THERAVANCE INC Form 10-Q November 06, 2006

# 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, 2006

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** 

(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 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 November 1, 2006 was 50,636,432.

The number of shares of registrant s Class A common stock outstanding on November 1, 2006 was 9,401,498.

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#### PART I FINANCIAL INFORMATION

#### **ITEM 1. Financial Statements**

#### THERAVANCE, INC.

#### CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

	2006	ember 30, audited)		Dece 2005 *	mber 31,
Assets					
Current assets:					
Cash and cash equivalents	\$	85,730		\$	49,787
Marketable securities	137,5	525		112,1	38
Receivable from related party	272			990	
Prepaid and other current assets	3,858	3		3,903	3
Total current assets	227,3	385		166,8	318
Marketable securities	43,80	00		38,08	34
Restricted cash and cash equivalents	3,860			3,860	
Property and equipment, net	14,28			13,18	
Deferred sublease costs	1 1,20	, -		297	,,,
Notes receivable	2,924	L		2,496	í
Other assets	100			100	,
Total assets	\$	292,350		\$	224,835
Liabilities and stockholders equity					
Current liabilities:					
Accounts payable	\$	8,075		\$	8,118
Accrued personnel-related expenses	6,562	,		6.041	
Accrued clinical and development expenses	15.59			13,77	
Other accrued liabilities	2,000			1,997	
Current portion of notes payable	75	,		75	
Current portion of capital lease obligations	464			1,169	)
Current portion of deferred revenue	22,03	12		16,99	
Total current liabilities	54,80			48,17	
Total Current matrimes	34,60	<i>)</i> 1		40,17	3
Deferred rent	2,572	2		2,538	3
Notes payable	570			631	
Deferred revenue	136,5	555		111,2	251
Other long term liabilities	3,818	3		2,658	3
Commitments and contingencies					
Stockholders equity:					
Preferred stock, \$0.01 par value; 230 shares authorized, no shares issued and outstanding					
Common stock, \$0.01 par value; 200,000 shares authorized; 50,565 and 44,475 shares issued and outstanding at					
September 30, 2006 and December 31, 2005, respectively	505			444	
Class A Common Stock, \$0.01 par value; 30,000 shares authorized, 9,402 issued and outstanding at September					
30, 2006 and December 31, 2005, respectively	94			94	
Additional paid-in capital	833,4	152		676,2	299
Notes receivable from stockholders	(5		)	(17	
Deferred stock-based compensation	·			(4,96	5
Accumulated other comprehensive loss	(37		)	(503	
	(=00	075	)	(611,	768
Accumulated deficit	(739,	913	,	(011,	/00
Accumulated deficit Total stockholders equity	94,03		,	59,58	

 $<sup>*</sup> Condensed\ consolidated\ balance\ sheet\ at\ December\ 31,\ 2005\ has\ been\ derived\ from\ audited\ financial\ statements.$ 

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, 2006 2005		Nine Months Ende September 30, 2006	d 2005
Revenue (1)	\$ 5,524	\$ 3,006	\$ 14,657	\$ 8,676
Operating expenses:				
Research and development (2)	39,103	37,034	128,562	96,120
General and administrative (2)	7,868	5,349	24,041	18,200
Total operating expenses	46,971	42,383	152,603	114,320
Loss from operations	(41,447)	(39,377	) (137,946 )	(105,644)
Interest and other income	3,875	1,716	10,234	5,153
Interest and other expense	(208)	(125	) (495 )	(462)
Net loss	\$ (37,780)	\$ (37,786)	) \$ (128,207)	\$ (100,953)
Basic and diluted net loss per common share	\$ (0.63)	\$ (0.71	) \$ (2.18 )	\$ (1.90 )
Shares used in computing net loss per common share	59,762	53,416	58,702	53,155

<sup>(1)</sup> Amounts include revenue from GSK, a related party, of \$3,381 and \$9,741 for the three and nine months ended September 30, 2006, respectively, and \$3,006 and \$8,676 for the three and nine months ended September 30, 2005, respectively.

