

THERAVANCE INC  
Form 10-Q  
August 03, 2011  
[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-Q**

(Mark One)

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

**For the quarterly period ended June 30, 2011**

**OR**

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

**For the transition period from                      to**

**Commission File Number: 0-30319**

# THERAVANCE, INC.

(Exact Name of Registrant as Specified in its Charter)

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

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

**901 Gateway Boulevard**

**South San Francisco, CA 94080**

(Address of Principal Executive Offices including Zip Code)

**(650) 808-6000**

(Registrant's Telephone Number, Including Area Code)

---

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐  
(Do not check if a smaller reporting company)

Smaller reporting company ☐

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 July 27, 2011 was 84,766,987



Table of Contents

TABLE OF CONTENTS

|                                                                                                                  |    |
|------------------------------------------------------------------------------------------------------------------|----|
| <b><u>PART I. FINANCIAL INFORMATION</u></b>                                                                      | 3  |
| <u>Item 1. Financial Statements</u>                                                                              | 3  |
| <u>Condensed Consolidated Balance Sheets as of June 30, 2011 and December 31, 2010</u>                           | 3  |
| <u>Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2011 and 2010</u> | 4  |
| <u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2011 and 2010</u>           | 5  |
| <u>Notes to Condensed Consolidated Financial Statements</u>                                                      | 6  |
| <u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>             | 16 |
| <u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>                                        | 24 |
| <u>Item 4. Controls and Procedures</u>                                                                           | 24 |
| <b><u>PART II. OTHER INFORMATION</u></b>                                                                         | 24 |
| <u>Item 1A. Risk Factors</u>                                                                                     | 24 |
| <u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.</u>                                      | 39 |
| <u>Item 6. Exhibits</u>                                                                                          | 40 |
| <u>Signatures</u>                                                                                                | 41 |
| <u>Exhibit Index</u>                                                                                             | 42 |

[Table of Contents](#)**PART I FINANCIAL INFORMATION****Item 1. Financial Statements****THERAVANCE, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS**

(In thousands, except per share data)

|                                                                                                                                  | June 30,<br>2011<br>(Unaudited) | December 31,<br>2010<br>* |
|----------------------------------------------------------------------------------------------------------------------------------|---------------------------------|---------------------------|
| <b>Assets</b>                                                                                                                    |                                 |                           |
| Current assets:                                                                                                                  |                                 |                           |
| Cash and cash equivalents                                                                                                        | \$ 90,658                       | \$ 163,333                |
| Marketable securities                                                                                                            | 193,229                         | 146,301                   |
| Accounts receivable from related party                                                                                           | 32                              | 194                       |
| Notes receivable                                                                                                                 | 200                             | 531                       |
| Prepaid expenses and other current assets                                                                                        | 4,506                           | 5,995                     |
| Total current assets                                                                                                             | 288,625                         | 316,354                   |
| Restricted cash                                                                                                                  | 893                             | 893                       |
| Property and equipment, net                                                                                                      | 10,334                          | 10,215                    |
| Notes receivable                                                                                                                 | 340                             | 400                       |
| Other assets                                                                                                                     | 2,928                           | 3,340                     |
| Total assets                                                                                                                     | \$ 303,120                      | \$ 331,202                |
| <b>Liabilities and stockholders' net capital deficiency</b>                                                                      |                                 |                           |
| Current liabilities:                                                                                                             |                                 |                           |
| Accounts payable                                                                                                                 | \$ 2,165                        | \$ 2,128                  |
| Accrued personnel-related expenses                                                                                               | 5,154                           | 8,617                     |
| Accrued clinical and development expenses                                                                                        | 2,850                           | 2,801                     |
| Accrued interest on convertible subordinated notes                                                                               | 2,372                           | 2,372                     |
| Other current liabilities                                                                                                        | 1,935                           | 2,008                     |
| Note payable and capital lease, current                                                                                          | 162                             | 206                       |
| Deferred revenue, current                                                                                                        | 20,553                          | 21,922                    |
| Total current liabilities                                                                                                        | 35,191                          | 40,054                    |
| Convertible subordinated notes                                                                                                   | 172,500                         | 172,500                   |
| Deferred rent, non-current                                                                                                       | 5,518                           | 3,574                     |
| Note payable and capital lease, non-current                                                                                      |                                 | 69                        |
| Deferred revenue                                                                                                                 | 127,393                         | 137,425                   |
| Commitments and contingencies (Notes 4, 8 and 9)                                                                                 |                                 |                           |
| Stockholders' net capital deficiency:                                                                                            |                                 |                           |
| Common stock, \$0.01 par value; authorized: 200,000 shares; outstanding: 75,365 at June 30, 2011 and 70,950 at December 31, 2010 | 754                             | 710                       |

# Edgar Filing: THERAVANCE INC - Form 10-Q

Class A common stock, \$0.01 par value; authorized: 30,000 shares; outstanding: 9,402 at  
June 30, 2011 and December 31, 2010

|                                                            |             |             |
|------------------------------------------------------------|-------------|-------------|
|                                                            | 94          | 94          |
| Additional paid-in capital                                 | 1,210,006   | 1,177,359   |
| Accumulated other comprehensive income (loss)              | (8)         | 33          |
| Accumulated deficit                                        | (1,248,328) | (1,200,616) |
| Total stockholders' net capital deficiency                 | (37,482)    | (22,420)    |
| Total liabilities and stockholders' net capital deficiency | \$ 303,120  | \$ 331,202  |

---

\* Condensed consolidated balance sheet at December 31, 2010 has been derived from audited consolidated financial statements.

*See accompanying notes to condensed consolidated financial statements.*

Table of Contents**THERAVANCE, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(In thousands, except per share data)

(Unaudited)

|                                                                                                                                                                            | <b>Three Months Ended<br/>June 30,</b> |             | <b>Six Months Ended<br/>June 30,</b> |             |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|-------------|--------------------------------------|-------------|
|                                                                                                                                                                            | <b>2011</b>                            | <b>2010</b> | <b>2011</b>                          | <b>2010</b> |
| Revenue (including amounts from a related party of \$2,456 for the three months ended June 30, 2011 and 2010, and \$4,913 for the six months ended June 30, 2011 and 2010) | \$ 6,389                               | \$ 6,264    | \$ 12,719                            | \$ 11,979   |
| Operating expenses:                                                                                                                                                        |                                        |             |                                      |             |
| Research and development                                                                                                                                                   | 22,798                                 | 18,705      | 43,262                               | 39,057      |
| General and administrative                                                                                                                                                 | 7,248                                  | 6,991       | 14,417                               | 13,467      |
| Total operating expenses                                                                                                                                                   | 30,046                                 | 25,696      | 57,679                               | 52,524      |
| Loss from operations                                                                                                                                                       | (23,657)                               | (19,432)    | (44,960)                             | (40,545)    |
| Interest income                                                                                                                                                            | 118                                    | 134         | 263                                  | 229         |
| Interest expense                                                                                                                                                           | (1,506)                                | (1,508)     | (3,015)                              | (3,025)     |
| Net loss                                                                                                                                                                   | \$ (25,045)                            | \$ (20,806) | \$ (47,712)                          | \$ (43,341) |
| Basic and diluted net loss per share                                                                                                                                       | \$ (0.31)                              | \$ (0.28)   | \$ (0.59)                            | \$ (0.63)   |
| Shares used in computing basic and diluted net loss per share                                                                                                              | 81,811                                 | 73,282      | 81,415                               | 69,124      |

*See accompanying notes to condensed consolidated financial statements.*

Table of Contents**THERAVANCE, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands)

(Unaudited)

|                                                                                                                                                                 | <b>Six Months Ended June 30,</b> |             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|-------------|
|                                                                                                                                                                 | <b>2011</b>                      | <b>2010</b> |
| <b>Cash flows from operating activities</b>                                                                                                                     |                                  |             |
| Net loss                                                                                                                                                        | \$ (47,712)                      | \$ (43,341) |
| Adjustments to reconcile net loss to net cash used in operating activities:                                                                                     |                                  |             |
| Depreciation and amortization                                                                                                                                   | 3,407                            | 3,137       |
| Stock-based compensation                                                                                                                                        | 11,134                           | 9,820       |
| Forgiveness of notes receivable                                                                                                                                 | 1                                | 4           |
| Changes in operating assets and liabilities:                                                                                                                    |                                  |             |
| Receivables                                                                                                                                                     | (53)                             | (159)       |
| Prepaid expenses and other current assets                                                                                                                       | 1,717                            | 1,364       |
| Accounts payable                                                                                                                                                | 813                              | (283)       |
| Accrued personnel-related expenses, accrued clinical and development expenses, accrued interest on convertible subordinated notes and other current liabilities | (3,488)                          | (1,571)     |
| Deferred rent                                                                                                                                                   | 1,932                            | 931         |
| Deferred revenue                                                                                                                                                | (11,401)                         | (10,400)    |
| Other liabilities, non-current                                                                                                                                  |                                  | (389)       |
| Net cash used in operating activities                                                                                                                           | (43,650)                         | (40,887)    |
| <b>Cash flows from investing activities</b>                                                                                                                     |                                  |             |
| Purchases of property and equipment                                                                                                                             | (2,763)                          | (133)       |
| Purchases of marketable securities                                                                                                                              | (176,322)                        | (103,861)   |
| Sales of marketable securities                                                                                                                                  | 8,750                            |             |
| Maturities of marketable securities                                                                                                                             | 119,476                          | 70,000      |
| Release of restricted cash                                                                                                                                      |                                  | 417         |
| Additions to notes receivable                                                                                                                                   | (140)                            |             |
| Payments received on notes receivable                                                                                                                           | 530                              | 110         |
| Net cash used in investing activities                                                                                                                           | (50,469)                         | (33,467)    |
| <b>Cash flows from financing activities</b>                                                                                                                     |                                  |             |
| Payments on note payable and capital lease                                                                                                                      | (113)                            | (89)        |
| Proceeds from issuances of common stock, net                                                                                                                    | 21,557                           | 96,620      |
| Net cash provided by financing activities                                                                                                                       | 21,444                           | 96,531      |
| Net increase (decrease) in cash and cash equivalents                                                                                                            | (72,675)                         | 22,177      |
| Cash and cash equivalents at beginning of period                                                                                                                | 163,333                          | 47,544      |
| Cash and cash equivalents at end of period                                                                                                                      | \$ 90,658                        | \$ 69,721   |

*See accompanying notes to condensed consolidated financial statements.*



Table of Contents

**Theravance, Inc.**

**Notes to Condensed Consolidated Financial Statements**

**(Unaudited)**

**1. Basis of Presentation and Significant Accounting Policies**

*Basis of Presentation*

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 notes required by GAAP 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 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, results of operations and cash flows. The interim results are not necessarily indicative of the results of operations to be expected for the year ending December 31, 2011 or any other period.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2010 filed with the Securities and Exchange Commission (SEC) on February 28, 2011.

*Principles of Consolidation*

The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

*Use of Management's Estimates*

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates.

*Other-than-Temporary Impairment Assessment*

The Company reviews its investment portfolio to identify and evaluate investments that have indications of possible impairment. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, credit quality and the Company's conclusion that it does not intend to sell an impaired investment and is not more likely than not to be required to sell the security before it recovers its amortized cost basis. If the Company determines that the impairment of an investment is other-than-temporary, the investment is written down with a charge recorded in interest income.

#### *Inventory*

Inventory is stated at the lower of cost or market value and is included in prepaid and other current assets in the accompanying condensed consolidated balance sheets. Inventory is comprised of VIBATIV® active pharmaceutical ingredient. Inventory was \$0.5 million at June 30, 2011 and \$1.7 million at December 31, 2010. During the three months ended June 30, 2011, Astellas Pharma Inc. (Astellas) purchased \$1.2 million of VIBATIV® inventory from the Company at cost. If Astellas decides not to purchase some or any of the remaining VIBATIV® inventory, the Company will be required to expense a portion of, or the entire remaining, capitalized inventory.

#### *Research and Development Costs*

Research and development costs are expensed in the period that services are rendered or goods are received. Research and development costs consist of salaries and benefits, laboratory supplies and facility costs, as well as fees paid to third parties that conduct certain research and development activities on behalf of the Company, net of certain external research costs reimbursed by GlaxoSmithKline plc (GSK) and Astellas.

Table of Contents

*Fair Value of Stock-based Compensation Awards*

The Company uses the fair value method of accounting for stock-based compensation arrangements. Stock-based compensation arrangements currently include stock options granted, restricted stock unit awards (RSUs) granted, performance-contingent RSUs granted, restricted stock awards (RSAs) granted, and performance-contingent RSAs granted under the 2004 Equity Incentive Plan (2004 Plan) and the 2008 New Employee Equity Incentive Plan (2008 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). Non-statutory options, RSUs, and RSAs were granted under the 2008 Plan to the Company's newly hired employees until April 27, 2010, the date on which stockholders approved the Company's amended and restated 2004 Plan. No further awards will be granted under the 2008 Plan. Stock options were granted with an exercise price not less than 100% of the fair market value of the common stock on the date of grant. Stock options were generally granted with terms of up to ten years and vest over a period of four years.

The Company uses the Black-Scholes valuation model for stock-based payment awards granted. The Company's determination of the fair value of stock-based payment awards on the grant date using the Black-Scholes option valuation model requires the use of assumptions, including the expected term of the award and the expected stock price volatility. The Company used the simplified method as described in Staff Accounting Bulletin No. 107 for the expected option term. Beginning April 1, 2011, the Company used its historical volatility to estimate expected stock price volatility. Prior to April 1, 2011, the Company used peer company price volatility to estimate expected stock price volatility due to the Company's limited historical common stock price volatility since its initial public offering in 2004.

Stock-based compensation expense was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures 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 rates for stock options, RSUs and RSAs are based on its historical forfeiture experience.

The estimated fair value of stock options, RSUs and RSAs is expensed on a straight-line basis over the expected term of the grant and the fair value of performance-contingent RSUs and RSAs is expensed during the term of the award when the Company determines that it is probable that certain performance milestones will be achieved. Compensation expense for purchases under the ESPP is recognized based on the estimated fair value of the common stock during each offering period and purchase discount percentage.

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.

*Recent Accounting Updates*

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-05, *Presentation of Comprehensive Income* an update to Accounting Standards Codification (ASC) Topic 220, *Comprehensive Income*. The amendments of this update require that all nonowner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This update is to be applied retroactively and is effective for financial statements issued for fiscal years, and interim periods within those years, beginning after December 15, 2011, and interim and annual periods thereafter. This update will be

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

effective for the Company January 1, 2012. The Company does not expect the adoption of this guidance to have a material impact on its condensed consolidated financial statements.

In April 2010, the FASB issued ASU No. 2010-17, Revenue Recognition Milestone Method an update to ASC Topic 605, Revenue Recognition . The amendments of this update provide guidance on defining the milestone and determining when the use of the milestone method of revenue recognition for research and development transactions is appropriate. It provides criteria for evaluating if the milestone is substantive and clarifies that a vendor can recognize consideration that is contingent upon achievement of a milestone as revenue in the period in which the milestone is achieved, if the milestone meets all the criteria to be considered substantive. The guidance became effective on a prospective basis in fiscal years beginning on or after June 15, 2010 and early adoption was permitted. The Company elected to adopt the milestone method of revenue recognition on a prospective basis effective January 1, 2011. The election of the milestone method did not have a material impact on the Company's condensed consolidated financial statements. However, the election will result in different accounting treatment for future substantive milestones earned after the date of this adoption. Non-substantive milestones will continue to be recognized over the remaining performance period.

