

THERAVANCE INC
Form 10-Q
May 01, 2013
[Table of Contents](#)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2013

OR

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

For the transition period from _____ to _____

Commission File Number: 0-30319

THERAVANCE, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

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

901 Gateway Boulevard

South San Francisco, CA 94080

(Address of Principal Executive Offices, Including Zip Code)

(650) 808-6000

(Registrant's Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant 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 April 25, 2013 was 99,453,571.

Table of Contents

TABLE OF CONTENTS

PART I FINANCIAL INFORMATION

<u>Item 1. Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets as of March 31, 2013 and December 31, 2012</u>	3
<u>Condensed Consolidated Statements of Operations for the three months ended March 31, 2013 and 2012</u>	4
<u>Condensed Consolidated Statements of Comprehensive Income (Loss) for the three months ended March 31, 2013 and 2012</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2013 and 2012</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	30
<u>Item 4. Controls and Procedures</u>	30

PART II. OTHER INFORMATION

<u>Item 1A. Risk Factors</u>	31
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	47
<u>Item 6. Exhibits</u>	48
<u>Signatures</u>	49

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

(In thousands, except per share data)

	March 31, 2013 (Unaudited)	December 31, 2012 *
Assets		
Current assets:		
Cash and cash equivalents	\$ 266,070	\$ 94,849
Short-term investments	192,986	153,640
Receivable from collaboration arrangements (including amounts from a related party of \$254 at March 31, 2013 and \$123 at December 31, 2012)	2,217	1,064
Notes receivable, current		100
Prepaid expenses and other current assets	5,190	3,966
Inventories	8,049	7,514
Total current assets	474,512	261,133
Marketable securities	99,342	95,194
Restricted cash	833	833
Property and equipment, net	9,010	9,154
Notes receivable, non-current	140	140
Other assets, non-current	7,682	2,128
Total assets	\$ 591,519	\$ 368,582
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	\$ 3,525	\$ 5,377
Accrued personnel-related expenses	5,128	9,002
Accrued clinical and development expenses	6,054	6,550
Other accrued liabilities	2,678	2,072
Accrued interest on convertible subordinated notes	2,198	2,372
Deferred revenue, current	9,881	4,593
Total current liabilities	29,464	29,966
Convertible subordinated notes	460,000	172,500
Deferred rent	4,872	5,074
Deferred revenue, non-current	5,672	6,014
Commitments and contingencies (Notes 3, 7 and 9)		
Stockholders equity:		
Common stock, \$0.01 par value; authorized: 200,000 shares; outstanding: 99,304 at March 31, 2013 and 98,379 at December 31, 2012	993	984
Additional paid-in capital	1,462,288	1,488,447
Accumulated other comprehensive income	92	99
Accumulated deficit	(1,371,862)	(1,334,502)

Edgar Filing: THERAVANCE INC - Form 10-Q

Total stockholders' equity		91,511		155,028
Total liabilities and stockholders' equity	\$	591,519	\$	368,582

* Condensed consolidated balance sheet at December 31, 2012 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)

	Three Months Ended March 31,	
	2013	2012
Revenue from collaborative arrangements (including amounts from a related party of \$1,322 for the three months ended March 31, 2013, and \$1,430 for the three months ended March 31, 2012)	\$ 1,344	\$ 127,099
Operating expenses:		
Research and development	26,416	33,202
General and administrative	8,315	7,857
Total operating expenses	34,731	41,059
Income (loss) from operations	(33,387)	86,040
Interest and other income (expense), net	(1,237)	56
Interest expense	(2,736)	(1,502)
Net income (loss)	\$ (37,360)	\$ 84,594
Net income (loss) per share:		
Basic	\$ (0.39)	\$ 1.01
Diluted	\$ (0.39)	\$ 0.93
Weighted-average number of shares used in per share calculations:		
Basic	96,379	83,590
Diluted	96,379	92,080

See accompanying notes to condensed consolidated financial statements.

Table of Contents

THERAVANCE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(In thousands, except per share data)

(Unaudited)

	Three Months Ended March 31,	
	2013	2012
Net income (loss)	\$ (37,360)	\$ 84,594
Other comprehensive income:		
Net unrealized loss on available-for-sale securities, net of tax	(7)	(25)
Comprehensive income (loss)	\$ (37,367)	\$ 84,569

See accompanying notes to condensed consolidated financial statements.

Table of Contents

THERAVANCE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2013	2012
Cash flows from operating activities		
Net income (loss)	\$ (37,360)	\$ 84,594
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	1,898	1,910
Stock-based compensation	6,095	6,235
Gain on sale of available-for-sale securities	(1)	
Change in capped call option valuation	1,422	
Changes in operating assets and liabilities:		
Receivables from collaboration arrangements	(1,153)	160
Prepaid expenses and other current assets	(1,224)	(375)
Inventories	(2,481)	
Accounts payable	(221)	48
Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued liabilities	(3,176)	(5,363)
Accrued interest on convertible subordinated notes	(174)	(1,294)
Deferred rent	(202)	(143)
Deferred revenue	4,946	(127,100)
Net cash used in operating activities	(31,631)	(41,328)
Cash flows from investing activities		
Purchases of property and equipment	(740)	(1,103)
Purchases of available-for-sale securities	(104,125)	(35,671)
Maturities of available-for-sale securities	54,753	45,158
Sale of available-for-sale securities	5,000	
Payments received on notes receivable	100	
Net cash provided by (used in) investing activities	(45,012)	8,384
Cash flows from financing activities		
Payments on note payable and capital lease		(56)
Proceeds from issuances of common stock, net	2,991	2,532
Payments for capped calls	(36,800)	
Proceeds from issuances of convertible subordinated notes, net	281,673	
Net cash provided by financing activities	247,864	2,476
Net increase (decrease) in cash and cash equivalents	171,221	(30,468)
Cash and cash equivalents at beginning of period	94,849	44,778
Cash and cash equivalents at end of period	\$ 266,070	\$ 14,310

See accompanying notes to condensed consolidated financial statements.

Table of Contents

Theravance, Inc.

Notes to Condensed consolidated financial statements

(Unaudited)

1. DESCRIPTION OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Operations

Theravance, Inc. (the Company or 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.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of 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, comprehensive income (loss) and cash flows. The interim results are not necessarily indicative of the results of operations to be expected for the year ending December 31, 2013 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, 2012 filed with the Securities and Exchange Commission (SEC) on February 26, 2013.

Principles of Consolidation

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

Segment Reporting

The Company has determined that it operates in a single segment which is the discovery (research), development and commercialization of human therapeutics. Revenues are generated primarily from the Company's collaboration arrangements with GlaxoSmithKline plc (GSK), located in the United Kingdom, Astellas Pharma Inc. (Astellas) (through January 6, 2012), located in Japan, and Merck, located in the United States. All long-lived assets, which were comprised of property and equipment, are maintained in the United States.

Investments in Marketable Securities

The Company invests in short-term and long-term marketable securities, primarily corporate notes, government, government agency, and municipal bonds. The Company classifies its marketable securities as available-for-sale securities and reports them at fair value in cash equivalents, short-term investments or marketable securities on the condensed consolidated balance sheets with related unrealized gains and losses included as a component of stockholders' equity. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest and other income, on the condensed consolidated statements of operations. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in interest and other income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest and other income.

Table of Contents

The Company regularly reviews all of its investments for other-than-temporary declines in estimated fair value. The Company's review includes the consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, whether the Company has the intent to sell the securities and whether it is more likely than not that the Company will be required to sell the securities before the recovery of their amortized cost basis. When the Company's management determines that the decline in estimated fair value of an investment is below the amortized cost basis and the decline is other-than-temporary, the Company reduces the carrying value of the security and records a loss for the amount of such decline.

Inventories

Inventories consist of raw materials and work-in-process related to the production of VIBATIV® (telavancin). Raw materials include VIBATIV® active pharmaceutical ingredient (API). Work-in-process includes third party manufacturing and associated labor costs relating to the Company's personnel directly involved in the production process. Included in inventories are raw materials and work-in-process that may be used as clinical products, which are charged to research and development (R&D) expense when consumed. In addition, under certain commercialization agreements, the Company may sell VIBATIV® packaged in unlabeled vials that are recorded in work-in-process.

Inventories are stated at the lower of cost or market value. If information becomes available that suggests the inventories may not be realizable, the Company may be required to expense a portion or all of the previously capitalized inventories.

(in thousands)	March 31, 2013	December 31, 2012
Raw materials	\$ 3,531	\$ 5,668
Work-in-process	4,518	1,846
Finished goods		
Total inventory	\$ 8,049	\$ 7,514

Fair Value of Stock-Based Compensation Awards

The Company uses the Black-Scholes-Merton option pricing model to estimate the fair value of options granted under its equity incentive plans and rights to acquire stock granted under its employee stock purchase plan (ESPP). The Black-Scholes-Merton 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, Share-Based Payment, for the expected option term because the usage of its historical option exercise data is limited due to post-IPO exercise restrictions. 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.

Restricted Stock Units (RSUs) and Restricted Stock Awards (RSAs) are measured based on the fair market values of the underlying stock on the dates of grant.

Edgar Filing: THERAVANCE INC - Form 10-Q

Stock-based compensation expense was calculated based on awards ultimately expected to vest and was reduced for estimated forfeitures at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differed 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 estimated fair value of performance-contingent RSUs and RSAs is expensed using an accelerated method over the term of the award once the Company's management has determined that it is probable that performance milestones will be achieved. Compensation expense for RSUs and RSAs that contain performance conditions is based on the grant date fair value of the award. Compensation expense is recorded over the requisite service period based on management's best estimate as to whether it is probable that the shares awarded are expected to vest. The Company's management assesses the probability of the performance milestones being met on a continuous basis.

Compensation expense for purchases under the ESPP is recognized based on the fair value of the common stock on the date of offering, less the purchase discount percentage provided for in the plan.

Table of Contents

The Company has not recognized, and does not expect to recognize in the near future, any tax benefit related to employee stock-based compensation expense as a result of the full valuation allowance on the Company's deferred tax assets including deferred tax assets related to its net operating loss carryforwards.

2. NET INCOME (LOSS) PER SHARE

Basic net income (loss) per share for each period presented was computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding, less RSAs subject to forfeiture.

For the three months ended March 31, 2013, diluted net loss per share was identical to basic net loss per share since potential common shares were excluded from the calculation, as their effect was anti-dilutive.

For the three months ended March 31, 2012, diluted net income per share was computed by dividing net income plus interest on dilutive convertible subordinated notes by the weighted-average number of shares of common stock outstanding during the period, less RSAs subject to forfeiture, plus all additional common shares that would have been outstanding assuming dilutive potential common shares had been issued for dilutive convertible notes (see Note 6) and other dilutive securities.

Dilutive potential common shares were calculated based on the if-converted method. Under the if-converted method, when computing the dilutive effect of convertible notes, net income was adjusted to add back the amount of interest and debt issuance costs recognized in the period and the denominator was adjusted to add back the number of shares that would be issued if the convertible notes were settled in shares.

Dilutive potential common shares also include the dilutive effect of the common stock underlying in-the-money stock options and ESPP shares, and were calculated based on the average share price for each period using the treasury stock method. Under the treasury stock method, the exercise price of an option and the average amount of compensation cost, if any, for future service that the Company has not yet recognized when the option is exercised, are assumed to be used to repurchase shares in the current period. Dilutive potential common shares also reflect the dilutive effect of unvested restricted stock units.

The computations for basic and diluted net income (loss) per share were as follows:

(in thousands, except for per share amounts)	Three Months Ended	
	2013	2012
	March 31,	
Numerator:		
Net income (loss) basic	\$ (37,360)	\$ 84,594
Add: interest and issuance costs related to convertible notes		1,500
Net income (loss) diluted	\$ (37,360)	\$ 86,094

Edgar Filing: THERAVANCE INC - Form 10-Q

Denominator:

Weighted-average common shares outstanding	99,181	86,292
Less: unvested RSAs	(2,802)	(2,702)
Weighted-average common shares outstanding basic	96,379	83,590
Dilutive effect of equity incentive plans and ESPP		1,822
Dilutive effect of convertible subordinated notes		6,668
Weighted-average common shares outstanding and dilutive potential common shares diluted	96,379	92,080

Anti-Dilutive Securities

Common equivalent shares not included in the computation of diluted net income (loss) per share because their effect was anti-dilutive were as follows:

(in thousands)	Three Months Ended	
	2013	2012
Shares issuable under Equity Incentive Plans and ESPP	5,469	4,641
Shares issuable upon the conversion of convertible subordinated notes	14,256	
Total anti-dilutive securities	19,725	4,641

Table of Contents

3. COLLABORATIVE ARRANGEMENTS

GSK

LABA collaboration

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 two combination products: (1) RELVAR or BREO ELLIPTA (FF/VI), an investigational once-daily combination medicine consisting of a LABA, vilanterol (VI), and an inhaled corticosteroid (ICS), fluticasone furoate (FF) and (2) ANORO ELLIPTA (UMEC/VI), a once-daily investigational medicine combining a long-acting muscarinic antagonist (LAMA), umeclidinium bromide (UMEC), with a LABA, VI. For the treatment of asthma, the collaboration is developing FF/VI.

In the event that a product containing 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. Of these potential milestone payments, the Company estimates up to \$140.0 million could be payable during 2013 and all the milestone payments could be payable by the end of 2014. The Company is entitled to receive 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 ANORO ELLIPTA, royalties are upward tiering and range from the mid-single digits to 10%. However, if GSK is not selling a LABA/ICS combination product (e.g., FF/VI) at the time that the first other LABA combination (e.g., UMEC/VI) is launched, then the royalties described above for the LABA/ICS combination (e.g., FF/VI) medicine would be applicable.

