

THERAVANCE INC  
Form 10-Q  
November 06, 2006

**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, 2006

OR

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  No

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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  Accelerated Filer  Non-Accelerated Filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

The number of shares of registrant's common stock outstanding on 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)

	September 30, 2006 (Unaudited)	December 31, 2005 *
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 85,730	\$ 49,787
Marketable securities	137,525	112,138
Receivable from related party	272	990
Prepaid and other current assets	3,858	3,903
Total current assets	227,385	166,818
Marketable securities	43,800	38,084
Restricted cash and cash equivalents	3,860	3,860
Property and equipment, net	14,281	13,180
Deferred sublease costs		297
Notes receivable	2,924	2,496
Other assets	100	100
Total assets	\$ 292,350	\$ 224,835
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 8,075	\$ 8,118
Accrued personnel-related expenses	6,562	6,041
Accrued clinical and development expenses	15,593	13,779
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	22,032	16,994
Total current liabilities	54,801	48,173
Deferred rent	2,572	2,538
Notes payable	570	631
Deferred revenue	136,555	111,251
Other long term liabilities	3,818	2,658
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	833,452	676,299
Notes receivable from stockholders	(5)	(17)
Deferred stock-based compensation		(4,965)
Accumulated other comprehensive loss	(37)	(503)
Accumulated deficit	(739,975)	(611,768)
Total stockholders' equity	94,034	59,584
Total liabilities and stockholders' equity	\$ 292,350	\$ 224,835

\*Condensed consolidated balance sheet at December 31, 2005 has been derived from audited financial statements.

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*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,	
	2006	2005	2006	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

(1) 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.

(2) 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 Ended September 30,		Nine Months Ended 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
<b>Cash flows used in operating activities</b>		
Net loss	\$ (128,207 )	\$ (100,953 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,088	3,092
Stock-based compensation	16,484	3,934
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	2,593
Accounts payable and accrued liabilities	1,740	5,594
Accrued personnel-related expenses	521	213
Deferred rent	34	169
Deferred revenue	30,342	(676 )
Other long-term liabilities	1,290	
Net cash used in operating activities	(73,604 )	(85,577 )
<b>Cash flows (used in) provided by investing activities</b>		
Purchases of property and equipment	(4,157 )	(2,639 )
Purchases of marketable securities	(181,545 )	(103,783 )
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	(35,252 )	4,204
<b>Cash flows provided by financing activities</b>		
Payments on notes payable and capital leases	(766 )	(2,224 )
Net proceeds from issuances of common stock	145,565	4,545
Net cash provided by financing activities	144,799	2,321
Net increase (decrease) in cash and cash equivalents	35,943	(79,052 )
Cash and cash equivalents at beginning of period	49,787	101,411
Cash and cash equivalents at end of period	\$ 85,730	\$ 22,359
<b>Supplemental Disclosures of Cash Flow Information</b>		
Cash paid for interest	\$ 133	\$ 258
Non-cash investing and financing activities:		
Addition to (removal of) deferred stock-based compensation	\$ (4,965 )	\$ 896

*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*

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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 and 2005. The results 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*

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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 SFAS 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 Months Ended			
	September 30, 2006		2005		September 30, 2006		2005	
<b>Employee stock options</b>								
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	6.17	3	4
Volatility	0.51		0.7		0.51		0.7	
Weighted average estimated fair value of stock options granted	\$	13.39	\$	8.90	\$	15.61	\$	8.73
<b>Employee stock purchase plan issuances</b>								
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	0.7	
Weighted average estimated fair value of ESPP issuances	\$	8.07	\$	8.81	\$	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 Months Ended		Nine Months Ended	
	September 30, 2005		September 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)	Three Months Ended		Nine Months Ended	
	September 30, 2006	2005	September 30, 2006	2005
Basic and diluted:				
Net loss	\$ (37,780 )	\$ (37,786 )	\$ (128,207 )	\$ (100,953 )
Weighted average shares of common stock outstanding	59,927	53,649	58,883	53,404
Less: weighted average shares subject to repurchase	(165 )	(233 )	(181 )	(249 )
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*

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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*



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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:

(in thousands)	September 30, 2006			
	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 Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	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*

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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.

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

	Number of Shares Available for Grant (In thousands, except per share amounts)	Number of Shares Subject to Outstanding Options	Weighted- Average Exercise Price Per Share
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 )		\$ 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):

Exercise Price Per Share	Options Outstanding			Aggregate Intrinsic Value	Options Exercisable		Weighted- Average Remaining Contractual Life
	Number of Shares Subject to Outstanding Options	Weighted- Average Remaining Contractual Life	Number of Shares Subject to Options Unvested		Number of Shares Exercisable	Aggregate Intrinsic Value	
\$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*



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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*

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

	<b>September 30, 2006</b>
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*

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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*

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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 123(R) was \$0.3 million and \$1.2 million, respectively.

**8. Related Party Transactions**

*Related Parties*

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The Company's related parties are its directors, executive officers and GSK. Transactions with executive officers and directors include notes receivable, described below. Transactions with GSK are described in Note 3.

Robert V. Gunderson, Jr. is a director of the Company. The Company has engaged Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, of which Mr. Gunderson is a partner, as its primary legal counsel. Fees totaling \$0.4 million and \$0.5 million were incurred in the ordinary course of business in the nine months ended September 30, 2006 and 2005, respectively.

### *Notes Receivable*

The Company has provided loans to certain of its employees primarily to assist them with the purchase of a primary residence, which collateralizes the resulting loans. The Company has also allowed certain option holders to exercise their options by executing stock purchase agreements and full recourse notes payable to the Company. The balance of the notes receivable for stock option exercises is included in Stockholders' Equity on the Consolidated Balance Sheet. The loans issued for the exercise of stock options are dated prior to November 2001 and thus are not subject to variable accounting as required under EITF 00-23 Issues Related to the Accounting for Stock Compensation Under APB No. 25 and FASB Interpretation 44.

**Interest receivable related to the notes was approximately \$25,000 for both periods ending September 30, 2006 and December 31, 2005 and is included in other assets. The Company accrues interest on the notes at rates of up to 8.0%. The outstanding loans have maturity dates ranging from March 2007 through 2012.**

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

### Forward-Looking Statements

The information in this discussion contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended. Such statements are based upon current expectations that involve risks and uncertainties. Any statements contained herein that are not of historical fact, including, without limitation, statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans, goals and objectives, may be forward-looking statements. The words anticipates, believes, estimates, expects, intends, may, plans, projects, and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions, expectations or objectives disclosed in our forward-looking statements and the assumptions underlying our forward-looking statements may prove incorrect. Therefore, you should not place undue reliance on our forward-looking statements. Actual results or events may differ significantly from the results discussed in the forward-looking statements we make. Factors that might cause such a discrepancy include, but are not limited to those discussed below in Risk Factors in Item 1A of Part II and in the subsection entitled Liquidity and Capital Resources in this Item 2. All forward-looking statements in this document are based on information available to us as of the date hereof and we assume no obligation to update any such forward-looking statements.

### Executive Summary

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates. Theravance is focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections and gastrointestinal motility dysfunction. Of our five programs in development, two are in late stage our telavancin program focusing on treatment serious Gram-positive bacterial infections with Astellas Pharma Inc. (Astellas) and our Beyond Advair collaboration with GlaxoSmithKline (GSK). By leveraging our proprietary insight of multivalency to drug discovery focused on validated targets, we are pursuing a next generation drug discovery strategy designed to discover superior medicines in large markets. We commenced operations in 1997, and as of September 30, 2006, we had an accumulated deficit of \$740.0 million. None of our product candidates have been approved for marketing and sale to patients and we have not received any product revenue to date. Most of our spending to date has been for research and development activities and general and administrative expenses. We expect to incur substantial losses for at least the next several years as we continue to invest in research and development.