<sup>(2)</sup> Amounts include stock-based compensation, consisting of stock-based compensation expense under SFAS 123(R), the amortization of deferred stock-based compensation and the value of options issued to non-employees for services rendered, allocated as follows:

	Three Months September 30,		Nine Months I September 30	
	2006	2005	2006	2005
Research and development	\$ 3,042	\$ 785	\$ 9,378	\$ 2,466
General and administrative	1,674	307	7,106	1,468
Total stock-based compensation	\$ 4,716	\$ 1,092	\$ 16,484	\$ 3,934

See accompanying notes to condensed consolidated financial statements.

## THERAVANCE, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(Unaudited)

	Nine Months Ended September 30, 2006 2005				*	
Cash flows used in operating activities						
Net loss	\$	(128,207	)	\$	(100,953	)
Adjustments to reconcile net loss to net cash used in operating activities:						
Depreciation and amortization	3,08	8		3,09	2	
Stock-based compensation	16,4	84		3,93		
Forgiveness of notes receivable	42			145		
Other non-cash operating expenses	476			312		
Changes in operating assets and liabilities:						
Receivables, prepaid and other current assets	586			2,59	)3	
Accounts payable and accrued liabilities	1,74	0		5,59	94	
Accrued personnel-related expenses	521			213		
Deferred rent	34			169		
Deferred revenue	30,3	42		(676	5	)
Other long-term liabilities	1,29	0				
Net cash used in operating activities	(73,6	504	)	(85,	577	)
Cash flows (used in) provided by investing activities						
Purchases of property and equipment	(4,15		)	) (2,639		)
Purchases of marketable securities	(181	,545	) (103,783		3,783	)
Sales and maturities of marketable securities	150,	908	109,602			
Restricted cash and cash equivalents				677		
Additions to notes receivable	(850		) (160			)
Payments received on notes receivable	392			507		
Net cash (used in) provided by investing activities	(35,2	252	)	4,20	)4	
Cash flows provided by financing activities				/		
Payments on notes payable and capital leases	(766		)	(2,2		)
Net proceeds from issuances of common stock	145,			4,54		
Net cash provided by financing activities	144,			2,32		
Net increase (decrease) in cash and cash equivalents	35,9			(79,		)
Cash and cash equivalents at beginning of period		49,787			,411	
Cash and cash equivalents at end of period	\$ 85,730			\$	22,359	
Supplemental Disclosures of Cash Flow Information						
Cash paid for interest	\$	133		\$	258	
Non-cash investing and financing activities:	Ψ	133		Ψ	230	
Addition to (removal of) deferred stock-based compensation	\$	(4,965	)	\$	896	
Addition to (temoval of) deterred stock-based compensation	Ф	(4,903	)	Φ	090	

See accompanying notes to condensed consolidated financial statements.

Theravance, Inc. Notes to Condensed Consolidated Financial Statements

# 1. Basis of Presentation and Employee Stock-Based Compensation

Unaudited Interim Financial Information

The accompanying unaudited 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 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, 2006, and the results of operations and cash flows for the three and nine months ended September 30, 2006 are not necessarily indicative of the results of operations to be expected for the year ending December 31, 2006 or any other period.

The condensed consolidated balance sheet at December 31, 2005 has been derived from audited consolidated financial statements, which are contained in the Company s Annual Report on Form 10-K/A for the year ended December 31, 2005 filed with the Securities and Exchange Commission (SEC) on March 10, 2006 (2005 10-K). The accompanying condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the 2005 10-K.

Use of Management s Estimates

The preparation of 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 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 additional charges or benefits in operations.

Segment Reporting

The Company has determined that it operates in only one segment, which is the research and development of human therapeutics. In addition, all revenues are generated from United States entities, and all long-lived assets are maintained in the United States.

#### Reclassifications

Certain prior year expenses, relating to the amortization of deferred compensation and stock-based compensation expense related to the value of options issued to non-employees for services rendered have been reclassified from stock-based compensation expense to research and development and general and administrative expenses for consistency with the current year presentation. These reclassifications had no impact on previously reported total operating expenses or net loss.

