# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# **FORM 10-Q**

(Mark One)

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

For the quarterly period ended June 30, 2014

OR

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

For the transition period from

to

Commission File Number: 0-30319

# THERAVANCE, INC.

(Exact Name of Registrant as Specified in its Charter)

**Delaware** 

(State or Other Jurisdiction of Incorporation or Organization) 94-3265960

(I.R.S. Employer Identification No.)

951 Gateway Boulevard South San Francisco, CA 94080

(Address of Principal Executive Offices)

(650) 238-9600

(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 July 31, 2014 was 115,014,166.

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# PART I — FINANCIAL INFORMATION

# **Item 1. Financial Statements**

# THERAVANCE, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

Current assets	Dec	ember 31, 2013
Cash and cash equivalents         208,052           Restricted cash         14,232           Short-term investments         126,424           Accounts receivable, net of allowances of \$89 at December 31, 2013         —           Receivables from collaborative arrangements (including amounts from a related party of \$3,473 and \$2,247 at June 30, 2014 and December 31, 2013)         3,473           Prepaid expenses and other current assets         982           Inventories         —           Total current assets         353,163           Marketable securities         34,349           Restricted cash         833           Property and equipment, net         —           Intagible assets, net         194,880           Other assets         22,385           Total assets         \$605,610           Liabilities and stockholders' equity (deficit)         \$1,795           Current liabilities:         \$1,799           Accounts payable         \$1,799           Payable to a related party         15,000           Payable to Theravance Biopharma, Inc.         15,243           Accrued personnel-related expenses         1,023           Accrued clinical and development expenses         —		
Restricted cash         14,232           Short-term investments         126,424           Accounts receivable, net of allowances of \$89 at December 31, 2013         —           Receivables from collaborative arrangements (including amounts from a related party of \$3,473 and \$2,247 at June 30, 2014 and December 31, 2013)         3,473           Prepaid expenses and other current assets         982           Inventories         —           Total current assets         353,163           Marketable securities         34,345           Restricted cash         833           Property and equipment, net         —           Intangible assets, net         194,880           Other assets         22,385           Total assets         605,610           Liabilities and stockholders' equity (deficit)         Turrent liabilities:           Accounts payable         \$ 1,799           Payable to a related party         15,000           Payable to Theravance Biopharma, Inc.         15,243           Accrued personnel-related expenses         1,023           Accrued clinical and development expenses         —		
Short-term investments	\$	143,510
Accounts receivable, net of allowances of \$89 at December 31, 2013   Receivables from collaborative arrangements (including amounts from a related party of \$3,473 and \$2,247 at June 30, 2014 and December 31, 2013)   3,473		_
Receivables from collaborative arrangements (including amounts from a related party of \$3,473 and \$2,247 at June 30, 2014 and December 31, 2013)  Prepaid expenses and other current assets Inventories  Total current assets  Marketable securities  Restricted cash Property and equipment, net Intangible assets, net Other assets  Total assets  Accounts payable Payable to a related party Payable to Theravance Biopharma, Inc. Accrued personnel-related expenses  Accrued clinical and development expenses		321,615
\$2,247 at June 30, 2014 and December 31, 2013)       3,473         Prepaid expenses and other current assets       982         Inventories       —         Total current assets       353,163         Marketable securities       34,349         Restricted cash       833         Property and equipment, net       —         Intangible assets, net       194,880         Other assets       22,385         Total assets       \$605,610         Liabilities and stockholders' equity (deficit)       United by the counts payable or a related party       15,000         Payable to a related party       15,000         Payable to Theravance Biopharma, Inc.       15,243         Accrued personnel-related expenses       1,023         Accrued clinical and development expenses       —		199
Prepaid expenses and other current assets         982           Inventories         —           Total current assets         353,163           Marketable securities         34,349           Restricted cash         833           Property and equipment, net         —           Intangible assets, net         194,880           Other assets         22,385           Total assets         \$ 605,610           Liabilities and stockholders' equity (deficit)         United by the counts payable of a related party         15,000           Payable to a related party         15,000           Payable to Theravance Biopharma, Inc.         15,243           Accrued personnel-related expenses         1,023           Accrued clinical and development expenses         —		
Inventories		3,181
Total current assets  Marketable securities Restricted cash Property and equipment, net Intangible assets, net Other assets Total assets  Total assets  Liabilities and stockholders' equity (deficit)  Current liabilities:  Accounts payable Payable to a related party Payable to Theravance Biopharma, Inc. Accrued personnel-related expenses Accuded clinical and development expenses  Accuded clinical and development expenses  353,163 34,349 833 353,163 36,349 833 84,349 8		4,287
Marketable securities Restricted cash Property and equipment, net Intangible assets, net Other assets Total assets  Liabilities and stockholders' equity (deficit) Current liabilities: Accounts payable Payable to a related party Payable to Theravance Biopharma, Inc. Accrued personnel-related expenses Accound securities Accound securiti		10,406
Restricted cash Property and equipment, net Intangible assets, net Other assets Total assets  Liabilities and stockholders' equity (deficit)  Current liabilities: Accounts payable Payable to a related party Payable to Theravance Biopharma, Inc. Accrued personnel-related expenses Accrued clinical and development expenses		483,198
Restricted cash Property and equipment, net Intangible assets, net Other assets Total assets  Liabilities and stockholders' equity (deficit)  Current liabilities: Accounts payable Payable to a related party Payable to Theravance Biopharma, Inc. Accrued personnel-related expenses Accrued clinical and development expenses		
Property and equipment, net Intangible assets, net Other assets Other assets Total assets  Liabilities and stockholders' equity (deficit)  Current liabilities: Accounts payable Payable to a related party Payable to Theravance Biopharma, Inc. Accrued personnel-related expenses Accrued clinical and development expenses		55,374
Intangible assets, net Other assets Total assets Total assets  Liabilities and stockholders' equity (deficit)  Current liabilities: Accounts payable Payable to a related party Payable to Theravance Biopharma, Inc. Accrued personnel-related expenses Accrued clinical and development expenses  Accrued clinical and development expenses		833
Other assets 22,385 Total assets \$605,610  Liabilities and stockholders' equity (deficit)  Current liabilities: Accounts payable \$1,799 Payable to a related party 15,000 Payable to Theravance Biopharma, Inc. 15,243 Accrued personnel-related expenses 1,023 Accrued clinical and development expenses		10,238
Total assets \$ 605,610  Liabilities and stockholders' equity (deficit)  Current liabilities:  Accounts payable \$ 1,799  Payable to a related party 15,000  Payable to Theravance Biopharma, Inc. 15,243  Accrued personnel-related expenses 1,023  Accrued clinical and development expenses		124,257
Liabilities and stockholders' equity (deficit)  Current liabilities:  Accounts payable Payable to a related party Payable to Theravance Biopharma, Inc. 15,243 Accrued personnel-related expenses Accrued clinical and development expenses		7,355
Current liabilities:  Accounts payable Payable to a related party Payable to Theravance Biopharma, Inc. Accrued personnel-related expenses Accrued clinical and development expenses	\$	681,255
Current liabilities:  Accounts payable Payable to a related party Payable to Theravance Biopharma, Inc. Accrued personnel-related expenses Accrued clinical and development expenses		
Payable to a related party Payable to Theravance Biopharma, Inc. 15,243 Accrued personnel-related expenses 1,023 Accrued clinical and development expenses		
Payable to a related party Payable to Theravance Biopharma, Inc. 15,243 Accrued personnel-related expenses 1,023 Accrued clinical and development expenses	\$	7,583
Payable to Theravance Biopharma, Inc. 15,243 Accrued personnel-related expenses 1,023 Accrued clinical and development expenses —		40,000
Accrued personnel-related expenses 1,023 Accrued clinical and development expenses —		
Accrued clinical and development expenses —		10,881
		9,714
Accrued interest payable 11,013		2,800
Other accrued liabilities 4,834		4,137
Deferred revenue 1,082		9,289
Total current liabilities 49,994		84,404

