

THERAVANCE INC
Form 10-Q
November 14, 2005

**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, 2005

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)

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(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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes No

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 3, 2005 was 53,775,838.

The number of shares of registrant's Class A common stock outstanding on November 3, 2005 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, 2005 (Unaudited)	December 31, 2004 *
Assets		
Current assets:		
Cash and cash equivalents	\$ 22,359	\$ 101,411
Marketable securities	149,964	155,730
Receivable from related party	953	2,124
Prepaid and other current assets	3,735	5,203
Total current assets	177,011	264,468
Property and equipment, net	13,062	13,242
Restricted cash and cash equivalents	3,860	4,537
Deferred sublease costs	357	545
Notes receivable	2,592	2,989
Notes receivable from related parties		64
Other assets	106	177
Total assets	\$ 196,988	\$ 286,022
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	\$ 7,781	\$ 5,925
Accrued personnel-related expenses	7,828	7,615
Accrued clinical and development expenses	9,769	5,579
Other accrued liabilities	1,966	2,338
Current portion of notes payable	67	262
Current portion of capital lease obligations	995	2,359
Current portion of deferred revenue	12,021	10,959
Total current liabilities	40,427	35,037
Deferred rent	2,669	2,500
Notes payable	656	706
Capital lease obligations	458	1,073
Deferred revenue	54,601	56,339
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, issuable in series; 44,268 and 43,522 shares issued and outstanding at September 30, 2005 and December 31, 2004, respectively	442	435
Class A Common Stock, \$0.01 par value; 30,000 shares authorized, 9,402 issued and outstanding at September 30, 2005 and December 31, 2004, respectively	94	94
Additional paid-in capital	674,109	669,698
Notes receivable from stockholders	(27)	(495)
Deferred stock-based compensation	(6,255)	(10,079)
Accumulated other comprehensive loss	(629)	(682)

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Accumulated deficit	(569,557)	(468,604)
Total stockholders' equity	98,177	190,367
Total liabilities and stockholders' equity	\$ 196,988	\$ 286,022

**Condensed consolidated balance sheet at December 31, 2004 has been derived from audited financial statements.*

See accompanying notes to condensed consolidated financial statements.

THERAVANCE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Revenue from related party	\$ 3,006	\$ 2,637	\$ 8,676	\$ 6,200
Operating expenses:				
Research and development	36,249	20,411	93,654	59,694
General and administrative	5,042	3,255	16,732	15,959
Stock-based compensation*	1,092	2,292	3,934	6,160
Total operating expenses	42,383	25,958	114,320	81,813
Loss from operations	(39,377)	(23,321)	(105,644)	(75,613)
Interest and other income	1,716	1,243	5,153	2,762
Interest expense	(125)	(209)	(462)	(632)
Net loss	\$ (37,786)	\$ (22,287)	(100,953)	\$ (73,483)
Basic and diluted net loss per common share	\$ (0.71)	\$ (0.49)	\$ (1.90)	\$ (2.71)
Shares used in computing net loss per common share	53,416	45,123	53,155	27,097

* Stock-based compensation, consisting of amortization of deferred stock-based compensation and the value of options issued to non-employees for services rendered, is allocated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Research and development	\$ 785	\$ 1,395	\$ 2,466	\$ 3,180
General and administrative	307	897	1,468	2,980
Total non-cash stock-based compensation	\$ 1,092	\$ 2,292	\$ 3,934	\$ 6,160

See accompanying notes to condensed consolidated financial statements.

THERAVANCE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2005	2004
Cash flows (used in) provided by operating activities		
Net loss	\$ (100,953)	\$ (73,483)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,092	3,626
Stock-based compensation	3,934	6,160
Forgiveness of notes receivable	145	4,228
Other non-cash operating expenses	312	(415)
Changes in operating assets and liabilities:		
Receivables, prepaid and other current assets	2,593	(322)
Accounts payable and accrued liabilities	5,594	1,850
Accrued personnel-related expenses	213	1,352
Deferred rent	169	205
Deferred revenue	(676)	33,800
Net cash used in operating activities	(85,577)	(22,999)
Cash flows provided by investing activities		
Purchases of property and equipment	(2,639)	(1,401)
Purchases of marketable securities	(103,783)	(122,086)
Sales and maturities of marketable securities	109,602	38,931
Restricted cash and cash equivalents	677	1,201
Additions to notes receivable	(160)	(701)
Decrease in notes receivable	507	3,897
Net cash provided by (used in) investing activities	4,204	(80,159)
Cash flows used in financing activities		
Payments on notes payable and capital leases	(2,224)	(2,450)
Net proceeds from issuances of convertible preferred stock		175
Net proceeds from issuances of common stock	4,545	107,689
Net cash provided by financing activities	2,321	105,414
Net (decrease) increase in cash and cash equivalents	(79,052)	2,256
Cash and cash equivalents at beginning of period	101,411	35,748
Cash and cash equivalents at end of period	\$ 22,359	\$ 38,004
Supplemental Disclosures of Cash Flow Information		
Cash paid for interest	\$ 258	\$ 475
Non-cash investing and financing activities:		
Conversion of convertible preferred stock to common stock	\$	\$ 367,533
Repurchases/issuances of common stock for notes receivable	\$	\$ 11
Addition to deferred stock-based compensation	\$ 896	\$ 19,455

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, 2005, and the results of operations and cash flows for the three and nine months ended September 30, 2005 and 2004. The results for the three and nine months ended September 30, 2005 are not necessarily indicative of the results of operations to be expected for the year ending December 31, 2005.

