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, 2013

OR

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

For the transition period from to

Commission File Number: 0-30319

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

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

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

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

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

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

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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, 2013 (Unaudited)	December 31, 2012 *
Assets		
Current assets:		
Cash and cash equivalents	$ 266,070	$ 94,849
Short-term investments	192,986	153,640
Receivable from collaboration arrangements (including amounts from a related party of $254 at March 31, 2013 and $123 at December 31, 2012)	2,217	1,064
Notes receivable, current	—	100
Prepaid expenses and other current assets	5,190	3,966
Inventories	8,049	7,514
Total current assets	474,512	261,133
Marketable securities	99,342	95,194
Restricted cash	833	833
Property and equipment, net	9,010	9,154
Notes receivable, non-current	140	140
Other assets, non-current	7,682	2,128
Total assets	$ 591,519	$ 368,582
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,525	$ 5,377
Accrued personnel-related expenses	5,128	9,002
Accrued clinical and development expenses	6,054	6,550
Other accrued liabilities	2,678	2,072
Accrued interest on convertible subordinated notes	2,198	2,372
Deferred revenue, current	9,881	4,593
Total current liabilities	29,464	29,966
Convertible subordinated notes	460,000	172,500
Deferred rent	4,872	5,074
Deferred revenue, non-current	5,672	6,014
Commitments and contingencies (Notes 3, 7 and 9)		
Stockholders' equity:		
Common stock, $0.01 par value; authorized: 200,000 shares; outstanding: 99,304 at March 31, 2013 and 98,379 at December 31, 2012	993	984
Additional paid-in capital	1,462,288	1,488,447
Accumulated other comprehensive income	92	99
Accumulated deficit	(1,371,862)	(1,334,502)
Total stockholders' equity	91,511	155,028
Total liabilities and stockholders' equity	$ 591,519	$ 368,582

* Condensed consolidated balance sheet at December 31, 2012 has been derived from audited consolidated financial statements.

See accompanying notes to condensed consolidated financial statements.

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

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

See accompanying notes to condensed consolidated financial statements.

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

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

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2013	2012
Cash flows from operating activities		
Net income (loss)	$ (37,360)	$ 84,594
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	1,898	1,910
Stock-based compensation	6,095	6,235

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

See accompanying notes to condensed consolidated financial statements.

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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. (the Company or Theravance) is a biopharmaceutical company with a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. Theravance is focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections, and central nervous system (CNS)/pain.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. In the opinion of the Company's management, the unaudited condensed consolidated financial statements have been prepared on the same basis as audited consolidated financial statements and include all adjustments, consisting of only normal recurring adjustments, necessary for the fair presentation of the Company's financial position, results of operations, comprehensive income (loss) and cash flows. The interim results are not necessarily indicative of the results of operations to be expected for the year ending December 31, 2013 or any other period.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2012 filed with the Securities and Exchange Commission (SEC) on February 26, 2013.

Principles of Consolidation

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

Use of Management's Estimates

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

Segment Reporting

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

Investments in Marketable Securities

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

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

Inventories

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

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

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

Fair Value of Stock-Based Compensation Awards

The Company uses the Black-Scholes-Merton option pricing model to estimate the fair value of options granted under its equity incentive plans and rights to acquire stock granted under its employee stock purchase plan (ESPP). The Black-Scholes-Merton option valuation model requires the use of assumptions, including the expected term of the award and the expected stock price volatility. The Company used the "simplified" method as described in Staff Accounting Bulletin No. 107, "Share-Based Payment," for the expected option term because the usage of its historical option exercise data is limited due to post-IPO exercise restrictions. Beginning April 1, 2011, the Company used its historical volatility to estimate expected stock price volatility. Prior to April 1, 2011, the Company used peer company price volatility to estimate expected stock price volatility due to the Company's limited historical common stock price volatility since its initial public offering in 2004.

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

Stock-based compensation expense was calculated based on awards ultimately expected to vest and was reduced for estimated forfeitures at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differed from those estimates. The Company's estimated annual forfeiture rates for stock options, RSUs and RSAs are based on its historical forfeiture experience.

The estimated fair value of stock options, RSUs and RSAs is expensed on a straight-line basis over the expected term of the grant and the estimated fair value of performance-contingent RSUs and RSAs is expensed using an accelerated method over the term of the award once the Company's management has determined that it is probable that performance milestones will be achieved. Compensation expense for RSUs and RSAs that contain performance conditions is based on the grant date fair value of the award. Compensation expense is recorded over the requisite service period based on management's best estimate as to whether it is probable that the shares awarded are expected to vest. The Company's management assesses the probability of the performance milestones being met on a continuous basis.

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

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

2. NET INCOME (LOSS) PER SHARE

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

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

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

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

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

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

	Three Months Ended March 31,	
(in thousands, except for per share amounts)	2013	2012
Numerator:		
Net income (loss) — basic	$ (37,360)	$ 84,594
Add: interest and issuance costs related to convertible notes	—	1,500
Net income (loss) — diluted	$ (37,360)	$ 86,094
Denominator:		
Weighted-average common shares outstanding	99,181	86,292
Less: unvested RSAs	(2,802)	(2,702)
Weighted-average common shares outstanding — basic	96,379	83,590
Dilutive effect of equity incentive plans and ESPP	—	1,822
Dilutive effect of convertible subordinated notes	—	6,668
Weighted-average common shares outstanding and dilutive potential common shares — diluted	96,379	92,080

Anti-Dilutive Securities

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

	Three Months Ended March 31,	
(in thousands)	2013	2012
Shares issuable under Equity Incentive Plans and ESPP	5,469	4,641
Shares issuable upon the conversion of convertible subordinated notes	14,256	—
Total anti-dilutive securities	19,725	4,641

3. COLLABORATIVE ARRANGEMENTS

GSK

LABA collaboration

In November 2002, the Company entered into its 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 is developing two combination products: (1) RELVAR™ or BREO™ ELLIPTA™ (FF/VI), an investigational once-daily combination medicine consisting of a LABA, vilanterol (VI), and an inhaled corticosteroid (ICS), fluticasone furoate (FF) and (2) ANORO™ ELLIPTA™ (UMEC/VI), a once-daily investigational

medicine combining a long-acting muscarinic antagonist (LAMA), umeclidinium bromide (UMEC), with a LABA, VI. For the treatment of asthma, the collaboration is developing FF/VI.

In the event that a product containing VI is successfully developed and commercialized, the Company will be obligated to make milestone payments to GSK which could total as much as $220.0 million if both a single-agent and a combination product or two different combination products are launched in multiple regions of the world. Of these potential milestone payments, the Company estimates up to $140.0 million could be payable during 2013 and all the milestone payments could be payable by the end of 2014. The Company is entitled to receive annual royalties from GSK of 15% on the first $3.0 billion of annual global net sales and 5% for all annual global net sales above $3.0 billion. Sales of single-agent LABA medicines and combination medicines would be combined for the purposes of this royalty calculation. For other products combined with a LABA from the LABA collaboration, such as ANORO™ ELLIPTA™, royalties are upward tiering and range from the mid-single digits to 10%. However, if GSK is not selling a LABA/ICS combination product (e.g., FF/VI) at the time that the first other LABA combination (e.g., UMEC/VI) is launched, then the royalties described above for the LABA/ICS combination (e.g., FF/VI) medicine would be applicable.

2004 Strategic Alliance

In March 2004, the Company entered into its strategic alliance with GSK. Under this alliance, GSK received an option to license exclusive development and commercialization rights to product candidates from certain of the Company's discovery programs on pre-determined terms and on an exclusive, worldwide basis. Upon GSK's decision to license a program, GSK is responsible for funding all future development, manufacturing and commercialization activities for product candidates in that program. In addition, GSK is obligated to use diligent efforts to develop and commercialize product candidates from any program that it licenses. If the program is successfully advanced through development by GSK, the Company is entitled to receive clinical, regulatory and commercial milestone payments and royalties on any sales of medicines developed from the program. If GSK chooses not to license a program, the Company retains all rights to the program and may continue the program alone or with a third party.

In 2005, GSK licensed the Company's bifunctional muscarinic antagonist-beta$_2$ agonist (MABA) program for the treatment of COPD, and in October 2011, the Company and GSK expanded the MABA program by adding six additional Theravance-discovered preclinical MABA compounds (the "Additional MABAs"). GSK's development, commercialization, milestone and royalty obligations under the strategic alliance remain the same with respect to '081, the lead compound in the MABA program. GSK is obligated to use diligent efforts to develop and commercialize at least one MABA within the MABA program, but may terminate progression of any or all Additional MABAs at any time and return them to the Company, at which point the Company may develop and commercialize such Additional MABAs alone or with a third party. Both GSK and the Company have agreed not to conduct any MABA clinical studies outside of the strategic alliance so long as GSK is in possession of the Additional MABAs. If a single-agent MABA medicine containing '081 is successfully developed and commercialized, the Company is entitled to receive royalties from GSK of between 10% and 20% of annual global net sales up to $3.5 billion, and 7.5% for all annual global net sales above $3.5 billion. If a MABA medicine containing '081 is commercialized only as a combination product, such as a MABA/ICS, the royalty rate is 70% of the rate applicable to sales of the single-agent MABA medicine. For single-agent MABA medicines containing an Additional MABA, the Company is entitled to receive royalties from GSK of between 10% and 15% of annual global net sales up to $3.5 billion, and 10% for all annual global net sales above $3.5 billion. For combination products containing an Additional MABA, such as a MABA/ICS, the royalty rate is 50% of the rate applicable to sales of the single-agent MABA medicine. If a MABA medicine containing '081 is successfully developed and commercialized in multiple regions of the world, the Company could earn total contingent payments of up to $125.0 million for a single-agent medicine and up to $250.0 million for both a single-agent and a combination medicine. If a MABA medicine containing an Additional MABA is successfully developed and commercialized in multiple regions of the world, the Company could earn total contingent payments of up to $129.0 million. GSK has no further option rights on any of the Company's research or development programs under the strategic alliance.

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

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

GSK Contingent Payments and Revenue

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

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

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

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

Merck

Research Collaboration and License Agreement

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

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

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

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

R-Pharm CJSC

Development and Commercialization Agreements

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

TD-1792

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

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

VIBATIV®

The Company identified the deliverables at the inception of the VIBATIV® agreement. Under the agreement, the significant deliverables were determined to be the license, committee participation and a contingent obligation to supply R-Pharm with the API compound at R-Pharm's expense, subject to entering into a future supply agreement. The Company determined that the license represents a separate unit of accounting as the license, which includes rights to the Company's underlying technologies for VIBATIV®, has standalone value because the rights conveyed permit R-Pharm to perform all efforts necessary to use the Company's technologies to bring the compounds through development and, upon regulatory approval, commercialization. Also, the

Company determined that the committee participation represents a separate unit of accounting as R-Pharm could negotiate for and/or acquire these services from other third parties. The Company determined the best estimate of selling price for the license based on potential future cash flows under the arrangement over the estimated performance period. The Company determined the best estimate of selling price of the committee participation based on the nature and timing of the services to be performed.

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

Alfa Wassermann

Development and Commercialization Agreement

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

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

Clinigen Group

Commercialization Agreement

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

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

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

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Former Collaboration Arrangement with Astellas

License, Development and Commercialization Agreement

In November 2005, the Company entered into a global collaboration arrangement with Astellas for the license, development and commercialization of VIBATIV®. Under this agreement, Astellas paid the Company non-refundable cash payments totaling $191.0 million. In January 2012, Astellas exercised its right to terminate the collaboration agreement. The rights previously granted to Astellas ceased upon termination of the agreement and Astellas stopped all promotional sales efforts. Pursuant to the terms of the agreement, Astellas is entitled to a ten-year, 2% royalty on future net sales of VIBATIV®. Net revenue

recognized under this collaboration agreement was $125.7 million for the three months ended March 31, 2012, and the Company is no longer eligible to receive any further contingent payments from Astellas.

4. AVAILABLE-FOR-SALE SECURITIES

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

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

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

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

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

At March 31, 2013, all of the marketable securities have contractual maturities within two years and the average duration of marketable securities was approximately nine months. The Company does not intend to sell the investments which are in an unrealized loss position and it is unlikely that the Company will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. The Company has determined that the gross unrealized losses on its marketable securities at March 31, 2013, were temporary in nature. All marketable securities with unrealized losses have been in a loss position for less than twelve months.

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5. FAIR VALUE MEASUREMENTS

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

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

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

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

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

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

	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, 2013:				
U.S. government securities	$ 22,170	$ —	$ —	$ 22,170
U.S. government agency securities	81,260	71,624	—	152,884
U.S. corporate notes	56,259	26,042	—	82,301
U.S. commercial paper	—	59,120	—	59,120

Money market funds	233,827	—	—	233,827
Total assets measured at estimated fair value	$ 393,516	$ 156,786	$ —	$ 550,302
Liabilities at March 31, 2013:				
Convertible subordinated notes due 2015	$ 204,413	$ —	$ —	$ 204,413
Convertible subordinated notes due 2023	—	313,573	—	313,573
Total convertible subordinated notes	$ 204,413	$ 313,573	$ —	$ 517,986

	Estimated Fair Value Measurements at Reporting Date Using			
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, 2012:				
U.S. government securities	$ 27,205	$ —	$ —	$ 27,205
U.S. government agency securities	56,969	58,497	—	115,466
U.S. corporate notes	40,472	51,094	—	91,566
U.S. commercial paper	—	23,082	—	23,082
Money market funds	78,646	—	—	78,646
Total assets measured at estimated fair value	$ 203,292	$ 132,673	$ —	$ 335,965
Liabilities at December 31, 2012:				
Convertible subordinated notes due 2015	$ —	$ 194,050	$ —	$ 194,050

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

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

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

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

6. LONG-TERM DEBT

Long-term obligations are as follows:

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

Convertible Subordinated Notes Due 2015

In January 2008, the Company completed an underwritten public offering of $172.5 million aggregate principal amount of unsecured convertible subordinated notes which will mature on January 15, 2015. The financing raised proceeds, net of issuance costs, of $166.7 million. The notes bear interest at the rate of 3.0% per year, that is payable semi-annually in arrears in cash on January 15 and July 15 of each year, beginning on July 15, 2008. The issuance costs, which are included in other long-term assets, are being amortized over the life of the notes. Unamortized issuance costs totaled $1.5 million as of March 31, 2013. Amortization expense was $0.2 million in both the three months ended March 31, 2013 and 2012.

The notes are convertible, at the option of the holder, into shares of the Company's common stock at an initial conversion rate of 38.6548 shares per $1,000 principal amount of the notes, subject to adjustment in certain circumstances, which represents an initial conversion price of approximately $25.87 per share. Holders of the notes will be able to require the Company to repurchase some or all of their notes upon the occurrence of a fundamental change (as defined) at 100% of the principal amount of the notes being repurchased plus accrued and unpaid interest. The Company may not redeem the notes prior to January 15, 2012. On or after January 15, 2012 and prior to the maturity date, the Company, upon notice of redemption, may redeem for cash all or part of the notes if the last reported sale price of its common stock has been greater than or equal to 130% of the conversion price then in effect for at least 20 trading days during any 30 consecutive trading day period prior to the date on which it provides notice of redemption. The redemption price will equal 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest up to but excluding the redemption date. As of March 31, 2013, the Company did not provide notice of redemption or redeem any of the notes.

Convertible Subordinated Notes Due 2023

In January 2013, the Company completed an underwritten public offering of $287.5 million aggregate principal amount of unsecured convertible subordinated notes which will mature on January 15, 2023. The financing raised proceeds, net of issuance costs, of approximately $281.2 million, less $36.8 million to purchase two privately-negotiated capped call option transactions in connection with the issuance of the notes. The notes bear interest at the rate of 2.125% per year, that is payable semi-annually in arrears, in cash on January 15 and July 15 of each year, beginning on July 15, 2013. The issuance

costs, which are included in other long-term assets, are being amortized over the life of the notes. Unamortized issuance costs totaled $6.2 million as of March 31, 2013. Amortization expense was $0.1 million for the three months ended March 31, 2013.

The notes are convertible, at the option of the holder, into shares of the Company's common stock at an initial conversion rate of 35.9903 shares per $1,000 principal amount of the notes, subject to adjustment in certain circumstances, which represents an initial conversion price of approximately $27.79 per share. Holders of the notes will be able to require the Company to repurchase some or all of their notes upon the occurrence of a fundamental change (as defined) at 100% of the principal amount of the notes being repurchased plus accrued and unpaid interest. The Company may not redeem the notes prior to their stated maturity date.

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

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

7. STOCK-BASED COMPENSATION

Equity Incentive Plan

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

Employee Stock Purchase Plan

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

Performance-Contingent Restricted Stock Awards

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

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

In 2011, the Compensation Committee of the Company's Board of Directors approved the grant of 1,290,000 performance-contingent RSAs to senior management. These awards have dual triggers of vesting based upon the achievement of certain performance conditions over a six-year timeframe from 2011-2016 and continued employment, both of which must be satisfied in order for the RSAs to vest. Expense associated with these RSAs would be recognized, if at all, during these years depending on the probability of meeting the performance conditions. The maximum potential expense associated with the RSAs could be up to approximately $31.9 million (allocated as $6.3 million for research and development expense and $25.6 million for general and administrative expense) if all of the performance conditions are achieved on time. As of March 31, 2013, the Company had determined that the achievement of the requisite performance conditions was not probable and, as a result, no compensation expense has been recognized. As the RSAs are dependent upon the achievement of certain performance conditions, the expense associated with the RSAs may vary significantly from period to period. If sufficient performance conditions are achieved in the remainder of 2013, then the Company would recognize up to $15.6 million in stock-based compensation expense associated with these RSAs.

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

Performance-Contingent Restricted Stock Units

In 2010, the Compensation Committee of the Company's Board of Directors approved the grant of 210,000 performance-contingent RSUs to senior management. These awards have dual triggers of vesting based upon the successful achievement of certain corporate operating milestones during 2010 and 2011, as well as a requirement for continued employment through early 2014. As of February 11, 2011, both performance milestones had been deemed achieved, and time-based vesting commenced with respect to all of the performance-contingent RSU shares. As a result, compensation expense was $41,000 for the three months ended March 31, 2013 and $96,000 for the three months ended March 31, 2012, and the remaining unrecognized expense will be recognized over the remaining vesting period using the graded vesting expense attribution method.

Stock-Based Compensation Expense

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

	Three Months Ended March 31,	
(in thousands)	**2013**	**2012**
Research and development	$ 3,797	$ 3,529
General and administrative	2,298	2,706
Total stock-based compensation expense	$ 6,095	$ 6,235

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

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

Valuation Assumptions

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

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

Stockholders' Equity

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

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8. INCOME TAXES

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

9. COMMITMENTS AND CONTINGENCIES

Special Long-Term Retention and Incentive Equity Awards Program

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

Guarantees and Indemnifications

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

10. SUBSEQUENT EVENTS

Business Separation Announcement

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

Sale of Stock

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

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

Forward-Looking Statements

The information in this discussion contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements involve substantial risks, uncertainties and assumptions. All statements contained herein that are not of historical fact, including, without limitation, statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans, intentions, expectations, goals and objectives, may be forward-looking statements. The words "anticipates," "believes," "could," "designed," "estimates," "expects," "goal," "intends," "may," "objective," "plans," "projects," "pursuing," "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. Our key programs include: RELVAR™ or BREO™ ELLIPTA™ (fluticasone furoate/vilanterol), ANORO™ ELLIPTA™ (umeclidinium bromide/vilanterol) and MABA (Bifunctional Muscarinic Antagonist-Beta$_2$ Agonist), each partnered with GlaxoSmithKline plc (GSK), and our oral Peripheral Mu Opioid Receptor Antagonist program. By leveraging our proprietary insight of multivalency to drug discovery, we are pursuing a best-in-class strategy designed to discover superior medicines in areas of significant unmet medical need.

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

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

Recent Developments

Issuance of Convertible Subordinated Notes Due 2023

On January 24, 2013, we completed an underwritten public offering of $287.5 million aggregate principal amount of unsecured convertible subordinated notes which will mature on January 15, 2023. The financing raised proceeds, net of issuance costs, of approximately $281.2 million, less $36.8 million to purchase two privately-negotiated capped call option transactions in connection with the issuance of the notes. The notes bear interest at the rate of 2.125% per year, that is payable semi-annually in arrears, in cash on January 15 and July 15 of each year, beginning on July 15, 2013. The notes are convertible into shares of our common stock, at the option of the holder, at an initial conversion rate of 35.9903 shares per $1,000 principal amount of the notes, subject to adjustment in certain circumstances, which represents an initial conversion price of approximately $27.79 per share. Holders of the notes will

be able to require us to repurchase some or all of their notes upon the occurrence of a fundamental change (as defined) at 100% of the principal amount of the notes being repurchased plus accrued and unpaid interest. We may not redeem the notes prior to their stated maturity date.

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

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

Business Separation Announcement

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

Programs

Respiratory Programs with GlaxoSmithKline plc (GSK)

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

FF/VI is an investigational, once-daily inhaled corticosteroid/long-acting beta$_2$ agonist (LABA) combination treatment, comprising FF and VI, for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD) and patients with asthma. FF/VI is administered by a new dry powder inhaler called ELLIPTA™. RELVAR™ (FF/VI for the European Union (EU) and Japan), BREO™ (FF/VI for the United States (U.S.)), and ELLIPTA™ (for the EU, U.S. and Japan) are proposed brand names and use of these brand names has not yet been approved by any regulatory authority.

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

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

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

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

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

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

GSK961081 ('081) is an investigational, single molecule bifunctional bronchodilator with both muscarinic antagonist and beta$_2$ receptor agonist activities. Based on the results from the Phase 2b study, GSK and we plan to advance '081 monotherapy into Phase 3 and the '081/FF combination into Phase 3-enabling studies, later in 2013.

Bacterial Infections Programs

VIBATIV® (telavancin)

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

Glycopeptide-Cephalosporin Heterodimer — TD-1607

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

Central Nervous System (CNS)/Pain Programs

Oral Peripheral Mu Opioid Receptor Antagonist — TD-1211

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

Monoamine Reuptake Inhibitor — TD-9855

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

Theravance Respiratory Program

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

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

GI Motility Dysfunction Program

Velusetrag

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

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Collaborative Arrangements

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

In the event that a product containing VI is successfully developed and commercialized, we will be obligated to make milestone payments to GSK which could total as much as $220.0 million if both a single-agent and a combination product or two different combination products are launched in multiple regions of the world. Of these potential milestone payments, we estimate up to $140.0 million could be payable during 2013 and all the milestone payments could be payable by the end of 2014. We are entitled to receive annual royalties from GSK of 15% on the first $3.0 billion of annual global net sales and 5%

for all annual global net sales above $3.0 billion. Sales of single-agent LABA medicines and combination medicines would be combined for the purposes of this royalty calculation. For other products combined with a LABA from the LABA collaboration, such as ANORO™ ELLIPTA™, royalties are upward tiering and range from the mid-single digits to 10%. However, if GSK is not selling a LABA/ICS combination product (e.g., FF/VI) at the time that the first other LABA combination (e.g., UMEC/VI) is launched, then the royalties described above for the LABA/ICS combination (e.g., FF/VI) medicine would be applicable.

2004 Strategic Alliance

In March 2004, we entered into our strategic alliance with GSK. Under this alliance, GSK received an option to license exclusive development and commercialization rights to product candidates from certain of our discovery programs on pre-determined terms and on an exclusive, worldwide basis. Upon GSK's decision to license a program, GSK is responsible for funding all future development, manufacturing and commercialization activities for product candidates in that program. In addition, GSK is obligated to use diligent efforts to develop and commercialize product candidates from any program that it licenses. If the program is successfully advanced through development by GSK, we are entitled to receive clinical, regulatory and commercial milestone payments and royalties on any sales of medicines developed from the program. If GSK chooses not to license a program, we retain all rights to the program and may continue the program alone or with a third party.

