THERAVANCE INC Form 10-Q November 06, 2008 Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2008

OR

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

For the transition period from to

 \mathbf{X}

Commission File Number:

0-30319

THERAVANCE, INC.

(Exact Name of Registrant as Specified in its Charter)

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

901 Gateway Boulevard

South San Francisco, CA 94080

(Address of Principal Executive Offices including Zip Code)

(650) 808-6000

(Registrant s Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.					
		Yes x No o			
Indicate by check mark whet company. See definitions of one):		relerated filer, an accelerated filer, a non-accelerated filer, and smaller reporting cor	ccelerated filer, or a smaller reporting mpany in Rule 12b-2 of the Exchange Act. (Check		
Large accelerated filer X	Accelerated filer O	Non-accelerated filer O (Do not check if a smaller reporting con	Smaller reporting company O mpany)		
Indicate by check mark whet	ther the registrant is a shell con	npany (as defined in Rule 12b-2 of the Exc	change Act).		
		Yes o No x			
The number of shares of regi	istrant s common stock outstan	nding on October 31, 2008 was 52,444,264	1.		
The number of shares of registrant s Class A common stock outstanding on October 31, 2008 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)

	September 30, 2008 (Unaudited)	December 31, 2007 *
Assets		
Current assets:		
Cash and cash equivalents	\$ 128,966	\$ 86,433
Marketable securities	89,871	40,383
Receivable from related party	231	316
Notes receivable	311	223
Prepaid and other current assets	8,348	6,732
Total current assets	227,727	134,087
Marketable securities		2,456
Restricted cash	3,810	3,810
Property and equipment, net	17,328	20,091
Notes receivable	1,196	1,539
Other long-term assets	5,201	
Total assets	\$ 255,262	\$ 161,983
Liabilities and stockholders equity (net capital deficiency)		
Current liabilities:		
Accounts payable	\$ 2,527	\$ 6,957
Accrued personnel-related expenses	9,116	11,841
Accrued clinical and development expenses	4,881	11,318
Other accrued liabilities	3,072	2,797
Current portion of note payable	113	101
Current portion of deferred revenue	23,996	22,519
Total current liabilities	43,705	55,533
Convertible subordinated notes	172,500	
Deferred rent	1,680	2,003
Notes payable	349	435
Deferred revenue	158,510	166,136
Other long-term liabilities	3,670	4,140
Commitments and contingencies		
Stockholders equity (net capital deficiency):		

Preferred stock, \$0.01 par value, 230 shares authorized, no shares issued and outstanding

Common stock, \$0.01 par value; 200,000 shares authorized, issuable in series; 52,437 and 51,684 shares issued and outstanding at September 30, 2008 and December 31, 2007,		
respectively	523	516
Class A Common Stock, \$0.01 par value, 30,000 shares authorized, 9,402 issued and		
outstanding at September 30, 2008 and December 31, 2007	94	94
Additional paid-in capital	889,844	870,878
Accumulated other comprehensive income (loss)	(86)	57
Accumulated deficit	(1,015,527)	(937,809)
Total stockholders equity (net capital deficiency)	(125,152)	(66,264)
Total liabilities and stockholders equity (net capital deficiency) \$	255,262	\$ 161,983

* Condensed consolidated balance sheet at December 31, 2007 has been derived from audited consolidated financial statements.

See accompanying notes to condensed consolidated financial statements.

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THERAVANCE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data) (Unaudited)

	Three Months Ended September 30,				Nine Months Ended September 30,		
		2008		2007	2008		2007
Revenue (1)	\$	5,999	\$	5,669 \$	17,149	\$	16,372
Operating expenses:							
Research and development		20,075		31,964	66,850		124,319
General and administrative		6,494		8,462	22,916		26,772
Restructuring charges		50			5,113		
Total operating expenses		26,619		40,426	94,879		151,091
Loss from operations		(20,620)		(34,757)	(77,730)		(134,719)
Interest and other income		1,209		2,414	4,176		7,855
Interest expense		(1,517)		(21)	(4,164)		(75)
Net loss	\$	(20,928)	\$	(32,364) \$	(77,718)	\$	(126,939)
Basic and diluted net loss per common share	\$	(0.34)	\$	(0.53) \$	(1.27)	\$	(2.10)
Shares used in computing net loss per common share		61,545		60,664	61,247		60,384

⁽¹⁾ Revenue includes amounts from GSK, a related party, of \$3,324 and \$8,979 for the three and nine months ended September 30, 2008, respectively, and \$2,824 and \$8,473 for the three and nine months ended September 30, 2007, respectively.

See accompanying notes to condensed consolidated financial statements.