2004 Strategic Alliance

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 certain of the Company's discovery programs on pre-determined terms and on an exclusive, worldwide basis. 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. If the program is 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 the program. 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.

In 2005, GSK licensed the Company's bifunctional muscarinic antagonist-beta2 agonist (MABA) program for the treatment of COPD, and in October 2011, the Company and GSK expanded the MABA program by adding six additional Theravance-discovered preclinical MABA compounds (the Additional MABAs). GSK's development, commercialization, milestone and royalty obligations under the strategic alliance remain the same with respect to 081, the lead compound in the MABA program. GSK is obligated to use diligent efforts to develop and commercialize at least one MABA within the MABA program, but may terminate progression of any or all Additional MABAs at any time and

return them to the Company, at which point the Company may develop and commercialize such Additional MABAs alone or with a third party. Both GSK and the Company have agreed not to conduct any MABA clinical studies outside of the strategic alliance so long as GSK is in possession of the Additional MABAs. If a single-agent MABA medicine containing 081 is successfully developed and commercialized, 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. If a MABA medicine containing 081 is commercialized only as a combination product, such as a MABA/ICS, the royalty rate is 70% of the rate applicable to sales of the single-agent MABA medicine. For single-agent MABA medicines containing an Additional MABA, the Company is entitled to receive royalties from GSK of between 10% and 15% of annual global net sales up to \$3.5 billion, and 10% for all annual global net sales above \$3.5 billion. For combination products containing an Additional MABA, such as a MABA/ICS, the royalty rate is 50% of the rate applicable to sales of the single-agent MABA medicine. If a MABA medicine containing 081 is successfully developed and commercialized in multiple regions of the world, the Company could earn total contingent payments of up to \$125.0 million for a single-agent medicine and up to \$250.0 million for both a single-agent and a combination medicine. If a MABA medicine containing an Additional MABA is successfully developed and commercialized in multiple regions of the world, the Company could earn total contingent payments of up to \$129.0 million. GSK has no further option rights on any of the Company's research or development programs under the strategic alliance.

Table of Contents***Purchase of Common Stock under the Company's Governance Agreement and Common Stock Purchase Agreement with GSK***

In the first quarter of 2013, Glaxo Group Limited, an affiliate of GSK, purchased 116,527 shares of the Company's common stock at \$22.03 per share, for an aggregate purchase price of approximately \$2.6 million, pursuant to its periodic top-up rights under the Company's governance agreement with GSK dated June 4, 2004, as amended.

GSK Contingent Payments and Revenue

The potential future contingent payments related to the MABA program of \$363.0 million are not deemed substantive milestones due to the fact that the achievement of the event underlying the payment predominantly relates to GSK's performance of future development, manufacturing and commercialization activities for product candidates after licensing the program.

Revenue recognized from GSK under the LABA collaboration and strategic alliance agreements was as follows:

(in thousands)	Three Months Ended	
	March 31,	
	2013	2012
LABA collaboration	\$ 907	\$ 907
Strategic alliance MABA program license	415	523
Total revenue	\$ 1,322	\$ 1,430

Under the GSK collaboration arrangements, the Company is reimbursed for R&D expenses. These reimbursements have been reflected as a reduction of R&D expense. Reduction of R&D expense was \$0.2 million for the three months ended March 31, 2013 and \$45,000 for the three months ended March 31, 2012.

Merck***Research Collaboration and License Agreement***

In October 2012, the Company entered into a research collaboration and license agreement with Merck, known as MSD outside the United States and Canada, to discover, develop and commercialize novel small molecule therapeutics directed towards a target being investigated for the treatment of hypertension and heart failure. Under the agreement, the Company granted Merck a worldwide, exclusive license to the Company's therapeutic candidates. The Company received a \$5.0 million upfront payment in November 2012. Also, the Company will receive funding for research and be eligible for potential future contingent payments totaling up to \$148.0 million for the first indication and royalties on worldwide annual net sales of any products derived from the collaboration. The contingent payments are not deemed substantive milestones due to the fact that the achievement of the event underlying the payment predominantly relates to Merck's performance of future development and

Edgar Filing: THERAVANCE INC - Form 10-Q

commercialization activities. The initial research term is twelve months, with optional extensions by mutual agreement, and Merck can terminate the agreement at any time.

The Company identified the deliverables at the inception of the agreement. Under the agreement, the significant deliverables were determined to be the license, research services and committee participation. The Company determined that the license represents a separate unit of accounting as the license, which includes rights to the Company's underlying technologies for its therapeutic candidates, has standalone value because the rights conveyed permit Merck to perform all efforts necessary to use the Company's technologies to bring a therapeutic candidate through development and, upon regulatory approval, commercialization. Also, the Company determined that the research services and committee participation each represent separate units of accounting. The Company determined the best estimate of selling price for the license based on potential future cash flows under the arrangement over the estimated development period and determined the best estimate of selling price of the research services and committee participation based on the nature and timing of the services to be performed.

The \$5.0 million upfront payment received in November 2012 was allocated to three units of accounting based on the relative selling price method as follows: \$4.4 million to the license, \$0.4 million to the research services and \$0.2 million to the committee participation. The Company recognized revenue of \$4.4 million from the license in 2012 as the technical transfer activities were completed and the associated unit of accounting was delivered. The amount of the upfront payment allocated to the committee participation was deferred and is being recognized as revenue over the estimated performance period. The amount of the upfront payment allocated to the research services was deferred and is being recognized as a reduction of R&D expense as the underlying services are performed, as the nature of the research services is more appropriately characterized as R&D expense, consistent with the research reimbursements being received.

Table of Contents

Revenue recognized from Merck under the collaboration agreement was \$5,000 for the three months ended March 31, 2013. Amounts received and reflected as a reduction of R&D expense were \$1.5 million for the three months ended March 31, 2013.

R-Pharm CJSC

Development and Commercialization Agreements

In October 2012, the Company entered into a development and commercialization agreement with R-Pharm CJSC (R-Pharm) to develop and commercialize TD-1792, the Company's investigational glycopeptide-cephalosporin heterodimer antibiotic for the treatment of resistant Gram-positive infections, and a development and commercialization agreement with R-Pharm to develop and commercialize VIBATIV® (telavancin). Under each agreement, the Company granted R-Pharm exclusive development and commercialization rights in Russia, Ukraine, other member countries of the Commonwealth of Independent States, and Georgia. The Company received \$1.1 million in upfront payments for each agreement. Also, the Company is eligible to receive potential future contingent payments totaling up to \$10.0 million for both agreements and royalties on net sales by R-Pharm of 15% from TD-1792 and 25% from VIBATIV®. The contingent payments are not deemed substantive milestones due to the fact that the achievement of the event underlying the payment predominantly relates to R-Pharm's performance of future development and commercialization activities.

TD-1792

The Company identified two deliverables at the inception of the TD-1792 agreement, the license and committee participation. Additionally, at inception of the development and commercialization agreement, the Company had a contingent obligation to supply R-Pharm with API compound at R-Pharm's expense, either directly or through the Company's contract manufacturer, subject to entering into a future supply agreement. The Company determined that the license represents a separate unit of accounting as the license, which includes rights to the Company's underlying technologies for TD-1792, has standalone value because the rights conveyed permit R-Pharm to perform all efforts necessary to use the Company's technologies to bring the compounds through development and, upon regulatory approval, commercialization. Also, the Company determined that the committee participation represents a separate unit of accounting as R-Pharm could negotiate for and/or acquire these services from other third parties. In March 2013, the Company entered into a supply agreement for TD-1792 API compound under which the Company will sell its existing API compound to R-Pharm. Upon execution of this supply agreement, the Company determined that the supply agreement represents a separate unit of accounting under the development and commercialization arrangement. The Company determined the best estimate of selling price for the license agreement based on potential future cash flows under the arrangement over the estimated performance period. The Company determined the best estimate of selling price of the committee participation based on the nature and timing of the services to be performed and the best estimate of selling price for the supply agreement based on its fully burdened cost to manufacture the underlying API.

The \$1.1 million upfront payment for the TD-1792 agreement was allocated to the license and committee participation units of accounting based on the relative selling price method as follows: \$0.9 million to the license and \$0.1 million to the committee participation. The amount allocated to the license was deferred and will be recognized as revenue upon completion of technical transfer for the underlying license. The amount allocated to committee participation was deferred and is being recognized as revenue over the estimated performance period. Amounts to be received under the supply agreement described above will be recognized as revenue to the extent R-Pharm purchases API compound from the Company.

VIBATIV®

The Company identified the deliverables at the inception of the VIBATIV® agreement. Under the agreement, the significant deliverables were determined to be the license, committee participation and a contingent obligation to supply R-Pharm with the API compound at R-Pharm's expense, subject to entering into a future supply agreement. The Company determined that the license represents a separate unit of accounting as the license, which includes rights to the Company's underlying technologies for VIBATIV®, has standalone value because the rights conveyed permit R-Pharm to perform all efforts necessary to use the Company's technologies to bring the compounds through development and, upon regulatory approval, commercialization. Also, the Company determined that the committee participation represents a separate unit of accounting as R-Pharm could negotiate for and/or acquire these services from other third parties. The Company determined the best estimate of selling price for the license based on potential future cash flows under the arrangement over the estimated performance period. The Company determined the best estimate of selling price of the committee participation based on the nature and timing of the services to be performed.

Table of Contents

The \$1.1 million upfront payment for the VIBATIV® agreement was allocated to two units of accounting based on the relative selling price method as follows: \$1.0 million to the license and \$33,000 to the committee participation. The amount allocated to the license was deferred and will be recognized as revenue upon completion of technical transfer. The amount allocated to committee participation was deferred and is being recognized as revenue over the estimated performance period.

Alfa Wassermann

Development and Commercialization Agreement

In October 2012, the Company entered into a development and commercialization agreement with Alfa Wassermann società per azioni (S.p.A.) (Alfa Wassermann) for velusetrag (or TD-5108), the Company's investigational 5-HT4 agonist in development for gastrointestinal motility disorders. Under the agreement, the Company will collaborate in the execution of a two-part Phase 2 program to test the efficacy, safety and tolerability of velusetrag in the treatment of patients with gastroparesis. Alfa Wassermann has an exclusive option to develop and commercialize velusetrag in the European Union, Russia, China, Mexico and certain other countries, while the Company retains full rights to velusetrag in the US, Canada, Japan and certain other countries. The Company is entitled to receive funding for the Phase 2a study and a subsequent Phase 2b study if the parties agree to proceed. If Alfa Wassermann exercises its license option at the completion of the Phase 2 program, then the Company is entitled to receive a \$10.0 million option fee. If velusetrag is successfully developed and commercialized, the Company is entitled to receive potential future contingent payments totaling up to \$53.5 million, and royalties on net sales by Alfa Wassermann ranging from the low teens to 20%. The contingent payments are not deemed substantive milestones due to the fact that the achievement of the event underlying the payment predominantly relates to Alfa Wassermann's performance of future development and commercialization activities. At March 31, 2013, Alfa Wassermann's option right had not been exercised. The option right could be exercised within the next two years.

Reduction of R&D expense was \$0.2 million for the three months ended March 31, 2013.

Clinigen Group

Commercialization Agreement

In March 2013, the Company entered into a commercialization agreement with Clinigen Group plc (Clinigen) to commercialize VIBATIV® for the treatment of nosocomial pneumonia (hospital acquired), including ventilator-associated pneumonia, known or suspected to be caused by methicillin resistant *Staphylococcus aureus* (MRSA) when other alternatives are not suitable. Under the agreement, the Company granted Clinigen exclusive commercialization rights in the European Union and certain other European countries (including Switzerland and Europe). The Company received a \$5.0 million upfront payment in March 2013. Also, the Company is eligible to receive tiered royalty payments on net sales of VIBATIV®, ranging from 20% to 30%. The Company is responsible, either directly or through its vendors or contractors, for supplying at Clinigen's expense both API and finished drug product for Clinigen's commercialization activities. The agreement has a term of at least 15 years, with an option to extend exercisable by Clinigen. However, Clinigen may terminate the agreement at any time after it has initiated commercialization upon 12 months' advance notice.

Edgar Filing: THERAVANCE INC - Form 10-Q

The Company identified the deliverables at the inception of the agreement. Under the agreement, the significant deliverables were determined to be the license, manufacturing supply and committee participation. The Company determined that the license represents a separate unit of accounting as the license, which includes rights to the Company's underlying technologies for VIBATIV®, has standalone value because the rights conveyed permit Clinigen to perform all efforts necessary to use the Company's technologies to bring the compound through commercialization. Also, the Company determined that the committee participation represents a separate unit of accounting as Clinigen could negotiate for and/or acquire these services from other third parties. The Company determined the best estimate of selling price for the license based on potential future cash flows under the arrangement over the estimated commercialization period. The Company determined the best estimate of selling price for the manufacturing supply based on a fully burdened cost to purchase and transfer the underlying API and finished goods from the Company's third party contract manufacturer. The Company determined the best estimate of selling price of the committee participation based on the nature and timing of the services to be performed.

The \$5.0 million upfront payment will be allocated to two units of accounting based on the relative selling price method. The Company did not recognize any revenue from the license and committee participation as the technical transfer activities were not completed as of March 31, 2013 and the associated units of accounting were not delivered. The amount of the upfront payment allocated to the committee participation was deferred and will be recognized as revenue over the estimated performance period. Amounts received related to supply of API and finished goods supply, which will be manufactured by the Company's third party contract manufacturers, will be subject to a separate arrangement and will be recognized as revenue to the extent of future API and finished goods inventory sales.

