THERAVANCE INC
Form 10-Q
November 07, 2007

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2007

OR

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

For the transition period from to

Commission File Number:
0-30319

THERAVANCE, INC.

(Exact Name of Registrant as Specified in its Charter)

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

901 Gateway Boulevard

South San Francisco, CA 94080

(Address of Principal Executive Offices including Zip Code)

(650) 808-6000

(Registrant s Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No o

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

Large Accelerated Filer x Accelerated Filer o Non-Accelerated Filer o

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

Yes o No x

The number of shares of registrant s common stock outstanding on October 31, 2007 was 51,505,987.

The number of shares of registrant s Class A common stock outstanding on October 31, 2007 was 9,401,499.

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PART I FINANCIAL INFORMATION

ITEM 1. Financial Statements

THERAVANCE, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

	September 30, 2007 (Unaudited)	December 31, 2006 *
Assets		
Current assets:		
Cash and cash equivalents	$ 78,860	$ 72,388
Marketable securities	58,678	128,692
Receivable from related party	98	608
Notes receivable	437	1,142
Prepaid and other current assets	6,363	4,361
Total current assets	144,436	207,191
Marketable securities	28,983	34,490
Restricted cash and cash equivalents	3,810	3,860
Property and equipment, net	19,847	15,101
Notes receivable	1,547	1,782
Total assets	$ 198,623	$ 262,424
Liabilities and stockholders equity (deficit)		
Current liabilities:		
Accounts payable	$ 5,954	$ 16,011
Accrued personnel-related expenses	10,597	8,316
Accrued clinical and development expenses	14,952	13,608
Other accrued liabilities	2,795	2,314
Current portion of notes payable	98	87
Current portion of deferred revenue	22,740	19,273
Total current liabilities	57,136	59,609
Deferred rent	2,085	2,298
Notes payable	462	538
Deferred revenue	171,544	134,383
Other long term liabilities	8,281	2,286
Commitments and contingencies		
Stockholders equity (net capital deficiency):		
Preferred stock, $0.01 par value, 230 shares authorized, no shares issued and outstanding		
Common stock, $0.01 par value; 200,000 shares authorized, issuable in series; 51,461 and 50,746 shares issued and outstanding at September 30, 2007 and December 31, 2006, respectively	514	507
Class A Common Stock, $0.01 par value, 30,000 shares authorized, 9,402 issued and outstanding at September 30, 2007 and December 31, 2006	94	94
Additional paid-in capital	863,177	840,498
Notes receivable from stockholders		(3)
Accumulated other comprehensive income	81	26
Accumulated deficit	(904,751)	(777,812)
Total stockholders equity (net capital deficiency)	(40,885)	63,310
Total liabilities and stockholders equity (net capital deficiency)	$ 198,623	$ 262,424

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

See accompanying notes to condensed consolidated financial statements.

THERAVANCE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

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

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

See accompanying notes to condensed consolidated financial statements.

THERAVANCE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)
(Unaudited)

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

See accompanying notes to condensed consolidated financial statements.

Theravance, Inc.

Notes to Condensed Consolidated Financial Statements

September 30, 2007

(Unaudited)

1. Basis of Presentation and Significant Accounting Policies

Unaudited Interim Financial Statements

The accompanying unaudited condensed consolidated financial statements of Theravance, Inc. (the Company) have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of the Company s management, the unaudited condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and include all adjustments, consisting of only normal recurring adjustments, necessary for the fair presentation of the Company s financial position at September 30, 2007, the results of operations for the three and nine months ended September 30, 2007 and 2006 and the cash flows for the nine months ended September 30, 2007 and 2006. The results for the three and nine months ended September 30, 2007 are not necessarily indicative of the results of operations to be expected for the year ending December 31, 2007 or any other period.

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

Use of Management s Estimates

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

Segment Reporting

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

Inventory

Inventory is stated at the lower of cost or market and is included with prepaid and other current assets. Inventory consists of $3.8 million of commercial launch supplies of the Company s product candidate telavancin which is currently awaiting regulatory approval. Under the Company s 2005 License, Development and Commercialization Agreement with Astellas Pharma Inc. (Astellas), the Company is responsible to deliver to Astellas approximately six months of first commercial sale stock (as defined) in anticipation of the regulatory approval and commercialization of telavancin. If the Company s product candidate is approved by the U.S. Food and Drug Administration (FDA), the inventory costs would be reimbursed through a milestone payment required under the agreement.

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

Bonus Accruals

The Company has short-and long-term bonus programs for certain eligible employees. Bonuses are determined based on various criteria, including the achievement of corporate, departmental and individual goals. Bonus accruals are estimated based on various factors, including target bonus percentages per level of employee and probability of achieving the goals upon which bonuses are based. The Company s management periodically reviews the progress made towards the goals under the bonus programs. As bonus accruals are dependent upon management s judgments of the likelihood of achieving the various goals, in some cases over a period of time in excess of twelve months, it is possible for bonus expense to vary significantly in future periods if changes occur in those management estimates. During the nine months ended September 30, 2007, the Company recorded an increase in bonus expense and related accrual for non-officer employees of $8.5 million related to the achievement of the last clinical milestone under a long-term bonus plan established in 2004, which included the effect of a change in estimate of $7.1 million. As of September 30, 2007, the Company had fully accrued its bonus liability of approximately $12.4 million relating to its long-term bonus program, which ended in September 2007. The amounts accrued are scheduled to be paid to the employees in December of 2007, 2008 and 2009.

Fair Value of Share-based Payment Awards

The Company uses the fair value method of accounting for share-based compensation arrangements in accordance with Financial Accounting Standards Board Statement No. 123(R), Share-based Payment (SFAS123(R)). The Company adopted SFAS 123(R) on January 1, 2006 using the modified prospective method of transition. Under this method, compensation expense is recognized beginning with the effective date of adoption of SFAS 123(R) for all share-based payments (i) granted after the effective date of adoption and (ii) granted prior to the effective date of adoption and that remain unvested on the date of adoption. Share-based compensation arrangements covered by SFAS 123(R) currently include stock options granted, restricted shares issued and performance-contingent restricted stock unit awards (RSUs) granted under the 2004 Equity Incentive Plan, as amended, and purchases of common stock by the Company s employees at a discount to the market price during offering periods under the Company s Employee Stock Purchase Plan (ESPP). The estimated fair value of stock options and restricted shares is expensed on a straight-line basis over the expected term of the grant and the fair value of RSUs is expensed during the term of the award when the Company determines that it is probable that certain performance conditions will be met. Compensation expense for purchases under the ESPP is recognized based on the estimated fair value of the common stock during each offering period and the percentage of the purchase discount.

In conjunction with the adoption of SFAS 123(R), the Company changed its method of expensing the value of stock-based compensation from the accelerated method to the straight-line single-option method. Compensation expense for all share-based payment awards granted prior to January 1, 2006 will continue to be recognized using the accelerated method over the vesting period while the compensation expense for all share-based payment awards granted on or subsequent to January 1, 2006 is recognized using the straight-line single-option method. Stock-based compensation expense for stock options has been reduced for estimated forfeitures so that compensation expense is based on options ultimately expected to vest. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company s estimated annual forfeiture rate for stock options is 3.6%, based on its historical forfeiture experience.

Recent Accounting Pronouncements

In June 2007, the Emerging Issues Task Force (EITF) ratified a consensus on EITF Issue No. 07-3 (EITF 07-3), Accounting for Non-Refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities , which concluded that non-refundable advance payments for goods or services for use in research and development activities should be deferred and capitalized. EITF 07-3 is effective for the Company beginning in the first quarter of fiscal year 2008. The Company is currently evaluating the impact of the provisions of EITF 07-3 on its financial position, results of operations and cash flows and therefore, the impact of the adoption is unknown at this time.

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

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

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

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

Reclassification of Prior Year Amounts

Certain prior year amounts related to the classification of marketable securities in the condensed consolidated statement of cash flows and accrued interest related to notes receivable have been reclassified to conform to the current period s presentation. These reclassifications had no impact on previously reported results of operations or stockholders equity.

2. Net Loss per Share

Basic net loss per common share (Basic EPS) is computed by dividing net loss by the weighted-average number of common shares outstanding, less shares subject to repurchase. Diluted net loss per common share (Diluted EPS) is computed by dividing net loss by the weighted-average number of common shares outstanding, less shares subject to repurchase, plus dilutive potential common shares and shares subject to repurchase. At September 30, 2007, potential common shares consist of approximately 11,450,000 shares issuable upon the exercise of stock options, approximately 2,000,000 shares issuable under performance-contingent restricted stock unit awards and 18,000 shares issuable upon the exercise of a warrant. (The outstanding warrant was not exercised as of its expiration date of October 5, 2007 and therefore no stock was or will be issued under the warrant.) At September 30, 2006, potential common shares consist of approximately 10,620,000 shares issuable upon the exercise of stock options and 18,000 shares issuable upon the exercise of a warrant. Diluted EPS is identical to Basic EPS for all periods presented since potential common shares are excluded from the calculation, as their effect is anti-dilutive.