## Table of Contents

In October 2009, the FASB issued ASU No. 2009-13, *Revenue Recognition - Multiple-Deliverable Revenue Arrangements* a consensus of the FASB Emerging Issues Task Force, an update to ASC Topic 605, *Revenue Recognition*. The amendments of this update require companies to allocate the overall consideration to each deliverable by using a best estimate of the selling price of individual deliverables in the arrangement in the absence of vendor specific objective evidence or other third party evidence of the selling price. The guidance became effective on a prospective basis in fiscal years beginning on or after June 15, 2010 and early adoption was permitted. Companies may elect to adopt this guidance prospectively for all revenue arrangements entered into or materially modified after the date of adoption or retrospectively for all periods presented. The Company elected to adopt this update on a prospective basis effective January 1, 2011. The adoption of this update did not have a material impact on the Company's condensed consolidated financial statements. However, the election may result in different accounting treatment for future collaboration arrangements than the accounting treatment applied to previous and existing collaboration arrangements.

## 2. Net Loss per Share

Basic net loss per share (basic EPS) is computed by dividing net loss by the weighted average number of common shares outstanding during the period, less RSAs subject to forfeiture. Diluted net loss per share (diluted EPS) is computed by dividing net loss by the weighted average number of common shares outstanding during the period, less RSAs subject to forfeiture, plus dilutive potential common shares. 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.

### Weighted Average Shares Outstanding

The following table sets forth the computation of basic and diluted net loss and the weighted average number of shares used in computing basic and diluted net loss per share:

| (in thousands, except for per share amounts)                                          | Three Months Ended<br>June 30, |             | Six Months Ended<br>June 30, |             |
|---------------------------------------------------------------------------------------|--------------------------------|-------------|------------------------------|-------------|
|                                                                                       | 2011                           | 2010        | 2011                         | 2010        |
| Net loss                                                                              | \$ (25,045)                    | \$ (20,806) | \$ (47,712)                  | \$ (43,341) |
| Weighted average shares of common stock outstanding                                   | 84,263                         | 73,339      | 83,867                       | 69,181      |
| Less: unvested RSAs                                                                   | (2,452)                        | (57)        | (2,452)                      | (57)        |
| Weighted average shares used in computing basic and diluted net loss per common share | 81,811                         | 73,282      | 81,415                       | 69,124      |
| Basic and diluted net loss per common share                                           | \$ (0.31)                      | \$ (0.28)   | \$ (0.59)                    | \$ (0.63)   |

### Anti-dilutive securities

Securities that could potentially dilute basic EPS in the future that were not included in the computation of diluted EPS because their effect would have been anti-dilutive were as follows:

# Edgar Filing: THERAVANCE INC - Form 10-Q

| (in thousands)                                          | Three Months Ended<br>June 30, |        | Six Months Ended<br>June 30, |        |
|---------------------------------------------------------|--------------------------------|--------|------------------------------|--------|
|                                                         | 2011                           | 2010   | 2011                         | 2010   |
| Shares issuable upon the exercise of stock options      | 4,500                          | 6,191  | 4,663                        | 6,016  |
| Shares issuable under RSUs and RSAs                     | 944                            | 770    | 929                          | 881    |
| Shares issuable upon the conversion of convertible debt | 6,668                          | 6,668  | 6,668                        | 6,668  |
| Total anti-dilutive securities                          | 12,112                         | 13,629 | 12,260                       | 13,565 |

## 3. Comprehensive Loss

Comprehensive loss is comprised of net loss and changes in other comprehensive loss, which consists of unrealized gains and losses on the Company's marketable securities. Comprehensive loss was as follows:

| (in thousands)                                       | Three Months Ended<br>June 30, |             | Six Months Ended<br>June 30, |             |
|------------------------------------------------------|--------------------------------|-------------|------------------------------|-------------|
|                                                      | 2011                           | 2010        | 2011                         | 2010        |
| Net loss                                             | \$ (25,045)                    | \$ (20,806) | \$ (47,712)                  | \$ (43,341) |
| Other comprehensive loss:                            |                                |             |                              |             |
| Net unrealized loss on available-for-sale securities | (36)                           | (8)         | (41)                         | (61)        |
| Comprehensive loss                                   | \$ (25,081)                    | \$ (20,814) | \$ (47,753)                  | \$ (42,402) |

Table of Contents

**4. Collaboration Arrangements**

*LABA collaboration with GSK*

In November 2002, the Company entered into its long-acting beta2 agonist (LABA) collaboration with GSK to develop and commercialize once-daily LABA products for the treatment of chronic obstructive pulmonary disease (COPD) and asthma. For the treatment of COPD, the collaboration is developing combination products, RELOVAIR and the LAMA/LABA (GSK573719/vilanterol or 719/VI). For the treatment of asthma, the collaboration is developing RELOVAIR. RELOVAIR is an investigational once-daily combination medicine consisting of a LABA, VI, previously referred to as GW642444 or 444, and an inhaled corticosteroid (ICS), fluticasone furoate (FF). The LAMA/LABA, 719/VI, is an investigational once-daily combination medicine consisting of the long-acting muscarinic antagonist (LAMA) 719, and the LABA, VI.

The current lead product candidates in the LABA collaboration, VI and FF, were discovered by GSK. In the event that VI is successfully developed and commercialized, the Company will be obligated to make milestone payments to GSK which could total as much as \$220.0 million if both a single-agent and a combination product or two different combination products are launched in multiple regions of the world. If the results of the Phase 3 studies with RELOVAIR are positive, a portion of these potential milestone payments could be payable to GSK within the next two years. The Company is entitled to annual royalties from GSK of 15% on the first \$3.0 billion of annual global net sales and 5% for all annual global net sales above \$3.0 billion. Sales of single-agent LABA medicines and combination medicines would be combined for the purposes of this royalty calculation. For other products combined with a LABA from the LABA collaboration, such as 719/VI, royalties are upward tiering and range from the mid-single digits to 10%. However, if GSK is not selling a LABA/ICS combination product at the time that the first other LABA combination is launched, then the royalties described above for the LABA/ICS combination medicine would be applicable.

In connection with the LABA collaboration, in 2002, GSK purchased through an affiliate shares of the Company's Series E preferred stock for an aggregate purchase price of \$40.0 million.

*Strategic Alliance with GSK*

In March 2004, the Company entered into its strategic alliance with GSK. Under this alliance, GSK received an option to license exclusive development and commercialization rights to product candidates from all of the Company's full drug discovery programs initiated prior to September 1, 2007, on pre-determined terms and on an exclusive, worldwide basis. Pursuant to the terms of the strategic alliance agreement, the Company initiated three new full discovery programs between May 2004 and August 2007. These three programs are (i) the oral Peripheral Mu Opioid Receptor Antagonist (PuMA) program for opioid-induced constipation, (ii) the AT1 Receptor-Nephrilysin Inhibitor (ARNI) program for cardiovascular disease and (iii) the MonoAmine Reuptake Inhibitor (MARIN) program for chronic pain. GSK still has the right to license the ARNI and MARIN programs, and must exercise this right no later than sixty days subsequent to the final delivery to GSK of all material, data and supporting documentation relating to achievement of clinical proof-of-concept of the first product candidate in the applicable program. For these two programs, proof-of-concept is generally defined as the successful completion of a Phase 2a clinical study showing efficacy and tolerability. Under the terms of the strategic alliance agreement, GSK has only one opportunity to license each of the Company's programs.

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

Upon GSK's decision to license a program, GSK is responsible for funding all future development, manufacturing and commercialization activities for product candidates in that program. In addition, GSK is obligated to use diligent efforts to develop and commercialize product candidates from any program that it licenses. Consistent with the Company's strategy, the Company is obligated to use diligent efforts at the Company's sole cost to discover two structurally different product candidates for any programs on which GSK has an option 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 and royalties on any sales of medicines developed from these programs. For any programs licensed under this agreement, the royalty structure for a product containing one of the Company's compounds as a single active ingredient would result in an average percentage royalty rate in the low double digits. For single-agent MABA products, the Company is entitled to receive royalties from GSK of between 10% and 20% of annual global net sales up to \$3.5 billion, and 7.5% for all annual global net sales above \$3.5 billion. For combination products, such as a MABA/ICS, the royalty rate is 70% of the rate applicable to sales of single-agent MABA medicines. If a product is successfully commercialized, in addition to any royalty revenue that 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. If GSK chooses not to license a program, the Company retains all rights to the program and may continue the program alone or with a third party. To date, GSK has licensed the Company's two COPD programs: LAMA and MABA. In 2009, GSK returned the LAMA program to the Company because the formulation of the lead product candidate was incompatible with GSK's proprietary inhaler device. GSK has chosen not to license the Company's antibacterial, anesthesia, 5-HT4 and PuMA programs.

Table of Contents

In May 2004, GSK purchased through an affiliate 6,387,096 shares of the Company's Class A common stock for an aggregate purchase price of \$108.9 million and, upon the closing of the Company's initial public offering on October 8, 2004, GSK purchased through an affiliate an additional 433,757 shares of Class A common stock for an aggregate purchase price of \$6.9 million. In addition, GSK purchased through an affiliate in a private placement 5,750,000 shares of the Company's common stock for an aggregate purchase price of \$129.4 million on November 29, 2010. On February 24, 2011 and May 3, 2011, GSK purchased through an affiliate 152,278 shares and 261,299 shares, respectively, of the Company's common stock from the Company for an aggregate purchase price of \$3.6 million and \$6.7 million, respectively, pursuant to its rights under the Company's governance agreement with GSK dated June 4, 2004, as amended.

*GSK Upfront Fees, Milestone Payments and Revenue*

Upfront fees and certain milestone payments have been deferred and are being amortized ratably into revenue over the estimated period of performance (the product development period). Upfront fees and milestone payments received from GSK under the LABA collaboration and strategic alliance agreements were as follows:

| (in thousands)                     | Upfront Fees | Through June 30, 2011<br>Milestone Payments | Total      |
|------------------------------------|--------------|---------------------------------------------|------------|
| <i>GSK Collaborations</i>          |              |                                             |            |
| LABA/RELOVAIR collaboration(1)     | \$ 10,000    | \$ 50,000                                   | \$ 60,000  |
| Strategic alliance agreement       | 20,000       |                                             | 20,000     |
| Strategic alliance LAMA license(2) | 5,000        | 3,000                                       | 8,000      |
| Strategic alliance MABA license    | 5,000        | 13,000                                      | 18,000     |
| Total                              | \$ 40,000    | \$ 66,000                                   | \$ 106,000 |

(1) The Company does not currently expect to be eligible for any additional milestones under this collaboration.

(2) In August 2004, GSK exercised its right to license the Company's LAMA program pursuant to the terms of the strategic alliance. In 2009, GSK returned the program to the Company.

The eligible milestones related to the MABA program and any future milestones that may be earned if GSK exercises its right to license either ARNI or MARIN are not deemed substantive due to the fact that the outcome predominantly relates to GSK's performance of future development, manufacturing and commercialization activities for product candidates after licensing the program.

Revenue recognized through amortization of the deferred upfront fees and milestone payments from GSK under the LABA collaboration and strategic alliance agreement was as follows:

| (in thousands) | Three Months Ended<br>June 30, |      | Six Months Ended<br>June 30, |      |
|----------------|--------------------------------|------|------------------------------|------|
|                | 2011                           | 2010 | 2011                         | 2010 |

Edgar Filing: THERAVANCE INC - Form 10-Q

*GSK Collaborations*

|                                 |    |       |    |       |    |       |    |       |
|---------------------------------|----|-------|----|-------|----|-------|----|-------|
| LABA/ RELOVAIR collaboration    | \$ | 1,270 | \$ | 1,270 | \$ | 2,540 | \$ | 2,540 |
| Strategic alliance agreement    |    | 684   |    | 684   |    | 1,369 |    | 1,369 |
| Strategic alliance MABA license |    | 502   |    | 502   |    | 1,004 |    | 1,004 |
| Total                           | \$ | 2,456 | \$ | 2,456 | \$ | 4,913 | \$ | 4,913 |

Table of Contents*License, Development and Commercialization Agreement with Astellas*

In November 2005, the Company entered into a collaboration arrangement with Astellas for the development and commercialization of telavancin. In July 2006, Japan was added to the collaboration, thereby giving Astellas worldwide rights to this medicine. Under this arrangement, the Company is responsible for substantially all costs to develop and obtain U.S. regulatory approval for telavancin and Astellas is responsible for substantially all other costs associated with commercialization of telavancin. The Company is entitled to receive royalties from Astellas on global net sales of VIBATIV® that, on a percentage basis, range from the high teens to the upper twenties depending on sales volume.

Through June 30, 2011, the Company had received \$191.0 million in upfront, milestone and other fees from Astellas. The Company recorded these payments as deferred revenue and is amortizing them ratably over its estimated period of performance (development and commercialization period). The Company is eligible to receive up to an additional \$15.0 million in milestone payments. The Company has deemed \$10.0 million of the remaining potential milestone payments to be substantive as the Company is responsible for substantially all activities to develop and obtain U.S. regulatory approval for telavancin for the treatment of nosocomial pneumonia. However, the Company's management believes the likelihood of achieving this milestone is low. The remaining eligible milestone payment of \$5.0 million is not deemed substantive due to the fact that pursuing regulatory approval of telavancin in the regions of the world outside of the U.S. is predominantly the responsibility of Astellas.

Revenue recognized under this collaboration agreement was as follows:

| (in thousands)                               | Three Months Ended<br>June 30, |          | Six Months Ended<br>June 30, |          |
|----------------------------------------------|--------------------------------|----------|------------------------------|----------|
|                                              | 2011                           | 2010     | 2011                         | 2010     |
| Amortization of deferred revenue             | \$ 3,244                       | \$ 3,244 | \$ 6,488                     | \$ 6,487 |
| Royalties from net sales of VIBATIV®         | 694                            | 114      | 1,324                        | 124      |
| Proceeds from VIBATIV® delivered to Astellas | 1,171                          | 1,393    | 1,171                        | 1,393    |
| Cost of VIBATIV® delivered to Astellas       | (1,177)                        | (943)    | (1,177)                      | (938)    |
| Total net revenue                            | \$ 3,932                       | \$ 3,808 | \$ 7,806                     | \$ 7,066 |

**5. Marketable Securities**

The Company manages, monitors and measures its investments in highly liquid investment grade securities by major security type. Investments in debt securities are accounted for as available-for-sale securities, carried at fair value with unrealized gains and losses reported in accumulated other comprehensive income (loss), held for use in current operations and classified in current assets as marketable securities. The cost of securities sold is based on the specific-identification method.

