

THERAVANCE INC  
Form 10-Q  
May 08, 2007

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

# FORM 10-Q

(Mark One)

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

**For the quarterly period ended March 31, 2007**

**OR**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission File Number:  
0-30319**

# THERAVANCE, INC.

(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or  
Organization)

**94-3265960**  
(I.R.S. Employer  
Identification No.)

**901 Gateway Boulevard**  
**South San Francisco, CA 94080**

(Address of Principal Executive Offices including Zip Code)

**(650) 808-6000**

(Registrant's Telephone Number, Including Area Code)

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

Yes  No

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

Large Accelerated Filer  Accelerated Filer  Non-Accelerated Filer

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

Yes  No

The number of shares of registrant's common stock outstanding on April 30, 2007 was 50,874,381.

The number of shares of registrant's Class A common stock outstanding on April 30, 2007 was 9,401,498.

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## PART I FINANCIAL INFORMATION

## ITEM 1. Financial Statements

## THERAVANCE, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

|  | March 31,<br>2007<br>(Unaudited) | December 31,<br>2006<br>* |
|--|----------------------------------|---------------------------|
| <b>Assets</b>  |                                  |                           |
| Current assets:  |                                  |                           |
| Cash and cash equivalents  | \$ 77,152                        | \$ 72,388                 |
| Marketable securities  | 107,482                          | 128,692                   |
| Receivable from related party  | 229                              | 608                       |
| Notes receivable   | 17                               | 1,142                     |
| Prepaid and other current assets   | 5,805                            | 4,361                     |
| Total current assets   | 190,685                          | 207,191                   |
| Marketable securities  | 35,077                           | 34,490                    |
| Restricted cash and cash equivalents   | 3,830                            | 3,860                     |
| Property and equipment, net  | 16,183                           | 15,101                    |
| Notes receivable   | 1,884                            | 1,782                     |
| Total assets   | \$ 247,659                       | \$ 262,424                |
| <b>Liabilities and stockholders' equity</b>  |                                  |                           |
| Current liabilities:   |                                  |                           |
| Accounts payable   | \$ 8,818                         | \$ 16,011                 |
| Accrued personnel-related expenses   | 6,154                            | 8,316                     |
| Accrued clinical and development expenses  | 23,083                           | 13,608                    |
| Other accrued liabilities  | 3,519                            | 2,314                     |
| Current portion of notes payable   | 91                               | 87                        |
| Current portion of deferred revenue  | 21,221                           | 19,273                    |
| Total current liabilities  | 62,886                           | 59,609                    |
| Deferred rent  | 2,225                            | 2,298                     |
| Notes payable  | 513                              | 538                       |
| Deferred revenue   | 159,038                          | 134,383                   |
| Other long term liabilities  | 2,653                            | 2,286                     |
| <b>Commitments and Contingencies</b>   |                                  |                           |
| Stockholders' equity:  |                                  |                           |
| Preferred stock, \$0.01 par value, 230 shares authorized, no shares issued and outstanding   |                                  |                           |
| Common stock, \$0.01 par value; 200,000 shares authorized, issuable in series; 50,864 and 50,746 shares issued and outstanding at March 31, 2007 and December 31, 2006, respectively | 508                              | 507                       |
| Class A Common Stock, \$0.01 par value, 30,000 shares authorized, 9,402 issued and outstanding at March 31, 2007 and December 31, 2006   | 94                               | 94                        |
| Additional paid-in capital   | 846,924                          | 840,498                   |
| Notes receivable from stockholders   | (1                               | ) (3                      |
| Accumulated other comprehensive income   | 81                               | 26                        |
| Accumulated deficit  | (827,262                         | ) (777,812                |
| Total stockholders' equity   | 20,344                           | 63,310                    |
| Total liabilities and stockholders' equity   | \$ 247,659                       | \$ 262,424                |

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

*See accompanying notes to condensed consolidated financial statements.*

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## THERAVANCE, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

|  | <b>Three Months Ended</b> |              |
|--|---------------------------|--------------|
|  | <b>March 31,</b>          |              |
|  | <b>2007</b>               | <b>2006</b>  |
| Revenue (1)  | \$ 5,398                  | \$ 4,296     |
| Operating expenses:                                |                           |              |
| Research and development                           | 48,858                    | 48,708       |
| General and administrative                         | 8,798                     | 7,274        |
| Total operating expenses                           | 57,656                    | 55,982       |
| Loss from operations                               | (52,258 )                 | (51,686 )    |
| Interest and other income                          | 2,929                     | 2,885        |
| Interest and other expense                         | (121 )                    | (151 )       |
| Net loss   | \$ (49,450 )              | \$ (48,952 ) |
| Basic and diluted net loss per common share        | \$ (0.82 )                | \$ (0.86 )   |
| Shares used in computing net loss per common share | 60,061                    | 56,871       |

(1) Amounts include revenue from GSK, a related party, of \$2,824 and \$3,036 for the three months ended March 31, 2007 and 2006, respectively.

*See accompanying notes to condensed consolidated financial statements.*



## THERAVANCE, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

|   | Three Months Ended March 31, |              |
|---|------------------------------|--------------|
|   | 2007                         | 2006         |
| <b>Cash flows used in operating activities</b>                              |                              |              |
| Net loss  | \$ (49,450 )                 | \$ (48,952 ) |
| Adjustments to reconcile net loss to net cash used in operating activities: |                              |              |
| Depreciation and amortization   | 871                          | 898          |
| Stock-based compensation  | 5,788                        | 5,013        |
| Forgiveness of notes receivable   | 12                           | 17           |
| Other non-cash operating expenses   | (270 )                       | 11           |
| Changes in operating assets and liabilities:                                |                              |              |
| Receivables, prepaid and other current assets                               | (205 )                       | (136 )       |
| Accounts payable and accrued liabilities                                    | 2,307                        | 6,029        |
| Accrued personnel-related expenses  | (2,162 )                     | (2,091 )     |
| Deferred rent   | (73 )                        | 35           |
| Deferred revenue  | 26,603                       | (3,298 )     |
| Other long-term liabilities   | 382                          | 442          |
| Net cash used in operating activities                                       | (16,197 )                    | (42,032 )    |
| <b>Cash flows provided by (used in) investing activities</b>                |                              |              |
| Purchases of property and equipment   | (1,566 )                     | (464 )       |
| Purchases of marketable securities  | (43,702 )                    | (91,138 )    |
| Maturities of marketable securities   | 40,720                       | 33,418       |
| Sales of marketable securities  | 23,863                       | 12,791       |
| Release of restricted cash  | 30                           |              |
| Additions to notes receivable   | (150 )                       | (450 )       |
| Payments received on notes receivable                                       | 1,163                        | 53           |
| Net cash provided by (used in) investing activities                         | 20,358                       | (45,790 )    |
| <b>Cash flows provided by financing activities</b>                          |                              |              |
| Payments on notes payable and capital leases                                | (21 )                        | (266 )       |
| Net proceeds from issuances of common stock                                 | 624                          | 141,823      |
| Net cash provided by financing activities                                   | 603                          | 141,557      |
| Net increase in cash and cash equivalents                                   | 4,764                        | 53,735       |
| Cash and cash equivalents at beginning of period                            | 72,388                       | 49,787       |
| Cash and cash equivalents at end of period                                  | \$ 77,152                    | \$ 103,522   |
| <b>Supplemental disclosures of cash flow information</b>                    |                              |              |
| Non-cash investing and financing activities:                                |                              |              |
| Removal of deferred stock-based compensation                                | \$                           | \$ (4,965 )  |

