THERAVANCE INC
Form 10-Q
November 07, 2007

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 September 30, 2007

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 is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one)

Large Accelerated Filer x Accelerated Filer o Non-Accelerated Filer 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 October 31, 2007 was 51,505,987.

The number of shares of registrant s Class A common stock outstanding on October 31, 2007 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, 2007 (Unaudited)	December 31, 2006 *
Assets		
Current assets:		
Cash and cash equivalents	$ 78,860	$ 72,388
Marketable securities	58,678	128,692
Receivable from related party	98	608
Notes receivable	437	1,142
Prepaid and other current assets	6,363	4,361
Total current assets	144,436	207,191
Marketable securities	28,983	34,490
Restricted cash and cash equivalents	3,810	3,860
Property and equipment, net	19,847	15,101
Notes receivable	1,547	1,782
Total assets	$ 198,623	$ 262,424
Liabilities and stockholders equity (deficit)		
Current liabilities:		
Accounts payable	$ 5,954	$ 16,011
Accrued personnel-related expenses	10,597	8,316
Accrued clinical and development expenses	14,952	13,608
Other accrued liabilities	2,795	2,314
Current portion of notes payable	98	87
Current portion of deferred revenue	22,740	19,273
Total current liabilities	57,136	59,609
Deferred rent	2,085	2,298
Notes payable	462	538
Deferred revenue	171,544	134,383
Other long term liabilities	8,281	2,286
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; 51,461 and 50,746 shares issued and outstanding at September 30, 2007 and December 31, 2006, respectively	514	507
Class A Common Stock, $0.01 par value, 30,000 shares authorized, 9,402 issued and outstanding at September 30, 2007 and December 31, 2006	94	94
Additional paid-in capital	863,177	840,498
Notes receivable from stockholders		(3)
Accumulated other comprehensive income	81	26
Accumulated deficit	(904,751)	(777,812)
Total stockholders equity (net capital deficiency)	(40,885)	63,310
Total liabilities and stockholders equity (net capital deficiency)	$ 198,623	$ 262,424

* Condensed consolidated balance sheet at December 31, 2006 has been derived from audited consolidated financial statements.

See accompanying notes to condensed consolidated financial statements.

THERAVANCE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Revenue (1)	$ 5,669	$ 5,524	$ 16,372	$ 14,657
Operating expenses:				
Research and development	31,964	39,103	124,319	128,562
General and administrative	8,462	7,868	26,772	24,041
Total operating expenses	40,426	46,971	151,091	152,603
Loss from operations	(34,757)	(41,447)	(134,719)	(137,946)
Interest and other income	2,438	3,875	8,059	10,234
Interest and other expense	(45)	(208)	(279)	(495)
Net loss	$ (32,364)	$ (37,780)	$ (126,939)	$ (128,207)
Basic and diluted net loss per common share	$ (0.53)	$ (0.63)	$ (2.10)	$ (2.18)
Shares used in computing net loss per common share	60,664	59,762	60,384	58,702

(1) Revenue includes amounts from GSK, a related party, of $2,824 and $8,473 for the three and nine months ended September 30, 2007, respectively, and $3,381 and $9,741 for the three and nine months ended September 30, 2006, respectively.

See accompanying notes to condensed consolidated financial statements.

THERAVANCE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2007	**2006**
Cash flows used in operating activities		
Net loss	$ (126,939)	$ (128,207)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,525	2,695
Stock-based compensation	17,167	16,484
Forgiveness (net cancellation) of notes receivable	(6)	42
Other	(562)	476
Changes in operating assets and liabilities:		
Receivables, prepaid and other current assets	1,817	586
Accounts payable and accrued liabilities	(11,213)	1,740
Accrued personnel-related expenses	2,281	521
Deferred rent	(213)	34
Deferred revenue	40,628	30,342
Other long-term liabilities	6,011	1,290
Net cash used in operating activities	(68,504)	(73,997)
Cash flows provided by (used in) investing activities		
Purchases of property and equipment	(7,565)	(4,157)
Purchases of marketable securities	(78,732)	(181,545)
Maturities of marketable securities	100,945	105,924
Sales of marketable securities	53,888	45,377
Release of restricted cash	50	
Additions to notes receivable	(250)	(850)
Payments received on notes receivable	1,165	392
Net cash provided by (used in) investing activities	69,501	(34,859)
Cash flows provided by financing activities		
Payments on notes payable and capital leases	(65)	(766)
Net proceeds from issuances of common stock	5,540	145,565
Net cash provided by financing activities	5,475	144,799
Net increase in cash and cash equivalents	6,472	35,943
Cash and cash equivalents at beginning of period	72,388	49,787
Cash and cash equivalents at end of period	$ 78,860	$ 85,730
Supplemental disclosures of cash flow information		
Non-cash financing activity:		
Removal of deferred stock-based compensation	$	$ (4,965)