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

In November 2005, the Company entered into a global collaboration arrangement with Astellas for the license, development and commercialization of VIBATIV®. Under this agreement, Astellas paid the Company non-refundable cash payments totaling \$191.0 million. In January 2012, Astellas exercised its right to terminate the collaboration agreement. The rights previously granted to Astellas ceased upon termination of the agreement and Astellas stopped all promotional sales efforts. Pursuant to the terms of the agreement, Astellas is entitled to a ten-year, 2% royalty on future net sales of VIBATIV®. Net revenue recognized under this collaboration agreement was \$125.7 million for the three months ended March 31, 2012, and the Company is no longer eligible to receive any further contingent payments from Astellas.

4. AVAILABLE-FOR-SALE SECURITIES

Securities classified as available-for-sale at March 31, 2013 and December 31, 2012 are summarized below. Estimated fair value is based on quoted market prices for these or similar investments that were based on prices obtained from a commercial pricing service:

(in thousands)	March 31, 2013				
	Amortized Cost	Gross Unrealized Gains		Gross Unrealized Losses	Estimated Fair Value
U.S. government securities	\$ 22,157	\$ 13	\$	\$	\$ 22,170
U.S. government agencies	152,828	69		(13)	152,884
U.S. corporate notes	82,278	39		(16)	82,301
U.S. commercial paper	59,120				59,120
Money market funds	233,827				233,827
Total	\$ 550,210	\$ 121	\$	(29)	\$ 550,302

(in thousands)	December 31, 2012				
	Amortized Cost	Gross Unrealized Gains		Gross Unrealized Losses	Estimated Fair Value
U.S. government securities	\$ 27,197	\$ 10	\$	(2)	\$ 27,205
U.S. government agencies	115,397	85		(16)	115,466
U.S. corporate notes	91,544	32		(10)	91,566
U.S. commercial paper	23,082				23,082
Money market funds	78,646				78,646
Total	\$ 335,866	\$ 127	\$	(28)	\$ 335,965

The following table summarizes the classification of the available-for-sale securities on the Company's condensed consolidated balance sheets:

Edgar Filing: THERAVANCE INC - Form 10-Q

(in thousands)	March 31, 2013	December 31, 2012
Cash and cash equivalents	\$ 257,141	\$ 86,298
Short-term investments	192,986	153,640
Long-term marketable securities	99,342	95,194
Restricted cash	833	833
Total	\$ 550,302	\$ 335,965

At March 31, 2013, all of the marketable securities have contractual maturities within two years and the average duration of marketable securities was approximately nine 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 March 31, 2013, were temporary in nature. All marketable securities with unrealized losses have been in a loss position for less than twelve months.

Table of Contents**5. 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 Company's available-for-sale securities are measured at fair value on a recurring basis and the Company's convertible subordinated notes are not measured at fair value on a recurring basis. The estimated fair values were as follows:

Types of Instruments (in thousands)	Estimated Fair Value Measurements at Reporting Date Using				Total
	Quoted Prices in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3		
<i>Assets at March 31, 2013:</i>					
U.S. government securities	\$ 22,170	\$	\$	\$	22,170
U.S. government agency securities	81,260	71,624			152,884
U.S. corporate notes	56,259	26,042			82,301
U.S. commercial paper		59,120			59,120
Money market funds	233,827				233,827
Total assets measured at estimated fair value	\$ 393,516	\$ 156,786	\$	\$	550,302
<i>Liabilities at March 31, 2013:</i>					
Convertible subordinated notes due 2015	\$ 204,413	\$	\$	\$	204,413
Convertible subordinated notes due 2023		313,573			313,573
Total convertible subordinated notes	\$ 204,413	\$ 313,573	\$	\$	517,986

Estimated Fair Value Measurements at Reporting Date Using

Edgar Filing: THERAVANCE INC - Form 10-Q

Types of Instruments (in thousands)	Quoted Prices in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Total
<i>Assets at December 31, 2012:</i>				
U.S. government securities	\$ 27,205	\$	\$	\$ 27,205
U.S. government agency securities	56,969	58,497		115,466
U.S. corporate notes	40,472	51,094		91,566
U.S. commercial paper		23,082		23,082
Money market funds	78,646			78,646
Total assets measured at estimated fair value	\$ 203,292	\$ 132,673	\$	\$ 335,965
<i>Liabilities at December 31, 2012:</i>				
Convertible subordinated notes due 2015	\$	\$ 194,050	\$	\$ 194,050

Table of Contents

At March 31, 2013, securities with a total fair value of \$11.5 million were measured using Level 1 inputs in comparison to December 31, 2012, at which time the securities had a fair value of \$11.4 million and were measured using Level 2 inputs. The transfer to Level 1 from Level 2 was primarily the result of increased trading volume of the securities at and around March 31, 2013, compared to December 31, 2012.

At March 31, 2013, securities with a total fair value of \$10.1 million were measured using Level 2 inputs in comparison to December 31, 2012, at which time the securities had a fair value of \$10.1 million and were measured using Level 1 inputs. The transfer to Level 2 from Level 1 was primarily the result of decreased trading volume of the securities at and around March 31, 2013, compared to December 31, 2012.

At March 31, 2013, convertible subordinated notes with a total fair value of \$204.4 million were measured using Level 1 inputs in comparison to December 31, 2012, at which time the convertible subordinated notes had a fair value of \$194.1 million and were measured using Level 2 inputs. The transfer to Level 1 from Level 2 was primarily the result of increased trading volume of the securities at and around March 31, 2013, compared to December 31, 2012.

Due to their short-term maturities, the Company believes that the fair value of its bank deposits, receivables from collaboration partners, accounts payable and accrued expenses approximate their carrying value.

6. LONG-TERM DEBT

Long-term obligations are as follows:

(in thousands)	March 31, 2013	December 31, 2012
Convertible Subordinated Notes Due 2015	\$ 172,500	172,500
Convertible Subordinated Notes Due 2023	287,500	
Total	\$ 460,000	\$ 172,500

Convertible Subordinated Notes Due 2015

In January 2008, the Company completed 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, that is payable semi-annually in arrears in cash on January 15 and July 15 of each year, beginning on July 15, 2008. The issuance costs, which are included in other long-term assets, are being amortized over the life of the notes. Unamortized issuance costs totaled \$1.5 million as of March 31, 2013. Amortization expense was \$0.2 million in both the three months ended March 31, 2013 and 2012.

Edgar Filing: THERAVANCE INC - Form 10-Q

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. 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. As of March 31, 2013, the Company did not provide notice of redemption or redeem any of the notes.

Convertible Subordinated Notes Due 2023

In January 2013, the Company completed an underwritten public offering of \$287.5 million aggregate principal amount of unsecured convertible subordinated notes which will mature on January 15, 2023. The financing raised proceeds, net of issuance costs, of approximately \$281.2 million, less \$36.8 million to purchase two privately-negotiated capped call option transactions in connection with the issuance of the notes. The notes bear interest at the rate of 2.125% per year, that is payable semi-annually in arrears, in cash on January 15 and July 15 of each year, beginning on July 15, 2013. The issuance costs, which are included in other long-term assets, are being amortized over the life of the notes. Unamortized issuance costs totaled \$6.2 million as of March 31, 2013. Amortization expense was \$0.1 million for the three months ended March 31, 2013.

The notes are convertible, at the option of the holder, into shares of the Company's common stock at an initial conversion rate of 35.9903 shares per \$1,000 principal amount of the notes, subject to adjustment in certain circumstances, which represents an initial conversion price of approximately \$27.79 per share. 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 their stated maturity date.

Table of Contents

In connection with the offering of the notes, the Company entered into two privately-negotiated capped call option transactions with a single counterparty. The capped call option transaction is an integrated instrument consisting of a call option on its common stock purchased by the Company with a strike price equal to the conversion price of \$27.79 per share for the underlying number of shares and a cap price of \$38.00 per share. The cap component is economically equivalent to a call option sold by the Company for the underlying number of shares with a strike price of \$38.00 per share. As an integrated instrument, the settlement of the capped call coincides with the due date of the convertible debt. At settlement, the Company will receive from its hedge counterparty a number of the Company's common shares that will range from zero, if the stock price is below \$27.79 per share, to a maximum of 2,779,659 shares, if the stock price is above \$38.00 per share. However, if the market price of the Company's common stock, as measured under the terms of the capped call transactions, exceeds \$38.00 per share, there is no incremental anti-dilutive benefit from the capped call. The aggregate cost of the capped call options was \$36.8 million.

The terms of the capped call option agreements include a provision under which the Company would have been required to make cash payments to the counterparty if the debt offering did not close. As a result of this provision, the capped calls were recorded as derivative assets between the trade dates and the date of the closing of the debt offering, at which time the cash settlement provision was no longer applicable. Upon the closing of the debt offering, the capped call transactions met the criteria for classification as an equity instrument, and the Company reclassified the carrying value of the capped call derivative assets to stockholders' equity. The change in fair value between the trade dates and the date at which the capped call derivative assets were reclassified to stockholders' equity was \$1.4 million, which was recorded as interest and other income (expense), net, in the Company's condensed consolidated statement of operations for the three month-period ended March 31, 2013.

7. STOCK-BASED COMPENSATION

Equity Incentive Plan

The 2012 Equity Incentive Plan (2012 Plan) provides for the granting of stock options, time-based and performance-contingent restricted stock units, time-based and performance-contingent restricted stock awards, and stock appreciation rights to employees, officers, directors and consultants of the Company. As of March 31, 2013, total shares remaining available for issuance under the 2012 Plan were 3,683,117.

Employee Stock Purchase Plan

The 2004 Employee Stock Purchase Plan (ESPP) provides for the purchase of the Company's common stock to the Company's non-officer employees. As of March 31, 2013, total shares remaining available for issuance under the ESPP were 423,575.

Performance-Contingent Restricted Stock Awards

In 2013, the Compensation Committee of the Company's Board of Directors approved the grant of 44,500 performance-contingent RSAs to senior management. These awards have dual triggers of vesting based upon the achievement of one of three possible performance goals by December 31, 2014, as well as a requirement for continued employment through early 2017. As of March 31, 2013, the Company had determined that the achievement of the requisite performance condition was not probable and, as a result, no compensation expense has been

recognized.

In 2012, the Compensation Committee of the Company's Board of Directors approved the grant of 44,500 performance-contingent RSAs to senior management. These awards have dual triggers of vesting based upon the achievement of one of three possible performance goals by December 31, 2013, as well as a requirement for continued employment through early 2016. As of October 15, 2012, one of the performance goals had been deemed achieved and time-based vesting commenced with respect to these awards. As a result, compensation expense of \$87,000 was recognized for the three months ended March 31, 2013, and the remaining unrecognized expense will be recognized over the remaining vesting period using the graded vesting expense attribution method.

In 2011, the Compensation Committee of the Company's Board of Directors approved the grant of 1,290,000 performance-contingent RSAs to senior management. These awards have dual triggers of vesting based upon the achievement of certain performance conditions 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 conditions are achieved on time. As of March 31, 2013, 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 conditions, the expense associated with the RSAs may vary significantly from period to period. If sufficient performance conditions are achieved in the remainder of 2013, then the Company would recognize up to \$15.6 million in stock-based compensation expense associated with these RSAs.

Table of Contents

In 2011, the Compensation Committee of the Company's Board of Directors approved the grant of a 25,000 performance-contingent RSA to a non-executive officer that has dual triggers of vesting based upon the achievement of a performance condition over a timeframe from 2012-2013 and continued employment through 2014, both of which must be satisfied in order for the award to vest in full. The maximum potential expense associated with this award is approximately \$475,000, which would be recognized in increments based on the achievement of the performance condition. As of March 31, 2013, the Company had determined that the achievement of the requisite performance condition was not probable and, as a result, no compensation expense has been recognized.

Performance-Contingent Restricted Stock Units

In 2010, the Compensation Committee of the Company's Board of Directors approved the grant of 210,000 performance-contingent RSUs to senior management. These awards 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 commenced with respect to all of the performance-contingent RSU shares. As a result, compensation expense was \$41,000 for the three months ended March 31, 2013 and \$96,000 for the three months ended March 31, 2012, and the remaining unrecognized expense will be recognized over the remaining vesting period using the graded vesting expense attribution method.

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	
	March 31,	
	2013	2012
Research and development	\$ 3,797	\$ 3,529
General and administrative	2,298	2,706
Total stock-based compensation expense	\$ 6,095	\$ 6,235

Total stock-based compensation expense capitalized to inventory was \$0.1 million for the three months ended March 31, 2013, and none for the three months ended March 31, 2012.

As of March 31, 2013, unrecognized compensation expense, net of expected forfeitures, was as follows: \$5.9 million related to unvested stock options; \$21.5 million related to unvested RSUs; and \$30.7 million related to unvested RSAs (excludes performance-contingent RSAs).

Valuation Assumptions

Edgar Filing: THERAVANCE INC - Form 10-Q

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

	Three Months Ended March 31,	
	2013	2012
<i>Employee stock options</i>		
Risk-free interest rate	1.01%-1.14%	1.00%-1.17%
Expected life (in years)	6	6
Volatility	58%	55%
Dividend yield	%	%
Weighted-average estimated fair value of stock options granted	\$ 12.32	\$ 9.88

Stockholders Equity

For the three months ended March 31, 2013, approximately 119,490 shares were exercised at a weighted-average exercise price of \$8.00 per share, for total cash proceeds of approximately \$955,974.

Table of Contents

8. INCOME TAXES

The Company did not record a provision for income taxes for the three months ended March 31, 2012, because it expected to generate a taxable net operating loss for the fiscal year ending December 31, 2012. In addition, the deferred tax assets continue to be treated as having no current value and remain fully reserved.