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

3. Collaboration and Licensing Agreements

2002 Beyond Advair Collaboration with GSK

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

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

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thresholds by a Theravance-discovered LABA. In the event that a LABA product candidate discovered by GSK is successfully developed and commercially launched in multiple locations of the world, the Company will be obligated to make payments to GSK of up to $220.0 million. Based on available information, the Company does not estimate that a significant portion of these potential milestone payments to GSK are likely to be made in the next three years. In addition, the Company is entitled to receive the same royalties on product sales of medicines from the Beyond Advair collaboration, regardless of whether the product candidate originated with Theravance or with GSK. The royalty structure is downward tiering and would result in an average percentage royalty rate in the low- to mid-teens at annual net sales of up to approximately $4.0 billion and the average royalty rate would decline to single digits at annual net sales of more than $6.0 billion. Sales of single-agent LABA medicines and combination LABA/ICS medicines would be combined for the purposes of this royalty calculation.

The Company recorded the upfront and milestone payments as deferred revenue and they are being amortized ratably over the Company s estimated period of performance (the product development period). Collaboration revenue was $1.7 million and $2.2 million for the three months ended September 30, 2007 and 2006, respectively, and $5.1 million and $6.2 million for the nine months ended September 30, 2007 and 2006, respectively. Subsequent development milestones will be recorded as deferred revenue when received and amortized over the remaining period of performance during the development period. Additionally, certain costs related to the collaboration are reimbursable by GSK as an offset to research and development expense. For each of the three and nine months ended September 30, 2007 and 2006, reimbursable costs related to the collaboration were not material.

2004 Strategic Alliance with GSK

In March 2004, the Company entered into its strategic alliance with GSK for the development and commercialization of product candidates in a variety of therapeutic areas. In connection with the strategic alliance, the Company received a $20.0 million payment from GSK in May 2004. This payment is being amortized over the initial period during which GSK may exercise its right to license certain of its programs under the agreement, which the Company currently estimates to be through September 2011. In addition, in May 2004, an affiliate of GSK purchased approximately 6.4 million shares of the Company s Class A common stock for $108.9 million. Pursuant to a partial exercise of its rights under the agreement, upon the closing of the Company s initial public offering in October 2004, GSK purchased an additional 433,757 shares of Class A common stock for $6.9 million.

The alliance provides GSK with an option to license product candidates from the Company s full drug discovery programs initiated prior to September 1, 2007 on pre-determined terms and on an exclusive, worldwide basis. Upon licensing a program, GSK is responsible for funding all future development, manufacturing and commercialization activities for product candidates in that program. Consistent with the Company s strategy, the Company is obligated at its sole cost to discover two structurally different product candidates for any programs that are licensed by GSK under the alliance. If these programs are successfully advanced through development by GSK, the Company is entitled to receive clinical, regulatory and commercial milestone payments based on performance and royalties on any sales of medicines developed from these programs. The royalty structure for a product containing one of the Company s compounds as a single active ingredient in the programs licensed to date by GSK would result in an average percentage royalty rate in the low double digits. If a product is successfully commercialized, in addition to any royalty revenue the Company receives, the total upfront and milestone payments that the Company could receive in any given program that GSK licenses range from $130.0 million to $162.0 million for programs with single-agent medicines and up to $252.0 million for programs with both a single-agent and a combination medicine. To date, GSK has licensed the Company s two COPD programs: LAMA and MABA.

In August 2004, GSK exercised its right to license the Company s long-acting muscarinic antagonist program (LAMA) pursuant to the terms of the strategic alliance. The Company received a $5.0 million payment from GSK in connection with the licensing of this program. Through September 30, 2007, the Company received a milestone payment of $3.0 million from GSK related to clinical progress of its candidate. These payments are amortized ratably over the estimated period of performance (the product development period). The Company recognized $0.2 million and $0.3 million for the three months ended September 30, 2007 and 2006, respectively, and $0.6 million and $0.9 million for the nine months ended September 30, 2007 and 2006, respectively, in revenue related to the LAMA program. Additionally, the Company is reimbursed by GSK for certain costs related to the LAMA program as an offset to research and development expense. For the three and nine months ended September 30, 2007 and 2006, reimbursable costs were not material.

In March 2005, GSK exercised its right to license the Company s muscarinic antagonist-beta2 agonist (MABA) program pursuant to the terms of the strategic alliance. The Company received a $5.0 million payment from GSK in connection with the license of the Company s MABA program. Through September 30, 2007, the Company received a milestone payment of $3.0 million from GSK related to clinical progress of its candidate. This payment is being amortized

ratably over the estimated period of performance (the product development period). Collaboration revenue related to the MABA program was $0.3 million for each of the three months ended September 30, 2007 and 2006, respectively, and $0.8 million and $0.7 million for the nine months ended September 30, 2007 and 2006, respectively. Additionally, the Company is reimbursed by GSK for certain costs related to the MABA program as an offset to research and development expense. Reimbursements for the three and nine months ended September 30, 2007 and 2006 were not material.

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

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

2005 License, Development and Commercialization Agreement with Astellas

In November 2005, the Company entered into a collaboration arrangement with Astellas for the development and commercialization of telavancin. In July 2006, the Company and Astellas agreed to add Japan to their telavancin collaboration, thereby giving Astellas worldwide rights to this potential medicine. Through September 30, 2007, the Company had received $158.0 million in upfront, milestone and other fees from Astellas, which are being amortized ratably over the estimated period of performance (the estimated development and commercialization period). The Company recognized $2.8 million and $1.9 million in revenue for the three months ended September 30, 2007 and 2006, respectively, and $7.5 million and $4.6 million for the nine months ended September 30, 2007 and 2006, respectively. As of September 30, 2007, the Company was eligible to receive up to $70.0 million in remaining clinical and regulatory milestone payments, which includes up to $60.0 million related to regulatory filings and approvals in various regions of the world and $10.0 million if the FDA determines telavancin s superiority over vancomycin for hospital-acquired pneumonia (HAP) patients infected with methicillin-resistant *Staphylococcus aureus* (MRSA).

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

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

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

2006 License Agreement with AstraZeneca AB

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

4. Marketable Securities

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

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

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

5. Comprehensive Loss

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

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

6. Commitments

Guarantees and Indemnifications

The Company indemnifies its officers and directors for certain events or occurrences, subject to certain limits. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recognized any liabilities relating to these agreements as of September 30, 2007.

Purchase Obligations

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

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7. Stockholders Equity

Determining Fair Value of Stock-Based Compensation

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

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

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

As of September 30, 2007, there was $45.2 million of total unrecognized compensation cost related to unvested stock options. This cost is expected to be recognized over a weighted-average period of approximately 2.85 years. The Company has not recognized, and does not expect to recognize in the near future, any tax benefit related to employee stock-based compensation costs as a result of the full valuation allowance on the Company s net deferred tax assets including deferred tax assets related to its net operating loss carryforwards.

Stock-based compensation expense consists of the compensation cost for employee share-based awards, including restricted stock, and the value of options issued to non-employees for services rendered. The following table discloses the allocation of stock-based compensation expense included in the unaudited condensed consolidated statements of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2007**	**2006**	**2007**	**2006**
Research and development	$ 3,514	$ 3,042	$ 10,078	$ 9,378
General and administrative	2,359	1,674	7,089	7,106
Total	$ 5,873	$ 4,716	$ 17,167	$ 16,484

Stock Option Plans

During the nine months ended September 30, 2007, the Company granted stock options to purchase 1,954,456 shares at an average exercise price of $32.71 per share and granted 2,015,827 performance-contingent restricted stock unit awards (RSUs) whose weighted-average fair value was $32.63 per share, under the 2004 Equity Incentive Plan, as amended (the Plan). On April 25, 2007, an amendment to the Plan which, among other things, increased the number of shares authorized for issuance under the Plan from 3,700,000 to 7,200,000 shares, was approved by the Company s stockholders. As of September 30, 2007, total shares remaining available for issuance under the Plan were 796,358.

The RSUs granted to date have dual triggers of vesting based upon the successful achievement of certain clinical development milestones during 2008 and 2009, as well as a requirement for continued employment through 2009 and 2010. The issuance of shares underlying the RSUs would occur, if at all, during 2009 and 2010. Expense associated with RSUs would be recognized, if at all, during 2007 through 2009, depending on the probability of meeting the

performance conditions. The maximum potential expense associated with the RSUs could be up to approximately $66.0 million (allocated as $39.0 million for research and development expense and $27.0 million for general and administrative expense) if all of the milestones are successfully achieved on time. As of September 30, 2007, the Company had determined that none of the requisite performance conditions were probable and as a result, no compensation expense has been recognized. As vesting of the RSUs is dependent upon the successful achievement of the performance conditions, the expense associated with the RSUs may vary significantly from period to period.

