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# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, D.C. 20549**

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended March 31, 2014**

**OR**

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

**For the transition period from to**

**Commission File Number: 0-30319**

# THERAVANCE, INC.
(Exact Name of Registrant as Specified in its Charter)

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

**901 Gateway Boulevard**
**South San Francisco, CA 94080**
(Address of Principal Executive Offices)

**(650) 808-6000**
(Registrant's Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant 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 x No o

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 x | Accelerated filer o |
| Non-accelerated filer o (Do not check if a smaller reporting company) | Smaller reporting company o |

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

The number of shares of registrant's common stock outstanding on April 30, 2014 was 112,633,882.

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## PART I — FINANCIAL INFORMATION

### Item 1. Financial Statements

**THERAVANCE, INC.**
**CONDENSED CONSOLIDATED BALANCE SHEETS**
(In thousands, except per share data)

| | March 31, 2014 (Unaudited) | December 31, 2013 * |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 125,275 | $ 143,510 |
| Short-term investments | 245,648 | 321,615 |
| Accounts receivable, net of allowances of $209 and $89 at March 31, 2014 and December 31, 2013 | 3 | 199 |
| Receivables from collaborative arrangements (including amounts from a related party of $775 and $2,247 at March 31, 2014 and December 31, 2013) | 865 | 3,181 |
| Prepaid expenses and other current assets | 6,391 | 4,287 |
| Inventories | 11,014 | 10,406 |
| Total current assets | 389,196 | 483,198 |
| Marketable securities | 59,831 | 55,374 |
| Restricted cash | 833 | 833 |
| Property and equipment, net | 9,734 | 10,238 |
| Intangible assets, net | 137,477 | 124,257 |
| Other assets | 7,963 | 7,355 |
| Total assets | $ 605,034 | $ 681,255 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 5,546 | $ 7,583 |
| Payable to a related party | — | 40,000 |
| Accrued personnel-related expenses | 13,829 | 10,881 |
| Accrued clinical and development expenses | 9,890 | 9,714 |
| Accrued interest on convertible subordinated notes | 1,273 | 2,800 |
| Other accrued liabilities | 4,792 | 4,137 |
| Deferred revenue, current | 8,814 | 9,289 |
| Total current liabilities | 44,144 | 84,404 |
| Convertible subordinated notes | 287,500 | 287,500 |
| Deferred rent | 4,891 | 4,774 |
| Deferred revenue | 5,247 | 5,455 |
| Commitments and contingencies (Notes 3, 8 and 10) | | |
| Stockholders' equity: | | |
| Common stock, $0.01 par value; authorized: 200,000 shares; outstanding: 112,519 and 111,516 at March 31, 2014 and December 31, 2013 | 1,125 | 1,115 |
| Additional paid-in capital | 1,834,862 | 1,803,048 |
| Accumulated other comprehensive income | 171 | 162 |

| | | |
|---|---|---|
| Accumulated deficit | (1,572,906) | (1,505,203) |
| Total stockholders' equity | 263,252 | 299,122 |
| Total liabilities and stockholders' equity | $ 605,034 | $ 681,255 |

* Condensed consolidated balance sheet at December 31, 2013 has been derived from audited consolidated financial statements.

*See accompanying notes to condensed consolidated financial statements.*



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**THERAVANCE, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**
(In thousands, except per share data)
(Unaudited)

| | Three Months Ended March 31, | |
|---|---|---|
| | 2014 | 2013 |
| Revenue: | | |
| Product sales | $ 945 | $ — |
| Royalty revenue from a related party, net of intangible assets amortization of $1,780 and $0 for the three months ended March 31, 2014 and 2013 (Note 3) | (1,050) | — |
| Net revenue from collaborative arrangements (including amounts from a related party of $270 and $1,322 for the three months ended March 31, 2014 and 2013) | 270 | 1,344 |
| Total net revenue | 165 | 1,344 |
| Costs and expenses: | | |
| Cost of goods sold | 188 | — |
| Research and development | 43,387 | 26,416 |
| Selling, general and administrative | 22,834 | 8,315 |
| Total costs and expenses | 66,409 | 34,731 |
| Loss from operations | (66,244) | (33,387) |
| Other income (expense), net | (3) | (1,422) |
| Interest income | 188 | 185 |
| Interest expense | (1,644) | (2,736) |
| Net loss | $ (67,703) | $ (37,360) |
| Basic and diluted net loss per share | $ (0.62) | $ (0.39) |
| Shares used to compute basic and diluted net loss share | 109,859 | 96,379 |

*See accompanying notes to condensed consolidated financial statements.*



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**THERAVANCE, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**
(In thousands, except per share data)
(Unaudited)

| | Three Months Ended March 31, | |
|---|---|---|
| | 2014 | 2013 |
| Net loss | $ (67,703) | $ (37,360) |
| Other comprehensive income (loss): | | |
| Net unrealized gain (loss) on available-for-sale securities, net of tax | 9 | (7) |
| Comprehensive loss | $ (67,694) | $ (37,367) |

*See accompanying notes to condensed consolidated financial statements.*



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**THERAVANCE, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**
(In thousands)
(Unaudited)

| | Three Months Ended March 31, | |
|---|---|---|
| | 2014 | 2013 |
| **Cash flows from operating activities** | | |
| Net loss | $ (67,703) | $ (37,360) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 3,400 | 1,898 |
| Stock-based compensation | 13,535 | 6,095 |
| Change in fair value of capped-call derivative assets | — | 1,422 |
| Other non-cash items | (2) | (1) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (178) | — |
| Receivables from collaborative arrangements | 2,316 | (1,153) |
| Prepaid expenses and other current assets | (2,132) | (1,224) |
| Inventories | (430) | (2,481) |
| Other assets | (998) | — |
| Accounts payable | (1,174) | (221) |
| Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued liabilities | 4,448 | (3,176) |
| Accrued interest on convertible subordinated notes | (1,527) | (174) |
| Deferred rent expense | 116 | (202) |
| Deferred revenue | (308) | 4,946 |
| Net cash used in operating activities | (50,637) | (31,631) |
| | | |
| **Cash flows from investing activities** | | |
| Purchases of property and equipment | (1,620) | (740) |
| Purchases of available-for-sale securities | (56,649) | (104,125) |
| Maturities of available-for-sale securities | 122,399 | 54,753 |
| Sales of available-for-sale securities | 5,000 | 5,000 |
| Increase in intangible assets | (55,000) | — |
| Payments received on notes receivable | — | 100 |
| Net cash provided by (used in) investing activities | 14,130 | (45,012) |
| | | |
| **Cash flows from financing activities** | | |
| Proceeds from issuances of common stock, net | 18,272 | 2,991 |
| Purchase of capped-call options | — | (36,800) |
| Proceeds from issuances of convertible subordinated notes, net of debt issuance costs | — | 281,673 |
| Net cash provided by financing activities | 18,272 | 247,864 |
| | | |
| Net increase (decrease) in cash and cash equivalents | (18,235) | 171,221 |
| Cash and cash equivalents at beginning of period | 143,510 | 94,849 |
| Cash and cash equivalents at end of period | $ 125,275 | $ 266,070 |

*See accompanying notes to condensed consolidated financial statements.*



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**THERAVANCE, INC.**
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
(Unaudited)

**1. Description of Operations and Summary of Significant Accounting Policies**

***Description of Operations***

Theravance, Inc. (Theravance, the Company, the Registrant or we and other similar pronouns) 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 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 our opinion, 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 our financial position, results of operations, comprehensive 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, 2014 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, 2013 filed with the Securities and Exchange Commission (SEC) on March 3, 2014.

***Business Separation***

In April 2013, Theravance announced that its Board of Directors approved plans to separate its businesses into two independent publicly traded companies. The company to be spun-off, Theravance Biopharma, Inc. (Theravance Biopharma), filed an initial Form 10 with the SEC on August 1, 2013 and filed amendments of its Form 10 with the SEC on September 27, 2013, October 29, 2013, November 22, 2013, April 8, 2014, April 30, 2014 and May 7, 2014. After the spin-off, Theravance will be responsible for all development and commercial activities under the LABA collaboration and the Strategic Alliance agreements with Glaxo Group Limited (GSK). Theravance will be eligible to receive the associated potential royalty revenues from RELVAR®/BREO® ELLIPTA® (fluticasone furoate/vilanterol, "FF/VI"), ANORO™ ELLIPTA™ (umeclidinium bromide/vilanterol, "UMEC/VI") and potentially VI monotherapy and 15% of the potential royalty revenues from UMEC/VI/FF, MABA (Bifunctional Muscarinic Antagonist-Beta2 Agonist), and MABA/FF and other products that may be developed under the LABA collaboration and Strategic Alliance agreements. Theravance Biopharma will be a biopharmaceutical company focused on discovery, development and commercialization of small-molecule medicines in areas of significant unmet medical need. The result will be two independent, publicly traded companies with different business models enabling investors to align their investment philosophies with the strategic opportunities and financial objectives of the two independent companies. The condensed consolidated financial statements do not reflect any adjustments resulting from the planned business separation.

***Inventories***

Inventories consist of raw materials, work-in-process and finished goods related to the production of VIBATIV® (telavancin). Raw materials include VIBATIV® active pharmaceutical ingredient (API) and other raw materials. Work-in-process and finished goods include third party manufacturing costs and labor and indirect costs we incur 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, we 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. We determine the cost of inventory using the average-cost method for validation batches. We analyze our inventory levels quarterly and write down any inventory that is expected to become obsolete, that has a cost basis in excess of its expected net realizable value or for inventory quantities in excess of expected requirements.



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***Revenue Recognition***

Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. Determination of criteria (3) and (4) are based on management's judgments regarding the nature of the fee charged for products or services delivered and the collectability of those fees. Where the revenue recognition criteria are not met, we defer the recognition of revenue by recording deferred revenue until such time that all criteria are met.

*Collaborative Arrangements and Multiple-Element Arrangements*

Revenue from nonrefundable, up-front license or technology access payments under license and collaborative arrangements that are not dependent on any future performance by us is recognized when such amounts are earned. If we have continuing obligations to perform under the arrangement, such fees are recognized over the estimated period of continuing performance obligation.

We account for multiple element arrangements, such as license and development agreements in which a customer may purchase several deliverables, in accordance with FASB ASC Subtopic 605-25, "Multiple Element Arrangements." For new or materially amended multiple element arrangements, we identify the deliverables at the inception of the arrangement and each deliverable within a multiple deliverable revenue arrangement is accounted for as a separate unit of accounting if both of the following criteria are met: (1) the delivered item or items have value to the customer on a standalone basis and (2) for an arrangement that includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in our control. We allocate revenue to each non-contingent element based on the relative selling price of each element. When applying the relative selling price method, we determine the selling price for each deliverable using vendor-specific objective evidence ("VSOE") of selling price, if it exists, or third-party evidence ("TPE") of selling price, if it exists. If neither VSOE nor TPE of selling price exist for a deliverable, we use the best estimated selling price for that deliverable. Revenue allocated to each element is then recognized based on when the basic four revenue recognition criteria are met for each element.

For multiple-element arrangements entered into prior to January 1, 2011, we determined the delivered items under our collaborative arrangements did not meet the criteria to be considered separate accounting units for the purposes of revenue recognition. As a result, we recognized revenue from non-refundable, upfront fees and development contingent payments in the same manner as the final deliverable, which is ratably over the expected term of our performance of R&D services under the agreements. These upfront or contingent payments received, pending recognition as revenue, are recorded as deferred revenue and are classified as a short-term or long-term liability on the consolidated balance sheets and recognized over the estimated period of performance. We periodically review the estimated performance periods of our contracts based on the progress of our programs.

Where a portion of non-refundable upfront fees or other payments received are allocated to continuing performance obligations under the terms of a collaborative arrangement, they are recorded as deferred revenue and recognized as revenue or as an accrued liability and recognized as a reduction of research and development expenses ratably over the term of our estimated performance period under the agreement. We determine the estimated performance periods, and they are periodically reviewed based on the progress of the related program. The effect of any change made to an estimated performance period and, therefore revenue recognized, would occur on a prospective basis in the period that the change was made.

Under certain collaborative arrangements, we have been reimbursed for a portion of our research and development expenses. These reimbursements have been reflected as a reduction of research and development expense in our consolidated statements of operations, as we do not consider performing research and development services to be a part of our ongoing and central operations. Therefore, the reimbursement of research and developmental services and any amounts allocated to our research and development services are recorded as a reduction of research and development expense.

Amounts deferred under a collaborative arrangement in which the performance obligations are terminated will result in an immediate recognition of any remaining deferred revenue and accrued liability in the period that termination occurred, provided that there are no remaining performance obligations.

We account for contingent payments in accordance with FASB Subtopic ASC 605-28 "Revenue Recognition—Milestone Method." We recognize revenue from milestone payments when (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement and (ii) we do not have ongoing performance obligations related to the achievement of the milestone. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment (a) is commensurate with either our performance to achieve the milestone or the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from our performance to achieve the milestone, (b) relates solely to past



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performance, and (c) is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

Under our collaborative arrangements with GSK, and in accordance with FASB Subtopic ASC 808-10, "Collaborative Arrangements," royalty revenue earned is reduced by amortization expense resulting from the fees paid to GSK, which were capitalized as finite-lived intangible assets. When amortization expense exceeds amounts recognized for royalty revenues from GSK, negative revenue would be reported in our consolidated statements of operations.

*Product Revenues*

We sell VIBATIV® in the U.S. through a limited number of distributors, and title and risk of loss transfer upon receipt by these distributors. Healthcare providers order VIBATIV® through these distributors. Commencing in the first quarter of 2014, we record revenue on the sale of VIBATIV® on a sell-through basis, once the distributors sell the product to healthcare providers.

Product sales are recorded net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions. We reflect such reductions in revenue as either an allowance to the related account receivable from the distributor, or as an accrued liability, depending on the nature of the sales deduction. Sales deductions are based on management's estimates that consider payer mix in target markets, industry benchmarks and experience to date. We monitor inventory levels in the distribution channel, as well as sales of VIBATIV® by distributors to healthcare providers, using product-specific data provided by the distributors. Product return allowances are based on amounts owed or to be claimed on related sales. These estimates take into consideration the terms of our agreements with customers, historical product returns of VIBATIV® experienced by our former collaborative partner, Astellas, rebates or discounts taken, estimated levels of inventory in the distribution channel, the shelf life of the product, and specific known market events, such as competitive pricing and new product introductions. We update our estimates and assumptions each quarter and if actual future results vary from our estimates, we may adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment.

*Sales Discounts:* We offer cash discounts to our customers, generally 2% of the sales price, as an incentive for prompt payment. We expect our customers to comply with the prompt payment terms to earn the cash discount. We account for cash discounts by reducing accounts receivable by the full amount and recognizing the discount as a reduction of revenue in the same period the related revenue is recognized.

*Chargebacks and Government Rebates:* For VIBATIV® sales in the U.S., we estimate reductions to product sales for qualifying federal and state government programs including discounted pricing offered to Public Health Service (PHS) as well as government-managed Medicaid programs. Our reduction for PHS is based on actual chargebacks that distributors have claimed for reduced pricing offered to such health care providers. Our accrual for Medicaid is based upon statutorily-defined discounts, estimated payer mix, expected sales to qualified healthcare providers, and our expectation about future utilization. The Medicaid accrual and government rebates that are invoiced directly to us are recorded in other accrued liabilities on the consolidated balance sheet. For qualified programs that can purchase our products through distributors at a lower contractual government price, the distributors charge back to us the difference between their acquisition cost and the lower contractual government price, which we record as an allowance against accounts receivable.

