain U.S. regulatory approval for telavancin for cSSSI and

Table of Contents

HAP, and Astellas will be responsible for substantially all costs associated with commercialization and further development of telavancin.

*Horizon Program with GSK*



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

In November 2002, we entered into our Horizon collaboration agreement with GSK to develop and commercialize a LABA product candidate for the treatment of asthma and COPD. Each company contributed four LABA product candidates to the collaboration. Four large Phase 2b asthma studies commenced in December 2007, one with the lead LABA, 444 and three with the lead ICS 698, and in February 2008, a large Phase 2b COPD study with 444 was initiated.

We are entitled to receive the same royalties on product sales of medicines from the Horizon collaboration, regardless of whether the product candidate originated with Theravance or with GSK. The royalty structure is downward tiering and would result in an average percentage royalty rate in the low- to mid-teens at annual net sales of up to approximately \$4.0 billion and the average royalty rate would decline to single digits at annual net sales of more than \$6.0 billion for sales of single-agent LABA medicines and combination LABA/ICS medicines, which would be combined for the purposes of this royalty calculation. For other products combined with a LABA from the Horizon collaboration, 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.

As of June 30, 2008, we had received upfront and milestone payments from GSK of \$60.0 million related to the clinical progress of our candidates. GSK has determined to focus the collaboration's resources on the development of the lead LABA, 444, a GSK-discovered compound, together with the lead ICS. Accordingly, we do not expect to receive any further milestone payments from the Horizon program. In the event that a LABA product candidate discovered by GSK is successfully developed and commercially launched in multiple locations of the world, we will be obligated to make payments to GSK of up to \$220.0 million. 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 three years.

**We recorded the upfront and milestone payments as deferred revenue and they are being amortized ratably over our estimated period of performance. Collaboration revenue was \$1.7 million for each of the three months ended June 30, 2008 and 2007 and \$3.4 million for each of the six months ended June 30, 2008 and 2007. Subsequent development milestones, if any, will be recorded as deferred revenue when received and amortized over the remaining period of performance. Additionally, certain costs related to the collaboration are reimbursable by GSK as an offset to research and development expense. For each of the three and six months ended June 30, 2008 and 2007, reimbursable costs related to the collaboration were not material.**

### *2004 Strategic Alliance with GSK*

In March 2004, we entered into our strategic alliance with GSK for the development and commercialization of product candidates in a variety of therapeutic areas. In connection with the strategic alliance, we received a \$20.0 million payment from GSK in May 2004. This payment is being amortized over the initial period during which GSK may exercise its right to license certain of our programs under the agreement, which we currently estimate to be through September 2011.

The alliance provides GSK with 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. The remaining programs that GSK has the right to license are (i) our peripheral Opioid-Induced Bowel Dysfunction (PUMA) program, (ii) our AT1 Receptor Nephilysin Inhibitor hypertension (ARNI) program and (iii) our MonoAmine Reuptake Inhibitor chronic pain (MARIN) program. Upon licensing 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 based on performance 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 we receive, the total upfront and milestone payments that we could receive in



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

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 two

Table of Contents

of our COPD programs under the terms of the strategic alliance: LAMA and MABA. GSK has chosen not to license our bacterial infections program, our anesthesia program and our Gastrointestinal Motility Dysfunction program. There can be no assurance that GSK will license any other programs under the terms of the alliance agreement or at all, which could have an adverse effect on our business and financial condition.

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 the licensing of this program. Through June 30, 2008, we received a milestone payment of \$3.0 million from GSK related to clinical progress of our candidate. These payments are amortized ratably over the estimated period of performance (the product development period). We recognized \$0.2 million for each of the three months ended June 30, 2008 and 2007 and \$0.4 million for each of the six months ended June 30, 2008 and 2007 in revenue related to the LAMA. Additionally, we have been reimbursed by GSK for certain costs related to the LAMA program as an offset to research and development expense. For the three and six months ended June 30, 2008 and 2007, reimbursable costs were not material. We recently announced that GSK had informed us it intends to return the LAMA program to us because the current formulation of the lead product candidate, TD-4208, is incompatible with GSK's proprietary inhaler device. We and GSK are currently discussing the transfer of information and materials to us and we intend to explore partnerships with other companies for the further development of TD-4208.

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, 2008, we received a milestone payment of \$3.0 million from GSK related to clinical progress of our candidate and earned a \$10.0 million milestone payment for the successful achievement of proof-of-concept in the MABA Phase 2 study. We received the \$10.0 million milestone payment from GSK in July 2008. These amounts are being amortized ratably over the estimated period of performance (the product development period). Collaboration revenue related to the MABA program was \$0.3 million for each of the three months ended June 30, 2008 and 2007 and \$0.5 million for each of the six months ended June 30, 2008 and 2007. The next milestone associated with the MABA program is payable upon initiation of a Phase 3 program. Additionally, we are reimbursed by GSK for certain costs related to the MABA program as an offset to research and development expense. Reimbursements for the three and six months ended June 30, 2008 and 2007 were not material.

**RESULTS OF OPERATIONS***Revenue*

(in millions, except percentages)	Three months Ended				Six months Ended			
	June 30,		Change		June 30,		Change	
	2008	2007	\$	%	2008	2007	\$	%
Revenue	\$ 5.5	\$ 5.3	\$ 0.2	4%	\$ 11.2	\$ 10.7	\$ 0.5	5%

Revenue for the three and six months ended June 30, 2008 and 2007 primarily consisted of the amortization of upfront and milestone payments from GSK related to our Horizon collaboration and our strategic alliance and from Astellas related to our telavancin collaboration. The table below reflects the upfront and milestone payments received and earned through June 30, 2008:

**Agreements/Programs (in millions)**

	<b>Upfront and Milestone Payments</b>
<i>GSK Collaborations</i>	
Horizon collaboration	\$ 60.0
Strategic alliance agreement	20.0
Strategic alliance LAMA license	8.0
Strategic alliance MABA license	18.0
<i>Astellas license agreement</i>	159.0
<b>Total</b>	<b>\$ 265.0</b>