The estimated fair value amounts were determined using available market information. Available-for-sale debt securities recorded in cash equivalents, marketable securities or restricted cash in the Company's condensed consolidated balance sheets were as follows:

Edgar Filing: THERAVANCE INC - Form 10-Q

| (in thousands)                              | June 30, 2011  |                        |                         |                      | December 31, 2010 |                        |                         |                      |
|---------------------------------------------|----------------|------------------------|-------------------------|----------------------|-------------------|------------------------|-------------------------|----------------------|
|                                             | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value | Amortized Cost    | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
| U.S. government securities                  | \$ 66,496      | \$ 28                  | \$ (6)                  | \$ 66,518            | \$ 25,966         | \$ 10                  | \$                      | \$ 25,976            |
| U.S. government agencies                    | 77,717         | 18                     | (39)                    | 77,696               | 54,625            | 30                     | (7)                     | 54,648               |
| U.S. corporate notes                        | 21,100         | 1                      | (10)                    | 21,091               | 34,695            | 9                      | (9)                     | 34,695               |
| U.S. commercial paper                       | 44,356         |                        |                         | 44,356               | 97,221            |                        |                         | 97,221               |
| Money market funds                          | 72,393         |                        |                         | 72,393               | 91,805            |                        |                         | 91,805               |
| Total                                       | 282,062        | 47                     | (55)                    | 282,054              | 304,312           | 49                     | (16)                    | 304,345              |
| Less amounts classified as cash equivalents | (87,932)       |                        |                         | (87,932)             | (157,151)         |                        |                         | (157,151)            |
| Less amounts classified as restricted cash  | (893)          |                        |                         | (893)                | (893)             |                        |                         | (893)                |
| Amounts classified as marketable securities | \$ 193,237     | \$ 47                  | \$ (55)                 | \$ 193,229           | \$ 146,268        | \$ 49                  | \$ (16)                 | \$ 146,301           |

At June 30, 2011, all of the marketable securities had contractual maturities within twelve months and the average duration of marketable securities was approximately seven months. The Company does not intend to sell the investments which are in an unrealized loss position and it is unlikely that the Company will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. The Company has determined that the gross unrealized losses on its marketable securities at June 30, 2011 were temporary in nature. All marketable securities with unrealized losses have been in a loss position for less than twelve months.

Table of Contents**6. Fair Value Measurements**

The Company defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

The Company's valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect the Company's market assumptions. The Company classifies these inputs into the following hierarchy:

*Level 1 Inputs* Quoted prices for identical instruments in active markets.

*Level 2 Inputs* Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

*Level 3 Inputs* Unobservable inputs and little, if any, market activity for the assets.

The estimated fair values of the Company's financial assets were as follows:

|                                   | June 30, 2011                                                               |                                                         |                                                  |            |
|-----------------------------------|-----------------------------------------------------------------------------|---------------------------------------------------------|--------------------------------------------------|------------|
|                                   | Fair Value Measurements at Reporting Date Using                             |                                                         |                                                  |            |
|                                   | Quoted Prices<br>in Active<br>Markets for<br>Identical<br>Assets<br>Level 1 | Significant<br>Other<br>Observable<br>Inputs<br>Level 2 | Significant<br>Unobservable<br>Inputs<br>Level 3 | Total      |
| (in thousands)                    |                                                                             |                                                         |                                                  |            |
| U.S. government securities        | \$ 66,518                                                                   | \$                                                      | \$                                               | \$ 66,518  |
| U.S. government agency securities | 63,874                                                                      | 13,822                                                  |                                                  | 77,696     |
| U.S. corporate notes              | 20,522                                                                      | 569                                                     |                                                  | 21,091     |
| U.S. commercial paper             |                                                                             | 44,356                                                  |                                                  | 44,356     |
| Money market funds                | 72,393                                                                      |                                                         |                                                  | 72,393     |
| Total                             | \$ 223,307                                                                  | \$ 58,747                                               | \$                                               | \$ 282,054 |

|  | December 31, 2010                                                |                                              |                                       |
|--|------------------------------------------------------------------|----------------------------------------------|---------------------------------------|
|  | Fair Value Measurements at Reporting Date Using                  |                                              |                                       |
|  | Quoted Prices<br>in Active<br>Markets for<br>Identical<br>Assets | Significant<br>Other<br>Observable<br>Inputs | Significant<br>Unobservable<br>Inputs |

# Edgar Filing: THERAVANCE INC - Form 10-Q

| (in thousands)                    | Level 1 |         | Level 2 |         | Level 3 |    | Total   |
|-----------------------------------|---------|---------|---------|---------|---------|----|---------|
| U.S. government securities        | \$      | 25,976  | \$      |         | \$      |    | 25,976  |
| U.S. government agency securities |         | 24,375  |         | 30,273  |         |    | 54,648  |
| U.S. corporate notes              |         | 34,695  |         |         |         |    | 34,695  |
| U.S. commercial paper             |         |         |         | 97,221  |         |    | 97,221  |
| Money market funds                |         | 91,805  |         |         |         |    | 91,805  |
| Total                             | \$      | 176,851 | \$      | 127,494 | \$      | \$ | 304,345 |

## 7. Convertible Subordinated Notes

In January 2008, the Company closed an underwritten public offering of \$172.5 million aggregate principal amount of unsecured convertible subordinated notes which will mature on January 15, 2015. The financing raised proceeds, net of issuance costs, of \$166.7 million. The notes bear interest at the rate of 3.0% per year; which is payable semi-annually in arrears in cash on January 15 and July 15 of each year, beginning on July 15, 2008.

## Table of Contents

The notes are convertible, at the option of the holder, into shares of the Company's common stock at an initial conversion rate of 38.6548 shares per \$1,000 principal amount of the notes, subject to adjustment in certain circumstances, which represents an initial conversion price of approximately \$25.87 per share. The debt issuance costs, which are included in other long-term assets, are being amortized on a straight-line basis over the life of the notes.

Holders of the notes will be able to require the Company to repurchase some or all of their notes upon the occurrence of a fundamental change (as defined) at 100% of the principal amount of the notes being repurchased plus accrued and unpaid interest. The Company may not redeem the notes prior to January 15, 2012. On or after January 15, 2012 and prior to the maturity date, the Company, upon notice of redemption, may redeem for cash all or part of the notes if the last reported sale price of its common stock has been greater than or equal to 130% of the conversion price then in effect for at least 20 trading days during any 30 consecutive trading day period prior to the date on which it provides notice of redemption. The redemption price will equal 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest up to but excluding the redemption date.

The fair value of debt was estimated based on the quoted price of the instrument. The carrying values and estimated fair values for the notes were as follows.

| (in thousands)                 | June 30, 2011  |                      | December 31, 2010 |                      |
|--------------------------------|----------------|----------------------|-------------------|----------------------|
|                                | Carrying Value | Estimated Fair Value | Carrying Value    | Estimated Fair Value |
| Convertible subordinated notes | \$ 172,500     | \$ 190,409           | \$ 172,500        | \$ 202,391           |

## 8. Operating Lease

The Company leases its South San Francisco, California, facilities under a non-cancelable operating lease. Future minimum lease payments under this lease, exclusive of executory costs, at June 30, 2011, were as follows:

| (in thousands)            | Minimum Lease Commitments |
|---------------------------|---------------------------|
| Years ending December 31: |                           |
| Remainder of 2011         | \$ 2,229                  |
| 2012                      | 5,429                     |
| 2013                      | 5,029                     |
| 2014                      | 4,859                     |
| 2015                      | 5,005                     |
| Thereafter                | 23,962                    |
| Total                     | \$ 46,513                 |

## 9. Commitments and Contingencies

### 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 June 30, 2011.

## **10. Stock-Based Compensation**

### *Equity Incentive Plan*

The 2004 Plan provides for the granting of stock options, stock appreciation rights, RSUs and RSAs to employees, officers, directors and consultants of the Company. Stock options may be granted with an exercise price not less than 100% of the fair market value of the common stock on the date of grant. On April 27, 2010, an amendment and restatement of the 2004 Plan was approved by the Company's stockholders to, among other things, reserve additional shares of common stock for issuance thereunder. As of June 30, 2011, total shares remaining available for issuance under the 2004 Plan were 2,439,637.

### *Employee Stock Purchase Plan*

As of June 30, 2011, a total of 2,025,000 shares of common stock were approved and authorized for issuance under the Employee Stock Purchase Plan (ESPP). Through June 30, 2011, the Company issued 1,419,532 shares under the ESPP at an average price of \$9.90 per share.

## Table of Contents

### Stock-Based Compensation Expense

The allocation of stock-based compensation expense included in the condensed consolidated statements of operations was as follows:

| (in thousands)             | Three Months Ended<br>June 30, |          | Six Months Ended<br>June 30, |          |
|----------------------------|--------------------------------|----------|------------------------------|----------|
|                            | 2011                           | 2010     | 2011                         | 2010     |
| Research and development   | \$ 3,379                       | \$ 2,618 | \$ 6,511                     | \$ 5,145 |
| General and administrative | 2,896                          | 2,704    | 5,305                        | 4,675    |
| Total                      | \$ 6,275                       | \$ 5,322 | \$ 11,816                    | \$ 9,820 |

As of June 30, 2011, unrecognized compensation expense was as follows: \$6.5 million related to unvested stock options; \$24.4 million related to unvested RSUs; and \$26.4 million related to unvested RSAs.

### Compensation Awards

The Company granted the following compensation awards:

|                                | Six Months Ended<br>June 30, 2011              |                                                     | Six Months Ended<br>June 30, 2010              |                                                      |
|--------------------------------|------------------------------------------------|-----------------------------------------------------|------------------------------------------------|------------------------------------------------------|
|                                | Number of<br>Compensation<br>Awards<br>Granted | Weighted<br>Average<br>Exercise<br>Price/Fair Value | Number of<br>Compensation<br>Awards<br>Granted | Weighted<br>Average<br>Exercise Price/<br>Fair Value |
| 2004 Plan                      |                                                |                                                     |                                                |                                                      |
| Stock options                  | 307,500                                        | \$ 24.56                                            | 143,750                                        | \$ 16.37                                             |
| RSUs time-based                | 465,000                                        | 25.03                                               | 940,042                                        | 10.47                                                |
| RSAs time-based                | 1,148,000                                      | 24.70                                               |                                                |                                                      |
| RSUs performance-contingent(1) |                                                |                                                     | 210,000                                        | 10.12                                                |
| RSAs performance-contingent(2) | 1,290,000                                      | 24.73                                               |                                                |                                                      |
| 2008 Plan                      |                                                |                                                     |                                                |                                                      |
| Stock options                  |                                                | \$ 110,000                                          |                                                | \$ 10.95                                             |

(1) These performance-contingent RSUs awarded to senior management in 2010 have dual triggers of vesting based upon the successful achievement of certain corporate operating milestones during 2010 and 2011, as well as a requirement for continued employment through early 2014. As of February 11, 2011, both performance milestones had been deemed achieved, and time-based vesting had commenced with respect to all of the performance-contingent RSU shares.

(2) These performance-contingent RSAs granted to senior management in 2011 have dual triggers of vesting based upon the achievement of certain performance targets over a six-year timeframe from 2011-2016 and continued employment, both of which must be satisfied in order for the RSAs to vest. Expense associated with these RSAs would be recognized, if at all, during these years depending on the probability of meeting the performance conditions. The maximum potential expense associated with the RSAs could be up to approximately \$31.9 million (allocated as \$6.3 million for research and development expense and \$25.6 million for general and administrative expense) if all of the performance targets are achieved on time. As of June 30, 2011, the Company had determined that the achievement of the requisite performance conditions was not probable, and as a result, no compensation expense has been recognized. As the RSAs are dependent upon the achievement of certain performance targets, the expense associated with the RSAs may vary significantly from period to period.

## Table of Contents

### Valuation Assumptions

The range of weighted average assumptions used to estimate the fair value of stock options granted was as follows:

|                                                                | Three Months Ended<br>June 30, |             | Six Months Ended<br>June 30, |             |
|----------------------------------------------------------------|--------------------------------|-------------|------------------------------|-------------|
|                                                                | 2011                           | 2010        | 2011                         | 2010        |
| <b>Employee stock options</b>                                  |                                |             |                              |             |
| Risk-free interest rate                                        | 1.94%-2.57%                    | 2.42%-2.82% | 1.94%-2.57%                  | 2.42%-2.82% |
| Expected term (in years)                                       | 5-6                            | 5-6         | 5-6                          | 5-6         |
| Volatility                                                     | 0.53-0.55                      | 0.52        | 0.49-0.55                    | 0.48-0.52   |
| Dividend yield                                                 | %                              | %           | %                            | %           |
| Weighted average estimated fair value of stock options granted | \$ 13.09                       | \$ 8.41     | \$ 12.41                     | \$ 7.07     |
| <b>Employee stock purchase plan issuances</b>                  |                                |             |                              |             |
| Risk-free interest rate                                        | .07%-.54%                      | 0.22%-0.79% | .07%-.54%                    | 0.22%-0.79% |
| Expected term (in years)                                       | 0.5-2.0                        | 0.5-2.0     | 0.5-2.0                      | 0.5-2.0     |
| Volatility                                                     | 0.48-0.50                      | 0.50-0.69   | 0.48-0.50                    | 0.50-0.69   |
| Dividend yield                                                 | %                              | %           | %                            | %           |
| Weighted average estimated fair value of ESPP issuances        | \$ 9.25                        | \$ 5.86     | \$ 9.25                      | \$ 5.86     |

### Stockholders' equity

For the six months ended June 30, 2011, approximately 1,120,000 shares were exercised at a weighted average exercise price of \$8.90 per share for a total of \$10.0 million.

## 11. Subsequent Events

On August 2, 2011, the Company and GSK entered into an agreement pursuant to which GSK agreed to purchase through an affiliate, in a private placement, 102,466 shares of the Company's common stock for \$19.71 per share pursuant to its rights under the Company's governance agreement with GSK dated June 4, 2004, as amended.

On July 21, 2011, GlaxoSmithKline LLC, an affiliate of GSK, converted 6,820,854 shares of the Company's Class A common stock into the Company's common stock, and on July 22, 2011, Glaxo Group Limited, an affiliate of GSK, converted 2,580,645 shares of the Company's Class A common stock into the Company's common stock, in each case on a one share-for-one share basis in accordance with the terms of the Company's restated certificate of incorporation. Following these conversions there are no shares of the Company's Class A common stock outstanding.



Table of Contents

**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 forward-looking statements involve substantial risks, uncertainties and assumptions. All 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, intentions, expectations, goals and objectives, may be forward-looking statements. The words anticipates, believes, designed, estimates, expects, intend, may, objective, plans, projects, pursue, will, would and similar expressions (including the negatives thereof) 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 could materially differ from the plans, intentions, expectations and objectives disclosed in the forward-looking statements that we make. Factors that we believe could cause actual results or events to differ materially from our forward-looking statements include, but are not limited to those discussed below in Risk Factors in Item 1A of Part II and in Management's Discussion and Analysis of Financial Condition and Results of Operations in this Item 2 of Part I. 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.

**OVERVIEW**

**Executive Summary**

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. 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 central nervous system (CNS)/pain. The Company's key programs include: RELOVAIR, LAMA/LABA (719/vilanterol (VI)) and MABA (Bifunctional Muscarinic Antagonist-Beta2 Agonist), each partnered with GlaxoSmithKline plc, (GSK), and its oral Peripheral Mu Opioid Receptor Antagonist (PuMA) program. By leveraging its proprietary insight of multivalency to drug discovery, Theravance is pursuing a best-in-class strategy designed to discover superior medicines in areas of significant unmet medical need.

Our net loss was \$25.0 million in the second quarter and \$47.7 million in the first six months of 2011, compared with \$20.8 million and \$43.3 million for the same periods in 2010, respectively. Total operating expenses were \$30.1 million in the second quarter and \$57.7 million in the first six months of 2011, compared with \$25.7 million and \$52.5 million for the same periods in 2010, respectively. Cash, cash equivalents and marketable securities totaled \$283.9 million at June 30, 2011, a decrease of \$25.7 million since December 31, 2010. The decrease was primarily due to cash used in operations, partially offset by net proceeds of \$10.3 million received from our private placements of common stock to an affiliate of GSK.