Convertible subordinated notes	287,500	287,500
Non-recourse notes payable, due 2029	450,000	_
Deferred rent	13	4,774
Other long-term liabilities	1,300	_
Deferred revenue	4,329	5,455
Commitments and contingencies (Notes 3, 7 and 9)		
Stockholders' equity (deficit):		
Common stock, \$0.01 par value; authorized: 200,000 shares; outstanding: 113,285 and 111,516 at		
June 30, 2014 and December 31, 2013	1,133	1,115
Additional paid-in capital	1,444,105	1,803,048
Accumulated other comprehensive income	3,706	162
Accumulated deficit	(1,636,470)	(1,505,203)
Total stockholders' equity (deficit)	(187,526)	 299,122
Total liabilities and stockholders' equity (deficit)	\$ 605,610	\$ 681,255

<sup>\*</sup> Condensed consolidated balance sheet at December 31, 2013 has been derived from audited consolidated financial statements.

See accompanying notes to condensed consolidated financial statements.

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# THERAVANCE, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except per share data)

	Three Months Ended June 30,				Six Monti June	led	
		2014		2013	_	2014	 2013
Royalty revenue from a related party, net of intangible assets amortization: three months—2014-\$2,598; 2013-\$0; six months—							
2014-\$4,378; 2013-\$0 (Note 3) (1)	\$	663	\$	_	\$	(387)	\$ _
Net revenue from collaborative arrangements from a related party		271		1,322		541	 2,644
Total net revenue		934		1,322		154	2,644
Operating expenses:							
Research and development		2,125		2,412		4,812	4,451
General and administrative		8,603		5,808		19,859	11,864
Total operating expenses		10,728		8,220		24,671	16,315
Loss from operations		(9,794)		(6,898)		(24,517)	(13,671)
Other income (expense), net		83		8,192		80	6,770
Interest income		165		190		353	375
Interest expense		(10,327)		(3,025)		(11,971)	(5,761)
Loss from continuing operations before income taxes		(19,873)		(1,541)		(36,055)	(12,287)
Income tax expense		(278)		_		(278)	_
Loss from continuing operations, net of tax		(20,151)		(1,541)		(36,333)	(12,287)
Loss from discontinued operations (Notes 11 and 12):		(43,413)		(34,888)		(94,934)	 (61,502)
Net loss	\$	(63,564)	\$	(36,429)	\$	(131,267)	\$ (73,789)
Basic and diluted net loss per share:							
Continuing operations, net of tax	\$	(0.18)	\$	(0.02)	\$	(0.33)	\$ (0.13)
Discontinued operations		(0.39)		(0.35)		(0.86)	 (0.63)
Basic and diluted net loss per share	\$	(0.57)	\$	(0.37)	\$	(1.19)	\$ (0.76)
Shares used to compute basic and diluted net loss per share		110,974		97,603		110,419	 96,964

<sup>(1)</sup> Gross royalty revenue from a related party for the three and six months ended June 30, 2014 is \$3,261 and \$3,991, respectively.

 $See\ accompanying\ notes\ to\ condensed\ consolidated\ financial\ statements.$ 

# THERAVANCE, INC. CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

(In thousands, except per share data)

	Three Months Ended June 30,			Six Montl June			
	2014 2013		2014		2013		
Net loss	\$	(63,564)	\$	(36,429)	\$ (131,267)	\$	(73,789)
Other comprehensive income (loss):							
Net unrealized gain (loss) on available-for-sale securities		3,535		(107)	3,544		(114)
Comprehensive loss	\$	(60,029)	\$	(36,536)	\$ (127,723)	\$	(73,903)

See accompanying notes to condensed consolidated financial statements.

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# THERAVANCE, INC. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands) (Unaudited)

		Six Months E	<u>nded Ju</u>	ne 30,
		2014		2013
Cash flows from operating activities	ď	(121.207)	ď	(72.70)
Net loss	\$	(131,267)	\$	(73,789
Adjustments to reconcile net loss to net cash used in operating activities:		C 100		2.020
Depreciation and amortization		6,190		2,036
Stock-based compensation  Amount of short town investments		21,281		13,257 1,854
Amortization on premium of short-term investments		1,412		1,052
Change in fair value of capped-call derivative assets		(2)		
Other non-cash items		(2)		(3
Changes in operating assets and liabilities:		7.4		
Account receivables		74		(1.16)
Receivables from collaborative arrangements		(294)		(1,169
Prepaid expenses and other current assets		(177)		357
Inventories		(1,908)		(2,533
Other assets		(411)		_
Accounts payable		(5,832)		1,026
Payable to Theravance Biopharma, Inc., net		(1,738)		_
Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued				
liabilities		1,874		2,94
Accrued interest payable		8,213		2,540
Deferred rent		183		(370
Deferred revenue		(2,640)		4,120
Net cash used in operating activities		(105,042)		(48,317
Cash flows from investing activities				
Purchases of property and equipment		(556)		(1,43)
Purchases of available-for-sale securities		(142,861)		(211,79)
Maturities of available-for-sale securities		241,173		106,983
Sales of available-for-sale securities		5,000		17,600
Increase in intangible assets		(100,000)		(30,000
Payments received on notes receivable		140		100
Net cash provided by (used in) investing activities		2,896		(118,545
Cash flows from financing activities				
Cash and cash equivalents contributed to Theravance Biopharma, Inc.		(277,541)		
Proceeds from issuances of common stock, net		23,786		26,433
Purchase of capped-call options		25,700		(36,800
Change in restricted cash		(14,234)		(50,000
Proceeds from issuances of notes payable, net of debt issuance costs		434,677		281,623
Net cash provided by financing activities		166,688		271,256
Net increase in cash and cash equivalents		64,542		104,39
Cash and cash equivalents at beginning of period		143,510		94,849
Cash and cash equivalents at end of period	\$	208,052	\$	199,243
Supplemental disclosures of noncash information				
Contribution of net assets, excluding cash and cash equivalents to Theravance Biopharma, Inc.	\$	125,337	\$	

See accompanying notes to condensed consolidated financial statements.