Fair value of employee stock options

On January 1, 2006, the Company adopted the fair value recognition provisions of Financial Accounting Standards Board (FASB), Statement No. 123(R), Share-based Payment (SFAS123(R)), which requires the measurement and recognition of compensation expenses for all share-based payments made to employees and directors including stock options and employee stock purchases under the Company s 2004 Employee Stock Purchase Plan (employee stock purchases) based on estimated fair values. SFAS 123(R) supersedes the Company s previous accounting for employee stock options using the intrinsic-value method in accordance with Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees (APB No. 25), Financial Accounting Standards Board Interpretation (FIN) No. 44, Accounting for Certain Transactions Involving Stock Compensation, an interpretation of APB No. 25, and related interpretations and the disclosure-only provisions of SFAS No. 123, Accounting for Stock-Based Compensation (SFAS 123). In March 2005, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin No. 107 (SAB 107) relating to SFAS 123(R). The Company has applied the provisions of SAB 107 in its adoption of SFAS 123(R).

The Company adopted SFAS 123(R) using the modified-prospective transition method. Under this method,

compensation costs recognized during the three and nine months ended September 30, 2006 include: a) compensation costs for all share-based payment awards granted prior to, but not yet vested as of January 1, 2006, based on grant-date fair value estimated in accordance with the original provisions of SFAS 123; and b) compensation costs for all share-based payment awards granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R).

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 of the vesting periods 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 recognized in the Condensed Consolidated Statement of Operations for the three and nine months ended September 30, 2006 has been reduced for estimated forfeitures so that compensation expense is based on awards 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. In the Company s pro forma information required under SFAS 123 for the periods prior to 2006, the Company accounted for forfeitures as they occurred. In addition, under SFAS 123 (R), the Company elected to continue to use the Black-Scholes valuation model for share-based payment awards granted. For additional information, see Note 7. 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. Instead the Company is required to use the simplified method as described in SAB 107 relating to SFAS 123(R) for expected term and peer company price volatility, both of which have been 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.

In accordance with the modified-prospective transition method, the Company s Condensed Consolidated Financial Statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R). Total stock-based compensation expense recognized under SFAS 123(R) for the three months ended September 30, 2006 was \$4.7 million which consisted of \$4.4 million related to employee stock options and employee stock purchases, \$0.3 million related to the value of options issued to non-employees for services rendered and \$74,000 related to the value of shares of restricted stock. Total stock-based compensation expense recognized under SFAS 123(R) for the nine months ended September 30, 2006 was \$16.5 million which consisted of \$14.9 million related to employee stock options and employee stock purchases, \$1.4 million related to the value of options issued to non-employees for services rendered and \$0.2 million related to the value of shares of restricted stock. In addition, as of September 30, 2006, there was \$33.1 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 2.46 years. As a result of adopting FAS 123(R) on January 1, 2006, the Company s net loss for the three and nine months ended September 30, 2006 was \$3.8 million and \$13.3 million higher, respectively, than if the Company had continued to account for share-based compensation under APB No. 25 as it did in the comparable prior year periods. Accordingly, basic and diluted net loss per share for the three and nine months ended September 30, 2006 was \$0.06 and \$0.22 higher, respectively, than if the Company had continued to account for share-based compensation under APB No. 25. 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.

For the three and nine months ended September 30, 2005, stock-based compensation expense was \$1.1 million and \$3.9 million, respectively, consisting of amortization of deferred stock-based compensation, the value of options issued to non-employees for services rendered, and the amortization of deferred stock-based compensation expense related to the grant of restricted stock.

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	Nine M	Ionths Ended
	September 30, 2006	Septem 2005 2006	nber 30, 2005
Employee stock options			
Risk-free interest rate	4.67% 4.98 %	3.91% 4.08 % 4.57%	5.16 % 3.54% 4.08 %
Expected life (in years)	6.08 6.10	4 5.55 6	5.17 3 4
Volatility	0.51	0.7 0.51	0.7
Weighted average estimated fair value of stock options			
granted	\$ 13.39	\$ 8.90 \$ 1	15.61 \$ 8.73
Employee stock purchase plan issuances			
Risk-free interest rate	4.97%-5.00 %	2.58% 3.64 % 2.58%	5.00 % 2.58% 3.64 %
Expected life (in years)	0.5-2	2 0.50-2	.11 2
Volatility	0.30-0.38	0.7 0.30 (	0.70
Weighted average estimated fair value of ESPP issuances	\$ 8.07	\$ 8.81 \$ 9	9.01 \$ 8.81