Upfront and milestone payments received and earned from GSK and Astellas have been deferred and are being amortized ratably into revenue over the applicable estimated performance periods with end dates ranging between 2011 and 2021. Future revenue will include the ongoing amortization of remaining deferred revenue, which consists of \$136.4 million of upfront and milestone payments received through June 30, 2008 under our agreement with Astellas and \$52.1 million of upfront and milestone payments received through June 30, 2008 under our agreements with GSK. Deferred revenue related to the LAMA license with GSK was \$4.6 million at June 30, 2008. GSK recently informed us that it intends to return the LAMA program to us because the current formulation of the lead product candidate is incompatible with GSK's proprietary

Table of Contents

inhaler device. As a result, we expect to recognize the remaining deferred revenue related to the LAMA license in the second half of 2008, pending the execution of an appropriate license agreement with GSK.

**Research and development**

Research and development 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	
	2008	2007	\$	%	2008	2007	\$	%
External research and development	\$ 4.9	\$ 16.3	\$ (11.4)	(70)%	\$ 12.3	\$ 44.8	\$ (32.4)	(72)%
Employee-related	7.3	17.6	(10.3)	(59)%	18.2	28.4	(10.2)	(36)%
Stock-based compensation	1.9	3.2	(1.3)	(41)%	4.6	6.6	(2.0)	(30)%
Facilities, depreciation and other allocated	5.9	6.4	(0.5)	(8)%	11.7	12.6	(0.9)	(7)%
Total research and development expenses	\$ 20.0	\$ 43.5	\$ (23.5)	(54)%	\$ 46.8	\$ 92.4	\$ (45.5)	(49)%

Research and development expenses decreased for the three and six months ended June 30, 2008 compared to the same periods in 2007 primarily due to a decrease in external costs, lower employee related expenses and stock-based compensation costs primarily due to the reduction in force.

External research and development costs decreased for the three and six months ended June 30, 2008 compared to the same periods in 2007 primarily due to the completion of our Phase 3 HAP studies for telavancin and our Phase 2 clinical studies for TD-5108, our GI Motility Dysfunction compound and for TD-1792, our investigational antibiotic.

Employee-related expenses decreased for the three and six months ended June 30, 2008 compared to the same periods in 2007 primarily due to lower costs related to our non-officer long-term bonus program. In addition, during the three months ended June 30, 2008, we reduced our non-officer long-term bonus accrual by \$0.7 million due to the reduction in force. Stock-based compensation expenses decreased for the three and six months ended June 30, 2008 compared to the same periods in 2007 primarily due to the reduction in force. Stock-based compensation expense includes expenses related to employee stock options, restricted stock unit awards (RSUs), employee stock purchase plan issuances and the value of options and RSUs issued to non-employees for services rendered. Facilities, depreciation and other allocated expenses decreased for the three and six months ended June 30, 2008 compared to the same periods of 2007 primarily due to lower supplies and facilities administration costs in 2008.

During 2007, we granted performance-contingent RSUs to certain research and development employees, the vesting of which is tied to the successful achievement of certain corporate operating milestones during 2009, as well as a requirement for continued employment through certain dates in late 2009 and early 2010. The expense associated with these performance-contingent RSUs would be recognized in increments if the achievement of the performance conditions becomes probable. During the three months ended March 31, 2008, the Compensation

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

Committee of our Board of Directors approved management's recommendation to modify certain performance milestones and cancel 25% of the performance-contingent RSUs held by senior management, thereby reducing the maximum potential research and development expense to approximately \$37.8 million, a decrease of \$0.5 million from December 31, 2007. During the three months ended June 30, 2008, due to the reduction in force announced in April 2008, the maximum potential research and development expense was reduced to approximately \$33.1 million, a decrease of \$4.7 million from March 31, 2008. We determined that no requisite performance conditions were probable and as a result, no compensation expense was recognized during the period. In July 2008, the Compensation Committee amended the performance-contingent RSUs held by non-executive employees such that half of the shares underlying these RSUs will vest over time, and the other half will remain subject to certain performance targets. As a result, the maximum potential research and development expense associated with the performance-contingent RSUs, if all of the applicable performance milestones are successfully achieved on time, was further reduced to approximately \$21.4 million.

Research and development expenses for the second half of 2008 are expected to be driven largely by costs associated with the preparation for and submission of our telavancin NDA for HAP and a Phase 3-enabling study with TD-5108. We anticipate personnel-related research and development expenses will decrease as a result of our workforce restructuring which was begun in the second quarter of 2008.

Table of Contents

Under our agreement with Astellas, we are responsible for completion of the cSSSI and HAP telavancin Phase 3 programs, publication of the results of these studies, preparation and submission of a NDA to the FDA for the cSSSI indication and subsequently for the HAP indication, and manufacture of approximately six months of first commercial sale stock for launch in the United States. The telavancin cSSSI NDA remains under regulatory review and we plan to submit our telavancin NDA for HAP late in the fourth quarter of 2008. We are reliant on the efforts of third parties, including contract research organizations, consultants and contract manufacturing organizations for the completion of these obligations. While we cannot predict the time frame in which all of these responsibilities will be completed, we anticipate that our aggregate external costs associated with our obligations with regard to telavancin described above will be towards the upper end of the range of \$155.0 million to \$165.0 million. In addition, if the regulatory approval of telavancin is substantially further delayed or denied by the necessary regulatory bodies, or if new information becomes available that suggests that the telavancin inventory will not be realizable, we may be required to expense a portion or all of the capitalized inventory costs and/or have additional inventory manufactured.

We have not provided program costs in detail because we do not track, and have not tracked, all of the individual components (specifically the internal cost components) of our research and development expenses on a program basis. We do not have the systems and processes in place to accurately capture these costs on a program basis.