*See accompanying notes to condensed consolidated financial statements.*

**Theravance, Inc.**  
**Notes to Condensed Consolidated Financial Statements**

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

*Unaudited Interim Financial Information*

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The accompanying unaudited 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 March 31, 2007, and the results of operations and cash flows for the three months ended March 31, 2007 and 2006. The results for the three months ended March 31, 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 consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates based upon current assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual conditions may differ materially from the Company's current assumptions. This may result in the Company's estimates being incorrect and may require it to record additional charges or benefits in operations.

### *Segment Reporting*

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The Company has determined that it operates in only one segment, which is the research and development of human therapeutics. 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.

### *Fair Value of Employee Stock Options*

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 under the 2004 Equity Incentive Plan 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 is expensed on a straight-line basis over the expected term of the grant. 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 of the vesting periods while the compensation expense for all share-based payment awards granted on or subsequent to January 1, 2006 is recognized using the straight-line single-option method. Stock-based compensation expense has been reduced for estimated forfeitures so that compensation expense is based on awards ultimately expected to vest. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company's estimated annual forfeiture rate is 3.6%, based on its historical forfeiture experience.

*Recent Accounting Pronouncements*

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 fiscal years beginning after November 15, 2007. The Company has not yet determined the impact, if any, of adopting SFAS 159 on its consolidated financial statements.

In September 2006, 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. The provisions of SFAS 157 are effective for the Company beginning in the first quarter of fiscal year 2009. The Company is currently evaluating the impact of the provisions of SFAS 157 on its financial position, results of operations and cash flows and does not believe the impact of the adoption will be material.

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.

**2. Net Loss per Share**

Basic net loss per common share (Basic EPS) is computed by dividing net loss by the weighted-average number of common shares outstanding, less shares subject to repurchase. Diluted net loss per common share (Diluted EPS) is computed by dividing net loss by the weighted-average number of common shares outstanding, plus dilutive potential common shares. At March 31, 2007, potential common shares consist of 139,000 shares subject to repurchase (including 50,000 shares of restricted stock), 11,061,000 shares issuable upon the exercise of stock options and 18,000 shares issuable upon the exercise of warrants. At March 31, 2006, potential common shares consist of 186,000 shares subject to repurchase (including 50,000 shares of restricted stock), 10,639,000 shares issuable upon the exercise of stock options and 18,000 shares issuable upon the exercise of warrants. Diluted EPS is identical to Basic EPS for all periods presented since potential common shares are excluded from the calculation, as their effect is anti-dilutive.

| (in thousands, except for per share data)   | Three Months Ended |              |
|---|--------------------|--------------|
|   | March 31, 2007     | 2006         |
| Basic and diluted:  |                    |              |
| Net loss  | \$ (49,450 )       | \$ (48,952 ) |
| Weighted average shares of common stock outstanding                                   | 60,203             | 57,065       |
| Less: weighted average shares subject to repurchase                                   | (142 )             | (194 )       |
| Weighted average shares used in computing basic and diluted net loss per common share | 60,061             | 56,871       |
| Basic and diluted net loss per common share   | \$ (0.82 )         | \$ (0.86 )   |

**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 March 31, 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

thresholds by a Theravance-discovered LABA. In the event that a LABA

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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 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 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 its estimated period of performance (the product development period). Collaboration revenue was \$1.7 million and \$1.9 million for the three months ended March 31, 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 the three months ended March 31, 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 March 31, 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). For the three months ended March 31, 2007 and 2006, the Company recognized \$0.2 million and \$0.3 million, 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 months ended March 31, 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 March 31, 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). For the three months ended March 31, 2007 and 2006, the Company recognized \$0.3 million and \$0.2 million, respectively, in revenue related to the MABA program. Additionally, the Company is reimbursed by GSK for certain costs related to the MABA program as an offset to research and development expense. There were no reimbursements for the three months ended March 31, 2007 compared to \$0.1 million for the three months ended March 31, 2006.





GSK may increase its ownership of the Company's outstanding stock up to approximately 59.4% through the issuance by the Company to GSK of the number of shares of its common stock that the Company may be required to redeem from the Company's stockholders as described below. In June 2007, GSK is required to notify the Company whether it plans to require the Company to redeem (call), and upon notice of the date of the redemption to effect the call (the call date), each stockholder (including GSK, to the extent GSK holds common stock) will automatically be deemed to have submitted for redemption on the call date, 50% of the Company's common stock held by such stockholder at \$54.25 per share. If GSK exercises the call, the call date must occur no later than July 31, 2007. If GSK does not exercise its call right, each of the Company's stockholders (including GSK, to the extent GSK holds common stock) has the right 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. In either case, GSK is contractually obligated to pay to the Company the funds necessary for it to redeem the shares of common stock from its stockholders; however, GSK's maximum obligation for the shares subject to the put is capped at \$525.0 million. The Company is under no obligation to redeem its shares under the call or the put until it receives funds from GSK to redeem the shares. Alternatively, if the Company's stockholders exercise the put, GSK may elect to purchase the shares of common stock that are put directly from such stockholders. In connection with those arrangements, the Company has agreed not to issue new equity securities if it would cause more than approximately 54.2 million shares of common stock subject to the put (including securities vested and exercisable or convertible into shares of common stock) to be outstanding as of the put date. If GSK's ownership increases to more than 50% in 2007 as a result of the call or put, GSK is required to receive an extension of its option to license the Company's full drug discovery programs initiated prior to September 1, 2012; otherwise, this exclusive option does not apply to programs initiated after September 1, 2007.

