THERAVANCE INC
Form 10-Q
August 05, 2009
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2009

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.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**94-3265960**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

901 Gateway Boulevard

South San Francisco, CA 94080

(Address of Principal Executive Offices including Zip Code)

(650) 808-6000

(Registrant s Telephone Number, Including Area Code)

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

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

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

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

The number of shares of registrant s common stock outstanding on July 31, 2009 was 53,790,860.

The number of shares of registrant s Class A common stock outstanding on July 31, 2009 was 9,401,499.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

THERAVANCE, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

	June 30, 2009 (Unaudited)	December 31, 2008 *
Assets		
Current assets:		
Cash and cash equivalents	$ 61,098	$ 92,280
Marketable securities	114,585	108,325
Receivable from related party	248	287
Notes receivable	227	266
Prepaid and other current assets	8,315	8,803
Total current assets	184,473	209,961
Restricted cash	1,310	3,810
Property and equipment, net	14,712	16,206
Notes receivable	1,010	1,185
Other long-term assets	4,580	4,994
Total assets	$ 206,085	$ 236,156
Liabilities and stockholders net capital deficiency		
Current liabilities:		
Accounts payable	$ 1,823	$ 3,277
Accrued personnel-related expenses	7,958	8,932
Accrued clinical and development expenses	2,917	3,434
Other accrued liabilities	5,470	4,407
Current portion of note payable and capital lease	175	117
Current portion of deferred revenue	22,026	23,788
Total current liabilities	40,369	43,955
Convertible subordinated notes	172,500	172,500
Deferred rent	1,280	1,560
Notes payable and capital lease	359	319
Deferred revenue	150,495	152,771
Other long-term liabilities	543	
Commitments and contingencies		
Stockholders net capital deficiency:		
Preferred stock, $0.01 par value, 230 shares authorized, no shares issued and outstanding		
	538	525

Common stock, $0.01 par value; 200,000 shares authorized, issuable in series; 53,790 and 52,576 shares issued and outstanding at June 30, 2009 and December 31, 2008, respectively				
Class A Common Stock, $0.01 par value, 30,000 shares authorized, 9,402 issued and outstanding at June 30, 2009 and December 31, 2008		94		94
Additional paid-in capital		912,070		895,383
Accumulated other comprehensive income		198		501
Accumulated deficit		(1,072,361)		(1,031,452)
Total stockholders net capital deficiency		(159,461)		(134,949)
Total liabilities and stockholders net capital deficiency	$	206,085	$	236,156

* Condensed consolidated balance sheet at December 31, 2008 has been derived from audited consolidated financial statements.

See accompanying notes to condensed consolidated financial statements.

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THERAVANCE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	**2008**	**2009**	**2008**
Revenue (1)	$ 5,493	$ 5,505	$ 15,037	$ 11,150
Operating expenses:				
Research and development	20,020	19,996	39,577	46,775
General and administrative	6,796	7,256	13,848	16,422
Restructuring charges	30	5,063	1,313	5,063
Total operating expenses	26,846	32,315	54,738	68,260
Loss from operations	(21,353)	(26,810)	(39,701)	(57,110)
Interest and other income	1,172	1,295	1,819	2,967
Interest expense	(1,511)	(1,511)	(3,027)	(2,647)
Net loss	$ (21,692)	$ (27,026)	$ (40,909)	$ (56,790)
Basic and diluted net loss per share	$ (0.35)	$ (0.44)	$ (0.65)	$ (0.93)
Shares used in computing net loss per share	62,842	61,192	62,567	61,098

(1) Revenue includes amounts from GSK, a related party, of $2,708 and $9,656 for the three and six months ended June 30, 2009, respectively, and $2,830 and $5,654 for the three and six months ended June 30, 2008, respectively.

See accompanying notes to condensed consolidated financial statements.

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THERAVANCE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2009	**2008**
Cash flows from operating activities		
Net loss	$ (40,909)	$ (56,790)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,529	4,156
Stock-based compensation	10,387	8,646
Forgiveness of notes receivable	(23)	3
Changes in operating assets and liabilities:		
Receivables, prepaid and other current assets	545	(3,572)
Accounts payable and accrued liabilities	(1,092)	(3,799)
Accrued personnel-related expenses	(974)	(1,943)
Deferred rent	(280)	(202)
Deferred revenue	(4,038)	(10,150)
Other long-term liabilities	543	(485)
Net cash used in operating activities	(33,312)	(64,136)
Cash flows from investing activities		
Purchases of property and equipment	(359)	(791)
Purchases of marketable securities	(54,570)	(241,292)
Maturities of marketable securities	48,065	124,002
Sales of marketable securities		13,804
Release of restricted cash	2,500	
Additions to notes receivable		(100)
Payments received on notes receivable	238	160
Net cash used in investing activities	(4,126)	(104,217)
Cash flows from financing activities		
Payments on notes payable	(57)	(48)
Proceeds from issuances of common stock	6,313	2,845
Proceeds from issuance of convertible subordinated notes, net of issuance costs		166,733
Net cash provided by financing activities	6,256	169,530
Net increase (decrease) in cash and cash equivalents	(31,182)	1,177
Cash and cash equivalents at beginning of period	92,280	86,433
Cash and cash equivalents at end of period	$ 61,098	$ 87,610

See accompanying notes to condensed consolidated financial statements.

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Theravance, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of Theravance, Inc. (the Company) have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. In the opinion of the Company s management, the unaudited condensed consolidated financial statements have been prepared on the same basis as 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, 2009, the results of operations for the three and six months ended June 30, 2009 and 2008 and the cash flows for the six months ended June 30, 2009 and 2008. The Company has evaluated subsequent events through August 5, 2009, which is the date that the unaudited condensed consolidated financial statements were issued. The results for the three and six months ended June 30, 2009 are not necessarily indicative of the results of operations to be expected for the year ending December 31, 2009 or any other period.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2008 filed with the Securities and Exchange Commission (SEC) on February 26, 2009.

Use of Management s Estimates

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

Inventory

Inventory is stated at the lower of cost or market and is included with prepaid and other current assets in the condensed consolidated balance sheets. Inventory of $5.7 million as of June 30, 2009 consists 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 regulatory approval of telavancin is substantially further delayed or denied by the U.S. Food and Drug Administration (FDA), if the FDA determines that the Company s data are insufficient to support extended shelf life, or if the telavancin inventory is otherwise not realizable, the Company may be required to expense a portion or all of the capitalized inventory costs.

Other-than-Temporary Impairment Assessment

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

Research and Development Costs

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

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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. Share-based compensation arrangements covered by SFAS 123(R) currently include stock options granted, restricted shares issued, restricted stock unit awards (RSUs) granted and performance-contingent RSUs granted under the 2004 Equity Incentive Plan and the 2008 New Employee Equity Incentive Plan and purchases of common stock by the Company s employees at a discount to the market price during offering periods under the Company s Employee Stock Purchase Plan (ESPP). The estimated fair value of stock options, restricted shares and RSUs is expensed on a straight-line basis over the expected term of the grant and the fair value of performance-contingent RSUs is expensed during the term of the award when the Company determines that it is probable that certain performance milestones will be met. Compensation expense for purchases under the ESPP is recognized based on the estimated fair value of the common stock during each offering period and the percentage of the purchase discount.

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 the 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 and RSUs has been reduced for estimated forfeitures so that compensation expense is based on options and RSUs 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 rates for stock options and RSUs are based on its historical forfeiture experience.

Recent Accounting Pronouncements

In April 2009, the FASB issued FSP SFAS No. 115-2 and SFAS No. 124-2, Recognition and Presentation of Other-Than-Temporary Impairments (FSP SFAS No. 115-2 and SFAS No. 124-2). FSP SFAS No. 115-2 and SFAS No. 124-2 amends the other-than-temporary impairment guidance in GAAP for debt securities to make the guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. The Company adopted FSP SFAS No. 115-2 and SFAS No. 124-2 in the three months ended June 30, 2009 and has determined that the adoption had no material impact on its financial position, results of operations and cash flows.

In April 2009, the FASB issued FSP SFAS No. 107-1 and Accounting Principals Board No. 28-1, Interim Disclosures about Fair Value of Financial Instruments (FSP SFAS No. 107-1 and APB No. 28-1). This FSP amends FASB Statement No. 107, Disclosure about Fair Value of Financial Instruments, to require disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. This FSP also amends APB No. 28, Interim Financial Reporting, to require disclosures in summarized financial information at interim reporting periods. The Company adopted FSP SFAS No. 107-1 and APB No. 28-1 in the three months ended June 30, 2009 and has determined that the adoption had no material impact on its financial position, results of operations and cash flows.

In May 2009, the FASB issued Statement of Financial Accounting Standards No. 165, Subsequent Events (SFAS No. 165). SFAS No. 165 is intended to establish general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. It requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for selecting that date, that is, whether that date represents the date the financial statements were issued or were available to be

issued. The Company adopted SFAS No. 165 in the three months ended June 30, 2009 and has determined that the adoption had no material impact on its financial position, results of operations and cash flows.