The condensed consolidated balance sheet at December 31, 2004 has been derived from audited consolidated financial statements, which are contained in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 29, 2005. The accompanying condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2004.

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 our current assumptions. This may result in our estimates being incorrect and may require us to record additional charges or benefits in operations.

Reverse Stock Split

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On September 27, 2004, the Company effected a one for 1.55 reverse stock split of the Company's Common Stock and Class A Common Stock. All historical common share and per common share information has been changed to reflect this reverse stock split.

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.

Fair value of employee stock options

For purposes of disclosures pursuant to Statement of Financial Accounting Standards No. 123 (SFAS No. 123), as amended by SFAS No. 148, the estimated fair value of stock based employee compensation is amortized to expense over the vesting period of the options using the accelerated expense attribution method. 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 No. 123 had been applied to stock based employee compensation (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net loss, as reported	\$ (37,786)	\$ (22,287)	\$ (100,953)	\$ (73,483)
Add: Employee stock-based compensation calculated using the intrinsic value method	776	2,136	3,315	5,699
Less: Total employee stock compensation calculated using the fair value method	(3,386)	(3,008)	(12,555)	(9,521)
Pro forma net loss	\$ (40,396)	\$ (23,159)	\$ 110,193	\$ (77,305)
Net loss per common share, as reported	\$ (0.71)	\$ (0.49)	\$ (1.90)	\$ (2.71)
Pro forma net loss common per share	\$ (0.76)	\$ (0.51)	\$ (2.07)	\$ (2.85)

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 Black-Scholes method. As the Company's common stock has only recently become publicly traded, 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, 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 2005 initial public offering. As a result, it is likely that this valuation input will be revised downward as more historical data on stock price volatility becomes available. This revision would have the impact of reducing the value of the stock options. The Company will continue to evaluate its assumptions as additional historical data regarding volatility of the Company's stock and expected lives of its employee stock options becomes available. The weighted-average assumptions used to value employee stock based compensation for stock options granted and employee stock purchase plan issuances during the periods were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Employee stock options				
Risk-free interest rate	3.91%	4.08%	3.10%	3.54%
Expected life (in years)	4	4	5	3
Volatility	0.7	0.7	0.7	0.7
Weighted average estimated fair value of stock options granted	\$ 8.90	\$ 10.02	\$ 8.73	\$ 9.79
Employee stock purchase plan issuances				
Risk-free interest rate	2.58%	3.64%	2.58%	3.64%
Expected life (in years)	2	2	2	2
Volatility	0.7	0.7	0.7	0.7
Weighted average estimated fair value of ESPP issuances	\$ 8.81	\$ 8.81	\$ 8.81	\$ 8.81

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.

Recent Accounting Pronouncements

In June 2004, the Financial Accounting Standards Board (FASB) ratified Emerging Issues Task Force Issue No. 03-1 (EITF 03-1), *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*. EITF 03-1 includes new guidance for evaluating and recording impairment losses on debt and equity investments, as well as new disclosure requirements for investments that are deemed to be temporarily impaired. In September 2004, the Financial Accounting Standards Board approved the issuance of a FASB Staff Position to delay the recognition and measurement provisions of EITF 03-1. In June 2005, the FASB decided not to provide additional guidance on the meaning of other-than-temporary impairment under EITF 03-1. The FASB directed the staff to issue FASB Staff Position Paper (FSP) 115-1, *The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments (FSP 115-1)*, superseding EITF 03-1. FSP 115-1 will replace the accounting guidance on the determination of whether an investment is other-than-temporarily impaired as set forth in EITF 03-1 with references to existing other-than-temporary impairment guidance. FSP 115-1 will be effective for other-than-temporary impairment analysis conducted in periods beginning after December 15, 2005. The Company will evaluate the impact of FSP 115-1 on the Company's consolidated financial statements once the final guidance is issued.

On December 16, 2004, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 123 (revised 2004) (SFAS 123(R)), *Share-Based Payment*, which is a revision of SFAS 123. SFAS 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS 123(R) is similar to the approach described in SFAS 123. However, SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options and employee stock purchase plans, to be recognized in the statement of operations based on their fair values. Pro forma disclosure is no longer an alternative. On April 14, 2005, the SEC adopted a new rule deferring the required compliance dates for SFAS 123(R). In accordance with the new SEC rule, the accounting provisions of SFAS 123(R) will be effective for the Company for the annual period beginning January 1, 2006.

The Company is evaluating the requirements of SFAS 123(R) and expects that the adoption of SFAS 123(R) will have a material impact on the Company's consolidated results of operations and net loss per share, although it will have no impact on its overall financial position. The impact of adoption of Statement 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had the Company adopted Statement 123(R) in prior periods, the Company believes the impact of that standard would have approximated the impact of Statement 123 as described earlier, in the disclosure of pro forma net loss and net loss per share in Note 1 of our notes to our condensed consolidated financial statements.