See accompanying notes to condensed consolidated financial statements.

Theravance, Inc.

Notes to Condensed Consolidated Financial Statements

September 30, 2007

(Unaudited)

1. Basis of Presentation and Significant Accounting Policies

Unaudited Interim Financial Statements

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 footnotes required by generally accepted accounting principles 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, 2007, the results of operations for the three and nine months ended September 30, 2007 and 2006 and the cash flows for the nine months ended September 30, 2007 and 2006. The results for the three and nine months ended September 30, 2007 are not necessarily indicative of the results of operations to be expected for the year ending December 31, 2007 or any other period.

The condensed consolidated balance sheet at December 31, 2006 has been derived from audited consolidated financial statements, which are contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2006 filed with the Securities and Exchange Commission (SEC) on March 1, 2007 (2006 10-K). The accompanying condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the 2006 10-K.

Use of Management s Estimates

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

Segment Reporting

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 $3.8 million of commercial launch supplies of the Company s product candidate telavancin which is currently awaiting regulatory approval. 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 anticipation of the regulatory approval and commercialization of telavancin. 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 required under the agreement.

If the regulatory approval of the Company s product candidate is significantly delayed or denied by the necessary regulatory bodies, or if new information becomes available that suggests that the inventory will not be realisable, the Company may be required to expense a portion or all of the capitalized inventory costs. The amount that may be expensed may be partially offset by reimbursement through alternative arrangements with Astellas under terms of the Company s collaboration agreement. During the three months ended September 30, 2007, the Company expensed approximately $0.9 million of its previously capitalized inventory as it was determined to not be realisable for commercial launch supplies. This inventory, however, may be used to support future clinical trial activity.

Bonus Accruals

The Company has short-and long-term bonus programs for certain eligible employees. 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 changes occur in those management estimates. During the nine months ended September 30, 2007, the Company recorded an increase in bonus expense and related accrual for non-officer employees of $8.5 million related to the achievement of the last clinical milestone under a long-term bonus plan established in 2004, which included the effect of a change in estimate of $7.1 million. As of September 30, 2007, the Company had fully accrued its bonus liability of approximately $12.4 million relating to its long-term bonus program, which ended in September 2007. The amounts accrued are scheduled to be paid to the employees in December of 2007, 2008 and 2009.

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 Statement No. 123(R), Share-based Payment (SFAS123(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 performance-contingent 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 (ESPP). The estimated fair value of stock options and restricted shares is expensed on a straight-line basis over the expected term of the grant and the fair value of 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 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 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 is 3.6%, based on its historical forfeiture experience.

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. EITF 07-3 is effective for the Company beginning in the first quarter of fiscal year 2008. The Company is currently evaluating the impact of the provisions of EITF 07-3 on its financial position, results of operations and cash flows and therefore, the impact of the adoption is unknown at this time.

In February 2007, the Financial Accounting Standards Board (FASB) issued Statement on Financial Accounting Standards No. 159, The Fair Value Option for Financial Assets and Financial Liabilities (SFAS 159). SFAS 159 permits companies to make a one-time election to carry eligible types of financial assets and liabilities at fair value, even if fair value measurement is not required under U.S. GAAP. SFAS 159 is effective for the Company beginning in the first quarter of fiscal year 2008. The Company is currently evaluating the impact of the provisions of SFAS 159 on its financial position, results of operations and cash flows and therefore, the impact of the adoption is unknown at this time.