Our net loss for the three months ended September 30, 2006 was \$37.8 million compared to \$37.8 million during the same period of 2005. The third quarter net loss was primarily due to research and development costs associated with telavancin Phase 3 clinical programs and additional stock-based compensation expense associated with the implementation of SFAS 123(R). Research and development spending for the three months ended September 30, 2006 increased to \$39.1 million compared to \$37.0 million for the same period of 2005. This increase was primarily driven by the impact of SFAS 123(R) offset by lower external research and development costs associated with our two Phase 3 programs for telavancin. Total external research and development costs were \$20.6 million and \$22.0 million for the three months ended September 30, 2006 and 2005 respectively. Total research and development stock-based compensation expense for the three months ended September 30, 2006 was \$3.0 million compared to \$0.8 million for the same period in 2005. Cash, cash equivalents, and marketable securities totaled \$267.1 million at September 30, 2006, an increase of \$67.1 million since December 31, 2005. This increase was primarily due to the receipt of approximately \$139.8 million, net of issuance costs, from our public offering in February 2006, the receipt of \$35.0 million from Astellas which includes a \$25.0 million milestone payment and a \$10.0 million upfront payment for rights to telavancin in Japan, and \$8.0 million of milestone payments received from GSK, offset in part by net usage of cash.

Following are updates on the progress of our clinical programs:

#### Bacterial Infections Programs

##### *Telavancin*

We reported positive results from our Phase 3 studies for the treatment of patients with serious Gram-positive complicated skin and skin structure infections (cSSSI), including those due to resistant pathogens such as methicillin-resistant *Staphylococcus aureus* (MRSA), and plan to file a new drug application with the Food & Drug Administration by the end of the year.

Our Phase 3 program for the treatment of resistant Gram-positive hospital-acquired pneumonia continues to progress. Completion of enrollment in this program will likely occur during the first half of 2007.

*Heterodimer*

We recently completed multiple-dose Phase 1 studies of our unique heterodimer antibiotic, TD-1792, which combines the antibacterial activities of a glycopeptide and a beta-lactam in one molecule. The initial results of these studies demonstrated that TD-1792 was generally well tolerated and had a profile consistent with once-daily dosing.

Respiratory Programs

*Beyond Advair*

Our collaboration with GlaxoSmithKline (GSK) to develop and commercialize a Long-Acting Beta2 Agonist (LABA) product candidate for the treatment of asthma and chronic obstructive pulmonary disease (COPD) continues to progress, with two compounds expected to generate Phase 2b data by mid-2007.

*Inhaled Long-Acting Muscarinic Antagonist (LAMA) and Bifunctional Muscarinic Antagonist-Beta2 Agonist (MABA) Programs*

The first compound in our MABA program for the treatment of COPD successfully completed single-dose Phase 1 studies and has recently begun multiple-dose Phase 1 studies. Our LAMA program, also for COPD, continues to progress.

*Gastrointestinal (GI) Motility Dysfunction Program*

We recently initiated a Phase 2 clinical program in GI motility dysfunction with TD-5108, an investigational compound for the treatment of chronic constipation. The goal of this program is to develop a product with a once-a-day oral dosing and prokinetic efficacy superior to existing market-leading medicines.



## Critical Accounting Policies

As of the date of the filing of this quarterly report, we believe there have been no material changes to our critical accounting policies and estimates during the three and nine months ended September 30, 2006, compared to those discussed in our Annual Report on Form 10-K/A filed on March 10, 2006 (2005 10-K), except for the adoption of Financial Accounting Standards Board Statement FAS 123(R) as discussed below.

### *Share-based Payments*

On January 1, 2006, we adopted the fair value recognition provisions of SFAS 123(R), which requires the measurement and recognition of compensation expenses for all share-based payment awards made to employees and directors including stock options and employee stock purchases under our 2004 Employee Stock Purchase Plan (employee stock purchases) based on estimated fair values. SFAS 123(R) supersedes our previous accounting for employee stock options using the intrinsic-value method in accordance APB No. 25, FIN No. 44, Accounting for Certain Transactions Involving Stock Compensation, an interpretation of APB No. 25, and related to interpretations, and the disclosure-only provisions of SFAS No. 123.

We adopted SFAS 123(R) using the modified-prospective-transition method. Under this method, compensation costs recognized as of 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 FAS 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).

Options granted and employee stock purchases prior to January 1, 2006, are valued in accordance with SFAS 123. The expected volatility and expected term are based on the volatility and expected life assumptions used by similar entities within our industry. We used the accelerated method for expense attribution and 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). We estimated forfeitures and only recognized expense for those shares expected to vest. We used the straight-line single-option method for expense attribution. For the nine months ended September 30, 2006, we increased our estimated annual forfeiture rate from 2.4% to 3.6%, based on our historical forfeiture experience.

In accordance with the modified-prospective-transition method, our Condensed Consolidated Financial Statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R). As a result of adopting FAS 123(R) on January 1, 2006, our net loss for the three and nine months ended September 30, 2006 was \$3.8 million and \$13.3 million higher, respectively, than if we had continued to account for share-based compensation under APB No. 25 as we 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 we had continued to account for share-based compensation under APB No. 25. We have not recognized, and do 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 our net deferred tax assets and our net operating loss carryforwards. 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. We have not recognized, and do 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 our net deferred tax assets and our 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 fair value of each option award is estimated on the grant date using the Black-Scholes valuation model with the weighted average assumptions noted in the table in Note 1. As we have been operating as a public company for a period shorter than our estimated expected option life, we were unable to use actual price volatility or option life data as input assumptions within our Black-Scholes valuation model. Instead we were required to use the simplified method as described in SAB 107 related to SFAS 123(R) for expected term and peer companies' historical price volatility, both of which have been higher than actual results to date. The risk-free rate for periods within the contractual life of the option is based on the U.S. Government securities-Treasury constant maturities in effect at the time of the grant. The result of these assumptions used is an increase in the value of estimated stock-based compensation reflected in our condensed consolidated statements of operations.

These assumptions used in the calculation of the fair value of share-based compensation expense represent management's best estimates, but these estimates involve inherent uncertainties and the application of management's judgment. As a result, if other assumptions had been used, our stock-based compensation expense could have been materially different.

#### **Collaboration and Licensing Agreements**

*2005 License, Development and Commercialization Agreement with Astellas*

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

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

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

*2002 Beyond Advair Collaboration*

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In November 2002, we entered into our Beyond Advair collaboration agreement with 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, of which five product candidates either have completed or are in Phase 2a clinical studies while two product candidates are in the Phase 2b clinical program. As of September 30, 2006, we had received upfront and milestone payments from GSK of \$60.0 million related to the clinical progress of our candidates.

We recorded the upfront and milestone payments as deferred revenue, which are being amortized ratably over our estimated period of performance (the product development period), which we currently estimate 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, compared to \$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, we 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 alliance agreement, we 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 our programs under the agreement, which is currently estimated to be approximately seven and one-half years from the commencement of the strategic alliance. From this upfront payment, we 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 our LAMA program for the treatment of COPD pursuant to the terms of the strategic alliance. We received a \$5.0 million payment from GSK in connection with its licensing of our LAMA program. 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, we earned a \$3.0 million milestone payment, received in July 2005, from GSK related to the clinical progress of our candidate. This milestone payment was recorded as deferred revenue when earned and will be amortized over the remaining period of performance during the development period. We 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, we are 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. We 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 our MABA program for the treatment of COPD, and possibly asthma, pursuant to the terms of the strategic alliance. We have received \$8.0 million in milestones from GSK in connection with the license of our MABA program through September 30, 2006. 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. We 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 both 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. Additionally, we 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, we entered into a license agreement with AstraZeneca AB (AstraZeneca) pursuant to which we granted an exclusive, worldwide license to AstraZeneca to develop and commercialize our intravenous anesthetic compound TD-4756. We received a \$1.0 million upfront payment from AstraZeneca and are eligible to receive milestone payments and royalties on global sales. The upfront payment is being amortized ratably over the estimated period of performance which is currently estimated to be approximately one year. We recognized \$0.2 million and \$0.3 million in license revenue for the three and nine months ended September 30, 2006, respectively.