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, 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. At September 30, 2004, potential common shares consist of 300,000 shares subject to repurchase, 8,865,000 shares issuable upon the exercise of stock options and 65,000 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 September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Basic and diluted:				
Net Loss	\$ (37,786)	\$ (22,287)	\$ (100,953)	\$ (73,483)
Weighted average shares of common stock outstanding	53,649	45,457	53,404	27,444
Less: weighted average shares subject to repurchase	(233)	(333)	(249)	(347)
Weighted average shares used in computing basic and diluted net loss per common share	53,416	45,123	53,155	27,097
Basic and diluted net loss per common share	\$ (0.71)	\$ (0.49)	\$ (1.90)	\$ (2.71)

3. Agreements with GlaxoSmithKline

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, 2005, the Company received upfront and milestone payments of \$55.0 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 \$1.9 million and \$1.9 million for the three months ended September 30, 2005 and 2004, respectively, and \$5.7 million and \$5.1 million for the nine months ended September 30, 2005 and 2004, 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, the Company accrued reimbursements of \$0.1 million and \$0.3 million for the three and nine months ended September 30, 2004, respectively, as an offset to research and development expense for certain costs related to the collaboration that were reimbursable by GSK. Costs related to the collaboration, reimbursable by GSK, recorded for the three and nine months ended September 30, 2005 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 our programs under the agreement, which is currently estimated to be approximately seven and one-half years. The Company recognized \$0.7 million and \$0.8 million in revenue for the three months ended September 30, 2005 and 2004, respectively, and \$2.1 million and \$1.1 million for the nine months ended September 30, 2005 and 2004, respectively.

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 \$0.7 million in revenue related to the LAMA program for the three and nine months ended September 30, 2005, respectively. Additionally, the Company accrued reimbursements of \$0.1 million and \$1.4 million for the three months ended September 30, 2005 and 2004, respectively, and \$0.5 and \$1.4 million for the nine months ended September 2005 and 2004, respectively, as an offset to research and development expense for certain costs related to the LAMA program that were reimbursable by GSK.

In March 2005, GSK informed the Company of its decision to exercise 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. This payment is 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 \$0.2 million and \$0.3 million in revenue related to the MABA program for the three and nine months ended September 30, 2005, respectively. Additionally, the Company accrued reimbursements of \$0.1 million and \$2.5 million for the three and nine months ended September 30, 2005, respectively as an offset to research and development expense for certain costs related to the MABA program that were reimbursable by GSK.

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, 2005:

(in thousands)	September 30, 2005			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. government agencies	\$ 75,695	\$	\$ (417)	\$ 75,278
U.S. corporate notes	41,665		(59)	41,606
U.S. commercial paper	17,628			17,628
Asset-backed securities	35,633	1	(154)	35,480
Certificates of deposit	110			110
Money market funds	6,081			6,081
Total	176,812	1	(630)	176,183
Less amounts classified as cash and cash equivalents	(22,359)			(22,359)
Less amounts classified as restricted cash	(3,860)			(3,860)
Amounts classified as marketable securities	\$ 150,593	\$ 1	\$ (630)	149,964

The estimated fair value amounts have been determined by the Company using available market information. At September 30, 2005, approximately 60% of marketable securities mature within twelve months, and 23% of marketable securities mature between twelve and twenty-four months. The remaining 16% are asset-backed securities with effective maturities beyond 24 months. Average duration of available-for-sale securities was approximately four months at September 30, 2005.

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,	
	2005	2004	2005	2004
Net Loss	\$ (37,786)	\$ (22,287)	\$ (100,953)	\$ (73,483)
Other comprehensive income (loss):				
Net unrealized (loss) gain on available-for-sale securities	(122)	43	53	(225)
Comprehensive loss	\$ (37,908)	\$ (22,244)	\$ (100,900)	\$ (73,708)

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, 2005.

Purchase Obligations

At September 30, 2005, 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 had 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). At September 30, 2005, 78,837 shares were subject to repurchase under these outstanding note agreements.

During the nine months ended September 30, 2005, the Company issued 546,915 shares of common stock resulting from the exercise of stock options and warrants and received \$2.8 million in proceeds therefrom.

Through September 30, 2005, in connection with the grant of certain stock options to employees under the 2004 Equity Incentive Plan, 1997 Stock Plan and the Long-term Stock Option Plan, the Company recorded aggregate deferred stock-based compensation of \$58.1 million and amortized \$44.5 million as non-cash stock-based compensation expense, of which \$0.8 million and \$3.4 million of employee stock-based compensation expense was recorded for the three and nine months ended September 30, 2005. Deferred stock-based compensation represents the difference between the exercise price and the estimated fair value of the Company's common stock on the date these stock options were granted. The Company recognizes compensation expense for fixed awards in accordance with the accelerated expense attribution method under FIN No. 28, Accounting for Stock Appreciation Rights and Other Variable Stock Option Award Plans.

Employee Stock Purchase Plan

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In May 2005, the Company issued 92,972 shares under its 2004 Employee Stock Purchase Plan. On June 30, 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. The total number of remaining shares available for issuance under the plan as of September 30, 2005 was 532,028.

Restricted Stock

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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 a component of stockholders' equity and is being amortized over the service period. The value of the restricted stock award was based on the closing market price of the Company's common stock of \$17.91 on the date of award. Stock based compensation expense related to this award of \$0.1 million and \$0.2 million was recorded for the three and nine months ended September 30, 2005.

Director Compensation Program

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On June 30, 2005, pursuant to a director compensation program previously approved by the Compensation Committee of the Board of Directors, each of the Company's eight outside directors was granted an option to purchase 12,903 shares of common stock with an exercise price of \$17.00, which was the then fair market value of the Company's common stock.

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 \$0.5 million and \$2.6 million were incurred in the ordinary course of business in the nine months ended September 30, 2005 and 2004, respectively.

Notes Receivable

The Company has provided loans to certain of its officers and 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 (Deficit) 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 \$30,000 and \$0.2 million at September 30, 2005 and December 31, 2004, respectively, and is included in other assets. The Company accrues interest on the notes at rates ranging up to 10.5%. The outstanding loans have maturity dates ranging from November 2005 through 2014.