9. COMMITMENTS AND CONTINGENCIES

Special Long-Term Retention and Incentive Equity Awards Program

In 2011, the Company granted special long-term retention and incentive cash bonus awards to certain employees. The awards have dual triggers of vesting based upon the achievement of certain performance conditions over a six-year timeframe from 2011 through December 31, 2016 and continued employment. The maximum potential cash bonus expense associated with this program is \$38.2 million, which would be recognized in increments based on achievement of the performance conditions. As of March 31, 2013, the Company's management determined that the achievement of the requisite performance conditions was not probable and, as a result, no bonus expense has been recognized. If sufficient performance conditions are achieved in the remainder of 2013, then the Company would recognize up to \$18.7 million cash bonus expense in 2013.

Guarantees and Indemnifications

The Company indemnifies its officers and directors for certain events or occurrences, subject to certain limits. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recognized any liabilities relating to these agreements as of March 31, 2013.

10. SUBSEQUENT EVENTS

Business Separation Announcement

On April 25, 2013, the Company announced that its Board of Directors approved plans to separate its businesses into two independent publicly traded companies. One company will continue to manage all development and commercial responsibilities under the LABA collaboration with GSK and associated potential royalty revenues from RELVAR or BREO ELLIPTA, ANORO ELLIPTA and VI monotherapy with the intention of providing a consistent return of capital to stockholders, and one company will be a separate biopharmaceutical company focusing on the discovery, development and commercialization of small-molecule medicines in areas of significant unmet medical need.

Sale of Stock

On April 30, 2013, the Company and Glaxo Group Limited, an affiliate of GSK, entered into an agreement to purchase 193,563 shares of the Company's common stock at \$34.61 per share, for an aggregate purchase price of approximately \$6.7 million, pursuant to its rights under the Company's governance agreement with GSK dated June 4, 2004, as amended.

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, could, designed, estimates, expect, goal, intends, may, objective, plans, projects, pursuing, will, would and similar expressions (including the negatives thereof) are used 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. We are 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. Our key programs include: RELVAR or BREO ELLIPTA (fluticasone furoate/vilanterol), ANORO ELLIPTA (umeclidinium bromide/vilanterol) and MABA (Bifunctional Muscarinic Antagonist-Beta2 Agonist), each partnered with GlaxoSmithKline plc (GSK), and our oral Peripheral Mu Opioid Receptor Antagonist program. By leveraging our proprietary insight of multivalency to drug discovery, we are pursuing a best-in-class strategy designed to discover superior medicines in areas of significant unmet medical need.

In the first quarter of 2013, our net loss was \$37.4 million, compared with net income of \$84.6 million in the first quarter of 2012. Net income in the first quarter of 2012 reflects the recognition of deferred revenue of \$125.7 million from our global collaboration arrangement with Astellas Pharma Inc. (Astellas) for the development and commercialization of VIBATIV®. This recognition resulted from Astellas' January 6, 2012 termination of our agreement with them. Total operating expenses were \$34.7 million in the first quarter of 2013, compared with \$41.1 million in the same period in 2012. Cash and cash equivalents, short-term investments and marketable securities totaled \$558.4 million at March 31, 2013, an increase of \$214.7 million from December 31, 2012. The increase was primarily due to net proceeds of \$281.2 million received from the January 2013 issuance of convertible subordinated notes, less \$36.8 million to purchase two privately-negotiated capped call option transactions in connection with the issuance of the notes.

Edgar Filing: THERAVANCE INC - Form 10-Q

In 2012, our total operating expenses were \$148.8 million. We anticipate total operating expenses for 2013 to increase relative to 2012.

Recent Developments

Issuance of Convertible Subordinated Notes Due 2023

On January 24, 2013, we completed an underwritten public offering of \$287.5 million aggregate principal amount of unsecured convertible subordinated notes which will mature on January 15, 2023. The financing raised proceeds, net of issuance costs, of approximately \$281.2 million, less \$36.8 million to purchase two privately-negotiated capped call option transactions in connection with the issuance of the notes. The notes bear interest at the rate of 2.125% per year, that is payable semi-annually in arrears, in cash on January 15 and July 15 of each year, beginning on July 15, 2013. The notes are convertible into shares of our common stock, at the option of the holder, at an initial conversion rate of 35.9903 shares per \$1,000 principal amount of the notes, subject to adjustment in certain circumstances, which represents an initial conversion price of approximately \$27.79 per share. Holders of the notes will be able to require us 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. We may not redeem the notes prior to their stated maturity date.

Table of Contents

In connection with the offering of the notes, we entered into two privately-negotiated capped call option transactions with a single counterparty. The capped call option transaction is an integrated instrument consisting of a call option on our common stock purchased by us with a strike price equal to the conversion price of \$27.79 per share for the underlying number of shares and a cap price of \$38.00 per share. The cap component is economically equivalent to a call option sold by us for the underlying number of shares with a strike price of \$38.00 per share. As an integrated instrument, the settlement of the capped call coincides with the due date of the convertible debt. At settlement, we will receive from our hedge counterparty a number of our common shares that will range from zero, if the stock price is below \$27.79 per share, to a maximum of 2,779,659 shares, if the stock price is above \$38.00 per share. However, if the market price of our common stock, as measured under the terms of the capped call transactions, exceeds \$38.00 per share, there is no incremental anti-dilutive benefit from the capped call. The aggregate cost of the capped call options was \$36.8 million.

The terms of the capped call option agreements include a provision under which we would have been required to make cash payments to the counterparty if the debt offering did not close. As a result of this provision, the capped calls were recorded as derivative assets between the trade dates and the date of the closing of the debt offering, at which time the cash settlement provision was no longer applicable. Upon the closing of the debt offering, the capped call transactions met the criteria for classification as an equity instrument, and we reclassified the carrying value of the capped call derivative assets to stockholders' equity. The change in fair value between the trade dates and the date at which the capped call derivative assets were reclassified to stockholders' equity was \$1.4 million, which was recorded as interest and other income (expense), net, in our condensed consolidated statement of operations for the three month-period ended March 31, 2013.

Business Separation Announcement

On April 25, 2013, we announced that our Board of Directors approved plans to separate our businesses into two independent publicly traded companies. One company will continue to manage all development and commercial responsibilities under the LABA collaboration with GSK and associated potential royalty revenues from RELVAR or BREO ELLIPTA, ANORO ELLIPTA and VI monotherapy with the intention of providing a consistent return of capital to stockholders, and one company will be a separate biopharmaceutical company focused on discovery, development and commercialization of small-molecule medicines in areas of significant unmet medical need.

Programs

Respiratory Programs with GlaxoSmithKline plc (GSK)

RELVAR or BREO ELLIPTA (Fluticasone Furoate/Vilanterol, FF/VI)

FF/VI is an investigational, once-daily inhaled corticosteroid/long-acting beta2 agonist (LABA) combination treatment, comprising FF and VI, for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD) and patients with asthma. FF/VI is administered by a new dry powder inhaler called ELLIPTA. RELVAR (FF/VI for the European Union (EU) and Japan), BREO (FF/VI for the United States (U.S.)), and ELLIPTA (for the EU, U.S. and Japan) are proposed brand names and use of these brand names has not yet been approved by any regulatory authority.

Edgar Filing: THERAVANCE INC - Form 10-Q

On April 17, 2013, the Pulmonary-Allergy Drugs Advisory Committee to the U.S. Food and Drug Administration (FDA) recommended approval of BREO ELLIPTA for the treatment of COPD. The FDA Advisory Committee provides non-binding recommendations for consideration by the FDA, with the final decision on approval made by the FDA. The Prescription Drug User Fee Act (PDUFA) goal date for FF/VI is May 12, 2013.

On April 19, 2013, an article on the two replicate double-blind, parallel-group, randomized controlled trials comparing three doses of FF/VI with VI alone on the annual rate of exacerbations in patients with COPD became available in the online publication of the Lancet Respiratory Medicine.

ANORO ELLIPTA (Umeclidinium Bromide/Vilanterol, UMEC/VI)

UMEC/VI is a once-daily investigational medicine, combining a long-acting muscarinic antagonist (LAMA), UMEC, and a LABA, VI, for the maintenance treatment of patients with COPD. UMEC/VI is administered by the ELLIPTA dry powder inhaler. ANORO and ELLIPTA are proposed brand names and use of these brand names has not yet been approved by any regulatory authority.

In February 2013, GSK and we announced that the New Drug Application (NDA) for the investigational once-daily LAMA/LABA combination medicine, UMEC/VI, for patients with COPD, was accepted by the FDA indicating that the application is sufficiently complete to permit a substantive review. The PDUFA goal date was confirmed as December 18, 2013. In addition, the Marketing Authorization Application (MAA) for UMEC/VI has been validated for assessment by the European Medicines Agency (EMA). On April 22, 2013, GSK and we announced the submission of a regulatory application to the Japanese Ministry of Health, Labor and Welfare for UMEC/VI for patients with COPD. Regulatory submissions for UMEC/VI are planned in other countries during the course of 2013.

Table of Contents

Inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist (MABA)

GSK961081 (081) is an investigational, single molecule bifunctional bronchodilator with both muscarinic antagonist and beta2 receptor agonist activities. Based on the results from the Phase 2b study, GSK and we plan to advance 081 monotherapy into Phase 3 and the 081/FF combination into Phase 3-enabling studies, later in 2013.

Bacterial Infections Programs

VIBATIV® (telavancin)

VIBATIV® is a bactericidal, once-daily injectable lipoglycopeptide antibiotic approved in the U.S. and Canada for the treatment of adult patients with complicated skin and skin structure infections (cSSSI) caused by susceptible Gram-positive bacteria, including *Staphylococcus aureus*, both methicillin-resistant (MRSA) and methicillin-susceptible (MSSA) strains. In November 2012, we announced a favorable outcome of the FDA's Anti-Infective Drugs Advisory Committee meeting on VIBATIV® for the treatment of nosocomial pneumonia (NP) due to susceptible isolates of Gram-positive microorganisms. We remain in dialogue with the FDA on the NP indication and we are working toward re-establishing consistent product supply.

Glycopeptide-Cephalosporin Heterodimer TD-1607

In April 2013, we initiated a Phase 1 randomized, double-blind, placebo-controlled single-ascending dose study designed to evaluate the safety, tolerability and pharmacokinetics of TD-1607, administered intravenously. Discovered by us, TD-1607 is an investigational glycopeptide-cephalosporin heterodimer antibiotic for the treatment of serious, difficult-to-treat Gram-positive infections due to resistant strains of *Staphylococcus aureus*. TD-1607 has demonstrated potent activity *in vitro* and in preclinical *in vivo* models of infection.

Central Nervous System (CNS)/Pain Programs

Oral Peripheral Mu Opioid Receptor Antagonist TD-1211

TD-1211 is an investigational once-daily, orally administered, peripherally selective, multivalent inhibitor of the mu opioid receptor designed with a goal of alleviating gastrointestinal side effects of opioid therapy without affecting analgesia. In July 2012, we announced positive topline results from the Phase 2b Study 0084, the key study in the Phase 2b program evaluating TD-1211 as potential treatment for chronic, non-cancer pain patients with opioid-induced constipation. The Phase 2b program consisted of three studies (0074, 0076 and 0084) designed to evaluate doses and dosing regimens for Phase 3. We are currently evaluating our Phase 3 strategy due to potentially evolving FDA requirements for this class of drug.

Monoamine Reuptake Inhibitor TD-9855

TD-9855 is an investigational norepinephrine and serotonin reuptake inhibitor for the treatment of central nervous system conditions such as Attention-Deficit/Hyperactivity Disorder (ADHD) and chronic pain. TD-9855 is being evaluated in an ongoing Phase 2 study in adult patients with ADHD and in an ongoing Phase 2 study in patients with fibromyalgia. Both studies are progressing and results from the Phase 2 study in ADHD are anticipated to be reported late this year or in early 2014.

Theravance Respiratory Program

Long-Acting Muscarinic Antagonist (LAMA) TD-4208

TD-4208, an investigational LAMA for the treatment of COPD, is being evaluated in an ongoing randomized, double-blind, multiple-dose Phase 2b study to examine pharmacodynamics, safety and tolerability, and pharmacokinetics. Enrollment is on track and results from the Phase 2b study are anticipated to be reported late this year.

GI Motility Dysfunction Program

Velusetrag

Velusetrag, an oral, investigational medicine dosed once daily, is a highly selective agonist with high intrinsic activity at the human 5-HT₄ receptor. In October 2012, we entered into an exclusive development and commercialization agreement with Alfa Wassermann for velusetrag, our lead compound in the 5-HT₄ program, covering the EU, Russia, China, Mexico and certain other countries. In January 2013, we and Alfa Wassermann announced the initiation of a Phase 2 proof-of-concept study to evaluate the efficacy and safety of velusetrag for the treatment of patients with diabetic or idiopathic gastroparesis.

Table of Contents

Collaborative Arrangements

GSK

LABA collaboration

In November 2002, we entered into our 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 two combination products: (1) RELVAR or BREO ELLIPTA (FF/VI), an investigational once-daily combination medicine consisting of a LABA, vilanterol (VI), and an inhaled corticosteroid (ICS), fluticasone furoate (FF) and (2) ANORO ELLIPTA (UMEC/VI), a once-daily investigational medicine combining a long-acting muscarinic antagonist (LAMA), umeclidinium bromide (UMEC), with a LABA, VI. For the treatment of asthma, the collaboration is developing FF/VI. The FF/VI program is aimed at developing a once-daily combination LABA/ICS to succeed GSK's Advair®/Seretide (salmeterol and fluticasone as a combination) franchise, which had reported 2012 sales of approximately \$8.0 billion, and to compete with Symbicort® (formoterol and budesonide as a combination), which had reported 2012 sales of approximately \$3.2 billion. ANORO ELLIPTA, 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 2011 sales of approximately \$4.2 billion.