In 2005, GSK licensed our bifunctional muscarinic antagonist-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 '081, the lead compound in the MABA program. GSK is obligated to use diligent efforts to develop and commercialize at least one MABA within the MABA program, but may terminate progression of any or all Additional MABAs at any time and return them to us, at which point we may develop and commercialize such Additional MABAs alone or with a third party. Both GSK and we have agreed not to conduct any MABA clinical studies outside of the strategic alliance so long as GSK is in possession of the Additional MABAs. If a single-agent MABA medicine containing '081 is successfully developed and commercialized, we are entitled to receive royalties from GSK of between 10% and 20% of annual global net sales up to $3.5 billion, and 7.5% for all annual global net sales above $3.5 billion. If a MABA medicine containing '081 is commercialized only as a combination product, such as a MABA/ICS, the royalty rate is 70% of the rate applicable to sales of the single-agent MABA medicine. For single-agent MABA medicines containing an Additional MABA, we are entitled to receive royalties from GSK of between 10% and 15% of annual global net sales up to $3.5 billion, and 10% for all annual global net sales above $3.5 billion. For combination products containing an Additional MABA, such as a MABA/ICS, the royalty rate is 50% of the rate applicable to sales of the single-agent MABA medicine. If a MABA medicine containing '081 is successfully developed and commercialized in multiple regions of the world, we could earn total contingent payments of up to $125.0 million for a single-agent medicine and up to $250.0 million for both a single-agent and a combination medicine. If a MABA medicine containing an Additional MABA is successfully developed and commercialized in multiple regions of the world, we could earn total contingent payments of up to $129.0 million. GSK has no further option rights on any of our research or development programs under the strategic alliance.

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Purchase of Common Stock under our Governance Agreement and Common Stock Purchase Agreement with GSK

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

GSK Contingent Payments and Revenue

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

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

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

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

Merck

Research Collaboration and License Agreement

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

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

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

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

R-Pharm CJSC

Development and Commercialization Agreements

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

TD-1792

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

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

VIBATIV®

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

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

Alfa Wassermann

Development and Commercialization Agreement

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

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

Clinigen Group

Commercialization Agreement

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

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

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

Critical Accounting Policies and Estimates

As of the date of the filing of this quarterly report, we believe there have been no material changes or additions to our critical accounting policies and estimates during the three months ended March 31, 2013 compared to those discussed in our 2012 Annual Report on Form 10-K filed on February 26, 2013.

RESULTS OF OPERATIONS

Revenue

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

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

* Amount is less than $50,000.
** Calculation not meaningful.

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

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

Research & Development

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

	Three Months Ended March 31,		Change	
(in millions, except percentages)	2013	2012	$	%
Employee-related	$ 9.3	$ 10.2	$ (0.9)	(9)%
External research and development	7.1	13.2	(6.1)	(46)%
Stock-based compensation	3.8	3.5	0.3	9%
Facilities, depreciation and other allocated	6.2	6.3	(0.1)	(2)%
Total research and development expenses	$ 26.4	$ 33.2	$ (6.8)	(20)%

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

General and administrative

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

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

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

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Interest and other income (expense), net

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

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

* Calculation not meaningful.

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

Interest expense

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

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

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

amortization of issuance costs from our convertible subordinated notes issued in January 2008 and January 2013.

LIQUIDITY AND CAPITAL RESOURCES

Since our inception, we have financed our operations primarily through private placements and public offerings of equity and debt securities and payments received under corporate collaboration arrangements. At March 31, 2013, we had $558.4 million in cash, cash equivalents and marketable securities, excluding $0.8 million in restricted cash that was pledged as collateral for certain of our leases. In 2013, we issued and Glaxo Group Limited, an affiliate of GSK, purchased 116,527 shares of our common stock at $22.03 per share, for an aggregate purchase price of approximately $2.6 million on February 15, 2013 and 193,563 shares of our common stock at $34.61 per share, for an aggregate purchase price of approximately $6.7 million on April 30, 2013, pursuant to its periodic "top-up" rights under our governance agreement with GSK dated June 4, 2004, as amended.

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

We expect to incur substantial expenses as we continue our drug discovery and development efforts, particularly to the extent we advance our product candidates into and through clinical studies, which are very expensive. For example, TD-9855 in our MARIN program is in Phase 2 studies for both attention-deficit/hyperactivity disorder (ADHD) and fibromyalgia, and our LAMA compound TD-4208 commenced a Phase 2b study in December 2012. Also, in July 2012, we announced positive results from the key study in our Phase 2b program with TD-1211 in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation. Though we seek to partner this program, we may choose to progress TD-1211 into Phase 3 studies by ourselves, which would increase our operating expenses substantially. In addition, provided we can assure a reasonable source of VIBATIV® drug product, we intend to reintroduce VIBATIV® in the U.S. later in 2013, which will involve outside services costs associated with manufacturing and distribution capabilities. Furthermore, should we decide to commercialize VIBATIV® in the United States without a partner, we will incur significant costs and expenses associated with creating an independent sales and marketing organization with appropriate technical expertise and supporting infrastructure. We also intend to invest in other assets in our pipeline, including programs in earlier-stage clinical development and late-stage discovery. In addition, pursuant to our LABA collaboration with GSK (see the section entitled "GSK LABA Collaboration" above), we will be obligated to make milestone payments to GSK which could total as much as $220.0 million if both a single-agent and a combination product or two different combination products are launched in multiple regions of the world. Of these potential milestone payments, we estimate up to $140.0 million could be payable during 2013 and all the milestone payments could be payable by the end of 2014.

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

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

Adequacy of cash resources to meet future needs

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

Cash Flows

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

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

Cash Flows from Operating Activities

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

Cash Flows from Investing Activities

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

Cash Flows from Financing Activities

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

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OFF-BALANCE SHEET ARRANGEMENTS

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

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

Commitments and Contingencies

We indemnify our officers and directors for certain events or occurrences, subject to certain limits. We may be subject to contingencies that may arise from matters such as product liability claims, legal proceedings, shareholder suits and tax matters, as such, we are unable to estimate the potential exposure related to these indemnification agreements. We have not recognized any liabilities relating to these agreements as of March 31, 2013.

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

Contractual Obligations and Commercial Commitments

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

Pursuant to our LABA collaboration with GSK (see “GSK LABA Collaboration” above), we will be obligated to make milestone payments to GSK which could total as much as $220.0 million if both a single-agent and a combination product or two different combination products are launched in multiple regions of the world. Of these potential milestone payments, we estimate up to $140.0 million could be payable during 2013 and all the milestone payments could be payable by the end of 2014. We have not recognized any liabilities relating to this agreement as of March 31, 2013.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

We conducted an evaluation as of March 31, 2013, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, which are defined under SEC rules as controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Securities Exchange Act of 1934 (Exchange Act) (i) is recorded, processed, summarized and reported within required time periods and (ii) is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Limitations on the Effectiveness of Controls

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

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Changes in Internal Control over Financial Reporting

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

PART II. OTHER INFORMATION

Item 1A. Risk Factors

Risks Related to our Business

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

During the first quarter of 2012, we announced the completion of, and reported certain top-line data from, the Phase 3 registrational program for FF/VI in COPD and asthma. In July 2012, GSK submitted regulatory applications for FF/VI (proposed brand name RELVAR™) in Europe for both COPD and asthma, and for FF/VI (proposed brand name BREO™ ELLIPTA™) in the U.S. for COPD and both submissions have been accepted for review. In September 2012, GSK announced that it was commencing an additional Phase 3 study to complete the U.S. asthma filing package. The Phase 3b program for FF/VI in COPD commenced in February 2011. In April 2013, the FDA's Pulmonary-Allergy Drugs Advisory Committee (PADAC) discussed the New Drug Application (NDA) for FF/VI dry powder inhaler, sponsored by GSK, for the long-term maintenance treatment of airflow obstruction and for reducing exacerbations in patients with COPD (FF/VI COPD NDA). The Committee voted that the efficacy and safety data provide substantial evidence to support approval of BREO™ ELLIPTA™ as a once-daily inhaled treatment for the long-term, maintenance treatment of airflow obstruction in patients with COPD (9 for, 4 against) and also for the reduction of COPD exacerbations in patients with a history of exacerbations (9 for, 4 against). The FF/VI COPD NDA remains under review by the FDA, and the Committee's action is only a non-binding recommendation for the FDA's consideration. The FDA has the final decision making authority on the FF/VI COPD NDA, and it is not required to follow the Committee's recommendation. Any adverse developments or results or perceived adverse developments or results with respect to the FF/VI COPD NDA, other FF/VI regulatory submissions, the asthma Phase 3 study or the Phase 3b program will significantly harm our business and could cause the price of our securities to fall. Examples of such adverse developments include, but are not limited to:

- the FDA does not approve FF/VI on the May 12, 2013 PDUFA goal date, delays action on FF/VI beyond the PDUFA goal date, or issues a complete response letter or similar communication that calls into question the approvability of FF/VI; not every study, nor every dose in every study, in the Phase 3 programs for FF/VI achieved its primary endpoint and the FDA and/or other regulatory authorities may determine that additional clinical studies are required;

- inability to gain, or delay in gaining, regulatory approval for the new ELLIPTA™ investigational dry powder inhaler used in these programs;

- safety, efficacy or other concerns arising from clinical or non-clinical studies in these programs. For example, GSK is investigating seven cases of fatal pneumonia in the Phase 3 FF/VI COPD program, six of which were at a dose that is higher than the dose being pursued for approval and a majority of which occurred at one clinical site;

- safety, efficacy or other concerns arising from clinical or non-clinical studies with umeclidinium bromide/vilanterol (proposed brand name ANORO™ ELLIPTA™) (UMEC/VI) having to do with the LABA VI, which is also a component of FF/VI;

- regulatory authorities determining that the Phase 3 program in asthma or COPD raises safety concerns or does not demonstrate adequate efficacy; or

- any change in FDA policy or guidance regarding the use of LABAs to treat asthma.

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On February 18, 2010, the FDA announced that LABAs should not be used alone in the treatment of asthma and will require manufacturers to include this warning in the product labels of these drugs, along with taking other steps to reduce the overall use of these medicines. The FDA now requires that the product labels for LABA medicines reflect, among other things, that the use of LABAs is contraindicated without the use of an asthma controller medication such as an inhaled corticosteroid, that LABAs should only be used long-term in patients whose asthma cannot be adequately controlled on asthma controller medications, and that LABAs should be used for the shortest duration of time required to achieve control of asthma symptoms and discontinued, if possible, once asthma control is achieved. In addition, on March 10 and 11, 2010, the FDA held an Advisory Committee to discuss the design of medical research studies (known as "clinical trial design") to evaluate serious asthma outcomes (such as hospitalizations, a procedure using a breathing tube known as intubation, or death) with the use of LABAs in the treatment of asthma in adults, adolescents, and children. Further, in April 2011, the FDA announced that to further evaluate the safety of LABAs, it is requiring the manufacturers of currently marketed LABAs to conduct additional randomized, double-blind, controlled clinical trials comparing the addition of LABAs to inhaled corticosteroids versus inhaled corticosteroids alone. Results from these post-marketing studies are expected in 2017. It is unknown at this time what, if any, effect these or future FDA actions will have on the prospects for FF/VI. The current uncertainty regarding the FDA's position on LABAs for the treatment of asthma and the lack of consensus expressed at the March 2010 Advisory Committee may result in the FDA requiring additional asthma clinical trials in the United States (U.S.) for FF/VI and increase the overall risk for FF/VI for the treatment of asthma in the U.S.

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

The Phase 3 program for UMEC/VI with the combination of a LAMA umeclidinium bromide (UMEC), and a LABA, VI, for the treatment of COPD commenced in February 2011. In July 2012, GSK and we reported top-line results from four pivotal studies in this Phase 3 program and in August 2012, GSK and we announced the completion of this Phase 3 program and reported certain top-line data from the remaining studies in the registrational program. GSK submitted regulatory applications for UMEC/VI (proposed brand name ANORO™ ELLIPTA™) for the treatment of COPD in December 2012 in the U.S. and in January 2013 in Europe and both submissions have been accepted for review. GSK plans to make regulatory submissions in other countries during the course of 2013. Any adverse developments or results or perceived adverse developments or results with respect to these regulatory submissions or the UMEC/VI program will significantly harm our business and could cause the price of our securities to fall. Examples of such adverse developments include, but are not limited to:

- the FDA and/or other regulatory authorities determining that additional clinical studies are required with respect to the Phase 3 program in COPD;
- inability to gain, or delay in gaining, regulatory approval for the new ELLIPTA™ investigational dry powder inhaler used in the program;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in this program;
- safety, efficacy or other concerns arising from clinical or non-clinical studies with FF/VI having to do with the LABA, VI, which is also a component of UMEC/VI;
- regulatory authorities determining that the Phase 3 program in COPD raises safety concerns or does not demonstrate adequate efficacy; or
- any change in FDA policy or guidance regarding the use of LABAs combined with a LAMA to treat COPD.

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

The lead compound, GSK961081 (‘081), in the bifunctional muscarinic antagonist-beta$_2$ agonist (MABA) program with GSK has completed a Phase 2b study, a Phase 1 study in combination with fluticasone propionate (FP), an inhaled corticosteroid (ICS), and a number of Phase 3-enabling non-clinical studies. Based on the results from the Phase 2b study, GSK and Theravance plan to advance ‘081 monotherapy into Phase 3, and the ‘081/FF combination into Phase 3-enabling studies, later in 2013. Any adverse developments or results or perceived adverse developments or results with respect to these studies will harm our business and could cause the price of our securities to fall. Examples of such adverse developments include, but are not limited to:

- the FDA and/or other regulatory authorities determining that any of these studies do not demonstrate adequate safety or efficacy, or that additional non-clinical or clinical studies are required with respect to the MABA program;
- inability to gain, or delay in gaining, regulatory approval for the ELLIPTA™ dry powder inhaler used in the program;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in this program; or
- any change in FDA policy or guidance regarding the use of MABAs to treat COPD.

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

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

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

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

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

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

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

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

Our first NDA, for VIBATIV® (telavancin) for the treatment of complicated skin and skin structure infections (cSSSI) caused by susceptible Gram-positive bacteria in adult patients, was approved by the FDA in September 2009. In January 2009, we submitted a second telavancin NDA to the FDA for the NP indication based on data from our two Phase 3 studies referred to as the ATTAIN studies. These studies were conducted in accordance with the then current draft FDA guidelines and met their primary efficacy endpoint of clinical cure. During the fourth quarter of 2009 the FDA issued new draft guidance for antibacterial clinical trial design for the treatment of NP with a focus on mortality as the primary efficacy endpoint. In late 2009, we received a Complete Response Letter from the FDA indicating that the ATTAIN studies do not meet the new draft guidance and that additional clinical studies will be required for approval. While we do not plan to conduct additional clinical studies for NP, we have continued to engage with the FDA concerning the NP NDA. In late November 2012, the FDA's Anti-Infective Drugs Advisory Committee discussed the NP NDA for VIBATIV® and voted 6 (yes) and 9 (no) that the totality of the data presented provided substantial evidence of the safety and effectiveness of VIBATIV® for NP and voted 13 (yes) and 2 (no) that the totality of the data presented provided substantial evidence of the safety and effectiveness of VIBATIV® for the treatment of NP when other alternatives are not suitable. The NP NDA remains under review by the FDA. Any adverse developments or perceived adverse developments with respect to our NP NDA could adversely affect the prospects of VIBATIV® and could cause the price of our securities to fall. Lack of FDA approval for use of VIBATIV® to treat NP has adversely affected and may continue to adversely affect commercialization of this medicine in the U.S.

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

Generally, our strategy is to engage pharmaceutical or other healthcare companies with an existing sales and marketing organization and distribution system to market, sell and distribute our products. We may not be able to establish these sales and distribution relationships on acceptable terms, or at all. For any of our product candidates that receive regulatory approval in the future and are not covered by our current agreements with GSK or another partner, we will need a partner in order to commercialize such products unless we establish independent sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure. VIBATIV® was returned to us by Astellas (our former VIBATIV® collaboration partner) in January 2012, and if we cannot locate a suitable commercialization partner in the U.S. for this product, we intend to reintroduce it in the U.S. ourselves. At present, we have no sales or distribution personnel and a limited number of marketing personnel. The risks of commercializing VIBATIV® in the U.S. without a partner include:

- significant costs and expenses associated with creating an independent sales and marketing organization with appropriate technical expertise and supporting infrastructure and distribution capability, which costs and expenses are likely to exceed any product revenue from VIBATIV® for several years;
- our unproven ability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the unproven ability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products; and
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines.

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

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

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

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

- lack of effectiveness of product candidates during clinical studies;
- adverse events, safety issues or side effects relating to the product candidates or their formulation into medicines;

- inability to raise additional capital in sufficient amounts to continue our development programs, which are very expensive;
- the need to sequence clinical studies as opposed to conducting them concomitantly in order to conserve resources;
- our inability to enter into partnering arrangements relating to the development and commercialization of our programs and product candidates;
- our inability or the inability of our collaborators or licensees to manufacture or obtain from third parties materials sufficient for use in non-clinical and clinical studies;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines;
- failure of our partners to advance our product candidates through clinical development;
- delays in patient enrollment and variability in the number and types of patients available for clinical studies;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- varying regulatory requirements or interpretations of data among the FDA and foreign regulatory authorities; and
- a regional disturbance where we or our collaborative partners are enrolling patients in clinical trials, such as a pandemic, terrorist activities or war, political unrest or a natural disaster.

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

The FDA must approve any new medicine before it can be marketed and sold in the United States. We must provide the FDA and similar foreign regulatory authorities with data from preclinical and clinical studies that demonstrate that our product candidates are safe and effective for a defined indication before they can be approved for commercial distribution. We will not obtain this approval for a product candidate unless and until the FDA approves a NDA. The processes by which regulatory approvals are obtained from the FDA to market and sell a new product are complex, require a number of years and involve the expenditure of substantial resources. In order to market our medicines in foreign jurisdictions, we must obtain separate regulatory approvals in each country. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Conversely, failure to obtain approval in one or more jurisdictions may make approval in other jurisdictions more difficult.

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

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

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

Although our first product, VIBATIV®, is approved in the U.S. and Canada, none of our other product candidates have been approved by regulatory authorities. We are uncertain whether any of our other product candidates and our collaborative partners' product candidates will prove effective and safe in humans or meet applicable regulatory standards. In addition, our approach to applying our expertise in multivalency to drug discovery may not result in the creation of successful medicines. The risk of failure for our product candidates is high. For example, in late 2005, we discontinued our overactive bladder program based upon the results of our Phase 1 studies with compound TD-6301, and GSK discontinued development of TD-5742, the first LAMA compound licensed from us, after completing a single-dose Phase 1 study. In addition, although we believe the results of our Phase 2b program with TD-1211, our investigational mu-opioid antagonist, support progression into Phase 3 development, the FDA appears to be exploring whether there is evidence of a potential cardiovascular class effect related to opioid withdrawal associated with mu-opioid antagonists. Accordingly, we are currently evaluating our Phase 3 strategy due to the potentially evolving FDA requirements in this area. The data supporting our drug discovery and development programs is derived solely from laboratory experiments, non-clinical studies and clinical studies. A number of other compounds remain in the lead identification, lead optimization, preclinical testing or early clinical testing stages.

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

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

During the fourth quarter of 2011, the former third party manufacturer of VIBATIV® drug product notified the FDA of an ongoing investigation related to its production equipment and processes. The notification included all products manufactured at the third party manufacturer's facility which remain within expiry, including batches of manufactured but unreleased VIBATIV®. In November 2011, Astellas (our former VIBATIV® collaboration partner) voluntarily placed a hold on distribution of VIBATIV® to wholesalers, and cancelled pending orders for VIBATIV® with this manufacturer. In January 2013 the former third party manufacturer announced that it had voluntarily entered into a consent decree with the FDA that relates to current Good Manufacturing Practice (cGMP) requirements. In April 2013, we were advised by the FDA that its consent decree with the manufacturer prohibited the distribution of the VIBATIV® drug product lots previously manufactured but unreleased by this manufacturer. Consequently, this previously manufactured but unreleased VIBATIV® drug product will not become available for sale in the U.S. and our prior purchase orders for this inventory cannot be fulfilled. Additional VIBATIV® drug product will need to be manufactured to meet U.S. demand as well as demand from the E.U. and Canada. In May 2012 the European Commission suspended marketing authorization for VIBATIV® because the single-source VIBATIV® drug product supplier at that time did not meet cGMP requirements for the manufacture of VIBATIV®. No VIBATIV® drug product intended to meet E.U. specifications has as yet been manufactured.

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

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

With respect to our programs other than VIBATIV®, we have limited in-house production capabilities for non-clinical and early clinical study purposes, and depend primarily on a number of third-party API and drug product manufacturers. We may not have long-term agreements with these third parties and our agreements with these parties may be terminable at will by either party at any time. If, for any reason, these third parties are unable or unwilling to perform, or if their performance does not meet regulatory requirements, we may not be able to locate alternative manufacturers or enter into acceptable agreements with them. Any inability to acquire sufficient quantities of API and drug product in a timely manner from these third parties could delay clinical studies, prevent us from developing our product candidates in a cost-effective manner or on a timely basis. In addition, manufacturers of our API and drug product are subject to the FDA's cGMP regulations and similar foreign standards and we do not have control over compliance with these regulations by our manufacturers.

Our manufacturing strategy presents the following additional risks:

- because of the complex nature of our compounds, our manufacturers may not be able to successfully manufacture our APIs and/or drug products in a cost effective and/or timely manner and changing manufacturers for our APIs or drug products could involve lengthy technology transfer, validation and regulatory qualification activities for the new manufacturer. For example, we are in the process of transitioning to a new drug product manufacturer for VIBATIV®, and delays in technology transfer, validation and regulatory qualification activities could be encountered;

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

- some of the manufacturing processes for our APIs and drug products have not been scaled to quantities needed for continued clinical studies or commercial sales, and delays in scale-up to commercial quantities could delay clinical studies, regulatory submissions and commercialization of our product candidates; and

- because some of the third-party manufacturers are located outside of the U.S., there may be difficulties in importing our APIs and drug products or their components into the U.S. as a result of, among other things, FDA import inspections, incomplete or inaccurate import documentation or defective packaging.

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

Even if we receive regulatory approval for our product candidates, this approval may include limitations on the indicated uses for which we can market our medicines or the patient population that may utilize our medicines, which may limit the market for our medicines or put us at a competitive disadvantage relative to alternative therapies. For example, VIBATIV®'s U.S. labeling for cSSSI contains a boxed warning regarding the risks of use of VIBATIV® during pregnancy. Products with boxed warnings are subject to more restrictive advertising regulations than products without such warnings. In addition, the VIBATIV® labeling that was approved for the E.U. in 2011 specifies that VIBATIV® should be used only in situations where it is known or suspected that other alternatives are not suitable. These restrictions could make it more difficult to market VIBATIV®. In May 2012 the European Commission suspended marketing authorization for VIBATIV® because the single-source VIBATIV® drug product supplier at that time did not meet the cGMP requirements for the manufacture of VIBATIV®. With VIBATIV® approved in certain countries, we are subject to continuing regulatory obligations, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of promotion and marketing.

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In addition, the manufacturing, labeling, packaging, adverse event reporting, advertising, promotion and recordkeeping for the approved product remain subject to extensive and ongoing regulatory requirements. If we become aware of previously unknown problems with an approved product in the U.S. or overseas or at contract manufacturers' facilities, a regulatory authority may impose restrictions on the product, the contract manufacturers or on us, including requiring us to reformulate the product, conduct additional clinical studies, change the labeling of the product, withdraw the product from the market or require the contract manufacturer to implement changes to its facilities. For example, during the fourth quarter of 2011, the third party manufacturer of VIBATIV® drug product notified the FDA of an ongoing investigation related to its production equipment and processes. The notification included all products manufactured at the third party manufacturer's facility which remain within expiry, including batches of manufactured but unreleased VIBATIV®. Astellas (our former VIBATIV® collaboration partner) subsequently placed a voluntary hold on distribution of VIBATIV® to wholesalers and cancelled pending orders for VIBATIV® with this manufacturer. In April 2013, we were advised by the FDA that its consent decree with the manufacturer prohibited the distribution of the VIBATIV® drug product lots previously manufactured but unreleased by this manufacturer. Consequently, this previously manufactured but unreleased VIBATIV® drug product will not become available for sale in the U.S. and our prior purchase orders for this inventory cannot be fulfilled. With this supply termination and the termination of our VIBATIV® collaboration agreement with Astellas, commercialization of VIBATIV® has essentially stopped, we have experienced a significant drop in the sales of the product and the reputation of VIBATIV® in the marketplace will likely suffer.