**General and administrative**

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

(in millions, except percentages)	Three months Ended June 30,				Six months Ended June 30,			
	2008	2007	Change		2008	2007	Change	
	\$	\$	\$	%	\$	\$	\$	%
General and administrative	7.3	9.5	(2.2)	(23)%	16.4	18.3	(1.9)	(10)%

General and administrative expenses decreased for the three and six months ended June 30, 2008 compared to the same periods in 2007 primarily due to the reduction in force and lower external costs.

During 2007, we granted performance-contingent RSUs to certain general and administrative employees, the vesting of which is tied to the successful achievement of certain corporate operating milestones during 2009, as well as a requirement for continued employment through certain dates in late 2009 and early 2010. The expense associated with these performance-contingent RSUs would be recognized in increments if the achievement of the performance conditions becomes probable. During the three months ended March 31, 2008, the Compensation Committee of our Board of Directors approved management's recommendation to modify certain performance milestone targets and cancel 25% of the performance-contingent RSUs held by senior management, thereby reducing the maximum potential general and administrative expense to approximately \$21.8 million, a decrease of \$6.2 million from December 31, 2007. During the three months ended June 30, 2008, due to the reduction in force announced in April 2008, the maximum potential general and administrative expense was reduced to approximately \$20.3 million, a decrease of \$1.5 million from March 31, 2008. We determined that no requisite performance conditions were probable and as a result, no compensation expense was recognized during the quarter. In July 2008, the Compensation Committee amended the performance-contingent RSUs held by non-executive employees such that half of the shares underlying these RSUs will vest over time, and the other half will remain subject to certain performance targets. As a result, the maximum potential general and administrative expense associated with the performance-contingent RSUs,

if all of the applicable performance milestones are successfully achieved on time, was further reduced to approximately \$17.3 million.

***Restructuring charges***

In response to the completion of our Phase 3 development activities with telavancin and to reduce our overall cash burn rate, we announced on April 21, 2008 a plan to reduce our workforce by approximately 40% through layoffs from all departments throughout our organization. On April 23, 2008, we notified the employees impacted by the plan. For the three months ended June 30, 2008, we recorded charges totaling \$5.1 million related to severance, other termination benefits and outplacement services.

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

### Table of Contents

The following table summarizes the accrual balance and utilization by cost type for the restructuring for the three months ended June 30, 2008:

(in millions)	<b>Employee Severance and Benefits</b>	
Restructuring charges accrued	\$	5.1
Cash payments		(2.8)
Adjustments		
<b>Balance as of June 30, 2008</b>	<b>\$</b>	<b>2.3</b>

The remaining accrual as of June 30, 2008 is related to employee severance and related benefits and is expected to be paid within the next six months. As such, the restructuring accrual is recorded as a current liability within accrued personnel-related expenses. Several of our employees impacted by the plan have future service requirements extending beyond June 30, 2008. As a result, we anticipate that approximately \$0.7 million of additional severance and other termination benefits will be recognized over their service periods during the second half of 2008. The execution of the plan is expected to be completed by the end of 2008.

If we determine that any assets are impaired in the future, we may incur additional non-cash restructuring charges.

### *Interest and other income, net*

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

(in millions, except percentages)	Three months Ended June 30,				Six months Ended June 30,			
	2008	2007	Change		2008	2007	Change	
	\$	\$	\$	%	\$	\$	\$	%
Interest and other income, net	1.3	2.6	(1.3)	(50)%	3.0	5.4	(2.4)	(44)%

Interest and other income, net includes interest income earned on cash, cash equivalents and marketable securities, net realized gains on marketable securities, investment management fees on investments and net sublease income on facilities. Interest and other income, net decreased for the three and six months ended June 30, 2008 compared to the same periods in 2007 primarily due to a lower percentage of our portfolio being invested in corporate notes and securities, as well as lower average market rates of return during the periods in 2008.

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.

### *Interest expense*



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

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

(in millions, except percentages)	Three months Ended				Six months Ended			
	June 30,		Change		June 30,		Change	
	2008	2007	\$	%	2008	2007	\$	%
Interest expense	\$ 1.5	\$	\$ 1.5	*	\$ 2.6	\$	2.6	*

---

\* Calculation is not meaningful

Interest expense primarily consists of interest expense and debt amortization costs on our convertible subordinated notes issued in January 2008, as well as interest expense on other debt arrangements. Interest expense increased for the three and six months ended June 30, 2008 compared to the same periods in 2007 primarily due to the interest expense on our convertible subordinated notes.

### *Income taxes*

We adopted Financial Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48) effective January 1, 2007. The adoption of FIN 48 did not result in an adjustment to the beginning balance of our accumulated deficit. Under FIN 48, we have unrecognized tax benefits of \$33.2 million as of January 1, 2008. If we are eventually able to recognize these uncertain positions, \$33.2 million of the unrecognized benefit would reduce our effective tax rate. We currently have a full valuation allowance against our net deferred tax asset which would impact the timing of the effective tax rate benefit should any of these uncertain tax positions be favorably settled in the future.

Table of Contents

We are subject to federal and state examination for years 1996 and forward, by virtue of the tax attributes carrying forward from those years. We have no tax examinations currently in progress.

**LIQUIDITY AND CAPITAL RESOURCES**

As of June 30, 2008 and December 31, 2007, we had \$232.3 million and \$129.3 million, respectively, in cash, cash equivalents and marketable securities, in each case excluding \$3.8 million in restricted cash that was pledged as collateral for certain of our leased facilities.

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 and spending assumptions. If the activities related to telavancin, TD-5108, or our discovery programs are not successfully completed on schedule or cost significantly more than forecast; if the regulatory approval of telavancin is significantly further delayed; or if we are unsuccessful in our partnering activities, then the need for additional capital will increase. We cannot guarantee that future financing will be available in amounts or on terms acceptable to us, if at all. This could leave us without adequate financial resources to fund our operations as presently conducted.