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# THERAVANCE, INC. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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

#### **Description of Operations**

Theravance, Inc. (Theravance, the Company, or we and other similar pronouns) is a royalty management company focused on maximizing the potential value of the respiratory assets partnered with Glaxo Group Limited (GSK), including RELVAR®/BREO® ELLIPTA® (fluticasone furoate/ vilanterol, "FF/VI") and ANORO® ELLIPTA® (umeclidinium bromide/ vilanterol, "UMEC/VI"), with the intention of providing capital returns to stockholders. Under the Long-Acting Beta² Agonist (LABA) Collaboration Agreement and the Strategic Alliance Agreement with GSK (referred to herein as the GSK Agreements), Theravance is eligible to receive the associated royalty revenues from RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and if approved and commercialized, VI monotherapy. Theravance is also entitled to a 15% economic interest in any future payments made by GSK under its agreements originally entered into with us, and since assigned to Theravance Respiratory Company, LLC ("TRC"), relating to the combination of UMEC/VI/FF and the Bifunctional Muscarinic Antagonist-Beta² Agonist (MABA) program, as monotherapy and in combination with other therapeutically active components, such as an inhaled corticosteroid, and any other product or combination of products that may be discovered and developed in the future under the LABA Collaboration Agreement ("LABA Collaboration") with us, which has been assigned to TRC other than with respect to RELVAR®/BREO®ELLIPTA®, ANORO® ELLIPTA® and VI monotherapy.

# **Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. In our opinion, the unaudited condensed consolidated financial statements have been prepared on the same basis as audited consolidated financial statements and include all adjustments, consisting of only normal recurring adjustments, necessary for the fair presentation of our financial position, results of operations, comprehensive loss and cash flows. The interim results are not necessarily indicative of the results of operations to be expected for the year ending December 31, 2014 or any other period.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2013 filed with the Securities and Exchange Commission ("SEC") on March 3, 2014.

# **Business Separation**

On June 1, 2014, we separated our late-stage partnered respiratory assets from our biopharmaceutical research and drug development operations ("Spin-Off") by transferring our research and drug development operations into a wholly-owned subsidiary. We contributed \$393.0 million of cash, cash equivalents and marketable securities to Theravance Biopharma, Inc. ("Theravance Biopharma") and all outstanding shares of Theravance Biopharma were then distributed to our stockholders as a pro-rata dividend distribution on June 2, 2014 by issuing one ordinary share of Theravance Biopharma for every 3.5 shares held of Theravance common stock to stockholders of record on May 15, 2014. The separation resulted in Theravance Biopharma operating as an independent, publicly traded company.

The results of operations for our former research and drug development operations conducted by us and by Theravance Biopharma until June 1, 2014 are included as part of this report as discontinued operations. Refer to Notes 11 and 12, "Spin-Off of Theravance Biopharma, Inc.," and "Discontinued Operations" for further information.

Pursuant to a three-way master agreement entered into by and among us, Theravance Biopharma and GSK in connection with the Spin-Off, we agreed to sell that number of Theravance Biopharma shares withheld from a taxable dividend of Theravance Biopharma shares to GSK. After such Theravance Biopharma shares were sent to the transfer agent, we agreed to purchase the Theravance Biopharma shares from the transfer agent, rather than have them sold on the open market, in order to satisfy tax withholdings. GSK had an option to purchase these shares of Theravance Biopharma from us, but this option expired unexercised. Accordingly, at June 30, 2014, we owned 436,802 ordinary shares of Theravance Biopharma, which are accounted for as available-for-sale securities in the condensed consolidated balance sheets. These equity securities are discussed further in Note 4, "Available-for-Sale Securities".

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#### Inventories

All inventories were related to our former research and drug development operations and, thus, were contributed to Theravance Biopharma in connection with the Spin-Off. Accordingly, we have no inventories as of June 30, 2014.

Prior to the Spin-Off of Theravance Biopharma, our inventories consisted of raw materials, work-in-process and finished goods related to the production of VIBATIV® (telavancin). Raw materials include VIBATIV® active pharmaceutical ingredient (API) and other raw materials. Work-in-process

and finished goods included third party manufacturing costs and labor and indirect costs incurred in the production process. Included in inventories were raw materials and work-in-process that may be used as clinical products, which were charged to research and development expense when consumed. In addition, under certain commercialization agreements, we could sell VIBATIV® packaged in unlabeled vials that are recorded in work-in-process. Inventories were stated at the lower of cost or market value. We determined the cost of inventory using the average-cost method for validation batches. We analyzed our inventory levels quarterly and wrote down any inventory that was expected to become obsolete, that had a cost basis in excess of its expected net realizable value or for inventory quantities in excess of expected requirements.

Inventories were as follows:

(In thousands)	June 30, 2014	December 31, 2013
Raw materials	\$ —	\$ 5,138
Work-in-process	_	360
Finished goods	_	4,908
Total inventories	\$ —	\$ 10,406

#### **Revenue Recognition**

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

Collaborative Arrangements and Multiple-Element Arrangements

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

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

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

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

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

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

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

Under our collaborative arrangements with GSK, and in accordance with FASB Subtopic ASC 808-10, "Collaborative Arrangements," royalty revenue earned is reduced by amortization expense resulting from the fees paid to GSK, which were capitalized as finite-lived intangible assets. When

amortization expense exceeds amounts recognized for royalty revenues from GSK, negative revenue would be reported in our consolidated statements of operations.

#### Royalties

We recognize royalty revenue on licensee net sales of products with respect to which we have contractual royalty rights in the period in which the royalties are earned and reported to us and collectability is reasonably assured. Royalties are recognized net of amortization of intangible assets associated with any approval and launch milestone payments made to GSK.

#### Product Revenues

We currently have no product revenues following the spin-off of Theravance Biopharma.