2. Net Loss per Share

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

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Potential common shares that were excluded from the calculation are as follows:

(in thousands)	Three Months Ended June 30, 2009	Three Months Ended June 30, 2008	Six Months Ended June 30, 2009	Six Months Ended June 30, 2008
Shares issuable upon the exercise of stock options	9,179	11,070	9,529	11,080
Shares issuable under performance-contingent restricted stock unit awards	992	1,745	997	1,826
Shares issuable under restricted stock unit awards	1,890	448	1,524	230
Shares issuable upon the conversion of convertible debt	6,668	6,668	6,668	5,825

The calculation of basic and diluted net loss per share is as follows:

(in thousands, except for per share amounts)	Three Months Ended June 30, 2009	Three Months Ended June 30, 2008	Six Months Ended June 30, 2009	Six Months Ended June 30, 2008
Basic and diluted:				
Net loss	$ (21,692)	$ (27,026)	$ (40,909)	$ (56,790)
Weighted average shares of common stock outstanding	62,919	61,285	62,644	61,191
Less: unvested restricted shares	(77)	(93)	(77)	(93)
Weighted average shares used in computing basic and diluted net loss per common share	62,842	61,192	62,567	61,098
Basic and diluted net loss per share	$ (0.35)	$ (0.44)	$ (0.65)	$ (0.93)

3. Comprehensive Loss

Comprehensive loss is comprised of net loss and changes in other comprehensive income, which consists of net unrealized gains and losses on the Company s marketable securities. Comprehensive loss for the three and six months ended June 30, 2009 and 2008 is as follows:

(in thousands)	Three Months Ended June 30, 2009	Three Months Ended June 30, 2008	Six Months Ended June 30, 2009	Six Months Ended June 30, 2008
Net loss	$ (21,692)	$ (27,026)	$ (40,909)	$ (56,790)
Other comprehensive loss:				
Net unrealized loss on available-for-sale securities	(129)	(372)	(303)	(67)
Comprehensive loss	$ (21,821)	$ (27,398)	$ (41,212)	$ (56,857)

4. Restructuring Charges

In response to the completion of its Phase 3 development activities with telavancin and to reduce its overall cash burn rate, the Company announced a plan to reduce its workforce by approximately 40% through layoffs from all departments throughout the organization in April 2008.

In February 2009, the Company entered into a sublease agreement with a third party to sublease excess space in a portion of one of its South San Francisco, CA buildings. The sublease has a 37 month term that began March 2009. For the six months ended June 30, 2009, the Company recorded a restructuring charge of $1.3 million of which $1.1 million represents the fair value of the Company s lease payments and expenses less sublease income through March 2012.

The following table summarizes the accrual balance and utilization by cost type for the restructuring for the six months ended June 30, 2009:

(in thousands)	Employee Severance and Benefits	Excess Facilities
Balance as of December 31, 2008	$ 502	$
Restructuring charges accrued	50	1,264
Cash payments	(431)	(379)*
Adjustments		
Balance as of June 30, 2009	$ 121	$ 884

* Includes fair value of cash payments less sublease payments received

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To date, the cumulative amount of restructuring charges incurred was $6.8 million.

Several of the Company s employees impacted by the restructuring plan announced in April 2008 have future service requirements extending beyond June 30, 2009. As a result, the Company anticipates that approximately $0.1 million of additional severance and other termination benefits will be recognized over their service periods through the end of 2009. The restructuring accrual related to employee severance and benefits is recorded within accrued personnel-related expenses and the restructuring accrual related to excess facilities is recorded within other accrued liabilities and other long-term liabilities on the Company s condensed consolidated balance sheets.

5. Collaboration and Licensing Agreements

2005 License, Development and Commercialization Agreement with Astellas

In November 2005, the Company entered into a collaboration arrangement with Astellas for the development and commercialization of telavancin. In July 2006, Japan was added to the collaboration, thereby giving Astellas worldwide rights to this potential medicine. Through June 30, 2009, the Company has received $170.0 million in upfront, milestone and other fees from Astellas and the Company is eligible to receive up to an additional $50.0 million in remaining milestone payments related to regulatory filings and approvals in various regions of the world, primarily in the U.S. The Company recorded the payments as deferred revenue to be amortized ratably over its estimated period of performance (development and commercialization period). The Company recognized $2.8 million and $2.7 million in revenue under this agreement in the three months ended June 30, 2009 and 2008, respectively, and $5.4 million and $5.5 million in the six months ended June 30, 2009 and 2008, respectively. In April 2009, the FDA accepted the Company s nosocomial pneumonia (NP, also known as hospital acquired pneumonia or HAP) NDA filing. The NDA filing triggered a $10.0 million milestone payment from Astellas which the Company received and recorded as deferred revenue in April 2009.

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 is responsible for substantially all costs to develop and obtain U.S. regulatory approval for telavancin for complicated skin and skin structure infections (cSSSI) and NP, as well as for the manufacture of approximately six months of first commercial sale stock for launch of telavancin in the United States, and Astellas is responsible for substantially all other costs associated with commercialization and further development of telavancin.

Horizon Program with GSK

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

In connection with the Horizon program, in 2002 the Company received from GSK an upfront payment of $10.0 million and sold to an affiliate of GSK shares of the Company s Series E Preferred Stock for an aggregate purchase price of $40.0 million. In addition, the Company was eligible to receive up to $495.0 million in development, approval, launch and sales milestones and royalties on the sales of any product resulting from this program. Through June 30, 2009, the Company has received a total of $60.0 million in upfront and development milestone payments. GSK has determined to focus the collaboration s resources on the development of the lead LABA, GW642444, a GSK-discovered compound, together with GSK s ICS, fluticasone furoate. Accordingly, the Company does not expect to receive any further milestone payments from the Horizon program. In the event that a LABA product candidate discovered by GSK is successfully developed and commercialized, the Company would be obligated to make milestone payments to GSK which could total as much as $220.0 million if both a single agent and a combination product were launched in multiple regions of the world. Based on available information, the Company does not estimate that a significant portion of these potential milestone payments to GSK are likely to be made in the next two years. In addition, the Company is entitled to receive the same royalties on sales of medicines from the Horizon program, regardless of whether the product candidate originated with Theravance or with GSK. The Company is entitled to receive royalties of 15% on the first $3.0 billion of annual net sales, and 5% on annual net sales above $3.0 billion, for approved single-agent LABA and combination LABA-ICS medicines. Sales of single agent LABA medicines and combination medicines would be combined for the purposes of this royalty calculation. For other products combined with a LABA from the Horizon collaboration, such as a combination LABA/LAMA medicine, which are launched

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after a LABA/ICS combination medicine, royalties are upward tiering and range from the mid-single digits to 10%. However, if GSK is not selling a LABA/ICS combination product at the time that the first other LABA combination is launched, then the royalties described above for the LABA/ICS combination medicine are applicable.

The Company recorded the initial cash payment and subsequent milestone payments as deferred revenue to be amortized ratably over its estimated period of performance (the product development period). Collaboration revenue from GSK was $1.3 million and $1.7 million for the three months ended June 30, 2009 and 2008, respectively, and $2.5 million and $3.4 million for the six months ended June 30, 2009 and 2008, respectively.

2004 Strategic Alliance with GSK

In March 2004, the Company entered into its strategic alliance with GSK. Under this alliance, GSK received an option to license exclusive development and commercialization rights to product candidates from all of the Company s full drug discovery programs initiated prior to September 1, 2007, on pre-determined terms and on an exclusive, worldwide basis. Under the terms of the strategic alliance, GSK has only one opportunity to license each of the Company s programs. Upon GSK s decision to license a program, GSK is responsible for funding all future development, manufacturing and commercialization activities for product candidates in that program. In addition, GSK is obligated to use diligent efforts to develop and commercialize product candidates from any program that it licenses. Consistent with the Company s strategy, it is obligated at its sole cost to discover two structurally different product candidates for any programs that are licensed by GSK under the alliance. If these programs are successfully advanced through development by GSK, the Company is entitled to receive clinical, regulatory and commercial milestone payments and royalties on any sales of medicines developed from these programs. For product candidates licensed to date under this agreement, the royalty structure for a product containing one of its compounds as a single active ingredient would result in an average percentage royalty rate in the low double digits. If a product is successfully commercialized, in addition to any royalty revenue that the Company receives, the total upfront and milestone payments that it could receive in any given program that GSK licenses range from $130.0 million to $162.0 million for programs with single agent medicines and up to $252.0 million for programs with both a single agent and a combination medicine. If GSK chooses not to license a program, the Company retains all rights to the program and may continue the program alone or with a third party. To date, GSK has licensed the Company s two COPD programs: long-acting muscarinic antagonist (LAMA) and muscarinic antagonist-beta2 agonist (MABA). The Company received $5.0 million payments from GSK in connection with its license of each of the Company s LAMA and MABA programs in August 2004 and March 2005, respectively. GSK has chosen not to license the Company s bacterial infections program, anesthesia program or Gastrointestinal Motility Dysfunction program.

In connection with the strategic alliance with GSK, the Company received from GSK a payment of $20.0 million. This payment is being amortized over the initial performance period during which GSK may exercise its right to license certain of the Company s programs under the agreement, which it currently estimates to be through September 2011. In connection with the strategic alliance, the Company recognized $0.7 million in revenue for each of the three months ended June 30, 2009 and 2008 and $1.4 million in revenue for each of the six months ended June 30, 2009 and 2008. In addition, in May 2004, GSK purchased through an affiliate 6,387,096 shares of the Company s Class A common stock for an aggregate purchase price of $108.9 million.