The effect of the redemption of the Company's common stock pursuant to the call or the put would not cause a decrease to its cash balances, total assets, or total stockholders' equity. Accordingly, the Company has classified its common stock within stockholders' equity.

*2005 License, Development and Commercialization Agreement with Astellas*

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In November 2005, the Company entered into a collaboration arrangement with Astellas Pharma Inc. (Astellas) for the development and commercialization of telavancin. 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 March 31, 2007, the Company received \$133.0 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 \$2.1 million and \$1.3 million in revenue for the three months ended March 31, 2007 and 2006, respectively. The Company is eligible to receive up to \$95.0 million in remaining clinical and regulatory milestone payments, which includes up to \$85.0 million for approval of the complicated skin and skin structure infections (cSSSI) New Drug Application (NDA) and completion of the hospital-acquired pneumonia (HAP) clinical program and filing and approval of a supplemental NDA for HAP, and \$10.0 million if the Phase 3 data demonstrates telavancin's superiority over vancomycin for HAP patients infected with methicillin-resistant *Staphylococcus aureus* (MRSA).

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 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 also received an option to further develop and commercialize TD-1792, the Company's heterodimer antibiotic compound that recently completed enrollment in a Phase 2 clinical study.

*2006 License Agreement with AstraZeneca AB*

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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. Through March 31, 2006, the Company received a \$1.0 million upfront payment from AstraZeneca and is eligible to receive milestone payments and royalties on global sales. For the three months ended March 31, 2007, the Company recognized the remaining \$0.4 million of the upfront payment due to the completion of its performance obligations under the contract.

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#### 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 March 31, 2007:

| (in thousands)                                       | March 31, 2007 |                        |                         |                      |
|--|----------------|------------------------|-------------------------|----------------------|
|  | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
| U.S. government agencies                             | \$ 60,299      | \$ 46                  | \$ (23 )                | \$ 60,322            |
| U.S. corporate notes                                 | 51,509         | 8                      | (7 )                    | 51,510               |
| U.S. commercial paper                                | 66,383         |                        |                         | 66,383               |
| Asset-backed securities                              | 39,426         | 63                     | (6 )                    | 39,483               |
| Certificates of deposit                              | 80             |                        |                         | 80                   |
| Money market funds                                   | 5,763          |                        |                         | 5,763                |
| Total  | 223,460        | 117                    | (36 )                   | 223,541              |
| Less amounts classified as cash and cash equivalents | (77,152 )      |                        |                         | (77,152 )            |
| Less amounts classified as restricted cash           | (3,830 )       |                        |                         | (3,830 )             |
| Amounts classified as marketable securities          | \$ 142,478     | \$ 117                 | \$ (36 )                | \$ 142,559           |

The estimated fair value amounts have been determined by the Company using available market information. At March 31, 2007, approximately 62% of marketable securities mature within twelve months, 15% of marketable securities mature between twelve and twenty-four months and the remaining 23% have effective maturities beyond twenty-four months. Average duration of available-for-sale securities was approximately 6 months at March 31, 2007. The Company has determined that the gross unrealized losses on its marketable securities at March 31, 2007 were temporary in nature.

#### 5. Comprehensive Loss

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

| (in thousands)                                       | Three Months Ended |              |
|--|--------------------|--------------|
|  | March 31, 2007     | 2006         |
| Net loss   | \$ (49,450 )       | \$ (48,952 ) |
| Other comprehensive income (loss):                   |                    |              |
| Net unrealized gain on available-for-sale securities | 55                 | (1 )         |
| Comprehensive loss                                   | \$ (49,395 )       | \$ (48,953 ) |

#### 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 March 31, 2007.

##### *Purchase Obligations*

At March 31, 2007, the Company had outstanding purchase obligations, primarily for services from contract research and manufacturing organizations, totaling \$5.1 million.

#### 7. Stockholders' Equity

*Determining Fair Value of Stock-Based Compensation*

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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

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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 |       | Three Months Ended |       |
|--|--------------------|-------|--------------------|-------|
|  | March 31,          |       | March 31,          |       |
|  | 2007               |       | 2006               |       |
| <b>Employee stock options</b>                                  |                    |       |                    |       |
| Risk-free interest rate  | 4.48% - 4.82       | %     | 4.57% - 4.72       | %     |
| Expected life (in years)                                       | 6.04               | 6.08  | 6.17               |       |
| Volatility   | 0.48               |       | 0.51               |       |
| Dividend yield   |                    | %     |                    | %     |
| Weighted average estimated fair value of stock options granted | \$                 | 17.78 | \$                 | 16.23 |
| <b>Employee stock purchase plan issuances</b>                  |                    |       |                    |       |
| Risk-free interest rate  | 4.70% - 5.08       | %     | 2.58% - 4.42       | %     |
| Expected life (in years)                                       | 0.50               | 2.0   | 2.0                |       |
| Volatility   | 0.24 - 0.3         |       | 0.7                |       |
| Dividend yield   |                    | %     |                    | %     |
| Weighted average estimated fair value of ESPP issuances        | \$                 | 8.78  | \$                 | 9.05  |

As of March 31, 2007, there was \$39.8 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 2.7 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.

For the three months ended March 31, 2007 and 2006, stock-based compensation expense was \$5.8 million and \$5.0 million, respectively, consisting of amortization of deferred stock-based compensation, the value of options issued to non-employees for services rendered, and the amortization of deferred stock-based compensation expense related to the grant of restricted stock. The following table discloses the allocation of stock-based compensation expense included in the unaudited condensed consolidated statements of operations:

|                            | Three Months Ended |           |
|----------------------------|--------------------|-----------|
|                            | March 31,          | March 31, |
|                            | 2007               | 2006      |
| Research and development   | \$ 3,368           | \$ 3,046  |
| General and administrative | 2,420              | 1,967     |
|                            | \$ 5,788           | \$ 5,013  |

*Stock Option Plans*



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For the three months ended March 31, 2007, the Company granted stock options to purchase 828,043 shares at an average stock price of \$34.05, under the 2004 Equity Incentive Plan. As of March 31, 2007, total shares remaining available for issuance under the 2004 Equity Incentive Plan were 280,771. On April 25, 2007, an amendment to the Company's 2004 Equity Incentive Plan which, among other things, increased the number of shares authorized for issuance under the 2004 Equity Incentive Plan from 3,700,000 to 7,200,000 shares, was approved by the Company's stockholders.

The Company previously allowed certain stock option holders to exercise their options by executing stock purchase agreements and full-recourse notes payable to the Company. The stock purchase agreements provide the Company with the right to repurchase unvested shares. Certain full-recourse notes payable include forgiveness provisions whereby the Company forgives the unpaid principal of the note on its maturity date if the optionee remains in continuous service until the maturity date on the notes (see

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Notes Receivable discussion in Note 8). As of March 31, 2007, 87,095 shares were subject to repurchase under these outstanding note agreements.