**Program Highlights**

*Respiratory Programs*

Registrational Programs with RELOVAIR

The registrational programs with RELOVAIR in chronic obstructive pulmonary disease (COPD) and asthma have fully enrolled approximately 11,000 patients. RELOVAIR is an investigational once-daily medicine that combines fluticasone furoate (FF, an inhaled corticosteroid or ICS) and vilanterol (VI, a long-acting beta2 agonist or LABA) for the treatment of patients with COPD or asthma.

In COPD

The registrational program in COPD consists of five studies, including two 12-month exacerbation studies, two six-month efficacy and safety studies, and a detailed lung function profile study.

In June 2011, GSK and Theravance announced the results of two 6-month efficacy and safety Phase 3 studies of RELOVAIR for patients with COPD. Results of both studies support the continuation of the RELOVAIR development program in the COPD patient population. These data form part of the overall evaluation of the efficacy and safety of the RELOVAIR combination in COPD which, together with data from ongoing 12-month exacerbation studies, will be included in regulatory submissions around the world.

## Table of Contents

The two 6-month studies were placebo-controlled, double-blind, parallel-group studies that enrolled approximately 2,200 patients with moderate to severe COPD. Patients (approximately 200 per arm per study) were randomized to receive FF alone (100mcg, 200mcg), VI alone (25mcg), a combination of FF and VI (50mcg, 100mcg, or 200mcg FF plus VI 25mcg) or placebo. The studies evaluated improvement in lung function at two timepoints: over the first four hours after dosing on day 168 and 24 hours after the last dose of study drug.

These two 6-month FEV1 studies provided an initial insight into the pivotal program for RELOVAIR which is evaluating over 6,000 patients with COPD. The two larger 12-month exacerbation studies, which enrolled over 3,000 patients, will provide additional evaluation of the efficacy of RELOVAIR compared with VI. The full results of all the studies will be presented at future scientific meetings.

## In Asthma

The asthma registrational program is designed to determine the safety and efficacy of RELOVAIR in asthma patients who remain uncontrolled on current treatment. These studies include an exacerbation study, a 12-month safety study (which also supports the COPD program), a 12-week low-dose combination efficacy study, a 24-week high-dose combination efficacy study, a 24-week head-to-head study of RELOVAIR versus Advair®/Seretide, a 24-week study of FF versus fluticasone propionate, a 12-week study of VI versus salmeterol, and a hypothalamic-pituitary-adrenal (HPA) axis study.

## Phase 3b Program with RELOVAIR in COPD

The RELOVAIR Phase 3b COPD program is progressing with the large Phase 3b outcomes study of 16,000 patients, which will assess the potential for RELOVAIR to improve survival in patients with moderate COPD and a history of, or at risk for, cardiovascular disease. The results of this study are not required for the regulatory submission and will not form part of the initial New Drug Application (NDA)/Marketing Authorization Application (MAA).

In addition to the outcomes study, there are five ongoing Phase 3b COPD studies. Three of these studies are 12-week studies that will evaluate the 24-hour pulmonary function profile of RELOVAIR once daily compared with Advair®/Seretide twice daily in patients with COPD. These studies are targeted to enroll approximately 500 patients per study. The two other studies will evaluate the effect of RELOVAIR once-daily on arterial wall stiffness 1) compared with placebo and VI for a treatment period of 24 weeks and 2) compared with tiotropium for a treatment period of 12 weeks in patients with COPD. The estimated enrollments for these studies are 410 patients and 248 patients, respectively.

## LAMA/LABA Combination (GSK573719/Vilanterol or 719/VI) in COPD

Enrollment is in line with expectations for the seven studies in the Phase 3 program for the once-daily LAMA/LABA dual bronchodilator 719/VI. 719/VI combines two bronchodilators currently under development - 719, a long-acting muscarinic antagonist (LAMA) and VI, a LABA. These molecules act through two mechanisms: antagonism of acetylcholine muscarinic receptors and agonism of beta2 adrenoreceptors.

The LAMA/LABA Phase 3 program, which will evaluate over 5,000 patients with COPD globally, consists of a 52-week study to evaluate the long term safety and tolerability of 719 (125mcg) alone, as well as the combination 719/VI (125/25mcg), two large pivotal studies that will compare improvements in lung function between 719/VI, its components and placebo, two studies to compare the combination with its components and tiotropium and two studies to assess the effect of 719/VI on exercise endurance. The Phase 3 program will investigate two doses of 719 (125mcg and 62.5mcg) and 719/VI (125/25mcg and 62.5/25mcg).

Inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist (MABA) in COPD

Enrollment is in line with expectations for the Phase 2b study with GSK961081 ( 081) in patients with moderate to severe COPD. 081 is a single molecule bifunctional bronchodilator with both muscarinic antagonist and beta2 receptor agonist activity. The primary objective of this study is to evaluate dose response, dose interval, efficacy, and safety of 081 by studying once-daily (QD) doses (100mcg, 400mcg, and 800mcg), twice-daily (BID) doses (100mcg, 200mcg, and 400mcg), the active comparator salmeterol (50mcg BID) and placebo over a 28-day period. The overall aim of this Phase 2b study is to evaluate the safety and efficacy of 081 administered both once daily and twice daily over a 28-day period to allow the selection of an appropriate dose and dosing interval.

Table of Contents

*Central Nervous System (CNS)/Pain Program*

Oral Peripheral Mu Opioid Receptor Antagonist (PuMA) TD-1211

Recently, the first patient with opioid-induced constipation (OIC) was dosed in the Phase 2b program to assess the safety, tolerability and clinical activity of TD-1211 in patients with OIC. This study will evaluate doses and dose regimens to provide information for the design of the Phase 3 program. TD-1211 is an investigational once-daily, orally-administered, peripherally selective, multivalent inhibitor of the mu opioid receptor designed to alleviate gastrointestinal side effects of opioid therapy without affecting analgesia.

**Collaboration Arrangements**

*LABA collaboration with GSK*

In November 2002, we entered into our LABA collaboration with GSK to develop and commercialize once-daily LABA products for the treatment of COPD and asthma. For the treatment of COPD, the collaboration is developing combination products, RELOVAIR and the LAMA/LABA 719/VI. For the treatment of asthma, the collaboration is developing RELOVAIR. RELOVAIR is an investigational once-daily combination medicine consisting of a LABA, VI, previously referred to as GW642444 or 444, and an ICS, FF. The LAMA/LABA, 719/VI, is an investigational once-daily combination medicine consisting of the LAMA, 719, and the LABA, VI. The Phase 3 program with RELOVAIR is aimed at developing a next generation respiratory product to succeed GSK's Advair®/Seretide (salmeterol and fluticasone as a combination) franchise, which had reported 2010 sales of approximately \$7.97 billion, and to compete with Symbicort® (formoterol and budesonide as a combination), which had reported 2010 sales of approximately \$2.75 billion. 719/VI, which is also a combination product, is targeted as an alternative treatment option to Spiriva® (tiotropium), a once-daily, single-mechanism bronchodilator, which had reported 2010 sales of approximately \$3.8 billion.

The current lead product candidates in the LABA collaboration, VI and FF, were discovered by GSK. In the event that VI is successfully developed and commercialized, we will be obligated to make milestone payments to GSK which could total as much as \$220.0 million if both a single-agent and a combination product or two different combination products are launched in multiple regions of the world. If the results of the Phase 3 studies with RELOVAIR are positive, a portion of these potential milestone payments could be payable to GSK within the next two years. We are entitled to annual royalties from GSK of 15% on the first \$3.0 billion of annual global net sales and 5% for all annual global net sales above \$3.0 billion. Sales of single-agent LABA medicines and combination medicines would be combined for the purposes of this royalty calculation. For other products combined with a LABA from the LABA collaboration, such as 719/VI, royalties are upward tiering and range from the mid-single digits to 10%. However, if GSK is not selling a LABA/ICS combination product at the time that the first other LABA combination is launched, then the royalties described above for the LABA/ICS combination medicine would be applicable.

In connection with the LABA collaboration, in 2002, GSK purchased through an affiliate shares of our Series E preferred stock for an aggregate purchase price of \$40.0 million.

*Strategic Alliance with GSK*

In March 2004, we entered into our strategic alliance with GSK. Under this alliance, GSK received an option to license exclusive development and commercialization rights to product candidates from all of our full drug discovery programs initiated prior to September 1, 2007, on pre-determined terms and on an exclusive, worldwide basis. Pursuant to the terms of the strategic alliance agreement, we initiated three new full discovery programs between May 2004 and August 2007. These three programs are (i) our PμMA program for opioid-induced constipation, (ii) our AT1 Receptor-Nepriylsin Inhibitor (ARNI) program for cardiovascular disease and (iii) our MonoAmine Reuptake Inhibitor (MARIN) program for chronic pain. GSK still has the right to license the ARNI and MARIN programs, and must exercise this right no later than sixty days subsequent to the final delivery to GSK of all material, data and supporting documentation relating to achievement of clinical proof-of-concept of the first product candidate in the applicable program. For these two programs, proof-of-concept is generally defined as the successful completion of a Phase 2a clinical study showing efficacy and tolerability. Under the terms of the strategic alliance agreement, GSK has only one opportunity to license each of our programs.

Upon GSK's decision to license a program, GSK is responsible for funding all future development, manufacturing and commercialization activities for product candidates in that program. In addition, GSK is obligated to use diligent efforts to develop and commercialize product candidates from any program that it licenses. Consistent with our strategy, we are obligated to use diligent efforts at our sole cost to discover two structurally different product candidates for any programs on which GSK has an option under the alliance. If these programs are successfully advanced through development by GSK, we are entitled to receive clinical, regulatory and commercial milestone payments and royalties on any sales of medicines developed from these programs. For any programs licensed under this agreement, the royalty structure for a product containing one of our compounds as a single active ingredient would result in an average percentage royalty rate in the low double digits. For single-agent MABA products, we are entitled to receive royalties from GSK of between 10% and 20% of annual global net sales up to \$3.5 billion, and 7.5% for all annual global net sales above \$3.5 billion. For combination products, such as a MABA/ICS, the royalty rate is 70% of the rate applicable to sales of single-agent MABA medicines. If a product is successfully commercialized, in addition to any royalty revenue that we receive, the total

## Table of Contents

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. If GSK chooses not to license a program, we retain all rights to the program and may continue the program alone or with a third party. To date, GSK has licensed our two COPD programs: LAMA and MABA. In 2009, GSK returned the LAMA program to us because the formulation of the lead product candidate was incompatible with GSK's proprietary inhaler device. GSK has chosen not to license our antibacterial, anesthesia, 5-HT4 and PpMA programs. There can be no assurance that GSK will license either of the two remaining programs under the alliance agreement, which could have an adverse effect on our business and financial condition.

In May 2004, GSK purchased through an affiliate 6,387,096 shares of our Class A common stock for an aggregate purchase price of \$108.9 million and, upon the closing of our initial public offering on October 8, 2004, GSK purchased through an affiliate an additional 433,757 shares of Class A common stock for an aggregate purchase price of \$6.9 million. In addition, GSK purchased through an affiliate in a private placement 5,750,000 shares of our common stock for an aggregate purchase price of \$129.4 million on November 29, 2010. On February 24, 2011 and May 3, 2011, GSK purchased through an affiliate 152,278 shares and 261,299 shares, respectively, of our common stock from us for an aggregate purchase price of \$3.6 million and \$6.7 million, respectively, pursuant to its rights under our governance agreement with GSK dated June 4, 2004, as amended.

### *GSK Upfront Fees, Milestone Payments and Revenue*

The eligible milestones related to the MABA program and any future milestones that may be earned if GSK exercises its right to license either ARNI or MARIN are not deemed substantive due to the fact that the outcome predominantly relates to GSK's performance of future development, manufacturing and commercialization activities for product candidates after licensing the program.

Revenue recognized through amortization of the deferred upfront fees and milestone payments from GSK under the LABA collaboration and strategic alliance agreement was as follows:

| (in millions)                   | Three Months Ended<br>June 30, |        | Six Months Ended<br>June 30, |        |
|---------------------------------|--------------------------------|--------|------------------------------|--------|
|                                 | 2011                           | 2010   | 2011                         | 2010   |
| <i>GSK Collaborations</i>       |                                |        |                              |        |
| LABA/ RELOVAIR collaboration    | \$ 1.3                         | \$ 1.3 | \$ 2.5                       | \$ 2.5 |
| Strategic alliance agreement    | 0.7                            | 0.7    | 1.4                          | 1.4    |
| Strategic alliance MABA license | 0.5                            | 0.5    | 1.0                          | 1.0    |
| Total                           | \$ 2.5                         | \$ 2.5 | \$ 4.9                       | \$ 4.9 |

### *License, Development and Commercialization Agreement with Astellas*

In November 2005, we entered into a collaboration arrangement with Astellas for the development and commercialization of telavancin. In July 2006, Japan was added to the collaboration, thereby giving Astellas worldwide rights to this medicine.

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

Under this arrangement, we are responsible for substantially all costs to develop and obtain U.S. regulatory approval for telavancin and Astellas is responsible for substantially all other costs associated with commercialization of telavancin. We are entitled to receive royalties from Astellas on global net sales of VIBATIV® that, on a percentage basis, range from the high teens to the upper twenties depending on sales volume. The U.S. Food and Drug Administration (FDA) has approved VIBATIV® for the treatment of complicated skin and skin structure infections (cSSSI) caused by susceptible Gram-positive bacteria including both methicillin-resistant (MRSA) and methicillin-susceptible (MSSA) strains of *Staphylococcus aureus* in adult patients. VIBATIV® is also approved in Canada for the treatment of cSSSI in adult patients. The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion, recommending the granting of marketing authorization for telavancin for the treatment of adults with nosocomial pneumonia including ventilator-associated pneumonia, known or suspected to be caused by methicillin-resistant *Staphylococcus aureus* (MRSA).

Through June 30, 2011, we have received \$191.0 million in upfront, milestone and other fees from Astellas. We recorded these payments as deferred revenue and are amortizing them ratably over our estimated period of performance (development and commercialization period). We are eligible to receive up to an additional \$15.0 million in milestone payments. We have deemed \$10.0 million of the remaining potential milestone payments to be substantive as we are responsible for substantially all activities to develop and obtain U.S. regulatory approval for telavancin for the treatment of nosocomial pneumonia. However, management believes the likelihood of achieving this milestone is low. The remaining eligible milestone payment of \$5.0 million is not deemed substantive due to the fact that pursuing regulatory approval of telavancin in the regions of the world outside of the U.S. is predominantly the responsibility of Astellas.