## RESULTS OF OPERATIONS

**Revenue** We recognized revenue of \$5.5 million and \$14.7 million for the three and nine months ended September 30, 2006, respectively, and \$3.0 million and \$8.7 million for the three and nine months ended September 30, 2005, respectively. This revenue consisted of the amortization of upfront and milestone payments from GSK related to our Beyond Advair collaboration and our strategic alliance, from Astellas related to our telavancin collaboration and from AstraZeneca related to its license of TD-4756. Following are the upfront and milestone payments received through September 30, 2006 (in millions):

Agreements/Programs	Signed Agreement/Licensed Program	End of Estimated Performance Period	Upfront and Milestone Payments
<i>GSK Collaborations</i>			
Beyond Advair collaboration	2002	2010	\$ 60.0
Strategic alliance execution	2004	2011	20.0
Strategic alliance LAMA	2004	2011	8.0
Strategic alliance MABA	2005	2013	8.0
<i>Astellas Collaboration execution</i>	2005	2019	101.0
<i>AstraZeneca License Agreement</i>	2006	2007	1.0
Total			\$ 198.0

Upfront and milestone payments received from GSK, Astellas and AstraZeneca have been deferred and are being amortized ratably into revenue over the applicable estimated performance periods. Future revenue will include the ongoing amortization of remaining deferred revenue which consists of \$96.0 million of upfront and milestone payments received through September 30, 2006 under our agreement with Astellas; \$61.9 million of upfront and milestone payments received through September 30, 2006 under our agreements with GSK; and the \$0.7 million upfront payment received through September 30, 2006 under our license agreement with AstraZeneca.

### **Research and development**

Research and development expenses:

(in millions)	Three Months Ended		Nine Months Ended	
	September 30, 2006	2005	September 30, 2006	2005
External research and development	\$ 20.6	\$ 22.0	\$ 73.8	\$ 52.5
Employee-related	9.8	8.9	28.7	26.3
Stock-based compensation	3.0	0.8	9.4	2.4
Facilities, depreciation and other allocated	5.7	5.3	16.7	14.9
Total research and development expenses	\$ 39.1	\$ 37.0	\$ 128.6	\$ 96.1

Total research and development expenses increased 6% and 34%, respectively, for the three and nine months ended September 30, 2006 compared to the same periods in 2005. The increase for the quarter was primarily the result of higher stock-based compensation expense associated with the implementation of SFAS 123(R), offset by lower external research and development expenses. The lower external development costs for the quarter were primarily a result of our completion of patient enrollment of our Phase 3 cSSSI studies for telavancin (our lead antibiotic candidate). The year-to-date increase was primarily the result of higher external research and development expenses, which include increased clinical services and contract manufacturing activities supporting our two Phase 3 clinical studies for telavancin and Phase 1 clinical studies for GI motility dysfunction candidates, as well as higher stock-based compensation expense associated with the implementation of SFAS 123(R).

Employee-related expenses increased by \$0.9 million and \$2.4 million for the three and nine months ended September 30, 2006 compared to the same periods of 2005. This increase was due to generally higher salary and benefits costs in 2006. Facilities, depreciation and other allocated expenses increased by \$0.4 million and \$1.8 million, respectively, for the three and nine months ended September 30, 2006 compared to the same periods of 2005. The increase was primarily due to higher supplies and facilities administration costs in 2006.

Total research and development stock-based compensation expense recognized under SFAS 123(R) for the three and nine months ended September 30, 2006 was \$3.0 million and \$9.4 million, respectively, which consisted of stock-based compensation expense related to employee stock options, employee stock purchases, and the value of options issued to non-employees for services rendered. For the three and nine months ended September 30, 2005, stock-based compensation expense was \$0.8 million and \$2.4 million, respectively, which reflected the amortization of deferred stock-based compensation related to employees and the value of stock options granted to non-employees. In accordance with the modified-prospective-transition method, the research and development expenses for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R).





Research and development expenses for the balance of 2006 will be driven largely by clinical study enrollment, particularly for our hospital-acquired pneumonia (HAP) telavancin Phase 3 program, and for our GI and heterodimer programs. Should enrollment occur more quickly than forecast or should we begin various studies sooner than anticipated, it is possible that these expenses will increase. Under our agreement with Astellas, we are responsible for completion of the cSSSI and HAP telavancin Phase 3 programs, publication of the results of these studies, preparation and submission of a new drug application (NDA) to the United States Food and Drug Administration (FDA) for the cSSSI indication and subsequently for the HAP indication, and manufacture of sufficient quantities of active pharmaceutical ingredient (API) and drug product for launch. We are reliant on the efforts of third parties, including contract research organizations, consultants and contract manufacturing organizations for the completion of these obligations. While we cannot predict the time frame in which these responsibilities will be completed, we anticipate that our aggregate external costs associated with the telavancin Phase 3 programs will be towards the upper range of \$125.0 million to \$150.0 million.

Other external research and development expenses will be driven by our ongoing development efforts in our GI program and expenses associated with our additional early-stage drug discovery programs. However, actual expenses may vary considerably based upon timing of program initiation, study enrollment rates, and the timing and structure of any collaboration in which a partner may incur a portion of these expenses.

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

**General and administrative** General and administrative expenses increased to \$7.9 million and \$24.0 million for the three and nine months ended September 30, 2006, respectively, from \$5.3 million and \$18.2 million for the three and nine months ended September 30, 2005, respectively. The increases of \$2.6 million and \$5.8 million for the three and nine months ended September 30, 2006, respectively, are primarily due to higher stock-based compensation expense, as well as higher consulting and headcount related costs.

The total general and administrative stock-based compensation expense recognized under SFAS 123(R) for the three and nine months ended September 30, 2006 was \$1.7 million and \$7.1 million, respectively, which consisted of stock-based compensation expense related to employee stock options, to employee stock purchases, the value of options issued to non-employees for services rendered and to stock-based compensation expense related to restricted stock. For the three and nine months ended September 30, 2005, stock-based compensation expense was \$0.3 million and \$1.5 million, respectively, which reflected the amortization of deferred stock-based compensation related to employees and the value of stock options granted to non-employees. In accordance with the modified-prospective transition method, the general and administrative expenses for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R).

We anticipate general and administrative expenses will increase for the remainder of 2006 and subsequent years to support our growing discovery, development, manufacturing and commercialization efforts.

**Interest and other income** Interest and other income includes interest income earned on cash and marketable securities, net realized gains on marketable securities and net sublease income on facilities. Interest income increased to \$3.9 million and \$10.2 million, respectively, for the three and nine months ended September 30, 2006 from \$1.7 million and \$5.2 million for the three and nine months ended September 30, 2005, respectively, due to larger cash balances following the closing of our public offering in February 2006 and higher interest rates.

**Interest and other expense** Interest expense includes interest expense on capital lease and debt arrangements. Interest and other expense increased by approximately \$0.1 million for both the three and nine months ended September 30, 2006 when compared to the three and nine months ended September 30, 2005.

## LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2006 and December 31, 2005, we had \$267.1 million and \$200.0 million in cash, cash equivalents and marketable securities, respectively, in each case excluding \$3.9 million in restricted cash and cash equivalents that was pledged as collateral for certain of our leased facilities and equipment. In February 2006, we raised proceeds of approximately \$139.8 million, net of issuance costs, in a public offering of common stock. Additionally, we received \$35.0 million in upfront and milestone payments from Astellas, as well as \$8.0 million in milestone payments from GSK.