**Cash Flows**

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

(in millions)	Six months Ended	
	June 30,	
	2008	2007
Net cash used in operating activities	\$ (64.1)	\$ (58.7)
Net cash provided (used in) investing activities	\$ (104.2)	\$ 27.8
Net cash provided by financing activities	\$ 169.5	\$ 4.1

Net cash used in operating activities was \$64.1 million and \$58.7 million for the six months ended June 30, 2008 and 2007, respectively. Despite lower research and development and general and administrative expenses, the cash used in operations for the six months ended June 30, 2008 was higher when compared to the same period last year primarily due to \$32.0 million in payments received from Astellas during the first quarter of 2007.

Investing activities for the six months ended June 30, 2008 used cash of \$104.2 million while investing activities provided cash of \$27.8 million for the comparable period of 2007. The increase in 2008 resulted primarily from higher purchases of marketable securities as a result of our convertible subordinated notes offering.

Financing activities provided cash of \$169.5 million and \$4.1 million for the six months ended June 30, 2008 and 2007, respectively. The cash provided by financing activities in 2008 was primarily due to net proceeds of \$166.7 million received from the closing of our convertible subordinated notes offering in January 2008.

### **Contractual Obligations and Commitments**

On January 23, 2008, we closed an underwritten public offering of \$172.5 million aggregate principal amount of unsecured convertible subordinated notes which will mature on January 15, 2015. The financing raised proceeds, net of issuance costs, of \$166.7 million. The notes bear interest at the rate of 3.0% per year, 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.

In addition to our debt commitment mentioned above, our other outstanding contractual obligations relate to operating leases, fixed purchase commitments under contract research, development and clinical supply agreements and a note payable. 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 \$3.8 million, collateralized by an equal amount of restricted cash. The terms of the facilities leases require us to maintain an unrestricted cash and marketable securities balance of at least \$50.0 million on the last day of each calendar quarter.

Pursuant to our 2002 collaboration with GSK, in the event that a LABA product candidate discovered by GSK is successfully developed and commercially launched in multiple locations of the world, we are obligated to make milestone payments to GSK of up to an aggregate of \$220.0 million. Based on available information, we do not estimate that a significant portion of these potential milestone payments are likely to be made in the next three years.

**Table of Contents**

**Effect of Recent Accounting Pronouncements**



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

In June 2007, the Emerging Issues Task Force (EITF) ratified a consensus on EITF Issue No. 07-3 (EITF 07-3), *Accounting for Non-Refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, which concluded that non-refundable advance payments for goods or services for use in research and development activities should be deferred and capitalized. EITF 07-3 is effective beginning in the first quarter of fiscal year 2008. The Company adopted EITF 07-3 effective January 1, 2008 and has determined that the adoption had no material impact on our financial position, results of operations and cash flows.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles and expands disclosures about fair value measurements. SFAS 157 is effective beginning in the first quarter of fiscal year 2008. In February 2008, the FASB issued Statement of Financial Position No. 157-2, which delays the effective date of SFAS 157 for non-financial assets and non-financial liabilities and is effective for fiscal years beginning after November 15, 2008. The Company adopted SFAS 157 effective January 1, 2008 for financial assets and liabilities and has determined that the adoption had no material impact on our financial position, results of operations and cash flows.

### **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 2007 10-K.

**Table of Contents**



**Item 4. Controls and Procedures**



*Evaluation of Disclosure Controls and Procedures*

Evaluation of Disclosure Controls and Procedures

We conducted an evaluation as of June 30, 2008, 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*



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

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**



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

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**

**We commenced a workforce restructuring during the second quarter of 2008 to focus our efforts on our key research and exploratory development programs and to reduce our overall cash burn rate. Even after giving effect to this restructuring, we will not have sufficient cash to fully develop and commercialize our un-partnered product candidates, and the restructuring may impact our ability to execute our business plan.**

During the second quarter of 2008 we commenced a significant workforce restructuring involving the elimination of approximately 40% of our positions through layoffs from all departments throughout our organization, including senior management. Our objective with the restructuring is to reduce our overall cash burn rate and focus on our key clinical programs while maintaining core research and exploratory development capability. There can be no assurance that we will be able to reduce spending as planned or that unanticipated costs will not occur. Our restructuring efforts to focus on key programs may not prove successful due to a variety of factors, including, without limitation, risks that a smaller workforce may have difficulty partnering our product candidates, successfully completing research and development efforts and adequately monitoring our partners' development and commercialization efforts. In addition, we may in the future decide to restructure operations and reduce expenses further by taking such measures as additional reductions in our workforce and program spending. Any restructuring places a substantial strain on remaining management and employees and on operational resources and there is a risk that our business will be adversely affected by the diversion of management time to the restructuring efforts. There can be no assurance that following this restructuring, we will have sufficient cash resources to allow us to fund our operations as planned.

**If telavancin is not approved by regulatory agencies, including the U.S. Food and Drug Administration, our business will be adversely affected and the price of our securities will decline.**