9. Subsequent Event

On November 7, 2005 the Company entered into a License, Development and Commercialization Agreement with Astellas Pharma Inc. for the development and commercialization of the Company's investigational antibiotic, telavancin. In accordance with the terms of the agreement, upon closing, the Company will receive an upfront payment of \$65.0 million and will be eligible to receive clinical and regulatory milestone payments of up to \$156.0 million. In addition, the Company is entitled to receive royalties on global sales of telavancin, which on a percent basis, range from the high teens to the upper twenties. The closing of this transaction is contingent upon regulatory clearance under the Hart-Scott-Rodino Antitrust Improvements Act.

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, will, would and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. 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 the subsections entitled Liquidity and Capital Resources and Factors Affecting Results, Including Risks and Uncertainties. 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. Of our five programs in development, two are in late stage telavancin and the Beyond Advair collaboration with GSK. 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 disorders. 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, 2005, we had an accumulated deficit of \$569.6 million. None of our products 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.

The net loss for the three months ended September 30, 2005 was \$37.8 million compared to \$22.3 million during the same period of 2004, an increase of \$15.5 million. The increase was primarily due to higher research and development costs associated with telavancin Phase 3 clinical programs. Research and development spending for the three months ended September 30, 2005 increased to \$36.2 million compared to \$20.4 million for the same period of 2004. This increase was primarily driven by higher external research and development costs associated with Phase 3 telavancin clinical studies and Phase 1 clinical studies for the overactive bladder and gastrointestinal (GI) motility programs. Cash, cash equivalents, and short-term investments totaled \$172.3 million at the end of the third quarter 2005, a decrease of \$30.1 million during the third quarter 2005 and \$84.8 million since December 31, 2004.

Following are recent progress updates with certain of our development programs:

Telavancin

Telavancin is a rapidly bactericidal injectable antibiotic with a unique multifunctional mechanism of action that targets serious Gram-positive infections including drug-resistant *Staphylococcus aureus* strains. It is currently in two Phase 3 programs for the treatment of patients with skin structure infections (cSSSI) and hospital acquired pneumonia (HAP) infections due to Gram-positive bacteria.

Enrollment in the Phase 3 studies for the treatment of patients with complicated skin and skin structure infections cSSSI and hospital acquired pneumonia HAP infections due to Gram-positive bacteria are progressing according to our expectations and previous guidance.

Enrollment in our Phase 3 cSSSI and HAP studies are anticipated to be completed during the first half of 2006 and the second half of 2006, respectively.

Beyond Advair

Beyond Advair is a collaboration with GSK to develop and commercialize product candidates for the treatment of asthma and COPD. There are eight product candidates in the Beyond Advair collaboration, four contributed by Theravance and four contributed by GSK. Five of the eight product candidates have reached Phase 2a.

Phase 2b study initiation for compound GSK 159797 will not occur by the end of the year due to potential issues associated with the formulation. The Company is currently evaluating the issues associated with the formulation and the impact it will have on the projected timing for initiation of this study.

Compound GSK 642444 was moved into a multiple dose Phase 2a study in a dry powder inhaler (DPI) formulation. This Phase 2a study will assess the safety and efficacy of this compound in mild-to-moderate asthmatics, using a DPI formulation.

For Compound GSK 159802, we have recently begun enrolling patients in a single dose Phase 2a study in a DPI formulation. A multiple dose Phase 2a study is planned to further assess the safety and efficacy of this compound in mild-to-moderate asthmatics in 2006.

Overactive Bladder

We recently decided to terminate our overactive bladder program based upon the results of Phase 1 studies with the compound TD-6301.

We anticipate that research and development expenses will increase significantly, in particular, due to our two telavancin Phase 3 programs. These Phase 3 clinical programs will increase our research and development expenses significantly through at least 2006. Also we may experience higher spending on other programs to the extent that we enter later-stage clinical studies for our product candidates currently in Phase 1, and as we advance the development of our other product candidates. Depending on the timing and structure of any corporate collaborations, increases in spending may be partially offset by reimbursements or assumption of development costs by corporate partners.

We currently expect to continue to use the total net proceeds of our initial public offering to partially fund our telavancin Phase 3 clinical programs.

Critical Accounting Policies

As of the date of the filing of this quarterly report, we have not identified any critical accounting policies other than those discussed in our Annual Report on Form 10-K filed on March 29, 2005, and there have been no changes to the policies discussed therein.

Agreements with GlaxoSmithKline

2002 Beyond Advair Collaboration

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In November 2002, we entered into a collaboration agreement with GSK to develop and commercialize product candidates for the treatment of asthma and COPD. Each company contributed four LABA product candidates to the collaboration. Through September 30, 2005, we received upfront and milestone payments from GSK of \$55.0 million in connection with the collaboration.

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 \$1.9 million and \$1.9 million for the three months ended September 30, 2005 and 2004, respectively, and \$5.7 million and \$5.1 million for the nine months ended September 30, 2005 and 2004, 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, we accrued reimbursements of \$0.1 million and \$0.3 million for the three and nine months ended September 30, 2004, respectively, as an offset to research and development expense for certain costs related to the collaboration that were reimbursable by GSK. Costs related to the collaboration, reimbursable by GSK, recorded for the three and nine months ended September 30, 2005 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. We recognized \$0.7 million and \$0.8 million in revenue for the three months ended September 30, 2005 and 2004, respectively, and \$2.1 million and \$1.1 million for the nine months ended September 30, 2005 and 2004, respectively.

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, 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. We recognized \$0.3 million and \$0.7 million in revenue related to the LAMA program for the three and nine months ended September 30, 2005, respectively. Additionally, the Company accrued reimbursements of \$0.1 million and \$1.4 million for the three months ended September 30, 2005 and 2004, respectively, and \$0.5 and \$1.4 million for the nine months ended September 30, 2005 and 2004, respectively, as an offset to research and development expense for certain costs related to the LAMA program that were reimbursable by GSK.