Prior to the Spin-Off of Theravance Biopharma, we sold VIBATIV® in the U.S. through a limited number of distributors, and title and risk of loss transferred upon receipt of the product by these distributors. Healthcare providers ordered VIBATIV® through these distributors. Commencing in the first quarter of 2014, revenue on the sale of VIBATIV® was recorded on a sell-through basis, once the distributors sold the product to healthcare providers. As VIBATIV® is a product that is sold by Theravance Biopharma, the revenue from product sales are included within discontinued operations in the consolidated statements of operations for the three and six months ended June 30, 2014. There was no revenue from product sales for any period in 2013.

Product sales were recorded net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions. We reflected such reductions in revenue either as an allowance to the related account receivable from the distributor, or as an accrued liability, depending on the nature of the sales deduction. Sales deductions were based on management's estimates that considered payer mix in target markets, industry benchmarks and experience to date. We monitored inventory levels in the distribution channel, as well as sales of VIBATIV® by distributors to healthcare providers, using product-specific data provided by the distributors. Product return allowances were based on amounts owed or to be claimed on related sales. These estimates took into consideration the terms of our agreements with customers, historical product returns of VIBATIV® experienced by our former collaborative partner, Astellas Pharma, Inc. ("Astellas"), rebates or discounts taken, estimated levels of inventory in the distribution channel, the shelf life of the product, and specific known market events, such as competitive pricing and new product introductions.

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

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

<u>Distribution Fees and Product Returns:</u> We had written contracts with our distributors that include terms for distribution-related fees. We recorded distribution-related fees based on a percentage of the product sales price. We offered our distributors a right to return product purchased directly from us, which was principally based upon the product's expiration date. Additionally, we had granted more expansive return rights to our distributors following our product launch of VIBATIV®. Our policy was to accept returns for expired product during the six months prior to and twelve months after the product expiration date on product that had been sold to our distributors. We developed estimates for VIBATIV® product returns based upon historical VIBATIV® sales from our former collaborative partner, Astellas. We recorded distribution fees and product returns as an allowance against accounts receivable.

<u>Allowance for Doubtful Accounts:</u> We maintained a policy to record allowances for potentially doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. As of June 30, 2014 and December 31, 2013, there were no allowances for doubtful accounts as we have not had any write-offs historically.

#### **Variable Interest Entities**

We analyze any potential variable interest or special-purpose entities in accordance with the guidance of FASB Subtopic ASC 810-10, Consolidation of Variable Interest and Special-Purpose Entities. The party with the controlling financial interest, the primary beneficiary, is required to consolidate the entity that is determined to be a variable interest entity (VIE). We have determined TRC to be a VIE. We have the power to direct the economically significant activities of TRC and the obligation to absorb losses of, or the right to receive benefits from TRC. Therefore, we consolidate the financial results of TRC. The financial position and results of operations of TRC are not material as of and for the three and six months ended June 30, 2014.

# Intangible Assets

We capitalize fees paid to licensors related to agreements for approved products or commercialized products. We capitalize these fees as finite-lived intangible assets and amortize these intangible assets on a straight-line basis over their estimated useful lives upon the commercial launch of the product, which is expected to be shortly after regulatory approval of such product. The estimated useful lives of these intangible assets are based on a country-by-country and product-by-product basis, as the later of the expiration or termination of the last patent right covering the compound in such product in such country and 15 years from first commercial sale of such product in such country, unless the agreement is terminated earlier. Consistent with our policy for classification of costs under the research and development collaborative arrangements, the amortization of these intangible assets will be recognized as a reduction of royalty revenue. We review our intangible assets for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. The recoverability of finite-lived intangible assets is measured by comparing the asset's carrying amount to the expected

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#### Recently Issued Accounting Pronouncements Not Yet Adopted

In April 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-08, "Presentation of Financial Statements and Property, Plant and Equipment; Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity." ASU 2014-08 modifies the requirements for reporting discontinued operations. Under the amendments in ASU 2014-08, the definition of discontinued operation has been modified to only include those disposals of an entity that represent a strategic shift that has (or will have) a major effect on an entity's operations and financial results. ASU 2014-08 also expands the disclosure requirements for disposals that meet the definition of a discontinued operation and requires entities to disclose information about disposals of individually significant components that do not meet the definition of discontinued operations. ASU 2014-08 is effective for annual reporting periods, and interim periods within those years, beginning after December 15, 2014. We do not expect the adoption of this guidance to have a material effect on our consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which converges the FASB and the International Accounting Standards Board standards on revenue recognition. Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures. This guidance is effective for the fiscal years and interim reporting periods beginning after December 15, 2016, at which time we may adopt the new standard under the full retrospective method or the modified retrospective method. Early adoption is not permitted. We are currently evaluating the impact of adopting ASU 2014-09 on our consolidated financial statements and related disclosures.

#### 2. Net Loss per Share

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

For the three months and six months ended June 30, 2014 and 2013, diluted and basic net loss per share were identical since potential common shares were excluded from the calculation, as their effect was anti-dilutive.

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

	Three Months Ended June 30,				Six Mont June		ed
(In thousands, except for per share amounts)	2014		2013		2014		2013
Numerator:							
Loss from continuing operations, net of tax	\$ (20,151)	\$	(1,541)	\$	(36,333)	\$	(12,287)
Loss from discontinued operations	(43,413)		(34,888)		(94,934)		(61,502)
Net loss	\$ (63,564)	\$	(36,429)	\$	(131,267)	\$	(73,789)
Denominator:							
Weighted-average number of shares outstanding	113,163		100,316		112,608		99,677
Less: unvested RSAs	(2,189)		(2,713)		(2,189)		(2,713)
Weighted-average number of shares used to compute							
basic and diluted net loss per share	 110,974	_	97,603	_	110,419		96,964
Basic and diluted net loss per share:							
Continuing operations, net of tax	\$ (0.18)	\$	(0.02)	\$	(0.33)	\$	(0.13)
Discontinued operations	(0.39)		(0.35)		(0.86)		(0.63)
Basic and diluted net loss per share	\$ (0.57)	\$	(0.37)	\$	(1.19)	\$	(0.76)
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#### Anti-Dilutive Securities

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

	Three Months June 30		Six Months June 3	
(In thousands)	2014	2013	2014	2013
Shares issuable under equity incentive plans and ESPP	6,136	3,848	5,942	4,519
Shares issuable upon the conversion of convertible				
subordinated notes	17,869	17,015	17,869	15,643
Total anti-dilutive securities	24,005	20,863	23,811	20,162

### 3. Collaborative Arrangements

#### **Net Revenue from Collaborative Arrangements**

Net revenue from collaborative arrangements from continuing operations relates to our arrangement with GSK. Net revenue from other collaborative arrangements was reflected as discontinued operations in the consolidated statements of operations. Refer to Notes 1, 11 and 12, "Description of Operations and Summary of Significant Accounting Policies," "Spin-Off of Theravance Biopharma, Inc." and "Discontinued Operations" for further information.