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THERAVANCE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands) (Unaudited)

	Nine Months End	ed Septer	mber 30, 2007
Cash flows from operating activities			
Net loss	\$ (77,718)	\$	(126,939)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	5,744		2,525
Stock-based compensation	13,402		17,167
Loss on sale of equipment	42		
Forgiveness of notes receivable, net	9		(6)
Changes in operating assets and liabilities:			
Receivables, prepaid and other current assets	(2,960)		1,255
Accounts payable and accrued liabilities	(8,960)		(11,213)
Accrued personnel-related expenses	(2,725)		2,281
Deferred rent	(323)		(213)
Deferred revenue	(6,149)		40,628
Other long-term liabilities	(470)		6,011
Net cash used in operating activities	(80,108)		(68,504)
Cash flows from investing activities			
Purchases of property and equipment	(963)		(7,565)
Purchases of marketable securities	(296,939)		(78,732)
Maturities of marketable securities	234,177		100,945
Sales of marketable securities	13,804		53,888
Proceeds from sale of equipment	103		
Release of restricted cash			50
Additions to notes receivable	(100)		(250)
Payments received on notes receivable	331		1,165
Net cash provided by (used in) investing activities	(49,587)		69,501
Cook flows from floor in a activities			
Cash flows from financing activities	(74)		((5)
Payments on notes payable	(74)		(65)
Net proceeds from issuances of common stock	5,570		5,540
Proceeds from issuance of convertible subordinated notes, net of issuance costs	166,732		5 4775
Net cash provided by financing activities	172,228		5,475
Net increase in cash and cash equivalents	42,533		6,472
Cash and cash equivalents at beginning of period	86,433		72,388
Cash and cash equivalents at end of period	\$ 128,966	\$	78,860

See accompanying notes to condensed consolidated financial statements.

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Notes to Condensed Consolidated Financial Statements

(Unaudited)

1.	Basis of	Presentation	and Significant	: Accounting	Policies
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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 September 30, 2008, the results of operations for the three and nine months ended September 30, 2008 and 2007 and the cash flows for the nine months ended September 30, 2008 and 2007. The results for the three and nine months ended September 30, 2008 are not necessarily indicative of the results of operations to be expected for the year ending December 31, 2008 or any other period.

The accompanying condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2007 filed with the Securities and Exchange Commission (SEC) on February 26, 2008 (2007 10-K).

Use of Management s Estimates

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

Segment Reporting

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

Inventory

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

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

Bonus Accruals

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

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changes occur in those management estimates. As of September 30, 2008, the Company had approximately \$7.3 million remaining to be paid under its non-officer long-term bonus program. These payments are scheduled to be made in December of 2008 and 2009.

Other-than-Temporary Impairment Assessment

The Company reviews its investment portfolio to identify and evaluate investments that have indications of possible impairment. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, credit quality and the Company s ability and intent to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. If the Company determines that an investment impairment is other-than-temporary, the investment is written down with a charge recorded in interest and other income, net.

Fair Value of Share-based Payment Awards

The Company uses the fair value method of accounting for share-based compensation arrangements in accordance with Financial Accounting Standards Board (FASB) Statement No. 123(R), Share-based Payment (SFAS 123(R)). The Company adopted SFAS 123(R) on January 1, 2006 using the modified prospective method of transition. Under this method, compensation expense is recognized beginning with the effective date of adoption of SFAS 123(R) for all share-based payments (i) granted after the effective date of adoption and (ii) granted prior to the effective date of adoption and that remain unvested on the date of adoption. Share-based compensation arrangements covered by SFAS 123(R) currently include stock options granted, restricted shares issued and restricted stock unit awards (RSUs) granted under the 2004 Equity Incentive Plan, as amended, and purchases of common stock by the Company s employees at a discount to the market price during offering periods under the Company s Employee Stock Purchase Plan, as amended (ESPP). The estimated fair value of stock options, restricted shares and RSUs (excluding performance-contingent RSUs) is expensed on a straight-line basis over the expected term of the grant. The fair value of performance-contingent RSUs is expensed during the term of the award when the Company determines that it is probable that certain performance conditions will be met. Compensation expense for purchases under the ESPP is recognized based on the estimated fair value of the common stock during each offering period and the percentage of the purchase discount.