*Distribution Fees and Product Returns:* We have written contracts with our distributors that include terms for distribution-related fees. We record distribution-related fees based on a percentage of the product sales price. We offer our distributors a right to return product purchased directly from us, which is principally based upon the product's expiration date. Additionally, we have granted more expansive return rights to our distributors following our product launch of VIBATIV®. We will generally accept returns for expired product during the six months prior to and twelve months after the product expiration date on product that had been sold to our distributors. Product returned is generally not resalable given the nature of our products and method of administration. We have developed estimates for VIBATIV® product returns based upon historical VIBATIV® sales from our former collaborative partner, Astellas. We record distribution fees and product returns as an allowance against accounts receivable.

*Allowance for Doubtful Accounts:* We maintain a policy to record allowances for potentially doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. As of March 31, 2014 and December 31, 2013, there was no allowance for doubtful accounts.

*Royalties*

We recognize royalty revenue on licensee net sales of our products in the period in which the royalties are earned and reported to us and collectability is reasonably assured.



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***Intangible Assets***

We capitalize fees paid to licensors related to agreements for approved products or commercialized products. We capitalize these fees as finite-lived intangible assets and amortize these intangible assets on a straight-line basis over their estimated useful lives upon the commercial launch of the product, which is expected to be shortly after regulatory approval of such product. The estimated useful lives of these intangible assets are based on a country-by-country and product-by-product basis, as the later of the expiration or termination of the last patent right covering the compound in such product in such country and 15 years from first commercial sale of such product in such country, unless the agreement is terminated earlier. Consistent with our policy for classification of costs under the research and development collaborative arrangements, the amortization of these intangible assets will be recognized as a reduction of royalty revenue. We review our intangible assets for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. The recoverability of finite-lived intangible assets is measured by comparing the asset's carrying amount to the expected undiscounted future cash flows that the asset is expected to generate. The determination of recoverability typically requires various estimates and assumptions, including estimating the useful life over which cash flows will occur, their amount, and the asset's residual value, if any. We derive the required cash flow estimates from near-term forecasted product sales and long-term projected sales in the corresponding market.

**2. Net Loss per Share**

Basic net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding, less RSAs subject to forfeiture. Diluted net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding, less RSAs subject to forfeiture, plus all additional common shares that would have been outstanding, assuming dilutive potential common shares had been issued for other dilutive securities.

For the three months ended March 31, 2014 and 2013, diluted and basic net loss per share were identical since potential common shares were excluded from the calculation, as their effect was anti-dilutive.

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

| | Three Months Ended March 31, | |
|---|---|---|
| (In thousands, except per share data) | 2014 | 2013 |
| **Numerator:** | | |
| Net loss | $ (67,703) | $ (37,360) |
| | | |
| **Denominator:** | | |
| Weighted-average shares of stock outstanding | 112,052 | 99,181 |
| Less: unvested RSAs | (2,193) | (2,802) |
| Weighted-average shares used to compute basic and diluted net loss per share | 109,859 | 96,379 |
| | | |
| **Net loss per share:** | | |
| Basic and diluted net loss per share | $ (0.62) | $ (0.39) |

***Anti-Dilutive Securities***

The following common equivalent shares were not included in the computation of diluted net loss per share because their effect was anti-dilutive:

| | Three Months Ended March 31, | |
|---|---|---|
| (In thousands) | 2014 | 2013 |
| Shares issuable under equity incentive plans and ESPP | 3,211 | 5,469 |
| Shares issuable upon the conversion of convertible subordinated notes | 2,780 | 14,256 |
| Total anti-dilutive securities | 5,991 | 19,725 |



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**3. Collaborative Arrangements**

***Net Revenue from Collaborative Arrangements***

We recognized net revenue from collaborative arrangements as follows:

| | Three Months Ended March 31, | |
|---|---|---|
| (In thousands) | 2014 | 2013 |
| GSK | $ (780) | $ 1,322 |
| Other | — | 22 |
| Net revenue from collaborative arrangements | $ (780) | $ 1,344 |

***GSK***

*LABA Collaboration*

In November 2002, we entered into our long-acting beta$_2$ 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 has developed two combination products: (1) RELVAR®/BREO® ELLIPTA® (FF/VI), a 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 medicine combining a long-acting muscarinic antagonist (LAMA), umeclidinium bromide (UMEC), with a LABA, VI. For the treatment of asthma, RELVAR® ELLIPTA® is approved in multiple regions outside of North America and the collaboration is further developing FF/VI for the U.S.

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 payments to GSK for registrational and launch-related milestone fees, we paid a total of $140.0 million as of March 31, 2014 and recorded an additional $30.0 million liability in April 2014. These milestone fees paid or owed to GSK were capitalized as finite-lived intangible assets, which are being amortized over their estimated useful lives commencing upon the commercial launch of the product. We estimate the remaining potential milestone payments of $50.0 million could be payable by the end of 2014.

Total milestone fees paid of $140.0 million as of March 31, 2014 resulted from the following:

- In May 2013, the U.S. Food and Drug Administration (FDA) approved BREO® ELLIPTA® as an inhaled long-term, once-daily maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. It is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations.
- In September 2013, the Japanese Ministry of Health, Labour and Welfare (MHLW) approved RELVAR® ELLIPTA® for the treatment of bronchial asthma in cases where concurrent use of inhaled corticosteroid and long-acting inhaled beta$_2$ agonist is required.
- In October 2013, BREO® ELLIPTA® was launched in the U.S. for the treatment of COPD.
- In November 2013, the European Commission granted marketing authorization for RELVAR® ELLIPTA® for the regular treatment of asthma and the systematic treatment of COPD.
- In December 2013, RELVAR® ELLIPTA® was launched in Japan for the treatment of bronchial asthma.
- In December 2013, the U.S. FDA approved ANORO™ ELLIPTA™ as a combination anticholinergic/long-acting beta$_2$-adrenergic agonist (LABA) indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema.
- In January 2014, RELVAR® ELLIPTA® was launched in the European Union.

Total milestone fees recorded of $30.0 million in April 2014 resulted from the following:

- In April 2014, ANORO™ ELLIPTA™ was launched in the U.S. for the treatment of COPD.

We are entitled to receive annual royalties from GSK on sales of RELVAR®/BREO® ELLIPTA® as follows: 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 6.5% to 10%.



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Amortization expense resulting from the milestone fees paid to GSK, which are capitalized as finite-lived intangible assets, is a reduction to royalty revenue. When amortization expense exceeds amounts recognized for royalty revenue, negative revenue would be reported in our consolidated statements of operations.

*2004 Strategic Alliance*

In March 2004, we entered into our strategic alliance with GSK (the Strategic Alliance agreement and the LABA collaboration are together referred to herein as the GSK Agreements). 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. GSK has no further option rights on any of our research or development programs under the strategic alliance.

In 2005, GSK licensed our bifunctional muscarinic antagonist-beta$_2$ 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 GSK961081 ('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 as a combination product, such as '081/FF, 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 combination, 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.

*Agreements Entered into with GSK in Connection with the Spin-Off*

In conjunction with the planned spin-off of Theravance Biopharma, on March 3, 2014, we, Theravance Biopharma and GSK entered into a series of agreements clarifying how the companies will implement the spin-off and operate following the spin-off. We, Theravance Biopharma and GSK entered into a three-way master agreement providing for GSK's consent to the spin-off provided certain conditions are met. In addition, we and GSK also entered into amendments of our LABA collaboration and Strategic Alliance agreements, and Theravance Biopharma and GSK entered into a governance agreement, a

registration rights agreement and an extension agreement. The three-way master agreement is currently effective, but will terminate if the spin-off is not effected by June 30, 2014, and the other agreements will become effective upon the spin-off, provided that the spin-off is effected on or before June 30, 2014.

The amendments to the GSK Agreements do not change the economics or royalty rates. The amendments to the GSK Agreements do provide that GSK's diligent efforts obligations regarding commercialization matters under both agreements will change upon regulatory approval in either the United States or the European Union of UMEC/VI/FF or a MABA in combination with FF. Upon such regulatory approval, GSK's diligent efforts obligations as to commercialization matters under the GSK Agreements will have the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the collaboration agreement and strategic alliance agreement. Since GSK's commercialization efforts following such regulatory approval will be guided by a portfolio approach across products in which we will retain our full interests upon the spin-off and also products in which we will have retained only a portion of our interests upon the planned spin-off transaction, GSK's



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commercialization efforts may have the effect of reducing the overall value of our remaining interests in the GSK Agreements after the spin-off.

*Purchases of Common Stock under the Company's Governance Agreement and Common Stock Purchase Agreements with GSK*

During the first quarter of 2014, GSK purchased 342,229 shares of our common stock pursuant to its periodic "top-up" rights under our Amended and Restated Governance Agreement, dated as of June 4, 2004, as amended, among us, GSK and certain GSK affiliates, for an aggregate purchase price of approximately $12.9 million.

*GSK Contingent Payments and Revenue*

The potential future contingent payments receivable 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.

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

| | Three Months Ended March 31, | |
|---|---|---|
| **(In thousands)** | **2014** | **2013** |
| Royalty revenue | $ 730 | $ — |
| Amortization of intangible assets | (1,780) | — |
| Net royalty revenue | (1,050) | — |
| LABA collaboration | — | 907 |
| Strategic alliance—MABA program license | 270 | 415 |
| Total net revenue from GSK | $ (780) | $ 1,322 |

Amortization expense for intangible assets, which is a reduction to royalty revenue, exceeded amounts recognized for royalty revenues under the LABA Collaboration with GSK, resulting in negative revenue in the first quarter of 2014.

***Clinigen Group***

*Commercialization Agreement*

In March 2013, we entered into a commercialization agreement (the "Clinigen Commercialization Agreement") with Clinigen Group plc (Clinigen) to commercialize VIBATIV® for the treatment of hospital acquired nosocomial pneumonia, 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 Norway). 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% during the term of the agreement, and from a low double digit percentage to a mid-teen percentage if Clinigen exercises its post-term option. 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 twelve months' advance notice.

Under the Clinigen Commercialization Agreement, the significant deliverables were determined to be the license, committee participation and manufacturing supply. 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. We based the best estimate of selling price for the license on potential future cash flows under the arrangement over the estimated commercialization period. 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, and we based the best estimate of selling price on the nature and timing of the services to be performed. We based the best estimate of selling price for the manufacturing supply on a fully burdened cost to purchase and transfer the underlying API and finished goods from our third party contract manufacturer.

The $5.0 million upfront payment received in 2013 was allocated to two units of accounting based on the relative selling price method as follows: $4.9 million to the license and $0.1 million to the committee participation. We did not recognize any revenue



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from the license and committee participation as the technical transfer activities were not completed as of March 31, 2014 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 under a future separate supply agreement for API and finished goods, which will be manufactured by our third party contract manufacturers, will be recognized as revenue to the extent of future API and finished goods inventory sales.

***Reimbursement of R&D Costs***

Under certain collaborative arrangements, we are entitled to reimbursement of certain R&D costs. Our policy is to account for the reimbursement payments by our collaboration partners as reductions to R&D expense.

The following table summarizes the reductions to R&D expenses related to the reimbursement payments:

| | Three Months Ended March 31, | |
|---|---|---|
| (In thousands) | 2014 | 2013 |
| GSK | $ 43 | $ 171 |
| Merck | — | 1,429 |
| Alfa Wassermann | 72 | 208 |
| R-Pharm | 18 | 326 |
| Total reduction to R&D expense | $ 133 | $ 2,134 |

**4. Available-for-Sale Securities**

The classification of available-for-sale securities in the consolidated balance sheets is as follows:

| (In thousands) | March 31, 2014 | December 31, 2013 |
|---|---|---|
| Cash and cash equivalents | $ 119,160 | $ 125,009 |
| Short-term investments | 245,648 | 321,615 |
| Marketable securities | 59,831 | 55,374 |
| Restricted cash | 833 | 833 |
| Total | $ 425,472 | $ 502,831 |

The estimated fair value of available-for-sales securities is based on quoted market prices for these or similar investments that were based on prices obtained from a commercial pricing service. Available-for-sale securities are summarized below:

| | March 31, 2014 | | | |
|---|---|---|---|---|
| (In thousands) | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
| U.S. government securities | $ 37,042 | $ 74 | $ — | $ 37,116 |
| U.S. government agencies | 110,171 | 59 | — | 110,230 |
| U.S. corporate notes | 88,607 | 48 | (10) | 88,645 |
| U.S. commercial paper | 74,487 | — | — | 74,487 |
| Money market funds | 114,994 | — | — | 114,994 |
| Total | $ 425,301 | $ 181 | $ (10) | $ 425,472 |

| | December 31, 2013 | | | |
|---|---|---|---|---|
| (In thousands) | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
| U.S. government securities | $ 42,104 | $ 55 | $ (1) | $ 42,158 |
| U.S. government agencies | 141,278 | 61 | (8) | 141,331 |
| U.S. corporate notes | 94,923 | 54 | — | 94,977 |
| U.S. commercial paper | 102,021 | 2 | (1) | 102,022 |
| Money market funds | 122,343 | — | — | 122,343 |
| Total | $ 502,669 | $ 172 | $ (10) | $ 502,831 |

At March 31, 2014, all of the available-for-sale securities had contractual maturities within two years and the average duration of marketable securities was approximately seven months. We do not intend to sell the investments that are in an unrealized



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loss position, and it is unlikely that we will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. We have determined that the gross unrealized losses on our marketable securities at March 31, 2104 were temporary in nature. All marketable securities with unrealized losses at March 31, 2014 have been in a loss position for less than twelve months.

During each of the three months ended March 31, 2014 and 2013, we sold available-for-sale securities totaling $5.0 million, and the related realized gains and losses were not significant in any of these periods.

**5. Fair Value Measurements**

We define 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.

Our valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect our market assumptions. We classify these inputs into the following hierarchy:

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

*Level 2*—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*—Unobservable inputs and little, if any, market activity for the assets.

Our available-for-sale securities are measured at fair value on a recurring basis and our convertible subordinated notes are not measured at fair value on a recurring basis. The estimated fair values were as follows:

| | Estimated Fair Value Measurements at Reporting Date Using: | | | |
|---|---|---|---|---|
| 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 |
| *Assets at March 31, 2014:* | | | | |
| U.S. government securities | $ 37,116 | $ — | $ — | $ 37,116 |
| U.S. government agency securities | 82,895 | 27,335 | — | 110,230 |
| U.S. corporate notes | 69,497 | 19,148 | — | 88,645 |
| U.S. commercial paper | 74,487 | — | — | 74,487 |
| Money market funds | 114,994 | — | — | 114,994 |
| Total assets measured at estimated fair value | $ 378,989 | $ 46,483 | $ — | $ 425,472 |
| *Liabilities at March 31, 2014:* | | | | |
| Convertible subordinated notes due 2023 | $ — | $ 369,685 | $ — | $ 369,685 |

| | Estimated Fair Value Measurements at Reporting Date Using | | | |
|---|---|---|---|---|
| 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 |
| *Assets at December 31, 2013:* | | | | |
| U.S. government securities | $ 42,158 | $ — | $ — | $ 42,158 |
| U.S. government agency securities | 98,236 | 43,095 | — | 141,331 |
| U.S. corporate notes | 61,591 | 33,386 | — | 94,977 |
| U.S. commercial paper | 3,499 | 98,523 | — | 102,022 |
| Money market funds | 122,343 | — | — | 122,343 |
| Total assets measured at estimated fair value | $ 327,827 | $ 175,004 | $ — | $ 502,831 |
| *Liabilities at December 31, 2013:* | | | | |
| Convertible subordinated notes due 2023 | $ — | $ 408,250 | $ — | $ 408,250 |



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At March 31, 2014, securities with a total fair value of $2.8 million were measured using Level 1 inputs in comparison to December 31, 2013, at which time the securities had a fair value of $2.9 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, 2014, compared to December 31, 2013.