We are also subject to regulation by regional, national, state and local agencies, including the Department of Justice, the Federal Trade Commission, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies with respect to VIBATIV®, as well as governmental authorities in those foreign countries in which any of our product candidates are approved for commercialization. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including non-clinical and clinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information and promotion. If we or any third parties that provide these services for us are unable to comply, we may be subject to regulatory or civil actions or penalties that could significantly and adversely affect our business. Any failure to maintain regulatory approval will limit our ability to commercialize our product candidates, which would materially and adversely affect our business and financial condition, which may cause the price of our securities to fall.

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

We have been engaged in discovering and developing compounds and product candidates since mid-1997. We may never generate sufficient revenue from the sale of medicines or royalties on sales by our partners to achieve profitability. As of March 31, 2013, we had an accumulated deficit of approximately $1.4 billion.

We expect to incur substantial expenses as we continue our drug discovery and development efforts, particularly to the extent we advance our product candidates into and through clinical studies, which are very expensive. For example, TD-9855 in our MARIN program is in Phase 2 studies for both attention-deficit/hyperactivity disorder (ADHD) and fibromyalgia and our LAMA compound TD-4208 commenced a Phase 2b study in December 2012. Also, in July 2012, we announced positive results from the key study in our Phase 2b program with TD-1211 in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation. Though we seek to partner this program, we may choose to progress TD-1211 into Phase 3 studies by ourselves, which would increase our operating expenses substantially. Furthermore, should we decide to commercialize VIBATIV® in the United States without a partner, we will incur significant costs and expenses associated with creating an independent sales and marketing organization with appropriate technical expertise, supporting infrastructure and distribution capabilities. As a result, we expect to continue to incur substantial losses for the foreseeable future. We are uncertain when or if we will be able to achieve or sustain profitability. Failure to become and remain profitable would adversely affect the price of our securities and our ability to raise capital and continue operations.

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

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

vilanterol (VI), which is the LABA product candidate in FF/VI, UMEC/VI and UMEC/VI/FF and which was discovered by GSK, is approved and launched in multiple regions of the world as both a single-agent and a combination product or two different combination products, we will be obligated to pay GSK milestone payments that could total as much as $220.0 million and we will not be entitled to receive any further milestone payments from GSK. Of these potential milestone payments, we estimate up to $140.0 million could be payable during 2013 and all the milestone payments could be payable by the end of 2014. Future financing to meet our capital needs may not be available in sufficient amounts or on terms acceptable to us, if at all. Even if we are able to raise additional capital, such financing may result in significant dilution to existing security holders. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to make reductions in our workforce and may be prevented from continuing our discovery and development efforts and exploiting other corporate opportunities. This could harm our business, prospects and financial condition and cause the price of our securities to fall.

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

The commercial success of VIBATIV® depends upon its acceptance by physicians, patients, third party payors and the medical community in general. We cannot be sure that VIBATIV® will be accepted by these parties. VIBATIV® competes with vancomycin, a relatively inexpensive generic drug that is manufactured by a variety of companies, and a number of existing antibacterials manufactured and marketed by major pharmaceutical companies and

others, and may compete against new antibacterials that are not yet on the market. Even if the medical community accepts that VIBATIV® is safe and efficacious for its indicated use, physicians may restrict the use of VIBATIV® due to the current product shortages stemming from the manufacturing issues at the previous drug product supplier, the January 2012 termination of our VIBATIV® collaboration agreement with Astellas, or otherwise. If we are unable to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, VIBATIV® is preferable to vancomycin and other antibacterial drugs, we may never generate meaningful revenue from VIBATIV® which could cause the price of our securities to fall. The degree of market acceptance of VIBATIV® depends on a number of factors, including, but not limited to:

- the demonstration of the clinical efficacy and safety of VIBATIV®;
- the experiences of physicians, patients and payors with the use of VIBATIV® in the U.S.;
- potential negative perceptions of physicians related to our inability to obtain FDA approval of our NP NDA, the product shortages and regional supply outages stemming from the manufacturing issues at the previous drug product supplier or the termination of our VIBATIV® collaboration agreement with Astellas in January 2012;
- potential negative perceptions of physicians related to the European Commission's suspension of marketing authorization for VIBATIV® because the previous single-source VIBATIV® drug product supplier did not meet the cGMP requirements for the manufacture of VIBATIV®;
- the advantages and disadvantages of VIBATIV® compared to alternative therapies;
- our ability to educate the medical community about the safety and effectiveness of VIBATIV®;
- the reimbursement policies of government and third party payors; and
- the market price of VIBATIV® relative to competing therapies.

If our partners do not satisfy their obligations under our agreements with them, or if they terminate our partnerships with them, we may not be able to develop or commercialize our partnered product candidates as planned.

We entered into our LABA collaboration agreement with GSK in November 2002, our strategic alliance agreement with GSK in March 2004, and our VIBATIV® collaboration agreement with Astellas in November 2005, which was terminated by Astellas in January 2012. In October 2012, we entered into an exclusive development and commercialization agreement with Alfa Wassermann for velusetrag, our lead compound in the 5-HT4 program, covering the EU, Russia, China, Mexico and certain other countries, and we entered into a research collaboration and license agreement with Merck to discover, develop and commercialize novel small molecule therapeutics for the treatment of cardiovascular disease on an exclusive, worldwide basis. In March 2013, we entered into a commercialization agreement with Clinigen Group plc for VIBATIV® in the European Union and certain other European countries (including Switzerland and Norway). In connection with these agreements, we have granted to these parties

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

Our partners might not fulfill all of their obligations under these agreements, and, in certain circumstances, they may terminate our partnership with them, as Astellas did in January 2012. In either event, we may be unable to assume the development and commercialization of the product candidates covered by the agreements or enter into alternative arrangements with a third party to develop and commercialize such product candidates. If a partner elected to promote its own products and product candidates in preference to those licensed from us, future payments to us could be reduced and our business and financial condition would be materially and adversely affected. Accordingly, our ability to receive any revenue from the product candidates covered by these agreements is dependent on the efforts of the partner. We could also become involved in disputes with a partner, which could lead to delays in or termination of our development and commercialization programs and time-consuming and expensive litigation or arbitration.

If a partner terminates or breaches its agreements with us, or otherwise fails to complete its obligations in a timely manner, the chances of successfully developing or commercializing product candidates under the collaboration could be materially and adversely affected. For example, Astellas terminated the VIBATIV® collaboration agreement in January 2012, and due to the termination, current product shortages, regional supply outages and suspension of marketing authorization in the European Union stemming from the manufacturing issues at the previous third party VIBATIV® drug product supplier, the commercialization of VIBATIV® in the U.S. has essentially stopped and the commercial introduction of VIBATIV® in the E.U. and Canada has been delayed.

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

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

MARIN and ARNI programs. We currently intend to seek additional third parties with which to pursue collaboration arrangements for the development and commercialization of our development programs and for the future commercialization of VIBATIV® in regions where it is not currently partnered. Collaborations with third parties regarding these programs or our other programs may require us to relinquish material rights, including revenue from commercialization of our medicines, on terms that are less attractive than our current arrangements or to assume material ongoing development obligations that we would have to fund. These collaboration arrangements are complex and time-consuming to negotiate, and if we are unable to reach agreements with third-party collaborators, we may fail to meet our business objectives and our financial condition may be adversely affected. We face significant competition in seeking third-party collaborators, especially in the current uncertain economy, which is driving many biotechnology and biopharmaceutical companies to seek to sell or license their assets. We may be unable to find third parties to pursue product collaborations on a timely basis or on acceptable terms. Furthermore, for any collaboration, we may not be able to control the amount of time and resources that our partners devote to our product candidates and our partners may choose to pursue alternative products. Our inability to successfully collaborate with third parties would increase our development costs and would limit the likelihood of successful commercialization of our product candidates which may cause the price of our securities to fall.

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

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

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

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

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

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

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

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

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

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

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

We are highly dependent on principal members of our management team and scientific staff to operate our business. Our company is located in northern California, which is headquarters to many other biotechnology and biopharmaceutical companies and many academic and research institutions. As a result, competition for certain skilled personnel in our market remains intense. None of our employees have employment commitments for any fixed period of time and they all may leave our employment at will. If we fail to retain our qualified personnel or replace them when they leave, we may be unable to continue our development and commercialization activities, which may cause the price of our securities to fall.

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

Although we have security measures in place, our internal computer systems and those of our CROs and other service providers are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any material system failure, accident or security breach could result in a material disruption to our business. For example, the loss of clinical trial data from completed or ongoing clinical trials of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If a disruption or security breach results in a loss of or damage to our data or regulatory applications, or inadvertent disclosure of confidential or proprietary information, we could incur liability, the further development of our product candidates could be delayed and the price of our securities could fall.

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

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

Risks Related to our Alliance with GSK

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

As of April 25, 2013, GSK beneficially owned approximately 26.7% of our outstanding capital stock, and GSK has the right to acquire stock from us to maintain its percentage ownership of our capital stock. GSK could have substantial influence in the election of our directors, delay or prevent a transaction in which stockholders might receive a premium over the prevailing market price for their shares and have significant control over certain changes in our business.

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

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

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

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

Further, pursuant to our certificate of incorporation, we renounce our interest in and waive any claim that a corporate or business opportunity taken by GSK constitutes a corporate opportunity of ours unless such corporate or business opportunity is expressly offered to one of our directors who is a director, officer or employee of GSK, primarily in his or her capacity as one of our directors.

GSK's significant ownership position and its rights under the governance agreement may deter or prevent efforts by other companies to acquire us, which could prevent our stockholders from realizing a control premium.

As of April 25, 2013, GSK beneficially owned approximately 26.7% of our outstanding capital stock. GSK may vote at its sole discretion on any proposal to effect a change of control of us or for us to issue equity securities to one or more parties that would result in that party or parties beneficially

owning more than 20% of our outstanding capital stock. Our governance agreement with GSK requires us to exempt GSK from our stockholder rights plan, affords GSK certain rights to offer to acquire us in the event third parties seek to acquire our stock and contains other provisions that could deter or prevent another company from seeking to acquire us. For example, GSK may offer to acquire 100% of our outstanding stock from stockholders in certain circumstances, such as if we are faced with a hostile acquisition offer or if our board of directors acts in a manner to facilitate a change in control of us with a party other than GSK. As a result of GSK's significant ownership and its rights under the governance agreement, other companies may be less inclined to pursue an acquisition of us and therefore we may not have the opportunity to be acquired in a transaction that stockholders might otherwise deem favorable, including transactions in which our stockholders might realize a substantial premium for their shares.

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

Under our governance agreement with GSK, GSK could previously sell or transfer our common stock only pursuant to a public offering registered under the Securities Act or pursuant to Rule 144 of the Securities Act. GSK no longer has contractual restrictions on its ability to sell or transfer our common stock on the open market, in privately negotiated transactions or otherwise, and these sales or transfers could create substantial declines in the price of our securities or, if these sales or transfers were made to a single buyer or group of buyers, could contribute to a transfer of control of our company to a third party.

Risks Related to Legal and Regulatory Uncertainty

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

We rely upon a combination of patents, patent applications, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any involuntary disclosure to or misappropriation by third parties of this proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. The status of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and is very uncertain. As of March 31, 2013, we owned 341 issued United States patents and 1,213 granted foreign patents, as well as additional pending United States and foreign patent applications. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be invalidated or be too narrow to prevent third parties from developing or designing around these patents. If the sufficiency of the breadth or strength of protection provided by our patents with respect to a product candidate is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, the product candidate. Further, if we encounter delays in our clinical trials or in obtaining regulatory approval of our product candidates, the patent lives of the related product candidates would be reduced.

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

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

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

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

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

The risks identified in the two preceding risk factors also apply to the intellectual property protection efforts of our partner, GSK. To the extent the intellectual property protection of any of the assets in the LABA collaboration are successfully challenged or encounter problems with the United States

Patent and Trademark Office or other comparable agencies throughout the world, the future commercialization of these potential medicines could be delayed or prevented. Any challenge to the intellectual property protection of a late-stage development asset arising from the LABA collaboration could harm our business and cause the price of our securities to fall.

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

The risk that we may be sued on product liability claims is inherent in the development and commercialization of pharmaceutical products. Side effects of, or manufacturing defects in, products that we or our partners develop or commercialize could result in the deterioration of a patient's condition, injury or even death. Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits tends to increase. Claims may be brought by individuals seeking relief for themselves or by individuals or groups seeking to represent a class. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forgo further commercialization of the applicable products.

Although we maintain general liability and product liability insurance, this insurance may not fully cover potential liabilities. In addition, inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercial production and sale of our products, which could adversely affect our business. Product liability claims could also harm our reputation, which may adversely affect our and our partners' ability to commercialize our products successfully, which could cause the price of our securities to fall.

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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. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable. We believe that pricing pressures at the state and federal level, as well as internationally, will continue and may increase, which may make it difficult for us to sell our potential medicines that may be approved in the future at a price acceptable to us or our collaborators, which may cause the price of our securities to fall.

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

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

Risks Related to Ownership of our Common Stock

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

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

- any adverse developments or results or perceived adverse developments or results with respect to the development of FF/VI with GSK, including, without limitation, any difficulties or delays encountered with regard to the regulatory path for FF/VI or any indication from clinical or non-clinical studies, including the large Phase 3b program, that FF/VI is not safe or efficacious (for example, the negative investor reaction to the topline results from the Phase 3 registrational programs for FF/VI announced in early 2012);
- any adverse developments or results or perceived adverse developments or results with respect to the development of UMEC/VI with GSK, including, without limitation, any difficulties or delays encountered with regard to the regulatory path for UMEC/VI, or any indication from clinical or non-clinical studies that UMEC/VI is not safe or efficacious;
- any adverse developments or results or perceived adverse developments or results with respect to the MABA program with GSK, including, without limitation, any further delays encountered in commencing the single-agent Phase 3 program, any difficulties or delays encountered with

regard to the regulatory path for '081, such as the '081/FF Phase 3-enabling studies planned for 2013 or any indication from non-clinical studies of '081 that the compound is not safe or efficacious;

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- any further adverse developments with respect to the commercialization of VIBATIV®, including, without limitation, the uncertainties surrounding drug product manufacture and supply, difficulties that may be encountered by Hospira in technology transfer activities and how, when and where VIBATIV® will be commercialized;
- any further adverse developments or perceived adverse developments with respect to our telavancin NP NDA, including, without limitation, adverse developments or perceived adverse developments with regard to the label for VIBATIV® if it is approved for NP;
- any adverse developments or perceived adverse developments in the field of LABAs, including any change in FDA policy or guidance (such as the pronouncement in February 2010 warning that LABAs should not be used alone in the treatment of asthma and related labeling requirements, the impact of the March 2010 FDA Advisory Committee discussing LABA clinical trial design to evaluate serious asthma outcomes or the FDA's April 2011 announcement that manufacturers of currently marketed LABAs conduct additional clinical studies comparing the addition of LABAs to inhaled corticosteroids versus inhaled corticosteroids alone);
- GSK's decisions whether or not to purchase, on a quarterly basis, sufficient shares of our common stock to maintain its ownership percentage taking into account our preceding quarter's option exercise and equity vesting activity;
- any announcements of developments with, or comments by, the FDA or other regulatory authorities with respect to products we or our partners have under development or have commercialized;
- our incurrence of expenses in any particular quarter that are different than market expectations;
- the extent to which GSK advances (or does not advance) FF/VI, UMEC/VI, UMEC/VI/FF, VI monotherapy and the MABA program through development into commercialization in all indications in all major markets;
- any adverse developments or perceived adverse developments with respect to our relationship with GSK, including, without limitation, disagreements that may arise between us and GSK;
- any adverse developments or perceived adverse developments with respect to our relationship with any of our research, development or commercialization partners other than GSK, including, without limitation, disagreements that may arise between us and any of those partners;
- any adverse developments or perceived adverse developments with respect to our partnering efforts with VIBATIV®, velusetrag, TD-1211, our MARIN and ARNI programs, TD-1792 or TD-4208;
- 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;

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

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

As of April 25, 2013, GSK beneficially owned approximately 26.7% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 5.5% of our outstanding capital stock. Based on our review of publicly available filings as of April 25, 2013, our three largest stockholders other than GSK collectively owned approximately 34.3% of our outstanding capital stock. These stockholders could control the outcome of actions taken by us that require stockholder approval, including a transaction in which stockholders might receive a premium over the prevailing market price for their shares.

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

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

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

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

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

On February 15, 2013, we completed the sale of 116,527 shares of our common stock to Glaxo Group Limited, an affiliate of GSK, at a price of $22.03 per share, resulting in aggregate gross proceeds of $2.6 million before deducting transaction expenses. Neither we nor the affiliate of GSK engaged any investment advisors with respect to the sale and no underwriting discounts or commissions were paid or will be paid to any party in connection with the sale. We issued and sold the shares in reliance upon an exemption from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended.

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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 the registrant and The Bank of New York, as Rights Agent, dated as of June 22, 2007	10-Q	6/30/07
4.3	Indenture dated as of January 23, 2008 by and between the registrant and The Bank of New York Trust Company, N.A., as trustee	8-K	1/23/08
4.4	Form of 3.0% Convertible Subordinated Note Due 2015 (included in Exhibit 4.3)		
4.5	Amendment to Amended and Restated Rights Agreement between the registrant and The Bank of New York Mellon Corporation, as Rights Agent, dated November 21, 2008	8-K	11/25/08
4.6	Indenture dated as of January 24, 2013 by and between the registrant and The Bank of New York Mellon Trust Company, N.A., as trustee	8-K	1/25/13
4.7	Form of 2.125% Convertible Subordinated Note Due 2023 (included in Exhibit 4.6)		
10.40	Base Capped Call Transaction dated January 17, 2013	8-K	1/23/13
10.41	Additional Capped Call Transaction dated January 18, 2013	8-K	1/23/13
10.42(+)	Commercialization Agreement with Clinigen Group plc dated March 8, 2013		
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended		
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended		

32	Certifications Pursuant to 18 U.S.C. Section 1350
101*	The following from the registrant's Quarterly Report on Form 10-Q for the period ended March 31, 2013, formatted in Extensible Business Reporting Language (XBRL) includes: (i) the Condensed Consolidated Statements of Operations for the three months ended March 31, 2013 and 2012, (ii) the Condensed Consolidated Balance Sheets as of March 31, 2013 and December 31, 2012, (iii) the Condensed Consolidated Statements of Comprehensive Income (Loss) for the three months ended March 31, 2013 and 2012, (iv) the Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2013 and 2012, and (v) Notes to Condensed Consolidated Financial Statements.

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

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

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SIGNATURES

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

Theravance, Inc.
(Registrant)

May 1, 2013	/s/ Rick E Winningham
Date	Rick E Winningham Chief Executive Officer
May 1, 2013	/s/ Michael W. Aguiar
Date	Michael W. Aguiar Senior Vice President, Finance and Chief Financial Officer

COMMERCIALIZATION AGREEMENT
by and between

THERAVANCE, INC.

and

CLINIGEN GROUP PLC
Dated: March 8, 2013

COMMERCIALIZATION AGREEMENT

This Commercialization Agreement ("**Agreement**") dated March 8, 2013, is made by and between THERAVANCE, INC., a Delaware corporation having its principal office at 901 Gateway Boulevard, South San Francisco, California 94080, United States ("**Theravance**"), and CLINIGEN GROUP PLC, Pitcairn House Crown Square, Centrum 100, BURTON UPON TRENT, DE14 2WW United Kingdom ("**Clinigen**"). Theravance and Clinigen may be referred to as a "**Party**" or together, the "**Parties**".

RECITALS

WHEREAS, Theravance invented a proprietary compound known as Telavancin (VIBATIV®) for the treatment of serious Gram-positive bacterial infections in humans;

WHEREAS, Clinigen and Theravance are willing to undertake commercialization activities in the Territory and to coordinate such activities and investment as provided by this Agreement with respect to Telavancin; and

WHEREAS, Clinigen and Theravance believe that a collaboration pursuant to this Agreement for the commercialization of Telavancin in the Territory would be desirable and compatible with their respective business objectives.

NOW, THEREFORE, in consideration of the foregoing premises and the representations, covenants and agreements contained herein, Theravance and Clinigen, intending to be legally bound, hereby agree as follows:

ARTICLE I. DEFINITIONS

For purposes of this Agreement, the following initially capitalized terms, whether used in the singular or plural, shall have the following meanings:

1.01 "**Adverse Drug Experience**" means any of: an "adverse drug experience," a "life-threatening adverse drug experience," a "serious adverse drug experience," or an "unexpected adverse drug experience," as those terms are defined at either 21 C.F.R.(S)312.32 or 21 C.F.R.(S)314.80 of the United States Code of Federal Regulations.

1.02 "**Affiliate**" of a Party means any Person, whether de jure or de facto, which directly or indirectly controls, is controlled by, or is under common control with such Person for so long as such control exists, where "control" means the decision-making authority as to such Person and, further, where such control shall be presumed to exist where a Person owns more than fifty percent (50%) of the equity (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) having the power to vote on or direct the affairs of the entity.

1.03 "**API Compound**" means bulk quantities of Telavancin active pharmaceutical ingredient compound prior to the commencement of secondary manufacturing resulting in the Licensed Product.

***CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

1.04 "**Annual Net Sales**" means Net Sales on a Calendar Year basis.

1.05 "**Breaching Party**" shall have the meaning set forth in Section 14.02.

1.06 "**Business Day**" means any day on which banking institutions in both San Francisco, California, United States and London, England are open for business.

1.07 "**Calendar Month**" means for each Calendar Year, each of the twelve (12) one-month periods.

1.08 "**Calendar Quarter**" means for each Calendar Year, each of the four (4) three-month periods ending March 31, June 30, September 30 and December 31; provided, however, that the first calendar quarter for the first Calendar Year shall extend from the Effective Date to the end of the first complete calendar quarter thereafter.

1.09 "**Calendar Year**" means, for the first calendar year, the period commencing on the Effective Date and ending on December 31 of the calendar year during which the Effective Date occurs, and each successive period beginning on January 1 and ending twelve (12) consecutive Calendar Months later on December 31.

1.10 "**Claim**" means all charges, complaints, actions, suits, proceedings, hearings, investigations, claims and demands.

1.11 "**Clinigen**" means Clinigen Group PLC, however in so far as Clinigen Group PLC has delegated rights and responsibilities to its Affiliates, the term "Clinigen" shall include such Affiliate in the context of such rights and responsibilities.

1.12 "**Clinigen Invention**" means an Invention invented solely or jointly by an employee, agent or contractor of Clinigen or its Affiliates (excluding Joint Inventions).

1.13 "**Clinigen Know-How**" means all present and future information directly relating to the Licensed Product or a Clinigen Invention that is required for Theravance to perform its obligations or exercise its rights under this Agreement or that facilitates manufacturing, or Commercialization of the Licensed Product outside the Territory, and which during the Term are in Clinigen's or any of its Affiliates' possession or control and are or become owned by, or otherwise may be licensed (provided there are no restrictions on Clinigen thereof) by, Clinigen. Clinigen Know-How does not include any Clinigen Patents, Theravance Patents, Joint Invention Patents, or Theravance Know-How.

1.14 "**Clinigen Patents**" means all present and future Patents (excluding Theravance Patents and Joint Invention Patents) owned by or licensed to Clinigen that cover a Theravance Compound and/or a Licensed Product and/or the making, having made, Commercialization, use, offer for sale, sale, exportation or importation of a Theravance Compound and/or a Licensed Product.

1.15 "**Commercialization**" means any and all activities directed to marketing, promoting, distributing, offering for sale and selling the Licensed Product, and importing and exporting (within the Territory) the Licensed Product (to the extent applicable). When used as a verb, "Commercialize" means to engage in commercialization.