Pro forma Information under SFAS 123 for Periods Prior to Fiscal 2006

The following table shows the pro forma effect on net loss and net loss per common share if the fair value recognition provisions of SFAS 123 had been applied to stock-based employee compensation (in thousands, except per share amounts) for the three and nine months ended September 30, 2005. For purposes of pro forma disclosures, pursuant to SFAS No. 123 as amended by SFAS No. 148, the Company amortized the estimated fair value of stock-based employee compensation to expense over the vesting period of the options using the accelerated expense attribution method:

	Three M Septemb			nths Ended er 30, 2005		
Net loss, as reported	\$	(37,786	)	\$	(100,953	)
Add: Employee stock-based compensation calculated using the intrinsic						
value method	776			3,315		
Less: Total employee stock compensation calculated using the fair value						
method	(3,386		)	(12,555		)
Pro forma net loss	\$	(40,396	)	\$	(110,193	)
Net loss per common share, as reported	\$	(0.71	)	\$	(1.90	)
Net loss common per share, pro forma	\$	(0.76	)	\$	(2.07	)

The foregoing pro forma information regarding net loss and net loss per common share has been determined as if the Company had accounted for its employee stock options and employee stock purchase plan issuances under the fair value method using the Black-Scholes valuation method. As the Company s common stock had only recently become publicly traded when these estimates were made, certain assumptions regarding stock price volatility and expected life were estimated by considering volatility and expected life assumptions used by similar entities within the Company s industry. In particular, prior to 2006, the volatility estimate of 70% is significantly higher than the Company s actual stock price volatility, which is approximately 30% since the Company s October 2004 initial public offering.

The Company does not currently pay dividends. On May 27, 2004, the Company s Board of Directors adopted the 2004 Employee Stock Purchase Plan (ESPP) that became effective on October 5, 2004, the date of the Company s initial public offering.

#### 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, plus dilutive potential common shares. At September 30, 2006, potential common shares consist of 158,000 shares subject to repurchase (including 50,000 shares of restricted stock), 10,402,000 shares issuable upon the exercise of stock options and 18,000 shares issuable upon the exercise of warrants. At September 30, 2005, potential common shares consist of 221,000 shares subject to repurchase (including 50,000 shares of restricted stock), 10,019,000 shares issuable upon the exercise of stock options and 18,000 shares issuable upon the exercise of warrants. Diluted EPS is identical to Basic EPS since potential common shares are excluded from the calculation, as their effect is anti-dilutive.

(in thousands, except for per share amounts)		ree Months tember 30,		ded 200	5		Nine Months September 30 2006		d 200	5	
Basic and diluted:		·			_		2000		_00	_	
Net loss	\$	(37,780	)	\$	(37,786	)	\$ (128,20	07)	\$	(100,95	3)
Weighted average shares of common stock outstanding	59,	927		53,	649		58,883		53,	404	
Less: weighted average shares subject to repurchase	(16	5	)	(23	3	)	(181	)	(24	9	)
Weighted average shares used in computing basic and diluted net loss											
per common share	59,	762		53,	416		58,702		53,	155	
Basic and diluted net loss per common share	\$	(0.63	)	\$	(0.71	)	\$ (2.18	)	\$	(1.90	)

#### 3. Collaboration and Licensing Agreements

2005 License, Development and Commercialization Agreement with Astellas

In November 2005, the Company entered into a collaboration arrangement with Astellas Pharma Inc. (Astellas) for the development and commercialization of telavancin worldwide, except Japan. The Company has received \$101.0 million from Astellas through September 30, 2006, and the Company is eligible to receive up to an additional \$131.0 million in clinical and regulatory milestone payments. The Company recorded these cash payments of \$101.0 million as deferred revenue, which are being amortized ratably over the estimated period of performance (the estimated development and commercialization period). The Company currently estimates the period of performance to be thirteen years from the effective date.

In July 2006, the Company and Astellas agreed to add Japan to their collaboration for the development and commercialization of the Company s investigational antibiotic, telavancin, thereby giving Astellas worldwide rights to this potential medicine. For these rights to telavancin in Japan, the Company received an upfront payment of \$10.0 million which has been recorded as deferred revenue, and is being amortized ratably over the estimated period of performance (the estimated development and commercialization period). The Company currently estimates the period of performance to be thirteen years from the effective date. The Company is eligible to receive a \$5.0 million milestone payment for regulatory approval in Japan, in addition to \$131.0 million in remaining clinical and regulatory milestone payments related to non-Japanese milestone events.