The following table summarizes equity award activity under the Plan, and related information:

	Number of Shares Available for Grant	Number of Shares Subject to Outstanding Options and Other Awards	Weighted-Average Exercise Price of Outstanding Options and Fair Value of Other Awards per Share
	(In thousands, except per share data)		
Balance at December 31, 2006	1,070	10,390	$ 12.92
Options granted	(828)	828	$ 34.05
Options exercised		(118)	$ 5.44
Options forfeited	39	(39)	$ 21.68
Balance at March 31, 2007	281	11,061	$ 14.55
Additional shares authorized	3,500		$
Options granted	(647)	647	$ 33.63
RSUs granted	(1,842)	1,842	$ 33.25
Options exercised		(336)	$ 6.22
Options and RSUs forfeited	105	(105)	$ 26.51
Balance at June 30, 2007	1,397	13,109	$ 18.24
Options granted	(479)	479	$ 29.15
RSUs and restricted stock awarded	(224)	174	$ 26.10
Options exercised		(210)	$ 7.65
Options and RSUs forfeited	102	(102)	$ 23.65
Balance at September 30, 2007	796	13,450	$ 18.85

No options were granted with exercise prices less than fair value of common stock on the date of grant during the nine months ended September 30, 2007 or the year ended December 31, 2006.

The total intrinsic value of the options exercised during the three months ended September 30, 2007 and 2006 was $4.5 million and $2.8 million, respectively, and the total fair value of options vested was $26.8 million and $0.7 million for the three months ended September 30, 2007 and 2006, respectively. The total intrinsic value of the options exercised during the nine months ended September 30, 2007 and 2006 was $16.6 million and $15.4 million, respectively, and the total fair value of options vested was $28.0 million and $4.3 million for the nine months ended September 30, 2007 and 2006, respectively. For the three and nine months ended September 30, 2007, the fair value of options vested was significantly higher when compared to the 2006 periods due to the unusual number of options that vested at the expiration of the put period in September of 2007.

As of September 30, 2007, all outstanding options to purchase common stock of the Company are summarized in the following table (in thousands, except years and per share data):

Exercise Price Per Share		Options Outstanding				Options Exercisable		
		Number of Shares Subject to Outstanding Options	Weighted-Average Remaining Contractual Life	Number of Shares Subject to Options Unvested	Aggregate Intrinsic Value	Number of Shares Exercisable	Aggregate Intrinsic Value	Weighted-Average Remaining Contractual Life
$ 1.32		46	2.17			46		2.17
$ 3.10		1,253	5.67	71		1,252		5.63
$ 8.53		2,685	4.06			2,685		4.06
$ 9.69		1,905	6.11	973		940		5.84
$ 12.40	$18.25	1,231	7.09	533		765		7.04
$ 18.26	$21.70	932	7.45	380		553		7.36
$ 21.71	$29.65	1,683	8.48	1,079		604		8.00
$ 29.66	$35.46	1,715	9.42	1,534		180		9.22
		11,450	6.62	4,570	$ 127,259	7,025	$ 104,261	5.61

Employee Stock Purchase Plan

Through September 30, 2007, the Company issued 392,317 shares under the 2004 Employee Stock Purchase Plan (ESPP) at an average price of $15.50 per share. The total number of remaining shares available for issuance under the plan at September 30, 2007 was 232,683. The total stock-based compensation expense recognized related to the ESPP under SFAS 123(R) for the three and nine months ended September 30, 2007 was $0.3 million and $1.1 million, respectively, and $0.3 million and $1.2 million for the three and nine months ended September 30, 2006, respectively.

Reserved Shares

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

	September 30, 2007
Subject to outstanding warrant	18
Stock option plans:	
Subject to outstanding options and RSUs	13,450
Available for future grants	796
Available for future ESPP purchases	233
Total	14,497

The outstanding warrant at September 30, 2007 was not exercised as of its expiration date of October 5, 2007 and therefore no stock was or will be issued under the warrant.

Restricted Stock

During the three months ended September 30, 2007, the Compensation Committee of the Company s Board of Directors approved an award of 50,000 shares of restricted common stock to a member of the Company s senior management. These restricted shares of stock vest based on continued service, with 33.3% of the shares vesting on July 30, 2010 and 33.3% of the shares vesting upon each of the next two anniversaries of such date. The Company valued the award at $1.3 million and will amortize that amount over the service period. The value of the restricted common stock award was based on the closing market price of the Company s common stock of $26.10 on the date of award. Stock-based compensation expense related to this award for the three months ended September 30, 2007 was $43,000.

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 stockholders put rights which occurred in September 2007, and 25% of the shares vesting upon each of the next two anniversaries of such date. The value was based on the closing market price of the Company s common stock of $17.91 on the date of award. The Company recognized stock-based compensation expense of $51,000 and $168,000 related to this award for the nine months ended September 30, 2007 and 2006, respectively. In September 2007, upon the vesting of the 25,000 common shares, 16,063 common shares were issued to the officer and the remaining 8,937 common shares were withheld by the Company to satisfy the officer s tax withholding requirements of approximately $250,000.

8. Related Party Transactions

Related Parties

The Company s related parties include 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 $0.4 million were incurred in the ordinary course of business for the nine months ended September 30, 2007 and 2006, respectively.

Notes Receivable

The Company has provided loans to certain of its employees primarily to assist them with the purchase of a primary residence, which collateralizes the resulting loans. Interest receivable was approximately $27,000 and $24,000 for the periods ended September 30, 2007 and December 31, 2006, respectively, and is included in prepaid and other current assets. The Company accrues interest on the notes at rates of up to 8.0%. The outstanding loans at September 30, 2007 had maturity dates ranging from October 2007 through July 2012.

9. Income Taxes

The Company adopted FIN 48 effective January 1, 2007. The adoption of FIN 48 did not result in an adjustment to the beginning balance of the Company s accumulated deficit.

Under FIN 48, the Company has unrecognized tax benefits of $26.7 million as of January 1, 2007. If the Company is eventually able to recognize these uncertain positions, $26.7 million of the unrecognized benefit would reduce its effective tax rate. The Company currently has a full valuation allowance against its net deferred tax asset which would impact the timing of the effective tax rate benefit should any of these uncertain tax positions be favorably settled in the future.

The Company is subject to federal and state examination for years 1996 and forward, by virtue of the tax attributes carrying forward from those years. There are no tax examinations currently in progress.

10. Subsequent Event

On October 22, 2007, the Company announced that the FDA issued an approvable letter for telavancin, a novel bactericidal, once-daily injectable antibiotic discovered by Theravance, for the treatment of cSSSI caused by Gram-positive bacteria, including resistant pathogens such as MRSA. Telavancin is the subject of the Company s collaboration with Astellas (see Note 3 above).

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

Forward-Looking Statements

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

Executive Summary

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates. Theravance is focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections and gastrointestinal motility dysfunction. Of our five programs in development, four are in late stage our telavancin program focusing on treating serious Gram-positive bacterial infections in collaboration with Astellas Pharma Inc. (Astellas), our Gastrointestinal Motility Dysfunction program, our Beyond Advair collaboration with GlaxoSmithKline plc (GSK) and TD-1792, our investigational antibiotic for the treatment of serious Gram-positive infections. 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, 2007, we had an accumulated deficit of $904.8 million. In December 2006, we submitted our first new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for telavancin for the treatment of complicated skin and skin structure infections (cSSSI) and we received an approvable letter from the FDA for the telavancin NDA in October 2007. None of our product candidates have been approved for marketing and sale and we have not received any product revenue to date. Most of our spending to date has been for research and development activities and general and administrative expenses. We expect to incur substantial losses for at least the next several years as we continue to invest in research and development.

Our net loss for the three months ended September 30, 2007 was $32.4 million compared to $37.8 million during the same period of 2006, or a 14% decrease. Revenue recognized under our collaboration agreements increased by 3% when compared to the same period of 2006. For the three months ended September 30, 2007, research and development costs decreased by 18% while general and administrative costs increased by 8% when compared to the same period of 2006. Cash, cash equivalents and marketable securities totaled $166.5 million at September 30, 2007, a decrease of $69.1 million since December 31, 2006. This decrease was primarily due to the net usage of cash in operations, offset by the receipt of $57.0 million from Astellas during the nine months ended September 30, 2007.