Table of Contents

Revenue recognized under this collaboration agreement was as follows:

| (in millions)                                | Three Months Ended<br>June 30, |       |      |       | Six Months Ended<br>June 30, |       |      |       |
|----------------------------------------------|--------------------------------|-------|------|-------|------------------------------|-------|------|-------|
|                                              | 2011                           |       | 2010 |       | 2011                         |       | 2010 |       |
| Amortization of deferred revenue             | \$                             | 3.2   | \$   | 3.2   | \$                           | 6.5   | \$   | 6.5   |
| Royalties from net sales of VIBATIV®         |                                | 0.7   |      | 0.1   |                              | 1.3   |      | 0.1   |
| Proceeds from VIBATIV® delivered to Astellas |                                | 1.2   |      | 1.4   |                              | 1.2   |      | 1.4   |
| Cost of VIBATIV® delivered to Astellas       |                                | (1.2) |      | (0.9) |                              | (1.2) |      | (0.9) |
| Total net revenue                            | \$                             | 3.9   | \$   | 3.8   | \$                           | 7.8   | \$   | 7.1   |

**Critical Accounting Policies and the Use of Estimates**

As of the date of the filing of this quarterly report, we believe there have been no material changes or additions to our critical accounting policies and estimates during the six months ended June 30, 2011 compared to those discussed in our 2010 Annual Report on Form 10-K filed on February 28, 2011, except as related to the adoption of Accounting Standards Update (ASU) No. 2010-17, Revenue Recognition Milestone Method an update to Accounting Standards Codification (ASC) Topic 605, Revenue Recognition and ASU No. 2009-13, Revenue Recognition - Multiple-Deliverable Revenue Arrangements a consensus of the FASB Emerging Issues Task Force, an update to ASC Topic 605, Revenue Recognition.

We adopted ASU 2010-17 and elected the milestone method which did not have a material impact on our condensed consolidated financial statements. However, the election will result in different accounting treatment for future substantive milestones earned after the date of this adoption and non-substantive milestones will continue to be recognized over an estimated performance period.

For future agreements that may include contingent milestone payments, we will evaluate whether a milestone is substantive in nature. Where a substantive milestone is achieved in a collaboration arrangement, and we have no obligations remaining after achievement of the milestone and the corresponding payment is reasonably assured, we will recognize the payment as earned. If we determine a milestone is not substantive, then the revenues from the related milestone payment will be recognized on a straight-line basis over an estimated performance period.

**RESULTS OF OPERATIONS****Revenue**

Revenue, compared to the same periods in 2010, was as follows:

Change

Change

# Edgar Filing: THERAVANCE INC - Form 10-Q

| (in millions, except percentages) | Three months Ended<br>June 30, |        |        |    | Six months Ended<br>June 30, |         |        |    |
|-----------------------------------|--------------------------------|--------|--------|----|------------------------------|---------|--------|----|
|                                   | 2011                           | 2010   | \$     | %  | 2011                         | 2010    | \$     | %  |
| Revenue                           | \$ 6.4                         | \$ 6.3 | \$ 0.1 | 2% | \$ 12.7                      | \$ 12.0 | \$ 0.7 | 6% |

From GSK, we recognize revenue from the amortization of upfront fees and milestone payments related to our LABA collaboration and strategic alliance agreements. From Astellas, we recognize revenue from the amortization of upfront and milestone payments related to our telavancin collaboration, royalties from net sales of VIBATIV® and the impact of VIBATIV® inventory transfers or dispositions. Revenue remained relatively flat at \$6.4 million in the second quarter and \$12.7 million in the first six months of 2011, from the comparable periods in 2010.

Upfront fees and certain milestone payments have been deferred and are being amortized ratably into revenue over the estimated period of performance (the product development period). Upfront fees and milestone payments received from GSK under the LABA collaboration and strategic alliance agreements and from Astellas under the telavancin collaboration were as follows:

| (in millions)                      | Upfront and Other<br>Fees | Through June 30, 2011<br>Milestone<br>Payments | Total    |
|------------------------------------|---------------------------|------------------------------------------------|----------|
| <i>GSK Collaborations</i>          |                           |                                                |          |
| LABA/RELOVAIR collaboration(1)     | \$ 10.0                   | \$ 50.0                                        | \$ 60.0  |
| Strategic alliance agreement       | 20.0                      |                                                | 20.0     |
| Strategic alliance LAMA license(2) | 5.0                       | 3.0                                            | 8.0      |
| Strategic alliance MABA license    | 5.0                       | 13.0                                           | 18.0     |
| <i>Astellas License agreement</i>  | 70.0                      | 121.0                                          | 191.0    |
| Total                              | \$ 110.0                  | \$ 187.0                                       | \$ 297.0 |

(1) We do not currently expect to be eligible for any additional milestones under this collaboration.

(2) In August 2004, GSK exercised its right to license our LAMA program pursuant to the terms of the strategic alliance. In 2009, GSK returned the program to us.

Table of Contents

Upfront fees and certain milestone payments received from GSK and Astellas have been deferred and are being amortized ratably into revenue over the estimated period of performance with end dates ranging between 2011 and 2021. Future revenue will include the ongoing amortization of upfront and milestone payments earned, royalties from Astellas on net sales of VIBATIV® and proceeds from Astellas for transfers of inventory offset by our cost of inventory no longer realizable. We periodically review and, if necessary, revise the estimated periods of performance of our contracts.

**Research & Development**

Research and development (R&D) expenses, compared to the same periods in 2010, were as follows:

| (in millions, except percentages)            | Three months Ended<br>June 30, |         | Change |     | Six months Ended<br>June 30, |         | Change |     |
|----------------------------------------------|--------------------------------|---------|--------|-----|------------------------------|---------|--------|-----|
|                                              | 2011                           | 2010    |        |     | 2011                         | 2010    |        |     |
|                                              | \$                             | \$      | \$     | %   | \$                           | \$      | \$     | %   |
| Employee-related                             | 8.5                            | 7.3     | 1.2    | 16% | 16.7                         | 15.3    | 1.4    | 9%  |
| External R&D                                 | 5.2                            | 3.3     | 1.9    | 58% | 8.4                          | 7.4     | 1.0    | 14% |
| Stock-based compensation                     | 3.4                            | 2.6     | 0.8    | 31% | 6.5                          | 5.1     | 1.4    | 27% |
| Facilities, depreciation and other allocated | 5.7                            | 5.5     | 0.2    | 4%  | 11.7                         | 11.3    | 0.4    | 4%  |
| Total R&D expenses                           | \$ 22.8                        | \$ 18.7 | \$ 4.1 | 22% | \$ 43.3                      | \$ 39.1 | \$ 4.2 | 11% |

R&D expenses increased to \$22.8 million in the second quarter and to \$43.3 million in the first six months of 2011, from the comparable periods in 2010. Both of these increases were primarily due to the higher external costs related to clinical and non-clinical activities and higher employee-related expenses.

During the first quarter of 2011, we granted special long-term retention and incentive equity awards to executive officers and certain employees and special long-term retention and incentive cash bonus awards to certain employees. The vesting of these awards is tied to the achievement of certain performance targets over a six-year timeframe from 2011 through December 31, 2016 and continued employment, both of which must be satisfied in order for vesting to occur. The maximum potential expense for R&D associated with this program is \$6.3 million related to stock-compensation expense and \$35.4 million related to cash bonus expense, which would be recognized in increments based on achievement of the performance conditions. As of June 30, 2011, we determined that the achievement of the requisite performance conditions was not probable, and as a result, no compensation expense has been recognized. Management believes the likelihood of achieving all of the performance targets is remote.

R&D expenses for 2011 are expected to be higher compared to 2010. R&D expenses in 2011 will be driven largely by employee related expenses, costs associated with our continued development efforts in our PuMA program for opioid-induced constipation with TD-1211, our MARIN program for chronic pain with TD-9855, and costs associated with our earlier stage clinical programs and new drug discovery programs. 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**

# Edgar Filing: THERAVANCE INC - Form 10-Q

General and administrative (G&A) expenses, compared to the same periods in 2010, were as follows:

| (in millions, except percentages) | Three months Ended |        |        |    | Six months Ended |         |        |    |
|-----------------------------------|--------------------|--------|--------|----|------------------|---------|--------|----|
|                                   | June 30,           |        | Change |    | June 30,         |         | Change |    |
|                                   | 2011               | 2010   | \$     | %  | 2011             | 2010    | \$     | %  |
| G&A expenses                      | \$ 7.2             | \$ 7.0 | \$ 0.2 | 3% | \$ 14.4          | \$ 13.5 | \$ 0.9 | 7% |

G&A expenses increased to \$7.2 million in the second quarter and to \$14.4 million in the first six months of 2011, from the comparable periods in 2010. Both of these increases were primarily due to higher employee related expenses.

Table of Contents

During the first quarter of 2011, we granted special long-term retention and incentive equity awards to executive officers and certain employees and special long-term retention and incentive cash bonus awards to certain employees. The vesting of these awards is tied to the achievement of certain performance targets over a six-year timeframe from 2011 through December 31, 2016 and continued employment, both of which must be satisfied in order for the vesting to occur. The maximum potential expense for G&A associated with this program is \$25.6 million related to stock-compensation expense and \$4.4 million related to cash bonus expense, which would be recognized in increments based on achievement of the performance conditions. As of June 30, 2011, we determined that the achievement of the requisite performance conditions was not probable, and as a result, no compensation expense has been recognized. Management believes the likelihood of achieving all of the performance targets is remote.

We anticipate G&A expenses for the remaining quarters of 2011 to be at similar quarterly levels to the first half of the year.

**Interest income**

Interest income, compared to the same periods in 2010, was as follows:

| (in millions, except percentages) | Three months Ended<br>June 30, |        | Change |   | Six months Ended<br>June 30, |        | Change |     |
|-----------------------------------|--------------------------------|--------|--------|---|------------------------------|--------|--------|-----|
|                                   | 2011                           | 2010   |        |   | 2011                         | 2010   |        |     |
| Interest income                   | \$ 0.1                         | \$ 0.1 | \$     | % | \$ 0.3                       | \$ 0.2 | \$ 0.1 | 50% |

Interest income remained relatively flat at \$0.1 million in the second quarter and \$0.3 million in the first six months of 2011, from the comparable period in 2010.

We expect interest income to fluctuate in the future due to changes in average cash equivalents and marketable securities balances and changes in market interest rates.

**Interest expense**

Interest expense, compared to the same periods in 2010, was as follows:

| (in millions, except percentages) | Three months Ended<br>June 30, |        | Change |   | Six months Ended<br>June 30, |        | Change |   |
|-----------------------------------|--------------------------------|--------|--------|---|------------------------------|--------|--------|---|
|                                   | 2011                           | 2010   |        |   | 2011                         | 2010   |        |   |
| Interest expense                  | \$ 1.5                         | \$ 1.5 | \$     | % | \$ 3.0                       | \$ 3.0 | \$     | % |

Interest expense is primarily comprised of interest expense and amortization of debt issuance costs from our convertible subordinated notes issued in January 2008.

## **LIQUIDITY AND CAPITAL RESOURCES**

### **Liquidity**

Since our inception, we have financed our operations primarily through private placements and public offerings of equity and debt securities and payments received under corporate collaboration arrangements. As of June 30, 2011, we had \$283.9 million in cash, cash equivalents and marketable securities, excluding \$0.9 million in restricted cash that was pledged as collateral for certain of our leases.

We expect to incur substantial expenses as we continue our discovery and development efforts; particularly to the extent we advance our product candidates into clinical studies, which are very expensive. We believe that our cash, cash equivalents and marketable securities will be sufficient to meet our anticipated operating needs for at least the next twelve months based upon current operating plans, milestone and royalty forecasts and spending assumptions. If our current operating plans, milestone and royalty forecasts or spending assumptions change, we may require additional funding sooner in the form of public or private equity offerings or debt financings. Furthermore, if in our view favorable financing opportunities arise, we may seek additional funding at any time. However, future financing may not be available in amounts or on terms acceptable to us, if at all. This could leave us without adequate financial resources to fund our operations as presently conducted. In addition, we regularly explore debt restructuring and/or reduction alternatives, including through tender offers, redemptions, repurchases or otherwise, all consistent with the terms of our debt agreements.

Table of Contents*Cash Flows*

Cash flows, compared to the same period in 2010, were as follows:

| (in millions)                             | Six Months Ended<br>June 30, |        |      |        |
|-------------------------------------------|------------------------------|--------|------|--------|
|                                           | 2011                         |        | 2010 |        |
| Net cash used in operating activities     | \$                           | (43.7) | \$   | (40.9) |
| Net cash used in investing activities     | \$                           | (50.5) | \$   | (33.5) |
| Net cash provided by financing activities | \$                           | 21.4   | \$   | 96.5   |

Cash used in operations increased \$2.8 million for the six months ended June 30, 2011, compared to the same period in 2010, primarily due to higher uses of cash for operating liabilities.

Cash used in investing activities increased \$17.0 million for the six months ended June 30, 2011, compared to the same period in 2010, primarily resulting from higher cash balances being invested in short-term investments during the first six months of 2011, compared to the same period in 2010.

Cash provided by financing activities decreased \$75.1 million for the six months ended June 30, 2011, compared to the same period in 2010, primarily due to net proceeds of \$93.5 million received from our public offering of common stock that closed in March 2010, partially offset by proceeds of \$10.3 million received from our private placements with GSK during the six months ended June 30, 2011.

**Off Balance-Sheet Arrangements**

We lease various real properties under an operating lease that generally requires us to pay taxes, insurance, maintenance, and minimum lease payments. This lease has options to renew.

We have not entered into any off-balance sheet financial arrangements and have not established any structured finance or special purpose entities. We have not guaranteed any debts or commitments of other entities or entered into any options on non-financial assets.

**Contractual Obligations and Commercial Commitments**

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

During the first six months of 2011, there have been no significant changes in our payments due under contractual obligations, as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2010.

We indemnify our officers and directors for certain events or occurrences, subject to certain limits. We may be subject to contingencies that may arise from matters such as product liability claims, legal proceedings, shareholder suits and tax matters, as such, we are unable to estimate the potential exposure related to these indemnification agreements. We have not recognized any liabilities relating to these agreements as of June 30, 2011.

Pursuant to our LABA collaboration with GSK, in the event that a LABA product candidate discovered by GSK is successfully developed and commercialized, we will be obligated to make milestone payments to GSK which could total as much as \$220.0 million if both a single-agent and a combination product or two different combination products are launched in multiple regions of the world. The current lead LABA, VI, was discovered by GSK. If the results of the Phase 3 studies with RELOVAIR are positive, a portion of these potential milestone payments could be payable to GSK within the next two years. We have not recognized any liabilities relating to these agreements as of June 30, 2011.

### RECENT ACCOUNTING UPDATES

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-05, *Presentation of Comprehensive Income* an update to Accounting Standards Codification (ASC) Topic 220, *Comprehensive Income*. The amendments of this update require that all nonowner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This update is to be applied retroactively and is effective for financial statements issued for fiscal years, and interim periods within those years, beginning after December 15, 2011, and interim and annual periods thereafter. This update will be effective for us January 1, 2012. We do not expect the adoption of this guidance to have a material impact on our condensed consolidated financial statements.

In April 2010, the FASB issued ASU No. 2010-17, *Revenue Recognition - Milestone Method* an update to ASC Topic 605, *Revenue Recognition*. The amendments of this update provide guidance on defining the milestone and determining when the use of the milestone method of revenue recognition for research and development transactions is appropriate. It provides criteria for evaluating if the milestone is substantive and clarifies that a vendor can recognize consideration that is contingent upon achievement of a milestone as revenue in the period in which the milestone is achieved, if the milestone meets all the criteria to be considered

Table of Contents

substantive. The guidance became effective on a prospective basis in fiscal years beginning on or after June 15, 2010 and early adoption was permitted. We elected to adopt the milestone method of revenue recognition on a prospective basis effective January 1, 2011. The election of the milestone method did not have a material impact on our condensed consolidated financial statements. However, the election will result in different accounting treatment for future substantive milestones earned after the date of this adoption. Non-substantive milestones will continue to be recognized over the remaining performance period.