We believe that our cash, cash equivalents and marketable securities will be sufficient to meet our anticipated operating needs for at least the next eighteen months based upon current operating and spending assumptions. We expect to incur substantial expenses as we continue our drug discovery and development efforts, particularly to the extent we advance our product candidates into and through clinical studies, which are very expensive. We also expect expenditures to increase as we continue to invest in our research and development and administrative infrastructure to support our expanded operations. As a result, we may choose to raise additional funds in advance of our operating needs, if we expand more rapidly than we presently anticipate, or if our operating costs exceed our expectations. Pursuant to the restrictions described below in our agreements with GSK, we cannot sell significant additional equity until the expiration of the call and put arrangements in 2007, but we may sell debt securities or incur indebtedness, subject to limitations under our agreements with GSK. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations. We cannot guarantee that future financing will be available in amounts or on terms acceptable to us, if at all.

Our governance agreement with GSK limits the number of shares of capital stock that we may issue and the amount of debt that we may incur. Prior to the termination of the call and put arrangements with GSK in 2007, without the prior written consent of GSK, we may not issue any equity securities if it would cause more than approximately 54.2 million shares of common stock, or securities that are vested and exercisable or convertible into shares of common stock, to be outstanding as of the put date. As a result of our public offering in February 2006, we cannot sell significant additional equity securities until the expiration of the call and put arrangements in 2007. In addition:

- If, on or immediately after the termination of the call and put arrangements with GSK in 2007, GSK directly or indirectly controls more than 35.1% of our outstanding capital stock, then without the prior written consent of GSK, we may not issue more than an aggregate of approximately 16.1 million shares of our capital stock after September 1, 2007 through August 2012; and
- Prior to the termination of the call and put arrangements with GSK in 2007, we may not borrow money or otherwise incur indebtedness of more than \$100.0 million or if such indebtedness would cause our consolidated debt to exceed our cash and cash equivalents and marketable securities.

These limits on issuing equity and debt could leave us without adequate financial resources to fund our discovery and development efforts in the event that GSK does not license development programs pursuant to our alliance agreement and no other third parties enter into collaborations with us for these programs. This could result in a reduction of our discovery and development efforts and our ability to commercialize product candidates and generate revenues and may cause us to enter into collaborations with third parties on less favorable terms.

#### **Cash Flows**

Net cash used in operating activities was \$73.6 million and \$85.6 million for the nine months ended September 30, 2006 and 2005, respectively. Although research and development and general and administrative expenses increased in the 2006 period, the increase was offset by \$35.0 million in upfront and milestone payments received from Astellas, as well as \$8.0 million in milestone payments from GSK during the first nine months of 2006.

Investing activities used cash of \$35.3 million and provided cash of \$4.2 million for the nine months ended September 30, 2006 and 2005, respectively. The decrease in 2006 primarily results from net purchases of marketable securities.

Financing activities provided cash of \$144.8 million and \$2.3 million for the nine months ended September 30, 2006 and 2005, respectively. The increase in cash provided by financing activities was primarily due to proceeds, net of issuance costs, of approximately \$139.8 million from our public offering of common stock in February 2006.

### Contractual Obligations and Commitments

Our major outstanding contractual obligations relate to our notes payable, capital leases from equipment financings, operating leases and fixed purchase commitments under contract research, development and clinical supply agreements. These contractual obligations as of September 30, 2006, are as follows (in millions):

	Less than 1 year	1-3 years	4-5 years	After 5 years	Total
Notes payable	\$ 0.1	\$ 0.2	\$ 0.3	\$ 0.1	\$ 0.7
Capital lease obligations	0.5				0.5
Operating leases	6.5	12.7	13.0	3.3	35.5
Purchase obligations	4.4	1.0			5.4
Total	\$ 11.5	\$ 13.9	\$ 13.3	\$ 3.4	\$ 42.1

As security for performance of our obligations under the operating leases for our headquarters, we have issued letters of credit in the aggregate of \$3.8 million, collateralized by an equal amount of restricted cash. Additionally, we have restricted cash of \$0.1 million as collateral for certain equipment leases. The terms of these facilities and equipment leases require us to maintain an unrestricted cash and marketable securities balance of at least \$50.0 million on the last day of each calendar quarter.

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

### Item 3. Quantitative and Qualitative Disclosure About Market Risk

There have been no significant changes in our market risk or how our market risk is managed compared to the disclosures in Item 7A of our 2005 10-K.

### Item 4. Controls and Procedures

#### *Evaluation of Disclosure Controls and Procedures.*

#### Evaluation of Disclosure Controls and Procedures

We conducted an evaluation as of September 30, 2006, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, which are defined under SEC rules as controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Securities Exchange Act of 1934 (Exchange Act) is recorded, processed, summarized and reported within required time periods. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

#### *Limitations on the Effectiveness of Controls*

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

### Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) in connection with the evaluation required under paragraph (d) of Rule 13a-15 under the Exchange Act, which occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**Item 1A. Risk Factors**

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

**Risks Related to our Business**

**If our product candidates, including telavancin which is currently in Phase 3 clinical studies for hospital-acquired pneumonia, are determined to be unsafe or ineffective in humans, our business will be adversely affected and our stock price will decline.**

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We have never commercialized any of our product candidates. We are uncertain whether any of our compounds or product candidates will prove effective and safe in humans or meet applicable regulatory standards. In addition, our approach to applying our expertise in multivalency to drug discovery is unproven and may not result in the creation of successful medicines. The risk of failure for all of our compounds and product candidates is high. For example, in late 2005 we discontinued our overactive bladder program based upon the results of our Phase 1 studies with compound TD-6301. To date, the data supporting our drug discovery and development programs is derived solely from laboratory, preclinical studies and clinical studies. A number of other compounds remain in the lead identification, lead optimization, preclinical testing and early clinical testing stages. It is impossible to predict when or if any of our compounds and product candidates will prove effective or safe in humans or will receive regulatory approval. If we are unable to discover and develop medicines that are effective and safe in humans, our business will fail.

**Any failure or delay in commencing or completing clinical studies for our product candidates, such as a further delay in completing our Phase 3 hospital-acquired pneumonia (HAP) clinical studies for telavancin, would likely cause our stock price to decline.**



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

- delays in patient enrollment, which we have experienced in our Phase 3 HAP program for telavancin, and variability in the number and types of patients available for clinical studies;
- poor effectiveness of product candidates during clinical studies;
- adverse events, safety issues or side effects relating to the product candidates or their formulation into medicines;
- our inability or the inability of our collaborators or licensees to manufacture or obtain from third parties materials sufficient for use in preclinical and clinical studies;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- a regional disturbance where we are enrolling patients in our clinical trials, such as a pandemic, terrorist activities or war, or a natural disaster;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines;
- varying interpretation of data by the Food and Drug Administration (FDA) and similar foreign regulatory agencies; and
- failure of our partners to advance our product candidates through clinical development.

For example, in the second quarter of 2006, we announced that it would be challenging to complete enrollment of our Phase 3 HAP clinical program for telavancin by the end of the year. It now appears likely that the HAP program will complete enrollment during the first half of 2007. There can be no assurance that delays in this program or other programs will not occur in the future. Such clinical study delays could impede the commercialization of our compounds and therefore would likely cause our stock price to decline.