At March 31, 2014, securities with a total fair value of $1.0 million were measured using Level 2 inputs in comparison to December 31, 2013, at which time the securities had a fair value of $1.0 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, 2014, compared to December 31, 2013.

Due to their short-term maturities, we believe that the fair value of our bank deposits, receivables from collaborative arrangements, accounts payable and accrued expenses approximate their carrying value.

## 6. Inventories

Inventories were as follows:

| (In thousands) | March 31, 2014 | December 31, 2013 |
|---|---|---|
| Raw materials | $ 3,997 | $ 5,138 |
| Work-in-process | 2,225 | 360 |
| Finished goods | 4,792 | 4,908 |
| Total inventories | $ 11,014 | $ 10,406 |

## 7. Intangible Assets

Intangible assets, which consist of registrational and launch-related milestone fees paid or owed to GSK, were as follows:

| | March 31, 2014 | | | |
|---|---|---|---|---|
| (In thousands) | Weighted | Gross | Accumulated | Net Carrying |

| | Average Remaining Amortization Period (Years) | Carrying Value | Amortization | Value |
|---|---|---|---|---|
| FDA approval and launch of BREO® ELLIPTA® in the U.S. | 15.4 | $ 60,000 | $ (1,579) | $ 58,421 |
| MHLW approval and launch of RELVAR® ELLIPTA® in Japan | 14.7 | 20,000 | (444) | 19,556 |
| European Commission approval and launch of RELVAR® ELLIPTA® | 14.8 | 30,000 | (500) | 29,500 |
| FDA approval of ANORO™ ELLIPTA™ in the U.S. | 15.2 | 30,000 | — | 30,000 |
| Total intangible assets | | $ 140,000 | $ (2,523) | $ 137,477 |

| | December 31, 2013 | | | |
|---|---|---|---|---|
| (In thousands) | Weighted Average Remaining Amortization Period (Years) | Gross Carrying Value | Accumulated Amortization | Net Carrying Value |
| FDA approval and launch of BREO® ELLIPTA® in the U.S. | 15.7 | $ 60,000 | $ (632) | $ 59,368 |
| MHLW approval and launch of RELVAR® ELLIPTA® in Japan | 14.9 | 20,000 | (111) | 19,889 |
| European Commission approval of RELVAR® ELLIPTA® | 15 | 15,000 | — | 15,000 |
| FDA approval of ANORO™ ELLIPTA™ in the U.S. | 15.2 | 30,000 | — | 30,000 |
| Total intangible assets | | $ 125,000 | $ (743) | $ 124,257 |

Additional information regarding these milestone fees is included in Note 3 “Collaborative Arrangements.” Amortization expense for the BREO® ELLIPTA® intangible asset for the U.S. region and the RELVAR® ELLIPTA® intangible asset for the Japan region began in the fourth quarter of 2013 and for the RELVAR® ELLIPTA® intangible asset for the European Union region began in the first quarter of 2014. Amortization expense is recorded as a reduction in revenue from collaborative arrangements. Amortization



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expense in the first quarter of 2014 was $1.8 million. Estimated annual amortization expense of intangible assets is $8.1 million for 2014, $9.1 million for each of the years from 2015 to 2018 and $94.7 million thereafter.

**8. Stock-Based Compensation**

***Equity Incentive Plan***

The 2012 Equity Incentive Plan (2012 Plan) provides for the grant of stock options, time-based and performance-contingent RSUs, time-based and performance-contingent RSAs, and stock appreciation rights to employees, non-employee directors and consultants. As of March 31, 2014, total shares remaining available for issuance under the 2012 Plan were 2,925,115.

***Performance-Contingent RSAs***

Over the past three years, the Compensation Committee of the Company’s Board of Directors (the “Compensation Committee”) has approved grants of performance-contingent RSAs to senior management and a non-executive officer. Generally, these awards have dual triggers of vesting based upon the achievement of certain performance goals by a pre-specified date, as well as a requirement for continued employment. When the performance goals are probable of achievement for these types of awards, time-based vesting and, as a result, recognition of stock-based compensation expense commence.

Included in these performance-contingent RSAs is the grant of 1,290,000 special long-term retention and incentive performance-contingent RSAs to senior management in 2011. 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 require continued employment. The maximum potential expense associated with this program, net of forfeitures, is $28.2 million related to stock-based compensation expense, which would be recognized in increments based on achievement of the performance conditions.

As of March 31, 2014, we determined that the achievement of the requisite performance conditions for vesting of the first tranche of these awards was probable and, as a result, $6.8 million of the total stock-based compensation expense of $7.0 million related to this grant was recognized in the first quarter of 2014.

In May 2014, the Compensation Committee approved the modification of certain performance conditions for the second tranche of awards related to this grant. The modification permitted recognition of partial achievement of the original performance conditions that were met prior to the business separation. Therefore, we determined that the achievement of the modified performance conditions for this tranche was probable. As a result an additional $4.3 million of stock-based compensation expense will be recognized over a one year vesting period commencing in May 2014. In addition, the remaining unvested equity award was restructured to reflect the change in our Company and to address potential retention concerns following the business separation.

***Stock-Based Compensation Expense***

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

| | Three Months Ended March 31, | |
|---|---|---|
| (In thousands) | 2014 | 2013 |
| Research and development | $ 5,439 | $ 3,797 |
| Selling, general and administrative | 8,096 | 2,298 |
| Total stock-based compensation expense | $ 13,535 | $ 6,095 |

Total stock-based compensation expense capitalized to inventory was not material for the first quarter of 2014 and was $0.1 million for first quarter of 2013.

As of March 31, 2014, unrecognized compensation expense, net of expected forfeitures, was as follows: $19.8 million related to unvested stock options; $12.7 million related to unvested RSUs; and $21.9 million related to unvested RSAs (excludes performance-contingent RSAs).

***Valuation Assumptions***

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2014 | 2013 |
| ***Employee stock options*** | | |
| Risk-free interest rate | 1.78-1.95% | 1.01%-1.14% |
| Expected term (in years) | 6 | 6 |
| Volatility | 60% | 58% |
| Dividend yield | —% | —% |
| Weighted-average estimated fair value of stock options granted | $ 21.29 | $ 12.32 |



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***Stockholders' Equity***

For the three months ended March 31, 2014, approximately 433,000 shares were exercised at a weighted-average exercise price of $15.34 per share, for total cash proceeds of approximately $6,636,000.

**9. Income Taxes**

We did not record a provision for income taxes for the three months ended March 31, 2014 and 2013, because we expect to and did generate a taxable net operating loss for the fiscal years ended December 31, 2014 and 2013. In addition, the deferred tax assets remain fully offset by a valuation allowance or uncertain tax position liabilities.

**10. Commitments and Contingencies**

***Special Long-Term Retention and Incentive Cash Awards Program***

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. The maximum potential cash bonus expense associated with this program is $38.2 million, which would be recognized in increments based on the probable achievement of the performance conditions.

As of March 31, 2014, we determined that the achievement of the requisite performance conditions for the first tranche of these awards was probable and, as a result, $9.1 million of the total cash bonus expense of $9.5 million related to this grant was recognized in the first quarter of 2014.

In May 2014, the Compensation Committee approved the modification of certain performance conditions for the second tranche of awards related to this grant. The modification permitted recognition of partial achievement of the original performance conditions that were met prior to the business separation. Therefore, we determined that the achievement of the requisite performance conditions for this tranche was probable. As a result an additional $5.0 million of cash bonus expense will be recognized over a one year vesting period commencing in May 2014. In addition, a portion of the remaining cash award was restructured to address potential retention concerns following the business separation.

**11. Subsequent Event**

***Private Placement of $450 Million of 9% Non-Recourse Notes***

In April 2014, we entered into certain note purchase agreements relating to the private placement of $450.0 million aggregate principal amount of non-recourse 9% fixed rate term notes due 2029 (the "2029 Notes") issued by our wholly-owned subsidiary.

The 2029 Notes are secured by a security interest in a segregated bank account established to receive 40% of royalties from global net sales occurring on or after April 1, 2014 and ending upon the earlier of full repayment of principal or May 15, 2029 due to us under the LABA Collaboration with GSK. The 2029 Notes bear an annual interest rate of 9%, with interest and principal paid quarterly beginning November 15, 2014. The 2029 Notes may be redeemed at any time prior to maturity, in whole or in part, at specified redemption premiums. Prior to May 15, 2016, in the event that the specified portion of royalties received in a quarter is less than the interest accrued for the quarter, the principal amount of the 2029 Notes will increase by the interest shortfall amount for that period. Since the principal and interest payments on the 2029 Notes are based on royalties from product sales, which will vary from quarter to quarter, the 2029 Notes may be repaid prior to the final maturity date in 2029.

From the net proceeds of the offering of approximately $434.3 million, we established a $32.0 million milestone payment reserve account to fund 40% of any future milestone payments that could become payable under the LABA Collaboration with GSK. This milestone reserve account is a segregated bank account in which the $32.0 million is retained. As part of this sale, we incurred approximately $15.7 million in transaction costs, which will be amortized to interest expense over the estimated life of the 2029 Notes.

**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 revenue, projected costs, prospects, plans, intentions, expectations, goals and objectives, may be forward-looking statements. The words "anticipates," "believes," "could," "designed," "estimates," "expects," "goal," "intends," "may," "objective," "plans," "projects," "pursue," "will," "would" and similar expressions (including the negatives thereof) are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions, expectations or objectives disclosed in our forward-looking statements and the assumptions underlying our forward-looking statements may prove incorrect. Therefore, you should not place undue reliance on our forward-looking statements. Actual results or events could materially differ from the plans, intentions, expectations and objectives disclosed in the forward-looking statements that we make. Factors that we believe could cause actual results or events to differ materially from our forward-looking statements include, but are not limited, to those discussed below in "Risk Factors" in Item 1A of Part II and in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Item 2 of Part I. All forward-looking statements in this document are based on information available to us as of the date hereof and we assume no obligation to update any such forward-looking statements.

**OVERVIEW**

**Executive Summary**

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. 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. Theravance's key programs include: RELVAR®/BREO® ELLIPTA® (fluticasone furoate/vilanterol, "FF/VI"), ANORO™ ELLIPTA™ (umeclidinium bromide/vilanterol, "UMEC/VI") and MABA (Bifunctional Muscarinic Antagonist-Beta$_2$ Agonist), each partnered with Glaxo Group Limited (GSK), and our Long-Acting Muscarinic 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 2014, our net loss was $67.7 million, an increase of $30.3 million from $37.4 million in the first quarter of 2013 primarily due to an increase in our costs and expenses. In the first quarter of 2014, our costs and expenses were $66.4 million, an increase of $31.7 million from $34.7 million in the first quarter of 2013 primarily due to higher employee-related expenses, including stock-based compensation expense, external-related costs for key Phase 2 clinical trials, expansion of commercial activities related to VIBATIV and external legal and accounting fees incurred in connection with our separation strategy. Cash, cash equivalents, and marketable securities totaled $430.8 million on March 31, 2014, a decrease of $89.7 million from December 31, 2013 primarily due to registrational and launch-related milestone payments to GSK of $55.0 million and cash used in operations, partially offset by net proceeds of $18.3 million received from issuances of our common stock.

**Recent Developments**

***Private Placement of $450 Million of 9% Non-Recourse Notes***

In April 2014, we entered into certain note purchase agreements relating to the private placement of $450.0 million aggregate principal amount of non-recourse 9% fixed rate term notes due 2029 (the "2029 Notes") issued by our wholly-owned subsidiary. The 2029 Notes are secured by a security interest in a segregated bank account established to receive 40% of royalties from global net sales occurring on or after April 1, 2014 and ending upon the earlier of full repayment of principal or May 15, 2029 due to us under the LABA Collaboration with GSK.

***Business Separation Announcement***

In April 2013, Theravance announced that its Board of Directors approved plans to separate its businesses into two independent publicly traded companies. The company to be spun-off, Theravance Biopharma, Inc. (Theravance Biopharma), filed an initial Form 10 with the SEC on August 1, 2013 and filed amendments of its Form 10 with the SEC on September 27, 2013, October 29, 2013, November 22, 2013, April 8, 2014, April 30, 2014 and May 7, 2014. After the spin-off, Theravance will be responsible for all





development and commercial activities under the LABA collaboration and the Strategic Alliance agreements with GSK. Theravance will be eligible to receive the associated potential royalty revenues from FF/VI (RELVAR®/BREO® ELLIPTA®), UMEC/VI (ANORO™ ELLIPTA™) and potentially VI monotherapy and 15% of the potential royalty revenues from UMEC/VI/FF, MABA, and MABA/FF and other products that may be developed under the LABA collaboration and Strategic Alliance agreements. Theravance Biopharma will be a biopharmaceutical company focused on discovery, development and commercialization of small-molecule medicines in areas of significant unmet medical need. The result will be two independent, publicly traded companies with different business models enabling investors to align their investment philosophies with the strategic opportunities and financial objectives of the two independent companies.

**Program Highlights**

***Respiratory Programs with GlaxoSmithKline plc (GSK)***

*RELVAR®/BREO® ELLIPTA® (fluticasone furoate/vilanterol "FF/VI")*

RELVAR®/BREO® ELLIPTA® has been approved in 42 countries for marketing and has been launched in 12 countries, including the U.S., Canada, Japan, and U.K., as of April 25, 2014. In April 2014, GSK and Theravance announced that the Therapeutic Goods Administration (TGA) has approved BREO™ ELLIPTA® for the treatment of patients with asthma or COPD in Australia. In April 2014, GSK announced its intention to file BREO® for asthma in the U.S. in 2014.

BREO® ELLIPTA® is the proprietary name in the U.S., Canada and Australia for the once-daily combination medicine of an inhaled corticosteroid (ICS), fluticasone furoate "FF", and a long-acting beta$_2$-agonist (LABA), vilanterol "VI" (FF/VI) administered using the ELLIPTA®, a dry powder inhaler (DPI). RELVAR® ELLIPTA® is the proprietary name for FF/VI outside of the U.S., Canada and Australia. BREO® ELLIPTA® is not indicated for the relief of acute bronchospasm or for the treatment of asthma in the U.S. or Canada.

In April 2014, GSK and Theravance announced the start of a Phase 3 efficacy and safety study of FF/VI evaluating the contribution of the ICS component on lung function, in patients with COPD. Positive results from this study will help support a potential filing of FF/VI for the treatment of patients with COPD in Japan.

In March 2014, GSK and Theravance announced that recruitment of patients into the "Study to Understand Mortality and MorbidITy", known as SUMMIT, has completed enrollment of 16,000 patients. The aim of this study is to determine the impact of RELVAR®/BREO® ELLIPTA® (FF/VI) on all-cause mortality amongst patients with moderate COPD who have cardiovascular disease (CVD) or are at increased risk for CVD. As an event-driven study, the exact duration of the treatment phase will depend on the mortality rate within the study. However, it is anticipated that each patient will participate in the study in the range of 16-53 months.

In February 2014, GSK submitted a regulatory application to the China Food and Drug Administration (CFDA) for FF/VI, administered using the ELLIPTA® inhaler, for asthma and COPD.