The Company recognized \$1.9 million and \$4.6 million in revenue for the three and nine months ended September 30, 2006, respectively.

2002 Beyond Advair Collaboration

In November 2002, the Company entered into a collaboration agreement with an affiliate of 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), which the Company and GSK refer to as the Beyond Advair Collaboration. Through September 30, 2006, the Company has received upfront and milestone payments of \$60.0 million from GSK in connection with this collaboration.

The Company recorded these upfront and milestone payments as deferred revenue, which are being amortized ratably over the Company s estimated period of performance (the product development period), which is currently estimated

to be eight years from the collaboration s inception. Collaboration revenue was \$2.2 million and \$6.2 million for the three and nine months ended September 30, 2006, respectively, and \$1.9 million and \$5.7 million for the three and nine months ended September 30, 2005, 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 the three and nine months ended September 30, 2006, there were no costs related to the collaboration that were reimbursable by GSK; and for the three and nine months ended September 30, 2005, these costs were not material.

#### 2004 Strategic Alliance

In March 2004, the Company entered into a strategic alliance with GSK for the development and commercialization of product candidates in a variety of therapeutic areas. In connection with the strategic alliance agreement, the Company received a \$20.0 million payment in May 2004. This payment is being amortized over the period during which GSK may exercise its right to license certain of the Company s programs under the agreement, which is currently estimated to be approximately seven and one-half years from the commencement for the strategic alliance. The Company recognized \$0.7 million in revenue for each of the three months ended September 30, 2006 and 2005 and \$2.1 million in revenue for each of the nine months ended September 30, 2006 and 2005.

In August 2004, GSK exercised its right to license the Company s long-acting muscarinic antagonist program (LAMA) for the treatment of COPD pursuant to the terms of the strategic alliance. The Company received a \$5.0 million payment from GSK in connection with its licensing of this program. This payment is being amortized ratably over the estimated period of performance (the product development period), which is currently estimated to be approximately seven and one-half years from the date GSK acquired the license. In June 2005, the Company earned a \$3.0 million milestone payment, received in July 2005, from GSK in connection with initiation of a Phase 1 trial under the LAMA program. This milestone was recorded as deferred revenue when earned and will be amortized over the remaining period of performance during the development period. The Company recognized \$0.3 million and \$0.3 million in revenue related to the LAMA program for the three months ended September 30, 2006 and 2005, respectively, and \$0.9 million and \$0.7 million in revenue for the nine months ended September 30, 2006 and 2005, respectively. 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, 2006 there were no reimbursable costs. The Company accrued reimbursements of \$0.1 million and \$0.5 million for the three and nine months ended September 30, 2005.

In March 2005, GSK exercised its right to license the Company s muscarinic antagonist / beta2 agonist (MABA) program for the treatment of COPD, and possibly asthma, 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. In March 2006, the Company earned a \$3.0 million milestone payment, received in April 2006, from GSK in connection with initiation of a Phase 1 trial under the MABA program. These payments are being amortized ratably over the estimated period of performance (the product development period), which is currently estimated to be approximately eight years from the date GSK acquired the license. The Company recognized \$0.3 million and \$0.7 million in revenue related to the MABA program for the three and nine months ended September 30, 2006, respectively, compared to \$0.2 million and \$0.3 million recognized for the three and nine months ended September 30, 2005, respectively. As an offset to research and development expense, certain costs related to the MABA program are reimbursable by GSK. Reimbursements for the three and nine months ended September 30, 2006 were not material. The Company accrued reimbursements of \$0.1 million and \$2.5 million for the three and nine months ended September 30, 2005, respectively.

2006 License Agreement with AstraZeneca AB

In May 2006, the Company and AstraZeneca AB (AstraZeneca) entered into a license agreement pursuant to which the Company granted an exclusive, worldwide license to AstraZeneca to develop and commercialize its intravenous anesthetic compound TD-4756. The Company received a \$1.0 million upfront payment from AstraZeneca and is eligible to receive milestone payments and royalties on global sales. This payment is being amortized ratably over the estimated period of performance which is currently estimated to be approximately one year. The Company recognized \$0.2 million and \$0.3 million in license revenue for the three and nine months ended September 30, 2006, respectively.