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

Recent Accounting Pronouncements

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

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

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 $Reclassification\ of\ Prior\ Period\ Amounts$

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

2. Net Loss per Share

Basic net loss per common share (Basic EPS) is computed by dividing net loss by the weighted-average number of common shares outstanding during the period, less shares subject to repurchase. Diluted net loss per common share (Diluted EPS) is computed by dividing net loss by the weighted-average number of common shares outstanding during the period, less shares subject to repurchase, plus dilutive potential common shares and shares subject to repurchase. Diluted EPS is identical to Basic EPS for all periods presented since potential common shares are excluded from the calculation, as their effect is anti-dilutive. The Company s potentially dilutive common shares include outstanding options to purchase shares of common stock, outstanding restricted stock unit awards and common shares issuable upon the conversion of convertible debt.

At September 30, 2008, potential common shares consist of approximately 10,052,000 shares issuable upon the exercise of stock options, approximately 1,146,000 shares issuable under performance-contingent restricted stock unit awards and approximately 1,237,000 shares issuable under restricted stock unit awards. At September 30, 2007, potential common shares consist of approximately 11,450,000 shares issuable upon the exercise of stock options, 2,000,000 shares issuable under performance-contingent restricted stock unit awards and approximately 18,000 shares issuable upon the exercise of a warrant. (The outstanding warrant subsequently expired on October 5, 2007 without being exercised and as a result, no stock was issued under the warrant).

	Three Mon Septem	 	Nine Mon Septem	
(in thousands, except for per share amounts)	2008	2007	2008	2007
Basic and diluted:				
Net loss	\$ (20,928)	\$ (32,364) \$	(77,718)	\$ (126,939)
Weighted average shares of common stock outstanding	61,625	60,724	61,327	60,468
Less: unvested restricted shares	(80)	(60)	(80)	(84)
Weighted average shares used in computing basic and diluted				
net loss per common share	61,545	60,664	61,247	60,384
Basic and diluted net loss per common share	\$ (0.34)	\$ (0.53) \$	(1.27)	\$ (2.10)

3. Comprehensive Loss

Comprehensive loss is comprised of net loss and changes in other comprehensive income (loss), which consists of net unrealized gains and losses on the Company s marketable securities. Comprehensive loss for the three and nine months ended September 30, 2008 and 2007 is as follows:

	Three Mon Septem		Nine Mon Septem	
(in thousands)	2008	2007	2008	2007
Net loss	\$ (20,928)	\$ (32,364) \$	(77,718)	\$ (126,939)
Other comprehensive income (loss):				
Changes in net unrealized gain (loss) on marketable				
securities	(76)	47	(143)	55
Comprehensive loss	\$ (21,004)	\$ (32,317) \$	(77,861)	\$ (126,884)

4. Restructuring Charges

In response to the completion of its Phase 3 development activities with telavancin and to reduce its overall cash burn rate, in April 2008 the Company announced a plan to reduce its workforce by approximately 40% through layoffs from all departments throughout the organization. For the three and nine months ended September 30, 2008, the Company recorded charges totaling \$50,000 and \$5.1 million, respectively. These amounts relate to severance, other termination benefits and outplacement services and include a non-cash charge of \$42,000 related to the sale of equipment.

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

	Employee
(in thousands)	Severance and Benefits
Balance as of June 30, 2008	\$ 2,247
Restructuring charges accrued	147
Cash payments	(1,930)
Adjustments	(140)
Balance as of September 30, 2008	\$ 324

The remaining accrual as of September 30, 2008 and adjustments to the accrual through September 30, 2008 are related to employee severance and related benefits. Several of the Company s employees impacted by the plan have future service requirements extending beyond September 30, 2008. As a result, the Company anticipates that approximately \$0.6 million of additional severance and other termination benefits will be recognized over their service periods through the end of 2009. The execution of the restructuring plan is expected to be completed by the end of 2009 when the remaining accrual is expected to be paid. The restructuring accrual is recorded within accrued personnel-related expenses.

5. Collaboration and Licensing

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 telavancin collaboration, thereby giving Astellas worldwide rights to this potential medicine. Through September 30, 2008, the Company had received \$159.0 million in upfront, milestone and other fees from Astellas, which are being amortized ratably over the estimated period of performance (the estimated development and commercialization period). The Company recognized \$2.7 million and \$2.8 million in revenue for the three months ended September 30, 2008 and 2007, respectively, and \$8.2 million and \$7.5 million in revenue for the nine months ended September 30, 2008 and 2007, respectively. As of September 30, 2008, the Company was eligible to receive up to \$60.0 million in remaining milestone payments related to regulatory filings and approvals in various regions of the world.