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1.16 "**Confidential Information**" means all secret, confidential or proprietary information, data or know-how (including Clinigen Know-How and Theravance Know-How) whether provided in written, oral, graphic, video, computer or other form, provided by one Party (the "Disclosing Party") to the other Party (the "Receiving Party") pursuant to this Agreement or generated pursuant to this Agreement, including but, not limited to, information relating to the Disclosing Party's existing or proposed research, Development efforts, patent applications, business or products, the terms of this Agreement and any other materials that have not been made available by the Disclosing Party to the general public. Confidential information shall not include any information or materials that the Receiving Party can document with competent written proof:

(a) were already known to the Receiving Party (other than under an obligation of confidentiality) at the time of disclosure by the Disclosing Party;

(b) were generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure or development, as the case may be, and other than through any act or omission of a Party in breach of such Party's confidentiality obligations under this Agreement;

(d) were disclosed to a Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others; or

(e) were independently discovered or developed by or on behalf of the Receiving Party without the use of the Confidential Information belonging to the other Party.

Notwithstanding the foregoing, specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the rightful possession of the Receiving Party merely because they are contained within more general public disclosures or more general information in the rightful possession of the Receiving Party.

1.17 "**Country**" means any generally recognized sovereign entity.

1.18 "**Defense Notice**" shall have the meaning set forth in Section 12.03(b).

1.19 "**Development**" or "**Develop**" means nonclinical and clinical drug development activities, including, among other things: test method development and stability testing, characterization of impurities, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing of nonclinical and clinical supplies, current Good Manufacturing Practices audits, current Good Clinical Practices audits, current Good Laboratory Practices audits, analytical method validation, manufacturing process validation, cleaning validation, scale-up and post approval changes, quality assurance/quality control development, statistical analysis and report writing, nonclinical and clinical studies (including Phase 3B/Phase 4 Studies), regulatory filing submission and approval, and regulatory affairs related to the foregoing. When used as a verb, "Develop" means to engage in development.

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1.20 "**Diligent Efforts**" means the carrying out of obligations in a sustained manner consistent with the efforts a Party devotes to a product of similar market potential, profit potential or strategic value, based on conditions then prevailing and as if such Party and its Affiliates had no financial stake in any Directly Competing Product with the objective of Commercializing the Licensed Product in the Territory in accordance with the general guidelines outlined in Section 3.04, and the other terms and conditions of this Agreement. Diligent Efforts requires that: (i) each Party promptly assign responsibility for such obligations to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis; (ii) each Party set and consistently seek to achieve specific and meaningful objectives for carrying out such obligations; and (iii) each Party consistently make and implement decisions and allocate resources designed to advance progress with respect to such objectives.

1.21 "**Directly Competing Product**" means one or more compounds, products, or combination products, other than the Licensed Product, [***].

1.22 "**Disclosing Party**" shall have the meaning set forth in Section 1.16.

1.23 "**Disclosure Letter**" means the letter from Theravance addressed to Clinigen of even date herewith .

1.24 "**Effective Date**" means the date of the last signature to this Agreement.

1.25 "**EMA**" means the European Medicines Agency and any successor agency thereto.

1.26 "**European Union**" means the union of member states of the European community, its territories and possessions as of the Effective Date.

1.27 "**Excluded Claim**" shall have the meaning set forth in Section 15.05(f).

1.28 "**FDA**" means the United States Food and Drug Administration and any successor agency thereto.

1.29 "**Field**" means veterinary or human pharmaceutical use of the Licensed Product.

1.30 "**First Commercial Sale**" means the first shipment of commercial quantities of any Licensed Product sold to a Third Party by a Party or its Affiliates or sublicensees in a Country in the Territory after receipt of Marketing Authorization Approval for such Licensed Product in such Country. Sales for test marketing, sampling and promotional uses, clinical trial purposes or compassionate or similar uses shall not constitute a First Commercial Sale.

1.31 "**Force Majeure Event**" shall have the meaning set forth in Section 15.03.

1.32 "**Fully Burdened Cost**" means [***].

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1.33 "**Governmental Authority**" means any court, tribunal, arbitrator, agency, judicial, executive or legislative body, commission, official or other instrumentality of

(a) any government of any Country,

(b) a federal, state, province, regional, county, city, municipal or other political subdivision thereof,

(c) any supranational body or

(d) any patent and trademark office of any Country.

1.34 "**Hatch-Waxman Certification**" shall have the meaning set forth in Section 13.04.

1.35 "**Housemark**" means the name and logo of Clinigen or Theravance or any of their respective Affiliates as identified by one Party to the other from time to time.

1.36 "**Indemnified Party**" shall have the meaning set forth in Section 12.03(a).

1.37 "**Indemnifying Party**" shall have the meaning set forth in Section 12.03(a).

1.38 "**ICH**" means the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.39 "**including**" means including without limitation.

1.40 "**Infringement Claim**" shall have the meaning set forth in Section 13.03(a).

1.41 "**Infringement Notice**" shall have the meaning set forth in Section 13.03(b).

1.42 **"Improvement"** means any finding, enhancement, discovery, technology, information, invention, addition, modification, adaptation, advance, development, formulation, variation, or change (whether or not patented or patentable) with respect to a Theravance Compound and/or a Licensed Product conceived, developed and/or reduced to practice before or during the Term which is reasonably useful or necessary in connection with the use, manufacture, distribution, import/export, sale, Development, or Commercialization of a Licensed Product.

1.43 "**Invention**" means any invention, industrial design, utility model, know-how, discovery or Improvement (whether patentable or not) invented, created or developed before or during the Term that is specifically related to a Theravance Compound and/or a Licensed Product, such as discoveries and ideas made as a result of research, manufacturing, Development or Commercialization.

1.44 "**Joint Invention**" means an Invention invented jointly by an employee, agent or contractor of Theravance or its Affiliates and an employee, agent or contractor of Clinigen or its Affiliates.

1.45 "**Joint Invention Patents**" means all present and future Patents covering Joint Inventions.

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1.46 "**Joint Steering Committee**" shall have the meaning set forth in Section 3.01(b).

1.47 "**Laws**" means all laws, statutes, rules, regulations (including, without limitation, current Good Manufacturing Practice Regulations as specified in 21 C.F.R. (S)(S) 210 and 211; Investigational New Drug Application regulations at 21 C.F.R. (S) 312; World Health Organization Good Manufacturing Practices, the European Union Guide to Good Manufacturing Practice for Medicinal Products, the body of European Union legislation in the pharmaceutical sector as is compiled in Volume 1 and Volume 5 of the publication "The rules governing medicinal products in the European Union" including European Union Directive 2001/83/EC, applicable ICH Guidelines; NDA regulations at 21 C.F.R. (S) 314, relevant provisions of the Federal Food, Drug and Cosmetic Act and other laws and regulations enforced by the FDA, and ordinances and other pronouncements having the binding effect of law of any Governmental Authority.

1.48 "**Licensed Product**" means any study test materials, pharmaceutical composition or product containing a Theravance Compound as an active ingredient.

1.49 "**Losses**" means any and all damages (including all incidental, consequential and statutory damages), awards, deficiencies, settlement amounts, defaults, assessments, fines, dues, penalties, costs, fees, liabilities, obligations, taxes, liens, losses, lost profits and expenses (including without limitation court costs, interest and reasonable fees of attorneys, accountants and other experts) incurred by or awarded to Third Parties and required to be paid to Third Parties with respect to a Claim by reason of any judgment, order, decree, stipulation or injunction, or any settlement entered into in accordance with the provisions of this Agreement, together with all documented out-of-pocket costs and expenses incurred in complying with any judgments, orders, decrees, stipulations and injunctions that arise from or relate to a Claim of a Third Party.

1.50 "**Major Market Country**" shall mean each of the United Kingdom, Germany, France, Italy and Spain.

1.51 "**Marketing Authorization**" means, with respect to a Country, any and all regulatory authorization(s) required by the relevant Governmental Authority to market and sell the Licensed Product in such Country.

1.52 "**Marketing Authorization Approval**" shall mean the decision(s) of a Governmental Authority to issue, renew, amend and/or register Marketing Authorization.

1.53 "**Marketing Plan**" means the plan, prepared by and mutually agreed upon by the Parties, identifying the core strategic, commercial and promotional claims and objectives for the Licensed Product in the Territory as reviewed and approved under 5.01(a).

1.54 "**Net Sales**" means the gross sales of the Licensed Product sold by Clinigen, its Affiliates or their licensees (or such licensees' Affiliates) to a Third Party, less the following to the extent borne by the seller and not taken into account in determining gross sales price: (a) deduction of cash, trade and quantity discounts actually given; (b) discounts, refunds, rebates, chargebacks, retroactive price adjustments, and any other allowances actually given which effectively reduce the net selling price, including institutional rebate or discount; and (c) credits and allowances for product returns actually made.

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1.55 "**Net Sales Report**" shall have the meaning set forth in Section 6.03(b).

1.56 "**Officers**" shall have the meaning set forth in Section 3.01(e)(ii).

1.57 "**Patents**" means any and all issued patents and patent applications existing upon the Effective Date and in the future, including, without limitation, provisional applications, continuation applications, substitutions, continuations-in-part, divisional applications, renewals, Patent Cooperation Treaty applications, and all letters patent granted thereon, invention patents, utility model patents, industrial design patents, all patents-of-addition, reexaminations, reissues, registrations, confirmations, revalidations, certificates of addition, utility models and petty patents, including extensions or restorations of terms thereof by existing or future extension or restoration mechanisms (including regulatory extensions), pediatric use extensions, supplementary protection certificates or any other such right, together with any foreign counterparts thereof.

1.58 "**Patent Resolution Issue**" shall have the meaning set forth in Section 13.02(i).

1.59 "**Person**" means any natural person, corporation, general partnership, limited partnership, limited liability company, joint venture, joint-stock company, proprietorship or other business organization or legal entity.

1.60 "**Phase 3B/Phase 4 Studies**" means those activities which provides for a clinical study or studies of the Licensed Product conducted in accordance with ICH and local standards, which are not required for receipt of Marketing Authorization in the Territory and which are principally intended to support the marketing and Commercialization of the Licensed Product, including without limitation investigator or institution initiated trials, clinical experience trials, and studies conducted to fulfill local commitments made as a condition of any Marketing Authorization.

1.61 "**Post-Term Option**" shall have the meaning set forth in Section 2.07.

1.62 "**Promotional Materials**" means the written, printed, video or graphic advertising, promotional, educational and communication materials (other than Licensed Product labeling) for marketing, advertising and promotion of the Licensed Product in the Territory.

1.63 "**Receiving Party**" shall have the meaning set forth in Section 1.16.

1.64 "**Recording Party**" shall have the meaning set forth in Section 6.09.

1.65 "**Step-In Rights**" shall have the meaning set forth in Section 13.02(d).

1.66 "**Taxes**" shall have the meaning set forth in Section 6.08.

1.67 "**Telavancin**" means the chemical compound known as Telavancin, the chemical structure of which is attached as **Exhibit A**.

1.68 "**Term**" means, on a Country-by-Country basis, the period from the Effective Date until the later of (a) the expiration or termination of the last Valid Claim of the last Theravance Patent, Clinigen Patent, or Joint Invention Patent covering a Theravance Compound and/or the

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Licensed Product and/or its use or process of manufacture or (b) fifteen (15) years after First Commercial Sale in the Territory, unless this Agreement is terminated earlier in accordance with Article XIV.

1.69 "**Territory**" shall mean the following European Union countries: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, England, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Poland, Portugal, Romania, Scotland, Slovakia, Slovenia, Spain, Sweden, and Wales; *plus* the following non-European Union countries: Switzerland and Norway; *plus* the following acceding and candidate countries: Croatia, Iceland, Montenegro, Serbia, Macedonia, Turkey, Albania, Bosnia and Herzegovina, Kosovo; *plus* the following additional countries within Europe: Andorra, Liechtenstein, Monaco, San Marino, and Vatican City, but excluding Armenia, Azerbaijan, Belarus, Georgia, Moldova, Russia and Ukraine.

1.70 "**Theravance**" means Theravance, Inc., a Delaware corporation, however in so far as Theravance, Inc. has delegated rights and responsibilities to its Affiliates, the term "Theravance" shall include such Affiliate in the context of such rights and responsibilities. For example, in the provisions of this Agreement that address a Marketing Authorization, the term "Theravance" includes Theravance UK Limited.

1.71 "**Theravance Compound**" means Telavancin as well as all salts, esters, complexes, chelates, hydrates, isomers, stereoisomers, crystalline and amorphous forms, prodrugs, solvates, pegylated and other modified forms, metabolites and metabolic precursors (whether active or inactive) of Telavancin.

1.72 "**Theravance Invention**" means an Invention invented solely or jointly by an employee, contractor or agent of Theravance or its Affiliates (excluding Joint Inventions).

1.73 "**Theravance Know-How**" means all present and future information directly relating to the Licensed Product or a Theravance Invention, including all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, nonclinical and clinical trial results, manufacturing procedures, test procedures and purification techniques, (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed, and other discoveries, developments, inventions and other intellectual property (whether or not confidential, proprietary, patented or patentable) that are required for Clinigen to perform its obligations or exercise its rights under this Agreement or that facilitates manufacturing, Development, or Commercialization of the Licensed Product in the Territory, and which during the Term are in Theravance's or any of its Affiliates' possession or control and are or become owned by, or otherwise may be licensed (provided there are no restrictions on Theravance thereof) by, Theravance. Theravance Know-How does not include any Theravance Patents, Clinigen Patents, Joint Invention Patents, or Clinigen Know-How.

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1.74 "**Theravance Patents**" means all present and future Patents (excluding Clinigen Patents and Joint Invention Patents) owned by or licensed to Theravance or any of its Affiliates that cover a Theravance Compound and/or a Licensed Product and/or the making, having made, use, Development,

Commercialization, offer for sale, sale, exportation or importation of a Theravance Compound and/or a Licensed Product. All the Theravance Patents as of the Effective Date are shown in **Exhibit B**.

1.75 "**Theravance Trademarks**" means all trademarks and community designs to which Theravance or any of its Affiliates have rights relating to a Licensed Product in the Territory, excluding any Theravance Housemark. The Theravance Trademarks for which there are registrations or pending applications relating thereto as of the Effective Date are set forth in **Exhibit C**.

1.76 "**Third Party**" means a Person who is not a Party or an Affiliate of a Party.

1.77 "**Third Party Claim**" shall have the meaning set forth in Section 12.03(a).

1.78 "**United States**" means the United States of America, its territories and possessions.

1.79 "**Valid Claim**" means any claim(s) pending in a patent application or in an unexpired patent which has not been held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not has been admitted to be invalid or unenforceable through reissue or disclaimer. If in any Country there should be two or more such decisions conflicting with respect to the validity of the same claim, the decision of the higher or highest tribunal shall thereafter control; however, should the tribunals be of equal rank, then the decision or decisions upholding the claim shall prevail when the decisions are equal in number, and the majority of decisions shall prevail when the conflicting decisions are unequal in number.

ARTICLE II. RIGHTS AND OBLIGATIONS

2.01 License Grants from Theravance to Clinigen.

(a) Commercialization License. Subject to the terms of this Agreement, including without limitation Section 2.03(a), Theravance hereby grants to Clinigen, and Clinigen accepts, an exclusive (even as to Theravance and its Affiliates) sublicensable, transferrable license under the Theravance Patents, Theravance Know-How, Theravance Inventions and Theravance's rights in the Joint Inventions and/or Joint Invention Patents to Commercialize the Licensed Product in the Field in the Territory. The exclusivity specified in this Section 2.01(a) means and shall be construed in the following manner: Theravance and its Affiliates reserve a sublicensable, transferrable right under the Theravance Patents, Theravance Know-How, Theravance Inventions and Theravance's rights in the Joint Inventions and/or Joint Invention Patents to Commercialize the Licensed Product within or outside of the Field, outside of the Territory.

(b) Trademark License. Subject to the terms of this Agreement, including without limitation Section 2.03(a), Theravance hereby grants to Clinigen, and Clinigen accepts, an exclusive (even as to Theravance and its Affiliates) sublicensable, transferrable license under the Theravance Trademarks, Theravance's rights in the Theravance Trademarks and the trade

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dress associated with such Trademarks excepting out the logos of, and references to, Third Parties unless required by applicable Law, together with all the goodwill of the business symbolized thereby, for the purpose of Commercialization of the Licensed Product in the Field in the Territory. The exclusivity specified in this Section 2.01(b) means and shall be construed in the following manner: Theravance and its Affiliates reserve a sublicensable, transferrable right under the Theravance Trademarks and Theravance's rights in the Theravance Trademarks for the purpose of Development and Commercialization of the Licensed Product within or outside of the Field, outside of the Territory.

(c) Further Assurances. Theravance and Clinigen agree that they will duly cooperate in executing and registering with required Governmental Authorities this Agreement and/or any other agreements (including entering into separate license agreements, as applicable) in accordance with which Clinigen and/or Theravance are granted rights and licenses in order to effectuate the rights and licenses granted hereunder. Theravance and Clinigen shall execute and cause their respective Affiliates to execute any and all documents and perform and cause their respective Affiliates to perform any and all actions necessary to ensure that this Agreement and/or any other agreements granting Clinigen and/or Theravance rights and licenses duly comply with all applicable government requirements.

2.02 License Grants from Clinigen to Theravance. Effective only upon the existence of any Clinigen Patent, Clinigen Know-How, Clinigen Inventions, Joint Invention and/or Joint Invention Patents, and subject to the terms of this Agreement, including without limitation Section 2.03(b), Clinigen grants to Theravance, and Theravance accepts the following licenses outside the Territory:

(a) Development License: an exclusive (even as to Clinigen and its Affiliates), royalty-free, sublicensable, transferrable license for the entire term of legal protection under the Clinigen Patents, Clinigen Know-How, Clinigen Inventions and Clinigen's rights in the Joint Inventions and/or Joint Invention Patents to use and Develop the API Compound and the Licensed Product within or outside of the Field, inside and outside the Territory. For the avoidance of doubt, the licenses granted in this Section 2.02 shall not alter in any way the licenses granted by Theravance to Clinigen under this Agreement.

(b) Commercialization License: an exclusive (even as to Clinigen and its Affiliates), royalty-free, sublicensable, transferrable license for the entire term of legal protection under the Clinigen Patents, Clinigen Know-How, Clinigen Inventions and Clinigen's rights in the Joint Inventions and/or Joint Invention Patents to Commercialize the Licensed Product within or outside of the Field, outside the Territory.

(c) Manufacturing License: a non-exclusive, royalty-free, sublicensable, transferrable license for the entire term of legal protection under the Clinigen Patents, Clinigen Know-How, Clinigen Inventions and Clinigen's rights in the Joint Inventions and/or Joint Invention Patents to import, export, use, make and have made API Compound and formulated Licensed Product within or outside of the Field, inside and outside the Territory.

2.03 Licenses to Third Parties. The licenses granted to Clinigen under Section 2.01 shall not prevent Theravance from granting:

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(a) licenses to Third Parties under Theravance Patents, Theravance Know-How, Theravance Inventions, Theravance's rights in the Joint Inventions and/or Joint Invention Patents to Develop the API Compound and the Licensed Product inside or outside the Territory;

(b) licenses to Third Parties under Theravance Patents, Theravance Know-How, Theravance Inventions, Theravance's rights in the Joint Inventions and/or Joint Invention Patents to Commercialize the Licensed Product outside the Territory; and

(c) licenses to Third Parties under the Theravance Patents, Theravance Know-How, Theravance Inventions, Theravance's rights in the Joint Inventions and/or Joint Invention Patents to import, export, use, make and have made the API Compound and the Licensed Product inside or outside the Territory.

For the avoidance of doubt, the licenses granted in this Section 2.03 shall not alter in any way the licenses granted by Theravance to Clinigen under this Agreement.

2.04 Co-Ownership in the Joint Inventions and Joint Invention Patents. If the applicable Laws do not require granting a license in and to the Joint Inventions and Joint Inventions Patent as provided in Section 2.01 to Section 2.03 above, the Parties herewith unambiguously agree and acknowledge, and provide their express consent and approval, that each of Theravance and Clinigen have a right to use the Joint Inventions and Joint Invention Patents in accordance with the terms provided in Section 2.01 to Section 2.03 above unless otherwise is agreed by the Parties in writing with regard to any Joint Invention or Joint Invention Patent.

2.05 Sublicensing and Subcontracting. Each Party may sublicense or subcontract its rights, if any, to Develop, manufacture and/or Commercialize the API Compound and the Licensed Product in whole or in part to one or more of its Affiliates, provided that the rights sublicensed or subcontracted to such Affiliate shall automatically terminate upon a change of control of such Affiliate in connection with which such Affiliate ceases to be an Affiliate of such Party. Each Party may also sublicense or subcontract its rights, if any, to Develop, manufacture and/or Commercialize the API Compound and the Licensed Product, in whole or in part, to one or more Third Parties provided, however, that any such sublicense from Clinigen shall require the prior written consent of Theravance, such consent not to be unreasonably withheld. Each Party shall secure all appropriate covenants, obligations and rights from any such sublicensee or subcontractor granted by it under this Agreement, including, but not limited to, intellectual property rights and confidentiality obligations in any such agreement or other relationship, to ensure that such sublicensee can comply with all of such Party's covenants and obligations to the other Party under this Agreement that are applicable to the sublicensees. Each Party's rights to sublicense, subcontract or otherwise transfer its rights granted under this Article II are limited to those expressly set forth in this Section 2.05.

2.06 Trademarks and Housemarks.

(a) Trademarks. The Licensed Product shall be Commercialized under trademarks in the Territory (and trade dress selected and approved by the Joint Steering Committee). Clinigen shall exclusively own all trademarks in the Territory other than the Theravance Trademarks, and shall be responsible for the procurement, filing and maintenance of

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trademark registrations in the Territory for such trademarks and all costs and expenses related thereto. Theravance shall be responsible for the procurement, filing and maintenance of trademark registrations in the Territory for the Theravance Trademarks and all costs and expenses related thereto. Clinigen shall also exclusively own all trade dress and copyrights associated with the Licensed Product in the Territory. Theravance agrees not to register or, in connection with the sale of any product, use in the Territory any trademark or trade dress which is identical to or confusingly similar to any of Clinigen's trademarks or trade dress used for a Licensed Product unless otherwise agreed between the Parties. Clinigen agrees not to register or, in connection with the sale of any product, use any trademark which is identical to or confusingly similar to any of Theravance's trademarks used for a Licensed Product unless otherwise agreed between the Parties.

(b) Housemarks. Each Party acknowledges the goodwill and reputation that has been associated with the other Party's Housemarks over the years, and shall use such Housemarks in a manner that maintains and promotes such goodwill and reputation and is consistent with trademark guidelines. Each Party shall take all reasonable precautions and actions to protect the goodwill and reputation that has inured to the other Party's Housemarks, shall refrain from doing any act that is reasonably likely to impair the reputation of such Housemarks, and shall cooperate fully to protect such Housemarks.

2.07 Post-Term Option. Following the expiration of the Term (unless this Agreement is terminated earlier in accordance with Article XIV, in which case this provision has no force or effect) Clinigen shall have the option (the "Post-Term Option"), on a Country-by-Country basis, to continue to have the exclusive right to Commercialize the Licensed Product in such Countries in the Territory under Section 2.01 and the other terms and conditions of this Agreement applicable to Section 2.01. Clinigen will notify Theravance in writing as to whether or not it is exercising the Post-Term Option, and for which Countries in the Territory, within thirty (30) days of the expiration of the Term. After such date the Post-Term Option will expire.

ARTICLE III. GOVERNANCE

3.01 Joint Steering Committee.

(a) Purpose. The purposes of the Joint Steering Committee shall be (i) to determine the overall strategy for this collaboration between the Parties and (ii) to coordinate the Parties' activities hereunder. The Parties intend that their respective organizations will work together and will use Diligent Efforts to assure success of the collaboration in accordance with Section 3.04.