In the event that a product containing 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. Of these potential milestone payments, we estimate up to \$140.0 million could be payable during 2013 and all the milestone payments could be payable by the end of 2014. We are entitled to receive 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 ANORO ELLIPTA, royalties are upward tiering and range from the mid-single digits to 10%. However, if GSK is not selling a LABA/ICS combination product (e.g., FF/VI) at the time that the first other LABA combination (e.g., UMEC/VI) is launched, then the royalties described above for the LABA/ICS combination (e.g., FF/VI) medicine would be applicable.

2004 Strategic Alliance

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 certain of our discovery programs on pre-determined terms and on an exclusive, worldwide basis. 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. If the program is 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 the program. 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.

In 2005, GSK licensed our bifunctional muscarinic antagonist-beta2 agonist (MABA) program for the treatment of COPD, and in October 2011, we and GSK expanded the MABA program by adding six additional Theravance-discovered preclinical MABA compounds (the Additional

MABAs). GSK's development, commercialization, milestone and royalty obligations under the strategic alliance remain the same with respect to 081, the lead compound in the MABA program. GSK is obligated to use diligent efforts to develop and commercialize at least one MABA within the MABA program, but may terminate progression of any or all Additional MABAs at any time and return them to us, at which point we may develop and commercialize such Additional MABAs alone or with a third party. Both GSK and we have agreed not to conduct any MABA clinical studies outside of the strategic alliance so long as GSK is in possession of the Additional MABAs. If a single-agent MABA medicine containing 081 is successfully developed and commercialized, 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. If a MABA medicine containing 081 is commercialized only as a combination product, such as a MABA/ICS, the royalty rate is 70% of the rate applicable to sales of the single-agent MABA medicine. For single-agent MABA medicines containing an Additional MABA, we are entitled to receive royalties from GSK of between 10% and 15% of annual global net sales up to \$3.5 billion, and 10% for all annual global net sales above \$3.5 billion. For combination products containing an Additional MABA, such as a MABA/ICS, the royalty rate is 50% of the rate applicable to sales of the single-agent MABA medicine. If a MABA medicine containing 081 is successfully developed and commercialized in multiple regions of the world, we could earn total contingent payments of up to \$125.0 million for a single-agent medicine and up to \$250.0 million for both a single-agent and a combination medicine. If a MABA medicine containing an Additional MABA is successfully developed and commercialized in multiple regions of the world, we could earn total contingent payments of up to \$129.0 million. GSK has no further option rights on any of our research or development programs under the strategic alliance.

Table of Contents*Purchase of Common Stock under our Governance Agreement and Common Stock Purchase Agreement with GSK*

In 2013, Glaxo Group Limited, an affiliate of GSK, purchased 116,527 shares of our common stock at \$22.03 per share, for an aggregate purchase price of approximately \$2.6 million on February 15, 2013 and 193,563 shares of our common stock at \$34.61 per share, for an aggregate purchase price of approximately \$6.7 million on April 30, 2013, pursuant to its periodic top-up rights under our governance agreement with GSK dated June 4, 2004, as amended.

GSK Contingent Payments and Revenue

The potential future contingent payments related to the MABA program of \$363.0 million are not deemed substantive milestones due to the fact that the achievement of the event underlying the payment predominantly relates to GSK's performance of future development, manufacturing and commercialization activities for product candidates after licensing the program.

Revenue recognized from GSK under the LABA collaboration and strategic alliance agreements was as follows:

(in millions)	Three Months Ended	
	2013	March 31, 2012
LABA collaboration	\$ 0.9	\$ 0.9
Strategic alliance MABA program license	0.4	0.5
Total revenue	\$ 1.3	\$ 1.4

Under the GSK collaboration arrangements, we are reimbursed for research and development (R&D) expenses. These reimbursements have been reflected as a reduction of R&D expense. Reduction of R&D expense was \$0.2 million for the three months ended March 31, 2013 and \$45,000 for the three months ended March 31, 2012.

*Merck**Research Collaboration and License Agreement*

In October 2012, we entered into a research collaboration and license agreement with Merck, known as MSD outside the United States and Canada, to discover, develop and commercialize novel small molecule therapeutics directed towards a target being investigated for the treatment of hypertension and heart failure. Under the agreement, we granted Merck a worldwide, exclusive license to our therapeutic candidates. We received a \$5.0 million upfront payment in November 2012. Also, we will receive funding for research and be eligible for potential future contingent payments totaling up to \$148.0 million for the first indication and royalties on worldwide annual net sales of any products derived from the collaboration. The contingent payments are not deemed substantive milestones due to the fact that the achievement of the event

underlying the payment predominantly relates to Merck's performance of future development and commercialization activities. The initial research term is twelve months, with optional extensions by mutual agreement, and Merck can terminate the agreement at any time.

We identified the deliverables at the inception of the agreement. Under the agreement, the significant deliverables were determined to be the license, research services and committee participation. We determined that the license represents a separate unit of accounting as the license, which includes rights to our underlying technologies for its therapeutic candidates, has standalone value because the rights conveyed permit Merck to perform all efforts necessary to use our technologies to bring a therapeutic candidate through development and, upon regulatory approval, commercialization. Also, we determined that the research services and committee participation each represent separate units of accounting. We determined the best estimate of selling price for the license based on potential future cash flows under the arrangement over the estimated development period and determined the best estimate of selling price of the research services and committee participation based on the nature and timing of the services to be performed.

The \$5.0 million upfront payment received in November 2012 was allocated to three units of accounting based on the relative selling price method as follows: \$4.4 million to the license, \$0.4 million to the research services and \$0.2 million to the committee participation. We recognized revenue of \$4.4 million from the license in 2012 as the technical transfer activities were completed and the associated unit of accounting was delivered. The amount of the upfront payment allocated to the committee participation was deferred and is being recognized as revenue over the estimated performance period. The amount of the upfront payment allocated to the research services was deferred and is being recognized as a reduction of R&D expense as the underlying services are performed, as the nature of the research services is more appropriately characterized as R&D, consistent with the research reimbursements being received.

Table of Contents

Revenue recognized from Merck under the collaboration agreement was \$5,000 for the three months ended March 31, 2013. Amounts received and reflected as a reduction of R&D expense were \$1.5 million for the three months ended March 31, 2013.

R-Pharm CJSC

Development and Commercialization Agreements

In October 2012, we entered into a development and commercialization agreement with R-Pharm CJSC (R-Pharm) to develop and commercialize TD-1792, our investigational glycopeptide-cephalosporin heterodimer antibiotic for the treatment of resistant Gram-positive infections, and a development and commercialization agreement with R-Pharm to develop and commercialize VIBATIV® (telavancin). Under each agreement, we granted R-Pharm exclusive development and commercialization rights in Russia, Ukraine, other member countries of the Commonwealth of Independent States, and Georgia. We received \$1.1 million in upfront payments for each agreement. Also, we are eligible to receive potential future contingent payments totaling up to \$10.0 million for both agreements and royalties on net sales by R-Pharm of 15% from TD-1792 and 25% from VIBATIV®. The contingent payments are not deemed substantive milestones due to the fact that the achievement of the event underlying the payment predominantly relates to R-Pharm's performance of future development and commercialization activities.

TD-1792

We identified two deliverables at the inception of the TD-1792 agreement, license and committee participation. Additionally, at inception of the development and commercialization agreement, we had a contingent obligation to supply R-Pharm with API compound at R-Pharm's expense, either directly or through our contract manufacturer, subject to entering into a future supply agreement. We determined that the license represents a separate unit of accounting as the license, which includes rights to our underlying technologies for TD-1792, has standalone value because the rights conveyed permit R-Pharm to perform all efforts necessary to use our technologies to bring the compounds through development and, upon regulatory approval, commercialization. Also, we determined that the committee participation represents a separate unit of accounting as R-Pharm could negotiate for and/or acquire these services from other third parties. In March 2013, we entered into a supply agreement for TD-1792 API compound under which we will sell our existing API compound to R-Pharm. Upon execution of this supply agreement, we determined that the supply agreement represents a separate unit of accounting under the development and commercialization arrangement. We determined the best estimate of selling price for the license agreement based on potential future cash flows under the arrangement over the estimated performance period. We determined the best estimate of selling price of the committee participation based on the nature and timing of the services to be performed and determined the best estimate of selling price for the supply agreement based on our fully burdened cost to manufacture the underlying API.

The \$1.1 million upfront payment for the TD-1792 agreement was allocated to the license and committee participation units of accounting based on the relative selling price method as follows: \$0.9 million to the license and \$0.1 million to the committee participation. The amount allocated to the license was deferred and will be recognized as revenue upon completion of technical transfer for the underlying license. The amount allocated to committee participation was deferred and is being recognized as revenue over the estimated performance period. Amounts to be received under the supply agreement described above will be recognized as revenue to the extent R-Pharm purchases API compound from us.

VIBATIV®

We identified the deliverables at the inception of the VIBATIV® agreement. Under the agreement, the significant deliverables were determined to be the license, committee participation and a contingent obligation to supply R-Pharm with API compound at R-Pharm's expense, subject to entering into a future supply agreement. We determined that the license represents a separate unit of accounting as the license, which includes rights to our underlying technologies for VIBATIV®, has standalone value because the rights conveyed permit R-Pharm to perform all efforts necessary to use our technologies to bring the compounds through development and, upon regulatory approval, commercialization. Also, we determined that the committee participation represents a separate unit of accounting as R-Pharm could negotiate for and/or acquire these services from other third parties. We determined the best estimate of selling price for the license based on potential future cash flows under the arrangement over the estimated performance period. We determined the best estimate of selling price of the committee participation based on the nature and timing of the services to be performed.

The \$1.1 million upfront payment for the VIBATIV® agreement was allocated to two units of accounting based on the relative selling price method as follows: \$1.0 million to the license and \$33,000 to the committee participation. The amount allocated to the license was deferred and will be recognized as revenue upon completion of technical transfer. The amount allocated to committee participation was deferred and is being recognized as revenue over the estimated performance period.

Table of Contents

Alfa Wassermann

Development and Commercialization Agreement

In October 2012, we entered into a development and commercialization agreement with Alfa Wassermann società per azioni (S.p.A.) (Alfa Wassermann) for velusetrag (or TD-5108), our investigational 5-HT4 agonist in development for gastrointestinal motility disorders. Under the agreement, we will collaborate in the execution of a two-part Phase 2 program to test the efficacy, safety and tolerability of velusetrag in the treatment of patients with gastroparesis. Alfa Wassermann has an exclusive option to develop and commercialize velusetrag in the European Union, Russia, China, Mexico and certain other countries, while we retain full rights to velusetrag in the US, Canada, Japan and certain other countries. We are entitled to receive funding for the Phase 2a study and a subsequent Phase 2b study if the parties agree to proceed. If Alfa Wassermann exercises its license option at the completion of the Phase 2 program, then we are entitled to receive a \$10.0 million option fee. If velusetrag is successfully developed and commercialized, we are entitled to receive potential future contingent payments totaling up to \$53.5 million, and royalties on net sales by Alfa Wassermann ranging from the low teens to 20%. The contingent payments are not deemed substantive milestones due to the fact that the achievement of the event underlying the payment predominantly relates to Alfa Wassermann's performance of future development and commercialization activities. At March 31, 2013, Alfa Wassermann's option right had not been exercised. The option right could be exercised within the next two years.

Reduction of R&D expense was \$0.2 million for the three months ended March 31, 2013.

Clinigen Group

Commercialization Agreement

In March 2013, we entered into a commercialization agreement with Clinigen Group plc (Clinigen) to commercialize VIBATIV® for the treatment of nosocomial pneumonia (hospital acquired), including ventilator-associated pneumonia, known or suspected to be caused by methicillin resistant *Staphylococcus aureus* (MRSA) when other alternatives are not suitable. Under the agreement, we granted Clinigen exclusive commercialization rights in the European Union and certain other European countries (including Switzerland and Europe). We received a \$5.0 million upfront payment in March 2013. Also, we are eligible to receive tiered royalty payments on net sales of VIBATIV®, ranging from 20% to 30%. We are responsible, either directly or through our vendors or contractors, for supplying at Clinigen's expense both API and finished drug product for Clinigen's commercialization activities. The agreement has a term of at least 15 years, with an option to extend exercisable by Clinigen. However, Clinigen may terminate the agreement at any time after it has initiated commercialization upon 12 months advance notice.

We identified the deliverables at the inception of the agreement. Under the agreement, the significant deliverables were determined to be the license, manufacturing supply and committee participation. We determined that the license represents a separate unit of accounting as the license, which includes rights to our underlying technologies for VIBATIV®, has standalone value because the rights conveyed permit Clinigen to perform all efforts necessary to use our technologies to bring the compound through commercialization. Also, we determined that the committee participation represents a separate unit of accounting as Clinigen could negotiate for and/or acquire these services from other third parties. We determined the best estimate of selling price for the license based on potential future cash flows under the arrangement over the

Edgar Filing: THERAVANCE INC - Form 10-Q

estimated commercialization period. We determined the best estimate of selling price for the manufacturing supply based on a fully burdened cost to purchase and transfer the underlying API and finished goods from our third party contract manufacturer. We determined the best estimate of selling price of the committee participation based on the nature and timing of the services to be performed.

The \$5.0 million upfront payment will be allocated to two units of accounting based on the relative selling price method. We did not recognize any revenue from the license and committee participation as the technical transfer activities were not completed as of March 31, 2013 and the associated units of accounting were not delivered. The amount of the upfront payment allocated to the committee participation was deferred and will be recognized as revenue over the estimated performance period. Amounts received related to supply of API and finished goods supply, which will be manufactured by our third party contract manufacturers, will be subject to a separate arrangement and will be recognized as revenue to the extent of future API and finished goods inventory sales.