Following are updates on the progress of our clinical programs as of October 31, 2007:

Bacterial Infections Programs

Telavancin

During October, we announced that the FDA issued an approvable letter for telavancin for the treatment of cSSSI caused by Gram-positive bacteria, including resistant pathogens such as methicillin-resistant *Staphylococcus aureus* (MRSA). The FDA letter indicated that the telavancin application is approvable, subject to: resolution of current good manufacturing practices (cGMP) compliance issues not specifically related to telavancin at a third-party manufacturer; and submission of revised labeling or re-analyses of clinical data or additional clinical data. We and Astellas believe that no additional clinical studies will need to be initiated to respond to the approvable letter. Telavancin is also under review for its safety and efficacy by regulatory authorities in the European Union for the treatment of complicated skin and soft tissue infections and in Canada for the treatment of cSSSI.

We are on track to report summary data from our Phase 3 program in hospital-acquired pneumonia (HAP) by the end of 2007.

TD-1792

In July we announced positive results from an approximately 200-patient study in cSSSI with TD-1792, our next-generation antibiotic for the treatment of Gram-positive infections, including resistant pathogens such as MRSA. We are evaluating the potential of this compound in more serious infections such as bacteremia.

Respiratory Programs

Beyond Advair

In our collaboration with GSK to develop and commercialize a once-daily Long-Acting Beta2 Agonist (LABA) product candidate for the treatment of asthma and chronic obstructive pulmonary disease (COPD), GSK has advised us that the development program for the inhaled corticosteroid and LABA is progressing to plan.

Inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist (MABA) Program

Our lead compound in the MABA program for the treatment of COPD, GSK961081, commenced a Phase 2 study in late October, 2007.

Inhaled Long Acting Muscarinic Antagonist (LAMA) Program

Our lead compound in the LAMA program for COPD has successfully completed pre-Phase 1 safety studies.

Gastrointestinal (GI) Motility Dysfunction Program

We recently obtained a positive outcome from our end-of-Phase 2 meeting with the FDA for TD-5108, our highly selective 5-HT4 receptor agonist for the treatment of GI motility dysfunction such as chronic idiopathic constipation (CIC) and constipation-predominant irritable bowel syndrome. The FDA confirmed that the TD-5108 data package, including the results of the approximately 400-patient Phase 2 ACCORD study that we reported in June 2007, was adequate to progress TD-5108 into Phase 3 efficacy and safety studies in patients with CIC. The FDA also indicated that the size of the clinical program should be consistent with the International Conference on Harmonisation (ICH) guidelines for the development of drugs for chronic use. Additionally, we began enrolling patients in a Phase 1 thorough QTc study, or a study in healthy subjects to evaluate the effect of TD-5108 on electrical activity of the heart, during the third quarter.

Critical Accounting Policies

As of the date of the filing of this quarterly report, we believe there have been no material changes or additions to our critical accounting policies and estimates during the three and nine months ended September 30, 2007 compared to those discussed in our Annual Report on Form 10-K filed on March 1, 2007 (2006 10-K), except for the adoption of our inventory policy, the change in estimate under our bonus accrual policy and the adoption of Financial Interpretation No. 48 Accounting for Uncertainty in Income Taxes, as discussed below.

Inventory

Inventory is stated at the lower of cost or market and is included with prepaid and other current assets. Inventory consists of $3.8 million of commercial launch supplies of our product candidate telavancin which is currently awaiting regulatory approval. Under our 2005 License, Development and Commercialization Agreement with Astellas, we are responsible to deliver to Astellas approximately six months of first commercial sale stock (as defined) in preparation for the regulatory approval and commercialization of telavancin. If our product candidate is approved by the FDA, the inventory costs incurred would be reimbursed through a milestone payment.

If the regulatory approval of our product candidate is substantially delayed or denied by the necessary regulatory bodies, or if new information becomes available that suggests that the inventory will not be realisable, we may be required to expense a portion or all of the capitalized inventory costs. A portion of the amount that may be expensed may be offset by

reimbursement through alternative arrangements with Astellas under terms of our collaboration agreement. During the three months ended September 30, 2007, we expensed approximately $0.9 million of our previously capitalized inventory as it was determined to not be realisable for commercial launch supplies. This inventory, however, may be used to support future clinical trial activity.

Bonus Accruals

We have short- and long-term bonus programs for certain eligible employees. Bonuses are determined based on various criteria, including the achievement of corporate, departmental and individual goals. Bonus accruals are estimated based on various factors, including target bonus percentages per level of employee and probability of achieving the goals upon which bonuses are based. Management periodically reviews the progress made towards the goals under the bonus programs. As bonus accruals are dependent upon management s judgments of the likelihood of achieving the various goals, in some cases over a period of time in excess of twelve months, it is possible for bonus expense to vary significantly in future periods if changes occur in those management estimates. During the nine months ended September 30, 2007, we recorded an increase in bonus expense and related accrual for non-officer employees of $8.5 million related to the achievement of the last clinical milestone under a long-term bonus plan established in 2004, which included the effect of a change in estimate of $7.1 million. As of September 30, 2007, we had fully accrued our bonus liability of approximately $12.4 million relating to our long-term bonus program, which ended in September 2007.

Income taxes

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

Collaboration and Licensing Agreements

2002 Beyond Advair Collaboration with GSK

In November 2002, we entered into our Beyond Advair collaboration agreement with GSK to develop and commercialize LABA product candidates for the treatment of asthma and COPD. Each company contributed four LABA product candidates to the collaboration, and in April 2007, we reported results from the Phase 2b clinical program for GSK s product candidate GSK642444 (444) and Theravance s product candidate GSK159797 (797). Both 444 and 797, dosed once daily, achieved clinically significant increases in bronchodilation at least equivalent to that of salmeterol dosed twice daily. The lead compound in development, 444, is scheduled to progress into Phase 2b studies in asthma and COPD.

As of September 30, 2007, we had received upfront and milestone payments from GSK of $60.0 million related to the clinical progress of our candidates, and could receive up to $445.0 million in remaining milestones allocated as follows: up to $75.0 million related to the achievement of certain clinical milestones by a Theravance-discovered LABA, up to $220.0 million related to approval and launch of a product containing a Theravance-discovered LABA in multiple regions in the world, and up to $150.0 million related to the achievement of certain sales thresholds by a Theravance-discovered LABA. In the event that a LABA product candidate discovered by GSK is successfully developed and commercially launched in multiple locations of the world, we will be obligated to make payments to GSK of up to $220.0 million. Based on available information, we do not estimate that a significant portion of these potential milestone payments to GSK are likely to be made in the next three years. In addition, we are entitled to receive the same royalties on product sales of medicines from the Beyond Advair collaboration, regardless of whether the product candidate originated with Theravance or with GSK. The royalty structure is downward tiering and would result in an average percentage royalty rate in the low- to mid-teens at annual net sales of up to approximately $4.0 billion and the average royalty rate would decline to single digits at annual net sales of more than $6.0 billion. Sales of single agent LABA medicines and combination LABA/ICS medicines would be combined for the purposes of this royalty calculation.

We recorded the upfront and milestone payments as deferred revenue and they are being amortized ratably over our estimated period of performance (the product development period). Collaboration revenue was $1.7 million and $2.2 million for the three months ended September 30, 2007 and 2006, respectively, and $5.1 million and $6.2 million for the nine months ended September 30, 2007 and 2006, respectively. Subsequent development milestones will be recorded as deferred revenue when

received and amortized over the remaining period of performance during the development period. Additionally, certain costs related to the collaboration are reimbursable by GSK as an offset to research and development expense. For each of the three and nine months ended September 30, 2007 and 2006, reimbursable costs related to the collaboration were not material.

2004 Strategic Alliance with GSK

In March 2004, we entered into our strategic alliance with GSK for the development and commercialization of product candidates in a variety of therapeutic areas. In connection with the strategic alliance, we received a $20.0 million payment from GSK in May 2004. This payment is being amortized over the initial period during which GSK may exercise its right to license certain of our programs under the agreement, which we currently estimate to be through September 2011. In addition in May 2004, GSK through an affiliate, purchased approximately 6.4 million shares of our Class A common stock for $108.9 million. Pursuant to a partial exercise of its rights under the agreement, upon the closing of our initial public offering in October 2004, GSK purchased an additional 433,757 shares of Class A common stock for $6.9 million.

The alliance provides GSK with an option to license product candidates from our full drug discovery programs initiated prior to September 1, 2007, on pre-determined terms and on an exclusive, worldwide basis. Upon licensing a program, GSK is responsible for funding all future development, manufacturing and commercialization activities for product candidates in that program. Consistent with our strategy, we are obligated at our sole cost to discover two structurally different product candidates for any programs that are licensed by GSK under the alliance. If these programs are successfully advanced through development by GSK, we are entitled to receive clinical, regulatory and commercial milestone payments based on performance and royalties on any sales of medicines developed from these programs. The royalty structure for a product containing one of our compounds as a single active ingredient in the programs licensed to date by GSK would result in an average percentage royalty rate in the low double digits. If a product is successfully commercialized, in addition to any royalty revenue we receive, the total upfront and milestone payments that we could receive in any given program that GSK licenses range from $130.0 million to $162.0 million for programs with single-agent medicines and up to $252.0 million for programs with both a single-agent and a combination medicine. To date, GSK has licensed two of our COPD programs: LAMA and MABA.