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 received a \$5.0 million payment from GSK in connection with the license of our MABA program. This payment is 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 \$0.2 million and \$0.3 million in revenue related to the MABA program for the three and nine months ended September 30, 2005, respectively. Additionally, we accrued reimbursements of \$0.1 million and \$2.5 million for the three and nine months ended September 30, 2005, respectively, as an offset to research and development expense for certain costs related to the MABA program that were reimbursable by GSK.

RESULTS OF OPERATIONS

Revenue We recognized revenue of \$3.0 million and \$8.7 million for the three and nine months ended September 30, 2005, respectively, and \$2.6 million and \$6.2 million for the three and nine months ended September 30, 2004, respectively. This revenue was due entirely to the amortization of upfront and milestone payments from GSK related to our Beyond Advair collaboration and strategic alliance agreements. Following are the upfront and milestone payments received from GSK under the Beyond Advair collaboration and strategic alliance agreements through September 30, 2005 (in millions).

Agreements/Programs	GSK Signed Agreement/Licensed Program	End of Estimated Development Period	Upfront and Milestone Payments
Beyond Advair collaboration	2002	2010	\$ 55.0
Strategic alliance execution	2004	2011	20.0
Strategic alliance LAMA	2004	2011	8.0
Strategic alliance MABA license	2005	2013	5.0
Total			\$ 88.0

Upfront and milestone payments received from GSK under the Beyond Advair collaboration and strategic alliance agreements have been deferred and are being amortized ratably into revenue over the applicable estimated development periods. Revenue for the remainder of 2005 will be comprised of the ongoing amortization of deferred revenue that relates to the \$88.0 million of upfront and milestone payments received through September 30, 2005 under our agreements with GSK and any additional upfront or milestone payments earned under current or new agreements with GSK or other collaboration partners.

On November 7, 2005 we entered into a License, Development and Commercialization Agreement with Astellas Pharma Inc. for the development and commercialization of our investigational antibiotic, telavancin. In accordance with the terms of the agreement, upon closing, we will receive an upfront payment of \$65.0 million and will be eligible to receive clinical and regulatory milestone payments of up to \$156.0 million. In addition, we are entitled to receive royalties on global sales of telavancin, which on a percent basis, range from the high teens to the upper twenties. The closing of this transaction is contingent upon regulatory clearance under the Hart-Scott-Rodino Antitrust Improvements Act.

Research and development

Research and development expenses:

(in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
External research and development	\$ 22.0	\$ 8.4	\$ 52.5	\$ 21.7
Employee-related	8.9	7.4	26.3	23.9
Facilities, depreciation and other allocated	5.3	4.6	14.9	14.1
Total research and development expenses	\$ 36.2	\$ 20.4	\$ 93.7	\$ 59.7

Total research and development expenses increased 77% and 57% for the three and nine months ended September 30, 2005, respectively, compared to the same periods in 2004. These increases were primarily the result of higher external research and development expenses and increased employee costs. The higher external development costs primarily related to preclinical and clinical services and contract manufacturing activities supporting Phase 3 clinical studies for telavancin (our lead antibiotic candidate) as well as Phase 1 clinical studies for TD-2749 (our lead gastrointestinal (GI) disorders candidate) and TD-6301 (our overactive bladder candidate), which increased by \$10.6 million and \$27.4 million compared to the three and nine months ended September 30, 2004, respectively.

We recently decided to terminate our overactive bladder program. This decision was based upon the results of Phase 1 studies of our overactive bladder candidate. We do not expect to incur significant further research and development expenses associated with this program other than costs required to close out various studies and sites.

Employee-related expenses increased \$1.5 million and increased \$2.4 million for the three and nine months ended September 30, 2005 compared to the same periods of 2004, respectively. These increases were due to generally higher salary and benefits costs in the 2005 periods partially offset by the forgiveness of an executive loan of \$1.0 million and related employee income and employment taxes of \$0.8 million in June 2004. Facilities, depreciation and other allocated expenses for the three and nine months ended September 30, 2005 were relatively unchanged from the 2004 periods.

We anticipate that research and development expenses will continue to increase substantially in 2005 and subsequent years as we increase our research and development efforts and as our existing and future product candidates proceed through preclinical studies and more costly clinical studies. In particular, we expect our external research and development expenses to increase significantly through at least 2006, driven primarily by our Phase 3 clinical programs for telavancin. Other external research and development expenses will be driven by our ongoing development efforts in gastrointestinal prokinetic studies and any additional drug discovery programs that we may move into development. 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.

General and administrative General and administrative expenses increased to \$5.0 million and \$16.7 million for the three and nine months ended September 30, 2005, respectively, from \$3.3 million and \$16.0 million for the three and nine months ended September 30, 2004, respectively. The increases of \$1.7 million and \$0.7 million were due to higher employee and facilities related expenses and telavancin pre launch marketing costs for the three and nine months ended September 30, 2005 compared with the same periods in 2004. These increases were partially offset by the forgiveness of an executive loan in June 2004 of \$3.0 million and related

employee income and employment taxes of \$3.2 million. Included in the higher employee expenses for the nine months ended September 30, 2005 was a bonus expense accrual of \$1.1 million paid to an executive.

We anticipate general and administrative expenses will increase in the remainder of 2005 and subsequent years to support our discovery and development efforts, commercial development activities and expanded operational infrastructure, including costs associated with operating as a public company, which include costs incurred to comply with the Sarbanes-Oxley Act.