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

|                              | Number of Shares Available for Grant<br>(In thousands, except per share data) | Number of Shares Subject to Outstanding Options | Weighted-Average Exercise Price Per Share |
|------------------------------|---|---|---|
| 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                                  |

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

The weighted-average fair value of options granted with exercise prices equal to the fair value of common stock on the date of grant for the three months ended March 31, 2007 and 2006 was \$17.78 and \$16.23, respectively. The total intrinsic value of the options exercised for the three months ended March 31, 2007 and 2006 was \$3.0 million and \$7.5 million, respectively, and the total fair value of options vested is \$0.2 million and \$1.1 million for the three months ended March 31, 2007 and 2006, respectively.

As of March 31, 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                             |   |  | Aggregate Intrinsic Value | Options Exercisable          |                           | Weighted-Average Remaining Contractual Life |
|--------------------------|---|---|--|---------------------------|------------------------------|---------------------------|---|
|                          | Number of Shares Subject to Outstanding Options | Weighted-Average Remaining Contractual Life | Number of Shares Subject to Options Unvested |                           | Number of Shares Exercisable | Aggregate Intrinsic Value |   |
| \$0.20                   | 10  | 0.5   |  |                           | 10                           |                           | 0.5   |
| \$1.32                   | 67  | 2.7   |  |                           | 67                           |                           | 2.7   |
| \$3.10                   | 1,474   | 6.2   | 163  |                           | 1,474                        |                           | 6.2   |
| \$8.53                   | 2,925   | 4.6   | 1  |                           | 2,925                        |                           | 4.6   |
| \$9.69                   | 1,935   | 7.0   | 1,620  |                           | 29                           |                           | 7.1   |
| \$12.40 \$18.25          | 1,258   | 7.7   | 1,052  |                           | 196                          |                           | 7.4   |
| \$18.26 \$21.70          | 1,006   | 8.1   | 993  |                           |                              |                           |   |
| \$21.71 \$29.65          | 1,486   | 9.0   | 1,370  |                           |                              |                           |   |
| \$29.66 \$35.46          | 900   | 9.8   | 900  |                           |                              |                           |   |
|                          | 11,061  | 6.9   | 6,099  | \$ 169,419                | 4,701                        | \$ 106,374                | 5.2   |

*Employee Stock Purchase Plan*

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Through March 31, 2007, the Company issued 331,048 shares under the 2004 Employee Stock Purchase Plan (ESPP) at an average price of \$13.92 and the total number of remaining shares available for issuance under the plan was 293,952. The total stock-based compensation expense recognized related to the ESPP under SFAS 123(R) for each of the three months ended March 31, 2007 and 2006 was \$0.4 million.

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*Reserved Shares*

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

|                                     | <b>March 31,<br/>2007</b> |
|-------------------------------------|---------------------------|
| Subject to outstanding warrant      | 18                        |
| Stock option plans:                 |                           |
| Subject to outstanding options      | 11,061                    |
| Available for future grants         | 281                       |
| Available for future ESPP purchases | 294                       |
| Total                               | 11,654                    |

### **8. Related Party Transactions**

*Related Parties*

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

Robert V. Gunderson, Jr. is a director of the Company. The Company has engaged Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, of which Mr. Gunderson is a partner, as its primary legal counsel. Fees totaling \$0.1 million and \$0.3 million were incurred in the ordinary course of business in the three months ended March 31, 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. The Company has also allowed certain option holders to exercise their options by executing stock purchase agreements and full recourse notes payable to the Company. The balance of the notes receivable for stock option exercises is included in Stockholders' Equity on the condensed consolidated balance sheets. The loans issued for the exercise of stock options are dated prior to November 2001 and thus are not subject to variable accounting as required under EITF 00-23 Issues Related to the Accounting for Stock Compensation under APB No. 25 and FASB Interpretation 44.

**Interest receivable related to the notes was approximately \$24,000 for each of the periods ending March 31, 2007 and December 31, 2006 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 March 31, 2007 had maturity dates ranging from April 2007 through 2014.**

### **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 \$24.6 million as of January 1, 2007. If the Company is eventually able to recognize these uncertain positions, \$24.6 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.**

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

### Forward-Looking Statements

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

### Executive Summary

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates. Theravance is focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections and gastrointestinal motility dysfunction. Of our five programs in development, two are in late stage our telavancin program focusing on treating serious Gram-positive bacterial infections with Astellas Pharma Inc. (Astellas) and our Beyond Advair collaboration with GlaxoSmithKline plc (GSK). By leveraging our proprietary insight of multivalency to drug discovery focused on validated targets, we are pursuing a next generation drug discovery strategy designed to discover superior medicines in large markets. We commenced operations in 1997, and as of March 31, 2007, we had an accumulated deficit of \$827.3 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). However, none of our products candidates have been approved for marketing and sale to patients and we have not received any product revenue to date. Most of our spending to date has been for research and development activities and general and administrative expenses. We expect to incur substantial losses for at least the next several years as we continue to invest in research and development.

Our net loss for the three months ended March 31, 2007 was \$49.5 million compared to \$49.0 million during the same period of 2006, or a 1% increase. Revenue recognized under our collaboration agreements increased by 26% when compared to the same period of 2006. For the comparable quarters, research and development costs were relatively unchanged while general and administrative costs increased by 21%. Cash, cash equivalents and marketable securities totaled \$219.7 million at March 31, 2007, a decrease of \$15.9 million since December 31, 2006. This decrease was primarily due to the net usage of cash in operations, offset by the receipt of \$32.0 million from Astellas which included a \$31.0 million milestone payment.

Following are updates on the progress of our clinical programs as of April 30, 2007:

#### Bacterial Infections Programs

##### *Telavancin*

In February 2007, the FDA accepted the filing of our NDA for telavancin for the treatment of cSSSI caused by Gram-positive bacteria, including resistant pathogens such as methicillin-resistant *Staphylococcus aureus* (MRSA). In conjunction with the filing of our NDA, we received a milestone payment from our partner Astellas.

Our Phase 3 program for the treatment of hospital-acquired pneumonia (HAP) caused by Gram-positive bacteria, including resistant pathogens such as MRSA, continues to progress. The final Independent Data Monitoring Committee meeting was successfully completed during the first quarter with no changes to the program required. We expect to complete enrollment late in the first half of 2007.