In October 2009, the FASB issued ASU No. 2009-13, Revenue Recognition - Multiple-Deliverable Revenue Arrangements a consensus of the FASB Emerging Issues Task Force, an update to ASC Topic 605, Revenue Recognition. The amendments of this update require companies to allocate the overall consideration to each deliverable by using a best estimate of the selling price of individual deliverables in the arrangement in the absence of vendor specific objective evidence or other third party evidence of the selling price. The guidance became effective on a prospective basis in fiscal years beginning on or after June 15, 2010 and early adoption was permitted. Companies may elect to adopt this guidance prospectively for all revenue arrangements entered into or materially modified after the date of adoption or retrospectively for all periods presented. We elected to adopt this update on a prospective basis effective January 1, 2011. The adoption of this update did not have a material impact on our condensed consolidated financial statements. However, the election may result in different accounting treatment for future collaboration arrangements than the accounting treatment applied to previous and existing collaboration arrangements.

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

During the first six months of 2011, there have been no significant changes in our market risk or how our market risk is managed, as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2010.

**Item 4. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures.*

We conducted an evaluation as of June 30, 2011, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, which are defined under SEC rules as controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Securities Exchange Act of 1934 (Exchange Act) is recorded, processed, summarized and reported within required time periods. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

*Limitations on the Effectiveness of Controls*

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system

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

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 was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act, which occurred during our most recent fiscal quarter which has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **Item 1A. Risk Factors**

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

Table of Contents

**Risks Related to our Business**

*If the RELOVAIR Phase 3 program in asthma or chronic obstructive pulmonary disease (COPD) does not demonstrate safety and efficacy, the RELOVAIR program will be significantly delayed or terminated, our business will be harmed, and the price of our securities could fall.*

The RELOVAIR Phase 3 registrational program for COPD commenced in October 2009, the RELOVAIR Phase 3 registrational program for asthma commenced in March 2010 and the RELOVAIR Phase 3b program for COPD commenced in February 2011. Any adverse developments or results or perceived adverse developments or results with respect to the RELOVAIR program will significantly harm our business and could cause the price of our securities to fall. Examples of such adverse developments include, but are not limited to:

- the U.S. Food and Drug Administration (FDA) determining that additional clinical studies are required with respect to the Phase 3 program in asthma or COPD;
- inability to gain, or delay in gaining, regulatory approval for the new delivery device used in the program;
- safety or other concerns arising from ongoing preclinical or clinical studies in this program, including, without limitation, the COPD outcomes study initiated in February 2011;
- safety or other concerns arising from the long-acting muscarinic antagonist (LAMA)/long-acting beta2 agonist (LABA) Phase 3 program having to do with the LABA vilanterol, or VI, which is also a component of RELOVAIR ;
- the Phase 3 program in asthma or COPD raising safety concerns or not demonstrating efficacy; or
- any change in FDA policy or guidance regarding the use of LABAs to treat asthma.

On February 18, 2010, the FDA announced that LABAs should not be used alone in the treatment of asthma and will require manufacturers to include this warning in the product labels of these drugs, along with taking other steps to reduce the overall use of these medicines. The FDA will now require that the product labels for LABA medicines reflect, among other things, that the use of LABAs is contraindicated without the use of an asthma controller medication such as an inhaled corticosteroid, that LABAs should only be used long-term in patients whose asthma cannot be adequately controlled on asthma controller medications, and that LABAs should be used for the shortest duration of time required to achieve control of asthma symptoms and discontinued, if possible, once asthma control is achieved. In addition, on March 10 and 11, 2010, the FDA held an Advisory Committee to discuss the design of medical research studies (known as clinical trial design ) to evaluate serious asthma outcomes (such as hospitalizations, a procedure using a breathing tube known as intubation, or death) with the use of LABAs in the treatment of

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

asthma in adults, adolescents, and children. Further, in April 2011, the FDA announced that to further evaluate the safety of LABAs, it is requiring the manufacturers of currently marketed LABAs to conduct additional randomized, double-blind, controlled clinical trials comparing the addition of LABAs to inhaled corticosteroids versus inhaled corticosteroids alone. These post-marketing studies are to begin in 2011 with results expected in 2017. It is unknown at this time what, if any, effect these or future FDA actions will have on the development of RELOVAIR. The current uncertainty regarding the FDA's position on LABAs for the treatment of asthma and the lack of consensus expressed at the March 2010 Advisory Committee may result in increased time and cost of the asthma clinical trials in the United States for RELOVAIR and increase the overall risk of the RELOVAIR asthma program in the United States.

***If the 719/VI Phase 3 program for the treatment of COPD does not demonstrate safety and efficacy, the 719/VI program will be significantly delayed or terminated, our business will be harmed, and the price of our securities could fall.***

The 719/VI Phase 3 program with the combination of the LABA, VI, and the LAMA GSK573719, or 719, for the treatment of COPD commenced in February 2011. Any adverse developments or results or perceived adverse developments or results with respect to the 719/VI program will significantly harm our business and could cause the price of our securities to fall. Examples of such adverse developments include, but are not limited to:

- the FDA determining that additional clinical studies are required with respect to the Phase 3 program in COPD;
- inability to gain, or delay in gaining, regulatory approval for the new delivery device used in the program;
- safety or other concerns arising from ongoing preclinical or clinical studies in this program;
- safety or other concerns arising from the RELOVAIR Phase 3 program having to do with the LABA, VI, which is also a component of 719/VI;

Table of Contents

- the Phase 3 program in COPD raising safety concerns or not demonstrating efficacy; or
- any change in FDA policy or guidance regarding the use of LABAs combined with a LAMA to treat COPD.

***If the MABA program for the treatment of COPD does not demonstrate safety and efficacy, the MABA program will be significantly delayed or terminated, our business will be harmed, and the price of our securities could fall.***

The lead compound, GSK961081 ( 081), in the bifunctional muscarinic antagonist-beta2 agonist (MABA) program with GSK is currently being evaluated in a Phase 2b study and a number of non-clinical studies. Any adverse developments or results or perceived adverse developments or results with respect to these studies will harm our business and could cause the price of our securities to fall. Examples of such adverse developments include, but are not limited to:

- the FDA determining that any of these studies do not demonstrate adequate safety or efficacy, or that additional non-clinical or earlier stage clinical studies are required with respect to the MABA program;
- inability to gain, or delay in gaining, regulatory approval for the new delivery device used in the program;
- safety or other concerns arising from ongoing non-clinical studies in this program;
- the Phase 2b clinical study raising safety concerns or not demonstrating efficacy; or
- any change in FDA policy or guidance regarding the use of MABAs to treat COPD.

***If telavancin is not approved in additional countries and for additional indications, our business will be adversely affected and the price of our securities could fall.***

On October 28, 2009, Astellas Pharma Europe B.V., a subsidiary of our telavancin partner, Astellas Pharma Inc. (Astellas), announced that it submitted a new European Marketing Authorization Application (MAA) for telavancin to the European Medicines Agency for the treatment of complicated skin and soft tissue infections (cSSTI) and nosocomial pneumonia (NP). On May 20, 2011 we announced that the CHMP adopted a positive opinion, recommending the granting of marketing authorization for telavancin for the treatment of adults with NP including

ventilator-associated pneumonia, known or suspected to be caused by MRSA. The CHMP also noted that telavancin should be used only in situations where it is known or suspected that other treatment alternatives are not suitable. If, notwithstanding this positive opinion, the European Medicines Agency does not approve the MAA for NP, requires data from additional clinical studies regarding telavancin, or if telavancin is ultimately approved by the European Medicines Agency for NP but with restrictions, including labeling that may further limit the targeted patient population, our business will be harmed and the price of our securities could fall. The CHMP did not recommend that telavancin be approved for the treatment of cSSTI.

Our first New Drug Application (NDA), for VIBATIV® (telavancin) for the treatment of complicated skin and skin structure infections (cSSSI) caused by susceptible Gram-positive bacteria in adult patients, was approved by the FDA in September 2009. In January 2009, we submitted a second telavancin NDA to the FDA for the NP indication based on data from our two Phase 3 clinical studies referred to as the ATTAIN studies. During the fourth quarter of 2010 the FDA issued new draft guidance for antibacterial clinical trial design for the treatment of NP with a focus on mortality as the primary efficacy endpoint. The ATTAIN studies, which were conducted pursuant to then-current draft FDA guidelines and completed prior to the issuance of this new draft guidance, used clinical response as the primary efficacy endpoint. In late 2010, we received a Complete Response Letter from the FDA indicating that the ATTAIN studies do not meet the new draft guidance and that additional clinical studies will be required for approval. We do not plan to conduct additional clinical studies for NP, but we do intend to continue to engage with FDA concerning the NP NDA. Lack of FDA approval for use of telavancin to treat NP has adversely affected and will continue to adversely affect commercialization of this medicine in the United States.

***If any product candidates, in particular those in any respiratory program with GSK, are determined to be unsafe or ineffective in humans, our business will be adversely affected and the price of our securities could fall.***

Although our first approved product, VIBATIV®, was commercially launched in the U.S. by our partner Astellas in November 2009, we have not yet commercialized any of our other product candidates. We are uncertain whether any of our other 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 may not result in the creation of successful medicines. The risk of failure for our 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, and GSK discontinued development of TD-5742, the first LAMA compound licensed from us, after completing a single-dose Phase 1 study. The data supporting our drug discovery and development programs is derived

Table of Contents

solely from laboratory experiments, preclinical studies and clinical studies. A number of other compounds remain in the lead identification, lead optimization, preclinical testing or early clinical testing stages.

Several well-publicized Complete Response letters issued by the FDA and safety-related product withdrawals, suspensions, post-approval labeling revisions to include boxed warnings and changes in approved indications over the last few years, as well as growing public and governmental scrutiny of safety issues, have created an increasingly conservative regulatory environment. The implementation of new laws and regulations, and revisions to FDA clinical trial design guidance, have increased uncertainty regarding the approvability of a new drug. Further, there are additional requirements for approval of new drugs, including advisory committee meetings for new chemical entities, and formal risk evaluation and mitigation strategy (REMS) at the FDA's discretion. These new laws, regulations, additional requirements and changes in interpretation could cause non-approval or further delays in the FDA's review and approval of our product candidates.

***With regard to all of our programs, any delay in commencing or completing clinical studies for product candidates and any adverse results from clinical or preclinical studies or regulatory obstacles product candidates may face, would harm our business and could cause the price of our securities to fall.***

Each of our product candidates must undergo extensive preclinical and clinical studies as a condition to regulatory approval. Preclinical and clinical studies are expensive, take many years to complete and study results may lead to delays in further studies or decisions to terminate programs. For example, we had planned to commence the Phase 2b clinical study in our MABA program with GSK in 2009, but the program was delayed until late 2010.

The commencement and completion of clinical studies for our product candidates may be delayed and programs may be terminated due to many factors, including, but not limited to:

- lack of effectiveness of product candidates during clinical studies;
- adverse events, safety issues or side effects relating to the product candidates or their formulation into medicines;
- inability to raise additional capital in sufficient amounts to continue our development programs, which are very expensive;
- the need to sequence clinical studies as opposed to conducting them concomitantly in order to conserve resources;
- our inability to enter into partnering arrangements relating to the development and commercialization of our programs and product candidates;

- our inability or the inability of our collaborators or licensees to manufacture or obtain from third parties materials sufficient for use in preclinical and clinical studies;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines;
- failure of our partners to advance our product candidates through clinical development;
- delays in patient enrollment and variability in the number and types of patients available for clinical studies;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- varying interpretations of data by the FDA and similar foreign regulatory agencies; and
- a regional disturbance where we or our collaborative partners are enrolling patients in our clinical trials, such as a pandemic, terrorist activities or war, political unrest or a natural disaster.

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

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

Table of Contents

from the FDA to market and sell a new product are complex, require a number of years and involve the expenditure of substantial resources. In order to market our medicines in 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. Conversely, failure to obtain approval in one or more jurisdictions may make approval in other jurisdictions more difficult.

Clinical studies involving our product candidates may reveal that those candidates are ineffective, inferior to existing approved medicines, unacceptably toxic, or that they 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 in development, we may not receive regulatory approval of any of these product candidates and our business and financial condition will be materially harmed and the price of our securities may fall.

***VIBATIV® may not be accepted by physicians, patients, third party payors, or the medical community in general.***

The commercial success of VIBATIV® depends upon its acceptance by physicians, patients, third party payors and the medical community in general. We cannot be sure that VIBATIV® will be accepted by these parties. VIBATIV® competes with vancomycin, a relatively inexpensive generic drug that is manufactured by a variety of companies, and a number of existing antibacterials manufactured and marketed by major pharmaceutical companies and others, and may compete against new antibacterials that are not yet on the market. Even if the medical community accepts that VIBATIV® is safe and efficacious for its indicated use, physicians may choose to restrict the use of VIBATIV®. If we and our partner, Astellas, are unable to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, VIBATIV® is preferable to vancomycin and other antibacterial drugs, we may never generate meaningful revenue from VIBATIV® which could cause the price of our securities to fall. The degree of market acceptance of VIBATIV® depends on a number of factors, including, but not limited to:

- the demonstration of the clinical efficacy and safety of VIBATIV®;
- the experiences of physicians, patients and payors with the use of VIBATIV® in the U.S.;
- whether or not VIBATIV® is approved by regulatory authorities in Europe or other jurisdictions;
- the advantages and disadvantages of VIBATIV® compared to alternative therapies;

- potential negative perceptions of physicians related to our inability to obtain FDA approval of our NP NDA;
- our and Astellas' ability to educate the medical community about the safety and effectiveness of VIBATIV®;
- the reimbursement policies of government and third party payors; and
- the market price of VIBATIV® relative to competing therapies.

***Our telavancin collaboration partner relies on a single manufacturer for product supply, as we do for a number of our product candidates, and our business will be harmed if these manufacturers are not able to satisfy demand and alternative sources are not available.***

All manufacture of telavancin active pharmaceutical ingredient (API) and drug product is now our collaboration partner's responsibility. For the foreseeable future, we anticipate that our collaboration partner may rely on a single source of supply of telavancin API and a single source of supply of telavancin drug product. If, for any reason, these third parties are unable or unwilling to perform, or if their performance does not meet regulatory requirements, including maintaining current good manufacturing practice (cGMP) compliance, our collaboration partner may not be able to locate alternative manufacturers, enter into favorable agreements with them or obtain sufficient quantities of API and drug product in a timely manner. Any inability to acquire sufficient quantities of

Table of Contents

API and drug product in a timely manner from current or future sources could adversely affect the commercialization of telavancin and could cause the price of our securities to fall.

During an inspection of our collaboration partner's supplier for telavancin drug product in the first half of 2011, the FDA noted deficiencies, not specifically related to the manufacture of telavancin drug product, with the supplier's production and quality systems. We believe, based on communications with our collaboration partner, that the telavancin drug product manufactured to date by the supplier will not be affected and will remain available for sale in the United States. However, additional telavancin drug product will need to be manufactured to meet longer-term United States demand as well as demand from foreign countries where telavancin is or may be approved for use in the future. We are unable to predict the amount of time it will take for the supplier and the FDA to resolve the Good Manufacturing Practice compliance issues, during which time production could be delayed. Although our collaboration partner may begin the process of identifying and qualifying an alternative manufacturer for telavancin, this process will likely take a significant amount of time. If the current supplier is unable to manufacture telavancin in sufficient quantities on a timely basis, and if our collaboration partner is unable to arrange for supplemental or alternative commercial manufacture of telavancin on a timely basis, the commercialization of telavancin will be adversely affected, our business will be harmed and the price of securities could fall.