Stock-based compensation Employee and non-employee stock-based compensation expense decreased to \$1.1 million and \$3.9 million for the three and nine months ended September 30, 2005, respectively, from \$2.3 million and \$6.2 million for the three and nine months ended September 30, 2004, respectively. These amounts reflect the amortization of deferred stock-based compensation, much of which was recorded in the years ended December 31, 2004 and 2003. For the nine months ended September 30, 2005 we recorded deferred stock-based compensation of \$0.9 million related to the grant of restricted stock of which \$0.2 million was amortized for the nine months ended September 30, 2005. For the three and nine months ended September 30, 2004, we recorded deferred stock-based compensation of \$2.9 million and \$19.5 million, respectively, for stock options granted in 2004 at prices below the deemed fair value on the option grant dates.

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 \$1.7 million and \$5.2 million in the three and nine months ended September 30, 2005, respectively, from \$1.2 million and \$2.8 million in the three and nine months ended September 30, 2004, respectively, due to higher cash balances following the closing of the GSK strategic alliance in May 2004 and the closing of our initial public offering in October 2004.

Interest and other expense Interest expense includes interest expense on capital lease and debt arrangements. Interest and other expense decreased to \$0.1 million and \$0.5 million in the three and nine months ended September 30, 2005, respectively, from \$0.2 million and \$0.6 million in the three and nine months ended September 30, 2004, respectively, due to declining capital lease and debt balances.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2005 and December 31, 2004, we had \$172.3 million and 257.1 million in cash, cash equivalents and marketable securities, respectively, excluding \$3.9 million and \$4.5 million in restricted cash and cash equivalents that was pledged as collateral for certain of our leased facilities and equipment.

We believe that our cash, cash equivalents and marketable securities, will be sufficient to meet our anticipated operating needs for at least the next year based upon current operating and spending assumptions. However, 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 invest in administrative infrastructure to support our expanded operations. As a result, we may need to raise additional funds more quickly if we choose to expand more rapidly than we presently anticipate, or if our operating costs exceed our expectations.

We expect to require additional capital to continue the development of our existing and future compounds and will likely seek to raise it within the next 12 months. Subject to the restrictions in our agreements with GSK, we may seek to sell additional equity or debt securities, or both, or incur indebtedness under one or more credit facilities. 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. After estimating the number of shares we will require for equity incentive plans through the termination of the call and put arrangements and excluding the impact of shares and stock options which are not subject to the call and put, we believe that we may issue up to a total of approximately 5.0 million new shares of capital stock for capital raising purposes during this period. 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 \$85.6 million and \$23.0 million for the nine months ended September 30, 2005 and 2004, respectively. The increase in cash used in operations was primarily due to an increase in research and development and general and administrative expenses and a decrease in cash payments received from GSK related to the 2004 strategic alliance.

Investing activities provided cash of \$4.2 million and used cash of \$80.2 million for the nine months ended September 30, 2005 and 2004, respectively. The increase in 2005 primarily results from an increase in proceeds from net sales and maturities of marketable securities, partially offset by an increase in capital expenditures.

Financing activities provided cash of \$2.3 million and \$105.4 million for the nine months ended September 30, 2005 and 2004, respectively. The decrease in cash provided by financing activities was primarily due to GSK's purchase of our Class A common stock in connection with the 2004 strategic alliance in May 2004.

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, 2005, 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	\$	0.2	\$	0.2	\$ 0.7
Capital lease obligations		1.0		0.5					1.5
Operating leases		6.7		12.6		12.6		9.9	41.8
Purchase obligations		4.3		1.0		0.1			5.4
Total	\$	12.1	\$	14.3	\$	12.9	\$	10.1	\$ 49.4

As security for performance of our obligations under the operating leases for our headquarters, we have issued letters of credit totaling \$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 four years.

FACTORS AFFECTING RESULTS, INCLUDING RISKS AND UNCERTAINTIES

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 are determined to be unsafe or ineffective in humans, we will not receive product revenue.**

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, we recently 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 and preclinical studies and limited clinical studies. Our most advanced product candidate, telavancin, is currently in Phase 3 clinical studies. In addition, a number of other compounds remain in the lead identification, lead optimization and preclinical 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, we will not receive product revenue.

If the 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.

The Food and Drug Administration (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 filed an NDA with the FDA or made a comparable filing 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.

Any failure or delay in commencing or completing clinical studies for our product candidates could severely harm our business.

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. To date we have not completed the clinical studies of any product candidate. The commencement and completion of clinical studies for our product candidates may be delayed by many factors, including:

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;

delays in patient enrollment, which we have experienced, and variability in the number and types of patients available for clinical studies;

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

poor effectiveness of product candidates during clinical studies;

unforeseen safety issues or side effects;

governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; and

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

It is possible that none of our product candidates will complete clinical studies in any of the markets in which we, our collaborators or licensees intend to sell those product candidates. Accordingly, we, our collaborators or licensees may not receive the regulatory approvals needed to market our product candidates. Any failure or delay in commencing or completing clinical studies or obtaining regulatory approvals for our product candidates would delay commercialization of our product candidates and severely harm our business and financial condition.

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 and increasing losses for the foreseeable future.

We have been engaged in discovering and developing compounds and product candidates since mid-1997. We have not generated any product sales revenue to date. We may never generate revenue from selling medicines or achieve profitability. As of September 30, 2005, we had an accumulated deficit of approximately \$569.6 million. We expect our research and development expenses to continue to increase as we continue to initiate new discovery programs and expand our development programs. As a result, we expect to continue to incur substantial and increasing 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 products and we could be forced to share our rights to commercialize our product candidates with third parties on terms that may not be favorable to us.