# Net Royalty Revenue from GSK

Net revenue recognized under our GSK Agreements was as follows:

	Three Months Ended June 30,				Six Mont June	ed
(In thousands)		2014		2013	2014	2013
Royalty revenue	\$	3,261	\$		\$ 3,991	\$
Amortization of intangible assets		(2,598)		_	(4,378)	_
Net royalty revenue		663			 (387)	 
LABA collaboration		_		907	_	1,814
Strategic alliance—MABA program license		271		415	541	830
Total revenue	\$	934	\$	1,322	\$ 154	\$ 2,644

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

#### LABA Collaboration

In November 2002, we entered into our Long-Acting Beta<sub>2</sub> Agonist (LABA) collaboration with GSK to develop and commercialize once-daily LABA products for the treatment of chronic obstructive pulmonary disease (COPD) and asthma. For the treatment of COPD, the collaboration has developed two combination products: (1) RELVAR®/BREO® ELLIPTA® (FF/VI), a once-daily combination medicine consisting of a LABA, vilanterol (VI), and an inhaled corticosteroid (ICS), fluticasone furoate (FF) and (2) ANORO® ELLIPTA® (UMEC/VI), a once-daily medicine combining a long-acting muscarinic antagonist (LAMA), umeclidinium bromide (UMEC), with a LABA, VI. For the treatment of asthma, RELVAR® ELLIPTA® is approved in multiple regions outside of North America and the collaboration is further developing FF/VI for the U.S.

In the event that a product containing VI is successfully developed and commercialized, we are 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. As of June 30, 2014, we have paid a total of \$185.0 million of these milestones and have an accrued a liability of \$15.0 million. In July 2014, we recorded an additional \$10.0 million accrued liability. These milestone fees paid or owed to GSK were capitalized as finite-lived intangible assets, which are being amortized over their estimated useful lives commencing upon the commercial launch of the product. We estimate the remaining potential milestone payments of \$10.0 million could become payable by the end of 2014.

Total milestone fees paid of \$185.0 million and accrued as a liability of \$15.0 million at June 30, 2014 resulted from the following:

- In May 2013, the U.S. Food and Drug Administration (FDA) approved BREO® ELLIPTA® as an inhaled long-term, once-daily maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. It is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations.
- · In September 2013, the Japanese Ministry of Health, Labour and Welfare (MHLW) approved RELVAR® ELLIPTA® for the treatment of bronchial asthma in cases where concurrent use of inhaled corticosteroid and long-acting inhaled beta2 agonist is required.
- · In October 2013, BREO® ELLIPTA® was launched in the U.S. for the treatment of COPD.

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- · In November 2013, the European Commission granted marketing authorization for RELVAR® ELLIPTA® for the regular treatment of asthma and the systematic treatment of COPD.
- · In December 2013, RELVAR® ELLIPTA® was launched in Japan for the treatment of bronchial asthma.
- In December 2013, the FDA approved ANORO® ELLIPTA® as a combination anticholinergic/long-acting beta2-adrenergic agonist (LABA) indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema.
- · In January 2014, RELVAR® ELLIPTA® was launched in the European Union.
- · In April 2014, ANORO® ELLIPTA® was made available in the U.S. for the treatment of COPD.
- In May 2014, the European Commission granted marketing authorization for ANORO(R) (umeclidinium/vilanterol) as a once-daily, maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD.
- · In June 2014, ANORO® ELLIPTA® was made available in the European Union.

Total milestone fees recorded of \$10.0 million in July 2014 resulted from the following:

· In July 2014, the Japanese MHLW approved ANORO® ELLIPTA® for the relief of various symptoms due to airway obstruction with COPD in cases where concurrent use of long-acting inhaled muscarinic antagonist and long-acting inhaled beta₂ agonist is required.

We are entitled to receive annual royalties from GSK on sales of RELVAR®/BREO® ELLIPTA® as follows: 15% on the first \$3.0 billion of annual global net sales and 5% for all annual global net sales above \$3.0 billion. Sales of single-agent LABA medicines and combination medicines would be combined for the purposes of this royalty calculation. For other products combined with a LABA from the LABA Collaboration, such as ANORO® ELLIPTA®, royalties are upward tiering and range from 6.5% to 10%.

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

2004 Strategic Alliance

In March 2004, we entered into our strategic alliance with GSK (the Strategic Alliance Agreement and the LABA Collaboration Agreement are together referred to herein as the GSK Agreements). Under this alliance, GSK received an option to license exclusive development and commercialization rights to product candidates from certain of our discovery programs on pre-determined terms and on an exclusive, worldwide basis. Upon GSK's decision to license a program, GSK is responsible for funding all future development, manufacturing and commercialization activities for product candidates in that program. In addition, GSK is obligated to use diligent efforts to develop and commercialize product candidates from any program that it licenses. If the program is successfully advanced through development by GSK, we are entitled to receive clinical, regulatory and commercial milestone payments and royalties on any sales of medicines developed from the program. If GSK chooses not to license a program, we retain all rights to the program and may continue the program alone or with a third party. GSK has no further option rights on any of our research or development programs under the strategic alliance.

In 2005, GSK licensed our bifunctional muscarinic antagonist-beta<sub>2</sub> agonist (MABA) program for the treatment of COPD, and in October 2011, we and GSK expanded the MABA program by adding six additional Theravance-discovered preclinical MABA compounds (the "Additional MABAs"). GSK's development, commercialization, milestone and royalty obligations under the strategic alliance remain the same with respect to GSK961081 ('081), the lead compound in the MABA program. GSK is obligated to use diligent efforts to develop and commercialize at least one MABA within the MABA program, but may terminate progression of any or all Additional MABAs at any time and return them to us, at which point we may develop and commercialize such Additional MABAs alone or with a third party. Both GSK and we have agreed not to conduct any MABA clinical studies outside of the strategic alliance so long as GSK is in possession of the Additional MABAs. If a single-agent MABA medicine containing '081 is successfully developed and commercialized, we are entitled to receive royalties from GSK of between 10% and 20% of annual global net sales up to \$3.5 billion, and 7.5% for all annual global net sales above \$3.5 billion. If a MABA medicine containing '081 is commercialized as a combination product, such as '081/FF, the royalty rate is 70% of the rate applicable to sales of the single-agent MABA medicine. For single-agent MABA medicines containing an Additional MABA, we are entitled to receive royalties from GSK of between 10% and 15% of annual global net sales up to \$3.5 billion, and 10% for all annual global net sales above \$3.5 billion. For combination products containing an Additional MABA, such as a MABA/ICS combination, the royalty rate is 50% of the rate applicable to sales of the single-agent MABA medicine. If a MABA medicine containing '081 is successfully developed and commercialized in multiple regions of the world, we could earn total contingent payments of up to \$125.0 million for a single-agent medicine and up to \$250.0 million for both a single-agent and a combination medicine. If a MABA medicine containing an Additional MABA is successfully developed and commercialized in multiple regions of the world, we could earn total contingent payments of up to \$129.0 million.