(b) Members. Within thirty (30) days after the Effective Date, the Parties shall establish a joint steering committee (the "Joint Steering Committee"), which shall consist of four (4) members, two (2) of whom shall be designated by each of Clinigen and Theravance and shall have appropriate expertise, with at least one (1) member from each Party being at least at a vice president level or higher in the case of Theravance and a member of its senior management in the case of Clinigen. Each of Clinigen and Theravance may replace any or all of its representatives on the Joint Steering Committee at any time upon written notice to the other Party. A Party may designate a substitute to temporarily attend and perform the functions of such Party's designee at

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any meeting of the Joint Steering Committee. Clinigen and Theravance each may, on advance written notice to the other Party, invite non-member representatives of such Party to attend meetings of the Joint Steering Committee. Each Party shall secure all appropriate covenants, obligations and rights from any such members, substitute members or non-member representatives permitted herein, including, but not limited to confidentiality obligations and intellectual property rights, to ensure that such Party can comply with all of such Party's covenants and obligations to the other Party under this Agreement. The Joint Steering Committee shall be chaired by a representative of Theravance on the Joint Steering Committee. The other representative of Theravance on the Joint Steering Committee shall serve as secretary of the Joint Steering Committee.

(c) Responsibilities. The Joint Steering Committee shall perform the following functions:

(i) Oversee the Commercialization of the Licensed Product in the Territory pursuant to the terms of this Agreement. Have joint approval of, designs and protocols (if any) as well as internal publication plans and primary publications of clinical and nonclinical studies featuring a Licensed Product (e.g., publications for major international peer-reviewed journals and conferences);

(ii) At each meeting of the Joint Steering Committee, review Net Sales for the year-to-date as available;

(iii) Coordinate and monitor regulatory strategy and activities for the Licensed Product in the Territory in accordance with Article VIII;

(iv) Review and approve the trademarks selected under Section 2.06;

(v) Discuss the state of the markets for the Licensed Product in the Territory and opportunities and issues concerning the Commercialization of the Licensed Product in the Territory, including consideration of marketing and promotional strategy, marketing research plans, labeling and Licensed Product positioning;

(vi) Life cycle management of, and intellectual property protection for, the Licensed Product in the Territory;

(vii) At each meeting of the Joint Steering Committee, review the status of the major Commercialization activities related to the Licensed Product in the Territory and any results therefrom; and

(viii) Have such other responsibilities as may be assigned to the Joint Steering Committee pursuant to this Agreement or as may be mutually agreed upon by the Parties from time to time.

Notwithstanding the foregoing, Clinigen (and not the Joint Steering Committee) shall have the authority to establish and adjust pricing, develop go-to-market strategies and develop and implement marketing processes.

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(d) Meetings. The Joint Steering Committee shall meet in person at least twice during every Calendar Year, and more frequently (i) as mutually agreed by the Parties or (ii) as required to resolve disputes or disagreements, on such dates, and at such places and times, as such Parties shall agree; provided that the Parties shall endeavor to have the first meeting of the Joint Steering Committee within thirty (30) days after the establishment of the Joint Steering Committee and no more than sixty (60) days after the Effective Date of this Agreement. Meetings of the Joint Steering Committee may also be held by means of telecommunications or video conferences as deemed appropriate by the Parties.

(e) Decision-Making.

(i) The Joint Steering Committee may make decisions with respect to any subject matter that is subject to the Joint Steering Committee's decision-making authority and functions as set forth in Section 3.01(c). All decisions of the Joint Steering Committee shall be made by consensus, with the representatives from each Party presenting a unified position on behalf of such Party. The Joint Steering Committee shall use Diligent Efforts to resolve the matters within its roles and functions or otherwise referred to it.

(ii) With respect to any unresolved issue, if the Joint Steering Committee cannot reach consensus within ten (10) Business Days after the matter has been brought to the Joint Steering Committee's attention, then such issue shall be referred to the Chief Executive Officer of Theravance and the Chief Executive Officer of Clinigen (collectively, the "Officers") for resolution. The Parties agree that use of the Officers for resolution of any unresolved issues will be on an exceptional basis. If the Officers are unable to reach consensus within thirty (30) days after the matter has been referred to them, the final decision will be made by the chairman of the Joint Steering Committee.

3.02 Minutes of Joint Steering Committee Meetings. Definitive minutes of all Joint Steering Committee meetings shall be finalized no later than thirty (30) days after the meeting to which the minutes pertain as follows:

(a) Distribution of Minutes. Within ten (10) days after a Joint Steering Committee meeting, the secretary of such committee shall prepare and distribute to all members of such committee draft minutes of the meeting. Such minutes shall provide a list of any issues yet to be resolved, either within such committee or through the relevant resolution process.

3.03 Expenses. Each Party shall be responsible for all travel and related costs and expenses for its members and other representatives to attend meetings of, and otherwise participate on, the Joint Steering Committee.

3.04 General Guidelines and Coordination Efforts. In all matters related to the Commercialization collaboration established by this Agreement, the Parties shall strive to balance as best they can the legitimate interests and concerns of the Parties and to jointly make key manufacturing, regulatory and Commercialization decisions related to the Licensed Product in the Territory in order to maximize the value of the Licensed Product both inside and outside the Territory, independent of the then-current Development status of the Licensed Product outside the Territory. In all matters relating to this Agreement, the Parties shall seek to comply with good

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pharmaceutical and environmental practices in accordance with ICH standards and consistent with practices generally acceptable to Governmental Authorities in the United States (including the FDA), the European Union (including the EMA) and its member states and the other competent Governmental Authorities in the Territory. The Parties intend, following the Effective Date, to organize meetings of internal staff to communicate and explain the provisions of this Agreement to ensure the efficient and timely Commercialization of the Licensed Product in the Territory.

ARTICLE IV. MARKETING AUTHORIZATIONS

4.01 Obligation for Transferring and Maintaining Marketing Authorizations.

(a) Transfer of Marketing Authorization. As soon as practicable but no more than sixty (60) days after the Effective Date, Theravance will transfer to Clinigen the relevant Marketing Authorization(s) for the Licensed Product in the Territory. If the transfer of the relevant Marketing Authorization(s) for the Licensed Product is not possible within such sixty (60) day period, then Theravance and Clinigen will use Diligent Efforts to complete the transfer as promptly as possible thereafter. For the purpose of such transfer, Theravance shall transfer or assign the Marketing Authorization(s) for the Licensed Product to Clinigen and/or cause that Marketing Authorization(s) for the Licensed Product to issue in the name of Clinigen. Theravance shall execute and deliver all documents reasonably necessary to effect that transfer, assignment or issuance, and take all actions reasonably necessary to effect that transfer, assignment or issuance. Theravance hereby appoints Clinigen as Theravance's attorney-in-fact, with full power of substitution, to execute, deliver and file in Theravance's name any documents and take any actions reasonably necessary or desirable to transfer or assign any Marketing Authorization(s) for the Licensed Product to Clinigen or cause any Marketing Authorization(s) for the Licensed Product to issue in the name of Clinigen. It is expressly agreed that any communication with Governmental Authorities within the Territory (including but not limited to the EMA) after the Effective Date by Theravance or any other entity acting in the name or on behalf of Theravance requires the prior written approval of Clinigen. After the transfer, Clinigen will be the Marketing Authorization holder and will maintain such Marketing Authorization. Should there be a variation in the FDA approval that would necessitate a variation in Marketing Authorization(s), Theravance must inform Clinigen as soon as practicable, but not more than fifteen (15) days after such variation has become effective. Following the expiration of the Term, and except for such Countries (if any) for which Clinigen has exercised the Post-Term Option, Clinigen will transfer the relevant Marketing Authorization(s) to Theravance or Theravance's designee in the Territory and Theravance or Theravance's designee will become the Marketing Authorization holder for such Marketing Authorization(s).

(b) Diligent Efforts. Clinigen will, in accordance with the priorities agreed by the Joint Steering Committee, exercise Diligent Efforts in pursuing any further required Marketing Authorization Approvals necessary to Commercialize the Licensed Product in each Country of the Territory. Theravance will, in accordance with the priorities agreed by the Joint Steering Committee, exercise Diligent Efforts in providing Clinigen with evidence confirming that there is, within the marketing authorization dossier for the Licensed Product, an authorized manufacturing site which fulfills the requirements set out in Article 41 of Directive 2001/83/EC and otherwise provide Clinigen the information necessary to maintain the Marketing Authorization Approvals.

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(c) Clinigen Funding Responsibility. Clinigen shall bear all costs and expenses associated with obtaining any further Marketing Authorization Approvals for the Licensed Product in each Country of the Territory during the Term. Clinigen will be the Marketing Authorization holder for any such approvals in any Country in the Territory during the Term. Following the expiration of the Term, Theravance or Theravance's designee will become the Marketing Authorization holder for any such approvals in any Country in the Territory other than those Countries for which Clinigen has exercised the Post-Term Option.

(d) Theravance Assistance. To the extent reasonably required by Clinigen for the exercise of their rights hereunder, Theravance shall provide free of charge to Clinigen the existing US, Canadian and European Union regulatory dossier and, within reason, other related documents such as variations, amendments and supporting information for the Licensed Product (in CTD format), as well as stability data according to ICH guidelines. Upon Clinigen's request, and at Theravance's sole discretion and cost, Theravance will endeavor to provide Clinigen such other reasonable assistance as may be reasonably required by Clinigen to achieve its Marketing Authorization Approval objectives and Diligent Efforts obligations related to the Licensed Product, which such assistance may be provided directly or through Theravance's vendors or contractors.

4.02 Transfer of Information from Theravance to Clinigen. As soon as practicable but no more than sixty (60) days after the Effective Date, the Parties shall determine what additional existing information and materials relating to the Licensed Product are necessary for Clinigen's Marketing Authorization Approval obligations pursuant to this Article IV, and establish a process for transferring such information and material to Clinigen (including, to the extent available, in appropriate electronic format) or provide means of access thereto reasonably acceptable to both Parties. Clinigen may request attendance at Theravance-agreed audits as an observer.

4.03 Non-EU Countries. If the legal authority to market and sell the Licensed Product in a Country in the Territory that is not a member of the European Union requires a local Marketing Authorization and/or regulatory authorization in addition to the EMA Marketing Authorization, such as a wholesale trading license, that Clinigen does not possess, then Clinigen shall be permitted to obtain such Marketing Authorization and/or regulatory authorization in addition to the EMA Marketing Authorization to Commercialize the Licensed Product in that Country in the Territory through partners, sublicensees, subcontractors or local distributors who shall obtain and possess such licenses as trustee for Clinigen. For the sake of clarity and avoidance of doubt, such local partners, sublicensees, subcontractors or local distributors shall not be entitled to any rights or licenses beyond the scope of the rights and license granted to Clinigen under this Agreement.

ARTICLE V. COMMERCIALIZATION

5.01 Marketing Plans.

(a) General. The Joint Steering Committee shall be consulted upon and review an overall Marketing Plan for the Licensed Product in the Territory prepared by Clinigen. Each Marketing Plan shall define the goals and objectives for Commercializing the Licensed Product in the Territory and in the pertinent Calendar Year. Clinigen shall be responsible for pricing and market approach, but major strategic changes to this plan shall require Joint Steering

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Committee approval. Major strategic changes are defined as changes in Territory (additions or deletions), the application for or withdrawal of Marketing Authorizations in any Country in the Territory or regulatory issues.

(b) Contents of Each Marketing Plan.

(i) Clinigen shall be responsible for developing and executing the overall Marketing Plan for the Licensed Product. Such Marketing Plan shall contain as appropriate results of market research and strategy, including market size, dynamics, growth, customer segmentation, customer targeting, competitive analysis and Licensed Product positioning in each Country in the Territory; and sales plans for each Country or other pertinent geographic subdivision of the Territory.

(ii) The Joint Steering Committee shall retain the authority to review and approve core advertising and promotion programs and strategies in each Country in the Territory, including literature, media plans, symposia and speaker programs; and Phase 3B/Phase 4 Studies to be conducted (if any) in the Territory, in recognition of the requirements of applicable Laws.

5.02 Obligations for Commercialization. Clinigen shall use Diligent Efforts to Commercialize the Licensed Product in each Country in the Territory in accordance with the then-current Marketing Plan and to ensure that Licensed Product intended for sale in the Territory is not exported from or sold outside of the Territory.

5.03 Commercialization.

(a) Clinigen Responsibility. Under the guidance provided by the Joint Steering Committee,

(i) Clinigen shall have the responsibility for Commercialization of the Licensed Product for distribution and sale in each Country in the Territory. Clinigen shall bear all costs and expenses associated with the Commercialization of the Licensed Product for sale or distribution in the Territory.

(ii) Clinigen shall have the sole responsibility to distribute, sell, record sales and collect payments for the Licensed Product in the Territory.

(iii) Considering the input provided by the Joint Steering Committee (subject to applicable Laws), Clinigen shall have the responsibility for establishing and modifying the terms and conditions with respect to the sale of the Licensed Product in the Territory, including, without limitation, the price or prices at which the Licensed Product will be sold, any discount applicable to payments or receivables, and similar matters.

(iv) Clinigen will be responsible for storage after delivery to Clinigen, order receipt, order fulfillment, shipping and invoicing of the Licensed Product in the Territory.

(b) Semi-Annual Reports. Clinigen shall provide the Joint Steering Committee a formal Commercialization report semi-annually. Such reports shall set forth in detail the results of Clinigen's Commercialization activities related to the Licensed Product performed during such semi-annual period in each Country in the Territory.

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(c) Theravance Assistance. Upon Clinigen's request, and as agreed and coordinated by the Joint Steering Committee, Theravance will endeavor to provide Clinigen such reasonable assistance as may be reasonably required by Clinigen to achieve its Commercialization objectives and Diligent Efforts obligations related to the Licensed Product, which such assistance may be provided directly or through Theravance's vendors or contractors. Clinigen will reimburse Theravance within thirty (30) days of receipt of invoice for all of Theravance's fully burdened internal and external costs associated with providing such support or assistance to Clinigen.

5.04 Theravance Access to and Use of Commercial Information. Clinigen will provide Theravance with full and timely access free of charge to any and all information and data generated by or on behalf of Clinigen and its Affiliates or sublicensees or subcontractors related to Commercialization of the Licensed Product. Theravance will have the unrestricted right, subject to its obligations under Article X, to use and cite any such information and data to support Development and Commercialization of the Licensed Product outside the Territory.

ARTICLE VI. FINANCIAL PROVISIONS

6.01 Signing Fee. Two (2) Business Days after the Effective Date, Clinigen shall pay to Theravance a non-creditable, non-refundable amount of Five Million United States Dollars (U.S. $5,000,000.00).

6.02 Payment of Royalties on Net Sales.

(a) During Calendar Years 2013 and 2014.

(i) Patent Royalties. As further partial consideration for the acquisition of license rights under the Theravance Patents by Clinigen under this Agreement, where there is a Valid Claim of a Theravance Patent or a Joint Patent covering a Theravance Compound and/or the Licensed Product and/or its use or process of manufacture in a Country of the Territory at the time Net Sales in such Country occur, Clinigen shall pay Theravance, within thirty (30) days after the end of each Calendar Quarter during the Calendar Years 2013 and 2014, royalty payments as follows:

1) On total Annual Net Sales in the Territory up to and including [***]: 20%

2) On total Annual Net Sales in the Territory between [***]

3) On total Annual Net Sales in the Territory greater than [***]: 30%

(ii) Know-How Royalty. As further partial consideration for the acquisition of license rights under the Theravance Know-How by Clinigen under this Agreement, where an obligation to pay royalties under Section 6.02(a)(i) is not applicable in the

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Territory, Clinigen shall pay Theravance, within thirty (30) days after the end of each Calendar Quarter during the Calendar Years 2013 and 2014, royalty payments as follows:

1) On total Annual Net Sales in the Territory up to and including [***]

2) On total Annual Net Sales in the Territory between [***]

3) On total Annual Net Sales in the Territory greater than [***]

(b) Beginning January 1, 2015.

(i) Patent Royalties. As further partial consideration for the acquisition of license rights under the Theravance Patents by Clinigen under this Agreement, where there is a Valid Claim of a Theravance Patent or a Joint Patent covering a Theravance Compound and/or the Licensed Product and/or its use or process of manufacture in a Country of the Territory at the time Net Sales in such Country occur, Clinigen shall pay Theravance, within thirty (30) days after the end of each Calendar Quarter from January 1, 2015 and during the remainder of the Term, royalty payments as follows:

1) On total Annual Net Sales in the Territory up to and including [***]

2) On total Annual Net Sales in the Territory greater than [***]: 30%

(ii) Know-How Royalty. As further partial consideration for the acquisition of license rights under the Theravance Know-How by Clinigen under this Agreement, where an obligation to pay royalties under Section 6.02(b)(i) is not applicable in the Territory, Clinigen shall pay Theravance, within thirty (30) days after the end of each Calendar Quarter from January 1, 2015 and during the remainder of the Term, royalty payments as follows:

1) On total Annual Net Sales in the Territory up to and including [***]

2) On total Annual Net Sales in the Territory greater than [***]

(iii) Post-Term Royalty. As further partial consideration for the acquisition of exclusive rights to continue to sell the Licensed Product following its exercise of the Post-Term Option, Clinigen shall pay Theravance, within thirty (30) days after the end of each Calendar Quarter from the date the Post-Term Option is exercised, royalty payments as follows:

1) On total Annual Net Sales in the Territory up to and including [***]

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2) On total Annual Net Sales in the Territory greater than [***]

6.03 Royalty Responsibilities; Net Sales Reports.

(a) Payments to Third Parties.

(i) Subject to Section 6.03(a)(ii), if, as a result of a settlement approved by both Parties or as a result of a final non-appealable judgment, Clinigen is required to pay any amounts to a Third Party directly because using or selling the Licensed Product in a Country of the Territory is found to infringe the rights of such Third Party, Clinigen shall deduct [***] of any such amount paid to such Third Party from the royalties otherwise due Theravance on Net Sales of the Licensed Product in such Country.

(ii) Clinigen shall pay any amounts owed to a Third Party as a result of the use of Clinigen Patents or Clinigen Know-How with respect to sales of Licensed Product and shall not deduct any of such amounts from the royalties due Theravance.

(b) Net Sales Report. Within thirty (30) days after the end of each Calendar Quarter, Clinigen shall submit to Theravance a written report setting forth on a Country-by-Country basis Net Sales during such Calendar Quarter, total royalty payments due Theravance, relevant market share data and any payments made to any Third Party pursuant to Section 6.03(a)(i) (each a "Net Sales Report").

6.04 GAAP. All financial terms and standards defined or used in this Agreement for sales or activities shall be governed by and determined in accordance with United States generally accepted accounting principles, consistently applied.

6.05 Currencies. Monetary conversion from the currency used in the Territory into United States Dollars shall be calculated as follows, unless otherwise mutually agreed to by the Parties: the quarterly rate shall be the daily closing spot rates on the last Business Day of the relevant Calendar Quarter using the exact figures provided by the Financial Times.

6.06 Manner of Payments. All sums due under this Article VI shall be payable in United States Dollars by bank wire transfer in immediately available funds to such bank account(s) set forth in Section 15.17 of this Agreement. Clinigen shall notify Theravance as to the date and amount of any such wire transfer to Theravance at least five (5) Business Days prior to such transfer.

6.07 Interest on Late Payments. If Clinigen shall fail to make a timely payment pursuant to this Article VI, any such payment that is not paid on or before the date such payment is due under this Agreement shall bear interest, to the extent permitted by applicable Laws, at the average one-month London Inter-Bank Offering Rate (LIBOR) for the United States Dollar as reported from time to time in *The Wall Street Journal*, effective for the first date on which payment was delinquent and calculated on the number of days such payment is overdue or, if such rate is not regularly published, as published in such source as the Joint Steering Committee agrees.

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6.08 Taxes. Clinigen shall be responsible for all taxes, levies and other duties on Licensed Product sale arising out of this Agreement ("Taxes") other than taxes attributable to Theravance income. If Clinigen is required by applicable law (after giving effect to any applicable tax treaty) to deduct or withhold any Taxes (other than taxes attributable to Theravance income) from or in respect of any amount payable to Theravance under this Agreement, (a) Clinigen shall make the necessary withholding or deduction of applicable Taxes and pay the relevant taxation authority the minimum amount necessary to comply with the applicable law, and (b) the corresponding amount payable hereunder shall be increased as may be necessary so that after Clinigen makes all required deductions or withholdings, Theravance shall receive an amount equal to the amount it would have received had no such deductions or withholdings been made. Should Theravance be able, within the maximum period allowable by applicable law, to utilize as a tax credit or tax deduction any amounts withheld or deducted by Clinigen as provided above, Theravance shall promptly notify Clinigen of the amount of such tax credit or other tax benefit within thirty (30) days after such amount can first be calculated and, at the time of such notice, refund the amount of such credit (or amount of tax saved with respect

to such deduction) to Clinigen, or, if Clinigen so requests in writing prior to such time, provide a credit for such amount to Clinigen hereunder whereby Clinigen shall be entitled to deduct such amount from the next payment due to Theravance under this Agreement. Both Parties shall reasonably cooperate with each other, including by providing such certifications or other documentation, as may reasonably be necessary to obtain any exemption, reduction or exception available under applicable law from any such deduction or withholding from amounts payable hereunder.

6.09 Financial Records; Audits. Clinigen shall keep, and shall cause its Affiliates, sublicensees and subcontractors to keep, such accurate and complete records of Net Sales as are necessary to determine the amounts due to Theravance under this Agreement and such records shall be retained by Clinigen or any of its Affiliates or sublicensees (in such capacity, the "Recording Party") during the Term. During normal business hours and with reasonable advance notice to the Recording Party, such records shall be made available for inspection, review and audit, at the request and expense of Theravance, by an independent certified public accountant, or the local equivalent, appointed by Theravance and reasonably acceptable to the Recording Party for the sole purpose of verifying the accuracy of the Recording Party's accounting reports and payments made or to be made pursuant to this Agreement; provided, however, that such audits may not be performed by Theravance more than once per Calendar Year. Such accountants shall be instructed not to reveal to Theravance the details of their review, except for (i) such information as is required to be disclosed under this Agreement and (ii) such information presented in a summary fashion as is necessary to report the accountants' conclusions to Theravance, and all such information shall be deemed Confidential Information of the Recording Party; provided, however, that in any event such information may be presented to Theravance in a summary fashion as is necessary to report the accountants' conclusions. All costs and expenses incurred in connection with performing any such audit shall be paid by Theravance unless the audit discloses at least a five percent (5%) shortfall, in which case the Recording Party will bear the full cost of the audit for such Calendar Year. Theravance will be entitled to recover any shortfall in payments due to it as determined by such audit plus interest thereon calculated in accordance with Section 6.07, or alternatively shall have the right to offset and deduct any such shortfall in payments due to it against payments Theravance is otherwise required to make to the Reporting Party under this Agreement. The documents from which were calculated the sums due under this Article VI shall

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be retained by the relevant Party during the Term. If the Recording Party is not Clinigen, Clinigen shall cause its Affiliate or sublicensee to perform the obligations under this Section 6.09.

ARTICLE VII. PROMOTIONAL MATERIALS

7.01 Markings of Promotional Materials. To the extent not forbidden under applicable Laws, and further to the extent reasonably practicable, all Promotional Materials for use with the Licensed Product in the Territory will, at Theravance's sole discretion, indicate the contribution of the license from Theravance for the Licensed Product. Subject to the foregoing, the Theravance Housemark and the Clinigen Housemark shall both be given exposure and prominence on all Promotional Materials, as well as labeling, package inserts or outserts and packaging for the Licensed Product in the Territory. Unless required by applicable Laws, Theravance at its sole discretion may choose not to have the Theravance Housemark displayed on such Promotional Materials or labeling.

7.02 Statements Consistent with Labeling. Clinigen and its Affiliates, sublicensees and subcontractors shall ensure that sales representatives detail the Licensed Product in a manner and consistent with the requirements of applicable Laws.