Critical Accounting Policies and 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 three months ended March 31, 2013 compared to those discussed in our 2012 Annual Report on Form 10-K filed on February 26, 2013.

Table of Contents**RESULTS OF OPERATIONS****Revenue**

Revenue, as compared to the prior year period, was as follows:

(in millions, except percentages)	Three Months Ended		Change	
	2013	March 31, 2012	\$	%
Collaborative arrangements:				
GSK collaboration arrangements	\$ 1.3	\$ 1.4	\$ (0.1)	(7)%
Astellas collaboration arrangement		125.7	(125.7)	(100)%
Other collaboration arrangements	*		*	**
Total revenues	\$ 1.3	\$ 127.1	\$ (125.8)	99%

* Amount is less than \$50,000.

** Calculation not meaningful.

Revenues decreased 99% to \$1.3 million in the first quarter of 2013, from the comparable period in 2012. The revenues recognized in the first quarter of 2012 reflect the accelerated recognition of deferred revenue of \$125.7 million from our global collaboration arrangement with Astellas for the development and commercialization of VIBATIV® in the first quarter of 2012. This accelerated recognition was the result of the termination of the Astellas agreement on January 6, 2012.

A portion of our upfront fees and certain contingent payments received from our collaboration arrangements other than with Astellas have been deferred and are being amortized ratably into revenue or research and development expense over the estimated performance period. Future revenue will include the ongoing amortization of upfront and contingent payments earned. We periodically review and, if necessary, revise the estimated periods of our performance pursuant to these contracts.

Research & Development

Research and development expenses, as compared to the prior year period, were as follows:

	Three Months Ended	Change
	March 31,	

Edgar Filing: THERAVANCE INC - Form 10-Q

(in millions, except percentages)	2013		2012		\$	%
Employee-related	\$	9.3	\$	10.2	\$ (0.9)	(9)%
External research and development		7.1		13.2	(6.1)	(46)%
Stock-based compensation		3.8		3.5	0.3	9%
Facilities, depreciation and other allocated		6.2		6.3	(0.1)	(2)%
Total research and development expenses	\$	26.4	\$	33.2	\$ (6.8)	(20)%

R&D expenses decreased 20% to \$26.4 million in the first quarter of 2013, from the comparable period in 2012. The decrease in the first quarter of 2013 was primarily due to lower external R&D costs resulting from the completion of our Phase 2 studies in our program for opioid-induced constipation with TD-1211 in 2012 and, to a lesser extent, from an increase in collaborative partner R&D reimbursements.

General and administrative

General and administrative expenses, as compared to the prior year period, were as follows:

(in millions, except percentages)	Three Months Ended				Change	
	2013		2012		\$	%
		March 31,				
General and administrative	\$	8.3	\$	7.9	\$ 0.4	5%

G&A expenses increased 5% to \$8.3 million in the first quarter of 2013, from the comparable period in 2012. The increase in the first quarter of 2013 was primarily due to higher consulting services costs and higher facilities-related costs partially offset by a decrease in employee related costs driven by a decrease in stock-based compensation expense. Stock-based compensation expense for the first quarter of 2013 was \$2.3 million compared with \$2.7 million for the same period in 2012.

Table of Contents**Interest and other income (expense), net**

Interest and other income (expense), net, as compared to the prior year period, were as follows:

(in millions, except percentages)	Three Months Ended March 31,		Change	
	2013	2012	\$	%
Interest and other income (expense), net	\$ (1.2)	\$ 0.1	\$ (1.3)	*%

* Calculation not meaningful.

Interest and other income (expense), net decreased \$1.3 million to \$1.2 million expense, net in the first quarter of 2013, from the comparable period in 2012. Other expense was \$1.4 million in the first quarter of 2013, and is entirely comprised of the change in fair value of the capped call instruments related to our convertible subordinated notes issued in January 2013. For further discussion, see the section entitled "Recent Developments" above. The other expense was partially offset by a slight increase in interest income primarily due to an increase in our cash and cash equivalents, short-term investments and marketable securities balances resulting from the net proceeds of our January 2013 issuance of 2.125% convertible subordinated notes due in 2023 less the cost of entering into capped call option transactions related to such notes.

Interest expense

Interest expense, as compared to the prior year period, was as follows:

(in millions, except percentages)	Three Months Ended March 31,		Change	
	2013	2012	\$	%
Interest expense	\$ 2.7	\$ 1.5	\$ 1.2	80%

Interest expense increased 80% to \$2.7 million in the first quarter of 2013, from the comparable period in 2012, primarily due to interest expense and amortization of issuance cost for our convertible subordinated notes issued in January 2013. Interest expense is primarily comprised of interest expense and amortization of issuance costs from our convertible subordinated notes issued in January 2008 and January 2013.

LIQUIDITY AND CAPITAL RESOURCES

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. At March 31, 2013, we had \$558.4 million in cash, cash equivalents and

marketable securities, excluding \$0.8 million in restricted cash that was pledged as collateral for certain of our leases. In 2013, we issued and Glaxo Group Limited, an affiliate of GSK, purchased 116,527 shares of our common stock at \$22.03 per share, for an aggregate purchase price of approximately \$2.6 million on February 15, 2013 and 193,563 shares of our common stock at \$34.61 per share, for an aggregate purchase price of approximately \$6.7 million on April 30, 2013, pursuant to its periodic top-up rights under our governance agreement with GSK dated June 4, 2004, as amended.

On January 24, 2013, we completed an underwritten public offering of \$287.5 million aggregate principal amount of unsecured 2.125% convertible subordinated notes due 2023. The financing raised proceeds, net of issuance costs, of approximately \$281.2 million, less \$36.8 million of payments on privately-negotiated capped call option transactions in connection with the issuance of the notes. In connection with the offering of the notes, we entered into privately-negotiated capped call option transactions with an aggregate cost of \$36.8 million.

We expect to incur substantial expenses as we continue our drug discovery and development efforts, particularly to the extent we advance our product candidates into and through clinical studies, which are very expensive. For example, TD-9855 in our MARIN program is in Phase 2 studies for both attention-deficit/hyperactivity disorder (ADHD) and fibromyalgia, and our LAMA compound TD-4208 commenced a Phase 2b study in December 2012. Also, in July 2012, we announced positive results from the key study in our Phase 2b program with TD-1211 in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation. Though we seek to partner this program, we may choose to progress TD-1211 into Phase 3 studies by ourselves, which would increase our operating expenses substantially. In addition, provided we can assure a reasonable source of VIBATIV® drug product, we intend to reintroduce VIBATIV® in the U.S. later in 2013, which will involve outside services costs associated with manufacturing and distribution capabilities. Furthermore, should we decide to commercialize VIBATIV® in the United States without a partner, we will incur significant costs and expenses associated with creating an independent sales and marketing organization with appropriate technical expertise and supporting infrastructure. We also intend to invest in other assets in our pipeline, including programs in earlier-stage clinical development and late-stage discovery. In addition, pursuant to our LABA collaboration with GSK (see the section entitled "GSK LABA Collaboration" above), 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. Of these potential milestone payments, we estimate up to \$140.0 million could be payable during 2013 and all the milestone payments could be payable by the end of 2014.

Table of Contents

In 2012, we issued purchase orders to Astellas for the purchase of VIBATIV® API and other raw materials of up to \$7.7 million, and as of December 31, 2012 we had purchased \$5.8 million pursuant to these orders. The remaining API and other raw materials will not be purchased.

In 2011, we granted special long-term retention and incentive cash bonus awards to certain employees. The awards have dual triggers of vesting based upon the achievement of certain performance conditions over a six-year timeframe from 2011 through December 31, 2016 and continued employment. As of March 31, 2013, we determined that the achievement of the requisite performance conditions was not probable and, as a result, no compensation expense has been recognized. If sufficient performance conditions are achieved in 2013, then we would recognize up to \$18.7 million related to cash bonus expense in 2013.

Adequacy of cash resources to meet future needs

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 currently planned. 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.

Cash Flows

Cash flows, as compared to the prior year period, were as follows:

(in millions)	Three Months Ended	
	2013	March 31, 2012
Net cash used in operating activities	\$ (31.6)	\$ (41.3)
Net cash provided by (used in) investing activities	\$ (45.0)	\$ 8.4
Net cash provided by financing activities	\$ 247.9	\$ 2.5

Cash Flows from Operating Activities

Cash used in operations decreased \$9.7 million in the first quarter of 2013, from the comparable period in 2012. The decrease was primarily due to lower uses of cash for operating liabilities resulting from a decrease in R&D activity.

Cash Flows from Investing Activities

Cash used in investing activities increased \$53.4 million in the first quarter of 2013, from the comparable period in 2012. The increase was primarily due to an increase in purchases of marketable securities with the net proceeds received from the January 2013 issuance of 2.125% convertible subordinated notes due in 2023.

Cash Flows from Financing Activities

Cash provided by financing activities increased \$245.4 million in the first quarter of 2013, from the comparable period in 2012. The increase was due to net proceeds of \$281.2 million received from the January 2013 issuance of 2.125% convertible subordinated notes due in 2023, less \$36.8 million of payments on privately-negotiated capped call option transactions in connection with the issuance of the notes.

Table of Contents

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.

Commitments and Contingencies

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 March 31, 2013.

In 2011, we granted special long-term retention and incentive RSAs to members of senior management and special long-term retention and incentive cash bonus awards to certain employees. The awards have dual triggers of vesting based upon the achievement of certain performance conditions over a six-year timeframe from 2011 through December 31, 2016 and continued employment. The maximum potential expense associated with this program is \$31.9 million related to stock-based compensation expense and \$38.2 million related to cash bonus expense, which would be recognized in increments based on achievement of the performance conditions. As of March 31, 2013, we determined that the achievement of the requisite performance conditions was not probable and, as a result, no compensation expense has been recognized. If sufficient performance conditions are achieved in 2013, then we would recognize up to \$15.6 million in stock-based compensation expense associated with these RSAs and \$18.7 million related to cash bonus expense in 2013.

Contractual Obligations and Commercial Commitments

There have been no significant changes in our payments due under contractual obligations, compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2012.

Pursuant to our LABA collaboration with GSK (see GSK LABA Collaboration above), 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. Of these potential milestone payments, we estimate up to \$140.0 million could be payable during 2013 and all the milestone payments could be payable by the end of 2014. We have not recognized any liabilities relating to this agreement as of March 31, 2013.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

During the first three months of 2013, there have been no significant changes in our market risk or how our market risk is managed, compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2012.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

We conducted an evaluation as of March 31, 2013, 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) (i) is recorded, processed, summarized and reported within required time periods and (ii) is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. 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 at the reasonable assurance level.

Limitations on the Effectiveness of Controls

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

Table of Contents

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

Risks Related to our Business

If the FDA does not approve FF/VI on the May 12, 2013 Prescription Drug User Fee Act (PDUFA) goal date, or if FDA's action on FF/VI is delayed beyond the PDUFA goal date, or if regulatory authorities determine that the Phase 3 programs for FF/VI in asthma and/or chronic obstructive pulmonary disease (COPD) do not demonstrate adequate safety and efficacy, the continued development of FF/VI may be significantly delayed, it may not be approved by regulatory authorities, and even if approved it may be subject to restrictive labeling, any of which will harm our business, and the price of our securities could fall.

During the first quarter of 2012, we announced the completion of, and reported certain top-line data from, the Phase 3 registrational program for FF/VI in COPD and asthma. In July 2012, GSK submitted regulatory applications for FF/VI (proposed brand name RELVAR) in Europe for both COPD and asthma, and for FF/VI (proposed brand name BREO ELLIPTA) in the U.S. for COPD and both submissions have been accepted for review. In September 2012, GSK announced that it was commencing an additional Phase 3 study to complete the U.S. asthma filing package. The Phase 3b program for FF/VI in COPD commenced in February 2011. In April 2013, the FDA's Pulmonary-Allergy Drugs Advisory Committee (PADAC) discussed the New Drug Application (NDA) for FF/VI dry powder inhaler, sponsored by GSK, for the long-term maintenance treatment of airflow obstruction and for reducing exacerbations in patients with COPD (FF/VI COPD NDA). The Committee voted that the efficacy and safety data provide substantial evidence to support approval of BREO ELLIPTA as a once-daily inhaled treatment for the long-term, maintenance treatment of airflow obstruction in patients with COPD (9 for, 4 against) and also for the reduction of COPD exacerbations in patients with a history of exacerbations (9 for, 4 against). The FF/VI COPD NDA remains under review by the FDA, and the Committee's action is only a non-binding recommendation for the FDA's consideration. The FDA has the final decision making authority on the FF/VI COPD NDA, and it is not required to follow the Committee's recommendation. Any adverse developments or results or perceived adverse developments or results with respect to the FF/VI COPD NDA, other FF/VI regulatory submissions, the asthma Phase 3 study or the Phase 3b 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 does not approve FF/VI on the May 12, 2013 PDUFA goal date, delays action on FF/VI beyond the PDUFA goal date, or issues a complete response letter or similar communication that calls into question the approvability of FF/VI; not every study, nor every dose in every study, in the Phase 3 programs for FF/VI achieved its primary endpoint and the FDA and/or other regulatory authorities may determine that additional clinical studies are required;

Edgar Filing: THERAVANCE INC - Form 10-Q

- inability to gain, or delay in gaining, regulatory approval for the new ELLIPTA investigational dry powder inhaler used in these programs;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in these programs. For example, GSK is investigating seven cases of fatal pneumonia in the Phase 3 FF/VI COPD program, six of which were at a dose that is higher than the dose being pursued for approval and a majority of which occurred at one clinical site;
- safety, efficacy or other concerns arising from clinical or non-clinical studies with umeclidinium bromide/vilanterol (proposed brand name ANORO ELLIPTA) (UMEC/VI) having to do with the LABA VI, which is also a component of FF/VI;
- regulatory authorities determining that the Phase 3 program in asthma or COPD raises safety concerns or does not demonstrate adequate efficacy; or
- any change in FDA policy or guidance regarding the use of LABAs to treat asthma.