Telavancin is approved in Canada for the treatment of cSSSI in adult patients, and in May 2011 the Committee for Medicinal Products for Human Use of the European Medicines Agency adopted a positive opinion, recommending the granting of market authorization for telavancin for the treatment of adults with nosocomial pneumonia. The supplier has been inspected by foreign regulatory agencies, and certain of the supplier's manufacturing compliance issues raised by FDA are also of concern to Canada and EU regulatory authorities. If the supplier is not able to resolve these matters, commercial introduction of telavancin in Canada and/or in Europe could be delayed, which could harm our business and cause the price of securities to fall.

We have limited in-house production capabilities for pre-clinical and early clinical study purposes, and depend primarily on a number of third-party 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, or if their performance does not meet regulatory requirements, we may not be able to locate alternative manufacturers or enter into favorable agreements with them. Any inability to acquire sufficient quantities of API and drug product in a timely manner from these third parties could delay clinical studies, prevent us from developing our product candidates in a cost-effective manner or on a timely basis. In addition, manufacturers of our API and drug product are subject to the FDA's cGMP regulations and similar foreign standards and we do not have control over compliance with these regulations by our manufacturers.

Our manufacturing strategy presents the following additional risks:

- because of the complex nature of our compounds, our manufacturers may not be able to successfully manufacture our APIs and/or drug products in a cost effective and/or timely manner and changing manufacturers for our APIs or drug products could involve lengthy technology transfer and validation activities for the new manufacturer;
- the processes required to manufacture certain of our APIs and drug products are specialized and available only from a limited number of third-party manufacturers;

- some of the manufacturing processes for our APIs and drug products have not been scaled to quantities needed for continued clinical studies or commercial sales, and delays in scale-up to commercial quantities could delay clinical studies, regulatory submissions and commercialization of our product candidates; and
- because some of the third-party manufacturers are located outside of the U.S., there may be difficulties in importing our APIs and drug products or their components into the U.S. as a result of, among other things, FDA import inspections, incomplete or inaccurate import documentation or defective packaging.

*Even if our product candidates receive regulatory approval, as VIBATIV® has, commercialization of such products may be adversely affected by regulatory actions and oversight.*

Even if we receive regulatory approval for our product candidates, this approval may include limitations on the indicated uses for which we can market our medicines or the patient population that may utilize our medicines, which may limit the market for our medicines or put us at a competitive disadvantage relative to alternative therapies. For example, VIBATIV® s labeling contains a boxed warning regarding the risks of use of VIBATIV® during pregnancy. Products with boxed warnings are subject to more restrictive advertising regulations than products without such warnings. These restrictions could make it more difficult to market VIBATIV® effectively. Further, now that VIBATIV® is approved, we remain subject to continuing regulatory obligations, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of promotion and marketing.

Table of Contents

In addition, the manufacturing, labeling, packaging, adverse event reporting, advertising, promotion and recordkeeping for the approved product remain subject to extensive and ongoing regulatory requirements. If we become aware of previously unknown problems with an approved product in the U.S. or overseas or at contract manufacturers' facilities, a regulatory agency may impose restrictions on the product, the contract manufacturers or on us, including requiring us to reformulate the product, conduct additional clinical studies, change the labeling of the product, withdraw the product from the market or require the contract manufacturer to implement changes to its facilities. For example, during the first half of 2011, U.S. and foreign regulatory agencies inspected the third party manufacturer that is the sole supplier of telavancin drug product for our collaboration partner and noted deficiencies, not specifically related to the manufacture of telavancin drug product, with the supplier's production and quality systems. We are unable to predict the amount of time it will take for the supplier and the regulatory agencies to resolve the Good Manufacturing Practice compliance issues and whether they may interrupt commercialization of telavancin in the U.S. and Canada and, if telavancin is approved in Europe, delay commercialization in Europe. In addition, we may experience a significant drop in the sales of the product, our royalties on product revenues and reputation in the marketplace may suffer, and we could face lawsuits.

We are also subject to regulation by regional, national, state and local agencies, including the Department of Justice, the Federal Trade Commission, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies with respect to VIBATIV®, as well as governmental authorities in those foreign countries in which any of our product candidates are approved for commercialization. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including preclinical and clinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information and promotion. If we or any third parties that provide these services for us 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, which may cause our stock price to decline.

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

We have been engaged in discovering and developing compounds and product candidates since mid-1997. Our first approved product, VIBATIV®, was launched by our partner Astellas in the U.S. in November 2009, and to date we have received modest royalty revenues. From the commercial launch through June 30, 2011, Astellas recorded VIBATIV® net sales of \$18 million. We recognize royalty revenue from Astellas in the period the royalties are earned based on net sales of VIBATIV® by Astellas as reported to us by Astellas. We may never generate sufficient revenue from the sale of medicines or royalties on sales by our partners to achieve profitability. As of June 30, 2011, we had an accumulated deficit of approximately \$1.2 billion.

We expect to incur substantial expenses as we continue our drug discovery and development efforts, particularly to the extent we advance our product candidates into and through clinical studies, which are very expensive. As a result, we expect to continue to incur substantial losses for the foreseeable future. We are uncertain when or if we will be able to achieve or sustain profitability. Failure to become and remain profitable would adversely affect the price of our securities 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.***

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

We need large amounts of capital to support our research and development efforts. If we are unable to secure capital to fund our operations we will not be able to continue our discovery and development efforts and we might have to enter into strategic collaborations that could require us to share commercial rights to our medicines to a greater extent than we currently intend. Based on our current operating plans, milestone and royalty forecasts and spending assumptions, we believe that our cash and cash equivalents and marketable securities will be sufficient to meet our anticipated operating needs for at least the next twelve months. We are likely to require additional capital to fund operating needs thereafter. Though we have no current intention to do so, if we were to conduct additional studies to support the telavancin NP NDA and we were required to fund such studies, our capital needs could increase substantially. We intend to continue clinical development of the lead compounds in our PpMA and MARIN programs. In July 2011 we initiated a Phase 2b study in our PpMA program, and we anticipate initiating an additional Phase 2b study for PpMA and additional Phase 1 studies and a Phase 2 study for MARIN. We also intend to conduct a number of other preclinical and clinical studies in other programs. In addition, under our LABA collaboration with GSK, in the event that vilanterol (VI), which is the current lead LABA product candidate in the RELOVAIR and LAMA/LABA ( 719/VI) programs and which was discovered by GSK, is approved and launched in multiple regions of the world as both a single agent and a combination product or two different combination products, we will be obligated to pay GSK milestone payments that could total as much as \$220.0 million and we would not be

Table of Contents

entitled to receive any further milestone payments from GSK. Future financing to meet our capital needs may not be available in sufficient amounts or on terms acceptable to us, if at all. Even if we are able to raise additional capital, such financing may result in significant dilution to existing security holders. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to make additional reductions in our workforce and may be prevented from continuing our discovery and development efforts and exploiting other corporate opportunities. This could harm our business, prospects and financial condition and cause the price of our securities to fall.

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

We entered into our LABA collaboration agreement with GSK in November 2002, our strategic alliance agreement with GSK in March 2004, and our telavancin development and commercialization agreement with Astellas in November 2005. In connection with these agreements, we have granted to these parties certain rights regarding the use of our patents and technology with respect to compounds in our development programs, including development and marketing rights. Under our GSK agreements, GSK has full responsibility for development and commercialization of any product candidates in the RELOVAIR, LAMA/LABA (719/VI) and MABA programs. 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 license, development and commercialization agreement with Astellas, Astellas is responsible for the commercialization of VIBATIV® and any royalties to us from net sales of VIBATIV® will depend upon Astellas' ability to commercialize the medicine.

Our partners might not fulfill all of their obligations under these agreements, and, in certain circumstances, they may terminate our partnership with them. In either 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 LABA 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 product candidates under the collaboration could be materially and adversely affected. For example, under the terms of our telavancin license, development and commercialization agreement, Astellas has the right to terminate the agreement since VIBATIV® was not approved by December 31, 2008. If Astellas chooses to terminate the agreement, the further commercialization of VIBATIV® would be delayed, our business could be harmed and the price of our securities could fall.

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 certain of our product candidates, GSK may in the future seek to negotiate more favorable terms on a project-by-project basis. To date, GSK has licensed our LAMA program and our MABA program under the terms of the strategic alliance agreement and has chosen not to license our antibacterial, anesthesia, 5-HT4 and PuMA programs. In February 2009, GSK returned the LAMA program to us because the formulation of the lead product candidate was incompatible with GSK's proprietary inhaler device. 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, or its return of programs to us, 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 securities.

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

As of July 27, 2011, GSK beneficially owned approximately 18.4% of our outstanding capital stock. Pursuant to our strategic alliance with GSK, GSK has the right to license exclusive development and commercialization rights to our product candidates arising from (i) our AT1 Receptor-Neprilysin Inhibitor (ARNI) program for cardiovascular disease and (ii) our MonoAmine Reuptake Inhibitor (MARIN) program for chronic pain. Because GSK is not required to decide whether to license each development program until after we have taken the lead compound in the program through a successful Phase 2 proof-of-concept study, we may be unable to collaborate with other partners with respect to these programs until we have expended substantial resources to advance them through clinical studies. We may not have sufficient funds to pursue such programs in the event GSK does not license them at an early stage. Pharmaceutical companies other than GSK that may be interested in developing products with us may be less inclined to do so

Table of Contents

because of our relationship with GSK, or because of the perception that development programs that GSK does not license, or returns to us, pursuant to our strategic alliance agreement are not promising programs. If our ability to work with present or future strategic partners or collaborators is adversely affected as a result of our strategic alliance with GSK, our business prospects may be limited and our financial condition may be adversely affected which could cause the price of our securities to fall.

***If we are unable to enter into future collaboration arrangements or if any such collaborations with third parties are unsuccessful, we will be unable to fully develop and commercialize our product candidates and our business will be adversely affected.***

We have active collaborations with GSK for the RELOVAIR<sup>®</sup>, LAMA/LABA ( 719/VI) and MABA programs and with Astellas for VIBATIV<sup>®</sup>, and we have licensed our anesthesia compound to AstraZeneca AB (AstraZeneca). Additional collaborations will be needed to fund later-stage development of our product candidates that have not been licensed to a collaborator, and to commercialize these product candidates if approved by the necessary regulatory agencies. Each of TD-5108, our lead compound in the 5-HT<sub>4</sub> program, TD-1792, our investigational antibiotic, and TD-1211, the lead compound in our PuMA program for opioid-induced constipation, has successfully completed a Phase 2 proof-of-concept study, and TD-4208, our LAMA compound that GSK returned to us in February 2009 under the terms of the strategic alliance agreement, has completed a single-dose Phase 1 study. We currently intend to seek third parties with which to pursue collaboration arrangements for the development and commercialization of these compounds. Collaborations with third parties regarding these programs or our other programs may require us to relinquish material rights, including revenue from commercialization of our medicines, on terms that are less attractive than our current arrangements or to assume material ongoing development obligations that we would have to fund. These collaboration arrangements are complex and time-consuming to negotiate, and if we are unable to reach agreements with third-party collaborators, we may fail to meet our business objectives and our financial condition may be adversely affected. We face significant competition in seeking third-party collaborators, especially in the current uncertain economy, which is driving many biotechnology and biopharmaceutical companies to seek to sell or license their assets. We may be unable to find third parties to pursue product collaborations on a timely basis or on acceptable terms. Furthermore, for any collaboration, we may not be able to control the amount of time and resources that our partners devote to our product candidates and our partners may choose to pursue alternative products. Our inability to successfully collaborate with third parties would increase our development costs and would limit the likelihood of successful commercialization of our product candidates which may cause our stock price to decline.

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

We depend on independent clinical investigators, contract research organizations and other third-party service providers in the conduct of our preclinical and clinical studies for our product candidates. We rely heavily on these parties for execution of our preclinical and clinical studies, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that our clinical studies are conducted in accordance with good clinical practices (GCPs) and other regulations as required by the FDA and foreign regulatory agencies, and the applicable protocol. Failure by these parties to comply with applicable regulations, GCPs and protocols in conducting studies of our product candidates can result in a delay in our development programs or non-approval of our product candidates by regulatory authorities.

The FDA enforces good clinical practices and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators and trial sites. For example, in connection with the FDA's review of our telavancin NDAs, the FDA conducted inspections of Theravance and certain of our study sites, clinical investigators and CROs. If we or any of the third parties on which we have relied to conduct our clinical studies are determined to have failed to comply with GCPs, the study protocol or applicable regulations, the clinical data generated in our studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs, could result in significant additional costs and could cause the price of our securities to fall.

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

Our ability to succeed in the future depends on our ability to demonstrate and maintain a competitive advantage with respect to our approach to the discovery and development of medicines. Our objective is to discover, develop and commercialize new small molecule medicines with superior efficacy, convenience, tolerability and/or safety. We expect that any medicines that we commercialize with our collaborative partners 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:

Table of Contents

- discover and develop medicines that are superior to other products in the market;
- attract and retain qualified 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. Other companies are engaged in the discovery of medicines that would compete with the product candidates that we are developing.

Any new medicine that competes with a generic or proprietary 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. VIBATIV® must demonstrate these advantages, as it competes with vancomycin, a relatively inexpensive generic drug that is manufactured by a number of companies, and a number of existing antibacterial drugs marketed by major and other pharmaceutical companies. If we are not able to compete effectively against our current and future competitors, our business will not grow, our financial condition and operations will suffer and the price of our securities could fall.

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

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

Generally, our strategy is to engage pharmaceutical or other healthcare companies with an existing sales and marketing organization and distribution system to market, sell and distribute our products. We may not be able to establish these sales and distribution relationships on acceptable terms, or at all. If we receive regulatory approval to commence commercial sales of any of our product candidates that are not covered by our current agreements with GSK, Astellas or AstraZeneca, we will need a partner in order to commercialize such products unless we establish a sales and marketing organization with appropriate technical expertise and supporting distribution capability. At present, we have

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

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

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

***If we lose key management or scientific personnel, or if we fail to retain our key employees, our ability to discover and develop our product candidates will be impaired.***

We are highly dependent on principal members of our management team and scientific staff to operate our business. Our company is located in northern California, which is headquarters to many other biotechnology and biopharmaceutical companies and many academic and research institutions. As a result, competition for certain skilled personnel in our market remains intense. None of

Table of Contents

our employees have employment commitments for any fixed period of time and they all may leave our employment at will. If we fail to retain our remaining qualified personnel or replace them when they leave, we may be unable to continue our development and commercialization activities, which may cause our stock price to decline.

***Our business and operations would suffer in the event of system failures.***

Although we have security measures in place, our internal computer systems and those of our CROs and other service providers are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. We have not experienced any material system failure, accident or security breach to date, but if such an event were to occur, it could result in a material disruption to our business. For example, the loss of clinical trial data from completed or ongoing clinical trials of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If a disruption or security breach results in a loss of or damage to our data or regulatory applications, or inadvertent disclosure of confidential or proprietary information, we could incur liability, the further development of our product candidates could be delayed and the price of our securities could fall.