*Heterodimer*

Our Phase 2 cSSSI clinical study with TD-1792, our investigational heterodimer antibiotic for the treatment of serious Gram-positive infections, including resistant pathogens such as MRSA, recently completed enrollment and the program remains on track.

Respiratory Programs

*Beyond Advair*

In April 2007, we reported positive results of two studies in our Phase 2b clinical program assessing the safety and efficacy of GSK642444 ( 444) and GSK159797 ( 797) in the Beyond Advair 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). Both 444 and 797, dosed once daily, achieved clinically significant increases in bronchodilation at least equivalent to that of salmeterol dosed twice daily. Both compounds will continue in development, with the lead compound, 444, progressing into larger studies and the backup compound, 797, continuing in a dose optimization study.

*Inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist (MABA) Program*

Our MABA program for the treatment of COPD continues to progress with the lead compound, GSK961081, expected to begin a Phase 2 clinical study later this year.

*Inhaled Long Acting Muscarinic Antagonist (LAMA) Program*

Our lead compound in the LAMA program for COPD continues to progress in preclinical safety studies.

*Gastrointestinal (GI) Motility Dysfunction Program*

Our Phase 2 study with TD-5108 in patients with chronic constipation recently completed enrollment and the program remains on track.

**Critical Accounting Policies**

As of the date of the filing of this quarterly report, we believe there have been no material changes to our critical accounting policies and estimates during the three months ended March 31, 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 Financial Interpretation Number 48 Accounting for Uncertainty in Income Taxes, as discussed below.

*Income taxes*

In July 2006, the 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*



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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 we recently 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. Both compounds will continue in development, with the lead compound, 444, progressing into larger studies and the backup compound, 797, continuing in a dose optimization study.

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As of March 31, 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 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 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 \$1.9 million for the three months ended March 31, 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 the three months ended March 31, 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 long-acting muscarinic antagonist program (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 March 31, 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). For the three months ended March 31, 2007 and 2006, we recognized \$0.2 million and \$0.3 million, 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 months ended March 31, 2007 and 2006, reimbursable costs were not material.

In March 2005, GSK exercised its right to license our muscarinic antagonist-beta2 agonist (MABA) program 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 March 31, 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). For the three months ended March 31, 2007 and 2006, we recognized \$0.3 million and \$0.2 million, respectively, in revenue related to the MABA



program. Additionally, we are reimbursed by GSK for certain costs related to the MABA program as an offset to research and development expense. There were no reimbursements for the three months ended March 31, 2007 compared to \$0.1 million for the three months ended March 31, 2006.

GSK may increase its ownership of our outstanding stock up to approximately 59.4% through the issuance by Theravance to GSK of the number of shares of its common stock that we may be required to redeem from our stockholders as described below. In June 2007, GSK is required to notify the Company whether it plans to require us to redeem ( call ), and upon notice of the date of the redemption to effect the call (the call date ), each stockholder (including GSK, to the extent GSK holds common stock) will automatically be deemed to have submitted for redemption on the call date, 50% of our common stock held by such stockholder at \$54.25 per share. If GSK exercises the call, the call date must occur no later than July 31, 2007. If GSK does not exercise its call right, each of our stockholders (including GSK, to the extent GSK holds common stock) has the right 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. In either case, GSK is contractually obligated to pay to us the funds necessary for us to redeem the shares of common stock from our stockholders; however, GSK s maximum obligation for the shares subject to the put is capped at \$525.0 million. We are under no obligation to redeem our shares under the call or the put until we receive funds from GSK to redeem the shares. Alternatively, if our stockholders exercise the put, GSK may elect to purchase the shares of common stock that are put directly from our stockholders. In connection with those arrangements, we have agreed not to issue new equity securities if it would cause more than approximately 54.2 million shares of common stock subject to the put (including securities vested and exercisable or convertible into shares of common stock) to be outstanding as of the put date. If GSK s ownership increases to more than 50% in 2007 as a result of the call or put, GSK will receive an extension of its option to license our full drug discovery programs initiated prior to September 1, 2012; otherwise, this exclusive option does not apply to programs initiated after September 1, 2007.

The effect of the redemption of our common stock pursuant to the call or the put would not cause a decrease to our cash balances, total assets, or total stockholders equity. Accordingly, we have classified our common stock within stockholders equity.

*2005 License, Development and Commercialization Agreement with Astellas*

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In November 2005, we entered into a collaboration arrangement with Astellas for the development and commercialization of telavancin. In July 2006, we agreed with Astellas to add Japan to our telavancin collaboration, thereby giving Astellas worldwide rights to this potential medicine. Through March 31, 2007, we received \$133.0 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 \$2.1 million and \$1.3 million in revenue for three months ended March 31, 2007 and 2006, respectively. We are eligible to receive up to \$95.0 million in remaining clinical and regulatory milestone payments, which includes up to \$85.0 million for approval of the cSSSI NDA and completion of the HAP clinical program and filing and approval of a supplemental NDA for HAP, and \$10.0 million if the Phase 3 data demonstrates telavancin's superiority over vancomycin for HAP patients infected with MRSA.

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 also received an option to further develop and commercialize TD-1792, our heterodimer antibiotic compound that recently completed enrollment in a Phase 2 clinical study.

### *2006 License Agreement with AstraZeneca AB*

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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. Through March 31, 2006, we received a \$1.0 million upfront payment from AstraZeneca and are eligible to receive milestone payments and royalties on global sales. For the three months ended March 31, 2007, we recognized the remaining \$0.4 million of the upfront payment due to the completion of our performance obligations under the contract.

### **RESULTS OF OPERATIONS**

*Revenue* We recognized revenue of \$5.4 million and \$4.3 million for the three months ended March 31, 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, from Astellas related to our telavancin collaboration and from AstraZeneca related to

its license of TD-4756. Following are the upfront and milestone payments received through March 31, 2007 (in millions):

| Agreements/Programs                  | Upfront and<br>Milestone<br>Payments |
|--------------------------------------|--------------------------------------|
| <i>GSK Collaborations</i>            |                                      |
| Beyond Advair collaboration          | \$ 60.0                              |
| Strategic alliance agreement         | 20.0                                 |
| Strategic alliance LAMA license      | 8.0                                  |
| Strategic alliance MABA license      | 8.0                                  |
| <i>Astellas license agreement</i>    | 133.0                                |
| <i>AstraZeneca license agreement</i> | 1.0                                  |
| Total                                | \$ 230.0                             |

Upfront and milestone payments received from GSK, Astellas and AstraZeneca have been deferred and are being amortized ratably into revenue over the applicable estimated performance periods with end dates ranging between 2007 and 2019. Future revenue will include the ongoing amortization of remaining deferred revenue which consists of \$124.0 million of upfront and milestone payments received through March 31, 2007 under our agreement with Astellas and \$56.2 million of upfront and milestone payments received through March 31, 2007 under our agreements with GSK.