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and

expands disclosures about fair value measurements. SFAS 157 is effective for the Company beginning in the first quarter of fiscal year 2008. The Company is currently evaluating the impact of the provisions of SFAS 157 on its financial position, results of operations and cash flows and therefore, the impact of the adoption is unknown at this time.

In July 2006, the FASB issued Financial Interpretation No. (FIN) 48, Accounting for Uncertainty in Income Taxes (FIN 48) as an interpretation of SFAS No. 109, Accounting for Income Taxes (SFAS 109). This Interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with SFAS 109 and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This Interpretation also provides guidance on derecognizing, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company adopted FIN 48 effective January 1, 2007.

Reclassification of Prior Year Amounts

Certain prior year amounts related to the classification of marketable securities in the condensed consolidated statement of cash flows and accrued interest related to notes receivable 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.

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, 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, less shares subject to repurchase, plus dilutive potential common shares and shares subject to repurchase. At September 30, 2007, potential common shares consist of approximately 11,450,000 shares issuable upon the exercise of stock options, approximately 2,000,000 shares issuable under performance-contingent restricted stock unit awards and 18,000 shares issuable upon the exercise of a warrant. (The outstanding warrant was not exercised as of its expiration date of October 5, 2007 and therefore no stock was or will be issued under the warrant.) At September 30, 2006, potential common shares consist of approximately 10,620,000 shares issuable upon the exercise of stock options and 18,000 shares issuable upon the exercise of a warrant. 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.

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except for per share amounts)	**2007**	**2006**	**2007**	**2006**
Basic and diluted:				
Net loss	$ (32,364)	$ (37,780)	$ (126,939)	$ (128,207)
Weighted average shares of common stock outstanding	60,724	59,927	60,468	58,883
Less: weighted average shares subject to repurchase	(60)	(165)	(84)	(181)
Weighted average shares used in computing basic and diluted net loss per common share	60,664	59,762	60,384	58,702
Basic and diluted net loss per common share	$ (0.53)	$ (0.63)	$ (2.10)	$ (2.18)

3. Collaboration and Licensing Agreements

2002 Beyond Advair Collaboration with GSK

In November 2002, the Company entered into its Beyond Advair collaboration agreement with GlaxoSmithKline plc (GSK) to develop and commercialize long-acting beta2 agonist (LABA) product candidates for the treatment of asthma and chronic obstructive pulmonary disease (COPD). Each company contributed four LABA product candidates to the collaboration.

As of September 30, 2007, the Company has received upfront and milestone payments from GSK of $60.0 million related to the clinical progress of its candidates, and could receive up to $445.0 million in remaining milestones allocated as follows: up to $75.0 million related to the achievement of certain clinical milestones by a Theravance-discovered LABA, up to $220.0 million related to approval and launch of a product containing a Theravance-discovered LABA in multiple regions in the world, and up to $150.0 million related to the achievement of certain sales

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thresholds by a Theravance-discovered LABA. 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 are likely to be made in the next three years. In addition, the Company is entitled to receive the same royalties on product sales of medicines from the Beyond Advair 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. Sales of single-agent LABA medicines and combination LABA/ICS medicines would be combined for the purposes of this royalty calculation.

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 (the product development period). Collaboration revenue was $1.7 million and $2.2 million for the three months ended September 30, 2007 and 2006, respectively, and $5.1 million and $6.2 million for the nine months ended September 30, 2007 and 2006, respectively. Subsequent development milestones will be recorded as deferred revenue when received and amortized over the remaining period of performance during the development period. 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, 2007 and 2006, 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. In addition, in May 2004, an affiliate of GSK purchased approximately 6.4 million shares of the Company s Class A common stock for $108.9 million. Pursuant to a partial exercise of its rights under the agreement, upon the closing of the Company s initial public offering in October 2004, GSK purchased an additional 433,757 shares of Class A common stock for $6.9 million.