*ANORO™ ELLIPTA® (umeclidinium bromide/vilanterol, UMEC/VI)*

On April 28, 2014, GSK and Theravance announced that ANORO™ ELLIPTA®, the first once-daily product approved in the U.S. that combines two long-acting bronchodilators in a single inhaler for the maintenance treatment of COPD, is now available in U.S. retail pharmacies. The FDA-approved strength of ANORO™ ELLIPTA® is UMEC/VI 62.5 mcg/25 mcg.

In February 2014, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion recommending marketing authorization for UMEC/VI under the proposed brand name ANORO® as a once-daily, maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. The proposed strength is UMEC/VI 55 mcg / 22 mcg.

UMEC/VI is also under regulatory review by a number of other regulatory authorities, including Japanese Ministry of Health, Labour and Welfare.

In March 2014, GSK and Theravance announced positive results from three Phase 3 studies. Two studies comparing the efficacy and safety of ANORO™ ELLIPTA® with inhaled corticosteroid/long-acting beta$_2$-adrenergic agonist combination, ADVAIR® DISKUS® (fluticasone propionate/salmeterol 'FSC 250/50') and the third comparing the efficacy and safety of ANORO™ ELLIPTA® with SERETIDE® DISKUS® 'FSC 500/50' in patients with COPD and no history of moderate to severe COPD exacerbations in the last year. In each of the studies UMEC/VI achieved a



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statistically significant improvement in lung function, measured as weighted mean forced expiratory volume in one second (wm FEV1) over 0-24 hours at the end of the 12 week study (Day 84), compared to either dose of FSC.

*Inhaled Bifunctional Muscarinic Antagonist-Beta$_2$ Agonist (MABA) — GSK961081*

GSK961081 ('081) is an investigational, single molecule bifunctional bronchodilator discovered by Theravance with both muscarinic antagonist and beta$_2$ receptor agonist activities. Preclinical Phase 3-enabling studies and a Phase 1 study with healthy volunteers of the combination '081/FF are ongoing to explore its potential as a once-daily medicine delivered in the ELLIPTA® inhaler.

***Theravance Respiratory Program***

*Long-Acting Muscarinic Antagonist (LAMA) — TD-4208*

In April 2014, Theravance initiated a dose-ranging Phase 2b study with TD-4208 as a nebulized aqueous solution in patients with moderate to severe COPD. TD-4208 is an investigational inhaled LAMA discovered using Theravance's multivalent approach to drug design. The Phase 2b study will evaluate the bronchodilator effect, safety and tolerability of four doses of TD-4208 and placebo in patients with moderate to severe COPD. Approximately 350 patients will be randomized to receive one of four doses of TD-4208 inhalation solution (44 mcg, 88 mcg, 175 mcg, 350 mcg) or placebo once daily via a jet nebulizer for 28 days in a double-blind, parallel group study. The primary endpoint of the study is trough forced expiratory volume in one second (FEV1) after the 28-day treatment period. Secondary endpoints include measurements of serial FEV1 on Day 28 and Day 1 and safety and tolerability assessments.

***Bacterial Infections Program***

*VIBATIV® (telavancin)*

In March 2014, Theravance was informed by its partner, Clinigen Group plc ("Clinigen") that it had received a notification that the European Commission (EC) lifted the Europe-wide suspension of the Marketing Authorization for VIBATIV® (telavancin) for the treatment of adults with 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. Theravance and Clinigen have an exclusive commercialization agreement in the European Union and certain other European countries (including Switzerland and Norway) for VIBATIV®.

***Central Nervous System (CNS)/Pain Program***

*Norepinephrine and Serotonin Reuptake Inhibitor — TD-9855*

In April 2014, Theravance announced positive results from a Phase 2 study of TD-9855, an investigational norepinephrine and serotonin reuptake inhibitor (NSRI), in patients with fibromyalgia (FM). The Phase 2 randomized, double-blind, parallel-group, placebo-controlled study evaluated the safety and efficacy of two doses of TD-9855 (5 mg and 20 mg) in 392 patients. Study medication was administered once-daily for up to 6 weeks. The primary endpoint of the study was improvement in pain. Secondary endpoints assessed improvement in core symptoms of fibromyalgia using established fibromyalgia measures, the Fibromyalgia Impact Questionnaire (FIQ) and the Patient Global Impression of Change scale (PGIC). Impact on common symptoms of fibromyalgia was also evaluated as exploratory endpoints. The study demonstrated statistically significant and clinically meaningful improvements in the primary and secondary endpoints at the 20 mg dose of TD-9855 compared to placebo. The 5 mg dose did not meet statistical significance for the primary endpoint. Both doses were generally well tolerated. The five most common treatment-emergent adverse events reported were headache, nausea, dizziness, insomnia and constipation. Changes in heart rate and blood pressure with TD-9855 were within the range of those seen in approved drugs in this class. Two serious adverse events were reported in TD-9855 treatment groups, with one assessed as possibly treatment related in the 5 mg group. Topline results support further development of TD-9855.



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***GI Motility Dysfunction Programs***

*Velusetrag*

In April 2014, Theravance announced the positive topline results from a Phase 2 study with velusetrag for the treatment of patients with diabetic or idiopathic gastroparesis. Velusetrag is an oral, once-daily, investigational 5-HT4 selective agonist discovered by Theravance and partnered with Alfa Wassermann S.p.A. (Alfa Wassermann). Improvement in gastric emptying time was observed with all doses of velusetrag (5, 15, 30 mg). The primary endpoint of the study was the proportion of patients with at least a 20 percent improvement in gastric emptying (GE) as measured by half-time (t1/2), the time to half-emptying of the stomach of the biomarker, on Day 7 of each treatment period. Forty-seven percent more of the patients in the 30 mg velusetrag group demonstrated at least a 20% improvement in gastric emptying (GE t1/2) compared to patients in the placebo group (velusetrag 30 mg 52%, placebo 5%; $p<0.001$), which is a statistically significant increase. All doses of velusetrag improved gastric emptying t1/2 by 34-52 minutes versus 13 minutes for placebo. The 30 mg dose demonstrated statistically significant differences relative to placebo in percentage change and absolute change in minutes. Similar treatment effects were observed in both diabetic and idiopathic gastroparetic patients treated with velusetrag. All doses of velusetrag were generally well tolerated. The two most common adverse events were diarrhea and headache. One serious adverse event of pyelonephritis was observed during post-treatment follow-up on velusetrag 30 mg and was assessed as not related to study drug by the investigator. Based on these results, Theravance and Alfa Wassermann have agreed to advance velusetrag into a Phase 2b study later this year.

*TD-8954*

TD-8954 is a selective 5-HT4 receptor agonist. Theravance recently initiated a Phase 2a study to evaluate the safety, tolerability and pharmacodynamics of a single-dose of TD-8954 administered intravenously compared to metoclopramide in critically ill patients with enteral feeding intolerance. The objective of the study is assessment of adverse events and the ability to tolerate feeding.

**Collaborative Arrangement with GSK**

***LABA Collaboration***

In November 2002, we entered into our long-acting beta$_2$ agonist (LABA) collaboration with GSK to develop and commercialize once-daily LABA products for the treatment of COPD and asthma. For the treatment of COPD, the collaboration has developed two combination products: (1) RELVAR®/BREO® ELLIPTA® (FF/VI) (BREO® ELLIPTA® is the proprietary name in the U.S. and Canada and RELVAR® ELLIPTA® is the proprietary name outside the U.S. and Canada), a 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 medicine combining a long-acting muscarinic antagonist (LAMA), umeclidinium bromide (UMEC), with a LABA, VI. Under the collaboration agreements between the parties, GSK and Theravance are exploring various paths to create triple therapy medications. The use of triple therapy is supported by the GOLD (Global initiative for chronic Obstructive Lung Disease) guidelines in high-risk patients with severe COPD and a high risk of exacerbations. One potential triple therapy path is the combination of UMEC/VI (two bronchodilators) and FF (an inhaled corticosteroid), to be administered via the ELLIPTA® investigational dry powder inhaler, which triple therapy program GSK has referred to as Diamond. GSK recently announced its goal of advancing Diamond into Phase 3 in either 2014 or 2015. For the treatment of asthma, RELVAR® ELLIPTA® is approved in multiple regions outside of North America and the collaboration is further developing FF/VI for the U.S. 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 2013 sales of approximately $8.3 billion, and to compete with Symbicort ® (formoterol and budesonide as a combination), which had reported 2013 sales of approximately $3.5 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 2013 sales of approximately $4.7 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 payments to GSK for registrational and launch-related milestone fees, we paid a total of $140.0 million as of March 31, 2014 and recorded an additional $30.0 million liability in April 2014. These milestone fees paid or owed to GSK were capitalized as finite-lived intangible assets, which are being amortized over their estimated useful lives commencing upon the commercial launch of the product. We estimate the remaining potential milestone payments of $50.0 million could be payable by the end of 2014.



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Total milestone fees paid of $140.0 million as of March 31, 2014 resulted from the following:

- In May 2013, the U.S. Food and Drug Administration (FDA) approved BREO® ELLIPTA® as an inhaled long-term, once-daily maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. It is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations.
- In September 2013, the Japanese Ministry of Health, Labour and Welfare (MHLW) approved RELVAR® ELLIPTA® for the treatment of bronchial asthma in cases where concurrent use of inhaled corticosteroid and long-acting inhaled beta$_2$ agonist is required.
- In October 2013, BREO® ELLIPTA® was launched in the U.S. for the treatment of COPD.
- In November 2013, the European Commission granted marketing authorization for RELVAR® ELLIPTA® for the regular treatment of asthma and the systematic treatment of COPD.
- In December 2013, RELVAR® ELLIPTA® was launched in Japan for the treatment of bronchial asthma.
- In December 2013, the U.S. FDA approved ANORO™ ELLIPTA™ as a combination anticholinergic/long-acting beta$_2$-adrenergic agonist (LABA) indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema.
- In January 2014, RELVAR® ELLIPTA® was launched in the European Union.

Total milestone fees recorded of $30.0 million in April 2014 resulted from the following:

- In April 2014, ANORO™ ELLIPTA™ was launched in the U.S. for the treatment of COPD.

We are entitled to receive annual royalties from GSK on sales of RELVAR®/BREO® ELLIPTA® as follows: 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 6.5% to 10%.

Amortization expense resulting from the milestone fees paid to GSK, which are capitalized as finite-lived intangible assets, is a reduction to royalty revenue. When amortization expense exceeds amounts recognized for royalty revenue, negative revenue would be reported in our consolidated statements of operations.

***2004 Strategic Alliance***

In March 2004, we entered into our strategic alliance with GSK (the Strategic Alliance agreement and the LABA collaboration are together referred to herein as the GSK Agreements). 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. GSK has no further option rights on any of our research or development programs under the strategic alliance.

In 2005, GSK licensed our 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 GSK961081 ('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 as a combination product, such as a '081/FF, 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 combination, 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



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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.

***Agreements Entered into with GSK in Connection with the Spin- Off***

In conjunction with the planned spin-off of Theravance Biopharma, on March 3, 2014, we, Theravance Biopharma and GSK entered into a series of agreements clarifying how the companies will implement the spin-off and operate following the spin-off. We, Theravance Biopharma and GSK entered into a three-way master agreement providing for GSK's consent to the spin-off provided certain conditions are met. In addition, we and GSK also entered into amendments of our LABA collaboration and Strategic Alliance agreements (GSK Agreements), and Theravance Biopharma and GSK entered into a governance agreement, a registration rights agreement and an extension agreement. The three-way master agreement is currently effective, but will terminate if the spin-off is not effected by June 30, 2014, and the other agreements will become effective upon the spin-off, provided that the spin-off is effected on or before June 30, 2014.

The amendments to the GSK Agreements do not change the economics or royalty rates. The amendments to the GSK Agreements do provide that GSK's diligent efforts obligations regarding commercialization matters under both agreements will change upon regulatory approval in either the United States or the European Union of UMEC/VI/FF or a MABA in combination with FF. Upon such regulatory approval, GSK's diligent efforts obligations as to commercialization matters under the GSK Agreements will have the objective of focusing on the best interests of patients and maximizing the net value of the

overall portfolio of products under the collaboration agreement and strategic alliance agreement. Since GSK's commercialization efforts following such regulatory approval will be guided by a portfolio approach across products in which we will retain our full interests upon the spin-off and also products in which we will have retained only a portion of our interests upon the planned spin-off transaction, GSK's commercialization efforts may have the effect of reducing the overall value of our remaining interests in the GSK Agreements after the spin-off.

***Purchases of Common Stock by GSK***

During the first quarter of 2014, GSK purchased 342,229 shares of our common stock pursuant to its periodic "top-up" rights under our Amended and Restated Governance Agreement, dated as of June 4, 2004, as amended, among us, GSK and certain GSK affiliates, for an aggregate purchase price of $12.9 million.

***GSK Contingent Payments and Revenue***

The potential future contingent payments receivable 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.

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

| | Three Months Ended March 31, | |
|---|---|---|
| **(In thousands)** | **2014** | **2013** |
| Royalty revenue | $ 730 | $ — |
| Amortization of intangible assets | (1,780) | — |
| Net royalty revenue | (1,050) | — |
| LABA collaboration | — | 907 |
| Strategic alliance—MABA program license | 270 | 415 |
| Total net revenue from GSK | $ (780) | $ 1,322 |

Amortization expense for intangible assets, which is a reduction to royalty revenue, exceeded amounts recognized for royalty revenues under the LABA Collaboration with GSK, resulting in negative revenue in the first quarter of 2014. Estimated annual amortization expense of intangible assets is $8.1 million for 2014.

Under the GSK collaboration arrangements, we are reimbursed for research and development expenses. These reimbursements have been reflected as a reduction of research and development expense and were not material in the first quarter of 2014 and were $0.2 million for the first quarter of 2013.



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**Critical Accounting Policies and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

***Revenue Recognition***

Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. Determination of criteria (3) and (4) are based on management's judgments regarding the nature of the fee charged for products or services delivered and the collectability of those fees. Where the revenue recognition criteria are not met, we defer the recognition of revenue by recording deferred revenue until such time that all criteria are met.

*Product Revenues*

We sell VIBATIV® in the U.S. through a limited number of distributors, and title and risk of loss transfer upon receipt by these distributors. Healthcare providers order VIBATIV® through these distributors. Commencing in the first quarter of 2014, we record revenue on the sale of VIBATIV® on a sell-through basis, once the distributors sell the product to healthcare providers.

Product sales are recorded net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions. We reflect such reductions in revenue as either an allowance to the related account receivable from the distributor, or as an accrued liability, depending on the nature of the sales deduction. Sales deductions are based on management's estimates that consider payer mix in target markets, industry benchmarks and experience to date. We monitor inventory levels in the distribution channel, as well as sales of VIBATIV® by distributors to healthcare providers, using product-specific data provided by the distributors. Product return allowances are based on amounts owed or to be claimed on related sales. These estimates take into consideration the terms of our agreements with customers, historical product returns of VIBATIV® experienced by our former collaborative partner, Astellas, rebates or discounts taken, estimated levels of inventory in the distribution channel, the shelf life of the product, and specific known market events, such as competitive pricing and new product introductions. We update our estimates and assumptions each quarter and if actual future results vary from our estimates, we may adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment.

*Sales Discounts:* We offer cash discounts to our customers, generally 2% of the sales price, as an incentive for prompt payment. We expect our customers to comply with the prompt payment terms to earn the cash discount. We account for cash discounts by reducing accounts receivable by the full

amount and recognizing the discount as a reduction of revenue in the same period the related revenue is recognized.