ARTICLE VIII. REGULATORY MATTERS

8.01 Regulatory Filings. Clinigen shall also be solely responsible for filing any additional regulatory applications for the Licensed Product in the Territory with the appropriate Governmental Authorities and will use Diligent Efforts in seeking appropriate Marketing Authorization and Marketing Authorization Approval for the Licensed Product in each Country in the Territory. If agreed by the Joint Steering Committee, and if consistent with Clinigen's Diligent Efforts obligations, Clinigen may choose not to seek Marketing Authorization and Marketing Authorization Approval for the Licensed Product in a particular Country. The regulatory approvals which may be required for the performance of this Agreement include, without limitation: permission to conduct any clinical trials in the Territory, permissions necessary for conduct of clinical trials in the Territory (e.g., permission for importation of a medicinal preparation for clinical trials, permission for exportation of biological materials), Marketing Authorization and Marketing Authorization Approval. Upon Clinigen's request, and as agreed and coordinated by the Joint Steering Committee, Theravance will endeavor to provide Clinigen such reasonable assistance as may be reasonably required by Clinigen to fulfill its responsibilities hereunder. Such Theravance assistance may be provided directly or through Theravance's vendors or contractors. Clinigen shall be responsible for maintaining the regulatory approvals obtained under this Section 8.01 and shall solely own all such regulatory approvals in the Territory. Clinigen shall be fully responsible for bearing all costs and expense associated with undertaking and completing said registration activities in the Territory, including but not limited to the costs of preparing and prosecuting applications for such regulatory approvals and fees payable to regulatory agencies in obtaining and maintaining same.

8.02 Access to and Use of Regulatory Filings.

(a) Clinigen will provide Theravance with full and timely access free of charge to any and all regulatory filings and associated data generated by or on behalf of Clinigen

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and its Affiliates or sublicensees or subcontractors related to the Licensed Product. Theravance will have the unrestricted right to use and cite any such regulatory filings and associated data to support Development and Commercialization of the Licensed Product outside the Territory.

(b) Theravance will, on an annual basis, provide Clinigen with an index listing all regulatory filings relating to the Licensed Product outside the Territory. At Clinigen's request, Theravance will provide Clinigen with full and timely access free of charge to any and all such regulatory filings and associated data generated by or on behalf of Theravance and its Affiliates or sublicensees or subcontractors that is reasonably necessary for the Commercialization of the Licensed Product inside the Territory. Clinigen will have the right to use and cite any such regulatory filings and associated data to fulfill its obligations under this Agreement inside the Territory.

8.03 Exchange of Drug Safety Information.

(a) Clinigen shall be responsible for recording, investigating, summarizing, notifying, reporting and reviewing all Adverse Drug Experiences in the Territory in accordance with applicable Laws and shall require that its Affiliates, sublicensees and subcontractors (i) adhere to all requirements of applicable Laws that relate to the reporting and investigation of Adverse Drug Experiences in the Territory, and (ii) inform the Joint Steering Committee promptly of such matters arising therefrom.

(b) Theravance shall notify Clinigen as soon as practicable of all "adverse reactions", "serious adverse reactions" and "unexpected adverse reactions" as such terms are defined in Directive 2001/83/EC and all "adverse events," "adverse experiences" and "adverse drug reactions" as such terms are defined in ICH E2A that occur outside the Territory to enable Clinigen to comply with the Guideline on good pharmacovigilance practices (GVP) Module VI — Management and reporting of adverse reactions to medicinal products.

8.04 Recalls or Other Corrective Action. Each Party shall, as soon as practicable, notify the other Party of any recall information received by it in sufficient detail to allow the Parties to comply with any and all applicable Laws. Clinigen shall promptly notify Theravance of any material actions to be taken by Clinigen with respect to any recall or market withdrawal or other corrective action related to the Licensed Product in the Territory prior to such action to permit Theravance a reasonable opportunity to consult with Clinigen with respect thereto. All costs and expenses with respect to a recall, market withdrawal or other corrective action in the Territory shall be borne by Clinigen, subject to Clinigen's right to be indemnified pursuant to Section 12.02 if applicable. Clinigen shall have sole responsibility for and shall make all decisions with respect to any recall, market withdrawals or any other corrective action related to the Licensed Product in the Territory.

8.05 Events Affecting Integrity or Reputation. The Parties shall notify each other immediately of any circumstances of which they are aware and which could impair the integrity and reputation of the Licensed Product or if a Party is threatened by the unlawful activity of any Third Party in relation to the Licensed Product, which circumstances shall include, by way of illustration, deliberate tampering with or contamination of the Licensed Product by any Third Party as a means of extorting payment from the Parties or another Third Party. In any such

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circumstances, the Parties shall use Diligent Efforts to limit any damage to the Parties and/or to the Licensed Product. The Parties shall promptly call a Joint Steering Committee meeting to discuss and resolve such circumstances.

ARTICLE IX. ORDERS; SUPPLY AND RETURNS

9.01 Orders and Bookings of Sales. Except as otherwise expressly stated in this Agreement, Clinigen shall have the right in the Territory to (i) receive, accept and fill orders for Licensed Product sold by Clinigen, (ii) control invoicing, order processing and collection of accounts receivable for Licensed Product sold by Clinigen and (iii) record in its books of account sales of Licensed Product sold by Clinigen.

9.02 Supply of API Compound for Commercial Requirements. Theravance shall be responsible, either directly or through Theravance's vendors or contractors, for supplying at Clinigen's expense API Compound for Commercialization activities in the Territory. Clinigen will reimburse Theravance within forty five (45) days of receipt of itemized invoices for all of Theravance's Fully Burdened Cost incurred after the Effective Date associated with supplying such API Compound as mutually agreed by the Parties. Such API Compound shall be manufactured and supplied in accordance with all applicable Laws and then current Good Manufacturing Practices. A forecast for API Compound requirements for Commercialization of the Licensed Product in the Territory shall be prepared and periodically updated by the Joint Steering Committee and coordinated with the applicable Marketing Plan for the Licensed Product.

9.03 Supply of Licensed Product for Commercialization. Theravance shall be responsible, either directly or through Theravance's vendors or contractors, for supplying at Clinigen's expense formulated, packaged and labeled Licensed Product for Commercialization activities in the Territory or, at Clinigen's request, unlabeled finished product for Clinigen to manage packaging and labeling within the Territory. Such formulated, packaged and labeled Licensed Product shall be manufactured and supplied in accordance with all applicable Laws and then current Good Manufacturing Practices. Clinigen will reimburse Theravance within thirty (30) days of receipt of itemized invoices for all of Theravance's Fully Burdened Cost incurred after the Effective Date associated with supplying such formulated Licensed Product as mutually agreed by the Parties. A forecast for formulated, packaged and labeled Licensed Product requirements for Commercialization in the Territory shall be prepared and periodically updated by the Joint Steering Committee and coordinated with the applicable Marketing Plan for the Licensed Product. During the three (3) month period following the Effective Date, the Parties shall in good faith use Diligent Efforts to enter into a supply agreement to carry out the principles set forth in this Section 9.03 and to address manufacturing of the API Compound and the formulated Licensed Product, to comply with regulatory requirements for sale in the Territory.

9.04 Manufacturing in the Territory. If the Joint Steering Committee decides to have the Licensed Product made, packaged or labeled by a Third Party in the Territory and assigns responsibility to Clinigen to supervise or manage such work and Clinigen accepts such responsibility, then Clinigen shall have a non-exclusive, royalty-free, sublicensable, transferrable license under the Theravance Patents, Theravance Trademarks, Theravance Know-How, Theravance Inventions and Theravance's rights in the Joint Inventions and/or Joint Invention Patents to import, export, use, make and have made API Compound and formulated Licensed

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Product within the Field and inside the Territory to the extent necessary to fulfill its assigned responsibilities, subject to any limitations established by Theravance. For the sake of clarity and avoidance of doubt, the foregoing license shall not expand Clinigen's rights with respect to the Commercialization of the Licensed Products.

ARTICLE X. CONFIDENTIAL INFORMATION

10.01 Confidential Information. Each of Clinigen and Theravance and their respective Affiliates and sublicensees shall keep all Confidential Information received from the other Party with the same degree of care it maintains the confidentiality of its own Confidential Information. Each of Clinigen and Theravance undertake and make their respective Affiliates and sublicensees undertake to take any and all steps or actions necessary or desirable under applicable legislation to keep secret the Confidential Information disclosed under this Agreement. Neither Party or its respective Affiliates or sublicensees shall use such Confidential Information for any purpose other than in the performance of or as described in this Agreement, or disclose the same to any other Person other than to such of its agents or contractors who have a need to know such Confidential Information to implement the terms of this Agreement or enforce its rights under this Agreement. A Receiving Party shall advise any agent or contractor who receives such Confidential Information of the confidential nature thereof and of the obligations contained in this Agreement relating thereto, and the Receiving Party shall ensure that all such agents comply with such obligations as if they had been a Party hereto. The Confidential Information may be disclosed in confidence to the Receiving Party's employees, directors, officers, agents, contractors and any other Persons on a need to know basis on the condition that it is not to be reproduced, copied or used for any other purpose than the purpose for which it is provided hereunder. No disclosure of the Confidential Information shall be made by the Receiving Party to its employees, directors, officers, agents and other Persons unless and until such employees, directors, officers, agents, contractors and other Persons have agreed in writing: (a) to hold such Confidential Information in confidence at least to the extent that the Receiving Party is obligated hereunder; and (b) not to use such Confidential Information, except as permitted by the terms of this Agreement. Upon termination of this Agreement, the Receiving Party shall return or destroy, at the Disclosing Party's request, all documents, tapes or other media containing Confidential Information of the Disclosing Party that remain in the Receiving Party's, its agents' or contractors' possession, except that the Receiving Party may keep one copy of the Confidential Information in the legal department files of the Receiving Party, solely for archival purposes. Such archival copy shall be deemed to be the property of the Disclosing Party, and shall continue to be subject to the provisions of this Article X notwithstanding any earlier termination of this Agreement or otherwise. Each Party will be liable for breach of this Article X by any of its agents, Affiliates, sublicensees, subcontractors, or its Affiliates' sublicensees and subcontractors.

10.02 Permitted Disclosure and Use. Notwithstanding Section 10.01, a Party may disclose Confidential Information belonging to the other Party only to the extent such disclosure is reasonably necessary to: (a) obtain Marketing Authorization of the Licensed Product or any other necessary permissions, approvals and other documents issued by Governmental Authorities; (b) enforce the provisions of this Agreement; or (c) comply with Laws. If a Party deems it necessary to disclose Confidential Information of the other Party pursuant to this Section 10.02, such Party shall give reasonable advance notice of such intended disclosure to the other Party to permit such other Party sufficient opportunity to object to such disclosure or to take measures to ensure

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confidential treatment of such information. The Receiving Party will cooperate reasonably with the Disclosing Party's efforts to protect the confidentiality of the information. Notwithstanding Section 10.01, the Theravance may use and disclose the Confidential Information of Clinigen as necessary to make, have made and Develop the Licensed Product and to make, have made and Develop additional compounds or products for the treatment of bacterial infections so long as the recipient of such Confidential Information is bound by confidentiality obligations no less restrictive than contemplated by the Parties in this Agreement and the Clinigen is named as an intended third party beneficiary of such confidentiality agreement.

10.03 Publications. Subject to any Third Party rights existing as of the Effective Date, Clinigen shall submit to the Joint Steering Committee for review and approval (i) all proposed academic, scientific or medical publications relating to a Licensed Product or any research or Development activities under this Agreement and intended for major international peer reviewed journals, (ii) public presentations for major international conferences relating to a Licensed Product or any research or Development activities under this Agreement and (iii) a copy of any other publications or public presentations related to the Licensed Product or any research or Development activities under this Agreement not covered by (i) and (ii) on a full and timely access basis, in each case for review in connection with preservation of Patent rights, and trade secrets, to determine whether Confidential Information should be modified or deleted from the proposed publication or public presentation and/or to confirm consistency with industry standard and customary good publication practice. Written copies of such proposed publications and presentations shall be submitted to the Joint Steering Committee no later than sixty (60) days before submission for publication or presentation and the Joint Steering Committee shall provide its comments with respect to such publications and presentations within ten (10) Business Days after its receipt of such written copy. The review period may be extended for an additional sixty (60) days if a representative of the non-publishing Party on the Joint Steering Committee can demonstrate a reasonable need for such extension including, but not limited to, the preparation and filing of patent applications. By mutual agreement of the Parties, this period may be further extended. The Parties will each comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of other parties in any publications relating to the Licensed Product or any research or Development activities under this Agreement.

10.04 Public Announcements. Except as may be expressly permitted under Section 10.03 or required by applicable Laws and subject to the final two sentences of this Section 10.04, neither Party will make any public announcement of any information regarding this Agreement, the Licensed Product or any research or Development activities under this Agreement without the prior written approval of the other Party, which approval shall not be withheld unreasonably. Once any statement is approved for disclosure by the Parties or information is otherwise made public in accordance with the preceding sentence, either Party may make a subsequent public disclosure of the contents of such statement without further approval of the other Party. Notwithstanding the foregoing, within sixty (60) days following the Effective Date, appropriate representatives of the Parties will meet and agree upon a process and principles for reaching timely consensus on how the Parties will make public disclosure concerning this Agreement, the Licensed Product or any research and Development activities under this Agreement.

10.05 Confidentiality of this Agreement. The terms of this Agreement shall be Confidential Information of each Party and, as such, shall be subject to the provisions of this Article X.

10.06 Survival. The obligations and prohibitions contained in this Article X shall survive the expiration or termination of this Agreement for a period of ten (10) years.

ARTICLE XI. REPRESENTATIONS AND WARRANTIES; COVENANTS

11.01 Mutual Representations and Warranties. Theravance and Clinigen each represents and warrants to the other as of the Effective Date that:

(a) Such Party:

(i) is a company duly organized, validly existing, and in good standing under the Laws of its incorporation;

(ii) is duly qualified as a corporation and in good standing under the Laws of each jurisdiction where its ownership or lease of property or the conduct of its business requires such qualification, where the failure to be so qualified would have a material adverse effect on its financial condition or its ability to perform its obligations hereunder;

(iii) has the requisite corporate power and authority and the legal right to conduct its business as now conducted and hereafter contemplated to be conducted;

(iv) has or will obtain all necessary licenses, permits, consents, or approvals from or by, and has made or will make all necessary notices to, all Governmental Authorities having jurisdiction over such Party, to the extent required for the ownership and operation of its business, where the failure to obtain such licenses, permits, consents or approvals, or to make such notices, would have a material adverse effect on its financial condition or its ability to perform its obligations hereunder; and

(v) is in compliance with its charter documents;

(b) The execution, delivery and performance of this Agreement by such Party and all instruments and documents to be delivered by such Party hereunder:

(i) are within the corporate power of such Party;

(ii) have been duly authorized by all necessary or proper corporate action;

(iii) do not conflict with any provision of the charter documents of such Party;

(iv) will not, to the best of such Party's knowledge, violate any Laws or regulation or any order or decree of any court of governmental instrumentality; will not violate or conflict with any terms of any indenture, mortgage, deed of trust, lease, agreement, or other

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instrument to which such Party is a party, or by which such Party or any of its property is bound, which violation would have a material adverse effect on its financial condition or on its ability to perform its obligations hereunder;

(c) This Agreement has been duly executed and delivered by such Party and constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms, except as such enforceability may be limited by applicable insolvency and other Laws affecting creditors' rights generally, or by the availability of equitable remedies; and

(d) All of its employees, officers, and consultants have executed agreements or have existing obligations under Laws requiring assignment to such Party of all Inventions made by such individuals during the course of and as the result of their association with such Party, and obligating such individuals to maintain as confidential such Party's Confidential Information.

11.02 Additional Clinigen Representations and Warranties. Clinigen further represents, warrants to Theravance as of the Effective Date that:

(a) Clinigen has utilized its own scientific, marketing and distribution expertise and experience to analyze and evaluate both the scientific and commercial value of this collaboration and, except for the specific warranties and representations made by Theravance hereunder, has solely relied on such analysis and evaluations in deciding to enter into this Agreement; and

(b) Neither Clinigen nor any of its Affiliates is a party to or otherwise bound by any oral or written contract or agreement that will result in any Person obtaining any interest in, or that would give to any Person any right to assert any claim in or with respect to, any of Clinigen's rights granted under this Agreement.

11.03 Additional Theravance Representations and Warranties. Theravance further represents and warrants to Clinigen as of the Effective Date that:

(a) Having carried out and completed diligent searches in relation to the Theravance Patents and Theravance Trademarks, and other than as set forth in the Disclosure Letter, Theravance is not aware, nor has been made aware, of any conflict or likely future conflict with the intellectual property rights of any Third Party with respect to Theravance Patents, Theravance Inventions, Theravance Know-How or Theravance Trademarks or which will arise as a result of the Commercialization of the Licensed Products.

(b) Exhibit B sets forth a complete and accurate list of the Theravance Patents as of the Effective Date.

(c) Exhibit C sets forth a complete and accurate list of the registrations or pending applications for Theravance Trademarks as of the Effective Date.

(d) Theravance is the sole and exclusive owner of the entire right, title and interest in each of the Theravance Patents, Theravance Trademarks, Theravance Inventions,

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Theravance Know-How and Marketing Authorizations. As of the Effective Date, the Theravance Patents, Theravance Trademarks, Theravance Inventions, Theravance Know-How and Marketing Authorizations are not subject to any encumbrance, lien or claim of ownership by any Third Party, and Theravance is not aware of any facts that would preclude Theravance from having unencumbered title to the Theravance Patents, Theravance Trademarks, Theravance Inventions, Theravance Know-How and Marketing Authorizations. Other than as set forth in the Disclosure Letter, Theravance has not received any notice of any claim by any Third Party challenging the ownership or right to use of Theravance in and to the Theravance Patents, Theravance Trademarks, or Marketing Authorizations, or challenging its right to use or ownership of any of the Theravance Know-How or Theravance Inventions, or making any adverse claim of ownership thereof.

(e) To the knowledge of Theravance, no intellectual property rights other than those under the Theravance Patents, Theravance Know-How, Theravance Inventions, Theravance's rights in the Joint Inventions and/or Joint Invention Patents, and Theravance Trademarks are necessary for Clinigen to Commercialize the Licensed Products, except as set forth in the Disclosure Letter.

(f) To the knowledge of Theravance, no Third Party is infringing any of the issued Theravance Patents nor has Theravance put any Third Party on notice of infringing any of the issued Theravance Patents except as set forth in the Disclosure Letter.

(g) To the knowledge of Theravance, no Third Party is infringing any of the Theravance Trademarks nor has Theravance put any Third Party on notice of infringing any of the Theravance Trademarks.

(h) There is no pending, decided or settled opposition, interference proceeding, reexamination proceeding, cancellation proceeding, injunction, lawsuit, hearing, investigation, complaint, arbitration, mediation, demand, International Trade Commission investigation, decree, or any other dispute, disagreement, or claim involving a Theravance Patent, in each case alleged in writing to Theravance (collectively referred to herein as "Disputes"), nor to the knowledge of Theravance has any such Dispute been threatened, in each case challenging the legality, validity, enforceability or ownership of any Theravance Patent.

(i) Theravance has not received notice from any Third Party of a claim that an issued patent of any Third Party would be infringed by the manufacture, having made, use, Development, Commercialization, distribution, marketing, offer for sale, sale, exportation or importation of a Theravance Compound and/or a Licensed Product under this Agreement;

(j) To Theravance's knowledge, each of the Theravance Patents is valid and enforceable (if issued) or subsisting and not abandoned (if pending). Theravance has not received notice from any Third Party of a claim asserting the invalidity, misuse, unregisterability or unenforceability of any of the Theravance Patents, or challenging its right to use or ownership of any of the Theravance Patents, Theravance Inventions, or the Theravance Know-How, or making any adverse claim of ownership thereof;

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(k) To Theravance's knowledge, the conception, development and reduction to practice of the Theravance Inventions, Theravance Know-How and the inventions claimed in the Theravance Patents have not constituted or involved the misappropriation of trade secrets or other rights or property of any Third Party. Theravance has not received notice from any Third Party that any trade secrets or other intellectual property rights of such Third Party would be misappropriated by the development and reduction to practice of the Theravance Inventions, Theravance Know-How, or the inventions claimed in the Theravance Patents;

(l) Other than as set forth in the Disclosure Letter, there is no claim or demand of any Person or entity pertaining to, or any proceeding which is pending or, to the knowledge of Theravance, threatened, that challenges the validity, use or existence of any Theravance Patent, Theravance Know-How, Theravance Invention, Theravance Trademark, Marketing Authorization, the rights granted herein to Clinigen in respect of any Theravance Patent, Theravance Know-How, Theravance Invention, Theravance Trademark, Marketing Authorization, or claims that any default exists under any license with respect to any Theravance Patent, Theravance Know-How, Theravance Invention, or Theravance Trademark, Marketing Authorization or to

which Theravance is a party, except where such claim, demand or proceeding would not materially and adversely affect the ability of Theravance to carry out its obligations under this Agreement; and

(m) To Theravance's belief and knowledge the production of formulated Licensed Products that meet the regulatory requirements in the Territory is technically possible.

11.04 Covenants.

(a) Compliance. Each Party hereby covenants and agrees during the Term that it shall carry out its obligations or activities hereunder in accordance with (i) the terms of this Agreement and (ii) all applicable Laws.

(b) Clinigen Covenant, Agreement and Obligation Relating to Further Commercialization. Clinigen and its Affiliates and Clinigen's and its Affiliates' licensees and sublicensees under this Agreement [***].

11.05 Disclaimer of Warranty. Subject to the specific warranties and representations given under Section 11.01 through and including Section 11.03, nothing in this Agreement shall be construed as a warranty or representation by either Party (i) that the Licensed Product made, used, sold or otherwise disposed of under this Agreement is or will be free from infringement of patents, copyrights, trademarks, industrial design or other intellectual property rights of any Third Party, (ii) regarding the effectiveness, value, safety, non-toxicity, patentability, or non-infringement of any patent technology, the Licensed Product or any information or results provided by either Party pursuant to this Agreement or (iii) that the Licensed Product will obtain Marketing Authorization or appropriate pricing approval in the Territory. Each Party explicitly accepts all of the same as experimental and for Development purposes, and without any express or implied warranty from the other Party. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS, WAIVES, RELEASES, AND RENOUNCES ANY WARRANTY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

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11.06 Breach by Clinigen. Breach of any Clinigen representation or warranty specified in Section 11.01 and Section 11.02 above shall constitute a material breach of this Agreement by Clinigen. Without any prejudice to any other remedies granted to Theravance by this Agreement and/or by applicable Laws, in this event Theravance may unilaterally refuse to perform this Agreement in whole or in any part without recourse to a court thus having this Agreement terminated upon thirty (30) days written notice. Such termination shall become effective at the end of such thirty (30) day period, unless Clinigen cures such breach, during such thirty (30) day period, or if such breach is curable but not within such thirty (30) day period, and Clinigen initiates and diligently pursues a cure for such breach then such termination shall become effective at the end of forty-five (45) days unless Clinigen cures such breach. Clinigen shall fully reimburse Theravance for all damages, costs and expenses (including actual damages and lost profit) resulting from such refusal to perform.

11.07 Consequences of Breach by Clinigen. Clinigen further undertakes to fully reimburse and compensate Theravance for all direct damages, costs and expenses (including reasonable attorneys' fees), which Theravance may suffer or which may be asserted against Theravance caused by, or arising in connection with:

(a) any material breach by Clinigen of representations and warranties provided by Clinigen hereunder;

(b) the relationship between Clinigen and any of its Affiliates, employees, agents or contractors, including, but not limited to, all authors of the Clinigen Know-How, Clinigen Patents, Clinigen Inventions and Joint Inventions and other owners of intellectual property used by Clinigen for performance of its obligations under this Agreement; or

(c) any claim of any party alleging that the ownership, disposal and/or use by Theravance (or any of its respective Affiliates, sublicensees or subcontractors), of the Clinigen Know-How, Clinigen Patents, Clinigen Inventionsand/or Joint Inventions infringes upon such party's intellectual property or related rights or other such party's rights or interests.