Through June 30, 2009, the Company has received $46.0 million in upfront and milestone payments from GSK relating to the strategic alliance agreement. In addition, pursuant to a partial exercise of its rights under the governance agreement, upon the closing of the Company s initial public offering on October 8, 2004, GSK purchased through an affiliate an additional 433,757 shares of Class A common stock for $6.9 million.

In August 2004, GSK exercised its right to license the Company s LAMA program pursuant to the terms of the strategic alliance. The Company received a $5.0 million payment from GSK in connection with its licensing of the Company s LAMA program. Through June 30, 2009, the Company received a milestone payment from GSK of $3.0 million related to clinical progress of the Company s product candidate. These payments were being amortized ratably over the estimated period of performance (the product development period). During the three months ended March 31, 2009, the Company recognized the remaining $4.2 million of deferred revenue related to the LAMA program as a result of the program being returned to the Company from GSK. The recognition of the remaining deferred revenue related to the LAMA program had a favorable impact on basic and diluted net loss per share of $0.07 for the six months ended June 30, 2009. For the three and six months ended June 30, 2008, the Company recognized $0.2 million and $0.4 million, respectively, in revenue related to the LAMA program.

In March 2005, GSK exercised its right to license the Company s MABA program pursuant to the terms of the strategic alliance. The Company received a $5.0 million payment from GSK in connection with the license of the Company s

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MABA program. Through June 30, 2009, the Company received milestone payments from GSK of $13.0 million related to clinical progress of its candidate. These payments are being amortized ratably over the estimated period of performance (the product development period). In connection with the MABA program, the Company recognized $0.8 million and $0.3 million in revenue for the three months ended June 30, 2009 and 2008, respectively and $1.5 million and $0.5 million for the six months ended June 30, 2009 and 2008, respectively.

6. Marketable Securities

The Company manages, monitors and measures its investments in highly liquid investment-grade securities by major security type. The following is a summary of the Company s cash, cash equivalents, marketable securities and restricted cash by major security type at June 30, 2009 and December 31, 2008:

	June 30, 2009			
(in thousands)	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Estimated Fair Value**
U.S. government securities	$ 45,402	$ 29	$ (1)	$ 45,430
U.S. government agency securities	37,915	143		38,058
U.S. corporate notes	22,102	36	(13)	22,125
U.S. commercial paper	8,969	3		8,972
Money market funds	62,408			62,408
Total	176,796	211	(14)	176,993
Less amounts classified as cash and cash equivalents	(61,098)			(61,098)
Less amounts classified as restricted cash	(1,310)			(1,310)
Amounts classified as marketable securities	$ 114,388	$ 211	$ (14)	$ 114,585

	December 31, 2008			
(in thousands)	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Estimated Fair Value**
U.S. government securities	$ 39,483	$ 149	$	$ 39,632
U.S. government agency securities	28,785	284		29,069
U.S. corporate notes	19,635	55	(13)	19,677
U.S. commercial paper	24,916	26		24,942
Certificates of deposit	60			60
Money market funds	91,035			91,035
Total	203,914	514	(13)	204,415
Less amounts classified as cash and cash equivalents	(92,280)			(92,280)
Less amounts classified as restricted cash	(3,810)			(3,810)
Amounts classified as marketable securities	$ 107,824	$ 514	$ (13)	$ 108,325

The estimated fair value amounts were determined using available market information. At June 30, 2009, 100% of marketable securities have contractual maturities within twelve months and the average duration of marketable securities was approximately five months. The Company does not intend to sell the investments which are in an unrealized loss position and it is not more likely than not the Company will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. The Company has determined that the gross

unrealized losses on its marketable securities at June 30, 2009 were temporary in nature.

7. Fair Value Measurements

SFAS No. 157, Fair Value Measurements (SFAS 157) defines fair value, establishes a framework for measuring fair value under GAAP and enhances disclosures about fair value measurements. Fair value is defined under SFAS 157 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. 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.

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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 the Company s market assumptions. SFAS 157 classifies these inputs into the following hierarchy:

Level 1 Inputs Quoted prices for identical instruments in active markets.

Level 2 Inputs Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3 Inputs Unobservable inputs and little, if any, market activity for the assets.

The fair values of the Company s financial assets were as follows at June 30, 2009 and December 31, 2008:

	June 30, 2009 Fair Value Measurements at Reporting Date Using			
(in thousands)	**Quoted Prices in Active Markets for Identical Assets Level 1**	**Significant Other Observable Inputs Level 2**	**Significant Unobservable Inputs Level 3**	**Total**
U.S. government securities	$ 45,430	$	$	$ 45,430
U.S. government agency securities	38,058			38,058
U.S. corporate notes	12,037	10,088		22,125
U.S. commercial paper		8,972		8,972
Money market funds	62,408			62,408
Total	$ 157,933	$ 19,060	$	$ 176,993

	December 31, 2008 Fair Value Measurements at Reporting Date Using			
(in thousands)	**Quoted Prices in Active Markets for Identical Assets Level 1**	**Significant Other Observable Inputs Level 2**	**Significant Unobservable Inputs Level 3**	**Total**
U.S. government securities	$ 39,632	$	$	$ 39,632
U.S. government agency securities	28,103	966		29,069
U.S. corporate notes	9,712	9,965		19,677
U.S. commercial paper		24,942		24,942
Certificates of deposit	60			60
Money market funds	91,035			91,035
Total	$ 168,542	$ 35,873	$	$ 204,415

8. Convertible Subordinated Notes

On January 23, 2008, the Company closed an underwritten public offering of $172.5 million aggregate principal amount of unsecured convertible subordinated notes 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. The debt issuance costs, which are included in other long-term assets, are being amortized on a straight-line basis over the life of the notes.

Holders of the notes will be able to require the Company to repurchase some or all of their notes upon the occurrence of a fundamental change (as defined) at 100% of the principal amount of the notes being repurchased plus accrued and unpaid interest. The Company may not redeem the notes prior to January 15, 2012. On or after January 15, 2012 and prior to the maturity date, the Company, upon notice of redemption, may redeem for cash all or part of the notes if the last

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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.

The following table presents the carrying values and estimated fair values for the notes as of June 30, 2009 and December 31, 2008. The estimated fair value amounts were determined using available market information.

	June 30, 2009		December 31, 2008	
(in thousands)	Carrying value	Estimated fair value	Carrying value	Estimated fair value
Convertible subordinated notes	$ 172,500	$ 126,204	$ 172,500	$ 103,931

9. Stock-Based Compensation

Equity Incentive Plans

The Company issues stock options, restricted stock awards and RSUs under the 2004 Equity Incentive Plan (which includes shares remaining available for issuance under the Company s 1997 Stock Option Plan and Long-Term Stock Option Plan), as amended (the 2004 Plan) and the 2008 New Employee Equity Incentive Plan, as amended (the 2008 Plan).

2008 New Employee Equity Incentive Plan

In January 2008, the Company adopted 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. Stock options may be granted with an exercise price not less than 100% of the fair market value of the common stock on the date of grant. Stock options are generally granted with terms of up to ten years and vest over a period of four years. For the six months ended June 30, 2009, the Company granted stock options to purchase 133,000 shares at a weighted average exercise price of $14.83 and granted 10,000 RSUs with a weighted-average fair value of $14.31 per share under the 2008 Plan. For the six months ended June 30, 2008, no options, restricted stock or RSUs were granted under the 2008 Plan. As of June 30, 2009, there were 162,374 shares remaining available for issuance under the 2008 Plan. On July 21, 2009, the Company s compensation committee approved an amendment to the 2008 Plan which increased the number of shares authorized for issuance under the 2008 Plan from 500,000 to 700,000 shares.

2004 Equity Incentive Plan

The 2004 Plan provides for the granting of stock options, restricted stock awards, stock appreciation rights and RSUs to employees, officers, directors and consultants of the Company. Stock options may be granted with an exercise price not less than 100% of the fair market value of the common stock on the date of grant. Stock options are generally granted with terms of up to ten years and vest over a period of four years. For the six months ended June 30, 2009, the Company granted 928,911 RSUs with a weighted-average fair value of $14.66 per share and 42,000 stock options with a weighted-average exercise price of $14.98 per share under the 2004 Plan. For the six months ended June 30, 2008, the Company granted 89,394 RSUs with a weighted-average fair value of $12.98 per share and 1,500 stock options with a weighted-average exercise price of $12.97 per share under the 2004 Plan. As of June 30, 2009, there were 812,840 shares remaining available for issuance under the 2004 Plan.

For the six months ended June 30, 2009 and 2008, the Company granted zero and 113,636 performance-contingent RSUs, respectively, to employees. These performance-contingent RSUs have dual triggers of vesting based upon the successful achievement of certain corporate operating milestones during 2009, as well as a requirement for continued employment through 2009 and 2010. The issuance of shares underlying the RSUs would occur, if at all, during 2009 and 2010. Expense associated with RSUs will be recognized, if any, during 2009, depending on the probability of meeting the performance milestones. As of June 30, 2009, the Company had determined that none of the requisite performance milestones were probable and as a result, no compensation expense has been recognized.