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

On March 3, 2014, in contemplation of the Spin-Off, we, Theravance Biopharma and GSK entered into a series of agreements clarifying how the companies would implement the Spin-Off and operate following the Spin-Off. We, Theravance Biopharma and GSK entered into a three-way master agreement providing for GSK's consent to the Spin-Off provided certain conditions were met. In addition, we and GSK also entered into amendments of our GSK Agreements, and Theravance Biopharma and GSK entered into a governance agreement, a registration rights agreement and an extension agreement. The three-way master agreement was effective on June 1, 2014 when we transferred our research and drug development operations to Theravance Biopharma. Pursuant to a three-way master agreement entered into by and among us, Theravance Biopharma and GSK in connection with the Spin-Off, we agreed to sell that number of Theravance Biopharma shares withheld from a taxable dividend of Theravance Biopharma shares to GSK. After such Theravance Biopharma shares were sent to the transfer agent, we agreed to purchase the Theravance Biopharma shares from the transfer agent, rather than have them sold on the open market, in order to satisfy tax withholdings. GSK had an option to purchase these shares of Theravance Biopharma from us, but this option expired unexercised. Accordingly, at June 30, 2014, we owned 436,802 ordinary shares of Theravance Biopharma, which are accounted for as available-for-sale securities in the condensed consolidated balance sheets.

The amendments to the GSK Agreements do not change the economics or royalty rates under the GSK Agreements, though the assignment of the Strategic Alliance Agreement and portions of the LABA Collaboration to TRC do change how the economics are allocated between Theravance Biopharma and us. The amendments to the GSK Agreements do provide that GSK's diligent efforts obligations regarding commercialization matters under both agreements will change upon regulatory approval in either the United States or the European Union of UMEC/VI/FF or a MABA in combination with FF. Upon such regulatory approval, GSK's diligent efforts obligations as to commercialization matters under the GSK Agreements will have the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK Agreements. Since GSK's commercialization efforts following such regulatory approval will be guided by a portfolio approach across products in which we will retain our full interests upon the Spin-Off and also products in which we will have retained only a portion of our interests upon the planned Spin-Off transaction, GSK's commercialization efforts may have the effect of reducing the overall value of our remaining interests in the GSK Agreements after the Spin-Off.

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

During the first six months of 2014, GSK purchased 659,999 shares of our common stock pursuant to its periodic "top-up" rights under our Amended and Restated Governance Agreement, dated as of June 4, 2004, as amended, among us, GSK and certain GSK affiliates, for an aggregate purchase price of approximately \$21.4 million.

GSK Contingent Payments and Revenue

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

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#### 4. Available-for-Sale Securities

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

(In thousands)	June 30, 2014		Dece	mber 31, 2013
Cash and cash equivalents	\$	184,994	\$	125,009
Short-term investments		126,424		321,615
Marketable securities		34,349		55,374
Restricted cash		833		833
Total	\$	346,600	\$	502,831

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

	June 30, 2014								
(In thousands)		Amortized Cost		Gross Unrealized Gains		Gross Unrealized Losses		Estimated Fair Value	
U.S. government securities	\$	23,509	\$	44	\$	_	\$	23,553	
U.S. government agencies		54,712		15		(5)		54,722	
U.S. corporate notes		33,632		7		(11)		33,628	
U.S. commercial paper		34,942		_		_		34,942	
Equity securities		10,269		3,656		_		13,925	
Money market funds		185,830		_				185,830	
Total	\$	342,894	\$	3,722	\$	(16)	\$	346,600	

Equity securities consist of ordinary shares of Theravance Biopharma owned by us as of June 30, 2014. These equity securities are restricted securities and can only be resold pursuant to a registration statement or an exemption from registration under the Securities Act of 1933, as amended (the "Securities Act"). We expect to be able to sell these shares pursuant to Rule 144 promulgated under the Securities Act after the satisfaction of a six-month holding period and, therefore, have classified them as available-for-sale marketable securities.

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

At June 30, 2014, all of the available-for-sale debt securities had contractual maturities within two years and the average duration of marketable securities was approximately seven months. We do not intend to sell the investments that are in an unrealized loss position, and it is unlikely that we will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. We have determined that the gross unrealized losses on our marketable securities at June 30, 2104 were temporary in nature. All marketable securities with unrealized losses at June 30, 2014 have been in a loss position for less than twelve months.

During the six months ended June 30, 2014 and 2013, we sold available-for-sale securities totaling \$5.0 million and \$17.6 million, and the related realized gains and losses were not significant in any of these periods.

# 5. Fair Value Measurements

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

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

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

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

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Our available-for-sale securities are measured at fair value on a recurring basis and our debt is carried at the amortized cost 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	τ	Significant Unobservable Inputs Level 3		Total		
Assets at June 30, 2014:										
U.S. government securities	\$	23,553	\$	_	\$	_	\$	23,553		
U.S. government agency securities		_		54,722		_		54,722		
U.S. corporate notes		_		33,628		_		33,628		
U.S. commercial paper		_		34,942		_		34,942		
Equity securities		13,925		_		_		13,925		
Money market funds		185,830		_		_		185,830		
Total assets measured at estimated fair value	\$	223,308	\$	123,292	\$		\$	346,600		
Liabilities at June 30, 2014:			_							
Convertible subordinated notes due 2023	\$	_	\$	417,148	\$	_	\$	417,148		
Non-recourse notes due 2029		_		454,500		_		454,500		
Total fair value of liabilities	\$		\$	871,648	\$		\$	871,648		

	Estimated Fair Value Measurements at Reporting Date Using									
Types of Instruments (In thousands)	Quoted Prices in Active Markets for Identical Assets Level 1		Significant Other Observable Inputs Level 2		Significant Unobservable Inputs Level 3			Total		
Assets at December 31, 2013:										
U.S. government securities	\$	42,158	\$	_	\$	_	\$	42,158		
U.S. government agency securities		98,236		43,095		_		141,331		
U.S. corporate notes		61,591		33,386		_		94,977		
U.S. commercial paper		3,499		98,523		_		102,022		
Money market funds		122,343		_		_		122,343		
Total assets measured at estimated fair value	\$	327,827	\$	175,004	\$		\$	502,831		
Liabilities at December 31, 2013:										
Convertible subordinated notes due 2023	\$		\$	408,250	\$	<u> </u>	\$	408,250		

At June 30, 2014, securities with a total fair value of \$5.4 million were measured using Level 2 inputs in comparison to December 31, 2013, at which time the securities had a fair value of \$5.4 million and were measured using Level 1 inputs.