*Chargebacks and Government Rebates:* For VIBATIV® sales in the U.S., we estimate reductions to product sales for qualifying federal and state government programs including discounted pricing offered to Public Health Service (PHS) as well as government-managed Medicaid programs. Our reduction for PHS is based on actual chargebacks that distributors have claimed for reduced pricing offered to such health care providers. Our accrual for Medicaid is based upon statutorily-defined discounts, estimated payer mix, expected sales to qualified healthcare providers, and our expectation about future utilization. The Medicaid accrual and government rebates that are invoiced directly to us are recorded in other accrued liabilities on the consolidated balance sheet. For qualified programs that can purchase our products through distributors at a lower contractual government price, the distributors charge back to us the difference between their acquisition cost and the lower contractual government price, which we record as an allowance against accounts receivable.

*Distribution Fees and Product Returns:* We have written contracts with our distributors that include terms for distribution-related fees. We record distribution-related fees based on a percentage of the product sales price. We offer our distributors a right to return product purchased directly us, which is principally based upon the product's expiration date. Additionally, we have granted more expansive return rights to our distributors following our product launch of VIBATIV®. We will generally accept returns



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for expired product during the six months prior to and twelve months after the product expiration date on product that had been sold to the distributors. Product returned is generally not resalable given the nature of our products and method of administration. We have developed estimates for VIBATIV® product returns based upon historical VIBATIV® sales from our former collaborative partner, Astellas. We record distribution fees and product returns as an allowance against accounts receivable.

*Allowance for Doubtful Accounts:* We maintain a policy to record allowances for potentially doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. As of March 31, 2014 and December 31, 2013, there was no allowance for doubtful accounts.

*Royalties*

We recognize royalty revenue on licensee net sales of our products in the period in which the royalties are earned and reported to us and collectability is reasonably assured.

*Collaborative Arrangements and Multiple Element Arrangements*

We generate revenue from collaboration and license agreements for the development and commercialization of our product candidates. Collaboration and license agreements may include non-refundable upfront payments, partial or complete reimbursement of research and development costs, supply arrangement, contingent payments based on the occurrence of specified events under our collaborative arrangements, license fees and royalties on sales of product candidates if they are successfully approved and commercialized. Our performance obligations under the collaborations may include the transfer of intellectual property rights in the form of licenses, obligations to provide research and development services and related materials, supply of active pharmaceutical ingredient (API) and/or drug product, and obligations to participate on certain development and/or commercialization committees with the collaborative partners. We make judgments that affect the periods over which we recognize revenue. We periodically review our estimated periods of performance based on the progress under each arrangement and account for the impact of any changes in estimated periods of performance on a prospective basis.

On January 1, 2011, we adopted an accounting standards update that amends the guidance on accounting for new or materially modified multiple-element arrangements that we enter into subsequent to January 1, 2011. This guidance removed the requirement for objective and reliable evidence of fair value of the undelivered items in order to consider a deliverable a separate unit of accounting. It also changed the allocation method such that the relative-selling-price method must be used to allocate arrangement consideration to all the units of accounting in an arrangement. This guidance established the following hierarchy that must be used in estimating selling price under the relative-selling-price method: (1) vendor-specific objective evidence of fair value of the deliverable, if it exists, (2) third-party evidence of selling price, if vendor-specific objective evidence is not available or (3) vendor's best estimate of selling price (BESP) if neither vendor-specific nor third-party evidence is available.

We may determine that the selling price for the deliverables within collaboration and license arrangements should be determined using BESP. The process for determining BESP involves significant judgment on our part and includes consideration of multiple factors such as estimated direct expenses and other costs, and available data. We have determined BESP for license units of accounting based on market conditions, similar arrangements entered into by third parties and entity-specific factors such as the terms of previous collaborative agreements, our pricing practices and pricing objectives, the likelihood that clinical trials will be successful, the likelihood that regulatory approval will be received and that the products will become commercialized. We have also determined BESP for services-related deliverables based on the nature of the services to be performed and estimates of the associated effort as well as estimated market rates for similar services.

For each unit of accounting identified within an arrangement, we determine the period over which the performance obligation occurs. Revenue is then recognized using either a proportional performance or straight-line method. We recognize revenue using the proportional performance method when the level of effort to complete our performance obligations under an arrangement can be reasonably estimated. Direct labor hours or full time equivalents are typically used as the measurement of performance. The total amount of deferred revenue based on BESP at March 31, 2014 was $7.1 million. Any changes in the remaining estimated performance obligation periods under these collaborative arrangements will not have a significant impact on the results of operations, except for a change in estimated performance period resulting from the termination of a collaborative arrangement, which would result in immediate recognition of the related deferred revenue.

Our collaborative agreements with GSK and our former collaborative arrangement with Astellas were entered into prior to January 1, 2011. The delivered items under these collaborative agreements did not meet the criteria required to be accounted for as separate accounting units for the purposes of revenue recognition. As a result, revenue from non-refundable, upfront fees and development contingent payments were recognized ratably over the expected term of our performance of R&D services under the

agreements. These upfront or contingent payments received, pending recognition as revenue, were recorded as deferred revenue and recognized over the estimated performance periods.

Under our GSK collaborative arrangements we recognized negative revenue of $0.8 million and revenue of $1.3 million for the three months ended March 31, 2014 and 2013. The remaining deferred revenue under the GSK strategic alliance agreement is $5.7 million at March 31, 2014. Any change in the estimated performance period, which is predominantly based on GSK's development timeline, will not have a significant impact on the results of operations, except for a change in estimated performance period resulting from the termination of the MABA program that would result in immediate recognition of the deferred revenue.

On January 1, 2011, we also adopted an accounting standards update that provides guidance on revenue recognition using the milestone method. Payments that are contingent upon achievement of a substantive milestone are recognized in their entirety in the period in which the milestone is achieved. Milestones are defined as events that can be achieved based only on our performance and as to which, at the inception of the arrangement, there is substantive uncertainty about whether the milestone will be achieved. Events that are contingent only on the passage of time or only on third-party performance are not considered milestones subject to this guidance. Further, the amounts received must relate solely to prior performance, be reasonable relative to all of the deliverables and payment terms in the agreement and commensurate with our performance to achieve the milestone after commencement of the agreement. Total contingent payments that may become payable to us under our collaborative agreements were up to $429.5 million at March 31, 2014 and are considered non-substantive.

Under our collaborative arrangements with GSK, and in accordance with FASB Subtopic ASC 808-10, "Collaborative Arrangements," royalty revenue earned is reduced by amortization expense resulting from the fees paid to GSK, which were capitalized as finite-lived intangible assets. When amortization expense exceeds amounts recognized for royalty revenues from GSK, negative revenue would be reported in our consolidated statements of operations.

Amounts related to research and development funding is recognized as the related services or activities are performed, in accordance with the contract terms. Payments may be made to us based on the number of full-time equivalent researchers assigned to the collaborative project and the related research and development expenses incurred. Accordingly, reimbursement of research and development expenses pursuant to the cost-sharing provisions of our agreements with certain collaborative partners are recognized as a reduction of research and development expenses. For the first quarter of 2014, we recorded a reduction in our research and development expenses of $0.1 million for reimbursement of research and development expenses related to these collaborative arrangements.

***Intangible Assets***

We capitalize fees paid to licensors related to agreements for approved products or commercialized products. We capitalize these fees as finite-lived intangible assets and amortize these intangible assets on a straight-line basis over their estimated useful lives upon the commercial launch of the product, which is expected to be shortly after regulatory approval of such product. The estimated useful lives of these intangible assets are based on a country-by-country and product-by-product basis, as the later of the expiration or termination of the last patent right covering the compound in such product in such country and 15 years from first commercial sale of such product in such country, unless the agreement is terminated earlier. Consistent with our policy for classification of costs under the research and development collaborative arrangements, the amortization of these intangible assets will be recognized as a reduction of royalty revenue.

We review our intangible assets for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. The recoverability of finite-lived intangible assets is measured by comparing the asset's carrying amount to the expected undiscounted future cash flows that the asset is expected to generate. The determination of recoverability typically requires various estimates and assumptions, including estimating the useful life over which cash flows will occur, their amount, and the asset's residual value, if any. We derive the required cash flow estimates from near-term forecasted product sales and long-term projected sales in the corresponding market.

Our gross intangible assets of $140.0 million at March 31, 2014 consist of registrational and launch-related to milestone fees paid or owed to GSK (see "Collaborative Arrangements with GSK" above for more information). These intangible assets are considered finite-lived intangible assets, which will be amortized over their estimated useful lives using the straight-line method commencing upon commercial launch.

***Inventories***

Inventories of $11.0 million and $10.4 million at March 31, 2014 and December 31, 2013 are stated at the lower of cost or market value. Raw materials include VIBATIV® active pharmaceutical ingredient (API) and other raw materials. Work-in-process and





finished goods include third party manufacturing costs and labor and indirect costs we incur 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. We have recently commenced commercial sales of VIBATIV®. The realization of the carrying value of our VIBATIV® inventory is dependent upon significant increases in sales volumes of VIBATIV®. If information becomes available that suggests the inventories may not be realizable, we may be required to expense a portion or all of the previously capitalized inventories.

**Results of Operations**

***Net Revenue***

Total net revenue, as compared to the prior year period, was as follows:

| | Three Months Ended March 31, |
|---|---|

| (In thousands) | 2014 | 2013 | Change | |
|---|---|---|---|---|
| Product sales | $ 945 | $ — | $ 945 | —% |
| Royalty revenue | 730 | — | 730 | — |
| Amortization of intangible assets | (1,780) | — | (1,780) | — |
| Net royalty revenue | (1,050) | — | (1,050) | — |
| Net revenue from collaborative arrangements | 270 | 1,344 | (1,074) | (80) |
| Total net revenue | $ 165 | $ 1,344 | $ (1,179) | (88)% |

Total net revenue decreased in the first quarter of 2014 compared to the same period a year ago. Revenue for the first quarter of 2014 includes product sales, net royalty revenue and revenue from collaborative arrangements compared to the same period in 2013, which only includes revenue from collaborative arrangements. Product sales in the first quarter of 2014 resulted from the recognition of VIBATIV® product sales, which includes amounts that were previously deferred due to inherent uncertainties in estimating normal channel inventory at the distributors. Royalty revenue earned in the first quarter of 2014 of $0.7 million is related to net sales of RELVAR®/BREO® ELLIPTA® from GSK. Royalty revenue is reduced by amortization expense for intangible assets, which in the first quarter of 2014 exceeded amounts recognized for royalty revenues under the LABA Collaboration with GSK. Revenue from collaborative arrangements decreased in the first quarter of 2014 compared to the same period in 2013 as a result of deferred revenue under the LABA Collaboration Agreement with GSK being fully recognized in 2013.

A portion of our upfront fees and certain contingent payments received from our collaborative arrangements have been deferred and are being amortized ratably into revenue or R&D 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 performance pursuant to these contracts.

***Cost of Goods Sold***

Cost of goods sold, as compared to the prior year period, was as follows:

| | Three Months Ended March 31, | | | |
|---|---|---|---|---|
| (In thousands) | 2014 | 2013 | Change | |
| Cost of goods sold | $ 188 | $ — | $ 188 | —% |

Cost of goods sold was $0.2 million in the first quarter of 2014 compared to $0 in the same period a year ago as a result of recognizing VIBATIV® product sales in the first quarter of 2014.

***Research & Development***

Our R&D expenses consist primarily of employee-related costs, external costs, and various allocable expenses. We budget total R&D expenses on an internal department level basis, we do not have project or program level reporting capabilities. We manage and report our R&D activities across the following four cost categories:

1) Employee-related costs, which include salaries, wages and benefits;
2) Stock-based compensation, which includes expenses associated with our stock option and other award plans;
3) External costs, which include clinical trial related expenses, other contract research fees, consulting fees, and contract manufacturing fees; and
4) Facilities and other, which include laboratory and office supplies, depreciation and other allocated expenses, which include general and administrative support functions, insurance and general supplies.



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Our R&D expenses, as compared to prior year period, were as follows:

| | Three Months Ended March 31, | | | |
|---|---|---|---|---|
| (In thousands) | 2014 | 2013 | Change | |
| Employee-related | $ 19,535 | $ 9,295 | $ 10,240 | 110% |
| External-related | 11,958 | 7,140 | 4,818 | 67 |
| Stock-based compensation | 5,439 | 3,797 | 1,642 | 43 |
| Facilities, depreciation and other allocated | 6,455 | 6,184 | 271 | 4 |
| Total R&D expenses | $ 43,387 | $ 26,416 | $ 16,971 | 64% |

R&D expenses increased 64% to $43.4 million in the first quarter of 2014 compared to the same period a year ago primarily due to higher employee-related costs of $10.2 million, external-related costs of $4.8 million and stock-based compensation expense of $1.6 million. Employee-related costs and stock-based compensation expense increased primarily due to the probable achievement of performance conditions for the first tranche of awards under a special long-term retention and incentive equity and cash bonus awarded to certain employees in 2011, which resulted in additional stock-based compensation and cash bonus expense during the first quarter of 2014 of $9.3 million. The key clinical trials we were conducting in the first quarter of 2014 were our Phase 2 clinical study in our MARIN program with TD-9855 for fibromyalgia, a Phase 2b study in our LAMA program with TD-4208 and Phase 1 studies of TD-6450. In the comparable period in 2013 our key clinical trials primarily consisted of our Phase 2 clinical studies in our MARIN program with TD-9855 for ADHD and fibromyalgia, a Phase 2b study in our LAMA program with TD-4208 and Phase 1 studies of TD-1607.

Under certain of our collaborative arrangements we receive partial reimbursement of external costs and employee-related costs, which have been reflected as a reduction of R&D expenses of $0.1 million and $2.1 million for the three months ended March 31, 2014 and 2013.

***Selling, General & Administrative***

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

| (In thousands) | Three Months Ended March 31, 2014 | 2013 | Change | |
|---|---|---|---|---|
| Selling, general and administrative expenses | $ 22,834 | $ 8,315 | $ 14,519 | 175% |

Selling, general and administrative expenses increased 175% to $22.8 million in the first quarter of 2014 compared to the same period a year ago primarily due to higher stock-based compensation expense, external costs from VIBATIV® commercialization activities, an increase in external legal and accounting fees in connection with our separation strategy and higher employee-related costs. Stock-based compensation expense and employee-related costs increased primarily due to the probable achievement of performance conditions under a special long-term retention and incentive equity and cash bonus awarded to certain employees in 2011, which resulted in additional stock-based compensation and cash bonus expense during the first quarter of 2014 of $6.6 million. Selling, general and administrative expenses include stock-based compensation expense of $8.1 million and $2.3 million for the three months ended March 31, 2014 and 2013. Total external expenses related to the proposed company separation were $3.6 million for the first quarter of 2014.

***Interest Income and Other Income (Expense), net***

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

| (In thousands) | Three Months Ended March 31, 2014 | 2013 | Change | |
|---|---|---|---|---|
| Interest income | $ 188 | $ 185 | $ 3 | 2% |
| Other income (expense), net | (3) | (1,422) | 1,419 | (100) |

Interest income in the first quarter of 2014 approximated the same amount compared to the same period a year ago.

Other income (expense), net in the first quarter of 2013 includes $1.4 million due to the change in fair value of the capped call instruments related to our convertible subordinated notes issued in 2013.



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***Interest Expense***

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

| (In thousands) | Three Months Ended March 31, 2014 | 2013 | Change | |
|---|---|---|---|---|
| Interest expense | $ 1,644 | $ 2,736 | $ (1,092) | (40)% |

Interest expense decreased 40% to $1.6 million in 2014 compared to the same period a year ago primarily due to the conversion of our 3% convertible subordinated notes due 2015 into shares of our common stock by July 3, 2013.