Notwithstanding the definition of Losses, for the sake of clarity and avoidance of doubt, Clinigen shall not be liable to Theravance (or any of its respective Affiliates, sublicensees or subcontractors) to reimburse and/or compensate Theravance for any consequential, indirect, incidental or special damages under this Section 11.07.

11.08 Breach by Theravance. Breach of any Theravance representation or warranty specified in Section 11.01 and Section 11.03 above shall constitute a material breach of this Agreement by Theravance. Without any prejudice to any other remedies granted to Clinigen by this Agreement and/or by applicable Laws, in this event Clinigen may unilaterally refuse to perform this Agreement in whole or in any part without recourse to a court thus having this Agreement terminated upon thirty (30) days written notice. Such termination shall become effective at the end of such thirty (30) day period, unless Theravance cures such breach, during such thirty (30) day period, or if such breach is curable but not within such thirty (30) day period,

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and Theravance initiates and diligently pursues a cure for such breach then such termination shall become effective at the end of forty-five (45) days unless Theravance cures such breach. Theravance shall fully reimburse Clinigen for all damages, costs and expenses (including actual damages and lost profit)

resulting from such refusal to perform.

11.09 Consequences of Breach by Theravance. Theravance further undertakes to fully reimburse and compensate Clinigen all direct damages, costs and expenses (including reasonable attorneys' fees), which Clinigen may suffer or which may be asserted against Clinigen caused by, or arising in connection with:

(a) any material breach by Theravance of representations and warranties provided by Theravance hereunder;

(b) the relationship between Theravance and any of its Affiliates, employees, agents or contractors, including, but not limited to, all authors of the Theravance Know-How, Theravance Patents, Theravance Inventions and Joint Inventions and other owners of intellectual property used by Theravance for performance of its obligations under this Agreement; or

(c) any claim of any party alleging that the ownership, disposal and/or use by Clinigen (or any of its respective Affiliates, sublicensees or subcontractors) of the Theravance Know-How, Theravance Patents, Theravance Inventions and/or Joint Inventions infringes upon such party's intellectual property or related rights or other such party's rights or interests.

Notwithstanding the definition of Losses, for the sake of clarity and avoidance of doubt, Theravance shall not be liable to Clinigen (or any of its respective Affiliates, sublicensees or subcontractors) to reimburse and/or compensate Clinigen for any consequential, indirect, incidental or special damages under this Section 11.09.

ARTICLE XII. INDEMNIFICATION

12.01 Indemnification by Clinigen. Subject to Section 12.04 and Section 13.02, Clinigen shall defend, indemnify and hold harmless Theravance and its Affiliates and each of their officers, directors, employees, successors and assigns from and against all Claims of Third Parties, and all associated Losses, to the extent arising out of (a) Clinigen's negligence or willful misconduct in performing any of its obligations under this Agreement, (b) a breach by Clinigen of any of its representations, warranties, covenants or agreements under this Agreement, (c) the manufacture, use, handling, storage, marketing, sale, offering for sale, importation, distribution or other disposition of the API Compound or the Licensed Product by Clinigen, its Affiliates, agents or sublicensees, or (d) any agreement between Clinigen and a Third Party pertaining to the Licensed Product, except to the extent such Losses result from the negligence or willful misconduct of Theravance.

12.02 Indemnification by Theravance. Subject to Section 12.04 and Section 13.02, Theravance shall defend, indemnify and hold harmless Clinigen and its Affiliates and each of their officers, directors, employees, successors and assigns from and against all Claims of Third Parties, and all associated Losses, to the extent arising out of (a) Theravance's negligence or willful misconduct in performing any of its obligations under this Agreement, (b) a breach by Theravance of any of its representations, warranties, covenants or agreements under this Agreement, (c) an

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Infringement Claim, (d) the manufacture, use, handling, storage, marketing, sale, offering for sale, importation, distribution or other disposition of the API Compound or the Licensed Product by Theravance, its Affiliates, agents or sublicensees, or (e) any agreement between Theravance and a Third Party pertaining to the Licensed Product, except to the extent such Losses result from the negligence or willful misconduct of Clinigen.

12.03 Procedure for Indemnification.

(a) Notice. Each Party will notify promptly the other in writing if it becomes aware of a Claim (actual or potential) by any Third Party (a "Third Party Claim") for which indemnification may be sought by that Party and will give such information with respect thereto as the other Party shall reasonably request. If any proceeding (including any governmental investigation) is instituted involving any Party for which such Party may seek an indemnity under Section 12.01 or Section 12.02, as the case may be (the "Indemnified Party"), the Indemnified Party shall not make any admission or statement concerning such Third Party Claim, but shall promptly notify the other Party (the "Indemnifying Party") orally and in writing and the Indemnifying Party and Indemnified Party shall meet to discuss how to respond to any Third Party Claims that are the subject matter of such proceeding. The Indemnifying Party shall not be obligated to indemnify the Indemnified Party to the extent any admission or statement made by the Indemnified Party or any failure by such Party to notify the Indemnifying Party of the claim materially prejudices the defense of such claim.

(b) Defense of Claim. If the Indemnifying Party elects to defend or, if local procedural rules or Laws do not permit the same, elects to control the defense of a Third Party Claim, it shall be entitled to do so provided it gives notice to the Indemnified Party of its intention to do so within twenty-five (25) days after the receipt of the written notice from the Indemnified Party of the potentially indemnifiable Third Party Claim (the "Defense Notice"). The Indemnifying Party expressly agrees the Indemnifying Party shall be responsible for satisfying and discharging any award made to or settlement reached with the Third Party pursuant to the terms of this Agreement without prejudice to any provision in this Agreement or right at Laws which will allow the Indemnifying Party subsequently to recover any amount from the Indemnified Party to the extent the liability under such settlement or award was attributable to the Indemnified Party. Subject to compliance with the Defense Notice, the Indemnifying Party shall retain counsel reasonably acceptable to the Indemnified Party (such acceptance not to be unreasonably withheld, refused, conditioned or delayed) to represent the Indemnified Party and shall pay the reasonable fees and expenses of such counsel related to such proceeding. In any such proceeding, the Indemnified Party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of the Indemnified Party. The Indemnified Party shall not settle any claim for which it is seeking indemnification without the prior written consent of the Indemnifying Party which consent shall not be unreasonably withheld, refused, conditioned or delayed. The Indemnified Party shall, if requested by the Indemnifying Party, cooperate in all reasonable respects in the defense of such claim that is being managed and/or controlled by the Indemnifying Party. The Indemnifying Party shall not, without the written consent of the Indemnified Party (which consent shall not be unreasonably withheld, refused, conditioned or delayed), effect any settlement of any pending or threatened proceeding in which the Indemnified Party is, or based on the same set of facts could have been, a party and indemnity could have been sought hereunder by the Indemnified Party, unless such settlement

includes an unconditional release of the Indemnified Party from all liability on claims that are the subject matter of such proceeding. If the Defense Notice is not made, then neither Party shall have the right to control the defense of such Third Party Claim and the Parties shall cooperate in and be consulted on the material aspects of such defense at each Party's own expense; provided that if the Indemnifying Party does not make the Defense Notice, the Indemnifying Party may at any subsequent time during the pendency of the relevant Third Party Claim irrevocably elect, if permitted by local procedural rules or Laws, to defend and/or to control the defense of the relevant Third Party Claim so long as the Indemnifying Party also agrees to pay the reasonable fees and costs incurred by the Indemnified Party in relation to the defense of such Third Party Claim from the inception of the Third Party Claim until the date the Indemnifying Party assumes the defense or control thereof.

12.04 Assumption of Defense. Notwithstanding anything to the contrary contained herein, an Indemnified Party shall be entitled to assume the defense of any Third Party Claim with respect to the Indemnified Party, upon written notice to the Indemnifying Party pursuant to this Section 12.04, in which case the Indemnifying Party shall be relieved of liability under Section 12.01 or Section 12.02, as applicable, solely for such Third Party Claim and related Losses.

12.05 Insurance. During the Term of this Agreement and for a period of three (3) years after the termination or expiration of this Agreement, Clinigen shall obtain and/or maintain at its sole cost and expense, product liability insurance (including any self-insured arrangements) in amounts which are reasonable and customary in the Territory for companies of comparable size and activities. Such product liability insurance or self-insured arrangements shall insure against liability pertaining to its obligations under this Agreement including without prejudice to the generality of the foregoing, personal injury, physical injury, and property damage. Clinigen shall provide written proof of the existence of such insurance to Theravance upon request.

ARTICLE XIII. PATENTS and INVENTIONS

13.01 Inventions.

(a) Disclosure and Determination of Inventorship. Each Party shall promptly disclose to the other Party in writing any Inventions made by it during the Term. The determination of inventorship for such Inventions shall be made in accordance with the applicable patent Laws.

(b) Ownership of Inventions. Theravance shall own all Theravance Inventions and Clinigen shall own all Clinigen Inventions. Theravance and Clinigen shall each own an equal, undivided interest in all Joint Inventions.

13.02 Preparation, Prosecution and Maintenance of Patents.

(a) Preparation, Prosecution and Maintenance of Theravance Patents.

(i) Responsibility. Theravance shall have the exclusive right and the obligation to prepare, file, prosecute in a diligent manner (including without limitation by conducting interferences, oppositions and reexaminations or other similar proceedings), maintain (by timely paying all maintenance fees, renewal fees, and other such fees and expenses required

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under applicable Laws) and extend all Theravance Patents, in accordance with input from Clinigen as provided herein. Theravance may elect not to prepare, file, prosecute, maintain or extend Theravance Patents subject to the provisions of Section 13.02(d), or, if applicable, Theravance may cause its licensors or licensees to prepare, file, prosecute, maintain or extend Theravance Patents.

(ii) Abandonment. Theravance shall consult with Clinigen and comply with Section 13.02(d) prior to abandoning any Theravance Patents in the Territory.

(iii) Input. Theravance shall regularly advise Clinigen of the status of all Theravance Patents in the Territory, and, at Clinigen's request, shall provide Clinigen with copies of all documentation concerning Theravance Patents in the Territory, including all correspondence to and from any Governmental Authority. Prior to filing patent applications relating to Theravance Inventions or significant prosecution documents relating to Theravance Patents in the Territory, Theravance shall solicit Clinigen's advice on the content of the patent application or prosecution document and Theravance shall take into account Clinigen's reasonable comments related thereto, unless (without fault of Theravance) deadlines will not permit such review or Clinigen notifies Theravance that it does not wish to review such documents. In the event of a dispute between the Parties regarding the content of patent applications or prosecution documents, Theravance shall have the final decision-making authority with respect to any action relating to Theravance Inventions or Theravance Patents subject to the provisions of Section 13.02(d) and Section 13.02(i). Theravance and Clinigen shall agree on which Countries in the Territory corresponding Theravance Patents shall be filed within the priority period. For all Countries outside the Territory, Theravance shall make the final decision regarding which Countries corresponding Theravance Patents shall be filed.

(iv) Expenses. Theravance shall be responsible for all of Theravance's expenses to procure Theravance Patents in the Territory and outside the Territory, including all filing fees, translations, maintenance, annuities and protest proceedings.

(b) Preparation, Prosecution and Maintenance of Clinigen Patents.

(i) Responsibility. Clinigen shall have the exclusive right and the obligation to prepare, file, prosecute in a diligent manner (including without limitation by conducting interferences, oppositions and reexaminations or other similar proceedings), maintain (by timely paying all maintenance fees, renewal fees, and other such fees and expenses required under applicable Laws) and extend all Clinigen Patents, in accordance with input from Theravance as provided herein. Clinigen may elect not to prepare, file, prosecute, maintain or extend Clinigen Patents subject to the provisions of Section 13.02(e), or, if applicable, Clinigen may cause its licensors or licensees to prepare, file, prosecute, maintain or extend Clinigen Patents.

(ii) Abandonment. Clinigen shall consult with Theravance and comply with Section 13.02(e) prior to abandoning any Clinigen Patents.

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(iii) Input. Clinigen shall regularly advise Theravance of the status of all Clinigen Patents and, at Theravance's request, shall provide Theravance with copies of all documentation concerning Clinigen Patents, including all correspondence to and from any Governmental Authority. Prior to filing patent applications relating to Clinigen Inventions or significant prosecution documents relating to Clinigen Patents outside the Territory, Clinigen shall solicit Theravance's advice on the content of the patent application or prosecution document and Clinigen shall take into account Theravance's reasonable comments related thereto, unless (without fault of Clinigen) deadlines will not permit such review or Theravance notifies Clinigen that it does not wish to review such documents. In the event of a dispute between the Parties regarding the content of patent applications or prosecution documents, Clinigen shall have the final decision-making authority with respect to any action relating to Clinigen Inventions or Clinigen Patents subject to the provisions of Section 13.02(e) and Section 13.02(i). Theravance and Clinigen shall agree on which Countries in the Territory corresponding Clinigen Patents shall be filed within the priority period. For all Countries outside the Territory, Clinigen shall make the final decision regarding which Countries corresponding Clinigen Patents shall be filed, subject to Theravance's Step-In-Rights in Section 13.02(e).

(iv) Expenses. Clinigen shall be responsible for all of Clinigen's expenses to procure Clinigen Patents in the Territory and outside the Territory, including all filing fees, translations, maintenance, annuities and protest proceedings.

(c) Preparation, Prosecution and Maintenance of Joint Invention Patents.

(i) Responsibility. Theravance shall have the exclusive right and the obligation to prepare, file, prosecute in a diligent manner (including without limitation by conducting interferences, oppositions and reexaminations or other similar proceedings), maintain (by timely paying all maintenance fees, renewal fees, and other such fees and expenses required under applicable Laws) and extend all Joint Invention Patents, in accordance with input from Clinigen as provided herein. Theravance may elect not to prepare, file, prosecute, maintain or extend Joint Invention Patents subject to the provisions of Section 13.02(f), or, if applicable, Theravance may cause its licensors or licensees to prepare, file, prosecute, maintain or extend Joint Invention Patents. The Parties agree to cooperate in the preparation and prosecution of all Joint Invention Patents, including without limitation by obtaining and executing necessary powers of attorney and assignments by the named inventors, providing relevant technical reports to the filing Party concerning the Invention disclosed in Joint Invention Patents, and obtaining execution of such other documents which shall be needed in the filing and prosecution of Joint Invention Patents. Theravance and Clinigen shall be indicated as co-owners of the Joint Invention Patents in the all applicable documents and filings if it is not prohibited by applicable Laws.

(ii) Abandonment. Theravance and Clinigen shall agree to abandon, or comply with Section 13.02(f) prior to the abandonment of, any Joint Invention Patents.

(iii) Input. Theravance shall regularly advise Clinigen of the status of all Joint Invention Patents and, at Clinigen's request, shall provide Clinigen with copies of all

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documentation concerning Joint Invention Patents, including all correspondence to and from any Governmental Authority. Prior to filing patent applications relating to Joint Inventions or significant prosecution documents relating to Joint Invention Patents, Theravance shall solicit Clinigen's advice on the content of the patent application or prosecution document and Theravance shall take into account Clinigen's reasonable comments related thereto, unless (without fault of Theravance) deadlines will not permit such review or Clinigen notifies Theravance that it does not wish to review such documents. In the event of a dispute between the Parties regarding the content of patent applications or prosecution documents, Theravance shall have the final decision-making authority with respect to any action relating to Joint Inventions or Joint Invention Patents subject to the provisions of Section 13.02(f) and Section 13.02(i). Theravance and Clinigen shall agree on which Countries in the Territory corresponding Joint Invention Patents shall be filed within the priority period. For all Countries outside the Territory, Theravance shall make the final decision regarding which Countries corresponding Joint Invention Patents shall be filed subject to the provisions of Section 13.02(f).

(iv) Expenses. Clinigen shall be responsible for all of Theravance's external, properly documented, out-of-pocket expenses incurred after the Effective Date to procure Joint Invention Patents in the Territory, including without limitation all filing fees, translations, maintenance, annuities, and protest proceedings. Theravance will invoice Clinigen on a quarterly basis beginning the first Calendar Quarter following the Effective Date, setting forth all such expenses incurred. Reimbursement will be made to Theravance in United States Dollars within thirty (30) days of receipt of the invoice by Clinigen. Theravance shall be responsible for all of its external expenses to procure Joint Invention Patents outside the Territory and for its internal expenses associated with all Joint Invention Patents.

(d) Clinigen Step-In Rights for Theravance Inventions and Theravance Patents. If Theravance elects not to prepare and file a patent application for a Theravance Invention in any Country in the Territory or not to prosecute and maintain a Theravance Patent in any Country in the Territory, Theravance shall give Clinigen written notice thereof at least sixty (60) days prior to allowing any rights to the Theravance Invention or the Theravance Patent to lapse or become abandoned or unenforceable, and Clinigen shall thereafter have the right (hereinafter regardless of which Party is exercising such right, "Step-In Rights"), at its sole expense, to prepare and file a patent application for the Theravance Invention in such Country or to prosecute and maintain the Theravance Patent in such Country. Clinigen shall provide Theravance with written notice of its decision to exercise its Step-In Rights within thirty (30) days from receipt of the notice from Theravance regarding its decision not to prepare or file a patent application on a Theravance Invention in such Country or not to prosecute or maintain a Theravance Patent in such Country. Within ninety (90) days after the exercise of Step-In Rights by Clinigen for any Theravance Invention or Theravance Patent, Theravance shall assign all of its rights in and to the respective Theravance Invention and/or the Theravance Patent to Clinigen in such Country.

(e) Theravance Step-In Rights for Clinigen Inventions and Clinigen Patents. If Clinigen elects not to prepare and file a patent application for a Clinigen Invention in any Country or not to prosecute and maintain a Clinigen Patent in any Country, Clinigen shall give Theravance written notice thereof at least sixty (60) days prior to allowing any rights to the Clinigen Invention or the Clinigen Patent to lapse or become abandoned or unenforceable, and

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Theravance shall thereafter have the right, at its sole expense, to prepare and file a patent application for the Clinigen Invention in such Country or to prosecute and maintain the Clinigen Patent in such Country. Theravance shall provide Clinigen with written notice of its decision to exercise its Step-In Rights within thirty (30) days from receipt of the notice from Clinigen regarding its decision not to prepare or file a patent application on a Clinigen Invention in such Country or not to prosecute or maintain a Clinigen Patent in such Country. Within ninety (90) days after the exercise of Step-In Rights by Theravance for any Clinigen Invention or Clinigen Patent, Clinigen will assign all of its rights in and to the respective Clinigen Invention or the Clinigen Patent to Theravance in such Country.

(f) Step-In Rights for Joint Inventions and Joint Invention Patents. If Theravance elects not to prepare and file a patent application for a Joint Invention or not to prosecute and maintain a Joint Invention Patent, Theravance shall give Clinigen written notice thereof at least sixty (60) days prior to allowing any rights to the Joint Invention or the Joint Invention Patent to lapse or become abandoned or unenforceable, and Clinigen shall thereafter have the right, at its sole expense, to prepare and file a patent application for the Joint Invention or to prosecute and maintain the Joint Invention Patent. Clinigen shall provide Theravance with written notice of its decision to exercise its Step-In Rights within thirty (30) days from receipt of the notice from Theravance regarding its decision not to prepare or file a patent application on a Joint Invention or not to prosecute or maintain a Joint Invention Patent. Within ninety (90) days after the exercise of Step-In Rights by Clinigen for any Joint Invention or Joint Invention Patent, Theravance will assign all of its rights in the Joint Invention and/or the Joint Invention Patent to Clinigen.

(g) Execution of Documents. Each of the Parties shall execute or have executed by its appropriate Affiliates or agents such documents as may be necessary to prepare, file, prosecute, maintain or extend any Patents, and each Party shall cooperate with the other Party so far as reasonably necessary with respect to furnishing all information and data in its possession reasonably necessary to prepare, file, prosecute, maintain or extend any Patents.

(h) Patent Term Extensions. The Parties shall cooperate with each other to obtain patent term extensions or other extensions of patent rights, for a Licensed Product in the Territory, if available. The Joint Steering Committee shall determine which Patents the Parties shall endeavor to have extended in the Territory. If the Joint Steering Committee does not agree as to which Patents should be extended in the Territory, then the Parties shall resort to the dispute resolution procedures set forth in Section 3.01(e). Theravance shall determine which Theravance Patents the Parties shall endeavor to have extended outside the Territory. Theravance shall be responsible for filing all such extensions for Theravance Patents and Joint Invention Patents; and Clinigen shall be responsible for filing all such extensions for Clinigen Patents.

(i) Patent-Related Dispute Resolution. If the Parties disagree on any preparation, prosecution or maintenance issue for Patents which is not specifically addressed and resolved by this Article XIII (a "Patent Resolution Issue"), the Parties agree to seek guidance and resolution from an independent, mutually-acceptable patent attorney with experience and expertise relevant to the matter in dispute as further described in this Section 13.02(i) instead of resorting to arbitration process as described in Section 15.05. If the Parties reach an impasse as to any Patent Resolution Issue (even after resorting to Section 3.01(e)(ii)), then they shall submit

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the Patent Resolution Issue to an experienced patent attorney mutually-acceptable to the Parties, who does not otherwise perform work for either Party or any of its Affiliates, for resolution. The Parties shall engage such attorney within thirty (30) days after either Party notifies the other in writing of a Patent Resolution Issue impasse remaining unresolved after resorting to Section 3.01(e)(ii). If they cannot agree as to who such attorney shall be within such time period, then the total of two nominees of the Parties (one from each Party) shall select a third patent attorney who shall be the attorney to resolve the dispute. The Parties shall share equally the expenses incurred for the services of such patent attorney. Within fifteen (15) days after engaging the patent attorney, the Parties shall each submit necessary documentation to the patent attorney. Within five (5) Business Days thereafter, the Parties shall convene a meeting with the patent attorney during which each Party may orally present its position on the Patent Resolution Issue. The Parties shall endeavor to cause the patent attorney to render his or her guidance as to the Patent Resolution Issue within five (5) Business Days after such discussion. Neither Party shall engage in any ex parte communications with the patent attorney. The Parties shall accept and follow the guidance and resolution of the patent attorney absent any fraud in the proceedings.

13.03 Patent Infringement.

(a) Infringement Claims by Third Parties. With respect to any and all Claims instituted by Third Parties against Theravance or Clinigen or any of their respective Affiliates, sublicensees or subcontractors for patent infringement involving the manufacture, use, license, marketing, sale, offer for sale or importation of a Theravance Compound or Licensed Product in the Territory during the Term or for trademark infringement involving the Theravance Trademarks in the Territory during the Term (an "Infringement Claim"), Theravance shall defend, indemnify and hold harmless Clinigen and its Affiliates and each of their officers, directors, employees, successors and assigns from and against all such Infringement Claims of Third Parties, and all associated Losses in accordance with Article XII.

(b) Infringement of Theravance Patents. In the event that either Party becomes aware of actual or threatened infringement of a Theravance Patent or a Theravance Trademark during the Term, that Party will promptly notify the other Party in writing (an "Infringement Notice"). Theravance will have the first right but not the obligation to bring an infringement action against any Third Party. If Theravance elects to pursue such an infringement action, Theravance shall be solely responsible for the expenses associated with such action and Theravance shall retain all recoveries. During the Term, in the event that Theravance does not undertake such an infringement action within ninety (90) days after the Infringement Notice, Clinigen shall be permitted to do so in Theravance's name. If Clinigen elects to pursue such an infringement action, Clinigen shall be solely responsible for the expenses associated with such action and Clinigen shall retain all recoveries. If a Party is authorized to bring an infringement action under this Section 13.03 but the Party is not recognized by the applicable court or other relevant body as having the requisite standing to pursue such action, then the other Party shall join as a party-plaintiff. If Theravance recommends not pursuing an infringement action, and the Joint Steering Committee recommends not pursuing such infringement action, and Clinigen elects to pursue such infringement action by joining Theravance as a party plaintiff, then Clinigen agrees to indemnify and hold harmless Theravance for all Losses arising from the infringement action.