#### 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, 2006:

	September 30, 2006				
(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	
U.S. government agencies	\$ 63,109	\$ 61	\$ (130 )	\$ 63,040	
U.S. corporate notes	62,500	13	(16)	62,497	
U.S. commercial paper	77,601			77,601	
Asset-backed securities	52,326	66	(32)	52,360	
Certificates of deposit	7,435	1		7,436	
Money market funds	7,981			7,981	
Total	270,952	141	(178)	270,915	
Less amounts classified as cash and cash equivalents	(85,730 )			(85,730)	
Less amounts classified as restricted cash	(3,860)			(3,860)	
Amounts classified as marketable securities	\$ 181,362	\$ 141	\$ (178 )	\$ 181,325	

The estimated fair value amounts have been determined by the Company using available market information. At September 30, 2006, approximately 76% of marketable securities mature within twelve months, 6% of marketable securities mature between twelve and twenty-four months and the remaining 18% have effective maturities beyond twenty-four months. Average duration of available-for-sale securities was approximately 7 months at September 30, 2006. The Company has determined that the gross unrealized losses on its marketable securities at September 30, 2006 were temporary in nature.

#### 5. Comprehensive Loss

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

(in thousands)	Three Months E September 30, 2006	Ended 2005	Nine Months Ende September 30, 2006	d 2005
Net loss	\$ (37,780)	\$ (37,786)	\$ (128,207)	\$ (100,953)
Other comprehensive income (loss):				
Net unrealized gain (loss) on available-for-sale securities	455	(122)	466	53
Comprehensive loss	\$ (37,325)	\$ (37,908)	\$ (127,741)	\$ (100,900)

#### 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, 2006.

Purchase Obligations

At September 30, 2006, the Company had outstanding purchase obligations, primarily for services from contract research and manufacturing organizations, totaling \$5.4 million.

# 7. Stockholders Equity

Stock Option Plans

The Company issues stock options under the 2004 Equity Incentive Plan, which was adopted on May 27, 2004 by the Company s Board of Directors and became effective as of the date of the Company s initial public offering on October 5, 2004. The aggregate number of shares that may be awarded under the 2004 Equity Incentive Plan was 3,700,000 shares which were reserved for issuance under the 2004 Equity Incentive Plan plus 9,334,745 shares remaining available for issuance under the 1997 Stock Option Plan and the Long-Term Stock Option Plan as of the date the 2004 Equity Incentive Plan became effective. No further option grants will be made under the 1997 Stock Plan and the Long-Term Stock Option Plan. The 2004 Equity Incentive Plan provides for the granting of incentive and nonstatutory stock options to employees, officers, directors and consultants of the Company. Incentive stock options and nonstatutory 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 to six years. For the three months ended March 31, June 30 and September 30, 2006, the Company granted stock options to purchase 1,069,278, 369,021 and 83,700 shares at average stock prices of \$29.62, \$26.74 and \$24.39, respectively, under the 2004 Equity Incentive Plan. As of September 30, 2006, total shares remaining available for issuance under the 2004 Equity Incentive Plan were 1,167,910.

The Company previously allowed certain stock option holders to exercise their options by executing stock purchase agreements and full-recourse notes payable to the Company. The stock purchase agreements provide the Company with the right to repurchase unvested shares. Certain full-recourse notes payable include forgiveness provisions whereby the Company forgives the unpaid principal of the note on its maturity date if the optionee remains in continuous service until the maturity date on the notes (see Notes Receivable discussion in Note 8). As of September 30, 2006, 87,095 shares were subject to repurchase under these outstanding note agreements.

Options granted and employee stock purchases prior to January 1, 2006 are valued in accordance with SFAS 123. The Company used the Black-Scholes option valuation model and the accelerated method for expense attribution over the vesting periods. The volatility and expected life used to estimate the fair value of the options was based on considering the volatility and expected life assumptions used by similar entities within the Company s industry. The Company recognized option forfeitures as they occurred as allowed by SFAS 123.