Telavancin is the first product candidate for which we submitted a new drug application (NDA) to the U.S. Food and Drug Administration (FDA). On October 19, 2007, we received an approvable letter from the FDA indicating that our telavancin NDA is approvable, subject to: resolution of current good manufacturing practices (cGMP) compliance issues not specifically related to telavancin at our third-party manufacturer; and submission of revised labeling or re-analyses of clinical data or additional clinical data. Although we believe that no additional clinical studies will need to be initiated to respond to the approvable letter, there can be no assurance that we will be able to respond fully or adequately to the FDA's requests using currently existing clinical data, that our third-party manufacturer will successfully resolve the cGMP issues that the FDA noted, or that the FDA will approve the current telavancin NDA on the basis of existing preclinical and clinical data or at all. If we are required to undertake additional clinical trials or to identify and qualify a new contract manufacturer for telavancin, we would incur significant additional cost and regulatory action on our NDA would be materially delayed. On February 23, 2008, the FDA informed us that the Anti-Infective Drugs Advisory Committee (AIDAC) meeting scheduled for February 27, 2008 to review the NDA for telavancin for the treatment of complicated skin and skin structure infections (cSSSI) was cancelled. On March 3, 2008, we announced that we had been informed that the FDA had cancelled the AIDAC meeting in order to allow time for the FDA to further evaluate study site monitoring and study conduct to ensure data integrity in the telavancin Phase 3 cSSSI program. The FDA indicated that, due to study monitoring issues at a single study site managed by the primary contract research organization for the cSSSI program, the agency intends to evaluate additional sites and that additional questions could arise after further evaluation. If following this additional site evaluation the FDA continues to have concerns about the integrity of the data in our telavancin Phase 3 program, it is likely that our NDA will not be approved which would harm our business and cause the price of our securities to fall. On March 4, 2008, the FDA accepted for review our complete response to the approvable letter and assigned a Prescription Drug User Fee Act (PDUFA) target date of July 21, 2008, but as of August 6, 2008, we had not yet received an action letter regarding the NDA from the FDA. The FDA had previously indicated that it did not expect to take final action on the telavancin NDA prior to completing its further evaluation of study site monitoring and study conduct in the Phase 3 cSSSI program, nor prior to resolution of the manufacturing issues not specifically related to telavancin cited in the approvable letter. Telavancin is also under review by European Union and Canadian regulatory agencies. Any adverse developments or results or perceived adverse developments or results with respect to our telavancin NDA or foreign

regulatory filings, the FDA's evaluation of additional study sites or study conduct, and, if rescheduled, the AIDAC meeting, could adversely affect the prospects of telavancin and would cause the price of our securities to fall.

Table of Contents

If the regulatory authorities require additional clinical data regarding telavancin, or if telavancin is ultimately approved by regulatory authorities but with labeling that materially limits the targeted patient population, our business will be harmed and the price of our securities will fall. Furthermore, if our third party manufacturer's cGMP issues are not satisfactorily resolved or regulatory action on telavancin is otherwise delayed for a lengthy period, or if a regulatory authority does not approve telavancin, our business will be harmed and the price of our securities will fall.

In addition, late in the second half of 2008 we plan to submit a NDA to the FDA for the additional indication of hospital-acquired pneumonia (HAP) for telavancin. Regulatory action with respect to this application could take a significant amount of time and could require that we undertake additional studies. Any adverse developments or results or perceived adverse developments or results with respect to our efforts to obtain approval of telavancin for this indication will cause the price of our securities to fall.

**If our product candidates, in particular telavancin, are determined to be unsafe or ineffective in humans, our business will be adversely affected and the price of our securities will decline.**

We have never commercialized any of our product candidates. We are uncertain whether any of our compounds or 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 compounds and 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, based on the results of Phase 1 studies. To date, 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 recent, well-publicized not-approvable letters issued by the FDA as well as safety-related product withdrawals, suspensions, post-approval labeling revisions to include black-box warnings and changes in approved indications, as well as growing public and governmental scrutiny of safety issues, have created an increasingly conservative regulatory environment. In addition, the FDA has begun to implement new standards and may change its interpretation of existing requirements for demonstrating that a product candidate is safe and effective, which could cause non-approval or delays in its approval of product candidates, including telavancin. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. If we are unable to discover and develop medicines that are effective and safe in humans, our business will fail.

**Any failure of a product candidate in clinical studies or any delay in commencing or completing clinical studies for our product candidates would harm our business and cause the price of our securities to decline.**

Each of our product candidates must undergo extensive preclinical and clinical studies as a condition to regulatory approval. Preclinical and clinical studies are expensive and take many years to complete. The commencement and completion of clinical studies for our product candidates may be delayed by many factors, including:

- poor effectiveness of product candidates during clinical studies;

- adverse events, safety issues or side effects relating to the product candidates or their formulation into medicines;
- 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;
- unreliable results from clinical studies, which we experienced in early 2008 with our thorough QTc study of TD-5108;
- inability to raise additional capital in sufficient amounts to continue our development programs, which are very expensive;
- the need to sequence clinical studies as opposed to conducting them concomitantly in order to conserve resources;

Table of Contents

- inability to enter into corporate partnering arrangements relating to the development and commercialization of our programs;
- delays in patient enrollment, which we experienced in our Phase 3 HAP 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;
- a regional disturbance where we are enrolling patients in our clinical trials, such as a pandemic, terrorist activities or war, or a natural disaster; and
- varying interpretation of data by the FDA and similar foreign regulatory agencies.

If our product candidates fail to demonstrate safety and effectiveness in clinical trials, or if our clinical trials are materially delayed, our business and financial condition will be adversely affected.

**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. In order to market our medicines in the European Union and other 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.

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

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, we may not receive regulatory approval of any of our product candidates and our business and financial condition will be materially harmed.

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

We have limited in-house production capabilities and depend entirely on a number of third-party active pharmaceutical ingredient (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 cGMP regulations and similar foreign standards and we do not have control over compliance with these regulations by our manufacturers.

We have had manufactured telavancin API and drug product sufficient for the anticipated six-month post-commercial launch supply in the event telavancin is approved for sale by regulatory authorities. However, our telavancin drug product has a limited shelf-life. If regulatory approval of telavancin is significantly further delayed, it is possible that we would have to manufacture additional telavancin launch supply and write off some or all of our telavancin inventory. We have a single source of supply of telavancin API and a single source of supply of telavancin drug product. During a mid-2007 audit of our supplier for telavancin drug product, a district office of the FDA noted deficiencies, not specifically related to the



Table of Contents

manufacture of telavancin drug product, with the supplier's quality and laboratory systems at the plant where telavancin is manufactured. In November 2007, the supplier received a warning letter from the FDA related to these issues. In March 2008, the FDA completed an on-site inspection of our supplier which resulted in the FDA issuing a Form 483, or a record of the FDA's observations, to the supplier. Our supplier has advised us that it submitted its response to the Form 483 in April 2008. We recently received correspondence from our supplier stating that it had met with the FDA regarding its response to the Form 483 and the FDA indicated that it would change our supplier's status in the FDA's database such that NDAs for product candidates manufactured by our supplier could be approved.