We need large amounts of capital to support our research and development efforts. If we are unable to secure capital to fund our operations we will not be able to continue our discovery and development efforts and we might have to enter into strategic collaborations that could require us to share commercial rights to our medicines to a greater extent than we currently intend. Based on our current operating plans, 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 year. We expect to 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. 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. 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 GSK does not satisfy its 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 and our strategic alliance agreement with GSK in March 2004. In connection with these agreements, we have granted to GSK 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 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.

GSK might not fulfill all of its obligations under these agreements. If GSK fails to fulfill its obligations under these agreements, we may be unable to assume the development of the product candidates covered by the agreements or enter into alternative arrangements with a third party to develop such product candidates. In addition, with the exception of product candidates in our Beyond Advair collaboration, GSK is not restricted from developing its own product candidates that compete with those licensed from us. If GSK elected to advance its own 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 GSK. We could also become involved in disputes with GSK, which could lead to delays in or termination of our development and commercialization programs and time-consuming and expensive litigation or arbitration. If GSK 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 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. To date GSK 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 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.

As of September 30, 2005, GSK beneficially owned approximately 17.5% of our outstanding capital stock, and will have the right in July 2007 to acquire up to approximately 60% of our common stock through the exercise of its call right. Other than our bacterial infections program and our anesthesia program, which GSK has not licensed 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, collaborators or consultants 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.

Although GSK has licensed our LAMA and our MABA programs, GSK has not licensed any of our other programs. 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 GSK. 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.

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.

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, our lead product candidate in our bacterial infections program. For TD-2749, our lead development compound in our gastrointestinal disorders program that we are responsible for seeing through clinical studies, we are using single sources to manufacture each of the drug substance and drug product. We have adequate supplies for the currently planned development activities for this compound, but if the supplier fails to continue to produce TD-2749 at acceptable quantity or quality levels, our future clinical studies could be delayed.

If we lose our relationships with contract research organizations, our drug development efforts could be delayed.

We are substantially dependent on third-party vendors and clinical research organizations for preclinical and clinical studies related to our drug discovery and development efforts. If we lose our relationship with any one or more of these providers, we could experience a significant delay in both identifying another comparable provider and then contracting for its services. We may be unable to retain an alternative provider on reasonable terms, if at all. Even if we locate an alternative provider, it is likely that this provider will need additional time to respond to our needs and may not provide the same type or level of service as the original provider. In addition, any clinical research organization that we retain will be subject to the FDA's regulatory requirements and similar foreign standards and we do not have control over compliance with these regulations by these providers. Consequently, if these practices and standards are not adhered to by these providers, the development and commercialization of our product candidates could be delayed, which could

severely harm our business and financial condition.

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.

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 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. In addition, in the markets that we are targeting, we expect to compete against current or future market-leading medicines.

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 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.

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

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

Generally, our strategy is to engage pharmaceutical or other healthcare companies with an existing sales and marketing organization and distribution system to market, sell and distribute our products. We may not be able to establish these sales and distribution relationships on acceptable terms, or at all. If we receive regulatory approval to commence commercial sales of any of our product candidates, other than those subject to our current or future agreements with GSK or pursuant to other strategic partnerships that we may enter into, 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.

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 pharmaceutical and 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.

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

Risks Related to 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.

As of September 30, 2005, GSK beneficially owned approximately 17.5% 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 60% 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. After estimating the number of vested and exercisable shares of common stock we will require for equity incentive plans through the termination of the call and put arrangements, we believe that we may issue up to a total of approximately 5.0 million new shares of capital stock for capital raising purposes during this period. 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. 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.

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 whether the put will have any supporting effect 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 1, 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.

After September 1, 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 our common stock were to be considered as not participating in corporate growth to any significant extent, a holder thereof may be required, during the period beginning upon such holder's acquisition of such stock and ending during the put period, to include currently in gross income a portion of the excess of \$19.375 per share over the fair market value of the stock at issuance;

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.

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. However, the status of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and is very uncertain. As of September 30, 2005, we had 57 issued United States patents and have received notices of allowance for 10 other United States patent applications. As of that date, we had 86 pending patent applications in the United States and 144 granted foreign patents. We also have 35 Patent Cooperation Treaty applications that permit us to pursue patents outside of the United States, and 473 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.

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 could 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. 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 could involve substantial litigation expenses and divert substantial employee resources from our business. If we fail to effectively enforce our proprietary rights against others, our business will be harmed.

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

The risk that we may be sued on product liability claims is inherent in the development of pharmaceutical products. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forgo further commercialization of those products. Although we maintain general liability and product liability insurance, this insurance may not fully cover potential liabilities. In addition, inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercial production and sale of our products, which could adversely affect our business.

Uncertainty regarding the effects of recent health care reform measures, trends in the managed health care and health insurance industries, and the likelihood of further legislative reform of the healthcare system could adversely affect our ability to sell our potential medicines profitably.

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 certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable. In the United States recently there have been federal and state government initiatives directed at lowering the total cost of health care, and we anticipate that Congress and state legislatures will continue to focus on health care reform, the cost of prescription drugs and the reform of the Medicare and Medicaid systems. For example, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the MMA) provides a new Medicare prescription drug benefit beginning in 2006 and mandates additional reforms. It is possible that the new Medicare prescription drug benefit, which will be managed by private health insurers and other managed care organizations, will 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.

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

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical, biological and radioactive materials. In addition, our operations produce hazardous waste products. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. 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.