The total intrinsic value of RSUs that vest solely over time at June 30, 2009 was $40.7 million. For the three and six months ended June 30, 2009, the Company expensed $2.2 million and $3.5 million, respectively, related to these RSUs. For the six months ended June 30, 2009, 352,928 of these RSUs vested.

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

(in thousands, except per share data)	Number of Shares Available for Grant	Number of Shares Subject to Outstanding Options	Weighted-Average Exercise Price of Outstanding Options	Number of Shares Subject to Outstanding RSUs	Weighted-Average Fair Value per Share at Grant
Balance at December 31, 2008	1,669	9,953	$ 16.01	2,260	$ 21.51
Granted	(958)	89	14.18	869	14.64
Exercised		(618)	8.22		
Released				(86)	19.71
Forfeited	233	(172)	28.00	(61)	17.10
Shares Withheld for Taxes	8				
Balance at March 31, 2009	952	9,252	16.29	2,982	19.82
Granted	(156)	86	15.58	70	14.93
Exercised		(65)	6.76		
Released				(266)	13.25
Forfeited	173	(168)	23.61	(5)	14.09
Shares Withheld for Taxes	6				
Balance at June 30, 2009	975	9,105	$ 16.21	2,781	$ 20.30

Employee Stock Purchase Plan

As of June 30, 2009, a total of 1,475,000 shares of common stock were approved and authorized for issuance under the ESPP. On April 24, 2009, the Company s stockholders approved an amendment to the ESPP which increased the number of shares authorized for issuance under the ESPP from 925,000 to 1,475,000 shares. Through June 30, 2009, the Company issued 837,325 shares under the ESPP at an average price of $11.92 per share. Total stock-based compensation expense recognized relating to the ESPP was $0.4 million and $35,000 for the three months ended June 30, 2009 and 2008, respectively, and $0.8 million and $0.4 million for the six months ended June 30, 2009 and 2008, respectively.

Valuation Assumptions

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,	
	2009	2008	2009	2008
Employee stock options				
Risk-free interest rate	1.65%-2.92%	3.50%-3.50%	1.55%-3.07%	2.74%-3.50%
Expected life (in years)	5-6	6	6	6
Volatility	0.51	0.49	0.49-.57	0.49
Dividend yield	%	%	%	%
Weighted average estimated fair value of stock options granted	$ 7.58	$ 6.60	$ 7.79	$ 9.75

Employee stock purchase plan issuances				
Risk-free interest rate	0.29%-0.88%	2.21%-2.80%	0.29%-0.88%	2.21%-2.80%
Expected life (in years)	0.5-2.0	0.5-2.0	0.5-2.0	0.5-2.0
Volatility	0.71-0.84	0.45-0.70	0.71-0.84	0.45-0.70
Dividend yield	%	%	%	%
Weighted average estimated fair value of ESPP issuances	$ 6.46	$ 5.42	$ 6.46	$ 5.42

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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:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2009**	**2008**	**2009**	**2008**
Research and development	$ 3,055	$ 1,870	$ 6,062	$ 4,592
General and administrative	2,219	1,862	4,325	4,054
Total	$ 5,274	$ 3,732	$ 10,387	$ 8,646

As of June 30, 2009, there was $16.1 million, $23.2 million and $1.0 million of total unrecognized compensation cost related to unvested stock options, RSUs (excluding performance-contingent RSUs) and restricted stock awards, respectively. These amounts are expected to be recognized over a weighted-average period of approximately 2.2 years, 3.2 years and 2.7 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.

10. 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, 2009.

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

Forward-Looking Statements

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

Executive Summary

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates. Theravance is focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections and gastrointestinal motility dysfunction. Our key programs include: telavancin for the treatment of serious Gram-positive bacterial infections with Astellas Pharma Inc. (Astellas) and the Horizon program and the bifunctional muscarinic antagonist-beta2 agonist (MABA) program with GlaxoSmithKline plc (GSK). By leveraging our proprietary insight of multivalency to drug discovery focused primarily on validated targets, we are pursuing a 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, 2009 was $21.7 million compared to $27.0 million during the same period of 2008, or a 20% decrease. For the three months ended June 30, 2009, research and development costs were even while general and administrative costs decreased by 7% when compared to the same period of 2008. Cash, cash equivalents

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and marketable securities totaled $175.7 million at June 30, 2009, a decrease of $24.9 million since December 31, 2008. The decrease was primarily due to cash used in operations.

Following are updates on the progress of our key programs:

Horizon

GSK has engaged with European and U.S. regulatory agencies to discuss study designs for the Horizon Phase 3 programs to evaluate a combination of a long-acting beta agonist (LABA) and an inhaled corticosteroid (ICS) for the treatment of chronic obstructive pulmonary disease (COPD) and asthma. GSK currently expects to initiate the Phase 3 program in COPD in October 2009. This program will include active comparators to evaluate the potential for superiority. GSK is waiting for feedback from the U.S. Food and Drug Administration (FDA) on the development of LABAs in asthma before finalizing the asthma Phase 3 program.

Telavancin

In late April 2009, the FDA accepted for review our response to the February 2009 Complete Response letter, which outlined requirements for approval of telavancin for the treatment of complicated skin and skin structure infections (cSSSI). The FDA assigned a Prescription Drug User Fee Act (PDUFA) goal date of September 16, 2009.

In early April 2009, the FDA accepted the filing of our New Drug Application (NDA) for telavancin for the treatment of nosocomial pneumonia (also known as hospital-acquired pneumonia) caused by Gram-positive bacteria such as methicillin-resistant *Staphylococcus aureus* (MRSA). The FDA has established a standard 10-month review for this NDA, with a PDUFA goal date of November 26, 2009. In conjunction with the filing of our NDA, in April 2009 we received a milestone payment of $10.0 million from our partner, Astellas.

Critical Accounting Policies and the Use of Estimates

As of the date of the filing of this quarterly report, we believe there have been no material changes or additions to our critical accounting policies and estimates during the three and six months ended June 30, 2009 compared to those discussed in our Annual Report on Form 10-K filed on February 26, 2009 (2008 10-K).

Collaboration and Licensing Agreements

2005 License, Development and Commercialization Agreement with Astellas

In November 2005, we entered into a collaboration arrangement with Astellas for the development and commercialization of telavancin. In July 2006, Japan was added to the collaboration, thereby giving Astellas worldwide rights to this potential medicine. Through June 30, 2009, we have received $170.0 million in upfront, milestone and other fees from Astellas and we are eligible to receive up to an additional $50.0 million in remaining milestone payments related to regulatory filings and approvals in various regions of the world, primarily in the U.S. We recorded the payments as deferred revenue to be amortized ratably over our estimated period of performance (development and commercialization period). We recognized $2.8 million and $2.7 million in revenue under this agreement in the three months ended June 30, 2009 and 2008, respectively, and $5.4 million and $5.5 million in the six months ended June 30, 2009 and 2008, respectively. In April 2009, the FDA accepted our nosocomial pneumonia NDA filing. The NDA filing triggered a $10.0 million milestone payment from Astellas which we received and recorded as deferred revenue in April 2009.

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 are responsible for substantially all costs to develop and obtain U.S. regulatory approval for telavancin for cSSSI and nosocomial pneumonia, as well as for the manufacture of approximately six months of first commercial sale stock for launch of telavancin in the United States, and Astellas is responsible for substantially all other costs associated with commercialization and further development of telavancin.

Horizon Program with GSK

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

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In connection with the Horizon program, in 2002 we received from GSK an upfront payment of $10.0 million and sold to an affiliate of GSK shares of our Series E Preferred Stock for an aggregate purchase price of $40.0 million. In addition, we were eligible to receive up to $495.0 million in development, approval, launch and sales milestones and royalties on the sales of any product resulting from this program. Through June 30, 2009, we have received a total of $60.0 million in upfront and development milestone payments. GSK has determined to focus the collaboration s resources on the development of the lead LABA, GW642444, a GSK-discovered compound, together with GSK s ICS, fluticasone furoate. Accordingly, we do not expect to receive any further milestone payments from the Horizon program. In the event that a LABA product candidate discovered by GSK is successfully developed and commercialized, we would be obligated to make milestone payments to GSK which could total as much as $220.0 million if both a single agent and a combination product were launched in multiple regions of the world. Based on available information, we do not estimate that a significant portion of these potential milestone payments to GSK are likely to be made in the next two years. In addition, we are entitled to receive the same royalties on sales of medicines from the Horizon program, regardless of whether the product candidate originated with Theravance or with GSK. We are entitled to receive royalties of 15% on the first $3.0 billion of annual net sales, and 5% on annual net sales above $3.0 billion, for approved single-agent LABA and combination LABA-ICS medicines. Sales of single agent LABA medicines and combination medicines would be combined for the purposes of this royalty calculation. For other products combined with a LABA from the 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.

We recorded the initial cash payment and subsequent milestone payments as deferred revenue to be amortized ratably over the estimated period of performance (the product development period). Collaboration revenue from GSK was $1.3 million and $1.7 million for the three months ended June 30, 2009 and 2008, respectively, and $2.5 million and $3.4 million for the six months ended June 30, 2009 and 2008, respectively.