The approvable letter that we received from the FDA in October 2007 indicated that the telavancin NDA is approvable subject to, among other things, our supplier's resolution of its cGMP compliance issues that are not specifically related to the manufacture of telavancin. We believe, based on communications with our supplier, that the status of our supplier has been changed by the FDA to allow products that are manufactured by our supplier to be approved. However, we are not aware of official action by the FDA that provides for final resolution of the issues noted in its warning letter. Accordingly, we are unable to predict the amount of time it will take for the supplier and the FDA to resolve these compliance issues in a formal manner, and any material further delay will harm our business and cause the price of our securities to fall. We may begin the process of identifying and qualifying an alternative manufacturer for telavancin. This process would involve significant cost to us and could take twelve to eighteen months to complete, which would cause a material delay to our NDA if the compliance issues at our current manufacturer remain unresolved. Further, if Astellas is unable to arrange for the expanded commercial manufacture of telavancin, the commercial introduction of telavancin, if approved, would be adversely affected.

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.

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

If approved by the relevant regulatory agencies, the commercial success of telavancin will depend upon its acceptance by physicians, patients, third party payors and the medical community in general. We cannot be sure that telavancin will be accepted by these parties even if it is approved by the relevant regulatory authorities. If approved, telavancin will compete 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 telavancin is safe and efficacious for its approved indications, physicians may choose to restrict the use of telavancin. If we and our partner, Astellas, are unable to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, telavancin is preferable to vancomycin and other existing or subsequently-developed anti-infective drugs, we may never generate meaningful revenue from telavancin. The degree of market acceptance of telavancin, if approved by the relevant regulatory agencies, will depend on a number of factors, including, but not limited to:

- the demonstration of the clinical efficacy and safety of telavancin;
- the labeling for telavancin that ultimately is approved by regulatory authorities;
- the advantages and disadvantages of telavancin compared to alternative therapies;
- our and Astellas' ability to educate the medical community about the safety and effectiveness of telavancin;

Table of Contents

- the reimbursement policies of government and third party payors; and
- the market price of telavancin relative to competing therapies.

**Even if our product candidates receive regulatory approval, commercialization of such products may be adversely affected by regulatory actions.**

Even if we receive regulatory approval, 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. Further, if we obtain regulatory approval, a marketed medicine and its manufacturer are subject to continual review, including review and approval of the manufacturing facilities. Discovery of previously unknown problems with a medicine may result in restrictions on its permissible uses, or on the manufacturer, including withdrawal of the medicine from the market. The FDA and similar foreign regulatory authorities may also implement additional new standards, or change their interpretation and enforcement of existing standards and requirements for the manufacture, packaging or testing of products at any time. If we are unable to comply, we may be subject to regulatory or civil actions or penalties that could significantly and adversely affect our business. Any failure to maintain regulatory approval will limit our ability to commercialize our product candidates, which would materially and adversely affect our business and financial condition.

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

We have been engaged in discovering and developing compounds and product candidates since mid-1997. We have not generated any product revenue to date. We may never generate revenue from selling medicines or achieve profitability. As of June 30, 2008, we had an accumulated deficit of approximately \$994.6 million.

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, 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. In addition, in the event that a LABA product candidate discovered by GSK is successfully developed and commercially launched in multiple regions in the world, we are obligated to pay GSK milestone payments of up to an aggregate of \$220.0 million under our Horizon program. 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 is advanced through regulatory approval and commercialization, we would not be entitled to receive any further milestone payments from GSK with regard to the Horizon 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 will 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.

**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 Horizon 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

Table of Contents

product candidates in the programs that it has in-licensed, including Horizon 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 Astellas telavancin agreement, Astellas is responsible for the commercialization of telavancin and any royalties to us from this program will depend upon Astellas' ability to launch and sell the medicine if it is approved.

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 Horizon program, our partners generally are not restricted from developing and commercializing their own products and product candidates that compete with those licensed from us. For example, GSK currently has at least one competing LAMA product candidate that is further advanced in development than our LAMA product candidate which it previously licensed from us. In July 2008 we announced that GSK informed us that it intends to return our LAMA program to us under the terms of the strategic alliance agreement. 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 in certain circumstances, including if the telavancin cSSSI NDA is not approved by December 2008, or if the FDA has not approved telavancin NDAs for both cSSSI and HAP by December 31, 2008. Since our cSSSI NDA may not be approved by December 2008, if ever, and since we have not yet filed the HAP NDA, Astellas will have the right to terminate our telavancin license, development and commercialization agreement beginning in December 2008. If Astellas chooses to terminate the agreement we would not be able to commercialize telavancin (if it is approved by regulatory authorities) without another corporate partner.

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 GI Motility Dysfunction program. In July 2008, we announced that GSK informed us that it intends to return our LAMA program to us under the terms of the strategic alliance agreement. 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.

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

As of July 31, 2008, GSK beneficially owned approximately 15.3% 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 peripheral Opioid-Induced Bowel Dysfunction (PUMA) program, (ii) our AT1 Receptor Nephilysin Inhibitor hypertension (ARNI) program and (iii) our MonoAmine Reuptake Inhibitor chronic pain (MARIN) program. Because GSK may license these three development programs at any time prior

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

to successful completion of 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.

Table of Contents

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

We have active collaborations with GSK for the Horizon 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 and TD-1792 has successfully completed a Phase 2 proof-of-concept study, and TD-4208, our LAMA compound that GSK has indicated it intends to return to us under the strategic alliance, 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. 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 and 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.