**Liquidity and Capital Resources**

***Liquidity***

Since our inception, we have financed our operations primarily through private placements and public offerings of equity and debt securities and payments received under collaborative arrangements. At March 31, 2014, we had $430.8 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. During the first quarter of 2014, we also made registrational and launch-related milestone payments to GSK of $55.0 million.

On June 4, 2013, we called for the redemption of all of our outstanding 3% Convertible Subordinated Notes due 2015 (the “2015 Notes”), pursuant to the redemption right in the indenture governing the 2015 Notes. All of the 2015 Notes, $172.5 million principal amount, were converted into 6,667,932 shares of our common stock between June 30, 2013 and July 3, 2013 and none were redeemed for cash.

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, in April 2014 we initiated a second Phase 2b study with TD-4208, our LAMA compound, and we announced positive results from a Phase 2 study of TD-9855 in our MARIN program for fibromyalgia. Also, in July 2012, Theravance 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 are seeking to partner these programs, we may choose to progress one or more of these programs into later-stage clinical studies by ourselves, which could increase our anticipated operating expenses substantially. Furthermore, if we cannot identify a suitable commercialization partner for VIBATIV® in the U.S., we will not be able to leverage a commercialization partner’s capabilities and infrastructure and we will incur all of the costs and expenses associated with our reintroduction of VIBATIV® in the U.S., including the creation of an independent sales and marketing organization with appropriate technical expertise, supporting infrastructure and distribution capabilities, expansion of medical affairs presence, manufacturing and third party vendor logistics and consultant support.

As part of the business separation announced in April 2013, we currently anticipate funding the new company with approximately $400.0 million. We expect this initial cash will fund the new company’s operations through significant potential corporate milestones for approximately the next two to three years after the completion of the spin-off, based on current operating plans and financial forecasts. Changes in our development or operating plans, the timing of, and our cash balance at the time of the spin-off, 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.

Pursuant to our LABA collaboration with GSK, 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 payments to GSK for registrational and launch-related milestone fees, we paid a total of $140.0 million as of March 31, 2014 and recorded an additional $30.0 million liability in April 2014. These milestone fees paid or owed to GSK were capitalized as finite-lived intangible assets, which are being

amortized over their estimated useful lives commencing upon commercial launch. We estimate the remaining potential milestone payments of $50.0 million could be payable by the end of 2014.

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, 2014, we determined that the achievement of the requisite performance conditions for the first tranche of these awards was probable and, as a result, a total of $9.5 million of cash bonus expense will be recognized in 2014. In May 2014, the Compensation Committee approved the modification of certain performance conditions for the second tranche of awards related to this grant. The modification permitted recognition of partial achievement of the original performance conditions that were met prior to the business separation. Therefore, we determined that the achievement of the requisite performance conditions for this tranche was probable. As a result an additional $5.0 million of cash bonus expense will be recognized over a one year vesting period commencing in May 2014. In addition, a portion of the remaining cash award was restructured to address potential retention concerns following the business separation.



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In April 2014, we entered into certain note purchase agreements relating to the private placement of $450.0 million aggregate principal amount of non-recourse 9% fixed rate term notes due 2029 issued by our wholly-owned subsidiary. The 2029 Notes are secured by a security interest in a segregated bank account established to receive 40% of royalties from global net sales occurring on or after April 1, 2014 and ending upon the earlier of full repayment of principal or May 15, 2029 due to us under the LABA Collaboration with GSK. Prior to May 15, 2016, in the event that the specified portion of royalties received in a quarter is less than the interest accrued for the quarter, the principal amount of the 2029 Notes will increase by the interest shortfall amount for that period. From the net proceeds of the offering of approximately $434.3 million, we established a $32.0 million milestone payment reserve account to fund 40% of any future milestone payments that could become payable under the LABA Collaboration with GSK. This milestone reserve account is a segregated bank account in which the $32.0 million is retained. As part of this sale, we incurred approximately $15.7 million in transaction costs, which will be amortized to interest expense over the estimated life of the 2029 Notes.

*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 and financials forecasts. If our current operating plans and financial forecasts 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 years, were as follows:

| | Three Months Ended March 31, | | |
|---|---|---|---|
| **(In thousands)** | **2014** | **2013** | **Change** |
| Net cash used in operating activities | $ 50,637 | $ 31,631 | $ 19,006 |
| Net cash provided by (used in) investing activities | 14,130 | (45,012) | 59,142 |
| Net cash provided by financing activities | 18,272 | 247,864 | (229,592) |

*Cash Flows from Operating Activities*

Cash used in operating activities is primarily driven by net loss, excluding the effect of non-cash charges or differences in the timing of cash flows and earnings recognition.

Net cash used in operating activities in the first quarter of 2014 of $50.6 million was primarily due to:

- $49.3 million used in operating expenses, after adjusting for non-cash related items of: $17.1 million consisting primarily of stock- based compensation expense of $13.5 million and depreciation and amortization expenses of $3.4 million;
- $3.1 million used for interest payments on convertible subordinated notes payable;
- $2.1 million used to increase prepaid expenses and other current assets;
- $1.0 million used to increase other assets;
- $0.4 million used to increase inventories;
- $2.3 million provided by the decrease in receivable from collaborative arrangements related to net receipts of royalty revenue and reimbursement of R&D services; and
- $3.2 million provided by the net increase in accrued liabilities due to $4.4 million increase in accrued personnel-related expenses, accrued clinical and development expense, and other accrued liabilities, and $1.2 million decrease in accounts payable primarily due to the timing of payments.

Net cash used in operating activities in the first quarter of 2013 of $31.6 million was primarily due to:

- $26.9 million used in operating expenses, after adjusting for non-cash related items of $7.8 million consisting primarily of stock- based compensation expense of $6.1 million, depreciation and amortization expenses of $1.9 million;
- $3.4 million used to decrease accrued liabilities primarily due to a $3.2 million decrease in accrued personnel-related expenses, accrued clinical and development expense;
- $2.6 million used for interest payments on convertible subordinated notes payable;
- $2.5 million used to increase inventories;
- $1.2 million used to increase receivable from collaborative arrangements related to reimbursement of R&D services
- $1.2 million used to increase prepaid expenses and other current assets; and

- $5.0 million received in upfront fees under our collaborative arrangements.



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*Cash Flows from Investing Activities*

Net cash provided by investing activities in the first quarter of 2014 of $14.1 million was primarily due to $65.8 million of maturities in available-for sale securities, net of purchases, partially offset by $55.0 million used for milestone payments to GSK.

Net cash used in investing activities in the first quarter of 2013 of $45.0 million was primarily due to $44.4 million in cash balances being invested in available-for-sale securities.

*Cash Flows from Financing Activities*

Net cash provided by financing activities in the first quarter of 2014 of $18.3 million was primarily due to net proceeds from the issuances of our common stock, which includes net proceeds of $12.9 million received from private placements of our common stock to an affiliate of GSK.

Net cash provided by financing activities in the first quarter of 2013 of $247.9 million was primarily due to net proceeds of $281.7 million received from the January 2013 issuance of 2.125% convertible subordinated notes due in 2023, partially offset by $36.8 million of payments on privately-negotiated capped call option transactions in connection with the issuance of the notes.

***Off-Balance Sheet Arrangements***

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***

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 $28.2 million related to stock-based compensation expense, net of forfeitures, 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, 2014, we determined that the achievement of the requisite performance conditions for the first tranche of these awards was probable and, as a result, a total of $7.0 million of stock-based compensation expense and $9.5 million of cash bonus expense will be recognized in 2014 related to this grant. In May 2014, the Compensation Committee approved the modification of certain performance conditions for the second tranche of these awards. The modification permitted recognition of partial achievement of the original performance conditions that were met prior to the business separation. Therefore, we determined that the achievement of the requisite performance conditions for this tranche was probable. As a result an additional $4.3 million of stock-based compensation expense and $5.0 million of cash bonus expense will be recognized over a one year vesting period commencing in May 2014. In addition, the remaining unvested equity award and a portion of the remaining cash award were restructured to reflect the change in our Company and to address potential retention concerns following the business separation.

**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, 2013.

Pursuant to our LABA collaboration with GSK, 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 payments to GSK for registrational and launch-related milestone fees, we paid a total of $140.0 million as of March 31, 2014 and recorded an additional $30.0 million liability in April 2014. These milestone fees paid or owed to GSK were capitalized as finite-lived intangible assets, which are being amortized over their estimated useful lives commencing upon commercial launch. We estimate the remaining potential milestone payments of $50.0 million could be payable by the end of 2014.

In April 2014, we entered into certain note purchase agreements relating to the private placement of $450.0 million aggregate principal amount of non-recourse 9% fixed rate term notes due 2029 issued by our wholly-owned subsidiary.

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

During the first three months of 2014, 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, 2013.



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In April 2014, we entered into certain note purchase agreements relating to the private placement of $450.0 million aggregate principal amount of non-recourse 9% fixed rate term notes due 2029 issued by our wholly-owned subsidiary.

**Item 4. Controls and Procedures.**

*Evaluation of Disclosure Controls and Procedures.*

We conducted an evaluation as of March 31, 2014, 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.

*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.



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**PART II. OTHER INFORMATION**

**ITEM 1A. RISK FACTORS**

**Risks Related to our Business**

***If the commercialization of RELVAR®/BREO® ELLIPTA® in the countries in which it has received regulatory approval encounter any delays or adverse developments, or perceived delays or adverse developments, or if sales or payor coverage do not meet investor expectations, our business will be harmed, and the price of our securities could fall.***

Under our agreements with our collaborative partner GSK, GSK has full responsibility for commercialization of BREO® ELLIPTA® and RELVAR® ELLIPTA®. GSK launched BREO® ELLIPTA® into the U.S. and Canadian markets in October 2013 and January 2014, respectively. GSK launched RELVAR® ELLIPTA® in Japan during December 2013 and in the United Kingdom, Germany and Denmark during January 2014. BREO® ELLIPTA® is the proprietary name in the United States (U.S.) and Canada and RELVAR® ELLIPTA® is the proprietary name outside the U.S. and Canada. As we expected, the initial launch of BREO® ELLIPTA® has been relatively slow, as this is a primary care product and we believe it will take time to obtain payor coverage and increase physician awareness. However, any delays or adverse developments or perceived delays or adverse developments with respect to the commercialization of RELVAR®/BREO® ELLIPTA® in the U.S., Europe, Japan, Canada, Australia or other countries in which RELVAR®/BREO® ELLIPTA® has received regulatory approval, including if sales or payor coverage do not meet investor expectations, will significantly harm our business and could cause the price of our securities to fall.

***If the commercialization of ANORO™ ELLIPTA™ (UMEC/VI) in the countries in which it has received regulatory approval encounter any delays or adverse developments, or perceived delays or adverse developments, or if sales or payor coverage do not meet investor expectations, our business will be harmed, and the price of our securities could fall.***

Following the December 2013 approval of ANORO™ ELLIPTA™ (UMEC/VI) by the U.S. Food and Drug Administration (FDA), GSK commercially launched ANORO™ ELLIPTA™ in the U.S. in April 2014. Any delays or adverse developments or perceived delays or adverse developments with respect to the commercialization of ANORO™ ELLIPTA™ in the U.S. or Canada, including if sales or payor coverage do not meet investor expectations, will significantly harm our business and could cause the price of our securities to fall.

***Any adverse developments or results or perceived adverse developments or results with respect to the Phase 3 programs for FF/VI in asthma or chronic obstructive pulmonary disease (COPD), for UMEC/VI in COPD or any future studies will significantly harm our business and could cause the price of our securities to fall, and If regulatory authorities in those countries in which approval has not yet been granted determine that the Phase 3 programs for FF/VI in asthma or COPD or the Phase 3 programs for UMEC/VI for COPD do not demonstrate adequate safety and efficacy, the continued development of FF/VI or UMEC/VI or both may be significantly delayed, they may not be approved by these 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.***

Although we have announced the completion of, and reported certain top-line data from, the Phase 3 registrational program for FF/VI in COPD and asthma, additional studies of FF/VI are underway. In September 2012, GSK announced that it was commencing an additional Phase 3 study to complete the U.S. asthma filing package of FF/VI, in December 2013 we and GSK announced positive results from that additional Phase 3 study, and in April 2014 GSK announced its plan to file FF/VI in the U.S. for asthma by the end of 2014. The Phase 3b program for FF/VI in COPD commenced in February 2011. Any adverse developments or results or perceived adverse developments or results with respect to the asthma Phase 3 study, the COPD Phase 3b program or any future studies will significantly harm our business and could cause the price of our securities to fall.

Although the FDA and Health Canada approved ANORO™ ELLIPTA™ in December 2013, it has not yet been approved in other countries. GSK submitted a regulatory application for UMEC/VI (proposed brand name ANORO®) for the treatment of COPD in Europe in January 2013 which was accepted for review and in February 2014 GSK and we announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion recommending marketing authorization for UMEC/VI (under the

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proposed brand name ANORO®) as a once daily, maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. A CHMP positive opinion is one of the final steps before marketing authorization is granted by the European Commission, but does not always result in marketing authorization. A final decision by the European Commission is anticipated during the second quarter of 2014. GSK also submitted a regulatory application for UMEC/VI (proposed brand name ANORO™ ELLIPTA™) in Japan in April 2013, which submission has been accepted for review. GSK plans to make regulatory submissions in other countries for FF/VI and UMEC/VI. Any adverse developments or results or perceived adverse developments or results with respect to these regulatory submissions (such as the 2013 withdrawal of the COPD submission from the Japanese New Drug Application), the FF/VI program, 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:

- not every study, nor every dose in every study, in the Phase 3 programs for FF/VI achieved its primary endpoint and regulatory authorities may determine that additional clinical studies are required;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in these programs having to do with the LABA VI, which is a component of FF/VI and UMEC/VI;
- 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;
- regulatory authorities determining that the Phase 3 programs in asthma or in COPD raise safety concerns or do not demonstrate adequate efficacy; or
- any change in FDA policy or guidance regarding the use of LABAs to treat asthma or the use of LABAs combined with a LAMA to treat COPD.

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 U.S. for FF/VI and increase the overall risk for FF/VI for the treatment of asthma in the U.S.

***RELVAR®/BREO® ELLIPTA® and ANORO™ ELLIPTA™ face substantial competition for their intended uses in the targeted markets from products discovered, developed, launched and commercialized by established pharmaceutical companies, which could cause the royalties payable to us pursuant to the Collaboration Agreement to be less than expected, which in turn would harm our business and could cause the price of our securities to fall.***

GSK has responsibility for obtaining regulatory approval, launching and commercializing RELVAR®/BREO® ELLIPTA® and ANORO™ ELLIPTA™ for their intended uses in the targeted markets around the world. While these products have received regulatory approval and been launched and commercialized in the United States and other targeted markets, the products face substantial competition from existing products previously developed and commercialized by competing pharmaceutical companies for the treatment of COPD and asthma and can expect to face additional competition from new products that are discovered, developed and commercialized by the same pharmaceutical companies and other competitors going forward.



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Many of these competitors are international in scope with substantial financial, technical and personnel resources that permit them to discover, develop, obtain regulatory approval and commercialize new products in a highly efficient and low cost manner at competitive prices to consumers. In addition, many of these competitors have substantial commercial infrastructures that facilitate commercializing their products in a highly efficient and low cost manner at competitive prices to consumers. The market for products developed for treatment of COPD and asthma continues to experience significant innovation and reduced cost in bringing products to market over time. There can be no assurance that these products will not be replaced by new products that are deemed more effective at lower cost to consumers. The ability of RELVAR®/BREO® ELLIPTA® and ANORO™ ELLIPTA™ to succeed and achieve the anticipated level of sales depends on the ability of these products to maintain a competitive advantage over other products with the same intended use in the targeted markets.