Options granted and employee stock purchases after January 1, 2006 are valued in accordance with SFAS 123(R). The Company uses the Black-Scholes option valuation model and the straight-line method single-option method for expense attribution. The expected term of the options granted is derived from the simplified method as described in SAB 107 relating to SFAS 123(R). The expected volatility used is based on historical volatilities of similar entities within the Company s industry which were commensurate with the Company s expected term assumption and also on the Company s historical volatility for certain expected term periods, where applicable, when valuing employee stock purchases. The Company estimated forfeitures and only recognized expense for those shares expected to vest. During the three months ended September 30, 2006, the Company increased its estimated annual forfeiture rate from 2.4% to 3.6%, based on its historical forfeiture experience.

As a result of adopting FAS 123(R) on January 1, 2006, the Company s net loss for the three and nine months ended September 30, 2006 was \$3.8 million and \$13.3 million higher, respectively, than if the Company had continued to account for share-based compensation under APB No. 25 as it did in the comparable prior year periods. Accordingly, basic and diluted net loss per share for the three and nine months ended September 30, 2006 was \$0.06 and \$0.22 higher, respectively, than if the Company had continued to account for share-based compensation under APB No. 25. The Company has not recognized, and does not expect to recognize in the near future, any tax benefit related to employee stock-based compensation cost as a result of the full valuation allowance on its net deferred tax assets and net operating loss carryforwards.

For the three and nine months ended September 30, 2006, under SFAS 123(R), in connection with the grant of certain stock options to employees under the 2004 Equity Incentive Plan, 1997 Stock Option Plan, and the Long-Term Stock Option Plan, the Company recorded stock-based compensation expense of \$4.1 million and \$13.7 million, respectively.

There are options to purchase shares of the Company's common stock held by consultants with exercise prices ranging from \$0.78 to \$9.69 per share. As of September 30, 2006, options to acquire 154,379 shares are subject to remeasurement of fair value using a Black-Scholes model over their remaining contractual terms. The following assumptions were used for the nine months ended September 30, 2006: a volatility factor ranging from 0.32 to 0.51, risk-free interest rates ranging from 4.7% to 5.1%, no dividend yield, and a life of the option equal to the full term, generally up to ten years from the date of grant. In accordance with SFAS 123, the Company recognized expense of \$0.3 million and \$1.4 million for the three and nine months ended September 30, 2006, respectively.

The following table summarizes option activity under the Company s stock option plans, and related information:

	Number Of Shares Of Shares Subject to Available Outstanding for Grant Options (In thousands, except per share and			unts)	Weigh Avera Exerci Per Sh	ge se Price
Balance at December 31, 2005	2,269		10,096		\$	9.82
Options granted	(1,069	)	1,069		\$	29.62
Options exercised			(355	)	\$	5.74
Options forfeited	171		(171	)	\$	13.15
Balance at March 31, 2006	1,371		10,639		\$	11.89
Options granted	(369	)	369		\$	26.74
Options exercised			(275	)	\$	5.26
Options forfeited	113		(113	)	\$	19.06
Shares repurchased	5				\$	3.10
Balance at June 30, 2006	1,120		10,620		\$	12.50
Options granted	(84	)	84		\$	24.39
Options exercised			(170	)	\$	6.06
Options forfeited	132		(132	)	\$	15.47
Shares repurchased					\$	
Balance at September 30, 2006	1,168		10,402		\$	12.66

No options were granted with exercise prices less than fair value of common stock on the date of grant during the nine months ended September 30, 2006 or the year ended December 31, 2005.

The weighted-average fair value of options granted with exercise prices equal to the fair value of common stock on the date of grant for the three and nine months ended September 30, 2006 was \$13.39 and \$15.61, respectively.

As of September 30, 2006, there was \$33.1 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 2.46 years. The total intrinsic value of the options exercised for the three months ended September 30, 2006 was \$2.8 million and the fair value of options vested is \$0.7 million for the three months ended September 30, 2006. The total intrinsic value of the options exercised for the nine months ended September 30, 2006 was \$15.4 million and the fair value of options vested is \$4.3 million for the nine months ended September 30, 2006.