**If telavancin or our other product candidates that we develop on our own or through collaborative partners are not approved by regulatory agencies, including the Food and Drug Administration, we will be unable to commercialize them.**

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The FDA must approve any new medicine before it can be marketed and sold in the United States. We must provide the FDA and similar foreign regulatory authorities with data from preclinical and clinical studies that demonstrate that our product candidates are safe and effective for a defined indication before they can be approved for commercial distribution. We will not obtain this approval for a product candidate unless and until the FDA approves a new drug application (NDA). In order to market our medicines in the European Union and other foreign jurisdictions, we must obtain separate regulatory approvals in each country. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We have not yet submitted an NDA to the FDA or made a comparable submission in any foreign country for any of our product candidates.

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

Frequently, product candidates that have shown promising results in early preclinical or clinical studies have subsequently suffered significant setbacks or failed in later clinical studies. In addition, clinical studies of potential products often reveal that it is not possible or practical to continue development efforts for these product candidates. If our clinical studies are substantially delayed or fail to prove the safety and effectiveness of our product candidates, we may not receive regulatory approval of any of our product candidates and our business and financial condition will be materially harmed.

Telavancin is the first product candidate for which we have conducted clinical trials, and it is the first product candidate for which we plan to submit an NDA to the FDA. We may not obtain regulatory approval to commercialize telavancin in the United States. In addition, we and our telavancin collaborator Astellas Pharma Inc. (Astellas) plan to seek regulatory approval for an additional indication for telavancin and foreign regulatory approvals for telavancin. We will be unable to generate any revenues from royalty payments from the commercialization and sale of telavancin if we fail to obtain these approvals.

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

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We do not have in-house manufacturing capabilities and depend entirely on a number of third-party compound manufacturers and active pharmaceutical ingredient formulators. We may not have long-term agreements with these third parties and our agreements with these parties may be terminable at will by either party at any time. If, for any reason, these third parties are unable or unwilling to perform, we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them. Any inability to acquire sufficient quantities of our compounds in a timely manner from these third parties could delay clinical studies and prevent us from developing our product candidates in a cost-effective manner or on a timely basis. In addition, manufacturers of our compounds are subject to the FDA's current Good Manufacturing Practices regulations and similar foreign standards and we do not have control over compliance with these regulations by our manufacturers.

Our manufacturing strategy presents the following additional risks:

- because of the complex nature of our compounds, our manufacturers may not be able to successfully manufacture our compounds in a cost effective or timely manner;
- some of the manufacturing processes for our compounds have not been tested in quantities needed for continued clinical studies or commercial sales, and delays in scale-up to commercial quantities could delay clinical studies, regulatory submissions and commercialization of our compounds; and

- because some of the third-party manufacturers and formulators are located outside of the U.S., there may be difficulties in importing our compounds or their components into the U.S. as a result of, among other things, FDA import inspections, incomplete or inaccurate import documentation or defective packaging.

**We have sufficient quantities of formulated drug product to complete all of the currently planned clinical studies of telavancin. We plan to manufacture additional bulk drug substance and drug product intended to meet our obligations to Astellas in connection with commercial launch in the event telavancin is approved for sale by regulatory authorities. If we are unable to do so in a timely manner the commercial introduction of telavancin, if approved, would be adversely affected.**

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**For our development compounds in our GI program and heterodimer program, we are using limited sources to manufacture the bulk drug substance and drug product. If any supplier fails to continue to produce supplies for our development activities for these compounds at acceptable quantity or quality levels, our clinical studies could be delayed.**

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

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If approved by the relevant regulatory agencies, the commercial success of telavancin will depend upon its acceptance by physicians, patients, third party payors and the medical community in general. We cannot be sure that telavancin will be accepted by these parties even if it is approved by the relevant regulatory authorities. If approved, telavancin will compete with vancomycin, a relatively inexpensive generic drug that is manufactured by a variety of companies, a number of existing anti-infectives manufactured and marketed by major pharmaceutical companies and others, and potentially against new anti-infectives that are not yet on the market. Even if the medical community accepts that telavancin is safe and efficacious for its approved indications, physicians may choose to restrict the use of telavancin. If we are unable to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, telavancin is preferable to vancomycin and other existing or subsequently-developed anti-infective drugs, we may never generate meaningful revenue from telavancin. The degree of market acceptance of telavancin depends on a number of factors, including, but not limited to:

- the demonstration of the clinical efficacy and safety of telavancin;
- the advantages and disadvantages of telavancin compared to alternative therapies;
- our and our collaborative partner's ability to educate the medical community about the safety and effectiveness of telavancin;
- the reimbursement policies of government and third party payors; and
- the market price of telavancin.

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



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



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

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We have been engaged in discovering and developing compounds and product candidates since mid-1997. We have not generated any product sales revenue to date. We may never generate revenue from selling medicines or achieve profitability. As of September 30, 2006, we had an accumulated deficit of approximately \$740.0 million.

We expect our research and development expenses to keep increasing as we continue to initiate new discovery programs and expand our development programs. As a result, we expect to continue to incur substantial losses for the foreseeable future. We are uncertain when or if we will be able to achieve or sustain profitability. Failure to become and remain profitable would adversely affect the price of our common stock and our ability to raise capital and continue operations.

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

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We need large amounts of capital to support our research and development efforts. If we are unable to secure capital to fund our operations we will not be able to continue our discovery and development efforts and we might have to enter into strategic collaborations that could require us to share commercial rights to our medicines to a greater extent than we currently intend. Based on our current operating plans, we believe that our cash and cash equivalents and marketable securities will be sufficient to meet our anticipated operating needs for at least the next eighteen months. We may require additional capital to fund operating needs thereafter.

In addition, in the event that a LABA product candidate discovered by GSK is successfully developed and commercially launched in multiple regions of the world, we are obligated to pay GSK milestone payments of up to an aggregate of \$220.0 million under our Beyond Advair collaboration. We may also need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate. Prior to the termination of the call and put arrangements with GSK, we may seek to sell debt securities or incur other indebtedness. After the termination of the call and put arrangements with GSK, we may seek to sell additional equity or debt securities, or both, or incur other indebtedness. The sale of additional equity or debt securities, if convertible, could result in the issuance of additional shares of our capital stock and could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, our ability to raise debt and equity financing is constrained by our alliance with GSK and we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all.

In particular, until the expiration of the put and call provisions with GSK, we will be contractually prohibited from selling significant additional equity securities to raise capital. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing research and development efforts. This could harm our business, prospects and financial condition and cause the price of our common stock to fall.

**If our partners do not satisfy their obligations under our agreements with them, we will be unable to develop our partnered product candidates as planned.**

**We entered into our Beyond Advair collaboration agreement with GSK in November 2002, our strategic alliance agreement with GSK in March 2004, and our telavancin development and commercialization agreement with Astellas in November 2005. In connection with these agreements, we have granted to these parties certain rights regarding the use of our patents and technology with respect to compounds in our development programs, including development and marketing rights. In connection with our GSK strategic alliance agreement, upon exercise of its license with respect to a particular development program, GSK will have full responsibility for development and commercialization of any product candidates in that program. Any future milestone payments or royalties to us from these programs will depend on the extent to which GSK advances the product candidate through development and commercial launch. In connection with our Astellas telavancin agreement, Astellas is responsible for the commercialization of telavancin and any royalties to us from this program will depend upon Astellas' ability to launch and sell the medicine if it is approved.**

Our partners might not fulfill all of their obligations under these agreements. In that event, we may be unable to assume the development and commercialization of the product candidates covered by the agreements or enter into alternative arrangements with a third party to develop and commercialize such product candidates. In addition, with the exception of product candidates in our Beyond Advair collaboration, our partners generally are not restricted from developing and commercializing their own products and product candidates that compete with those licensed from us. If a partner elected to promote its own products and product candidates in preference to those licensed from us, future payments to us could be reduced and our business and financial condition would be materially and adversely affected. Accordingly, our ability to

receive any revenue from the product candidates covered by these agreements is dependent on the efforts of the partner. We could also become involved in disputes with a partner, which could lead to delays in or termination of our development and commercialization programs and time-consuming and expensive litigation or arbitration. If a partner terminates or breaches its agreements with us, or otherwise fails to complete its obligations in a timely manner, the chances of successfully developing or commercializing our product candidates would be materially and adversely affected.