#### **Research and development**

| (in millions)                                | Three Months Ended<br>March 31, |         |
|--|---------------------------------|---------|
|  | 2007                            | 2006    |
| External research and development            | \$ 28.5                         | \$ 30.3 |
| Employee-related                             | 10.8                            | 9.6     |
| Stock-based compensation                     | 3.4                             | 3.0     |
| Facilities, depreciation and other allocated | 6.2                             | 5.8     |
| Total research and development expenses      | \$ 48.9                         | \$ 48.7 |

Total research and development expenses were relatively unchanged for the three months ended March 31, 2007 compared to the same period in 2006. Total external research and development costs decreased \$1.8 million, or 6%, for the three months ended March 31, 2007 compared to the same period in 2006. The lower external development costs for the quarter were primarily a result of our completion of patient enrollment of our Phase 3 cSSSI studies for telavancin (our lead antibiotic candidate) offset by increased external research and development costs associated with our two Phase 2 clinical studies for our heterodimer antibiotic and our GI compound.

Employee-related expenses increased \$1.2 million, or 13%, for the three months ended March 31, 2007 compared to the same period in 2006. This increase was primarily due to an increase headcount to support our clinical research programs and higher salary and benefits costs in 2007. Facilities, depreciation and other allocated expenses increased by \$0.4 million or 7% for the three months ended March 31, 2007 compared to the same period in 2006. This increase was primarily due to higher supplies and facilities administration costs in 2006.

Research and development stock-based compensation expense increased \$0.4 million or 13% for the three months ended March 31, 2007 compared to the same period in 2006, reflecting the amortization of deferred stock-based compensation related to employees and the value of stock options granted to non-employees.

Research and development expenses for the balance of 2007 will be driven largely by clinical studies, particularly for our HAP telavancin Phase 3 program, and for our GI and heterodimer programs. In addition, we have short- and long- term bonus programs in place for certain eligible non-executive officer employees related to certain clinical milestones. The achievement or failure to achieve these milestones during 2007 could result in a decrease or increase in our bonus accruals by approximately \$5.0 million. If earned, these bonuses would be paid over the next three years. 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 sufficient quantities of active pharmaceutical ingredient (API) and drug product for launch. We are reliant on the efforts of third parties, including contract research organizations, consultants and contract manufacturing organizations for the completion of these obligations. While we cannot predict the time frame in which these responsibilities will be completed, we anticipate that our aggregate external

costs associated with the telavancin Phase 3 programs will be towards the upper range of \$125.0 million to \$150.0 million.

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

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

**General and administrative** General and administrative expenses increased by \$1.5 million, or 21%, for the three months ended March 31, 2007, compared to the same period in 2006. This increase was primarily due to higher salary and stock-based compensation expenses, as well as higher information technology expenses related to the development and pre-launch preparation of telavancin.

Total general and administrative stock-based compensation expense increased \$0.5 million, or 23%, for the three months ended March 31, 2007 compared to the same period in 2006. Stock-based compensation includes expenses related to employee stock options, employee stock purchases, the value of options issued to non-employees for services rendered and to stock-based compensation expense related to restricted stock.

We anticipate general and administrative expenses will increase for the remainder of 2007 and subsequent years to support our growing discovery, development, manufacturing and commercialization efforts.

**Interest and other income** Interest and other income includes interest income earned on cash and marketable securities, net realized gains on marketable securities and net sublease income on facilities. Interest income was relatively flat for the three months ended March 31, 2007 compared to the same period in 2006.

**Interest and other expense** Interest expense includes interest expense on capital lease and debt arrangements. Interest and other expense were relatively flat for the three months ended March 31, 2007 when compared to the same period in 2006.

**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 \$24.6 million as of January 1, 2007. If we are eventually able to recognize these uncertain positions, \$24.6 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 March 31, 2007 and December 31, 2006, we had \$219.7 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 and cash equivalents that was pledged as collateral for certain of our leased facilities and equipment. In February 2007, we received payments of \$32.0 million from 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 eighteen months based upon current operating and spending assumptions. In the event that either or both of TD-5108 and TD-1792 successfully advance beyond Phase 2 we intend to pursue a collaboration arrangement for the development and commercialization of the compound(s). If we are unable to enter into such collaboration arrangement(s), or if those agreements require that we assume future development responsibilities, then our operating expenses will increase significantly and we may need to raise additional funds sooner than presently anticipated. We expect to incur substantial expenses as we continue our drug discovery and development efforts, particularly to the extent we advance our product candidates into and through clinical studies, which are very expensive. We also expect expenditures to increase as we continue to invest in our research and development and administrative infrastructure to support our expanded operations. As a result, we

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may raise additional funds in advance of our expected operating needs, if we expand more rapidly than we presently anticipate or if our operating costs exceed our expectations. Pursuant to the

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restrictions described below in our agreements with GSK, we cannot sell significant additional equity until the expiration of the call and put arrangements in 2007, but we may sell debt securities or incur indebtedness, subject to limitations under our agreements with GSK. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations. We cannot guarantee that future financing will be available in amounts or on terms acceptable to us, if at all.

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

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

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

#### **Cash Flows**

Net cash used in operating activities was \$16.2 million and \$42.0 million for the three months ended March 31, 2007 and 2006, respectively. Although research and development and general and administrative expenses increased in the 2007 period, the increase was offset by \$32.0 million received from Astellas.

Investing activities for the three months ended March 31, 2007 provided cash of \$20.4 million compared to the use of cash in investing activities of \$45.8 million for the comparable period of 2006. The increase in 2007 resulted primarily from net maturities and sales of marketable securities.

Financing activities provided cash of \$0.6 million and \$141.6 million for the three months ended March 31, 2007 and 2006, respectively. The cash provided by financing activities in 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 notes payable, operating leases and fixed purchase commitments under contract research, development and clinical supply agreements. 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**

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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 fiscal years beginning after November 15, 2007. We have not yet determined the impact, if any, of adopting SFAS 159 on our consolidated financial statements.

In September 2006, 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. The provisions of SFAS 157 are effective beginning in the first quarter of fiscal year 2009. We are currently evaluating the impact of the provisions of SFAS 157 on our financial position, results of operations and cash flows and do not believe the impact of the adoption will be material.