In August 2004, GSK exercised its right to license our LAMA pursuant to the terms of the strategic alliance. We received a $5.0 million payment from GSK in connection with the licensing of this program. Through September 30, 2007, we received a milestone payment of $3.0 million from GSK related to clinical progress of our candidate. These payments are amortized ratably over the estimated period of performance (the product development period). We recognized $0.2 million and $0.3 million for the three months ended September 30, 2007 and 2006, respectively, and $0.6 million and $0.9 million for the nine months ended September 30, 2007 and 2006, respectively, in revenue related to the LAMA program. Additionally, we are reimbursed by GSK for certain costs related to the LAMA program as an offset to research and development expense. For the three and nine months ended September 30, 2007 and 2006, reimbursable costs were not material.

In March 2005, GSK exercised its right to license our MABA program 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. Through September 30, 2007, we received a milestone payment of $3.0 million from GSK related to clinical progress of our candidate. This payment is being amortized ratably over the estimated period of performance (the product development period). Collaboration revenue related to the MABA program was $0.3 million for each of the three months ended September 30, 2007 and 2006 and $0.8 million and $0.7 million for the nine months ended September 30, 2007 and 2006, respectively. Additionally, we are reimbursed by GSK for certain costs related to the MABA program as an offset to research and development expense. Reimbursements for the three and nine months ended September 30, 2007 and 2006 were not material.

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

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

2005 License, Development and Commercialization Agreement with Astellas

In November 2005, we entered into a collaboration arrangement with Astellas for the development and commercialization of telavancin. In July 2006, we agreed with Astellas to add Japan to our telavancin collaboration, thereby giving Astellas worldwide rights to this potential medicine. Through September 30, 2007, we had received $158.0 million in upfront, milestone and other fees from Astellas, which are being amortized ratably over the estimated period of performance (the estimated development and commercialization period). We recognized $2.8 million and $1.9 million in revenue for the three months ended September 30, 2007 and 2006, respectively, and $7.5 million and $4.6 million for the nine months ended September 30, 2007 and 2006, respectively. As of September 30, 2007, we were eligible to receive up to $70.0 million in remaining clinical and regulatory milestone payments, which includes up to $60.0 million related to regulatory filings and approvals in various regions of the world, and $10.0 million if the FDA determines telavancin s superiority over vancomycin for HAP patients infected with MRSA.

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

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

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

2006 License Agreement with AstraZeneca AB

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

RESULTS OF OPERATIONS

Revenue We recognized revenue of $5.7 million and $5.5 million for the three months ended September 30, 2007 and 2006, respectively, and $16.4 million and $14.7 million for the nine months ended September 30, 2007 and 2006, respectively. This revenue primarily consisted of the amortization of upfront and milestone payments from GSK related to our Beyond Advair collaboration and our strategic alliance and from Astellas related to our telavancin collaboration. Following are the upfront and milestone payments received through September 30, 2007 (in millions):

Agreements/Programs		Upfront and Milestone Payments
GSK Collaborations		
Beyond Advair collaboration	$	60.0
Strategic alliance agreement		20.0
Strategic alliance LAMA license		8.0
Strategic alliance MABA license		8.0
Astellas license agreement		158.0
AstraZeneca license agreement		1.0
Total	$	255.0

Upfront and milestone payments received from GSK and Astellas have been deferred and are being amortized ratably into revenue over the applicable estimated performance periods with end dates ranging between 2011 and 2020. Future revenue will include the ongoing amortization of remaining deferred revenue which consists of $143.7 million of

upfront and milestone payments received through September 30, 2007 under our agreement with Astellas and $50.6 million of upfront and milestone payments received through September 30, 2007 under our agreements with GSK. We periodically review the estimated performance periods of our contracts and as such, during the third quarter of 2007, we revised performance periods for certain agreements based on the progress of our programs. We do not expect that these revisions will have a material impact on future revenue recognized under these contracts.

Research and development

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	**2007**	**2006**	**2007**	**2006**
External research and development	$ 11.4	$ 20.6	$ 56.2	$ 73.8
Employee-related	10.8	9.8	39.1	28.7
Stock-based compensation	3.5	3.0	10.1	9.4
Facilities, depreciation and other allocated	6.3	5.7	18.9	16.7
Total research and development expenses	$ 32.0	$ 39.1	$ 124.3	$ 128.6

Total research and development expenses decreased 18% and 3% for the three and nine months ended September 30, 2007, respectively, compared to the same periods in 2006. Total external research and development costs decreased $9.2 million, or 45%, for the three months ended September 30, 2007 compared to the same period in 2006. Total external research and development costs decreased $17.6 million, or 24%, for the nine months ended September 30, 2007 compared to the same period in 2006. The lower external development costs for the quarter and year-to-date periods were primarily a result of our completion of patient enrollment in our Phase 3 cSSSI studies for telavancin in 2006, offset by increased external research and development costs associated with our Phase 3 HAP studies for telavancin and our two Phase 2 clinical studies for TD-5108, our GI motility dysfunction compound and TD-1792, our investigational antibiotic, in 2007.

Employee-related expenses increased $1.0 million, or 10%, for the three months ended September 30, 2007 compared to the same period in 2006. Employee-related expenses increased $10.4 million, or 36%, for the nine months ended September 30, 2007 compared to the same period in 2006. The increase was primarily due to higher costs of non-officer incentive programs and increased headcount to support our clinical research programs in 2007. During the nine months ended September 30, 2007, we recorded an increase in bonus expense and related accrual for non-officer employees of $8.5 million related to the achievement of certain clinical milestones, which included the effect of a change in estimate of $7.1 million.

Research and development stock-based compensation expense increased $0.5 million, or 17%, for the three months ended September 30, 2007 compared to the same period in 2006. Research and development stock-based compensation expense increased $0.7 million, or 7%, for the nine months ended September 30, 2007 compared to the same period in 2006. The increases for the three and nine months ended September 30, 2007 were due primarily to increased headcount. Stock-based compensation includes expenses related to employee stock options, employee stock purchases and the value of options issued to non-employees for services rendered. Facilities, depreciation and other allocated expenses increased by $0.6 million or 11% and $2.2 million or 13% for the three and nine months ended September 30, 2007, respectively, over the comparable periods of 2006. These respective period increases were primarily due to higher supplies and facilities administration costs in 2007.

We have short- and long-term bonus programs in place for certain eligible employees related to the achievement of certain clinical milestones. During the third quarter of 2007, we achieved the last clinical milestone under a long-term bonus plan established in 2004, which resulted in a cumulative increase in bonus expense of $8.5 million for the nine months ended September 30, 2007. As of September 30, 2007, we have fully accrued our bonus liability of approximately $12.4 million relating to our long-term bonus program, which ended in September 2007. During the nine months ended September 30, 2007, we granted performance-contingent restricted stock unit awards (RSUs) to certain employees, the vesting of which is tied to the successful achievement of certain clinical development milestones during 2008 and 2009, as well as a requirement for continued employment through 2009 and 2010. The maximum potential expense for research and development associated with these RSUs could be up to $39.0 million, which would be recognized in increments based on the successful achievement of the performance conditions. To-date, we determined that no requisite performance conditions were probable and as a result, no compensation expense has been recognized.

Under our agreement with Astellas, we are responsible for completion of the cSSSI and HAP telavancin Phase 3 programs, publication of the results of these studies, preparation and submission of a NDA to the FDA for the cSSSI indication and subsequently for the HAP indication, and manufacture of approximately six months of first commercial sale stock for launch. We are reliant on the efforts of third parties, including contract research organizations, consultants and contract manufacturing organizations for the completion of these obligations.

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In September 2007, we announced that we retained full ownership rights of our GI Motility Dysfunction program and TD-1792, our investigational antibiotic compound, as a result of GSK s and Astellas respective decisions not to exercise their right to license these programs. We are currently reviewing plans for the future development of TD-1792 and the product candidates under the GI Motility Dysfunction program. We expect that our expenses would increase substantially if we decide to develop these product candidates internally instead of with collaborative partners.

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

General and administrative General and administrative expenses increased by $0.6 million, or 8%, for the three months ended September 30, 2007, compared to the same period in 2006. This increase was primarily due to higher stock-based compensation. General and administrative expenses increased by $2.7 million, or 11%, for the nine months ended September 30, 2007, compared to the same period in 2006. This increase was primarily due to higher employee costs and costs associated with preparation for the call and the put period under the strategic alliance with GSK.