In addition, while our strategic alliance with GSK sets forth pre-agreed upfront payments, development obligations, milestone payments and royalty rates under which GSK may obtain exclusive rights to develop and commercialize our product candidates, GSK may in the future seek to negotiate more favorable terms on a project-by-project basis. To date, GSK has only licensed our LAMA program and our MABA program under the terms of the strategic alliance agreement and has chosen not to license our bacterial infections program and our anesthesia program. There can be no assurance that GSK will license any other development program under the terms of the strategic alliance agreement, or at all. GSK's failure to license our development programs could adversely affect the perceived prospects of the product candidates that are the subject of these development programs, which could negatively affect both our ability to enter into collaborations for these product candidates with third parties and the price of our common stock.

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

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As of November 1, 2006, GSK beneficially owned approximately 15.7% of our outstanding capital stock, and will have the right in July 2007 to increase its ownership of our stock up to approximately 59.4% through the exercise of its call right. Other than our bacterial infections program and our anesthesia program, which GSK has decided not to license under the strategic alliance, GSK has the right to license exclusive development and commercialization rights to our product candidates arising from all of our current and future drug discovery and development programs initiated prior to September 1, 2007. This right will extend to our programs initiated prior to September 1, 2012 if GSK owns more than 50% of our common stock due to exercise of the call right or the put right. In brief, (i) the call right is GSK's right, in July 2007, to require us to redeem 50% of our common stock held by each stockholder at \$54.25 per share, and (ii) the put right is the right of each of our stockholders in August 2007, if GSK has not exercised its call right in July 2007, to require us to redeem up to 50% of their common stock at \$19.375 per share. Pharmaceutical companies other than GSK that may be interested in developing products with us are likely to be less inclined to do so because of our relationship with GSK, or because of the perception that development programs that GSK does not license pursuant to our strategic alliance agreement are not promising programs.

In addition, because GSK may license our development programs at any time prior to successful completion of a Phase 2 proof-of-concept study, we may be unable to collaborate with other partners with respect to these programs until we have expended substantial resources to advance them through clinical studies. Given the restrictions on our ability to raise capital provided for in our agreements with GSK, we may not have sufficient funds to pursue such programs in the event GSK does not license them at an early stage. If our ability to work with present or future strategic partners or collaborators is adversely affected as a result of our strategic alliance with GSK, our business prospects may be limited and our financial condition may be adversely affected.

**If we are unable to enter into future collaboration arrangements or if any such collaborations with third parties are unsuccessful, our profitability may be delayed or reduced.**



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To date, we have only entered into collaborations with GSK for the Beyond Advair, LAMA and MABA programs and with Astellas for telavancin, and we have licensed our anesthesia compound to AstraZeneca. As a result, we may be required to enter into collaborations with other third parties regarding our other programs whereby we have to relinquish material rights, including revenue from commercialization of our medicines, on terms that are less attractive than our current arrangements with these parties. Furthermore, our ability to raise additional capital to fund our drug discovery and development efforts is greatly limited as a result of our agreements with GSK. In addition, we may not be able to control the amount of time and resources that our collaborative partners devote to our product candidates and our partners may choose to pursue alternative products. Moreover, these collaboration arrangements are complex and time-consuming to negotiate. If we are unable to reach agreements with third-party collaborators, we may fail to meet our business objectives and our financial condition may be adversely affected. We face significant competition in seeking third-party collaborators and may be unable to find third parties to pursue product collaborations on a timely basis or on acceptable terms. Our inability to successfully collaborate with third parties would increase our development costs and could limit the likelihood of successful commercialization of our product candidates.

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**We depend on third parties in the conduct of our clinical studies for our product candidates.**

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We depend on independent clinical investigators, contract research organizations and other third party service providers in the conduct of our preclinical and clinical studies for our product candidates. We rely heavily on these parties for execution of our preclinical and clinical studies, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol. The failure of these third parties to complete activities on schedule or to conduct our studies in accordance with regulatory requirements and our protocols could delay or prevent the further development, approval and commercialization of our product candidates, which could severely harm our business and financial condition. For example, we have expanded the number of clinical research organizations working on our Phase 3 HAP program for telavancin due to slower than anticipated enrollment. Retaining alternative or additional service providers involves delays and additional costs. In addition, if we lose our relationship with any one or more of these third parties, we could experience a significant delay in both identifying another comparable service provider and then contracting for its services. We may be unable to retain an alternative service provider on reasonable terms, if at all. Even if we locate an alternative service provider, it is likely that this provider will need additional time to respond to our needs and may not provide the same level of service as the original service provider.

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

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

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

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

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

Any new medicine that competes with a generic market leading medicine must demonstrate compelling advantages in efficacy, convenience, tolerability and/or safety in order to overcome severe price competition and be commercially successful. If approved, telavancin must demonstrate these advantages, as it will compete with vancomycin, a relatively inexpensive generic drug that is manufactured by a number of companies, and a number of existing anti-infectives marketed by major pharmaceutical companies. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

As the principles of multivalency become more widely known, we expect to face increasing competition from companies and other organizations that pursue the same or similar approaches. Novel therapies, such as gene therapy or effective vaccines for infectious diseases, may emerge that will make both conventional and multivalent medicine discovery efforts obsolete or less competitive.

**We have no experience selling or distributing products and no internal capability to do so.**

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Generally, our strategy is to engage pharmaceutical or other healthcare companies with an existing sales and marketing organization and distribution system to market, sell and distribute our products. We may not be able to establish these sales and distribution relationships on acceptable terms, or at all. If we receive regulatory approval to commence commercial sales of any of our product candidates that are not covered by our current agreements with GSK, Astellas or AstraZeneca, we will have to establish a sales and marketing organization with appropriate technical expertise and supporting distribution capability. At present, we have no sales personnel and a limited number of marketing personnel. Factors that may inhibit our efforts to commercialize our products without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

**If we lose key scientists or management personnel, or if we fail to recruit additional highly skilled personnel, it will impair our ability to discover, develop and commercialize product candidates.**

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We are highly dependent on principal members of our management team and scientific staff, including our Chairman of the Board of Directors, P. Roy Vagelos, our Chief Executive Officer, Rick E Winningham, our Executive Vice President of Research, Patrick P.A. Humphrey, and our Senior Vice President of Development, Michael Kitt. These executives each have significant pharmaceutical industry experience and Dr. Vagelos and Dr. Humphrey are prominent scientists. The loss of Dr. Vagelos, Mr. Winningham, Dr. Humphrey or Dr. Kitt could impair our ability to discover, develop and market new medicines.

Our scientific team has expertise in many different aspects of drug discovery and development. Our company is located in northern California, which is headquarters to many other biopharmaceutical companies and many academic and research institutions. There is currently a shortage of experienced scientists, which is likely to continue, and competition for skilled personnel in our market is very intense. Competition for experienced scientists may limit our ability to hire and retain highly qualified personnel on acceptable terms. In addition, none of our employees have employment commitments for any fixed period of time and could leave our employment at will.

If we fail to identify, attract and retain qualified personnel, we may be unable to continue our development and commercialization activities.