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(c) Infringement of Clinigen Patents. In the event that either Party becomes aware of actual or threatened infringement of a Clinigen Patent or a Clinigen Trademark during the Term, that Party will promptly send an Infringement Notice to the other Party. Clinigen will have the first right but not the obligation to bring an infringement action against any Third Party. If Clinigen elects to pursue such an infringement action, Clinigen shall be solely responsible for the expenses associated with such action and Clinigen shall retain all recoveries. During the Term, in the event that Clinigen does not undertake such an infringement action within ninety (90) days after the Infringement Notice, Theravance shall be permitted to do so in Clinigen's name. If Theravance elects to pursue such an infringement action, Theravance shall be solely responsible for the expenses associated with such action and Theravance shall retain all recoveries. If a Party is authorized to bring an infringement action under this Section 13.03 but such Party is not recognized by the applicable court or other relevant body as having the requisite standing to pursue such action, then the other Party shall join as a party-plaintiff. If Clinigen recommends not pursuing an infringement action, and the Joint Steering Committee recommends not pursuing such infringement action, and Theravance elects to pursue such infringement action by joining Clinigen as a party plaintiff, then Theravance agrees to indemnify and hold harmless Clinigen for all Losses arising from the infringement action.

(d) Infringement of Joint Invention Patents. In the event that either Party becomes aware of actual or threatened infringement of a Joint Invention Patent during the Term, that Party will promptly send an Infringement Notice to the other Party. In such an event, the matter will be handled as provided in Section 13.03(b).

13.04 Notice of Certification. Each Party shall promptly give notice to the other of any certification filed under the "U.S. Drug Price Competition and Patent Term Restoration Act of 1984" as amended or as it may be amended (or any substantially similar patent and/or competition legislation in the Territory) claiming that any Patent is invalid or that infringement will not arise from the manufacture, use or sale of the Licensed Product by a Third Party ("Hatch-Waxman Certification"). This Section 13.04 is intended by the Parties to apply to any successor legislation in the U.S. and to any counterpart or substantially similar legislation outside the U.S.

(a) Notice. If a Party decides not to bring an infringement action against the entity making such a certification, the Party shall give notice to the other Party of its decision within twenty-one (21) days after receipt of notice of such certification.

(b) Option. The other Party then may, but is not required to, bring an infringement action against the entity that filed the certification.

(c) Name of Party. Any suit by either Party shall either be in the name of Theravance or in the name of Clinigen or jointly in the name of Theravance and Clinigen, as may be required by Laws.

13.05 Representation of Other Party. If a Party elects to pursue an infringement or other legal action under this Article XIII, the other Party not bringing suit may be represented in such an action by attorneys of its own choice and at its own expense. The Party bringing suit shall take the lead in and control any such action.

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13.06 Assistance. Each Party shall execute any legal papers necessary for the prosecution of an infringement or other legal action under this Article XIII and shall provide reasonable assistance as requested by the other Party.

13.07 Settlement. No settlement or consent judgment or other voluntary final disposition of any suit or legal action under this Article XIII may be entered into without the joint written consent of both Parties (which consent will not be withheld unreasonably).

ARTICLE XIV. TERM AND TERMINATION

14.01 Term and Expiration of Term. Unless otherwise mutually agreed to by the Parties, this Agreement shall commence on the Effective Date and shall end upon expiration of the Term, unless terminated early as contemplated hereunder. Unless terminated early under this Article XIV or unless and to the extent Clinigen has exercised the Post-Term Option, the licenses granted by Theravance to Clinigen pursuant to Section 2.01 and the licenses granted by Clinigen to Theravance pursuant to Section 2.02 shall be considered fully-paid and shall become non-exclusive upon expiration of the Term.

14.02 Termination for Material Breach. Either Party may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement subject to Section 14.05(a) in the event that the other Party (as used in this Section 14.02, the "Breaching Party") shall have materially breached or defaulted in the performance of any of its obligations. The Breaching Party shall, if such breach can be cured, have sixty (60) days after written notice thereof was provided to the Breaching Party by the non-breaching Party to remedy such default (or, if such default cannot be cured within such 60-day period, the Breaching Party must commence and diligently continue actions to cure such default during such 60-day period). Any such termination shall become effective at the end of such 60-day period unless the Breaching Party has cured any such breach or default prior to the expiration of such 60-day period (or, if such default is capable of being cured but cannot be cured within such 60-day period, the Breaching Party has commenced and diligently continued actions to cure such default provided always that, in such instance, such cure must have occurred within one hundred twenty (120) days after written notice thereof was provided to the Breaching Party by the non-breaching Party to remedy such default).

14.03 Theravance Right to Terminate the Agreement Due to Failure to Commercialize in a Major Market Country. Theravance may terminate this Agreement subject to Section 14.05(b), if there has been no First Commercial Sale in at least three of the Major Market Countries within six months following the later to occur of (i) Marketing Authorization Approval for such Major Market Country has been transferred to Clinigen pursuant to Regulation (EC) No. 2141/96 and (ii) receipt of Licensed Product from Theravance that meets all specifications required for Commercialization in such Major Market Country. Clinigen shall have sixty (60) days after written notice thereof was provided by Theravance to remedy such default (or, if curing such default requires more than such 60-day period, Clinigen must commence and diligently continue actions to cure such default during such 60-day period). Any such termination shall become effective at the end of such 60-day period unless Clinigen has cured such default prior to the expiration of such 60-day period (or, if such default is capable of being cured but cannot be cured within such 60-day period, Clinigen has commenced and diligently continued actions to cure such default provided always that, in such instance, such cure must have occurred within one hundred

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twenty (120) days after written notice thereof was provided to Clinigen by Theravance to remedy such default) unless:

(a) The Joint Steering Committee agrees to waive the default; or

(b) Theravance is a Breaching Party.

14.04 Clinigen Right to Terminate Agreement After Commercialization. At any time after First Commercial Sale, Clinigen shall have the right to terminate this Agreement, subject to Section 14.05(b), upon the provision of three-hundred sixty-five (365) days written notice.

14.05 Effects of Termination.

(a) Effect of Termination for Material Breach.

(i) Material Breach by Theravance. In the event this Agreement is terminated by Clinigen pursuant to Section 14.02 for material breach by Theravance or its Affiliates or sublicensees,

1) All licenses granted by Theravance to Clinigen under this Agreement shall survive subject to Clinigen's continued obligation to pay royalties on Net Sales to Theravance hereunder;

2) All licenses granted by Clinigen to Theravance under this Agreement shall terminate; and

3) Clinigen shall retain all of its rights to bring an action against Theravance for damages and any other available remedies in law or equity.

(ii) Material Breach by Clinigen. In the event that this Agreement is terminated by Theravance pursuant to Section 14.02 for material breach by Clinigen or its Affiliates or sublicensees:

1) Clinigen and its Affiliates or sublicensees shall, at their sole expense, promptly transfer to Theravance copies of all data, reports, records and materials in their possession or control that relate to the Licensed Product and return to Theravance, or destroy at Theravance's request, all relevant records and materials in their possession or control containing Confidential Information of Theravance (provided that Clinigen may keep one copy of such Confidential Information of Theravance for archival purposes only in accordance with Section 10.01);

2) Clinigen and its Affiliates or sublicensees shall, at their sole expense, transfer to Theravance, or shall cause their designee(s) to transfer to Theravance, ownership of all Marketing Authorizations and regulatory filings made or filed for the Licensed Product, such transfer to be as permitted by applicable Laws and regulations; otherwise Clinigen shall cooperate as necessary to permit Theravance to exercise its rights hereunder;

3) Theravance shall continue to have the unrestricted right to access, use and cite free of charge any information, data and regulatory filings generated by or on behalf of Clinigen or its Affiliates or sublicensees relating to the Licensed Product;

4) All of the provisions of Section 14.05(b) shall apply for the benefit of Theravance subject to the limitations set forth in Section 14.05(b);

5) All licenses granted by Theravance to Clinigen under this Agreement shall terminate and all licenses granted by Clinigen to Theravance under this Agreement shall survive;

6) Clinigen and its Affiliates and Clinigen's and its Affiliates' licensees and sublicensees under this Agreement [***]; and

7) Theravance shall retain all of its rights to bring an action against Clinigen for damages and any other available remedies in law or equity.

(b) Effect of Termination by Theravance Under Section 14.03 or by Clinigen Under Section 14.04. If Theravance terminates this Agreement under Section 14.03 or if Clinigen terminates this Agreement under Section 14.04, then at the sole election of Theravance, all or any of the following shall apply:

(i) Clinigen and its Affiliates and sublicensees shall, at their sole expense, promptly transfer to Theravance copies of all data, reports, records and materials in their possession or control that relate to the Licensed Product and return to Theravance, or destroy at Theravance's request, all relevant records and materials in their possession or control containing Confidential Information of Theravance (provided that Clinigen may keep one copy of such Confidential Information of Theravance solely for archival purposes in accordance with Section 10.01), subject to such Person's document retention obligations under applicable insurance policies, Laws and regulations, including EU GMP Directive 2003/94/EC and associated guidance;

(ii) Clinigen and its Affiliates and sublicensees shall, at their sole expense, transfer to Theravance, or shall cause their designee(s) to transfer to Theravance, ownership of all Marketing Authorizations and regulatory filings made or filed for the Licensed Product, such transfer to be as permitted by any Third Party licenses or other such prior rights and applicable Laws and regulations, otherwise Clinigen shall cooperate as necessary to permit Theravance to exercise its rights hereunder;

(iii) Theravance shall continue to have the unrestricted right to access, use and cite free of charge any information, data and regulatory filings generated by or on behalf of Clinigen or its Affiliates or sublicensees relating to the Licensed Product;

(iv) Theravance shall have the right at its sole expense, for its own benefit or together with or through a Third Party, to make, have made, Develop and Commercialize the Licensed Product in the Territory;

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(v) All licenses granted by Clinigen to Theravance under this Agreement shall survive, and in addition Clinigen and its Affiliates and sublicensees shall exclusively grant to Theravance all applicable licenses worldwide under the Clinigen Patents, Clinigen Inventions, Clinigen Know-How, and Clinigen's rights in the Joint Inventions and/or Joint Invention Patents to enable Theravance by itself and/or through one or more Third Party sublicensees to make, have made, Develop and Commercialize the Licensed Product worldwide. Clinigen shall also provide Theravance with all such information and data which Clinigen and its Affiliates and sublicensees reasonably have available, for example access to drug master file, clinical data and the like, and shall execute such instruments as Theravance reasonably requests, to enable Theravance and/or one or more Third Party sublicensees to obtain the appropriate Marketing Authorizations to market and sell the Licensed Product worldwide and for any other lawful purpose related to Development, manufacture and Commercialization of the Licensed Product worldwide;

(vi) All licenses granted by Theravance to Clinigen with respect to the Licensed Product under this Agreement shall terminate;

(vii) Clinigen and its Affiliates and sublicensees shall return to Theravance all available Licensed Product stock which is then held by Clinigen and its Affiliates and sublicensees or cause the Licensed Product stock to be provided to Theravance if held by a vendor or other Third Party on behalf of Clinigen; and

(viii) Clinigen shall provide Theravance with a perpetual royalty-free license to, or otherwise assign ownership of (to Theravance's satisfaction), all trademarks, trade dress and copyrights owned by Clinigen relating to the Licensed Product.

14.06 Accrued Rights; Surviving Obligations. Termination, relinquishment or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such termination, relinquishment or expiration. Such termination, relinquishment or expiration shall not relieve any Party from obligations which are expressly or by implication intended to survive termination, relinquishment or expiration of this Agreement, including without limitation Article X, and shall not affect or prejudice any provision of this Agreement which is expressly or by implication provided to come into effect on, or continue in effect after, such termination, relinquishment or expiration.

ARTICLE XV. MISCELLANEOUS

15.01 Relationship of the Parties. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other except as expressly provided in this Agreement. Neither Party shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee benefits of such employee. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, the legal relationship of the parties under this Agreement to Theravance shall be that of independent contractors. This Agreement does not constitute a formal legal partnership or joint venture between the Parties.

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15.02 Registration and Filing of This Agreement. To the extent, if any, that either Party concludes in good faith that it or the other Party is required to file or register this Agreement or a notification thereof with any Governmental Authority, including without limitation the U.S. Securities and Exchange Commission, the U.S. Federal Trade Commission, or the London Stock Exchange, in accordance with Laws, such Party shall inform the other Party thereof. Should both Parties jointly agree that either of them is required to submit or obtain any such filing, registration or notification, they shall cooperate, each at its own expense, in such filing, registration or notification and shall execute all documents reasonably required in connection therewith. In such filing, registration or notification, the Parties shall request confidential treatment of sensitive provisions of this Agreement, to the extent permitted by Laws. The Parties shall promptly inform each other as to the activities or inquiries of any such Governmental Authority relating to this Agreement, and shall reasonably cooperate to respond to any request for further information therefrom on a timely basis.

15.03 Force Majeure. The occurrence of an event which materially interferes with the ability of a Party to perform its obligations or duties hereunder which is not within the reasonable control of the Party affected, not due to malfeasance by such Party, and which could not with the exercise of due diligence have been avoided (each, a "Force Majeure Event"), including, but not limited to, an injunction, order or action by a Governmental Authority, fire, accident, labor difficulty, strike, riot, civil commotion, natural disaster, inability to obtain raw materials, delay or errors by shipping companies or change in law, shall not excuse such Party from the performance of its obligations or duties under this Agreement, but shall merely suspend such performance during the continuation of the Force Majeure. The Party prevented from performing its obligations or duties because of a Force Majeure Event shall promptly notify the other Party of the occurrence and particulars of such Force Majeure and shall provide the other Party, from time to time, with its best estimate of the duration of such Force Majeure Event and with notice of the resolution thereof. The Party so affected shall use Diligent Efforts to avoid or remove such causes of nonperformance as soon as is reasonably practicable. Upon resolution of the Force Majeure Event, the performance of any suspended obligation or duty shall promptly recommence. The Party subject to the Force Majeure Event shall not be liable to the other Party for any direct, indirect, consequential, incidental, special, punitive, exemplary or other damages arising out of or relating to the suspension or termination of any of its obligations or duties under this Agreement by reason of the occurrence of a Force Majeure Event, provided such Party complies in all material respects with its obligations under this Section 15.03.

15.04 Governing Law. This Agreement shall be construed, and the respective rights of the Parties determined, according to the law of the State of New York excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction

15.05 Dispute Resolution.

(a) The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach thereof. If the Parties do not fully settle, and a Party wishes to pursue the matter, each such dispute, controversy or claim that is not an "Excluded Claim" shall be finally resolved by binding arbitration in accordance with the Commercial Arbitration Rules and Supplementary Procedures for Large Complex Disputes of the American Arbitration Association ("AAA"), and judgment on the arbitration award may be entered in any court having jurisdiction thereof.

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(b) The arbitration shall be conducted by a panel of three persons experienced in the pharmaceutical business: within thirty (30) days after initiation of arbitration, each Party shall select one person to act as arbitrator and the two Party-selected arbitrators shall select a third arbitrator, who shall be unaffiliated with both Parties and their respective Affiliates, within thirty (30) days of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the AAA. The place of arbitration shall be New York, New York.

(c) Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' fees and any administrative fees of arbitration

(d) Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when

commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable New York statute of limitations.

(e) The Parties agree that, in the event of a good faith dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other judicial determination. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the dispute shall be refunded if an arbitrator or court determines that such payments are not due.

(f) As used in this Section 15.05, the term "Excluded Claim" shall mean a dispute, controversy or claim that concerns the validity or infringement of a patent, trademark or copyright.

15.06 Theravance Equitable Relief. Clinigen acknowledges and agrees that the restrictions set forth in Article X, Section 11.04(b) and Section 14.05(a)(ii)6) of this Agreement are reasonable and necessary to protect the legitimate interests of Theravance and that Theravance would not have entered into this Agreement in the absence of such restrictions, and that any breach or threatened breach of any such provision will result in irreparable injury to Theravance for which there will be no adequate remedy at law. In the event of a breach or threatened breach of Article X Section 11.04(b) or Section 14.05(a)(ii)6) Theravance shall be authorized and entitled to obtain from any court of competent jurisdiction equitable relief, whether preliminary or permanent, specific performance and an equitable accounting of all earnings, profits and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which Theravance may be entitled in law or equity. Clinigen agrees to waive any requirement

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that Theravance (a) post a bond or other security as a condition for obtaining any such relief, and (b) show irreparable harm, balancing of harms, consideration of the public interest or inadequacy of monetary damages as a remedy. Nothing in this Section 15.06 is intended, or should be construed, to limit Theravance's rights to equitable relief under 15.05(c) or any other remedy for a breach of any other provision of this Agreement.

15.07 Attorneys' Fees and Related Costs. In the event that any legal proceeding (other than pursuant to the arbitration dispute resolution provision in Section 15.05) is brought to enforce or interpret any of the provisions of this Agreement, the prevailing party shall be entitled to recover its reasonable attorneys' fees, court costs and expenses of litigation whether or not the action or proceeding proceeds to final judgment.

15.08 Assignment. This Agreement may not be assigned by either Party without the prior written consent of the other Party; provided, however, that either Party may assign this Agreement, in whole or in part, to any of its Affiliates if such Party guarantees the performance of this Agreement by such Affiliate; and provided further that either Party may assign this Agreement to a successor to all or substantially all of the assets of such Party whether by merger, sale of stock, sale of assets or other similar transaction. This Agreement shall be binding upon, and subject to the terms of the foregoing sentence, inure to the benefit of the Parties hereto, their permitted successors, legal representatives and assigns.

15.09 Notices. All demands, notices, consents, approvals, reports, requests and other communications hereunder must be in writing and will be deemed to have been duly given only if (a) delivered personally, by facsimile with confirmation of receipt, by mail (first class, postage prepaid), or by overnight delivery using a globally-recognized carrier, to the Parties at the following addresses:

Theravance:	Theravance, Inc. 901 Gateway Boulevard South San Francisco, CA 94080 Facsimile: [***] Attn: Head, Business Development
Clinigen:	Clinigen Group PLC Pitcairn House Crown Square Centrum 100, BURTON UPON TRENT DE14 2WW United Kingdom Facsimile: Attn: Chief Executive Officer

or to such other address as the addressee shall have last furnished in writing in accord with this provision to the addressor; or (b) sent electronically to all representatives of the addressee on the Joint Steering Committee with any attachments in a standard format (e.g., MSWord, PDF, etc.) and acknowledged by the recipient by a reply email. All notices sent electronically shall also be sent in paper form if requested by the recipient. All notices shall be deemed effective upon receipt by the addressee.

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15.10 Severability. In the event of the invalidity of any provisions of this Agreement or if this Agreement contains any gaps, the Parties agree that such invalidity or gap shall not affect the validity of the remaining provisions of this Agreement. The Parties will replace an invalid provision or fill any gap with valid provisions which most closely approximate the purpose and economic effect of the invalid provision or, in case of a gap, the Parties' presumed intentions. In the event that the terms and conditions of this Agreement are materially altered as a result of the preceding sentences, the Parties shall

renegotiate the terms and conditions of this Agreement in order to resolve any inequities. Nothing in this Agreement shall be interpreted so as to require either Party to violate any applicable Laws, rules or regulations.

15.11 Headings. The headings used in this Agreement have been inserted for convenience of reference only and do not define or limit the provisions hereof.

15.12 Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No waiver by any Party of any term or condition of this Agreement, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion. Except as expressly set forth in this Agreement, all rights and remedies available to a Party, whether under this Agreement or afforded by law or otherwise, will be cumulative and not in the alternative to any other rights or remedies that may be available to such Party.

15.13 Entire Agreement. This Agreement (including the exhibits and schedules hereto) constitutes the entire agreement between the Parties hereto with respect to the within subject matter and supersedes all previous agreements and understandings between the Parties, whether written or oral. This Agreement may be altered, amended or changed only by a writing making specific reference to this Agreement and signed by duly authorized representatives of Theravance and Clinigen.

15.14 No License. Nothing in this Agreement shall be deemed to constitute the grant of any license or other right in either Party, to or in respect of the Licensed Product, patent, trademark, Confidential Information, trade secret or other data or any other intellectual property of the other Party, except as expressly set forth herein.

15.15 Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including without limitation any creditor of either Party hereto. No such Third Party shall obtain any right under any provision of this Agreement or shall by reasons of any such provision make any Claim in respect of any debt, liability or obligation (or otherwise) against either Party hereto.

15.16 Counterparts. This Agreement may be executed in any two counterparts, each of which, when executed, shall be deemed to be an original and both of which together shall constitute one and the same document.

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15.17 Parties addresses and bank details

THERAVANCE, INC.

Theravance, Inc.
901 Gateway Blvd.
South San Francisco, CA 94080

[***]

CLINIGEN GROUP PLC

[***]

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IN WITNESS WHEREOF, Theravance and Clinigen, by their duly authorized officers, have executed this Agreement on the 8th day of March, 2013.

THERAVANCE, INC.	CLINIGEN GROUP PLC
By: /s/ Rick E Winningham	By: /s/ Peter George
Rick E Winningham	Peter George
Chief Executive Officer	Chief Executive Officer

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EXHIBIT A

Structure of Chemical Compound known as Telavancin

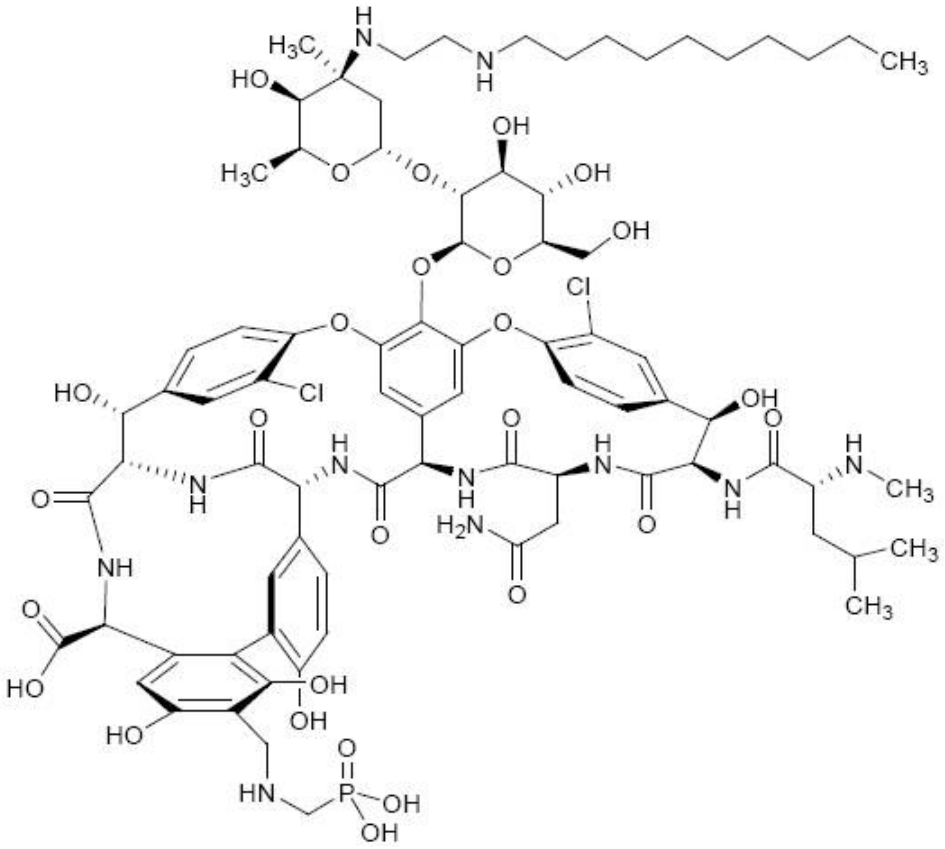

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EXHIBIT B

[***]

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EXHIBIT C

Theravance Trademarks as of the Effective Date in the Territory

[***]

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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 15d-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.

May 1, 2013
(Date)

/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 15d-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.

May 1, 2013
(Date)

/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, 2013 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.

May 1, 2013 By: /s/ Rick E Winningham
(Date)
Name: Rick E Winningham
Title: Chief Executive Officer
(Principal 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, 2013 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.

May 1, 2013 By: /s/ Michael W. Aguiar
(Date)
Name: Michael W. Aguiar
Title: Senior Vice President, Finance and Chief Financial Officer
(Principal Financial Officer)