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

Horizon Program with GSK

In November 2002, the Company entered into its Horizon collaboration agreement with GlaxoSmithKline plc (GSK) to develop and commercialize a long-acting beta₂ agonist (LABA) product candidate for the treatment of asthma and chronic obstructive pulmonary disease (COPD). Each company contributed four LABA product candidates to the collaboration. Four large Phase 2b asthma studies commenced in December 2007, one with the lead LABA, GW642444 (444), and three with the lead inhaled corticosteroid (ICS) GW685698 (698), and in February 2008 a large Phase 2b COPD study with 444 was initiated. All of these studies recently completed enrollment and the Company anticipates reporting results in late 2008 and early 2009.

The Company is entitled to receive the same royalties on product sales of medicines from the Horizon collaboration, regardless of whether the product candidate originated with Theravance or with GSK. The royalty structure is downward tiering and would result in an average percentage royalty rate in the low- to mid-teens at annual net sales of up to approximately \$4.0 billion and the average royalty rate would decline to single digits at annual net sales of more than \$6.0 billion for sales of single-agent LABA medicines and combination LABA/ICS medicines, which would be combined for the purposes of this royalty calculation. For other products combined with a LABA from the Horizon collaboration, such as a combination LABA/LAMA medicine, which are launched after a LABA/ICS combination medicine, royalties are upward tiering and range from the mid-single digits to 10%. However, if GSK is not selling a LABA/ICS combination product at the time that the first other LABA combination is launched, then the royalties described above for the LABA/ICS combination medicine are applicable.

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As of September 30, 2008, the Company had received upfront and milestone payments from GSK of \$60.0 million related to the clinical progress of its candidates. GSK has determined to focus the collaboration s resources on the development of the lead LABA, 444, a GSK-discovered compound, together with the lead ICS. Accordingly, the Company does not expect to receive any further milestone payments from the Horizon program. In the event that a LABA product candidate discovered by GSK is successfully developed and commercially launched in multiple locations of the world, the Company will be obligated to make payments to GSK of up to \$220.0 million. Based on available information, the Company does not estimate that a significant portion of these potential milestone payments to GSK is likely to be made in the next three years.

The Company recorded the upfront and milestone payments as deferred revenue and they are being amortized ratably over the Company s estimated period of performance. Collaboration revenue was \$1.7 million for each of the three months ended September 30, 2008 and 2007 and \$5.1 million for each of the nine months ended September 30, 2008 and 2007. Subsequent development milestones, if any, will be recorded as deferred revenue when received and amortized over the remaining period of performance. Additionally, certain costs related to the collaboration are reimbursable by GSK as an offset to research and development expense. For each of the three and nine months ended September 30, 2008 and 2007, reimbursable costs related to the collaboration were not material.

2004 Strategic Alliance with GSK

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

The alliance provides GSK with an option to license exclusive development and commercialization rights to product candidates from all of the Company s full drug discovery programs initiated prior to September 1, 2007, on pre-determined terms and on an exclusive, worldwide basis. The remaining programs that GSK has the right to license are (i) a peripheral Opioid-Induced Bowel Dysfunction (PUMA) program, (ii) a AT1 Receptor Neprilysin Inhibitor hypertension (ARNI) program and (iii) a MonoAmine Reuptake Inhibitor chronic pain (MARIN) program. Upon licensing a program, GSK is responsible for funding all future development, manufacturing and commercialization activities for product candidates in that program. In addition, GSK is obligated to use diligent efforts to develop and commercialize product candidates from any program that it licenses. Consistent with the Company s strategy, it is obligated at its sole cost to discover two structurally different product candidates for any programs that are licensed by GSK under the alliance. If these programs are successfully advanced through development by GSK, the Company is entitled to receive clinical, regulatory and commercial milestone payments based on performance and royalties on any sales of medicines developed from these programs. For product candidates licensed to date under this agreement, the royalty structure for a product containing one of the Company s compounds as a single active ingredient would result in an average percentage royalty rate in the low double digits. If a product is successfully commercialized, in addition to any royalty revenue it receives, the total upfront and milestone payments that it could receive in any given program that GSK licenses range from \$130.0 million to \$162.0 million for programs with single-agent medicines and up to \$252.0 million for programs with both a single-agent and a combination medicine. If GSK chooses not to license a program, the Company retains all rights to the program and may continue the program alone or with a third party. To date, GSK has licensed two of the Company s COPD programs under the terms of the strategic alliance: LAMA and MABA. GSK has chosen not to license the Company s bacterial infections program, anesthesia program and Gastrointestinal Motility Dysfunction program. There can be no assurance that GSK will license any other programs under the terms of the alliance agreement or at all, which could have an adverse effect on the Company s business and financial condition.