Failure to comply with Internal Control Attestation requirements could lead to loss of public confidence in our financial statements and negatively impact our stock price.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we will be required, beginning with our fiscal year ending December 31, 2005, to include in our annual report our assessment of the effectiveness of our internal control over financial reporting and our audited financial statements as of the end of fiscal 2005. Furthermore, our independent registered public accounting firm will be required to attest to whether our assessment of the effectiveness of our internal control over financial reporting is fairly stated in all material respects and separately report on whether it believes we maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005. We have prepared and are implementing a plan of action to assess the effectiveness of our internal control. If we fail to timely complete this assessment, or if our independent registered public accounting firm cannot timely attest to our assessment, we could be subject to regulatory sanctions and a loss of public confidence in our internal control and the reliability of our financial statements, which ultimately could negatively impact our stock price. In addition, any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to timely meet our regulatory reporting obligations.

General Company Related Risks

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

As of September 30, 2005, GSK beneficially owned approximately 17.5% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 15.7% 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 following 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.

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

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:

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;

the extent to which GSK advances (or does not advance) our product candidates through development into commercialization;

announcements regarding GSK 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;

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.

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

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

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

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

prohibiting stockholder action by written consent; and

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.

Recent Accounting Pronouncements

In June 2004, the FASB ratified Emerging Issues Task Force Issue No. 03-1 (EITF 03-1), *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*. EITF 03-1 includes new guidance for evaluating and recording impairment losses on debt and equity investments, as well as new disclosure requirements for investments that are deemed to be temporarily impaired. In September 2004, the Financial Accounting Standards Board approved the issuance of a FASB Staff Position to delay the recognition and measurement provisions of EITF 03-1. In June 2005, the FASB decided not to provide additional guidance on the meaning of other-than-temporary impairment under EITF 03-1. The FASB directed the staff to issue FASB Staff Position Paper (FSP) 115-1, *The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments (FSP 115-1)*, superseding EITF 03-1. FSP 115-1 will replace the accounting guidance on the determination of whether an investment is other-than-temporarily impaired as set forth in EITF 03-1 with references to existing other-than-temporary impairment guidance. FSP 115-1 will be effective for other-than-temporary impairment analysis conducted in periods beginning after December 15, 2005. We will evaluate the impact of FSP 115-1 on our consolidated financial statements once the final guidance is issued.

On December 16, 2004, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 123 (revised 2004) (SFAS 123(R)), *Share-Based Payment*, which is a revision of FASB Statement No. 123 (SFAS 123), *Accounting for Stock-Based Compensation*. SFAS 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS 123(R) is similar to the approach described in SFAS 123. However, SFAS 123(R) *requires* all share-based payments to employees, including grants of employee stock options and employee stock purchase plans, to be recognized in the statement of operations based on their fair values. Pro forma disclosure is no longer an alternative. On April 14, 2005, the SEC adopted a new rule deferring the required compliance dates for SFAS 123(R). In accordance with the new SEC rule, the accounting provisions of SFAS 123(R) will be effective for us for the annual period beginning January 1, 2006.

We are evaluating the requirements of SFAS 123(R) and we expect that the adoption of SFAS 123(R) will have a material impact on our consolidated results of operations and net loss per share, although it will have no impact on our overall financial position. The impact of adoption of Statement 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had we adopted Statement 123(R) in prior periods, we believe the impact of that standard would have approximated the impact of Statement 123 as described in the disclosure of pro forma net loss and net loss per share in Note 1 of our notes to our condensed consolidated financial statements included in Item 8, *Financial Statements and Supplementary Data* in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Our exposure to market risk is principally confined to our cash, cash equivalents, restricted cash and marketable securities. We have attempted to minimize risk by investing in high-quality financial instruments, primarily money market funds, federal agency notes, asset backed securities, corporate debt securities and U.S. treasury notes, with no security having an effective duration in excess of 2 years. Additionally, the securities in our investment portfolio are not leveraged. However, we are still subject to risk due to interest rate fluctuations and general market conditions, which may adversely impact the carrying value of our investment portfolio unless we are able to hold these securities until maturity. Our outstanding capital lease obligations and notes payable are all at fixed interest rates, and therefore, have minimal exposure to changes in interest rates.

Most of our transactions are conducted in U.S. dollars, although we do conduct some clinical and safety studies, and manufacture some active pharmaceutical product with vendors located outside the United States. Some of these expenses are paid in U.S. dollars, and some are paid in the local foreign currency. If the exchange rate undergoes a change of 10%, we do not believe that it would have a material impact on our results of operations or cash flows.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

Our chief executive officer and chief financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of September 30, 2005, have concluded that, as of such date, our disclosure controls and procedures were effective based on their evaluation of these controls and procedures required by paragraph (b) of Exchange Act Rules 13(a)-15 or 15d-15.

There have been no changes in our internal controls 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 2. Unregistered Sales of Equity Securities and Use of Proceeds

The net offering proceeds to us from the initial public offering of our common stock in October of 2004, after deducting underwriting discounts and commissions and offering expenses, were approximately \$102.1 million. Except as otherwise disclosed in Item 1 of Part 1, no offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. From October 4, 2004, the effective date of the registration statement for our initial public offering, to September 30, 2005, we estimate approximately \$42 million, consisting primarily of third party expenses, of the net offering proceeds were used to fund our Phase 3 clinical studies of telavancin. Such use of proceeds payments were not paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any of our affiliates.

Item 6. Exhibits

Exhibit Exhibit

Number	Description
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
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

(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.

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 14, 2005
Date

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

November 14, 2005
Date

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

Exhibit Index

Exhibit Exhibit

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