Table of Contents

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 now requires 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 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. Results from these post-marketing studies are expected in 2017. It is unknown at this time what, if any, effect these or future FDA actions will have on the prospects for FF/VI. 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 the FDA requiring additional asthma clinical trials in the United States (U.S.) for FF/VI and increase the overall risk for FF/VI for the treatment of asthma in the U.S.

If the FDA does not approve UMEC/VI on the December 18, 2013 PDUFA goal date, or if FDA's action on UMEC/VI is delayed beyond the PDUFA goal date, or if regulatory authorities determine that the Phase 3 program for UMEC/VI for the treatment of COPD does not demonstrate adequate safety and efficacy, continued development of UMEC/VI will be significantly delayed or terminated, our business will be harmed, and the price of our securities could fall.

The Phase 3 program for UMEC/VI with the combination of a LAMA umeclidinium bromide (UMEC), and a LABA, VI, for the treatment of COPD commenced in February 2011. In July 2012, GSK and we reported top-line results from four pivotal studies in this Phase 3 program and in August 2012, GSK and we announced the completion of this Phase 3 program and reported certain top-line data from the remaining studies in the registrational program. GSK submitted regulatory applications for UMEC/VI (proposed brand name ANORO ELLIPTA) for the treatment of COPD in December 2012 in the U.S. and in January 2013 in Europe and both submissions have been accepted for review. GSK plans to make regulatory submissions in other countries during the course of 2013. Any adverse developments or results or perceived adverse developments or results with respect to these regulatory submissions or the UMEC/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 and/or other regulatory authorities 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 ELLIPTA investigational dry powder inhaler used in the program;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in this program;
- safety, efficacy or other concerns arising from clinical or non-clinical studies with FF/VI having to do with the LABA, VI, which is also a component of UMEC/VI;

- regulatory authorities determining that the Phase 3 program in COPD raises safety concerns or does not demonstrate adequate 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 has completed a Phase 2b study, a Phase 1 study in combination with fluticasone propionate (FP), an inhaled corticosteroid (ICS), and a number of Phase 3-enabling non-clinical studies. Based on the results from the Phase 2b study, GSK and Theravance plan to advance 081 monotherapy into Phase 3, and the 081/FP combination into Phase 3-enabling studies, later in 2013. 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 and/or other regulatory authorities determining that any of these studies do not demonstrate adequate safety or efficacy, or that additional non-clinical or clinical studies are required with respect to the MABA program;
- inability to gain, or delay in gaining, regulatory approval for the ELLIPTA dry powder inhaler used in the program;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in this program; or
- any change in FDA policy or guidance regarding the use of MABAs to treat COPD.

Table of Contents

On April 25, 2013 we announced our intention to separate our businesses into two independent publicly traded companies by separating our late-stage partnered respiratory assets from our biopharmaceutical operations, the process of which may divert the attention of our management and employees, may disrupt our operations, will increase our professional services expenses and is subject to other risks.

On April 25, 2013 we announced our intention to separate our businesses into two independent publicly traded companies. One company will continue to manage all development and commercial responsibilities under the LABA collaboration with GSK and associated potential royalty revenues from FF/VI (RELVAR or BREO ELLIPTA), UMEC/VI (ANORO ELLIPTA) and VI monotherapy, and the separate new company will be a biopharmaceutical company focusing on the discovery, development and commercialization of small-molecule medicines in areas of significant unmet medical need. Our ability to effect the business separation is subject to the completion of numerous tasks, including but not limited to the preparation of audited financial statements for the new company, the completion of required regulatory filings, the receipt of a private letter ruling from the Internal Revenue Service (should we determine to proceed on a tax-free basis), and obtaining the consent of third parties to the transfer of contractual rights to the new company. The failure to obtain necessary approvals and consents could delay or make impractical our plan to effect the business separation. In addition, other transactions or developments could delay, prevent the completion of, or otherwise adversely affect the planned business separation. If the business separation is delayed or not consummated for any reason, we will not realize the anticipated benefits of the business separation as expected or at all.

The process to plan for and effect the business separation will demand a significant amount of time and effort from our management and certain employees. The diversion of our management's and employees' attention to the business separation process may disrupt our operations and may adversely impact the progress of our discovery and development efforts, disrupt our relationships with collaborators and increase employee turnover.

We currently anticipate funding the new company with approximately \$300 million at separation. We expect that this initial capitalization, along with potential revenue from sales of VIBATIV®, potential future royalties that accrue to the new company (which do not include FF/VI, UMEC/VI or VI monotherapy), potential future milestone payments, and other payments under collaboration and other agreements, would fund operations through significant potential corporate milestones for two or three years after the separation based on current operating plans. Changes in our development or operating plans or the timing of the business separation, however, could affect the amount of cash available for the two companies at the time of separation and the initial cash funding needed to adequately capitalize both companies. In addition, any delays in completion of the planned separation may increase the amount of time, effort, and expense that the Company devotes to the transaction and reduce the amount of funding available to both companies.

We cannot assure you that we will not undertake additional restructuring activities, that the planned business separation will be completed or if completed will succeed, or that the actual results will not differ materially from the results that the Company anticipates.

We will incur significant expenditures for professional services in connection with our planning and implementation of the business separation, including financial advisory, accounting and legal fees.

We have not yet determined whether the planned business separation can or will be effected on a tax-free basis. If it is not effected on a tax-free basis, the business separation is expected to result in use of the Company's current net operating losses and could also result in taxation for the Company. The dividend to effect the business separation may also result in tax liability for the Company's stockholders.

Table of Contents

If VIBATIV® is not approved for nosocomial pneumonia (NP) in the U.S. or is approved but is subject to restrictive labeling, the commercialization of VIBATIV® in the U.S. may continue to be adversely affected and the price of our securities could fall.

Our first 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 studies referred to as the ATTAIN studies. These studies were conducted in accordance with the then current draft FDA guidelines and met their primary efficacy endpoint of clinical cure. During the fourth quarter of 2009 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. In late 2009, 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. While we do not plan to conduct additional clinical studies for NP, we have continued to engage with the FDA concerning the NP NDA. In late November 2012, the FDA's Anti-Infective Drugs Advisory Committee discussed the NP NDA for VIBATIV® and voted 6 (yes) and 9 (no) that the totality of the data presented provided substantial evidence of the safety and effectiveness of VIBATIV® for NP and voted 13 (yes) and 2 (no) that the totality of the data presented provided substantial evidence of the safety and effectiveness of VIBATIV® for the treatment of NP when other alternatives are not suitable. The NP NDA remains under review by the FDA. Any adverse developments or perceived adverse developments with respect to our NP NDA could adversely affect the prospects of VIBATIV® and could cause the price of our securities to fall. Lack of FDA approval for use of VIBATIV® to treat NP has adversely affected and may continue to adversely affect commercialization of this medicine in the U.S.

If we cannot locate a suitable commercialization partner for VIBATIV® in the U.S. we will need to develop the capability to market, sell and distribute the product.

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. For any of our product candidates that receive regulatory approval in the future and are not covered by our current agreements with GSK or another partner, we will need a partner in order to commercialize such products unless we establish independent sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure. VIBATIV® was returned to us by Astellas (our former VIBATIV® collaboration partner) in January 2012, and if we cannot locate a suitable commercialization partner in the U.S. for this product, we intend to reintroduce it in the U.S. ourselves. At present, we have no sales or distribution personnel and a limited number of marketing personnel. The risks of commercializing VIBATIV® in the U.S. without a partner include:

- significant costs and expenses associated with creating an independent sales and marketing organization with appropriate technical expertise and supporting infrastructure and distribution capability, which costs and expenses are likely to exceed any product revenue from VIBATIV® for several years;
- 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; and

Edgar Filing: THERAVANCE INC - Form 10-Q

- 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.

If we are not able to partner VIBATIV® in the U.S. with a third party with marketing, sales and distribution capabilities and if we are not successful in recruiting sales and marketing personnel or in building an internal sales and marketing organization with appropriate technical expertise and supporting infrastructure and distribution capability, we will have difficulty commercializing VIBATIV® in the U.S., which would adversely affect our business and financial condition and which could cause the price of our securities to fall.

Table of Contents

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 non-clinical 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 non-clinical and clinical studies as a condition to regulatory approval. Non-clinical 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 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 non-clinical 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 regulatory requirements or interpretations of data among the FDA and foreign regulatory authorities; and
- a regional disturbance where we or our collaborative partners are enrolling patients in 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 with collaborative partners are not approved by regulatory authorities, 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 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.

Table of Contents

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 or non-clinical studies. In addition, clinical and non-clinical studies of potential products often reveal that it is not possible or practical to continue development efforts for these product candidates. If these 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.

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 product, VIBATIV®, is approved in the U.S. and Canada, none of our other product candidates have been approved by regulatory authorities. We are uncertain whether any of our other product candidates and our collaborative partners' 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. In addition, although we believe the results of our Phase 2b program with TD-1211, our investigational mu-opioid antagonist, support progression into Phase 3 development, the FDA appears to be exploring whether there is evidence of a potential cardiovascular class effect related to opioid withdrawal associated with mu-opioid antagonists. Accordingly, we are currently evaluating our Phase 3 strategy due to the potentially evolving FDA requirements in this area. The data supporting our drug discovery and development programs is derived solely from laboratory experiments, non-clinical 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 several years, as well as growing public and governmental scrutiny of safety issues, have created a 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 laws, regulations, additional requirements and changes in interpretation could cause non-approval or further delays in the FDA's review and approval of our and our collaborative partner's product candidates.

There currently is no reliable manufacturer for VIBATIV® drug product supply and our business will be harmed if a reliable source of VIBATIV® drug product is not qualified and engaged on a timely basis; we also rely on a single source of supply for a number of our product candidates, and our business will be harmed if any of these other single-source manufacturers are not able to satisfy demand and alternative sources are not available.

During the fourth quarter of 2011, the former third party manufacturer of VIBATIV® drug product notified the FDA of an ongoing investigation related to its production equipment and processes. The notification included all products manufactured at the third party manufacturer's facility which remain within expiry, including batches of manufactured but unreleased VIBATIV®. In November 2011, Astellas (our former

Edgar Filing: THERAVANCE INC - Form 10-Q

VIBATIV® collaboration partner) voluntarily placed a hold on distribution of VIBATIV® to wholesalers, and cancelled pending orders for VIBATIV® with this manufacturer. In January 2013 the former third party manufacturer announced that it had voluntarily entered into a consent decree with the FDA that relates to current Good Manufacturing Practice (cGMP) requirements. In April 2013, we were advised by the FDA that its consent decree with the manufacturer prohibited the distribution of the VIBATIV® drug product lots previously manufactured but unreleased by this manufacturer. Consequently, this previously manufactured but unreleased VIBATIV® drug product will not become available for sale in the U.S. and our prior purchase orders for this inventory cannot be fulfilled. Additional VIBATIV® drug product will need to be manufactured to meet U.S. demand as well as demand from the E.U. and Canada. In May 2012 the European Commission suspended marketing authorization for VIBATIV® because the single-source VIBATIV® drug product supplier at that time did not meet cGMP requirements for the manufacture of VIBATIV®. No VIBATIV® drug product intended to meet E.U. specifications has as yet been manufactured.

Table of Contents

If commercial manufacture of VIBATIV® drug product cannot be arranged on a timely basis, the commercialization of VIBATIV® in the U.S. will continue to be adversely affected and the commercial introduction of VIBATIV® in the E.U. and Canada will be further delayed. In each such case, our business will be harmed and the price of our securities could fall. In May 2012, we entered into a Technology Transfer and Supply Agreement with Hospira and technology transfer activities are in process. We must obtain regulatory approval for VIBATIV® drug product manufactured at Hospira's facility before any such product may be sold, and this regulatory approval process could extend through mid-2013 and beyond.

We have a single source of supply of telavancin API. If, for any reason, the single-source third party manufacturer of telavancin API is unable or unwilling to perform, or if its performance does not meet regulatory requirements, including maintaining cGMP compliance, we may not be able to locate alternative manufacturers, enter into acceptable agreements with them or obtain sufficient quantities of API in a timely manner. Any inability to acquire sufficient quantities of API in a timely manner from current or future sources could further adversely affect the commercialization of VIBATIV® and could cause the price of our securities to fall.