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

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# 6. Intangible Assets

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

	June 30, 2014									
(In thousands)	Weighted Average Remaining Amortization Period (Years)		Gross Carrying Value		Accumulated Amortization		Net Carrying Value			
FDA approval and launch of BREO® ELLIPTA® in the U.S.	15.2	\$	60,000	\$	(2,526)	\$	57,474			
MHLW approval and launch of RELVAR® ELLIPTA® in Japan	14.4		20,000		(778)		19,222			
European Commission approval and launch of										
RELVAR® ELLIPTA®	14.5		30,000		(1,000)		29,000			
FDA approval and launch of ANORO® ELLIPTA® in the U.S.	15.2		60,000		(652)		59,348			
European Commission approval and launch of										
ANORO® ELLIPTA®	15.2		30,000		(164)		29,836			
Total intangible assets		\$	200,000	\$	(5,120)	\$	194,880			

		December 31, 2013								
(In thousands)	Weighted	Gross	Accumulated	Net Carrying						
	Average	Carrying	Amortization	Value						
	Remaining	Value								

	Amortization Period (Years)			
FDA approval and launch of BREO® ELLIPTA® in the U.S.	15.7	\$ 60,000	\$ (632)	\$ 59,368
MHLW approval and launch of RELVAR® ELLIPTA® in Japan	14.9	20,000	(111)	19,889
European Commission approval of RELVAR® ELLIPTA®	15	15,000	_	15,000
FDA approval of ANORO® ELLIPTA® in the U.S.	15.3	30,000	_	30,000
Total intangible assets		\$ 125,000	\$ (743)	\$ 124,257

Additional information regarding these milestone fees is included in Note 3 "Collaborative Arrangements." Amortization expense for the BREO® ELLIPTA® intangible asset for the U.S. region and the RELVAR® ELLIPTA® intangible asset for the Japan region began in the fourth quarter of 2013, the RELVAR® ELLIPTA® intangible asset for the European Union region began in the first quarter of 2014 and the ANORO® ELLIPTA® intangible assets for the U.S. and European Union regions began in the second quarter of 2014. Amortization expense is recorded as a reduction in revenue from collaborative arrangements. Amortization expense for the three months and six months ended June 30, 2014 was \$2.6 million and \$4.4 million. The amortization expense for the same periods in 2013 is zero. Estimated annual amortization expense of intangible assets is \$10.9 million for 2014, \$13.0 million for each of the years from 2015 to 2018 and \$136.4 million thereafter.

# 7. Stock-Based Compensation

#### **Equity Incentive Plan**

The 2012 Equity Incentive Plan ("2012 Plan") provides for the grant of stock options, time-based and performance-contingent restricted stock units (RSUs), time-based and performance-contingent RSAs, and stock appreciation rights to employees, non-employee directors and consultants. As of June 30, 2014, total shares remaining available for issuance under the 2012 Plan were 2,533,778.

# Performance-Contingent RSAs

Over the past three years, the Compensation Committee of our Board of Directors (the "Compensation Committee") has approved grants of performance-contingent RSAs to senior management and a non-executive officer. Generally, these awards have dual triggers of vesting based upon the achievement of certain performance goals by a pre-specified date, as well as a requirement for continued employment. When the performance goals are probable of achievement for these types of awards, time-based vesting and, as a result, recognition of stock-based compensation expense commence. Included in these performance-contingent RSAs is the grant of 1,290,000 special long-term retention and incentive performance-contingent RSAs to senior management in 2011. The awards have dual triggers of vesting based upon the achievement of certain performance conditions over a six-year timeframe from 2011 through December 31, 2016 and require continued employment.

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

In May 2014, our Compensation Committee approved the modification of the remaining tranches related to these awards contingent upon the Spin-Off as the performance conditions associated with these awards were unlikely to be consistent with the new strategies of each company following the separation. The modification acknowledged the Spin-Off and permitted recognition of achievement of the original performance conditions that were met prior to the Spin-Off, triggering service-based vesting for a portion of the equity awards. The remaining tranches of the equity awards remain subject to performance and service conditions. The remaining potential stock-based compensation expense associated with these awards after the modification is \$24.5 million, of which \$10.7 million is expected to be recognized by either us or Theravance Biopharma, based on which company employs the individuals who hold these awards during the twelve-month service period commencing in June 2014.

# 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 June 30,					Six Mont Jun			
(In thousands)		2014		2013		2014		2013	
Research and development	\$	514	\$	198	\$	1,232	\$	307	
General and administrative		3,081		1,970		8,420		3,595	
Stock-based compensation expense from continuing									
operations		3,595		2,168		9,652		3,902	
Stock-based compensation from discontinued operations		4,152		4,994		11,629		9,355	
Total stock-based compensation expense	\$	7,747	\$	7,162	\$	21,281	\$	13,257	

Total stock-based compensation expense capitalized to inventory was \$78,000 and \$95,000 for the three and six months ended June 30, 2014. Total stock-based compensation expense capitalized to inventory was \$28,000 and \$170,000 for the three and six months ended June 30, 2013. Inventories were contributed to Theravance Biopharma in connection with the Spin-Off.

As of June 30, 2014, unrecognized compensation expense, net of expected forfeitures, was as follows: \$2.2 million related to unvested stock options; \$1.8 million related to unvested RSUs; and \$19.5 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 June 30,			Six Month June	ded	
	2014		2013	2014		2013
Employee stock options	 					
Risk-free interest rate	1.6%-2.1%		0.8%-1.3%	1.6%-2.1%		0.8%-1.3%
Expected term (in years)	5-6		5-6	5-6		5-6
Volatility	52%-60%		59%-60%	52%-60%		58%-60%
Dividend yield	0%-0.4%		—%	0%-0.4%		—%
Weighted-average estimated fair value of stock options granted	\$ 15.72	\$	17.64	\$ 17.43	\$	15.43
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In connection with the Spin-Off of Theravance Biopharma, all outstanding shares of Theravance Biopharma were distributed to our stockholders as a pro-rata dividend distribution on June 2, 2014 by issuing one share of Theravance Biopharma common stock for every 3.5 shares held of Theravance common stock to stockholders of record on May 15, 2014. Outstanding stock options and RSUs that were not eligible for the dividend distribution were adjusted for the Spin-Off of Theravance Biopharma. The number of shares and exercise price for all outstanding stock options were adjusted and the number of shares for all outstanding RSUs was adjusted. All other terms of these grants remain the same; provided, however, that the vesting and expiration of these grants are based on the holder's continuing employment or service with us or Theravance Biopharma, as applicable.