2004 Strategic Alliance with GSK

In March 2004, we entered into our strategic alliance with GSK. Under this alliance, GSK received an option to license exclusive development and commercialization rights to product candidates from our entire full drug discovery programs initiated prior to September 1, 2007, on pre-determined terms and on an exclusive, worldwide basis. Under the terms of the strategic alliance, GSK has only one opportunity to license each of our programs. Upon GSK s decision to license a program, GSK is responsible for funding all future development, manufacturing and commercialization activities for product candidates in that program. In addition, GSK is obligated to use diligent efforts to develop and commercialize product candidates from any program that it licenses. Consistent with our strategy, we are obligated at our sole cost to discover two structurally different product candidates for any programs that are licensed by GSK under the alliance. If these programs are successfully advanced through development by GSK, we are entitled to receive clinical, regulatory and commercial milestone payments and royalties on any sales of medicines developed from these programs. For product candidates licensed to date under this agreement, the royalty structure for a product containing one of our compounds as a single active ingredient would result in an average percentage royalty rate in the low double digits. If a product is successfully commercialized, in addition to any royalty revenue that we receive, the total upfront and milestone payments that we could receive in any given program that GSK licenses range from $130.0 million to $162.0 million for programs with single agent medicines and up to $252.0 million for programs with both a single agent and a combination medicine. If GSK chooses not to license a program, we retain all rights to the program and may continue the program alone or with a third party. To date, GSK has licensed our two COPD programs: long-acting muscarinic antagonist (LAMA) and muscarinic antagonist-beta2 agonist (MABA). We received $5.0 million payments from GSK in connection with our license of each of our LAMA and MABA programs in August 2004 and March 2005, respectively. GSK has chosen not to license our bacterial infections program, anesthesia program or Gastrointestinal Motility Dysfunction program.

In connection with the strategic alliance with GSK, we received from GSK a payment of $20.0 million. This payment is being amortized over the initial performance period during which GSK may exercise its right to license certain of our programs under the agreement, which we currently estimate to be through September 2011. In connection with the strategic alliance, we recognized $0.7 million in revenue for each of the three months ended June 30, 2009 and 2008 and $1.4 million in revenue for each of the six months ended June 30, 2009 and 2008. In addition, in May 2004, GSK purchased through an affiliate 6,387,096 shares of our Class A common stock for an aggregate purchase price of

$108.9 million.

Through June 30, 2009, we have received $46.0 million in upfront and milestone payments from GSK relating to the strategic alliance agreement. In addition, pursuant to a partial exercise of its rights under the governance agreement, upon the

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closing of our initial public offering on October 8, 2004, GSK purchased through an affiliate an additional 433,757 shares of Class A common stock for $6.9 million.

In August 2004, GSK exercised its right to license our LAMA program pursuant to the terms of the strategic alliance. We received a $5.0 million payment from GSK in connection with its licensing of our LAMA program. Through June 30, 2009, we received a milestone payment from GSK of $3.0 million related to clinical progress of our product candidate. These payments were being amortized ratably over the estimated period of performance (the product development period). During the three months ended March 31, 2009, we recognized the remaining $4.2 million of deferred revenue related to the LAMA program as a result of the program being returned to us from GSK. For the three and six months ended June 30, 2008, we recognized $0.2 million and $0.4 million, respectively, in revenue related to the LAMA program.

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, 2009, we received milestone payments from GSK of $13.0 million related to clinical progress of our candidate. These payments are being amortized ratably over the estimated period of performance (the product development period). In connection with the MABA program, we recognized $0.8 million and $0.3 million in revenue for the three months ended June 30, 2009 and 2008, respectively, and $1.5 million and $0.5 million for the six months ended June 30, 2009 and 2008, respectively.

RESULTS OF OPERATIONS

Revenue

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

	Three months Ended June 30,		Change		Six months Ended June 30,		Change	
(in millions, except percentages)	**2009**	**2008**	**$**	**%**	**2009**	**2008**	**$**	**%**
Revenue	$ 5.5	$ 5.5	$	%	$ 15.0	$ 11.2	$ 3.8	34%

Revenue increased for the six months ended June 30, 2009 compared to the same period in 2008 primarily due to recognition of the remaining $4.2 million deferred revenue for the LAMA program as a result of the program being returned to us from GSK in the three months ended March 31, 2009. Upfront and milestone payments received from GSK and Astellas are deferred upon receipt and are being amortized ratably into revenue over the applicable estimated performance periods with end dates ranging between 2011 and 2021. We periodically review the estimated performance periods of our contracts based on the progress of our programs. The remaining revenue for the three months and six months ended June 30, 2009 and 2008 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 through June 30, 2009:

Agreements/Programs (in millions)

		Upfront and Milestone Payments
GSK Collaborations		
Horizon collaboration	$	60.0
Strategic alliance agreement		20.0
Strategic alliance LAMA license		8.0
Strategic alliance MABA license		18.0
Astellas license agreement		170.0
Total	$	276.0

Future revenue will include the ongoing amortization of the upfront and milestone payments received through June 30, 2009 and any additional upfront or milestone payments earned under current or new agreements.

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Research & Development

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

(in millions, except percentages)	Three months Ended June 30, 2009	2008	Change $	Change %	Six months Ended June 30, 2009	2008	Change $	Change %
External research and development	$ 4.0	$ 4.9	$ (0.9)	(18)%	$ 6.7	$ 12.3	$ (5.6)	(46)%
Employee-related	7.1	7.3	(0.2)	(3)%	15.3	18.2	(2.9)	(16)%
Stock-based compensation	3.1	1.9	1.2	63%	6.1	4.6	1.5	33%
Facilities, depreciation and other allocated	5.8	5.9	(0.1)	(2)%	11.5	11.7	(0.2)	(2)%
Total research and development expenses	$ 20.0	$ 20.0	$	%	$ 39.6	$ 46.8	$ (7.2)	(15)%

Research and development expenses decreased for the six months ended June 30, 2009 compared to the same period in 2008 primarily due to a decrease in external costs and lower employee related expenses due to the reduction in force announced in April 2008. The decrease in external costs was due to lower expenses related to telavancin.

Research and development expenses for the remainder of 2009 are expected to be driven largely by employee related expenses, costs associated with our ongoing efforts to obtain FDA approval of telavancin, continued development efforts in our PUMA and GI Motility programs, as well as costs associated with new drug discovery programs.

Under our agreement with Astellas, we are responsible for completion of the telavancin Phase 3 programs, publication of the results of these studies and preparation and submission of an NDA to the FDA for the cSSSI and nosocomial pneumonia indications. We are also responsible for the manufacture of approximately six months of first commercial sale stock for launch of telavancin in the United States, and for providing Astellas with a commercially validated manufacturing process so that it can manufacture telavancin thereafter. The telavancin cSSSI NDA remains under regulatory review and the FDA accepted for review our telavancin NDA for nosocomial pneumonia in April 2009. We are reliant on the efforts of third parties, including contract research organizations, consultants, our partner Astellas, 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, in particular the time and costs required to complete regulatory review of both the cSSSI and the nosocomial pneumonia NDAs and to complete the transfer of the telavancin U.S. commercial launch supply and manufacturing process to Astellas, we anticipate that our aggregate net external costs associated with our obligations with regard to telavancin described above will be towards the upper end of the range of $160.0 million to $170.0 million. In addition, if the regulatory approval of telavancin is substantially further delayed or denied by the FDA, if the FDA determines that our data are insufficient to support extended shelf life, or if the telavancin inventory is otherwise not realizable, we may be required to expense a portion or all of the $5.7 million capitalized inventory costs as of June 30, 2009 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 periods, were as follows:

	Three months Ended June 30,		Change		Six months Ended June 30,		Change	
(in millions, except percentages)	**2009**	**2008**	**$**	**%**	**2009**	**2008**	**$**	**%**
General and administrative	$ 6.8	$ 7.3	$ (0.5)	(7)%	$ 13.8	$ 16.4	(2.6)	(16)%

General and administrative expenses decreased for the three months ended June 30, 2009 compared to the same period in 2008 primarily due to reduced external costs. General and administrative expenses decreased for the six months ended June 30, 2009 compared to the same period of 2008 primarily due to lower employee and facilities related costs due to the reduction in force announced in April 2008.

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We anticipate general and administrative expenses for the remainder of 2009 to be at similar levels to the first half of the year.

Restructuring charges

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

	Three months Ended June 30,		Change		Six months Ended June 30,		Change	
(in millions, except percentages)	**2009**	**2008**	**$**	**%**	**2009**	**2008**	**$**	**%**
Restructuring charges	$	$ 5.1	$ (5.1)	(100)%	$ 1.3	$ 5.1	$ (3.8)	(75)%

Restructuring charges decreased for the three and six months ended June 30, 2009 compared to the same periods in 2008. The expenses in 2009 were due to restructuring charges recognized for the sublease of excess space in a portion of one of our South San Francisco, CA buildings whereas the expenses in 2008 were due to restructuring charges recognized for severance and other termination benefit charges resulting for our workforce reduction announced in April 2008.

We do not anticipate incurring additional significant restructuring charges from the plan announced in April 2008 in future periods.