**Our principal facility is located near known earthquake fault zones, and the occurrence of an earthquake, extremist attack or other catastrophic disaster could cause damage to our facilities and equipment, which could require us to cease or curtail operations.**

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Our principal facility is located in the San Francisco Bay Area near known earthquake fault zones and therefore is vulnerable to damage from earthquakes. In October 1989, a major earthquake struck this area and caused significant property damage and a number of fatalities. We are also vulnerable to damage from other types of disasters, including power loss, attacks from extremist organizations, fire, floods, communications failures and similar events. If any disaster were to occur, our ability to operate our business could be seriously impaired. In addition, the unique nature of our research activities and of much of our equipment could make it difficult for us to recover from this type of disaster. We currently may not have adequate insurance to cover our losses resulting from disasters or other similar significant business interruptions and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business and financial condition.

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**Risks Related to GSK's Ownership of Our Stock**

**GSK's right to become a controlling stockholder of the Company and its right to membership on our board of directors may create conflicts of interest, and may inhibit our management's ability to continue to operate our business in the manner in which it is currently being operated.**

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As of November 1, 2006, GSK beneficially owned approximately 15.7% of our outstanding capital stock. In addition, GSK has certain rights to maintain its percentage ownership of our capital stock in the future, and in 2007, GSK may exercise its call right to acquire additional shares and thereby increase its ownership up to approximately 59.4% of our then outstanding capital stock. If GSK exercises this call right, or a sufficient number of our stockholders exercise the put right provided for in our certificate of incorporation, GSK could own a majority of our capital stock. In addition, GSK currently has the right to designate one member to our board of directors and, depending on GSK's ownership percentage of our capital stock after September 2007, GSK will have the right to nominate up to one-third of the members of our board of directors and up to one-half of the independent members of our board of directors. There are currently no GSK designated directors on our board of directors. GSK's control relationship could give rise to conflicts of interest, including:

- conflicts between GSK, as our controlling stockholder, and our other stockholders, whose interests may differ with respect to our strategic direction or significant corporate transactions; and
- conflicts related to corporate opportunities that could be pursued by us, on the one hand, or by GSK, on the other hand.

Further, pursuant to our certificate of incorporation, we renounce our interest in and waive any claim that a corporate or business opportunity taken by GSK constituted a corporate opportunity of ours unless such corporate or business opportunity is expressly offered to one of our directors who is a director, officer or employee of GSK, primarily in his or her capacity as one of our directors.

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

Our governance agreement with GSK requires us to exempt GSK from our stockholder rights plan, affords GSK certain rights to offer to acquire us in the event third parties seek to acquire our stock and contains other provisions that could deter or prevent another company from seeking to acquire us. For example, GSK may offer to acquire 100% of our outstanding stock from stockholders in certain circumstances, such as if we are faced with a hostile acquisition offer or if our board of directors acts in a manner to facilitate a change in control of us with a party other than GSK. In addition, pursuant to our strategic alliance agreement with GSK, GSK has the right to license all of our current and future drug discovery and development programs initiated prior to September 1, 2007 or, if GSK acquires more than 50% of our stock in 2007, prior to September 1, 2012. As a result, we may not have the opportunity to be acquired in a transaction that stockholders might otherwise deem favorable, including transactions in which our stockholders might realize a substantial premium for their shares.

**Our governance agreement with GSK limits our ability to raise debt and equity financing, undertake strategic acquisitions or dispositions and take certain other actions, which could significantly constrain and impair our business and operations.**

Our governance agreement with GSK limits the number of shares of capital stock that we may issue and the amount of debt that we may incur. Prior to the termination of the call and put arrangements with GSK in 2007, without the prior written consent of GSK, we may not issue any equity securities if it would cause more than approximately 54.2 million shares of common stock, or securities that are vested and exercisable or convertible into shares of common stock, to be outstanding as of the put date. Until the expiration of the put and call provisions with GSK, we will be contractually prohibited from selling significant additional equity securities to raise capital. In addition:

- If, on or immediately after the termination of the call and put arrangements with GSK in 2007, GSK directly or indirectly controls more than 35.1% of our outstanding capital stock, then without the prior written consent of GSK, we may not issue more than an aggregate of approximately 16.1 million shares of our capital stock after September 1, 2007 through August 2012; and
- Prior to the termination of the call and put arrangements with GSK in 2007, we may not borrow money or otherwise incur indebtedness of more than \$100.0 million or if such indebtedness would cause our consolidated debt to exceed our cash, cash equivalents and marketable securities.

These limits on issuing equity and debt could leave us without adequate financial resources to fund our discovery

and development efforts if GSK does not license additional development programs pursuant to our strategic alliance agreement, if we do not enter into alliances with third parties on similar or better terms for these programs, or if we do not earn any of the potentially significant milestones in the programs that we have currently partnered with GSK and Astellas.

These events could result in a reduction of our discovery and development efforts or could result in our having to enter into collaborations with other companies that could require us to share commercial rights to our medicines to a greater extent than we currently intend. In addition, if GSK's ownership of our capital stock exceeds 50% as a result of the call and put arrangements, we will be prohibited from engaging in certain acquisitions, the disposition of material assets or repurchase of our outstanding stock without GSK's consent. These restrictions could cause us to forego transactions that would otherwise be advantageous to us and our other stockholders.

**The market price of our common stock is not guaranteed, and could be adversely affected by the put and call arrangements with GSK.**

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In 2007, GSK has the right to require us to redeem 50% of our outstanding common stock for \$54.25 per share, and, if GSK does not exercise this right, our stockholders will have the right to cause us to redeem up to the same number of shares for \$19.375 per share. The existence of the call feature on 50% of our common stock at a fixed price of \$54.25 may act as a material impediment to our common stock trading above the \$54.25 per share call price. If the call is exercised, our stockholders would participate in valuations above \$54.25 per share only with respect to 50% of their shares. Therefore, even if our common stock trades above \$54.25 per share, 50% of each stockholder's shares could be called at \$54.25 per share. Similarly, because the put applies to only 50% of our common stock and is not exercisable prior to 2007, it is uncertain what effect the put will have on our stock price. Prior to the expiration of the put period, the price at which our common stock will trade may be influenced by the put right. Therefore, after the expiration of the put period, the market price of the common stock may decline significantly. In addition, while GSK is generally prevented from making any unsolicited tender offer for our common stock, any announcement by GSK that it does not intend to exercise the call or any offer GSK may make to our board of directors on terms less favorable than the call right described above could adversely affect our common stock price.

**After September 12, 2012, GSK could sell or transfer a substantial number of shares of our common stock, which could depress our stock price or result in a change in control of our company.**

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After September 12, 2012, GSK will have no restrictions on its ability to sell or transfer our common stock on the open market, in privately negotiated transactions or otherwise, and these sales or transfers could create substantial declines in the price of the outstanding shares of our common stock or, if these sales or transfers were made to a single buyer or group of buyers, could transfer control of our company to a third party.

As a result of the call and put arrangements with GSK, there are uncertainties with respect to various tax consequences associated with owning and disposing of shares of our common stock. Therefore, there is a risk that owning and/or disposing of our common stock may result in certain adverse tax consequences to our stockholders.

Due to a lack of definitive judicial and administrative interpretation, uncertainties exist with respect to various tax consequences resulting from the ownership of our common stock. These include:

- In the event we pay or are deemed to have paid dividends prior to the exercise and/or lapse of the put and call rights, individual stockholders may be required to pay tax on such dividends at ordinary income rates rather than capital gains rates, and corporate stockholders may be prevented from obtaining a dividends received deduction with respect to such dividend income;
- In the event that a common stockholder's put right were considered to be a property right separate from the common stock, such stockholder may be subject to limitations on recognition of losses and certain other adverse consequences with respect to the common stock and the put right (including the tolling of its capital gains holding period);
- The application of certain actual and constructive ownership rules could cause the redemption of our common stock to give rise to ordinary income and not to capital gain;
- A redemption of our common stock may be treated as a recapitalization pursuant to which a stockholder exchanges shares of common stock for cash and shares of new common stock not subject to call and put rights, in which case the stockholder whose shares were redeemed would be required to recognize gain, but not loss, in connection with this deemed recapitalization in an amount up to the entire amount of cash received (which gain may be taxed as

ordinary income and not capital gain); and

- The put right could prevent a stockholder's capital gain holding period for our common stock from running and thereby prevent a stockholder from obtaining long-term capital gain on any gain recognized on the disposition of the common stock.