In August 2004, GSK exercised its right to license the Company s long-acting muscarinic antagonist program (LAMA) pursuant to the terms of the strategic alliance. The Company had received a \$5.0 million payment from GSK in connection with the licensing of this program. Through

September 30, 2008, the Company received a milestone payment of \$3.0 million from GSK related to clinical progress of its candidate. These payments are amortized ratably over the estimated period of performance (the product development period). The Company recognized \$0.2 million for each of the three months ended September 30, 2008 and 2007 and \$0.6 million for each of the nine months ended September 30, 2008 and 2007 in revenue related to the LAMA program. Additionally, the Company has been reimbursed by GSK for certain costs related to the LAMA program as an offset to research and development expense. For the three and nine months ended September 30, 2008 and 2007, reimbursable costs were not material. In July 2008, we announced that GSK had informed us of its intent to return the LAMA program to Theravance because the current formulation of the lead product candidate, TD-4208, is incompatible with GSK s proprietary inhaler device. Deferred revenue related to the LAMA license with GSK was \$4.4

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million at September 30, 2008. The Company continues working with GSK to complete the return of the LAMA program from GSK to the Company and expects to recognize the remaining deferred revenue related to the LAMA license in the fourth quarter of 2008, pending the execution of an appropriate license agreement with GSK. The Company intends to explore partnerships with other companies for the further development of TD-4208.

In March 2005, GSK exercised its right to license the Company s bifunctional muscarinic antagonist-beta2 agonist (MABA) program pursuant to the terms of the strategic alliance. The Company received a \$5.0 million payment from GSK in connection with the license of the Company s MABA program. Through September 30, 2008, the Company received milestone payments of \$13.0 million from GSK related to clinical progress of its candidate. These amounts are being amortized ratably over the estimated period of performance (the product development period). Collaboration revenue related to the MABA program was \$0.8 million and \$0.3 million for each of the three months ended September 30, 2008 and 2007, respectively, and \$1.3 million and \$0.8 million for each the nine months ended September 30, 2008 and 2007, respectively. Additionally, the Company is reimbursed by GSK for certain costs related to the MABA program as an offset to research and development expense. Reimbursements for the three and nine months ended September 30, 2008 and 2007 were not material.

6. Marketable Securities

The Company invests in a variety of highly liquid investment-grade securities. The following is a summary of the Company s cash, cash equivalents, marketable securities and restricted cash at September 30, 2008:

September 30, 2008									
		Gross		Gross					
A	mortized Cost	τ	nrealized Gains				Estimated Fair Value		
\$	29,727	\$	27	\$		\$	29,754		
	32,873		1		(52)		32,822		
	7,535		2		(64)		7,473		
	48,587						48,587		
	60						60		
	103,951						103,951		
	222,733		30		(116)		222,647		
	(128,966)						(128,966)		
	(3,810)						(3,810)		
\$	89,957	\$	30	\$	(116)	\$	89,871		
	\$	\$ 29,727 32,873 7,535 48,587 60 103,951 222,733 (128,966) (3,810)	Cost \$ 29,727 \$ 32,873 7,535 48,587 60 103,951 222,733 (128,966) (3,810)	Amortized Cost Unrealized Gains \$ 29,727 \$ 27 32,873 1 7,535 2 48,587 60 103,951 222,733 30 (128,966) (3,810)	Amortized Cost Unrealized Gains Un S 29,727 \$ 27 \$ 32,873 1 7,535 2 48,587 60 103,951 222,733 30 (128,966) (3,810)	Amortized Cost Gross Unrealized Gains Gross Unrealized Losses \$ 29,727 \$ 27 \$ 32,873 \$ 7,535 2 (64) 48,587 60 60 103,951 222,733 30 (116) (128,966) (3,810) (3,810)	Amortized Unrealized Unrealized Losses \$ 29,727 \$ 27 \$ \$ 32,873		

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

7. Fair Value Measurements

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

SFAS 157 s valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect 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.

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The fair value of these financial assets was determined using the following inputs at September 30, 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	\$ 29,754	\$		\$	\$	29,754	
U.S. government agency securities			32,822			32,822	
U.S. corporate notes	5,976		1,497			7,473	
U.S. commercial paper			48,587			48,587	
Certificates of deposit	60					60	
Money market funds	103,951					103,951	
Total	\$ 139,741	\$	82,906	\$	\$	222,647	

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

8. Commitments

Guarantees and Indemnifications

The Company indemnifies its officers and directors for certain events or occurrences, subject to certain limits. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recognized any liabilities relating to these agreements as of September 30, 2008.

Purchase Obligations

At September 30, 2008, the Company had outstanding purchase obligations, primarily for services from contract research and manufacturing organizations, totaling \$3.4 million.

9. Convertible Subordinated Notes

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