Interest and other income, net

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

	Three months Ended June 30,		Change		Six months Ended June 30,		Change	
(in millions, except percentages)	**2009**	**2008**	**$**	**%**	**2009**	**2008**	**$**	**%**
Interest and other income, net	$ 1.2	$ 1.3	$ (0.1)	(8)%	$ 1.8	$ 3.0	$ (1.2)	(40)%

Interest and other income, net, decreased for the three and six months ended June 30, 2009 compared to the same periods in 2008 primarily due to lower average investment balances as well as lower average market rates of return during the periods in 2009.

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

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

	Three months Ended June 30,		Change		Six months Ended June 30,		Change	
(in millions, except percentages)	**2009**	**2008**	**$**	**%**	**2009**	**2008**	**$**	**%**
Interest expense	$ 1.5	$ 1.5	$	%	$ 3.0	$ 2.6	0.4	15%

Interest expense increased for the six months ended June 30, 2009 compared to the same period in 2008 due to a full period of interest expense and debt amortization costs on our convertible subordinated notes in 2009.

LIQUIDITY AND CAPITAL RESOURCES

Since our inception, we have financed our operations primarily through private placements and public offerings of equity and debt securities and payments received under corporate collaboration agreements. As of June 30, 2009 and December 31, 2008, we had $175.7 million and $200.6 million, respectively, in cash, cash equivalents and marketable securities, excluding $1.3 million and $3.8 million, respectively in restricted cash that was pledged as collateral for certain of our leases.

Although we expect our net cash used in operations to be lower in 2009 compared to 2008, we expect to incur substantial expenses as we continue our discovery and development efforts, particularly to the extent we advance our product candidates into clinical studies, which are very expensive. We believe that our cash, cash equivalents and marketable securities will be sufficient to meet our anticipated operating needs for at least the next twelve months based upon current operating plans, milestone forecasts and spending assumptions. We are likely to require additional capital to fund operating

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needs thereafter. If our current operating plans, milestone forecasts or spending assumptions change, then we may require additional funding sooner in the form of public or private equity offerings or debt financings. Furthermore, if favorable financing opportunities arise, we may seek additional funding sooner than currently planned. However, future financing may not be available in amounts or on terms acceptable to us, if at all, particularly if global financial and economic conditions do not improve or worsen. 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:

	Six Months Ended June 30,	
(in millions)	**2009**	**2008**
Net cash used in operating activities	$ (33.3)	$ (64.1)
Net cash used in investing activities	$ (4.1)	$ (104.2)
Net cash provided by financing activities	$ 6.3	$ 169.5

The decrease in cash used in operations for the six months ended June 30, 2009 compared to the same period in 2008 was primarily due to a lower net loss and changes in deferred revenue and prepaid and other current assets.

The decrease in cash used in investing activities for the six months ended June 30, 2009 compared to the same period in 2008 was primarily due to higher purchases of marketable securities in 2008 as a result of investing the proceeds of our convertible subordinated notes offering which closed in the first quarter of 2008.

The decrease in cash provided by financing activities for the six months ended June 30, 2009 compared to the same period in 2008 was primarily due to net proceeds of $166.7 million received from the closing of our convertible subordinated notes offering in the first quarter of 2008.

Contractual Obligations and Commitments

In January 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 which is being used for general corporate purposes. The notes bear interest at the rate of 3.0% per year, which is payable semi-annually in arrears in cash on January 15 and July 15 of each year, beginning on July 15, 2008. The notes are convertible, at the option of the holder, into shares of our common stock at an initial conversion rate of 38.6548 shares per $1,000 principal amount of the notes, subject to adjustment in certain circumstances, which represents an initial conversion price of approximately $25.87 per share.

In addition to our debt commitment 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 $1.3 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 Horizon collaboration with GSK, in the event that a LABA product candidate discovered by GSK is successfully developed and commercialized, we will be obligated to make milestone payments to GSK which could total as much as $220.0 million if both a single agent and a combination product were launched in multiple regions of the world. The current lead LABA candidate, GW642444, is a GSK-discovered compound. Based on available information, we do not estimate that any significant portion of these potential milestone payments to GSK is likely to be made in the next two years.

Effect of Recent Accounting Pronouncements

In April 2009, the FASB issued FSP SFAS No. 115-2 and SFAS No. 124-2, Recognition and Presentation of Other-Than-Temporary Impairments (FSP SFAS No. 115-2 and SFAS No. 124-2). FSP SFAS No. 115-2 and SFAS No. 124-2 amends the other-than-temporary impairment guidance in GAAP for debt securities to make the guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities

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in the financial statements. We adopted FSP SFAS No. 115-2 and SFAS No. 124-2 in the three months ended June 30, 2009 and have determined that the adoption had no material impact on our financial position, results of operations and cash flows.

In April 2009, the FASB issued FSP SFAS No. 107-1 and Accounting Principals Board No. 28-1, Interim Disclosures about Fair Value of Financial Instruments (FSP SFAS No. 107-1 and APB No. 28-1). This FSP amends FASB Statement No. 107, Disclosure about Fair Value of Financial Instruments, to require disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. This FSP also amends APB No. 28, Interim Financial Reporting, to require disclosures in summarized financial information at interim reporting periods. We adopted FSP SFAS No. 107-1 and APB No. 28-1 in the three months ended June 30, 2009 and have determined that the adoption had no material impact on our financial position, results of operations and cash flows.

In May 2009, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 165, Subsequent Events (SFAS No. 165). SFAS No. 165 is intended to establish general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. It requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for selecting that date, that is, whether that date represents the date the financial statements were issued or were available to be issued. We adopted SFAS No. 165 in the three months ended June 30, 2009 and have 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 2008 10-K.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We conducted an evaluation as of June 30, 2009, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, which are defined under SEC rules as controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Securities Exchange Act of 1934 (Exchange Act) is recorded, processed, summarized and reported within required time periods. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

Limitations on the Effectiveness of Controls

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

Changes in Internal Control over Financial Reporting

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

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PART II. OTHER INFORMATION

Item 1A. Risk Factors

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

Risks Related to our Business

If telavancin is not approved by regulatory agencies, including the U.S. Food and Drug Administration (FDA), our business will be adversely affected and the price of our securities could fall.

Telavancin is the first product candidate for which we submitted a new drug application (NDA) to the FDA. In October 2007, we received an approvable letter from the FDA indicating that our telavancin NDA for the treatment of complicated skin and skin structure infections (cSSSIs) 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. In March 2008, the FDA accepted for review our complete response to the approvable letter. In November 2008, the FDA s Anti-Infective Drugs Advisory Committee (AIDAC) gave telavancin a favorable recommendation for the treatment of cSSSIs caused by Gram-positive bacteria, provided that an acceptable risk management program can be developed to prevent its unintended use in pregnant women and women of child-bearing potential. In late February 2009, we announced that we had received a complete response letter from the FDA requiring a risk evaluation and mitigation strategy (REMS), data on patients with certain renal risk factors from the cSSSI and nosocomial pneumonia (NP, also known as hospital-acquired pneumonia or HAP) studies, revisions to the draft label, and a safety update. In April 2009, FDA accepted for review our response to the complete response letter and assigned a Prescription Drug User Fee Act (PDUFA) goal date of September 16, 2009.

In October 2008, we announced that Astellas Pharma Europe B.V., a subsidiary of our telavancin partner, Astellas Pharma Inc., voluntarily withdrew the European marketing authorization application (MAA) for telavancin for the treatment of complicated skin and soft tissue infections (cSSTI) from the European Medicines Agency (EMEA) based on communications from the Committee for Medicinal Products for Human Use (CHMP) of the EMEA that the data provided were not sufficient to allow the CHMP to conclude a positive benefit-risk balance for telavancin for the sole indication of cSSTI at that time. We continue to evaluate European regulatory strategy for cSSTI with our partner, Astellas. Based on discussions with our partner, we currently expect Astellas to submit a telavancin MAA for the treatment of cSSTI and NP later in 2009. Astellas Pharma Canada Inc. is in discussions with the Therapeutics Product Division (TPD) of Health Canada, the Canadian pharmaceuticals regulatory authority, on the proposed product monograph statements for telavancin in the treatment of cSSSI in Canada, which is required prior to approval of a new medicine in Canada.

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 could fall. Furthermore, any failure of our third-party manufacturer to stay in cGMP compliance, any further delay in regulatory action on telavancin or any regulatory decision to not approve telavancin will harm our business and could cause the price of our securities to fall.

In January 2009 we submitted a NDA to FDA for the additional indication of NP for telavancin and in April 2009 FDA accepted it for review and assigned a PDUFA goal date of November 26, 2009. Regulatory action with respect to this application could take a significant amount of time and could require that we present data from our NP program at an AIDAC meeting, or that we undertake additional studies. We believe that FDA may be considering a revision to its guidelines on NP antibacterial drug clinical trial design. If FDA retroactively applies revised clinical trial guidelines to our NP NDA review, and the data from our Phase 3 NP studies do not meet those guidelines, FDA could require data from additional clinical studies that comply with the new guidelines, which could result in significant delays and additional costs, or non-approval of the NP NDA. Any adverse developments or perceived adverse developments with respect to our efforts to obtain approval of telavancin for the NP indication, including a negative outcome from an AIDAC meeting, requirements for additional clinical data, delays in regulatory action, labeling limitations or non-approval, could cause the price of our securities to fall.