If sales of RELVAR®/BREO® ELLIPTA® and ANORO™ ELLIPTA™ are less than anticipated because of existing or future competition in the markets in which they are commercialized, including competition from existing and new products that are perceived as lower cost or more effective, our royalty payments will be less than anticipated, which in turn would harm our business and could cause the price of our securities to fall.

***If the MABA program for the treatment of COPD encounters further delays, does not demonstrate safety and efficacy or is 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 the inhaled corticosteroid, fluticasone propionate (“FP”), and a number of Phase 3-enabling non-clinical studies. ‘081 is now being progressed as a combination with FF delivered once-daily in the ELLIPTA® inhaler which requires additional work on non-clinical studies, manufacturing and a Phase 1 bioequivalence study. As a result, it is unlikely that a Phase 3 study with ‘081 will commence in 2014. Any further delays or adverse developments or results or perceived adverse developments or results with respect to the MABA program 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:

- GSK deciding to further delay or halt development of ‘081 monotherapy or the combination ‘081/FF;
- the FDA and/or other regulatory authorities determining that any of the ‘081 studies do not demonstrate adequate safety or efficacy, or that additional non-clinical or clinical studies are required with respect to the MABA 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.

***In February 2014, GSK noted an intention to move the UMEC/VI/FF (LABA/LAMA/ICS) program being developed under our LABA collaboration into Phase 3 in 2014 or 2015. If GSK is unable to meet that goal, if the program encounters delays, does not demonstrate safety and efficacy, is terminated, or if there are any adverse developments or perceived adverse developments with respect to the program, our business will be harmed, and the price of our securities could fall.***

Under the collaboration agreements between the parties, GSK and Theravance are exploring various paths to create triple therapy respiratory medications. The use of triple therapy is supported by the GOLD (Global initiative for chronic Obstructive Lung Disease) guidelines in high-risk patients with severe COPD and a high risk of exacerbations. One potential triple therapy path is the combination of UMEC/VI (two separate bronchodilators) and FF (an inhaled corticosteroid), to be administered via the ELLIPTA® dry powder inhaler, referred to as UMEC/VI/FF. In February 2014, GSK noted an intention to move UMEC/VI/FF into Phase 3 in 2014 or 2015. If GSK is unable to meet that goal, if the program encounters delays, does not demonstrate safety and efficacy, is terminated, or if there are any adverse developments or perceived adverse developments with respect to the program, our business will be harmed, and the price of our securities could fall.



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***In April 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 lengthy, complicated and ongoing process to separate the two businesses has and will continue to divert the attention of our management and employees, may disrupt our operations, has and will continue to increase our professional services expenses and may not be consummated in the second quarter of 2014 or at all.***

On April 25, 2013 we announced our intention to separate our businesses into two independent, publicly traded companies. On August 1, 2013, the company to be spun-off, Theravance Biopharma, Inc. (Theravance Biopharma), filed a preliminary Form 10 with the SEC, and subsequent amendments on September 27, 2013, October 29, 2013, November 22, 2013, April 8, 2014, April 30, 2014 and May 7, 2014. After the spin-off, Theravance will be responsible for all development and commercial activities under the LABA collaboration and the Strategic Alliance agreements with GSK. Theravance will be eligible to receive the associated potential royalty revenues from FF/VI (RELVAR®/BREO® ELLIPTA®), UMEC/VI (ANORO™ ELLIPTA™) and potentially VI monotherapy and 15% of the potential royalty revenues from UMEC/VI/FF, MABA, and MABA/FF and other products that may be developed under the LABA collaboration and Strategic Alliance agreements. Theravance Biopharma 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 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 separation is not completed by June 30, 2014, GSK’s consent to the terms of the separation will expire and we would have to determine whether to re-seek GSK’s consent, proceed without GSK’s consent or not proceed. 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, and the price of our securities is likely to fall.

In conjunction with the planned spin-off of Theravance Biopharma, on March 3, 2014, we, Theravance Biopharma and GSK entered into a series of agreements clarifying how the companies will implement the separation and operate following the spin-off. We, Theravance Biopharma and GSK entered into a three-way master agreement providing for GSK’s consent to the spin-off provided certain conditions are met. We and GSK also entered into amendments of our LABA Collaboration Agreement and Strategic Alliance Agreement, and Theravance Biopharma and GSK entered into a governance agreement, a registration rights agreement and an extension agreement. The master agreement is currently effective, but will terminate if the spin-off is not effected by June 30, 2014, and the other agreements will become effective upon the spin-off, provided that the spin-off is effected on or before June 30, 2014.

The amendments to the LABA collaboration agreement and the strategic alliance agreement do not change the royalty rates or other economic terms. The amendments do provide that GSK’s diligent efforts obligations regarding commercialization matters under both agreements will change upon regulatory approval in either the United States or the European Union of UMEC/VI/FF or a MABA combined with FF. Upon such regulatory approval, GSK’s diligent efforts obligations as to commercialization matters under the GSK Agreements will have the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the collaboration agreement and strategic alliance agreement. Since GSK’s commercialization efforts following such regulatory approval will be guided by a portfolio approach across products that we will retain our full interests in upon the separation and also products that we will have retained only a portion of our interests in upon the spin-off transaction, GSK’s commercialization efforts may have the effect of reducing the overall value of our remaining interests in the GSK Agreements after the spin-off.

The process of planning for and effecting the business separation will continue to 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 has and may continue to disrupt our operations and may adversely impact the progress of our discovery and development efforts, disrupt our relationships with collaborators and increase employee turnover.

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We currently anticipate funding Theravance Biopharma with approximately $400 million at separation. We expect this initial cash will fund the new company's operations through significant potential corporate milestones for approximately the next two to three years after the completion of the spin-off, based on current operating plans and financial forecasts. Changes in our development or operating plans, the timing of, and our cash balance at the time of, the spin-off, 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 we devote 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 we anticipate.

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

Under the terms of a separation and distribution agreement to be entered into between us and Theravance Biopharma, Theravance Biopharma will indemnify us from and after the spin-off with respect to (i) all debts, liabilities and obligations transferred to Theravance Biopharma in connection with the spin-off (including its failure to pay, perform or otherwise promptly discharge any such debts, liabilities or obligations after the spin-off), (ii) any misstatement or omission of a material fact in its information statement filed with the SEC, resulting in a misleading statement and (iii) any breach by it of certain agreements entered into between the parties in connection with the spin-off. Theravance Biopharma's ability to satisfy these indemnities, if called upon to do so, will depend upon its future financial strength and if we are not able to collect on indemnification rights from Theravance Biopharma, our financial condition may be harmed.

Under the terms of a transition services agreement to be entered into between us and Theravance Biopharma, Theravance Biopharma will provide us with a variety of administrative services for a period of time following the spin-off, including (i) record keeping support, (ii) finance, tax and accounting support to assist us in a secondary capacity to our own personnel, (iii) legal support, (iv) human resources support and (v) facilities support to the extent we continue to occupy separate space at our current South San Francisco, California facilities. We will be relying on Theravance Biopharma for execution of these administrative activities through the transition period, which is a period when Theravance Biopharma personnel will be highly focused on supporting their own newly public company. If there is any disruption in the provision of these services to us, or if the services provided to us are not provided in a timely or satisfactory manner, our business operations could be adversely affected.

***The amount of our net operating losses that will be used as a result of pre-spin-off restructuring is uncertain.***

As a part of the overall spin-off transaction, it is anticipated that certain assets that are transferred by us to Theravance Biopharma will result in taxable transfers pursuant to Section 367 of the Internal Revenue Code of 1986, as amended (the "Code"), or other applicable provisions of the Code and Treasury Regulations. The taxable gain recognized by us attributable to the transfer of certain assets to Theravance Biopharma will equal the excess of the fair market value of each asset transferred over our adjusted tax basis in such asset. Although our basis in the cash we transfer to Theravance Biopharma will be equal to the amount of such cash (and, therefore, no gain will be recognized on the transfer of such cash), our basis in other assets (other than cash) transferred to Theravance Biopharma may be significantly less than their respective fair market values, which could result in substantial taxable gain to us. The determination of the fair market value of non publicly traded assets is subjective and could be subject to adjustments or future challenge by the Internal Revenue Service ("IRS"), which could result in an increase in the amount of gain, and thus U.S. federal income tax, realized by us as a result of the transfer. Our U.S. federal income tax resulting from any gain recognized upon the transfer of our assets to Theravance Biopharma (including any increased U.S. federal income tax that may result from a subsequent determination of higher fair market values for the transferred assets), may be reduced by our net operating loss carryforward. Although federal and state tax laws impose restrictions on the utilization of net operating losses in the event of an ownership change, as defined in Section 382 of the Code, we conducted an analysis to determine whether an ownership change had occurred since inception through December 31, 2013, and concluded that we had undergone two ownership changes in prior years. However, notwithstanding the applicable annual limitations, we estimate that no portion of the net operating loss or credit carryforwards will expire before becoming available to reduce federal and state income tax liabilities. We had approximately $1.4 billion of net operating loss as of December 31, 2013. We expect our net operating loss carryforward and current projected losses will generally fully offset the U.S. federal income tax resulting from the



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gains we will realize in connection with the pre spin-off restructuring, although there is expected to be approximately 2 percent alternative minimum tax federal tax liability to the extent such gains are offset with net operating loss carryforwards from prior years. However, the amount of our net operating loss carryforward that will be used is uncertain as we are not seeking a pre-spin-off appraisal of the fair market value of our transferred assets, but instead will be determining fair market values after the spin-off in significant part on the trading prices of Theravance Biopharma shares following the spin-off.

***Our Stockholders could incur significant U.S. federal income tax liabilities.***

Because of uncertain issues relating to the taxable status of the planned distribution, we sought a private letter ruling from the IRS regarding the U.S. federal income tax consequences of the distribution of Theravance Biopharma ordinary shares to our stockholders substantially to the effect that the distribution, except for cash received in lieu of a fractional share of Theravance Biopharma ordinary shares, would qualify as tax-free under Sections 368(a)(1)(D) and 355 of the Code and, that, for U.S. federal income tax purposes, no gain or loss would be recognized by a holder of our common stock upon the receipt of Theravance Biopharma ordinary shares pursuant to the distribution. The IRS declined to issue such ruling and has informed us that in the view of the IRS, the distribution will fail to satisfy the requirements of Section 355 of the Code. Specifically, the IRS informed us that, in its view, we will not be engaged in an "active trade or business" immediately following the distribution, as required by Section 355 of the Code, and that the IRS intends to treat the distribution as a taxable transaction. Accordingly, all or a portion of the Theravance Biopharma ordinary shares you receive is expected be taxable to you as a dividend. If the spin-off is taxable, an amount equal to the fair market value of Theravance Biopharma ordinary shares received by you (including any fractional shares deemed to be received) on the distribution date will be treated as a taxable dividend to the extent of your ratable share of any current and accumulated earnings and profits of Theravance, measured as of the end of the year in which the distribution occurs, with the excess treated as a non- taxable

return of capital to the extent of your tax basis in our common stock and any remaining excess treated as a capital gain. You could incur significant U.S. federal income tax liabilities as a result of the distribution.

***Completion of the Proposed Spin-off of Theravance Biopharma will result in substantial changes in our Board and management.***

After the spin-off, our Chief Executive Officer is expected to work part time for us and part time for Theravance Biopharma and this arrangement is expected to last until the earlier of recruitment and transition of a new chief executive officer for Theravance or nine months following the spin-off. Although we will benefit from his deep knowledge of our business, as well as his familiarity with our systems, policies, procedures and mode of operation, the lack of his full time focus on our business may dilute his effectiveness on our behalf and therefore hurt our business. In addition, we also anticipate that some or all of the other senior officers remaining at Theravance may become officers of Theravance Biopharma following the spin-off as we recruit and integrate new officers for our royalty management business. Some of these senior officer transitions may occur quickly after the spin-off depending in part on our success in recruiting and integrating new officers into our management. In May 2014, we announced that in connection with the proposed spin-off, contingent upon the effectiveness of the spin-off and effective as of immediately after the payment of the dividend of Theravance Biopharma ordinary shares to our stockholders, Catherine J. Friedman, Paul Pepe and James L. Tyree will become members of our Board of Directors. Also in connection with the spin-off, current directors Henrietta H. Fore, Robert V. Gunderson, Jr., Burton G. Malkiel, Peter S. Ringrose, George M. Whitesides and William D. Young informed us that they intend to resign as members of our Board of Directors effective immediately after the effectiveness of appointment of the three new directors. At the time of the spin-off and for a period of time thereafter, these senior officer and board level changes could be disruptive to our operations, present significant management challenges and could harm our business.

***If we cannot identify a suitable commercialization partner for VIBATIV® in the U.S. we will bear the full cost of developing the capability to market, sell and distribute the product.***

Our general 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 collaboration agreements, we will need a partner in order to commercialize such products unless we establish independent sales, marketing and



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distribution capabilities with appropriate technical expertise and supporting infrastructure. VIBATIV® was returned to Theravance by Astellas Pharma Inc. (Astellas) (our former VIBATIV® collaboration partner) in January 2012. On August 14, 2013 we announced the reintroduction of VIBATIV® to the U.S. market with the commencement of shipments into the wholesaler channel. While we have contracted a small sales force and expanded our medical affairs presence, other commercialization alternatives for the U.S. market are being evaluated. The risks of commercializing VIBATIV® in the U.S. without a partner include:

- 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 could, depending on the scope and the method of the marketing effort, 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 educate adequate numbers of physicians about prescribing VIBATIV® in appropriate clinical situations; and
- 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.

Since our reintroduction of VIBATIV® to the U.S. market in August 2013, we commenced recognition of revenue on the sale of VIBATIV® in first quarter of 2014 of $0.9 million, reflecting our limited sales, marketing and medical affairs investment and the relatively slow sales ramp for a hospital-based antibiotic. 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 in successfully 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.

***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.

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 (for example, in 2013 when TD-9855 did not meet the primary efficacy endpoints in the Phase 2 study in adult patients with Attention-Deficit/Hyperactivity Disorder);
- 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;



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- 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.

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 VIBATIV®, discovered and developed by us, is approved in the U.S. and Canada, and RELVAR®/BREO® ELLIPTA® developed in collaboration with GSK, is approved in the U.S., EU, Japan, Canada, and a number of other countries, and ANORO™ ELLIPTA™ 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. More recently, in 2013 we discontinued the development of TD-9855 in adult patients with Attention-Deficit/Hyperactivity Disorder because it did not meet the primary efficacy endpoints in a Phase 2 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.



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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 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.

***We rely on a single manufacturer for the Active Pharmaceutical Ingredient (API) for telavancin and a separate, single manufacturer for VIBATIV® drug product supply. Our business will be harmed if either of these single-source manufacturers are not able to satisfy demand and alternative sources are not available.***

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

Our previous VIBATIV® commercialization partner failed to maintain a reliable source of drug product supply which resulted in critical product shortages and, eventually, suspension of commercialization. In May 2012, we entered into an agreement with Hospira Worldwide, Inc. (Hospira) to supply VIBATIV® drug product. In June 2013 the FDA approved Hospira as a VIBATIV® drug product manufacturer. Although we believe that Hospira will be a reliable supplier of VIBATIV® drug product, if it cannot perform or if its performance does not meet regulatory requirements, including maintaining cGMP compliance, and if commercial manufacture of VIBATIV® drug product cannot be arranged elsewhere on a timely basis, the commercialization of VIBATIV® in the U.S. could be adversely affected and the commercial introduction of VIBATIV® in the E.U. and Canada will be further delayed.