Total general and administrative stock-based compensation expense increased $0.7 million, or 41%, for the three months ended September 30, 2007 compared to the same period in 2006. Total general and administrative stock-based compensation expense was relatively unchanged for the nine months ended September 30, 2007 compared to the same period in 2006. Stock-based compensation includes expenses related to employee stock options, employee stock purchases and the value of options issued to non-employees for services rendered.

During the second and third quarters of 2007, we also granted RSUs to certain employees, the vesting of which is tied to the successful achievement of certain clinical development milestones during 2008 and 2009, as well as a requirement for continued employment through 2009 and 2010. The maximum potential general and administrative expense associated with these RSUs could be up to $27.0 million, which would be recognized in increments based on the successful achievement of the performance conditions. To-date, we determined that no requisite performance conditions were probable and as a result, no compensation expense has been recognized.

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 decreased for the three and nine months ended September 30, 2007 compared to the same periods in 2006, primarily due to lower average cash balances.

We expect interest and other income to fluctuate in the future with changes in average cash and investment balances and market interest rates.

Interest and other expense, net Interest expense includes interest expense on capital lease and debt arrangements. Interest and other expense decreased for the three and nine months ended September 30, 2007 compared to the same periods in 2006, primarily due to the conclusion of various lease contracts.

Income taxes We adopted FIN 48 effective January 1, 2007. The adoption of FIN 48 did not result in an adjustment to the beginning balance of our accumulated deficit. Under FIN 48, we have unrecognized tax benefits of $26.7 million as of January 1, 2007. If we are eventually able to recognize these uncertain positions, $26.7 million of the unrecognized benefit would reduce our effective tax rate. We currently have a full valuation allowance against our net deferred tax asset which would impact the timing of the effective tax rate benefit should any of these uncertain tax positions be favorably settled in the future.

We are subject to federal and state examination for years 1996 and forward, by virtue of the tax attributes carrying forward from those years. We have no tax examinations currently in progress.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2007 and December 31, 2006, we had $166.5 million and $235.6 million, respectively, in cash, cash equivalents and marketable securities, in each case excluding $3.8 million and $3.9 million, respectively, in restricted cash that was pledged as collateral for certain of our leased facilities and equipment. During the nine months ended September 30, 2007, we received payments of $57.0 million from Astellas primarily as a result of achieving certain clinical milestones under the terms of our collaboration agreement with Astellas.

We believe that our cash, cash equivalents and marketable securities will be sufficient to meet our anticipated operating needs for at least the next twelve months based upon current operating and spending assumptions. Each of TD-5108 and TD-1792 has successfully completed a Phase 2 proof-of-concept study and we may pursue collaboration arrangements for the development and commercialization of these compounds. If we are unable to enter into such collaboration arrangements, or if those agreements require that we assume future development responsibilities, then our operating expenses will increase significantly and we will need to raise additional funds. We expect expenditures to increase as we continue to invest in our highest priority research and development programs, particularly to the extent we advance our product candidates into and through clinical studies, which are very expensive. We are evaluating various alternatives to fund our business such as equity or debt financing, strategic partnerships with other pharmaceutical companies and financial partnerships, and will likely pursue one or more of these strategies within the next twelve months. We cannot guarantee that future financing will be available in amounts or on terms acceptable to us, if at all. This could leave us without adequate financial resources to fund our operations as presently conducted.

Cash Flows

Net cash used in operating activities was $68.5 million and $74.0 million for the nine months ended September 30, 2007 and 2006, respectively. The decrease of cash used in operations for the nine months ended September 30, 2007 was primarily due to $57.0 million in payments received from Astellas as well as lower research and development expenses, slightly offset by higher general and administrative expenses.

Investing activities for the nine months ended September 30, 2007 provided cash of $69.5 million compared to the use of cash in investing activities of $34.9 million for the comparable period of 2006. The increase in 2007 resulted primarily from lower purchases of marketable securities.

Financing activities provided cash of $5.5 million and $144.8 million for the nine months ended September 30, 2007 and 2006, respectively. The cash provided by financing activities in 2007 was primarily due to proceeds received from the issuance of common shares under our employee stock plans, while the cash provided by financing activities during the first nine months of 2006 was higher primarily due to proceeds, net of issuance costs, of approximately $139.8 million received from our public offering of common stock in February 2006.

Contractual Obligations and Commitments

Our major outstanding contractual obligations relate to our operating leases, fixed purchase commitments under contract research, development and clinical supply agreements and a note payable. As security for performance of certain obligations under the operating leases for our headquarters, we have issued letters of credit in the aggregate of approximately $3.8 million, collateralized by an equal amount of restricted cash. Additionally, we have restricted cash of $0.1 million as collateral for certain equipment leases. The terms of these facilities and equipment leases require us to maintain an unrestricted cash and marketable securities balance of at least $50.0 million on the last day of each calendar quarter.

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

Effect of Recent Accounting Pronouncements

In June 2007, the Emerging Issues Task Force (EITF) ratified a consensus on EITF Issue No. 07-3 (EITF 07-3), Accounting for Non-Refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities , which concluded that non-refundable advance payments for goods or services for use in research and development activities should be deferred and capitalized. EITF 07-3 is effective beginning in the first quarter of fiscal year 2008. We are currently evaluating the impact of the provisions of EITF 07-3 on our financial position, results of operations and cash flows and therefore, the impact of the adoption is unknown at this time.

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

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 is effective beginning in the first quarter of fiscal year 2008. We are currently evaluating the impact of the provisions of SFAS 157 on our financial position, results of operations and cash flows and therefore, the impact of the adoption is unknown at this time.

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

Item 3. Quantitative and Qualitative Disclosure about Market Risk

There have been no significant changes in our market risk or how our market risk is managed compared to the disclosures in Item 7A of our 2006 10-K.

Item 4. Controls and Procedures

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

Evaluation of Disclosure Controls and Procedures

We conducted an evaluation as of September 30, 2007, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, which are defined under SEC rules as controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Securities Exchange Act of 1934 (Exchange Act) is recorded, processed, summarized and reported within required time periods. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

Limitations on the Effectiveness of Controls

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

Changes in Internal Control over Financial Reporting

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

PART II. OTHER INFORMATION

Item 1A. Risk Factors.

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

Risks Related to our Business

If our product candidates, in particular telavancin, are determined to be unsafe or ineffective in humans, our business will be adversely affected and our stock price will decline.

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 our compounds and product candidates is high. For example, in late 2005 we discontinued our overactive bladder program based upon the results of our Phase 1 studies with compound TD-6301. To date, the data supporting our drug discovery and development programs is derived solely from laboratory experiments, preclinical studies and clinical studies. A number of other compounds remain in the lead identification, lead optimization, preclinical testing or early clinical testing stages.

On October 19, 2007 we received an approvable letter from the U.S. Food and Drug Administration (FDA) indicating that our telavancin new drug application (NDA) is approvable, subject to resolution of current good manufacturing practices (cGMP) compliance issues not specifically related to telavancin at our third-party manufacturer, and submission of revised labeling or re-analyses of clinical data or additional clinical data. Although we are working diligently toward submission of a complete response to the FDA and we believe that no additional clinical studies will need to be initiated to respond to the approvable letter, there can be no assurance that we will be able to respond fully or adequately to the FDA s requests using currently existing clinical data, that our third-party manufacturer will successfully resolve the cGMP issues that the FDA noted, or that the FDA will approve the current telavancin NDA on the basis of existing preclinical and clinical data or at all. Telavancin is also under review by European Union and Canadian regulatory agencies. If the regulatory authorities require additional clinical data, or the labeling for telavancin that is ultimately approved by regulatory authorities materially limits the targeted patient population, our business will be harmed and our stock price will fall. Furthermore, if our third party manufacturer s cGMP issues are not satisfactorily resolved or regulatory action on telavancin is otherwise delayed for a lengthy period, or if a regulatory authority does not approve telavancin, our business will be harmed and our stock price will fall.

Several recent, well-publicized safety-related product withdrawals, suspensions, post-approval labeling revisions to include black-box warnings and changes in approved indications, as well as growing public and governmental scrutiny of safety issues, have created an increasingly conservative regulatory environment. Therefore, there is a risk that the FDA may implement new standards or change their interpretation of existing requirements for demonstrating that a product candidate is safe and effective, which could cause non-approval or delays in its approval of product candidates, including telavancin. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. If we are unable to discover and develop medicines that are effective and safe in humans, our business will fail.

Any failure of a product candidate in clinical studies or any delay in commencing or completing clinical studies for our product candidates would likely cause our stock price to decline. In particular, if our Phase 3 HAP clinical studies with telavancin do not demonstrate adequate safety and/or efficacy, our potential market for telavancin will be smaller, our business will be harmed and our stock price will decline.