As of September 30, 2006, all outstanding options to purchase common stock of the Company are summarized in the following table (in thousands, except years and per share amounts):

	<b>Options Outs</b>				<b>Options Exerc</b>	Options Exercisable			
Exercise Price Per Share	Number of Shares Subject to Outstanding Options	Weighted- Average Remaining Contractual Life	Number of Shares Subject to Options Unvested	Aggregate Intrinsic Value	Number of Shares Exercisable	-	gregate rinsic ue	Weighted- Average Remaining Contractual Life	
\$0.20	19	1.0			19			1.0	
\$1.32	74	3.2			74			3.2	
\$3.10	1,579	6.7	367		1,558			6.7	
\$8.53	3,031	5.1	6		3,031			5.1	
\$9.69	1,935	7.5	1,645		30			7.6	
\$12.40 \$18.25	1,273	8.2	1,083		206			7.9	
\$18.26 \$21.70	1,030	8.6	1,030						
\$21.71 \$29.65	1,461	9.4	1,345						
	10,402	7.1	5,476	\$ 152,348	4,918	\$	99,875	5.7	

Restricted Stock

In March 2005, the Company s Board of Directors approved the grant of 50,000 shares of restricted stock to a member of the Company s senior management. These restricted shares of stock vest based on continued service, with 50% of the shares vesting following the expiration of the period during which the Company s stockholders may exercise their put to GSK in accordance with the Company s Certificate of Incorporation and 25% of the shares vesting upon each of the next two anniversaries of such date. The Company recorded the \$0.9 million value of this restricted stock grant as deferred compensation, a component of stockholders equity in March 2005, prior to the adoption of SFAS 123(R). The value was based on the closing market price of the Company s common stock of \$17.91 on the date of award. The Company recognized stock-based compensation expense of \$74,000 and \$220,000 related to this award for the three and nine months ended September 30, 2006, respectively.

Stock Subject to Repurchase

At September 30, 2006, there were 107,971 shares of the Company s common stock subject to the Company s right to repurchase at the original purchase price. These shares were issued upon the exercise of unvested stock options and the execution of certain stock purchase agreements. The Company s repurchase rights lapse generally over a four-year period.

Reserved Shares

The Company has reserved shares of common stock for future issuance as follows (shares in thousands):

	September 30, 2006
Subject to outstanding warrant	18
Stock option plans:	
Subject to outstanding options	10,402
Available for future grants	1,168
Available for future ESPP purchases	365
Total	11,953

Stock Options Exercised Early

The Company generally allows employees to exercise options issued under the 1997 Stock Plan and the Long-Term Stock Option Plan prior to vesting. In accordance with EITF 00-23, Issues Related to Accounting for Stock Compensation under APB Opinion No. 25 and FASB Interpretation No. 44, stock options granted or modified after March 21, 2002 that are subsequently exercised for cash prior to vesting are treated differently from prior grants and related exercises. The consideration received for an exercise of an option granted after the effective date of this guidance is considered to be a deposit of the exercise price and the related dollar amount is recorded as a liability. The liability is only reclassified into equity on a ratable basis as the option vests. The Company applied the guidance and recorded a liability of \$0.1 million and \$0.2 million in the consolidated balance sheets relating to 20,876 and 62,632 options granted that were exercised and unvested at September 30, 2006 and December 31, 2005, respectively. Furthermore, these shares are not presented as outstanding on the consolidated balance sheets, but are disclosed as outstanding options.

Employee Stock Purchase Plan

On May 27, 2004 the Company s Board of Directors adopted the 2004 Employee Stock Purchase Plan (ESPP) that became effective on the date of the Company s initial public offering. The ESPP allows employees to contribute up to 15% of their gross salary, through payroll deductions, towards the semi-annual purchase of shares of common stock of the Company. The Company s officers are currently excluded from participating in the ESPP. The price of each share will not be less than the lower of 85% of the fair market value of the Company s common stock on the last trading day prior to the commencement of the offering period or 85% of the fair market value of the Company s common stock on the last trading day of the purchase period. A total of 325,000 shares of common stock were initially reserved for issuance under the ESPP. In June 2005, the Company s stockholders approved an amendment to the 2004 Employee Stock Purchase Plan increasing the aggregate number of shares of common stock authorized for issuance under the plan by 300,000 shares.

Through September 30, 2006, the Company issued 260,402 shares under the ESPP at an average price of \$13.79 and the total number of remaining shares available for issuance under the plan was 364,598. There were 94,664 shares of common stock issued under the ESPP during the second quarter 2006. For the three and nine months ended September 30, 2006, the total stock-based compensation expense recognized related to the ESPP under SFAS