The alliance provides GSK with an option to license product candidates from the Company s full drug discovery programs initiated prior to September 1, 2007 on pre-determined terms and on an exclusive, worldwide basis. Upon licensing a program, GSK is responsible for funding all future development, manufacturing and commercialization activities for product candidates in that program. Consistent with the Company s strategy, the Company 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. The royalty structure for a product containing one of the Company s compounds as a single active ingredient in the programs licensed to date by GSK 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 the Company receives, the total upfront and milestone payments that the Company 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. To date, GSK has licensed the Company s two COPD programs: LAMA and MABA.

In August 2004, GSK exercised its right to license the Company s long-acting muscarinic antagonist program (LAMA) pursuant to the terms of the strategic alliance. The Company received a $5.0 million payment from GSK in connection with the licensing of this program. Through September 30, 2007, 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 and $0.3 million for the three months ended September 30, 2007 and 2006, respectively, and $0.6 million and $0.9 million for the nine months ended September 30, 2007 and 2006, respectively, in revenue related to the LAMA program. Additionally, the Company is 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, 2007 and 2006, reimbursable costs were not material.

In March 2005, GSK exercised its right to license the Company s 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, 2007, the Company received a milestone payment of $3.0 million from GSK related to clinical progress of its candidate. This payment is being amortized

ratably over the estimated period of performance (the product development period). Collaboration revenue related to the MABA program was $0.3 million for each of the three months ended September 30, 2007 and 2006, respectively, and $0.8 million and $0.7 million for the nine months ended September 30, 2007 and 2006, 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, 2007 and 2006 were not material.

In September 2007, the Company announced that it retained full ownership rights of its GI Motility Dysfunction program as a result of GSK s decision not to exercise its right to license the program under the strategic alliance. The Company is currently reviewing plans for the future development of this program.

Under the alliance, GSK had the right between June 1 and July 1, 2007, to elect to acquire (call) half of Theravance s outstanding shares of common stock at $54.25 per share. On June 29, 2007, GSK elected not to exercise the call, which triggered the right of the Company s stockholders to require the Company to redeem (put) up to 50% of their common stock at $19.375 per share between August 1 and September 12, 2007 with funds provided by GSK. One stockholder exercised his put right for one share of common stock. In exchange for GSK providing the funds to pay the redemption price for the one share of common stock, and pursuant to the Company s certificate of incorporation, the Company issued to GSK one share of its Class A common stock. The common share that the Company redeemed pursuant to the stockholder s exercise of the put right was retired and cancelled.

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, the Company and Astellas agreed to add Japan to their telavancin collaboration, thereby giving Astellas worldwide rights to this potential medicine. Through September 30, 2007, the Company had received $158.0 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 $2.8 million and $1.9 million in revenue for the three months ended September 30, 2007 and 2006, respectively, and $7.5 million and $4.6 million for the nine months ended September 30, 2007 and 2006, respectively. As of September 30, 2007, the Company was eligible to receive up to $70.0 million in remaining clinical and regulatory milestone payments, which includes up to $60.0 million related to regulatory filings and approvals in various regions of the world and $10.0 million if the FDA determines telavancin s superiority over vancomycin for hospital-acquired pneumonia (HAP) patients infected with methicillin-resistant *Staphylococcus aureus* (MRSA).

In August 2007, the Company received a $25.0 million milestone payment from Astellas after the last clinical visit (test of cure) by the last patient in the HAP Phase 3 program.

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

In addition to the license rights to telavancin, Astellas had an option to license TD-1792, the Company s investigational antibiotic, for further development and commercialization on substantially the same terms under which Astellas licensed telavancin. In September 2007, the Company announced that it retained full ownership rights of TD-1792 as a result of Astellas decision not to exercise its right to license the compound. The Company is currently reviewing plans for the future development of TD-1792.

2006 License Agreement with AstraZeneca AB

In May 2006, the Company entered into a license agreement with AstraZeneca AB (AstraZeneca) pursuant to which it granted an exclusive, worldwide license to AstraZeneca to develop and commercialize the Company s intravenous anesthetic compound TD-4756 for which the Company received a $1.0 million upfront payment. In addition, the Company is eligible to receive milestone payments and royalties on global sales. Through September 30, 2007, the Company had fully recognized the upfront payment as revenue ($0.4 million and $0.6 million in 2007 and 2006, respectively), due to the completion of its performance obligations under the contract.