With respect to our programs other than VIBATIV®, we have limited in-house production capabilities for non-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 acceptable 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, validation and regulatory qualification activities for the new manufacturer. For example, we are in the process of transitioning to a new drug product manufacturer for VIBATIV®, and delays in technology transfer, validation and regulatory qualification activities could be encountered;
- 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 U.S. labeling for cSSSI 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. In addition, the VIBATIV® labeling that was approved for the E.U. in 2011 specifies that VIBATIV® should be used only in situations where it is known or suspected that other alternatives are not suitable. These restrictions could make it more difficult to market VIBATIV®. In May 2012 the European Commission suspended marketing authorization for VIBATIV® because the single-source VIBATIV® drug product supplier at that time did not meet the cGMP requirements for the manufacture of VIBATIV®. With VIBATIV® approved in certain countries, we are 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 authority 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 fourth quarter of 2011, the third party manufacturer of VIBATIV® drug product notified the FDA of an ongoing investigation related to its production equipment and processes. The notification included all products manufactured at the third party manufacturer's facility which remain within expiry, including batches of manufactured but unreleased VIBATIV®. Astellas (our former VIBATIV® collaboration partner) subsequently placed a voluntary hold on distribution of VIBATIV® to wholesalers and cancelled pending orders for VIBATIV® with this manufacturer. In April 2013, we were advised by the FDA that its consent decree with the manufacturer prohibited the distribution of the VIBATIV® drug product lots previously manufactured but unreleased by this manufacturer. Consequently, this previously manufactured but unreleased VIBATIV® drug product will not become available for sale in the U.S. and our prior purchase orders for this inventory cannot be fulfilled. With this supply termination and the termination of our VIBATIV® collaboration agreement with Astellas, commercialization of VIBATIV® has essentially stopped, we have experienced a significant drop in the sales of the product and the reputation of VIBATIV® in the marketplace will likely suffer.

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 non-clinical 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 the price of our securities to fall.

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

We have been engaged in discovering and developing compounds and product candidates since mid-1997. We may never generate sufficient revenue from the sale of medicines or royalties on sales by our partners to achieve profitability. As of March 31, 2013, we had an accumulated deficit of approximately \$1.4 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. For example, TD-9855 in our MARIN program is in Phase 2 studies for both attention-deficit/hyperactivity disorder (ADHD) and fibromyalgia and our LAMA compound TD-4208 commenced a Phase 2b study in December 2012. Also, in July 2012, we announced positive results from the key study in our Phase 2b program with TD-1211 in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation. Though we seek to partner this program, we may choose to progress TD-1211 into Phase 3 studies by ourselves, which would increase our operating expenses substantially. Furthermore, should we decide to commercialize VIBATIV® in the United States without a partner, we will incur significant costs and expenses associated with creating an independent sales and marketing organization with appropriate technical expertise, supporting infrastructure and distribution capabilities. 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 or commercialize VIBATIV® and we could be forced to share our rights to commercialize our product candidates with third parties on terms that may not be favorable to us.

We need large amounts of capital to support our research and development efforts. If we are unable to secure capital to fund our operations we will not be able to continue our discovery and development efforts and we might have to enter into strategic collaborations that could require us to share commercial rights to our medicines to a greater extent than we currently intend. Based on our current operating plans, 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. If our current operating plans, milestone and royalty forecasts or spending assumptions change, we may seek additional funding sooner in the form of public or private equity offerings or debt financings. For example, if we chose to conduct Phase 3 studies with TD-1211 in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation by ourselves our capital needs would increase substantially. In addition, we initiated two Phase 2 studies with TD-9855 in the MARIN program and a Phase 2b study with our LAMA compound, TD-4208. We also intend to invest in other assets in our pipeline, including programs in earlier-stage clinical development and late-stage discovery. In addition, under our LABA collaboration with GSK, in the event that a product containing

Table of Contents

vilanterol (VI), which is the LABA product candidate in FF/VI, UMEC/VI and UMEC/VI/FF 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 will not be entitled to receive any further milestone payments from GSK. Of these potential milestone payments, we estimate up to \$140.0 million could be payable during 2013 and all the milestone payments could be payable by the end of 2014. 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 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.

VIBATIV® may not be accepted by physicians, patients, third party payors, or the medical community in general, and this risk is aggravated by the current critical product shortages and regional supply outages and the suspension of marketing authorization in the European Union.

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 restrict the use of VIBATIV® due to the current product shortages stemming from the manufacturing issues at the previous drug product supplier, the January 2012 termination of our VIBATIV® collaboration agreement with Astellas, or otherwise. If we 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.;

- potential negative perceptions of physicians related to our inability to obtain FDA approval of our NP NDA, the product shortages and regional supply outages stemming from the manufacturing issues at the previous drug product supplier or the termination of our VIBATIV® collaboration agreement with Astellas in January 2012;

- potential negative perceptions of physicians related to the European Commission's suspension of marketing authorization for VIBATIV® because the previous single-source VIBATIV® drug product supplier did not meet the cGMP requirements for the manufacture of VIBATIV®;

- the advantages and disadvantages of VIBATIV® compared to alternative therapies;

- our 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.

If our partners do not satisfy their obligations under our agreements with them, or if they terminate our partnerships with them, we may not be able to develop or commercialize 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 VIBATIV® collaboration agreement with Astellas in November 2005, which was terminated by Astellas in January 2012. In October 2012, we entered into an exclusive development and commercialization agreement with Alfa Wassermann for velusetrag, our lead compound in the 5-HT₄ program, covering the EU, Russia, China, Mexico and certain other countries, and we entered into a research collaboration and license agreement with Merck to discover, develop and commercialize novel small molecule therapeutics for the treatment of cardiovascular disease on an exclusive, worldwide basis. In March 2013, we entered into a commercialization agreement with Clinigen Group plc for VIBATIV® in the European Union and certain other European countries (including Switzerland and Norway). In connection with these agreements, we have granted to these parties

Table of Contents

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 FF/VI, UMEC/VI, UMEC/VI/FF, VI monotherapy and any product candidates in the MABA program. Any future milestone payments or royalties to us from these programs will depend on the extent to which GSK advances the product candidate through development and, if approved, commercialization. The Merck and Alfa Wassermann agreements provide us with research and development funding, respectively, for the programs under license, and if either partner decides not to progress the licensed program, we may not be able to develop or commercialize the program on our own.

Our partners might not fulfill all of their obligations under these agreements, and, in certain circumstances, they may terminate our partnership with them, as Astellas did in January 2012. 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. 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, Astellas terminated the VIBATIV® collaboration agreement in January 2012, and due to the termination, current product shortages, regional supply outages and suspension of marketing authorization in the European Union stemming from the manufacturing issues at the previous third party VIBATIV® drug product supplier, the commercialization of VIBATIV® in the U.S. has essentially stopped and the commercial introduction of VIBATIV® in the E.U. and Canada has been delayed.

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 FF/VI, UMEC/VI, UMEC/VI/FF, VI monotherapy and the MABA program, with Alfa Wassermann for velusetrag, with Merck for novel small molecule therapeutics for the treatment of cardiovascular disease, with Clinigen for VIBATIV® and with R-Pharm CJSC for VIBATIV® and TD-1792, our investigational antibiotic. Additional collaborations will be needed to fund later-stage development of our product candidates that have not been licensed to a collaborator or for territory that is not covered by the collaboration, and to commercialize these product candidates if approved by the necessary regulatory authorities. Each of velusetrag, our lead compound in the 5-HT4 program, TD-1792, our investigational antibiotic and TD-4208, our LAMA compound, has successfully completed a Phase 2 proof-of-concept study, and in July 2012 we reported positive results from a Phase 2b study with TD-1211, the lead compound in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation. In addition, in connection with the expansion of the MABA program under the strategic alliance with GSK in October 2011, GSK relinquished its right to option our MARIN and ARNI programs. We currently intend to seek additional third parties with which to pursue collaboration arrangements for the development and commercialization of our development programs and for the future commercialization of VIBATIV® in regions where it is not currently partnered. 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 the price of our securities to fall.

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 non-clinical and clinical studies for our product candidates. We rely heavily on these parties for execution of our non-clinical 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 authorities, 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.

Table of Contents

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:

- 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.

Table of Contents

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 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 qualified personnel or replace them when they leave, we may be unable to continue our development and commercialization activities, which may cause the price of our securities to fall.

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. Any material system failure, accident or security breach 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.

Edgar Filing: THERAVANCE INC - Form 10-Q

As of April 25, 2013, GSK beneficially owned approximately 26.7% 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.

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 is greater than 50.1%, then 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 significant ownership position and its rights under the governance agreement may deter or prevent efforts by other companies to acquire us, which could prevent our stockholders from realizing a control premium.

As of April 25, 2013, GSK beneficially owned approximately 26.7% of our outstanding capital stock. GSK may vote at its sole discretion on any proposal to effect a change of control of us or for us to issue equity securities to one or more parties that would result in that party or parties beneficially owning more than 20% of our outstanding capital stock. 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. As a result of GSK's significant ownership and its rights under the governance agreement, 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.

Under our governance agreement with GSK, GSK could previously sell or transfer our common stock only pursuant to a public offering registered under the Securities Act or pursuant to Rule 144 of the Securities Act. GSK no longer has contractual 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 March 31, 2013, we owned 341 issued United States patents and 1,213 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 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.

Table of Contents

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 the price of our securities to fall.

If the efforts of our partner, GSK, to protect the proprietary nature of the intellectual property related to the assets in the LABA collaboration 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.

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. 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.

Edgar Filing: THERAVANCE INC - Form 10-Q

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.

Table of Contents

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 the price of our securities to fall.

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

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical, biological and radioactive materials. In addition, our operations produce hazardous waste products. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. 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 companies' operating performance, in particular during the last several 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 development of FF/VI with GSK, including, without limitation, any difficulties or delays encountered with regard to the regulatory path for FF/VI or any indication from clinical or non-clinical studies, including the large Phase 3b program, that FF/VI is not safe or efficacious (for example, the negative investor reaction to the topline results from the Phase 3 registrational programs for FF/VI announced in early 2012);
- any adverse developments or results or perceived adverse developments or results with respect to the development of UMEC/VI with GSK, including, without limitation, any difficulties or delays encountered with regard to the regulatory path for UMEC/VI, or any indication from clinical or non-clinical studies that UMEC/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 further delays encountered in commencing the single-agent Phase 3 program, any difficulties or delays encountered with regard to the regulatory path for 081, such as the 081/FF Phase 3-enabling studies planned for 2013 or any indication from non-clinical studies of 081 that the compound is not safe or efficacious;

Table of Contents

- any further adverse developments with respect to the commercialization of VIBATIV®, including, without limitation, the uncertainties surrounding drug product manufacture and supply, difficulties that may be encountered by Hospira in technology transfer activities and how, when and where VIBATIV® will be commercialized;

- any further adverse developments or perceived adverse developments with respect to our telavancin NP NDA, including, without limitation, adverse developments or perceived adverse developments with regard to the label for VIBATIV® if it is approved for NP;

- 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);

- GSK's decisions whether or not to purchase, on a quarterly basis, sufficient shares of our common stock to maintain its ownership percentage taking into account our preceding quarter's option exercise and equity vesting activity;

- any announcements of developments with, or comments by, the FDA or other regulatory authorities with respect to products we or our partners have under development or have commercialized;

- our incurrence of expenses in any particular quarter that are different than market expectations;

- the extent to which GSK advances (or does not advance) FF/VI, UMEC/VI, UMEC/VI/FF, VI monotherapy and the MABA program through development into commercialization in all indications in all major markets;

- 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;

- any adverse developments or perceived adverse developments with respect to our relationship with any of our research, development or commercialization partners other than GSK, including, without limitation, disagreements that may arise between us and any of those partners;

- any adverse developments or perceived adverse developments with respect to our partnering efforts with VIBATIV®, velusetrag, TD-1211, our MARIN and ARNI programs, TD-1792 or TD-4208;

Edgar Filing: THERAVANCE INC - Form 10-Q

- announcements regarding GSK generally;
- announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors;
- developments concerning any collaboration we undertake with companies other than GSK;
- 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;

Table of Contents

- relative illiquidity in the public market for our common stock (our three largest stockholders other than GSK collectively owned approximately 34.3% of our outstanding capital stock as of April 25, 2013 based on our review of publicly available filings);
- any adverse developments or perceived adverse developments with respect to the proposed business separation and
- potential sales or purchases of our capital stock by GSK.

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

As of April 25, 2013, GSK beneficially owned approximately 26.7% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 5.5% of our outstanding capital stock. Based on our review of publicly available filings as of April 25, 2013, our three largest stockholders other than GSK collectively owned approximately 34.3% 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 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 February 15, 2013, we completed the sale of 116,527 shares of our common stock to Glaxo Group Limited, an affiliate of GSK, at a price of \$22.03 per share, resulting in aggregate gross proceeds of \$2.6 million before deducting transaction expenses. Neither we nor the affiliate of GSK engaged any investment advisors with respect to the sale and no underwriting discounts or commissions 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****(a) Index to Exhibits**

Exhibit Number	Description	Form	Incorporated by Reference Filing Date/Period End Date
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 the registrant 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 the registrant 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
4.6	Indenture dated as of January 24, 2013 by and between the registrant and The Bank of New York Mellon Trust Company, N.A., as trustee	8-K	1/25/13
4.7	Form of 2.125% Convertible Subordinated Note Due 2023 (included in Exhibit 4.6)		
10.40	Base Capped Call Transaction dated January 17, 2013	8-K	1/23/13
10.41	Additional Capped Call Transaction dated January 18, 2013	8-K	1/23/13
10.42(+)	Commercialization Agreement with Clinigen Group plc dated March 8, 2013		
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		

101* The following from the registrant's Quarterly Report on Form 10-Q for the period ended March 31, 2013, formatted in Extensible Business Reporting Language (XBRL) includes: (i) the Condensed Consolidated Statements of Operations for the three months ended March 31, 2013 and 2012, (ii) the Condensed Consolidated Balance Sheets as of March 31, 2013 and December 31, 2012, (iii) the Condensed Consolidated Statements of Comprehensive Income (Loss) for the three months ended March 31, 2013 and 2012, (iv) the Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2013 and 2012, and (v) Notes to Condensed Consolidated Financial Statements.

+ Application has been made to the Securities and Exchange Commission to seek confidential treatment of certain provisions. Omitted material for which confidential treatment has been requested has been filed separately with the Securities and Exchange Commission.

* XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Exchange Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

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)

May 1, 2013
Date

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

May 1, 2013
Date

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