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If the FDA does not approve progression of the Horizon program into Phase 3 asthma studies, or if the progression of the planned Phase 3 COPD studies do not proceed as anticipated, the Horizon program will be significantly delayed, our business will be materially harmed, and the price of our securities could fall.

In late 2008 and early 2009, we announced results from multiple Horizon program Phase 2b asthma studies and a chronic obstructive pulmonary disease (COPD) study. Any adverse developments or results or perceived adverse developments or results with respect to the Horizon program will significantly harm our business and could cause the price of our securities to fall. Examples of such adverse developments include, but are not limited to:

- the FDA determining that any of the Phase 2b asthma studies failed to meet study endpoints or raised safety concerns, or that additional clinical studies are required prior to commencing Phase 3 asthma studies;

- the FDA concluding that any of the Phase 3 enabling studies or other clinical or preclinical studies currently underway raise safety or other concerns;

- the FDA, after being presented with data from the Phase 2b studies as well as additional studies, requiring further evidence that either or both the long-acting beta2 agonist (LABA) and the inhaled corticosteroid (ICS) is a once-daily medication; or

- any change in FDA policy or guidance regarding the use of LABAs to treat asthma or COPD.

We commenced a workforce restructuring in April 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.

In April 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 was 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 maintain reduced 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, or any future restructuring, we will have sufficient cash resources to allow us to fund our operations as planned.

If our product candidates, in particular telavancin and the lead compounds in the Horizon program with GSK, are determined to be unsafe or ineffective in humans, our business will be adversely affected and the price of our securities could fall.

We have never commercialized any of our product candidates. We are uncertain whether any of our product candidates will prove effective and safe in humans or meet applicable regulatory standards. In addition, our approach to applying our expertise in multivalency to drug discovery may not result in the creation of successful medicines. The risk of failure for our product candidates is high. For example, in late 2005, we discontinued our overactive bladder program based upon the results of our Phase 1 studies with compound TD-6301, and GSK discontinued development of TD-5742, the first LAMA compound licensed from us, after completing initial Phase 1 studies. 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 well-publicized approvable and complete response letters issued by the FDA and safety-related product withdrawals, suspensions, post-approval labeling revisions to include black-box warnings and changes in approved indications over the last few years, as well as growing public and governmental scrutiny of safety issues, have created an increasingly conservative regulatory environment. The implementation of new laws and regulations, and revisions to FDA clinical trial design guidelines, may increase uncertainty regarding the approvability of a new drug. In addition, there are

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additional requirements for approval of new drugs, including advisory committee meetings for new chemical entities, and formal REMS at the FDA s discretion. These new laws, regulations, additional requirements and changes in interpretation could cause non-approval or further delays in the FDA s review and approval of product candidates, including telavancin. For example, in late February 2009 we announced that we had received a complete response letter regarding our telavancin cSSSI NDA requiring, among other things, a REMS. 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.

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

Each of our product candidates must undergo extensive 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;
- 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;
- inability to enter into partnering arrangements relating to the development and commercialization of our programs;
- our inability or the inability of our collaborators or licensees to manufacture or obtain from third parties materials sufficient for use in preclinical and clinical studies;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines;

- failure of our partners to advance our product candidates through clinical development;

- delays in patient enrollment, which we experienced in our Phase 3 NP program for telavancin, and variability in the number and types of patients available for clinical studies;

- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;

- a regional disturbance where we or our collaborative partners are enrolling patients in our clinical trials, such as a pandemic, terrorist activities or war, or a natural disaster; and

- varying interpretations of data by the FDA and similar foreign regulatory agencies.

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

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

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

Frequently, product candidates that have shown promising results in early preclinical or clinical studies have subsequently suffered significant setbacks or failed in later clinical studies. In addition, clinical studies of potential products often reveal that it is not possible or practical to continue development efforts for these product candidates. If our clinical studies are substantially delayed or fail to prove the safety and effectiveness of our product candidates, 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 sufficient telavancin API and drug product for the anticipated six-month 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 substantially further delayed or denied by the FDA, if the FDA determines that our data are insufficient to support extended shelf life, or if the telavancin inventory is otherwise not realizable, we may be required to expense a portion or all of the capitalized inventory costs and/or have additional inventory manufactured. 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 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. The approvable letter that we received from the FDA in October 2007 indicated that the telavancin cSSSI 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, until final action by the FDA on our telavancin NDA, we will not know if there has been 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 could 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 could cause a material further delay to approval of our cSSSI NDA. Further, if Astellas does not accept our commercial launch supply or is unable to arrange for the expanded commercial manufacture of telavancin, the commercial introduction of telavancin, if approved, would be adversely affected and the price of our securities may fall.

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;

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- 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;

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

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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, 2009, we had an accumulated deficit of approximately $1.1 billion.

We expect to incur substantial expenses as we continue our drug discovery and development efforts, particularly to the extent we advance our product candidates into and through clinical studies, which are very expensive. As a result, we expect to continue to incur substantial losses for the foreseeable future. We are uncertain when or if we will be able to achieve or sustain profitability. Failure to become and remain profitable would adversely affect the price of our securities and our ability to raise capital and continue operations.

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

We need large amounts of capital to support our research and development efforts. If we are unable to secure capital to fund our operations we will not be able to continue our discovery and development efforts and we might have to enter into strategic collaborations that could require us to share commercial rights to our medicines to a greater extent than we currently intend. Based on our current operating plans, milestone forecasts and spending assumptions, we believe that our cash and cash equivalents and marketable securities will be sufficient to meet our anticipated operating needs for at least the next twelve months. We are likely to require additional capital to fund operating needs thereafter. In addition, under our Horizon collaboration with GSK, in the event that a LABA product candidate discovered by GSK is successfully developed and commercialized, we will be obligated to pay GSK milestone payments which could total as much as $220.0 million if both a single agent and a combination product were launched in multiple regions of the world. 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 may have to make additional reductions in our workforce and may be prevented from continuing our discovery and development efforts and exploiting other corporate opportunities. This could harm our business, prospects and financial condition and cause the price of our securities to fall.

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

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

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 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

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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 licensed from us in 2004 and returned to us in February 2009 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 the telavancin cSSSI NDA is approved by FDA, we will need to implement its commercial launch with our partner Astellas. Preparing for and executing a launch could raise issues of potential conflict between Astellas and us which, if not resolved in a timely manner, could adversely impact the timing, strategy and success of the commercial introduction of telavancin.

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 FDA has not approved telavancin NDAs for both cSSSI and NP by December 31, 2008. Since neither our cSSSI NDA nor our NP NDA has been approved as of the date of the filing of this quarterly report, Astellas now has the right to terminate our telavancin license, development and commercialization agreement. If Astellas chooses to terminate the agreement we would not be able to commercialize telavancin (if it is approved by regulatory authorities) without another partner, which could result in a delay in the commercialization of telavancin.

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 February 2009, GSK returned the LAMA program to us because the current formulation of the lead product candidate is incompatible with GSK s proprietary inhaler device. There can be no assurance that GSK will license any other development program under the terms of the strategic alliance agreement, or at all. GSK s failure to license our development programs or its return of programs to us could adversely affect the perceived prospects of the product candidates that are the subject of these development programs, which could negatively affect both our ability to enter into collaborations for these product candidates with third parties and the price of our securities.

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

As of July 31, 2009, GSK beneficially owned approximately 14.9% 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 Neprilysin Inhibitor (ARNI) program for cardiovascular disease and (iii) our MonoAmine Reuptake Inhibitor (MARIN) program for chronic pain. Because GSK may license these three development programs

at any time prior 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.

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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, our lead GI Motility Dysfunction compound, and TD-1792, our investigational antibiotic, has successfully completed a Phase 2 proof-of-concept study, and TD-4208, our LAMA compound that GSK returned to us in February 2009 under the terms of the strategic alliance agreement, has completed a Phase 1 study. We currently intend to pursue collaboration arrangements for the development and commercialization of these compounds. Collaborations with third parties regarding these programs or our other programs may require us to relinquish material rights, including revenue from commercialization of our medicines, on terms that are less attractive than our current arrangements or to assume material ongoing development obligations that we would have to fund. These collaboration arrangements are complex and time-consuming to negotiate, and if we are unable to reach agreements with third-party collaborators, we may fail to meet our business objectives and our financial condition may be adversely affected. We face significant competition in seeking third-party collaborators, especially in the current weak economy which is driving many biotechnology and biopharmaceutical companies to seek to sell or license their assets, and we may be unable to find third parties to pursue product collaborations on a timely basis or on acceptable terms. Furthermore, for any collaboration, we may not be able to control the amount of time and resources that our partners devote to our product candidates and our partners may choose to pursue alternative products. Our inability to successfully collaborate with third parties would increase our development costs and would limit the likelihood of successful commercialization of our product candidates.

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, clinical investigators and a CRO, and the FDA s evaluation of these inspections resulted in additional inspections of study sites. Similar inspections are ongoing in connection with FDA s review of our telavancin NDA for the treatment of NP. If we or any of the third parties on which we have relied to conduct our clinical studies are determined to have failed to comply with GCPs, the study protocol or applicable regulations, the clinical data generated in our studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs and could result in significant additional costs.