4. Marketable Securities

The Company invests in a variety of highly liquid investment-grade securities. The following is a summary of the Company s available-for-sale securities at September 30, 2007:

	September 30, 2007			
(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. government agencies	$ 32,197	$ 48	$	$ 32,245
U.S. corporate notes	28,489	19	(6)	28,502
U.S. commercial paper	67,456			67,456
Asset-backed securities	26,894	29	(9)	26,914
Certificates of deposit	60			60
Money market funds	15,154			15,154
Total	170,250	96	(15)	170,331
Less amounts classified as cash and cash equivalents	(78,860)			(78,860)
Less amounts classified as restricted cash	(3,810)			(3,810)
Amounts classified as marketable securities	$ 87,580	$ 96	$ (15)	$ 87,661

The estimated fair value amounts have been determined by the Company using available market information. At September 30, 2007, approximately 63% of marketable securities have contractual maturities within twelve months, 13% of marketable securities have contractual maturities between twelve and twenty-four months and the remaining 24% have contractual maturities beyond twenty-four months. Average duration of available-for-sale securities was approximately 6 months at September 30, 2007. The Company has determined that the gross unrealized losses on its marketable securities at September 30, 2007 were temporary in nature.

5. Comprehensive Loss

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2007	2006	2007	2006
Net loss	$ (32,364)	$ (37,780)	$ (126,939)	$ (128,207)
Other comprehensive income:				
Net unrealized gain on available-for-sale securities	47	455	55	466
Comprehensive loss	$ (32,317)	$ (37,325)	$ (126,884)	$ (127,741)

6. 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, 2007.

Purchase Obligations

At September 30, 2007, the Company had outstanding purchase obligations, primarily for services from contract research and manufacturing organizations, totaling $3.5 million.

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7. Stockholders Equity

Determining Fair Value of Stock-Based Compensation

Under SFAS 123(R), the Company elected to continue to use the Black-Scholes valuation model for share-based payment awards granted. The Company s determination of the fair value of share-based payment awards on the grant date using option valuation models requires the input of highly subjective assumptions, including the expected price volatility and option life. As the Company has been operating as a public company for a period of time that is shorter than its estimated expected option life, the Company is unable to use actual price volatility or option life data as input assumptions within its Black-Scholes valuation model. As a result, the Company is required to use the simplified method as described in Staff Accounting Bulletin No.107 relating to SFAS 123(R) for expected option life and peer company price volatility. Both of these assumptions have resulted in Black-Scholes inputs that are higher than actual results to date. The result of this is an increase in the value of estimated stock-based compensation reflected in the Company s condensed consolidated statements of operations.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Employee stock options				
Risk-free interest rate	4.20-4.74%	4.67-4.98%	4.20-5.03%	4.57-5.16%
Expected life (in years)	5.52-6.08	6.08-6.10	5.29-6.08	5.55-6.17
Volatility	0.46-0.48	0.51	0.46-0.48	0.51
Dividend yield	%	%	%	%
Weighted average fair value of stock options granted	$ 14.98	$ 13.39	$ 16.85	$ 15.61
Employee stock purchase plan issuances				
Risk-free interest rate	4.95-4.98%	4.97-5.00%	4.95-4.98%	2.58-5.00%
Expected life (in years)	0.50-2.00	0.50-2.00	0.50-2.00	0.50-2.11
Volatility	0.26-0.30	0.30-0.38	0.26-0.30	0.30-0.70
Dividend yield	%	%	%	%
Weighted average fair value of ESPP issuances	$ 9.96	$ 8.07	$ 9.96	$ 9.01

As of September 30, 2007, there was $45.2 million of total unrecognized compensation cost related to unvested stock options. This cost is expected to be recognized over a weighted-average period of approximately 2.85 years. 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.

Stock-based compensation expense consists of the compensation cost for employee share-based awards, including restricted stock, and the value of options 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 September 30,		Nine Months Ended September 30,	
(in thousands)	**2007**	**2006**	**2007**	**2006**
Research and development	$ 3,514	$		