**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 NDA for the treatment of cSSSI, the FDA conducted inspections of Theravance and certain of our study sites and clinical investigators and a CRO. The FDA has indicated that, due to study monitoring issues at a single study site managed by the primary CRO for the telavancin Phase 3 cSSSI program, the agency intends to evaluate additional sites, and that additional questions could arise after further evaluation. 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.

**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

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

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 or on our own 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;



Table of Contents

- 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 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. If approved, telavancin must demonstrate these advantages, as it will compete 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 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.

**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 have to 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 following our second quarter workforce reduction 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, including our Chairman of the board of directors, P. Roy Vagelos, and our Chief Executive Officer, Rick E Winningham. These individuals each have significant pharmaceutical industry experience. The unexpected loss of Dr. Vagelos or Mr. Winningham could impair our ability to discover, develop and market new medicines.

During the second quarter of 2008 we commenced a significant workforce restructuring involving 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

Table of Contents

to many other biopharmaceutical companies and many academic and research institutions. As a result, competition for skilled personnel in our market is intense and following our restructuring, competitors may particularly target our remaining employees for their recruiting efforts. Also, in the future when we need to recruit new personnel, the occurrence of our second quarter 2008 workforce restructuring may make it more difficult to attract new personnel. None of our employees have employment commitments for any fixed period of time and could 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 principal facility is located near known earthquake fault zones, and the occurrence of an earthquake, extremist attack or other catastrophic disaster could cause damage to our facilities and equipment, which could require us to cease or curtail operations.**

Our principal facility is located in the San Francisco Bay Area near known earthquake fault zones and therefore is vulnerable to damage from earthquakes. In October 1989, a major earthquake struck this area and caused significant property damage and a number of fatalities. We are also vulnerable to damage from other types of disasters, including power loss, attacks from extremist organizations, fire, floods, communications failures and similar events. If any disaster were to occur, our ability to operate our business could be seriously impaired. In addition, the unique nature of our research activities and of much of our equipment could make it difficult for us to recover from this type of disaster. We currently 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, its right to membership on our board of directors 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 31, 2008, GSK beneficially owned approximately 15.3% of our outstanding capital stock, and GSK has the right to maintain its percentage ownership of our capital stock. In addition, GSK currently has the right to designate one member to our board of directors. There are currently no GSK designated directors on our board of directors. 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 constituted 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.

In addition, beginning in September 2008, 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
- that 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.

**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.

Table of Contents

**After September 2008, 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.**

Beginning in September 2008, 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.

**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, 2008, we owned 127 issued United States patents and 450 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 all of 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 our not infringing the patents and proprietary rights of third parties. Third parties may assert that we are employing their proprietary technology 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 may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties or pay royalties. In addition, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. In addition, in the future we could be required to initiate litigation to enforce our proprietary rights against infringement by third parties. Prosecution of these claims to enforce our rights against others would involve substantial litigation expenses and divert substantial employee resources from our business. If we fail to effectively enforce our proprietary rights against others, our

Table of Contents

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 of pharmaceutical products. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forgo further commercialization of those 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.

**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.

Legislative proposals to reform healthcare and government insurance programs, 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 ability to market our potential medicines and generate revenues. Cost containment measures that health care payors and providers are instituting and the effect of probable further health care reform 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.

#### **General Company Related Risks**

**The price of our securities may be extremely volatile and purchasers of our securities could incur substantial losses.**

The price of our securities may be extremely volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. 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 perceived adverse developments with respect to our telavancin NDA, including, without limitation, the issuance of a complete response letter or similar communication by the FDA, the FDA's evaluation of additional telavancin Phase 3 cSSSI clinical study sites and study conduct and, if rescheduled, our



Table of Contents

meeting with the Anti-Infective Drugs Advisory Committee to the FDA;

- any delay in the commercial distribution of telavancin if approved by regulatory authorities;
  
- any delay in submitting our telavancin NDA for the HAP indication to the FDA and any adverse development or perceived adverse development with respect to the FDA's review of the NDA, including without limitation the FDA's issuance of a refusal to file letter or a request for additional information;
  
- any adverse developments or results or perceived adverse developments or results with respect to the Horizon or MABA programs, including delays in ongoing or planned clinical studies or negative results from such studies;
  
- any difficulties or delays encountered with regard to the regulatory path for the Horizon program;
  
- any adverse developments or perceived adverse developments in the field of LABAs, including public health advisories and the results of the Drug Safety and Risk Management and Pulmonary-Allergy Drugs joint advisory committee meeting scheduled for late 2008;
  
- our recent workforce restructuring and uncertainties or perceived uncertainties related to the restructuring, including without limitation concerns regarding our ability to successfully manage our business with a reduced workforce, our ability to retain key employees, the possibility that we will have to implement further workforce reductions, and whether we will reduce costs to the extent we anticipate;
  
- the extent to which GSK advances (or does not advance) our product candidates through development into commercialization, which we recently experienced in July 2008 when GSK informed us of its intention to return to us our LAMA program that it licensed from us under the strategic alliance agreement in 2004;
  
- 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 Astellas' termination of our telavancin license, development and commercialization agreement, which it will have the right to do beginning in December 2008;
- any adverse developments or results or perceived adverse developments or results with respect to our GI Motility Dysfunction program or TD-1792;
- announcements regarding GSK's decisions whether or not to license any of our development programs or to return to us any previously licensed program;
- 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 testing or study results or the outcome of regulatory review relating to products under development by us, our partners or our competitors;
- regulatory developments in the United States and foreign countries;
- economic and other external factors beyond our control;
- sales of stock by us or by our stockholders, including sales by certain of our executive officers 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 and others of which may be entered into; and
- after September 2008, potential sales or purchases of our capital stock by GSK.

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

As of July 31, 2008, GSK beneficially owned approximately 15.3% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 13.6% of our outstanding capital stock. These stockholders could substantially control the outcome of actions taken by us that require stockholder approval. In addition, pursuant to our governance agreement with GSK, GSK currently has the right to nominate

Table of Contents

one member of our board of directors. For these reasons, 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 changes in our business.