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

poor effectiveness of product candidates during clinical studies;

adverse events, safety issues or side effects relating to the product candidates or their formulation into medicines;

our inability or the inability of our collaborators or licensees to manufacture or obtain from third parties materials sufficient for use in preclinical and clinical studies;

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

failure of our partners to advance our product candidates through clinical development;

delays in patient enrollment, which we experienced in our Phase 3 hospital-acquired pneumonia (HAP) program for telavancin, 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;

a regional disturbance where we are enrolling patients in our clinical trials, such as a pandemic, terrorist activities or war, or a natural disaster; and

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

We anticipate announcing the results of our telavancin Phase 3 HAP clinical studies in late 2007. Any adverse developments or results or perceived adverse developments or results with respect to our telavancin Phase 3 clinical studies for HAP will cause our stock price to fall.

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

The FDA must approve any new medicine before it can be marketed and sold in the United States. We must provide the FDA and similar foreign regulatory authorities with data from preclinical and clinical studies that demonstrate that our product candidates are safe and effective for a defined indication before they can be approved for commercial distribution. We will not obtain this approval for a product candidate unless and until the FDA approves a 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.

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

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

Telavancin is the first product candidate for which we conducted clinical studies, and it is the first product candidate for which we submitted a NDA to the FDA. On October 19, 2007 we received an approvable letter from the FDA indicating that the telavancin NDA is approvable, subject to resolution of cGMP compliance issues not specifically related to telavancin at a third-party manufacturer, and submission of revised labeling or re-analyses of clinical data or additional clinical data. Although we have received the approvable letter, we still may not obtain regulatory approval to commercialize telavancin in the United States. In addition, we plan to seek U.S. regulatory approval for the additional indication of HAP for telavancin if the results of our Phase 3 HAP clinical studies are favorable. Our telavancin collaborator, Astellas Pharma Inc. (Astellas), has submitted marketing authorizations for telavancin in the European Union and Canada for the treatment of complicated skin and soft tissue infections and cSSSI, respectively, and plans to seek additional foreign regulatory approvals for telavancin. We will be unable to generate revenue from royalty payments from the commercialization and sale of telavancin if we fail to obtain these approvals.

We rely on a number of manufacturers for our product candidates and we rely on a single manufacturer for supply of telavancin, 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 active pharmaceutical ingredient (API) and drug product manufacturers. 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 enter into favorable agreements with them. Any inability to acquire sufficient quantities of API and drug product in a timely manner from these third parties could delay clinical studies, prevent us from developing our product candidates in a cost-effective manner or on a timely basis, and adversely affect the commercial introduction of any approved products. In addition, manufacturers of our API and drug product are subject to the FDA s cGMP regulations and similar foreign standards and we do not have control over compliance with these regulations by our manufacturers.

We are in the process of having telavancin API and drug product manufactured for us in order to meet our obligations to Astellas in connection with commercial launch in the event telavancin is approved for sale by regulatory authorities. We have a single source of supply of telavancin API and a single source of supply of telavancin drug product. If we are unable to have telavancin manufactured in a timely manner, or if Astellas is unable to arrange for the expanded commercial manufacture of telavancin, the commercial introduction of telavancin, if approved, would be adversely affected. During a mid-2007 audit of our supplier for telavancin drug product, a district office of the FDA noted deficiencies, not specifically related to the manufacture of telavancin drug product, with the supplier s quality and laboratory systems at the plant where telavancin is manufactured. Although the supplier reported to us that it had responded to all noted deficiencies and had obtained verbal acknowledgment from the FDA s district office that it was in compliance, to date the supplier has been unable to reach formal resolution of these issues with the FDA. On October 19, 2007 we received an approvable letter from the FDA indicating that the telavancin NDA is approvable subject to, among other things, resolution of these cGMP compliance issues at our supplier. It is impossible to predict the amount of time it will take for the supplier and the FDA to resolve these compliance issues, and any material delay will harm our business and cause our stock price to fall.

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 APIs and/or drug products in a cost effective and/or timely manner and changing manufacturers for our APIs or drug products could involve lengthy technology transfer and validation activities for the new manufacturer;

the processes required to manufacture certain of our APIs and drug products are specialized and available only from a limited number of third-party manufacturers;

some of the manufacturing processes for our APIs and drug products have not been scaled to 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 product candidates; and

because some of the third-party manufacturers are located outside of the U.S., there may be difficulties in importing our APIs and drug products 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.

In addition, we are using a single source for the supply of our APIs and a single source for the supply of drug product for TD-1792, our next-generation antibiotic compound, as well as for TD-5108 in our GI Motility Dysfunction program. If any supplier fails to continue to produce supplies for our development activities for these compounds in acceptable quantity and/or quality, our clinical studies could be delayed.

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

If approved by the relevant regulatory agencies, the commercial success of telavancin will depend upon its acceptance by physicians, patients, third party payors and the medical community in general. We cannot be sure that telavancin will be accepted by these parties even if it is approved by the relevant regulatory authorities. If approved, telavancin will compete with vancomycin, a relatively inexpensive generic drug that is manufactured by a variety of companies, a number of existing anti-infectives manufactured and marketed by major pharmaceutical companies and others, and potentially against new anti-infectives that are not yet on the market. Even if the medical community accepts that

telavancin is safe and efficacious for its approved indications, physicians may choose to restrict the use of telavancin. If we are unable to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, telavancin is preferable to vancomycin and other existing or subsequently-developed anti-infective drugs, we may never generate meaningful revenue from telavancin. The degree of market acceptance of telavancin, if approved by the relevant regulatory agencies, will depend on a number of factors, including, but not limited to:

the demonstration of the clinical efficacy and safety of telavancin;

the labeling for telavancin that ultimately is approved by regulatory authorities;

the advantages and disadvantages of telavancin compared to alternative therapies;

our and our collaborative partner s ability to educate the medical community about the safety and effectiveness of telavancin;

the reimbursement policies of government and third party payors; and

the market price of telavancin.

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

Even if we receive regulatory approval, this approval may include limitations on the indicated uses for which we can market our medicines or the patient population that may utilize our medicines, which may limit the market for our medicines or put us at a competitive disadvantage relative to alternative therapies. 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 authorities may also implement new standards, or change their interpretation and enforcement of existing standards and requirements for the manufacture, packaging or testing of products at any time. If we are unable to comply, we may be subject to regulatory or civil actions or penalties that could significantly and adversely affect our business. Any failure to maintain regulatory approval will limit our ability to commercialize our product candidates, which would materially and adversely affect our business and financial condition.

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

We have been engaged in discovering and developing compounds and product candidates since mid-1997. We have not generated any product revenue to date. We may never generate revenue from selling medicines or achieve profitability. As of September 30, 2007, we had an accumulated deficit of approximately $904.8 million.

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

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

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 twelve months. We are likely 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 in the world, we are obligated to pay GSK milestone payments of up to an aggregate of $220.0 million under our Beyond Advair collaboration.

Each of TD-5108 and TD-1792 has successfully completed a Phase 2 proof-of-concept study and we may pursue collaboration arrangements for the development and commercialization of these compounds. If we are unable to enter into such collaboration arrangements, or if those agreements require that we assume future development responsibilities, then our operating expenses will increase significantly. We may also need to raise additional funds sooner than presently anticipated if our operating costs exceed our expectations. 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. 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 continuing our discovery and development efforts and exploiting other corporate opportunities. This could harm our business, prospects and financial condition and cause the price of our common stock to fall.

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

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

Our partners might not fulfill all of their obligations under these agreements. In that event, we may be unable to assume the development and commercialization of the product candidates covered by the agreements or enter into alternative arrangements with a third party to develop and commercialize such product candidates. In addition, with the exception of product candidates in our Beyond Advair collaboration, our partners generally are not restricted from developing and commercializing their own products and product candidates that compete with those licensed from us. If a partner elected to promote its own products and product candidates in preference to those licensed from us, future payments to us could be reduced and our business and financial condition would be materially and adversely affected. Accordingly, our ability to receive any revenue from the product candidates covered by these agreements is dependent on the efforts of the partner. We could also become involved in disputes with a partner, which could lead to delays in or termination of our development and commercialization programs and time-consuming and expensive litigation or arbitration. If a partner terminates or breaches its agreements with us, or otherwise fails to complete its obligations in a timely manner, the chances of successfully developing or commercializing our product candidates would be materially and adversely affected.

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

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

As of October 31, 2007, GSK beneficially owned approximately 15.4% of our outstanding capital stock. Pursuant to our strategic alliance with GSK, GSK has the right to license exclusive development and commercialization rights to our product candidates arising from our (i) peripheral Opioid-Induced Bowel Dysfunction (PUMA) program, (ii) our AT1 Receptor Neprilysin Inhibitor hypertension (ARNI) program and (iii) our MonoAmine Reuptake Inhibitor chronic pain (MARIN) program. Because GSK may license these three 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. We may not have sufficient funds to pursue such programs in the event GSK does not license them at an early stage. 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. If our ability to work with present or future strategic partners or collaborators is adversely affected as a result of our strategic alliance with GSK, our business prospects may be limited and our financial condition may be adversely affected.