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

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

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

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

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

Any new medicine that competes with a generic 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 need a partner in order to commercialize such products unless we establish a sales and marketing organization with appropriate technical expertise and supporting distribution capability. At present, we have no sales personnel and a limited number of marketing personnel. Factors that may inhibit our efforts to commercialize our products without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products;

- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are not able to partner with a third party and are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing our product candidates, which would adversely affect our business and financial condition.

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

We are highly dependent on principal members of our management team and scientific staff to operate our business. We have become even more dependent on existing personnel since the significant workforce restructuring announced in April 2008 which involved the elimination of approximately 40% of our positions through layoffs from all departments throughout our organization, including senior management. While we planned our restructuring with the purpose of focusing on our key clinical programs while maintaining core research and exploratory development capability, the restructuring has adversely affected the pace and breadth of our research and development efforts. While the remaining scientific team has expertise in many different aspects of drug discovery and exploratory development, there is less depth to the team and we are more susceptible to remaining team members voluntarily leaving employment with us. Our company is located in northern California, which is headquarters to many other biotechnology and biopharmaceutical companies and many academic and research institutions. As a result, competition for certain skilled personnel in our market remains intense. Also, when recruiting new personnel, the occurrence of our April 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 may leave our employment at will.

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

Our 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 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, 2009, GSK beneficially owned approximately 14.9% of our outstanding capital stock, and GSK has the right to maintain its percentage ownership of our capital stock. GSK could have substantial influence in the election of our directors, delay or prevent a transaction in which stockholders might receive a premium over the prevailing market price for their shares and have significant control over certain changes in our business.

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

- the offer includes no condition as to financing;

- the offer is approved by a majority of our independent directors;

- the offer includes a condition that the holders of a majority of the shares of the voting stock not owned by GSK accept the offer by tendering their shares in the offer; and

- 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.

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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.

GSK s rights under the strategic alliance and governance agreements may deter or prevent efforts by other companies to acquire us, which could prevent our stockholders from realizing a control premium.

Our governance agreement with GSK requires us to exempt GSK from our stockholder rights plan, affords GSK certain rights to offer to acquire us in the event third parties seek to acquire our stock and contains other provisions that could deter or prevent another company from seeking to acquire us. For example, GSK may offer to acquire 100% of our outstanding stock from stockholders in certain circumstances, such as if we are faced with a hostile acquisition offer or if our board of directors acts in a manner to facilitate a change in control of us with a party other than GSK. In addition, pursuant to our strategic alliance agreement with GSK, GSK has the right to license (i) our PUMA program, (ii) our ARNI program and (iii) our MARIN program. As a result of these rights, other companies may be less inclined to pursue an acquisition of us and therefore we may not have the opportunity to be acquired in a transaction that stockholders might otherwise deem favorable, including transactions in which our stockholders might realize a substantial premium for their shares.

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

GSK may sell or transfer our common stock either pursuant to a public offering registered under the Securities Act of 1933, as amended (the 1933 Act), or pursuant to Rule 144 of the 1933 Act. In addition, beginning in September 2012, GSK will have no restrictions on its ability to sell or transfer our common stock on the open market, in privately negotiated transactions or otherwise, and these sales or transfers could create substantial declines in the price of our securities or, if these sales or transfers were made to a single buyer or group of buyers, could contribute to a transfer of control of our company to a third party.

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, 2009, we owned 165 issued United States patents and 668 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.

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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 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, the new Presidential administration and its focus on health care costs, along with the trend toward managed healthcare in the United States could influence the purchase of healthcare products and reduce demand and prices for our products, if approved. This could harm our or our collaborators ability to market our potential medicines and generate revenues. Cost containment measures that health care payors and providers are instituting and the effect of 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.

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

The price of our securities has been extremely volatile and may continue to be so. The stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies, in particular during 2008 and 2009. 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 cSSSI NDA, including, without limitation, any outcome other than approval of our NDA by the FDA;

- any adverse developments or perceived adverse developments with respect to regulatory matters concerning telavancin in any foreign jurisdiction, in particular the MAA that we expect Astellas to file with EMEA and the application pending for cSSSI in Canada;

- any unanticipated delay in the commercial distribution of telavancin if approved by regulatory authorities;

- any adverse developments or perceived adverse developments with respect to the FDA s review of the telavancin NP NDA, including without limitation FDA s request for additional information, any major amendment submitted by us, and the outcome from any AIDAC meeting regarding the NP NDA;

- any adverse developments or results or perceived adverse developments or results with respect to the Horizon or MABA programs with GSK, including delays in planned clinical studies or disagreements with regulatory agencies regarding paths for development;

- any difficulties or delays encountered with regard to the regulatory path for the Horizon program;

- any adverse developments in the clinical and regulatory path for our GI Motility Dysfunction program;

- any adverse developments or perceived adverse developments in the field of LABAs, including public health advisories;

- our workforce restructuring commenced in April 2008 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 and the possibility that we will have to implement further workforce reductions;

- the extent to which GSK advances (or does not advance) our product candidates through development into commercialization, such as our experience with our LAMA program licensed from us by GSK in 2004 under the strategic alliance agreement and then returned to us by GSK in February 2009;

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- any adverse developments or perceived adverse developments with respect to our relationship with GSK;

- any adverse developments or perceived adverse developments with respect to our relationship with Astellas, including without limitation, disagreements that may arise between us and Astellas concerning regulatory strategy or the launch of telavancin, if approved, or Astellas termination of our telavancin license, development and commercialization agreement, which it now has the right to do;

- any adverse developments or results or perceived adverse developments or results with respect to our partnering efforts with our GI Motility Dysfunction program, TD-1792 or TD-4208, the LAMA product candidate that GSK returned to us in February 2009 under the terms of the strategic alliance agreement;

- 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 study results or the outcome of regulatory review relating to products under development by us, our partners or our competitors;

- regulatory developments in the United States and foreign countries;

- economic and other external factors beyond our control;

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

- potential sales or purchases of our capital stock by GSK.

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

As of July 31, 2009, GSK beneficially owned approximately 14.9% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 13.7% of our outstanding capital stock. Based on our review of publicly available filings as of July 31, 2009, our six largest stockholders other than GSK collectively owned approximately 55.5% of our outstanding capital stock. These stockholders could substantially control the outcome of actions taken by us that require stockholder approval, including a transaction in which stockholders might receive a premium over the prevailing market price for their shares.

Anti-takeover provisions in our charter and bylaws, in our rights agreement and in Delaware law could prevent or delay a change in control of our company.

Provisions of our certificate of incorporation and bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions include:

- requiring supermajority stockholder voting to effect certain amendments to our certificate of incorporation and bylaws;

- restricting the ability of stockholders to call special meetings of stockholders;

- prohibiting stockholder action by written consent; and

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- 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 24, 2009, in South San Francisco, California.

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

	Votes for	Votes withheld
P. Roy Vagelos, M.D.	56,474,537	365,219
Rick E Winningham	56,471,514	368,242
Jeffrey M. Drazan	56,551,275	288,481
Robert V. Gunderson, Jr.	41,970,432	14,869,324
Arnold J. Levine. Ph.D	56,523,474	316,282
Burton G. Malkiel, Ph.D.	56,536,751	303,005
William H. Waltrip	55,615,012	1,224,744
George M. Whitesides, Ph.D	56,303,090	536,666
William D. Young	56,522,325	317,431

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 550,000 shares. The table below presents the voting results:

	Affirmative Votes	Negative Votes	Votes Withheld
Approval of amendment to Employee Stock Purchase Plan	52,331,513	200,671	31,671

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, 2009. The table below presents the voting results:

	Affirmative Votes	Negative Votes	Votes Withheld
Ratification of independent registered public accounting firm	56,712,699	122,927	4,130

Item 6. Exhibits

Exhibit Number	Description	Form	Incorporated by Reference Filing Date/Period End Date
3.3	Amended and Restated Certificate of Incorporation	S-1	7/26/04
3.4	Certificate of Amendment of Restated Certificate of Incorporation	10-Q	3/31/07
3.5	Amended and Restated Bylaws (as amended by the board of directors April 25, 2007)	10-Q	9/30/08
4.1	Specimen certificate representing the common stock of the registrant	10-K	12/31/06
4.2	Amended and Restated Rights Agreement between Theravance, Inc. and The Bank of New York, as Rights Agent, dated as of June 22, 2007	10-Q	6/30/07
4.3	Indenture dated as of January 23, 2008 by and between Theravance, Inc. and The Bank of New York Trust Company, N.A., as trustee	8-K	1/23/08
4.4	Form of 3.0% Convertible Subordinated Note Due 2015 (included in Exhibit 4.3)		
4.5	Amendment to Amended and Restated Rights Agreement between the registrant and The Bank of New York Mellon Corporation, as Rights Agent, dated November 21, 2008	8-K	11/25/08
10.35	2008 New Employee Equity Incentive Plan, as amended July 21, 2009		

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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

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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 5, 2009 Date	/s/ Rick E Winningham Rick E Winningham Chief Executive Officer
August 5, 2009 Date	/s/ Michael W. Aguiar Michael W. Aguiar Senior Vice President, Finance and Chief Financial Officer

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