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

We have limited in-house production capabilities for preclinical and 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 preclinical and 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 many 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;



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- 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, the U.S. labeling for VIBATIV® contains a number of boxed warnings. Products with boxed warnings are subject to more restrictive advertising regulations than products without such warnings. In addition, the VIBATIV® labeling for hospital-acquired and ventilator associated bacterial pneumonia (HABP/VABP) in the U.S. and the E.U. specifies that VIBATIV® should be reserved for use when alternative treatments are not suitable. These restrictions make it more difficult to market 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.

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 utilized by Theravance's former commercialization partner notified the FDA of an ongoing investigation related to its production equipment and processes. In response to this notice, Theravance's former VIBATIV® commercialization partner 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. As a result of this supply termination, commercialization of VIBATIV® ceased for well over a year.

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.



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The risks identified in this risk factor relating to regulatory actions and oversight by agencies in the U.S. and throughout the world also apply to the commercialization of partnered products by our collaboration partners, and such regulatory actions and oversight may limit our collaboration partners' ability to commercialize such products, which could 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, 2014, we had an accumulated deficit of approximately $1.6 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, in April 2014 we initiated a second Phase 2b study with TD-4208, our LAMA compound, and we announced positive results from a Phase 2 study of TD-9855 in our MARIN program for fibromyalgia. 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 are seeking to partner these programs, we initiated the second Phase 2b study with TD-4208 ourselves and we may choose to progress one or more other programs into later stage clinical studies by ourselves, which could increase our anticipated operating expenses substantially. Furthermore, should we decide to continue to commercialize VIBATIV® in the United States without a partner, we will incur 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 maintain or 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 maintain or 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 and financial forecasts, 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 and financial forecasts change, we may seek additional funding sooner in the form of public or private equity offerings or debt financings. For example, we initiated a second Phase 2b study with TD-4208 in our LAMA program in April 2014, and if we choose to conduct Phase 3 studies with TD-1211 in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation, or progress TD-9855 in our MARIN program into later stage development and we choose to progress any of these other programs on our own, our capital needs would increase substantially. 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 vilanterol (VI), which is the LABA product candidate in FF/VI, UMEC/VI and UMEC/VI/FF and which was discovered by GSK, is successfully developed and commercialized 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. Of these potential payments to GSK for registrational and launch-related milestone fees, we have paid a total of $140.0 million as of March 31, 2014 and recorded an additional $30.0 million liability in April 2014, and we estimate that all the remaining milestone payments of $50.0 million could be payable by the end of 2014. We are not entitled to receive any further milestone payments from GSK under the LABA collaboration. Future financing to meet our capital needs may not be available



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in sufficient amounts or on terms acceptable to us, if at all. In addition, the significant amount of debt we recently borrowed (via a wholly owned subsidiary) may limit our ability to obtain future financing. 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.***

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. If we are unable to demonstrate to physicians that, based on experience,

clinical data, side-effect profiles and other factors, VIBATIV® for the treatment of complicated skin and skin structure infections (cSSSI) and HABP/VABP caused by susceptible Gram-positive bacteria in adult patients is a suitable alternative to vancomycin and other antibacterial drugs in certain clinical situations, 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 product shortages and regional supply outages that halted commercialization of VIBATIV® , stemming from the manufacturing issues at the previous drug product supplier;
- potential negative perceptions of physicians related to the European Commission's previous suspension of marketing authorization for VIBATIV® (which suspension has been lifted) because our prior VIBATIV® commercialization partner's 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 appropriate circumstances for use 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 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



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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. In September 2013, Merck terminated its Research Collaboration and License Agreement (which provided us with research funding for the program under license) and such termination became effective in December 2013. The Alfa Wassermann agreement provides us with development funding for velusetrag, our lead compound in the 5-HT4 program. We recently announced positive topline results from a Phase 2 with velusetrag for the treatment of patients with diabetic or idiopathic gastroparesis and we and Alfa Wassermann agreed to advance velusetrag into a Phase 2b study later in 2014, but if Alfa Wassermann decides not to progress the licensed program beyond the Phase 2b study, 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 with its VIBATIV® agreement and as Merck did in September 2013 with the cardiovascular disease collaboration. 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 our partners. 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. 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 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 Clinigen for VIBATIV® for the EU, and with other companies for regional development and commercialization of VIBATIV®. 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. Velusetrag, our lead compound in the 5 HT4 program, and TD-1792, our investigational antibiotic have successfully completed a Phase 2 proof of concept study. 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 and in April 2014 we initiated a second Phase 2b study with TD-4208, our LAMA compound. 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 program with TD-9855 and our ARNI program. 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. 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 prioritize alternative programs. 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.



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***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.

The FDA enforces GCPs and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators and trial sites. 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 using our proprietary insight in chemistry, biology and multivalency, where applicable. 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 in certain circumstances, 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.



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

***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**

***Because GSK is a strategic partner as well as a significant stockholder, it may take actions that in certain cases are materially harmful to both our business or to our other stockholders.***

Although GSK beneficially owns approximately 26.9% of our outstanding capital stock as of April 30, 2014, it is also a strategic partner with rights and obligations under our collaboration and strategic alliance agreements with GSK that cause its interests to differ from the interests of us and our other stockholders. In particular, GSK has a substantial respiratory product portfolio in addition to its products that are covered by our GSK agreements. GSK may make respiratory product portfolio decisions or statements about its portfolio which may be, or may be perceived to be, harmful to the respiratory products partnered with us. For example, GSK could promote its own respiratory products and/or delay or terminate the development or commercialization of the respiratory programs covered by our GSK agreements. Also, given the potential future royalty payments GSK may



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be obligated to pay under our GSK agreements, GSK may seek to acquire us to reduce those payment obligations. The timing of when GSK may seek to acquire us could potentially be when it possesses information regarding the status of drug programs covered by our GSK agreements that has not been publicly disclosed and is not otherwise known to us. As a result of these differing interests, GSK may take actions that it believes are in its best interest but which might not be in the best interests of either us or our other stockholders. In addition, upon regulatory approval of UMEC/VI/FF or a MABA/ICS in either the U.S. or the European Union, GSK's diligent efforts obligations as to commercialization matters under the GSK Agreements will have the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the collaboration agreement and strategic alliance agreement. Since GSK's commercialization efforts following such regulatory approval will be guided by a portfolio approach across products in which we will retain our full interests upon the separation and also products in which we will have retained only a portion of our interests upon the spin-off transaction, GSK's commercialization efforts may have the effect of reducing the overall value of our remaining interests in the GSK Agreements after the spin-off. In addition, GSK could also seek to challenge our post-spin-off operation of the limited liability company to be jointly owned by us and Theravance Biopharma as violating or allowing it to terminate the GSK agreements, including by violating the confidentiality provisions of those agreements or the master agreement between GSK, Theravance Biopharma and us entered into in connection with the proposed spin-off, or otherwise violating its legal rights. Although we believe our planned operation of the limited liability company fully complies with our GSK agreements and applicable law, there can be no assurance that we will prevail against any such claims by GSK. Moreover, regardless of the merit of any claims by GSK, we may incur significant cost and diversion of resources in defending them. In addition, any uncertainty about the our respiratory programs partnered with GSK or the enforceability of our GSK agreements could result in significant reduction in the market price of our securities and other material harm to our business.

***GSK has also indicated to us that it believes its consent may be required before we can engage in certain royalty monetization transactions with third parties, which may inhibit our ability to engage in these transactions.***

In the course of our recent discussions with GSK concerning the proposed spin-off of Theravance Biopharma, GSK has indicated to us that it believes that its consent may be required before we can engage in certain transactions designed to monetize the future value of royalties that may be payable to us from GSK under our GSK Agreements. GSK has informed us that it believes that there may be certain covenants included in these types of transactions that might violate certain provisions of the GSK Agreements. Although we believe that we can structure royalty monetization transactions in a manner that fully complies with the requirements of the GSK Agreements without GSK's consent, a third party in a proposed monetization transaction may nonetheless insist that we obtain GSK's consent for the transaction or re-structure the transaction on less favorable terms. We have obtained GSK's agreement that (i) after the spin-off of Theravance Biopharma, provided such spin-off occurs on or prior to June 30, 2014 and in compliance with our master agreement with GSK and Theravance Biopharma, we may grant certain pre-agreed covenants in connection with monetization of our interests in RELVAR/BREO, ANORO and vilanterol monotherapy and portions of our interests in TRC limited liability company, and (ii) it will not unreasonably withhold its consent to our requests to grant other covenants, provided, among other conditions, that in each case, the covenants are not granted in favor of pharmaceutical or biotechnology company with a product either being developed or commercialized for the treatment of respiratory disease. If we seek GSK's consent to grant covenants before the spin-off of Theravance Biopharma is effective or with respect to the granting of covenants other than pre-agreed covenants, we may not be able to obtain GSK's consent on reasonable terms, or at all. If we proceed with a royalty monetization transaction that is not otherwise covered by our agreement with GSK without GSK's consent, GSK could request that their consent be obtained or seek to enjoin or otherwise challenge the transaction as violating or allowing it to terminate the GSK agreements. Regardless of the merit of any claims by GSK, we would incur significant cost and diversion of resources in

defending against GSK's claims or asserting our own claims and GSK may seek concessions from us in order to provide its consent. Any uncertainty about whether or when we could engage in a royalty monetization transaction, the potential impact on the enforceability of the GSK agreements or the loss of potential royalties from our respiratory programs partnered with GSK, could impair our ability to pursue a return of capital strategy for our stockholders ahead of our receipt of significant royalties from GSK, result in significant reduction in the market price of our securities and cause other material harm to our business.



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

As of April 30, 2014, GSK beneficially owned approximately 26.9% of our outstanding capital stock, and GSK has the right to acquire stock from us to maintain its percentage ownership of our capital stock in certain circumstances. 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.

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.

The procedures governing GSK offers to ours stockholders to acquire outstanding voting stock set forth in the preceding two paragraphs are applicable until the termination of the governance agreement September 1, 2015 and thereafter the foregoing restrictions will not apply.

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 30, 2014, GSK beneficially owned approximately 26.9% 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.



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***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, 2014, we owned 385 issued United States patents and 1,385 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.

***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.



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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 and have likely increased with the reintroduction of VIBATIV®. 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. Also, changes in laws outside the U.S. are expanding our potential liability for injuries that occur during clinical trials. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forgo further commercialization of the applicable products.

Although we maintain general liability and product liability insurance, this insurance may not fully cover potential liabilities and we cannot be sure that our insurer will not disclaim coverage as to a future claim. 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. The cost of defending any product liability litigation or other proceeding, even if resolved in our favor, could be substantial and

uncertainties resulting from the initiation and continuation of product liability litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. 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.



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

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. For example, while BREO® ELLIPTA® was launched for the treatment of COPD in the United States in October 2013, GSK has experienced significant challenges in gaining acceptance for BREO® ELLIPTA® for treatment of COPD by some of the largest healthcare payors and providers in the United States. 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 commercialization of RELVAR®/BREO® ELLIPTA® and ANORO™ ELLIPTA™ with GSK, including, without limitation, if payor coverage is lower than anticipated or if sales of RELVAR®/BREO® ELLIPTA® and ANORO™ ELLIPTA™ are less than anticipated because of



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existing or future competition in the markets in which they are commercialized, including competition from existing and new products that are perceived as lower cost or more effective, and our royalty payments are less than anticipated;

- 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;
- 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, 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 progressing '081 and/or '081/FF or a decision by GSK to halt the program or any further development of certain drug candidates in the program, any difficulties or delays encountered with regard to the regulatory path for '081, either

alone or in combination with other therapeutically active ingredients, or any indication from non-clinical studies of '081 that the compound is not safe or efficacious;

- any further adverse developments or perceived adverse developments with respect to the commercialization of VIBATIV®;
- 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, equity vesting and debt conversion 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, TD-9855, TD-4208, TD-1792, TD-8954 or our cardiovascular program;
- 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;
- relative illiquidity in the public market for our common stock (our three largest stockholders other than GSK collectively owned approximately 36.6% of our outstanding capital stock as of February 14, 2014 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 30, 2014, GSK beneficially owned approximately 26.9% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 4.6% of our outstanding capital stock. Based on our review of publicly available filings as of April 30, 2014, our three largest stockholders other than GSK collectively owned approximately 36.6% 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 14, 2014, we completed the sale of 342,229 shares of our common stock to Glaxo Group Limited, an affiliate of GSK, at a price of $37.55 per share, resulting in aggregate gross proceeds of $12.9 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.



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**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 Theravance, Inc. and The Bank of New York, as Rights Agent, dated as of June 22, 2007 | 10-Q | 6/30/07 |
| 4.3 | 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 |
| 4.4 | Indenture dated as of January 24, 2013 by and between Theravance, Inc. and The Bank of New York Mellon Trust Company, N.A., as trustee | 8-K | 1/25/13 |
| 4.5 | Form of 2.125% Convertible Subordinated Note Due 2023 (included in Exhibit 4.4) | | |
| 10.43 | Master Agreement by and among Theravance, Inc., Theravance Biopharma, Inc. and Glaxo Group Limited, dated March 3, 2014 | 8-K/A | 3/6/2014 |
| 10.43* | Collaboration Agreement Amendment by and between Theravance, Inc. and Glaxo Group Limited dated March 3, 2014 | 8-K/A | 3/6/2014 |
| 10.43* | Strategic Alliance Agreement Amendment by and between Theravance, Inc. and Glaxo Group Limited dated March 3, 2014 | 8-K/A | 3/6/2014 |
| 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 | Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended March 31, 2014, formatted in XBRL: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Comprehensive Income (Loss), (iv) the Condensed Consolidated Statements of Cash Flows and (iv) the Notes to the 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.

**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.

Date: May 7, 2014

/s/ Rick E Winningham

**Rick E Winningham**
Chief Executive Officer

Date: May 7, 2014

/s/ Michael W. Aguiar

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

**Exhibit 31.1**

**Certification of Chief Executive Officer**
**Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Rick E Winningham, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Theravance, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2014

/s/ Rick E Winningham
**Rick E Winningham**
Chief Executive Officer
(Principal Executive Officer)

**Exhibit 31.2**

**Certification of Chief Financial Officer**
**Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Michael W. Aguiar, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Theravance Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2014

/s/ Michael W. Aguiar
**Michael W. Aguiar**
Senior Vice President, Finance and
Chief Financial Officer
(Principal Financial Officer)

**Exhibit 32**

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**
**PURSUANT TO**
**18 U.S.C. SECTION 1350,**
**AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Rick E Winningham, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Theravance Inc. on Form 10-Q for the three months ended March 31, 2014 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition of Theravance, Inc. at the end of the periods covered by such Quarterly Report on Form 10-Q and results of operations of Theravance, Inc. for the periods covered by such Quarterly Report on Form 10-Q.

Date: May 7, 2014

By: /s/ Rick E Winningham
**Rick E Winningham**
Chief Executive Officer

**CERTIFICATION OF CHIEF FINANCIAL OFFICER**
**PURSUANT TO**
**18 U.S.C. SECTION 1350,**
**AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Michael W. Aguiar, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Theravance Inc. on Form 10-Q for the three months ended March 31, 2014 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition of Theravance, Inc. at the end of the periods covered by such Quarterly Report on Form 10-Q and results of operations of Theravance, Inc. for the periods covered by such Quarterly Report on Form 10-Q.

Date: May 7, 2014

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