**Risks Related to Legal and Regulatory Uncertainty**



**If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.**

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

We rely upon a combination of patents, patent applications, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any involuntary disclosure to or misappropriation by third parties of this proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. The status of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and is very uncertain. As of September 30, 2006, we had 82 issued United States patents and have received notices of allowance for 9 other United States patent applications. As of that date, we had 94 pending patent applications in the United States and 293 granted foreign patents. We also have 24 Patent Cooperation Treaty applications that permit us to pursue patents outside of the United States, and 621 foreign national patent applications. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be too narrow to prevent third parties from developing or designing around these patents. If the sufficiency of the breadth or strength of protection provided by our patents with respect to a product candidate is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, the product candidate. Further, if we encounter delays in our clinical trials, the patent lives of the related drug candidates would be reduced.

In addition, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, for processes for which patents are difficult to enforce and for any other elements of our drug discovery and development processes that involve proprietary know-how, information and technology that is not covered by patent applications. Although we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or, if established, maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition and results of operations.

**Litigation or third-party claims of intellectual property infringement would require us to divert resources and may prevent or delay our drug discovery and development efforts.**

Our commercial success depends in part on our not infringing the patents and proprietary rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization. There are third party patents that may cover materials or methods for treatment related to our product candidates. At present we are not aware of any patent claims with merit that would adversely and materially affect our ability to develop our product candidates, but nevertheless the possibility of third party allegations cannot be ruled out. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Furthermore, parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties or pay royalties. In addition, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. In addition, in the future we could be required to initiate litigation to enforce our proprietary rights against infringement by third parties. Prosecution of these claims to enforce our rights against others would involve substantial litigation expenses and divert substantial employee resources from our business. If we fail to effectively enforce our proprietary rights against others, our business will be harmed.

**Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our medicines.**

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The risk that we may be sued on product liability claims is inherent in the development of pharmaceutical products. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forgo further commercialization of those products.

Although we maintain general liability and product liability insurance, this insurance may not fully cover potential liabilities. In addition, inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercial production and sale of our products, which could adversely affect our business.

**Government restrictions on pricing and reimbursement, as well as other healthcare payor cost-containment initiatives, may negatively impact our ability to generate revenues.**

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The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care may adversely affect one or more of the following:

- our ability to set a price we believe is fair for our potential medicines;
- our ability to generate revenues and achieve profitability; and
- the availability of capital.

In the United States, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the MMA ) will likely result in decreased reimbursement for prescription drugs, which may intensify industry-wide pressure to reduce prescription drug prices. This could harm our ability to market our potential medicines and generate revenues. The MMA, associated cost containment measures that health care payors and providers are instituting, and the effect of probable further health care reform could significantly reduce potential revenues from the sale of any product candidates approved in the future. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable. We believe that U.S. and international pricing pressures will continue and may increase, which may make it difficult for us to sell our potential medicines that may be approved in the future at a price acceptable to us or our collaborators.

**If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.**

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Our research and development activities involve the controlled use of potentially hazardous substances, including chemical, biological and radioactive materials. In addition, our operations produce hazardous waste products. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. Although we believe that our procedures for use, handling, storing and disposing of these materials comply with legally prescribed standards, we may incur significant additional costs to comply with applicable laws in the future. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business.

### **General Company Related Risks**

**Our stock price may be extremely volatile and purchasers of our common stock could incur substantial losses.**



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

Our stock price may be extremely volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The following factors, in addition to the other risk factors described in this section, may also have a significant impact on the market price of our common stock:

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- the extent to which GSK advances (or does not advance) our product candidates through development into commercialization, in particular any delay in the completion of the Phase 2b program in the Beyond Advair collaboration;
- any delay in filing our NDA for telavancin and any adverse development or perceived adverse development with respect to the FDA's review of the NDA, including without limitation the FDA's issuance of a refusal to file letter or a request for additional information;
- any adverse developments or results or perceived adverse developments or results with respect to our telavancin Phase 3 clinical studies;
- any adverse developments or results or perceived adverse developments or results with respect to any product candidates in the Beyond Advair collaboration;
- any adverse developments or results or perceived adverse developments or results with respect to our GI program or our heterodimer program;
- GSK's call right in 2007 for 50% of our common stock at \$54.25 per share;
- the put right and the expiration of the put right in 2007;
- announcements regarding GSK's decisions whether or not to license any of our product development programs;
- announcements regarding GSK or Astellas generally;
- announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors;
- developments concerning any collaboration we may undertake with companies other than GSK or Astellas;
- publicity regarding actual or potential testing or study results or the outcome of regulatory review relating to products under development by us, our partners or by our competitors;
- regulatory developments in the United States and foreign countries; and
- economic and other external factors beyond our control.

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

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

As of November 1, 2006, GSK beneficially owned approximately 15.7% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 13.7% of our outstanding capital stock. These stockholders could substantially control the outcome of actions taken by us that require stockholder approval. In addition, pursuant to our governance agreement with GSK, GSK currently has the right to nominate a director and beginning in September 2007 will have the right to nominate a certain number of directors depending on GSK's ownership percentage of our capital stock at the time. For these reasons, GSK could have substantial influence in the election of our directors, delay or prevent a transaction in which stockholders might receive a premium over the prevailing market price for their shares and have significant control over changes in our management or business.

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

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

- requiring supermajority stockholder voting to effect certain amendments to our certificate of incorporation and bylaws;
- restricting the ability of stockholders to call special meetings of stockholders;
- prohibiting stockholder action by written consent; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

In addition, our board of directors has adopted a rights agreement that may prevent or delay a change in control of us. Further, some provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

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**Item 6. Exhibits**

**Exhibit**

<b>Number</b>	<b>Exhibit Description</b>
3.3(1)	Amended and Restated Certificate of Incorporation
3.5(1)	Amended and Restated Bylaws
4.1(1)	Specimen certificate representing the common stock of the registrant
4.2(2)	Rights Agreement dated October 8, 2004
10.37+	Amendment to License, Development and Commercialization Agreement between the Company and Astellas Pharma Inc. dated as of July 18, 2006
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended
32	Certifications Pursuant to 18 U.S.C. Section 1350

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(1) Incorporated herein by reference to the exhibit of the same number in the Company's Registration Statement on Form S-1 (Commission File No. 333-116384).

(2) Incorporated herein by reference to the exhibit of the same number in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004.

+ Confidential treatment has been requested for certain portions which are omitted in the copy of the exhibit electronically filed with the Securities and Exchange Commission. The omitted information has been filed separately with the Securities and Exchange Commission pursuant to the Company's application for confidential treatment.

**SIGNATURES**

Pursuant to the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Theravance, Inc.  
(Registrant)

November 6, 2006  
Date

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

November 6, 2006  
Date

/s/ Michael W. Aguiar  
Michael W. Aguiar  
Senior Vice President, Finance  
and Chief Financial Officer

Exhibit Index

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32	Certifications Pursuant to 18 U.S.C. Section 1350

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(1) Incorporated herein by reference to the exhibit of the same number in the Company's Registration Statement on Form S-1 (Commission File No. 333-116384).

(2) Incorporated herein by reference to the exhibit of the same number in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004.

+ Confidential treatment has been requested for certain portions which are omitted in the copy of the exhibit electronically filed with the Securities and Exchange Commission. The omitted information has been filed separately with the Securities and Exchange Commission pursuant to the Company's application for confidential treatment.