### **Item 3. Quantitative and Qualitative Disclosure about Market Risk**

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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 March 31, 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*



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

### Changes in Internal Control over Financial Reporting

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

## **PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings.**

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The Company received a letter dated February 8, 2007 from the United States Environmental Protection Agency (EPA) indicating that the EPA is considering an administrative action against the Company for alleged violations of certain laws and regulations regarding organic effluent levels in waste generated by the Company. The Company has submitted further information to the EPA that we believe the EPA should consider before making a decision to proceed with the proposed administrative action. We intend to have further discussions with the EPA in the near future concerning this matter. While the Company believes it has

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information to show it has been in compliance and therefore no penalty should be assessed, if we are unable to convince the EPA that it should not proceed, we may be required to pay monetary penalties to the EPA.

In the future, we may become involved in litigation from time to time in the ordinary course of our business.

**Item 1A. Risk Factors.**

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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 and early clinical testing stages.

Although our new drug application (NDA) for telavancin is currently under review by the U.S. Food and Drug Administration (FDA), it is impossible to predict when or if any of our compounds and product candidates will prove effective or safe in humans or will receive regulatory approval. If we are unable to discover and develop medicines that are effective and safe in humans, our business will fail.

**Any failure of a product candidate in clinical studies or any delay in commencing or completing clinical studies for our product candidates, such as a further delay in completing our Phase 3 HAP clinical studies for telavancin, would likely cause our stock price to decline.**

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

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

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

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



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The FDA must approve any new medicine before it can be marketed and sold in the United States. We must provide the FDA and similar foreign regulatory authorities with data from preclinical and clinical studies that demonstrate that our product candidates are safe and effective for a defined indication before they can be approved for commercial distribution. We will not obtain this approval for a product candidate unless and until the FDA approves a 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 have conducted clinical studies, and it is the first product candidate for which we have submitted a NDA to the FDA. We 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 hospital acquired pneumonia for telavancin and our telavancin collaborator Astellas Pharma Inc. (Astellas) plans to seek foreign regulatory approvals for telavancin. We will be unable to generate any revenues from royalty payments from the commercialization and sale of telavancin if we fail to obtain these approvals.

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

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We do not have in-house manufacturing capabilities and depend entirely on a number of third-party 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 our compounds 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 current Good Manufacturing Practices regulations and similar foreign standards and we do not have control over compliance with these regulations by our manufacturers.

Our manufacturing strategy presents the following additional risks:

- because of the complex nature of our compounds, our manufacturers may not be able to successfully manufacture our compounds in a cost effective and/or timely manner;
- the processes required to manufacture certain of our compounds are specialized and available only from a limited number of third-party manufacturers;
- some of the manufacturing processes for our compounds 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 compounds; and
- because some of the third-party manufacturers and formulators are located outside of the U.S., there may be difficulties in importing our compounds or their components into the U.S. as a result of, among other things, FDA import inspections, incomplete or inaccurate import documentation or defective packaging.

We have sufficient quantities of drug product to complete all of the currently planned clinical studies of telavancin. We are in the process of manufacturing additional API and plan to manufacture drug product intended to meet our obligations to Astellas in connection with commercial launch in the event telavancin is approved for sale by regulatory authorities. If we are unable to do so in a

timely manner, 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.

For our heterodimer compound as well as TD-5108 in our GI program, we are using a limited number of sources to manufacture the API and drug product. 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.**

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

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

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

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

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

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We have been engaged in discovering and developing compounds and product candidates since mid-1997. We have not generated any product revenue to date. We may never generate revenue from selling medicines or achieve profitability. As of March 31, 2007, we had an accumulated deficit of approximately \$827.3 million.

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

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

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We need large amounts of capital to support our research and development efforts. If we are unable to secure capital to fund our operations we will not be able to continue our discovery and development efforts and we might have to enter into strategic

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collaborations that could require us to share commercial rights to our medicines to a greater extent than we currently intend. Based on our current operating plans, we believe that our cash and cash equivalents and marketable securities will be sufficient to meet our anticipated operating needs for at least the next eighteen months. We are likely to require additional capital to fund operating needs thereafter. In the event that either or both of TD-5108 and TD-1792 successfully advance beyond Phase 2 we intend to pursue a collaboration arrangement for the development and commercialization of the compound(s). If we are unable to enter into such collaboration arrangement(s), or if those agreements require that we assume future development responsibilities, then our operating expenses will increase significantly and we may need to raise additional funds sooner than presently anticipated.

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. We may also need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate or if our operating costs exceed our expectations. Prior to the termination of the call and put arrangements with GSK, we may seek to sell debt securities or incur other indebtedness. After the termination of the call and put arrangements with GSK, we may seek to sell additional equity or debt securities, or both, or incur other indebtedness. The sale of additional equity or debt securities, if convertible, could result in the issuance of additional shares of our capital stock and could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, our ability to raise debt and equity financing is constrained by our alliance with GSK and we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all.

In particular, until the expiration of the put and call provisions with GSK, we are contractually prohibited from selling significant additional equity securities to raise capital. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from 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.**



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

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

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

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

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As of April 30, 2007, GSK beneficially owned approximately 15.6% of our outstanding capital stock, and will have the right in July 2007 to increase its ownership of our stock up to approximately 59.4% through the exercise of its call right. Other than our bacterial infections program and our anesthesia program, which GSK has decided not to license under the strategic alliance, GSK has the right to license exclusive development and commercialization rights to our product candidates arising from all of our full drug discovery and development programs initiated prior to September 1, 2007. This right will extend to our programs initiated prior to September 1, 2012 if GSK owns more than 50% of our common stock due to exercise of the call right or the put right. In brief, (i) the call right is GSK's right, in June 2007, to notify us that we must redeem 50% of our common stock held by each stockholder in July 2007 at \$54.25 per share, and (ii) the put right is the right of each of our stockholders between August 1 and September 12, 2007, if GSK has not exercised its call right in June 2007, to require us to redeem up to 50% of their common stock at \$19.375 per share. Pharmaceutical companies other than GSK that may be interested in developing products with us are likely to be less inclined to do so because of our relationship with GSK, or because of the perception that development programs that GSK does not license pursuant to our strategic alliance agreement are not promising programs.

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

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

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

**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 each of our studies is conducted in accordance with the applicable protocol. The failure of these third parties to complete activities on schedule or to conduct our studies in accordance with regulatory requirements and our protocols could delay or prevent the further development, approval and commercialization of our product candidates, which could severely harm our business and financial condition. For example, in late 2005 we expanded the number of clinical research organizations working on our Phase 3 HAP program for telavancin due to slower than anticipated enrollment. Retaining alternative or additional service providers involves delays and additional costs. In addition, if we lose our relationship with any one or more of these third parties, we could experience a significant delay in both identifying another comparable service provider and then contracting for its services. We may be unable to retain an alternative service provider on reasonable terms, if at all. Even if we locate an alternative service provider, it is likely that this provider will need additional time to respond to our needs and may not provide the same level of service as the original service provider.