**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.

**Item 4. Submission of Matters to a Vote of Security Holders**

The Annual Meeting of Stockholders of Theravance Inc. was held on April 22, 2008, in South San Francisco, California.

The table below presents the results of the election to the Company's board of directors.

Edgar Filing: THERAVANCE INC - Form 10-Q

	Votes for	Votes withheld
P. Roy Vagelos, M.D.	46,823,149	238,152
Rick E Winningham	46,809,666	251,635
Jeffrey M. Drazan	45,808,749	1,252,552
Robert V. Gunderson, Jr.	31,986,304	15,074,997
Arnold J. Levine, Ph.D	46,823,049	238,252
Burton G. Malkiel, Ph.D.	46,817,257	244,044
William H. Waltrip	46,437,721	623,580
George M. Whitesides, Ph.D	45,994,662	1,066,639
William D. Young	45,607,528	1,453,773

The stockholders also approved an amendment to the Company's Employee Stock Purchase Plan (ESPP) to increase the aggregate number of shares authorized for issuance under the ESPP by 300,000 shares. The table below presents the voting results:

	Affirmative Votes	Negative Votes	Votes Withheld
Approval of amendment to Employee Stock Purchase Plan	38,814,148	255,753	16,153

The stockholders also ratified the selection by the Audit Committee of the Board of Directors of Ernst & Young LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2008. The table below presents the voting results:

	Affirmative Votes	Negative Votes	Votes Withheld
Ratification of independent registered public accounting firm	46,936,144	92,075	33,082

Table of Contents

**Item 5. Other Information**

(a) On June 22, 2008, we entered into a letter agreement (the "Agreement") with Michael Kitt, our former Senior Vice President, Development, in which we and Dr. Kitt agreed that Dr. Kitt's employment would terminate on June 22, 2008. Under this Agreement, we agreed to pay Dr. Kitt a severance payment of \$205,800 following his cessation of employment based on his length of employment and level of seniority at Theravance, and health insurance premiums through January 31, 2009. The Agreement also contains certain restrictive covenants, releases and other customary terms and conditions.

In connection with the Company's restructuring of its workforce, the decision has been made to eliminate the position of Senior Vice President, Technical Operations and Dr. Arthur Campbell will be departing from his position September 12, 2008.

**Table of Contents**

**Item 6. Exhibits**



Edgar Filing: THERAVANCE INC - Form 10-Q

Exhibit Number	Exhibit Description
3.3(1)	Amended and Restated Certificate of Incorporation
3.4(2)	Certificate of Amendment of Restated Certificate of Incorporation
3.5(2)	Amended and Restated Bylaws (as amended by the board of directors April 25, 2007)
4.1(3)	Specimen certificate representing the common stock of the registrant
4.2(4)	Amended and Restated Rights Agreement between Theravance, Inc. and The Bank of New York, as Rights Agent, dated as of June 22, 2007
4.3(5)	Indenture dated as of January 23, 2008 by and between Theravance, Inc. and The Bank of New York Trust Company, N.A., as trustee
4.4	Form of 3.0% Convertible Subordinated Note Due 2015 (included in Exhibit 4.3)
10.5	Amended and Restated Change in Control Severance Plan
10.40	Form of Time-Based Vesting Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement under 2004 Equity Incentive Plan (sales plan applicable to more than one award)
10.41	Form of Time-Based Vesting Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement under 2004 Equity Incentive Plan (sales plan applicable to one award)
10.42	Agreement between Michael Kitt and Theravance, Inc. dated June 22, 2008
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

- 
- (1) Incorporated herein by reference to the exhibit of the same number in the Company's amended Registration Statement on Form S-1 (No. 333-116384) filed with the SEC on July 26, 2004.
  - (2) Incorporated herein by reference to the exhibit of the same number in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.
  - (3) Incorporated herein by reference to the exhibit of the same number in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2006.
  - (4) Incorporated herein by reference to the exhibit of the same number in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007.
  - (5) Incorporated herein by reference to exhibit 4.4 in the Company's Current Report on Form 8-K filed on January 23, 2008.

**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 7, 2008  
Date

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

August 7, 2008  
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>Exhibit Description</b>
3.3(1)	Amended and Restated Certificate of Incorporation
3.4(2)	Certificate of Amendment of Restated Certificate of Incorporation
3.5(2)	Amended and Restated Bylaws (as amended by the board of directors April 25, 2007)
4.1(3)	Specimen certificate representing the common stock of the registrant
4.2(4)	Amended and Restated Rights Agreement between Theravance, Inc. and The Bank of New York, as Rights Agent, dated as of June 22, 2007
4.3(5)	Indenture dated as of January 23, 2008 by and between Theravance, Inc. and The Bank of New York Trust Company, N.A., as trustee
4.4	Form of 3.0% Convertible Subordinated Note Due 2015 (included in Exhibit 4.3)
10.5	Amended and Restated Change in Control Severance Plan
10.40	Form of Time-Based Vesting Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement under 2004 Equity Incentive Plan (sales plan applicable to more than one award)
10.41	Form of Time-Based Vesting Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement under 2004 Equity Incentive Plan (sales plan applicable to one award)
10.42	Agreement between Michael Kitt and Theravance, Inc. dated June 22, 2008
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



Edgar Filing: THERAVANCE INC - Form 10-Q

- (1) Incorporated herein by reference to the exhibit of the same number in the Company's amended Registration Statement on Form S-1 (No. 333-116384) filed with the SEC on July 26, 2004.
  
- (2) Incorporated herein by reference to the exhibit of the same number in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.
  
- (3) Incorporated herein by reference to the exhibit of the same number in the Company's Annual Report on Form 10-K.
  
- (4) Incorporated herein by reference to the exhibit of the same number in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007.
  
- (5) Incorporated herein by reference to exhibit 4.4 in the Company's Current Report on Form 8-K filed on January 23, 2008.