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

Our principal facility is located in the San Francisco Bay Area near known earthquake fault zones and therefore is vulnerable to damage from earthquakes. In October 1989, a major earthquake struck this area and caused significant property damage and a number of fatalities. We are also vulnerable to damage from other types of disasters, including power loss, attacks from extremist organizations, fire, floods, communications failures and similar events. If any disaster were to occur, our ability to operate our business could be seriously impaired. In addition, the unique nature of our research activities and of much of our equipment could make it difficult for us to recover from this type of disaster. We 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, which could cause the price of our securities to fall.

**Risks Related to our Alliance with GSK**

***GSK's ownership of a significant percentage of our stock and its ability to acquire additional shares of our stock may create conflicts of interest, and may inhibit our management's ability to continue to operate our business in the manner in which it is currently being operated.***

As of July 27, 2011, GSK beneficially owned approximately 18.4% of our outstanding capital stock, and GSK has the right to acquire stock from us to maintain its percentage ownership of our capital stock. 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 certain changes in our business.

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

In addition, GSK may make an offer to our stockholders to acquire outstanding voting stock that would bring GSK's percentage ownership of our voting stock to no greater than 60%, provided that:

- the offer includes no condition as to financing;
- the offer is approved by a majority of our independent directors;
- the offer includes a condition that the holders of a majority of the shares of the voting stock not owned by GSK accept the offer by tendering their shares in the offer; and
- the shares purchased will be subject to the same provisions of the governance agreement as are the shares of voting stock currently held by GSK.

Table of Contents

If pursuant to the provision described above GSK's ownership of us becomes greater than 50.1%, then *on or prior* to September 1, 2012 GSK is allowed to make an offer to our stockholders to merge with us or otherwise acquire outstanding voting stock that would bring GSK's percentage ownership of our voting stock to 100%, provided that;

- the offer includes no condition as to financing;
- the offer is approved by a majority of our independent directors;
- the offer includes a condition that the holders of a majority of the shares of the voting stock not owned by GSK accept the offer by tendering their shares in the offer; and
- the offer is for the greater of (a) the fair market value per share on the date immediately preceding the date of the first public announcement of the offer or (b) \$162.75 per share (as adjusted to take into account stock dividends, stock splits, recapitalizations and the like).

Furthermore, if pursuant to the provision described above GSK's ownership of us is greater than 50.1%, then *after* September 1, 2012, GSK is allowed to make an offer to our stockholders to acquire outstanding voting stock that would bring GSK's percentage ownership of our voting stock to 100%, provided that;

- the offer includes no condition as to financing;
- the offer is approved by a majority of our independent directors; and
- the offer includes a condition that the holders of a majority of the shares of the voting stock not owned by GSK accept the offer by tendering their shares in the offer.

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 constitutes a corporate opportunity of ours unless such corporate or business opportunity is expressly offered to one of our directors who is a director, officer or employee of GSK, primarily in his or her capacity as one of our directors.

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

Our governance agreement with GSK requires us to exempt GSK from our stockholder rights plan, affords GSK certain rights to offer to acquire us in the event third parties seek to acquire our stock and contains other provisions that could deter or prevent another company from seeking to acquire us. For example, GSK may offer to acquire 100% of our outstanding stock from stockholders in certain circumstances, such as if we are faced with a hostile acquisition offer or if our board of directors acts in a manner to facilitate a change in control of us with a party other than GSK. In addition, pursuant to our strategic alliance agreement with GSK, GSK has the right to license our ARNI program and our MARIN program. As a result of these rights, other companies may be less inclined to pursue an acquisition of us and therefore we may not have the opportunity to be acquired in a transaction that stockholders might otherwise deem favorable, including transactions in which our stockholders might realize a substantial premium for their shares.

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

GSK may sell or transfer our common stock either pursuant to a public offering registered under the Securities Act or pursuant to Rule 144 of the Securities Act. In addition, beginning in September 2012, GSK will have no restrictions on its ability to sell or transfer our common stock on the open market, in privately negotiated transactions or otherwise, and these sales or transfers could create substantial declines in the price of our securities or, if these sales or transfers were made to a single buyer or group of buyers, could contribute to a transfer of control of our company to a third party.

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

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

We rely upon a combination of patents, patent applications, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any involuntary disclosure to or misappropriation by third parties of this proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. The status of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and is very uncertain. As of June 30, 2011, we owned 248 issued United States patents and 748 granted foreign patents, as well as additional pending United States and foreign patent applications. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be invalidated or be too narrow to prevent third parties from

Table of Contents

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 or in obtaining regulatory approval of our product candidates, the patent lives of the related product 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 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, which could cause the price of our securities to fall.

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

Our commercial success depends in part on us and our partners not infringing the patents and proprietary rights of third parties. Third parties may assert that we or our partners are using their proprietary rights 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 or our partners 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, which may cause our stock price to decline.

***If the efforts of our partner, GSK, to protect the proprietary nature of the intellectual property related to the assets in the LABA collaboration, including RELOVAIR and LAMA/LABA ( 719/VI), are not adequate, the future commercialization of any medicines resulting from the LABA collaboration could be delayed or prevented, which would materially harm our business and could cause the price of our securities to fall.***

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

The risks identified in the two preceding risk factors also apply to the intellectual property protection efforts of our partner GSK. To the extent the intellectual property protection of any of the assets in the LABA collaboration are successfully challenged or encounter problems with the United States Patent and Trademark Office or other comparable agencies throughout the world, the future commercialization of these potential medicines could be delayed or prevented. Any challenge to the intellectual property protection of a late-stage development asset arising from the LABA collaboration could harm our business and cause the price of our securities to fall.

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

The risk that we may be sued on product liability claims is inherent in the development and commercialization of pharmaceutical products. Side effects of, or manufacturing defects in, products that we or our partners develop or commercialize could result in the deterioration of a patient's condition, injury or even death. Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits tends to increase. Our partner Astellas launched VIBATIV®, our first approved product, in the

Table of Contents

U.S. in November 2009. Claims may be brought by individuals seeking relief for themselves or by individuals or groups seeking to represent a class. 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 the applicable 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. Product liability claims could also harm our reputation, which may adversely affect our and our partners' ability to commercialize our products successfully, which could cause the price of our securities to fall.

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

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

- our or our collaborators' ability to set a price we believe is fair for our products, if approved;
- our ability to generate revenues and achieve profitability; and
- the availability of capital.

The Patient Protection and Affordable Care Act and other potential legislative or regulatory action regarding healthcare and insurance matters, along with the trend toward managed healthcare in the United States, could influence the purchase of healthcare products and reduce demand and prices for our products, if approved. This could harm our or our collaborators' ability to market our potential medicines and generate revenues. Cost containment measures that health care payors and providers are instituting and the effect of the Patient Protection and Affordable Care Act and further agency regulations that are likely to emerge in connection with the passage of this act could significantly reduce potential revenues from the sale of any product candidates approved in the future. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable. We believe that pricing pressures at the state and federal level, as well as internationally, will continue and may increase, which may make it difficult for us to sell our potential medicines that may be approved in the future at a price acceptable to us or our collaborators, which may cause our stock price to decline.

***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. We may incur significant additional costs to comply with these and other 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, which could cause the price of our securities to fall.

### **Risks Related to Ownership of our Common Stock**

*The price of our securities has been extremely volatile and may continue to be so, and purchasers of our securities could incur substantial losses.*

The price of our securities has been extremely volatile and may continue to be so. The stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies, in particular during the last few years. 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 securities:

- any adverse developments or results or perceived adverse developments or results with respect to the RELOVAIR program with GSK, including, without limitation, any difficulties or delays encountered with regard to the regulatory

Table of Contents

path for RELOVAIR, delays in completing the various Phase 3 studies or any indication from these studies that RELOVAIR is not safe or efficacious;

- any adverse developments or results or perceived adverse developments or results with respect to the LAMA/LABA ( 719/VI) program with GSK, including, without limitation, any difficulties or delays encountered with regard to the regulatory path for 719/VI, delays in completing the Phase 3 studies or any indication from these studies that 719/VI is not safe or efficacious;
- any adverse developments or results or perceived adverse developments or results with respect to the MABA program with GSK, including, without limitation, any indication from the Phase 2b and other clinical and preclinical studies of 081 that the compound is not safe or efficacious;
- any adverse developments or perceived adverse developments with respect to the commercialization of VIBATIV®, including, without limitation, any failure to meet market expectations with respect to the timing and volume of sales of VIBATIV®;
- any adverse developments or perceived adverse developments with respect to regulatory matters concerning telavancin in any foreign jurisdiction, in particular the European Medicines Agency's review of the MAA, about which we anticipate additional information during the second half of 2011;
- any further adverse developments or perceived adverse developments with respect to our telavancin NP NDA, which the FDA has determined cannot be approved without data from additional clinical studies;
- any adverse developments or perceived adverse developments in the field of LABAs, including any change in FDA policy or guidance (such as the pronouncement in February 2010 warning that LABAs should not be used alone in the treatment of asthma and related labeling requirements, the impact of the March 2010 FDA Advisory Committee discussing LABA clinical trial design to evaluate serious asthma outcomes or the FDA's April 2011 announcement that manufacturers of currently marketed LABAs conduct additional clinical studies comparing the addition of LABAs to inhaled corticosteroids versus inhaled corticosteroids alone);
- announcements regarding GSK's decisions whether or not to license any of our development programs or to return to us any previously licensed program, such as its decision in late 2010 not to license our PμMA program;
- GSK's decisions whether or not to purchase from us, on a quarterly basis, sufficient shares of common stock to maintain its ownership percentage taking into account our preceding quarter's option exercise and equity vesting activity;

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

- any announcements of developments with, or comments by, the FDA or other regulatory agencies with respect to products we or our partners have under development or have commercialized, such as the cGMP compliance issues that our VIBATIV® collaboration partner's single-source drug product supplier is facing with U.S. and foreign regulatory agencies;
- our incurrence of expenses in any particular quarter that are different than market expectations;
- the extent to which GSK advances (or does not advance) product candidates arising from our LABA collaboration or licensed from us under the strategic alliance agreement through development into commercialization;
- any adverse developments or perceived adverse developments with respect to our relationship with GSK, including, without limitation, disagreements that may arise between us and GSK concerning the public announcement of data (both timing and content) from the Phase 3 programs with RELOVAIR and 719/VI;
- any adverse developments or perceived adverse developments with respect to our relationship with Astellas, including, without limitation, disagreements that may arise between us and Astellas concerning commercialization of VIBATIV®, regulatory strategy or further development of telavancin, or Astellas' termination of our telavancin license, development and commercialization agreement;
- any adverse developments or perceived adverse developments with respect to our partnering efforts with our 5-HT4 program, PμMA program, TD-1792 or TD-4208;

Table of Contents

- 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 study results or the outcome of regulatory review relating to products under development by us, our partners or our competitors;
- regulatory developments in the United States and foreign countries;
- economic and other external factors beyond our control;
- sales of stock by us or by our stockholders, including sales by certain of our employees and directors whether or not pursuant to selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934;
- relative illiquidity in the public market for our common stock (our six largest stockholders other than GSK collectively owned approximately 47.5% of our outstanding capital stock as of July 27, 2011); and
- potential sales or purchases of our capital stock by GSK.

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

As of July 27, GSK beneficially owned approximately 18.4% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 6.5% of our outstanding capital stock. Based on our review of publicly available filings as of July 27, 2011, our six largest stockholders other than GSK collectively owned approximately 47.5% of our outstanding capital stock. These stockholders could control the outcome of actions taken by us that require stockholder approval, including a transaction in which stockholders might receive a premium over the prevailing market price for their shares.

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

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

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

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

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

On May 3, 2011, we completed the sale of 261,299 shares of our common stock to an affiliate of GSK at a price of \$25.60 per share, resulting in aggregate gross proceeds of \$6.7 million before deducting transaction expenses. Neither we nor the affiliate of GSK engaged any investment advisors with respect to the sale and no finders' fees were paid or will be paid to any party in connection with the sale. We issued and sold the shares in reliance upon an exemption from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended.

Table of Contents**Item 6. Exhibits**

| <b>Exhibit<br/>Number</b> | <b>Description</b>                                                                                                                                              | <b>Form</b> | <b>Incorporated<br/>by Reference<br/>Filing<br/>Date/Period<br/>End Date</b> |
|---------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|------------------------------------------------------------------------------|
| 3.3                       | Amended and Restated Certificate of Incorporation                                                                                                               | S-1         | 7/26/04                                                                      |
| 3.4                       | Certificate of Amendment of Restated Certificate of Incorporation                                                                                               | 10-Q        | 3/31/07                                                                      |
| 3.5                       | Amended and Restated Bylaws (as amended by the board of directors April 25, 2007)                                                                               | 10-Q        | 9/30/08                                                                      |
| 4.1                       | Specimen certificate representing the common stock of the registrant                                                                                            | 10-K        | 12/31/06                                                                     |
| 4.2                       | Amended and Restated Rights Agreement between Theravance, Inc. and The Bank of New York, as Rights Agent, dated as of June 22, 2007                             | 10-Q        | 6/30/07                                                                      |
| 4.3                       | Indenture dated as of January 23, 2008 by and between Theravance, Inc. and The Bank of New York Trust Company, N.A., as trustee                                 | 8-K         | 1/23/08                                                                      |
| 4.4                       | Form of 3.0% Convertible Subordinated Note Due 2015 (included in Exhibit 4.3)                                                                                   |             |                                                                              |
| 4.5                       | Amendment to Amended and Restated Rights Agreement between the registrant and The Bank of New York Mellon Corporation, as Rights Agent, dated November 21, 2008 | 8-K         | 11/25/08                                                                     |
| 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                                                                                                               |             |                                                                              |

Table of Contents

**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)

August 3, 2011  
Date

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

August 3, 2011  
Date

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

Table of Contents**EXHIBIT INDEX**

| <b>Exhibit<br/>Number</b> | <b>Description</b>                                                                                                                                              | <b>Form</b> | <b>Incorporated<br/>by Reference<br/>Filing<br/>Date/Period<br/>End Date</b> |
|---------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|------------------------------------------------------------------------------|
| 3.3                       | Amended and Restated Certificate of Incorporation                                                                                                               | S-1         | 7/26/04                                                                      |
| 3.4                       | Certificate of Amendment of Restated Certificate of Incorporation                                                                                               | 10-Q        | 3/31/07                                                                      |
| 3.5                       | Amended and Restated Bylaws (as amended by the board of directors April 25, 2007)                                                                               | 10-Q        | 9/30/08                                                                      |
| 4.1                       | Specimen certificate representing the common stock of the registrant                                                                                            | 10-K        | 12/31/06                                                                     |
| 4.2                       | Amended and Restated Rights Agreement between Theravance, Inc. and The Bank of New York, as Rights Agent, dated as of June 22, 2007                             | 10-Q        | 6/30/07                                                                      |
| 4.3                       | Indenture dated as of January 23, 2008 by and between Theravance, Inc. and The Bank of New York Trust Company, N.A., as trustee                                 | 8-K         | 1/23/08                                                                      |
| 4.4                       | Form of 3.0% Convertible Subordinated Note Due 2015 (included in Exhibit 4.3)                                                                                   |             |                                                                              |
| 4.5                       | Amendment to Amended and Restated Rights Agreement between the registrant and The Bank of New York Mellon Corporation, as Rights Agent, dated November 21, 2008 | 8-K         | 11/25/08                                                                     |
| 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                                                                                                               |             |                                                                              |