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

To date, we have entered into collaborations with GSK for the Beyond Advair, LAMA and MABA programs and with Astellas for telavancin, and we have licensed our anesthesia compound to AstraZeneca. Each of TD-5108 and TD-1792 has successfully completed a Phase 2 proof-of-concept study and we may pursue collaboration arrangements for the development and commercialization of these compounds. Collaborations with third parties regarding these programs or our other programs may require us to relinquish material rights, including revenue from commercialization of our medicines, on terms that are less attractive than our current arrangements. These collaboration arrangements are complex and time-consuming to negotiate, and 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. Furthermore, for any collaboration, we may not be able to control the amount of time and resources that our partners devote to our product candidates and our partners may choose to pursue alternative products. 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 depend on third parties in the conduct of our clinical studies for our product candidates.

We depend on independent clinical investigators, contract research organizations and other third party service providers in the conduct of our preclinical and clinical studies for our product candidates. We rely heavily on these parties for execution of our preclinical and clinical studies, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that our clinical studies are conducted in accordance with good clinical practices and other regulations as required by the FDA and foreign regulatory agencies, and the applicable protocol. The FDA enforces good clinical practices and other regulations through periodic inspections of trial sponsors, principal investigators and trial sites. For example, in connection with the FDA s review of our telavancin NDA for the treatment of cSSSI, the FDA conducted inspections of Theravance and certain of our study sites and clinical investigators. If we or any of the third parties on which we have relied to conduct our clinical studies are determined to have failed to comply with applicable good clinical practices and other regulations, the clinical data generated in our studies may be deemed unreliable and the FDA may decide to conduct additional audits or require us to perform additional clinical studies.

We face substantial competition from companies with more resources and experience than we have, which may result in others discovering, developing, receiving approval for 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 or in-license novel compounds that could make our product candidates obsolete. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or discovering, developing and commercializing medicines before we do. We are also aware of other companies that are engaged in the discovery of medicines that would compete with the product candidates that we are developing.

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

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

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

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

our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products;

the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

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

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 unexpected loss of Dr. Vagelos, Mr. Winningham, Dr. Humphrey or Dr. Kitt could impair our ability to discover, develop and market new medicines. Dr. Humphrey plans to transition out of his position at Theravance in late 2007 or early 2008. The Company has initiated a search to evaluate internal and external candidates to replace Dr. Humphrey as head of Research.

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

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

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

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 our Alliance with GSK

GSK s ownership of a significant percentage of our stock 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 October 31, 2007, GSK beneficially owned approximately 15.4% of our outstanding capital stock, and GSK has the right to maintain its percentage ownership of our capital stock. In addition, GSK currently has the right to designate one member to our board of directors. There are currently no GSK designated directors on our board of directors. 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 our (i) peripheral Opioid-Induced Bowel Dysfunction (PUMA) program, (ii) our AT1 Receptor Neprilysin Inhibitor hypertension (ARNI) program, and (iii) our MonoAmine Reuptake Inhibitor chronic pain (MARIN) program. As a result of these rights, other companies may be less inclined to pursue an acquisition of us and therefore 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.

After September 2008, 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.

Beginning in September 2008, GSK may sell or transfer our common stock either pursuant to a public offering registered under the Securities Act of 1933, as amended (the 1933 Act), or pursuant to Rule 144 of the 1933 Act. In addition, beginning in September 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 contribute to a transfer of control of our company to a third party.

As a result of the put arrangements with GSK which expired in September 2007, there are uncertainties with respect to various tax consequences associated with owning and disposing of shares of our common stock that were held during the periods that the put arrangements were effective. Therefore, there is a risk that owning and/or disposing of such 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 during periods when the put arrangements were effective and stockholders should consult with their tax advisors as to the tax consequences of disposing of such shares.

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. The status of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and is very uncertain. As of September 30, 2007, we had 108 issued United States patents and have received notices of allowance for 14 other United States patent applications. As of that date, we had 124 pending patent applications in the United States and 364 granted foreign patents. We also have 8 Patent Cooperation Treaty applications that permit us to pursue patents outside of the United States, and 796 foreign national patent applications. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be too narrow to prevent third parties from developing or designing around these patents. If the sufficiency of the breadth or strength of protection provided by our patents with respect to a product candidate is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, the product candidate. Further, if we encounter delays in our clinical trials, the patent lives of the related drug candidates would be reduced.

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

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

Our commercial success depends in part on our not infringing the patents and proprietary rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization. There are third party patents that may cover materials or methods for treatment related to our product candidates. At present we are not aware of any patent claims with merit that would adversely and materially affect our ability to develop our product candidates, but nevertheless the possibility of third party allegations cannot be ruled out. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Furthermore, parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve

substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties or pay royalties. In addition, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. In addition, in the future we could be required to initiate litigation to enforce our proprietary rights against infringement by third parties. Prosecution of these claims to enforce our rights against others would involve substantial litigation expenses and divert substantial employee resources from our business. If we fail to effectively enforce our proprietary rights against others, our business will be harmed.

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

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

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

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

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

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

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

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

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 in all material respects with legally prescribed standards, we may incur significant additional costs to comply with applicable laws in the future. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business.

General Company Related Risks

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

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:

any adverse developments or results or perceived adverse developments or results with respect to the Beyond Advair collaboration;

any adverse development or perceived adverse development with respect to our telavancin NDA or our response to the FDA s approvable letter received October 19, 2007;

any delay in the commercial distribution of telavancin if our NDA is approved by the FDA;

any adverse developments or results or perceived adverse developments or results with respect to our telavancin Phase 3 clinical studies for HAP. In this regard, we anticipate announcing the results of our telavancin Phase 3 HAP clinical studies in late 2007. If the results are unfavorable our stock price will fall;

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

any adverse developments or results or perceived adverse developments or results with respect to our GI Motility Dysfunction program or TD-1792;

announcements regarding GSK s decisions whether or not to license any of our product development programs;

announcements regarding GSK or Astellas generally;

announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors;

developments concerning any collaboration we may undertake with companies other than GSK or Astellas;

publicity regarding actual or potential testing or study results or the outcome of regulatory review relating to products under development by us, our partners or our competitors;

regulatory developments in the United States and foreign countries;

economic and other external factors beyond our control; and

sales of stock by us or by our stockholders, including sales by certain of our executive officers and directors pursuant to written pre-determined selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, some of which plans are currently in effect and others of which may be entered into.

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

As of October 31, 2007, GSK beneficially owned approximately 15.4% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 14.0% 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 one director. 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 business.

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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Issuer Purchases of Equity Securities

Period	Total Number of Common Shares Purchased (1)	Average Price Paid per Share (1)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (2)	Maximum Number of Shares that May Yet be Purchased Under the Plans or Programs (2)
July 1-31, 2007				
August 1-31, 2007				
September 1-30, 2007	8,938	$ 28.00	1	
	8,938			

(1) Includes common shares repurchased from an executive officer at $28.00 per share. Upon the vesting of 25,000 restricted shares of the officer in September 2007, 8,937 shares were repurchased by the Company for a total of $250,236 as payment for the officer s related withholding tax liability.

(2) During the fiscal quarter ended September 30, 2007, the Company repurchased one common share for $19.975 from a stockholder who exercised his put right under the Company s certificate of incorporation, which put right was described in the Company s tender offer statement dated August 1, 2007, as filed with the SEC on that date. After September 12, 2007, no further shares may be put by stockholders pursuant to the Company s certificate of incorporation and the Company s tender offer terminated immediately thereafter.

Item 6. Exhibits

Exhibit Number	Exhibit Description
3.3(1)	Restated Certificate of Incorporation
3.4(2)	Certificate of Amendment of Restated Certificate of Incorporation
3.5(2)	Amended and Restated Bylaws
4.1(3)	Specimen certificate representing the common stock of the registrant
4.2(4)	Amended and Restated Rights Agreement between Theravance, Inc. and The Bank of New York, as Rights Agent, dated as of June 22, 2007
10.43	Offer letter with Leonard Blum dated July 27, 2007
10.44+	First Addendum to the Terms & Conditions Dated February 17, 2004 between the Company and Ben Venue Laboratories, Inc. dated September 21, 2007
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 March 31, 2007.

(3) Incorporated herein by reference to the exhibit of the same number in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.

(4) 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 June 30, 2007.

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

SIGNATURES

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

Theravance, Inc.
(Registrant)

November 7, 2007
Date

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

November 7, 2007
Date

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

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

(2) Incorporated herein by reference to the exhibit of the same number in the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.

(3) Incorporated herein by reference to the exhibit of the same number in the Company s Annual Report on Form 10-K.

(4) 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 June 30, 2007.

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