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

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

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

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

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

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

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

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

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

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

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.

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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.**

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

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.**

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

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

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

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

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

As of April 30, 2007, GSK beneficially owned approximately 15.6% of our outstanding capital stock. In addition, GSK has certain rights to maintain its percentage ownership of our capital stock and in June of this year, GSK may exercise its call right to acquire additional shares in July 2007 and thereby increase its ownership up to approximately 59.4% of our then outstanding capital stock. If GSK exercises this call right, or a sufficient number of our stockholders exercise the put right provided for in our certificate of incorporation, GSK could own a majority of our capital stock. In addition, GSK currently has the right to designate one member to our board of directors and, depending on GSK's ownership percentage of our capital stock after September 2007, GSK will have the right to nominate up to one-third of the members of our board of directors and up to one-half of the independent members of our board of directors. There are currently no GSK designated directors on our board of directors. GSK's control relationship could give rise to conflicts of interest, including:

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

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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.**

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

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

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

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

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

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

These limits on issuing equity and debt could leave us without adequate financial resources to fund our discovery and development efforts if GSK does not license additional development programs pursuant to our strategic alliance agreement, if we do not enter into alliances with third parties on similar or better terms for these programs, or if we do not earn any of the potentially significant milestones in the programs that we have currently partnered with GSK and Astellas.

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

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



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

In June 2007, GSK has the right to require us to redeem 50% of our outstanding common stock in July 2007 for \$54.25 per share and, if GSK does not exercise this right, between August 1 and September 12, 2007 our stockholders will have the right to cause us to redeem up to the same number of shares for \$19.375 per share. The existence of the call feature on 50% of our common stock at a fixed price of \$54.25 may act as a material impediment to our common stock trading above the \$54.25 per share call price. If the call is exercised, our stockholders would participate in valuations above \$54.25 per share only with respect to 50% of their shares.

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Therefore, even if our common stock trades above \$54.25 per share, 50% of each stockholder's shares could be called at \$54.25 per share. Similarly, because the put applies to only 50% of our common stock and is not exercisable prior to August of 2007, it is uncertain what effect the put will have on our stock price. Prior to the expiration of the put period, the price at which our common stock will trade may be influenced by the put right. Therefore, after the expiration of the put period, the market price of the common stock may decline significantly. In addition, while GSK is generally prevented from making any unsolicited tender offer for our common stock, any announcement by GSK that it does not intend to exercise the call or any offer GSK may make to our board of directors on terms less favorable than the call right described above could adversely affect our common stock price. Furthermore, in the period before and during the time that the call and put rights may be exercised, our stock price may be highly volatile due to transactions in our stock or derivative instruments that are related to our stock.

**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.**

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If GSK owns less than 50.1% of our outstanding stock after the call and put rights expire, then 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, if GSK owns less than 50.1% of our outstanding stock after the call and put rights expire, then 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 transfer control of our company to a third party.

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

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

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

### **Risks Related to Legal and Regulatory Uncertainty**

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

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

We rely upon a combination of patents, patent applications, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any involuntary disclosure to or misappropriation by third parties of this proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. The status of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and is very uncertain. As of March 31, 2007, we had 90 issued United States patents and have received notices of

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allowance for 11 other United States patent applications. As of that date, we had 98 pending patent applications in the United States and 316 granted foreign patents. We also have 18 Patent Cooperation Treaty applications that permit us to pursue patents outside of the United States, and 693 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.**

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

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.**



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

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.

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

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

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

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

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

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

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

### **General Company Related Risks**

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

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

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

- any adverse developments or results or perceived adverse developments or results with respect to any product candidates in the Beyond Advair collaboration;
- any adverse development or perceived adverse development with respect to our telavancin NDA filed with the FDA;
- any adverse developments or results or perceived adverse developments or results with respect to our telavancin Phase 3 clinical studies for HAP;
- 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 program or our heterodimer compound;
- GSK's call right in June of this year to acquire 50% of our common stock at \$54.25 per share in July of this year (in particular, a decision by GSK not to exercise its call right or a perception on the part of investors that GSK is not likely to exercise its call right);

- the put right and the expiration of the put right between August 1 and September 12, 2007;
- transactions in our stock or derivative instruments that are related to our stock during the time that the call and put rights may be exercised;
- announcements regarding GSK's decisions whether or not to license any of our product development programs;
- announcements regarding GSK or Astellas generally;
- announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors;
- developments concerning any collaboration we may undertake with companies other than GSK or Astellas;
- publicity regarding actual or potential testing or study results or the outcome of regulatory review relating to products under development by us, our partners or by our competitors;
- regulatory developments in the United States and foreign countries; and
- economic and other external factors beyond our control.

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

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

As of April 30, 2007, GSK beneficially owned approximately 15.6% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 12.5% of our outstanding capital stock. These stockholders could substantially control the outcome of actions taken by us that require stockholder approval. In addition, pursuant to our governance agreement with GSK, GSK currently has the right to nominate a director and beginning in September 2007 will have the right to nominate a certain number of directors depending on GSK's ownership percentage of our capital stock at the time. For these reasons, GSK could have substantial influence in the election of our directors, delay or prevent a transaction in which stockholders might receive a premium over the prevailing market price for their shares and have significant control over changes in our management or business.

**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.**



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

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 6. Exhibits**

Exhibit

| Number  | Exhibit Description  |
|---------|--|
| 3.3(1)  | Restated Certificate of Incorporation  |
| 3.4     | Certificate of Amendment of Restated Certificate of Incorporation  |
| 3.5     | Amended and Restated Bylaws (as amended by the board of directors April 25, 2007)  |
| 4.1(2)  | Specimen certificate representing the common stock of the registrant   |
| 4.2(3)  | Rights Agreement dated October 8, 2004   |
| 10.3(4) | 2004 Equity Incentive Plan (as amended by the board of directors December 6, 2006 and approved by stockholders April 25, 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  |

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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 Annual Report on Form 10-K for the fiscal year ended December 31, 2006.

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

(4) Incorporated herein by reference to exhibit 10.38 in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2006.

**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)

May 8, 2007  
Date

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

May 8, 2007  
Date

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

Exhibit Index

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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 Annual Report on Form 10-K for the fiscal year ended December 31, 2006.

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

(4) Incorporated herein by reference to exhibit 10.38 in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2006.