Although the anti-dilution adjustments were required pursuant to the terms of each stock plan, the anti-dilution adjustments were calculated using a volume-weighted average stock price, rather than the stock price as of the date of the dividend distribution, which resulted in incremental compensation expense. The accounting impact of the adjustment to the outstanding stock options and RSUs that occurred in connection with the Spin-Off of Theravance Biopharma was measured by comparing of the fair values of the modified stock options and RSUs to our employees and directors immediately before and after the adjustment. As a result, we recognized incremental stock-based compensation expense of \$1.2 million in the second quarter of 2014, of which \$0.9 million is included in discontinued operations. All remaining unrecognized stock-based compensation expense associated with this adjustment will be recognized by Theravance Biopharma as it pertains to stock options and RSUs held by individuals now employed by Theravance Biopharma or one if its affiliates.

# Stockholders' Equity

For the six months ended June 30, 2014, options to purchase 79,000 shares of our common stock were exercised at a weighted-average exercise price of \$12.89 per share, for total cash proceeds of approximately \$1.0 million.

### 8. Income Taxes

As a part of the overall Spin-Off transaction, certain assets that were transferred by us to Theravance Biopharma resulted in taxable transfers pursuant to Section 367 of the Internal Revenue Code of 1986, as amended (the "Code"), or other applicable provisions of the Code and Treasury Regulations. The taxable gain attributable to the transfer of the certain assets to Theravance Biopharma was the excess of the fair market value of each asset transferred over our adjusted tax basis in such asset. The U.S. federal income tax gain on transfer of the assets to Theravance Biopharma was approximately \$0.4 billion. This taxable income is expected to be substantially offset by current year losses and our net operating loss carryforwards from prior years resulting in an income tax expense of approximately \$0.3 million.

As a result of the Spin-Off, we reversed approximately \$0.1 billion of our valuation allowance on certain deferred tax assets, primarily federal and state net operating losses, as of June 30, 2014. Our ability to utilize net operating losses is dependent upon the change in control provisions in Section 382 of the Code. We have not prepared a study of the potential limitation under Section 382 since December 31, 2013. While a formal update of the study has not been completed, we believe that we will not have limitations on the use of our net operating losses under Section 382 for the purposes of computing our income tax payable for the year ended December 31, 2014. As a result of our history of prior year losses and lack of available evidence supporting future taxable income, we believe that a valuation allowance on our remaining deferred tax assets as of June 30, 2014 remains appropriate. In addition, we also transferred gross deferred tax assets of approximately \$9 million with the corresponding full valuation allowance to Theravance Biopharma, Inc. as a result of the Spin-Off because the underlying tax benefits have been transferred to Theravance Biopharma, Inc.

#### 9. Commitments and Contingencies

# Lease Guarantee

Due to the Spin-Off of Theravance Biopharma, the leases for the facilities in South San Francisco, California, which formerly served as our headquarters, were assigned to Theravance Biopharma. We would be held liable by the landlord if Theravance Biopharma defaults under its lease obligations, and thus, we have in substance guaranteed the payments under the lease agreements for these facilities. As of June 30, 2014, the total lease payments for the duration of the lease, which runs through May 2020, were \$35.8 million. We would be responsible for lease related payments including utilities, property taxes, and common area maintenance, which may be as much as the actual lease payments. We recorded a non-current liability of \$1.3 million in our condensed consolidated balance sheet as of June 30, 2014 related to the estimated fair value of this lease guarantee. We prepared a discounted, probability-weighted cash flow analysis to calculate the estimated fair value of the lease guarantee as of Spin-Off. We were required to make assumptions regarding the probability of Theravance Biopharma's default on the lease payments, the likelihood of a sublease being executed, and the times at which these events could occur. The fair value of this lease guarantee was charged to additional paid in capital upon the Spin-Off, and any future adjustments to the carrying value of the obligation will be recorded to the condensed consolidated statement of operations.

In 2011, we granted special long-term retention and incentive cash bonus awards to certain employees. The awards have dual triggers of vesting based upon the achievement of certain performance conditions over a six-year timeframe from 2011 through December 31, 2016 and continued employment.

As of March 31, 2014, we determined that the achievement of the requisite performance conditions for the first tranche of these awards was probable and, as a result, \$9.1 million of cash bonus expense was recognized in the first quarter of 2014, the majority of which is included in discontinued operations. In May 2014, the total cash bonus of \$9.5 million for the first tranche was paid.

In May 2014, the Compensation Committee approved the modification of the remaining tranches related to these awards contingent upon the Spin-Off as the performance conditions associated with these awards were unlikely to be consistent with the new strategies of each company following the separation. The modification acknowledged the Spin-Off and permitted recognition of achievement of the original performance conditions that were met prior to the Spin-Off, triggering service-based vesting for a portion of the cash awards. The remaining tranches of the cash awards were forfeited. The maximum remaining potential cash bonus expense associated with these cash bonus awards after the modification is \$11.2 million, the majority of which is expected to be recognized by Theravance Biopharma over a twelve-month service period commencing in June 2014.

### 10. Notes Payable

#### Convertible Subordinated Notes Due 2023

In January 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 "2023 Notes"). 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 2023 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 2023 Notes are convertible, at the option of the holder, into shares of our common stock at an initial conversion rate of 35.9903 shares per \$1,000 principal amount of the 2023 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 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.

In connection with the offering of the 2023 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 would receive from our hedge counterparty a number of shares of our common shares that would range from zero, if the stock price was 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.

In accordance with the agreement for the 2023 Notes, the conversion rate was adjusted as a result of the completion of the Spin-Off of Theravance Biopharma. The conversion rate was adjusted based on the conversion rate immediately prior to the record date for the Spin-Off and the average of the stock dividend distributed to our common stockholders and our stock prices. This resulted in an adjusted conversion rate of 46.9087 shares per \$1,000 principal amount of the 2023 Notes, which represents an adjusted conversion price of approximately \$21.32 per share. As a result of the conversion rate adjustment, the capped call strike price and cap price were also adjusted accordingly as \$21.32 and \$29.16.

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

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

The 2029 Notes are secured by a security interest in a segregated bank account established to receive 40% of royalties due to us under the LABA Collaboration with GSK commencing on April 1, 2014 and ending upon the earlier of full repayment of principal or May 15, 2029. At June 30, 2014, the balance of the segregated bank account was \$0.2 million, which is classified as current restricted cash on our condensed consolidated balance sheet as these funds can only be used to make principal and interest payments on the 2029 Notes.

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The 2029 Notes bear an annual interest rate of 9%, with interest and principal paid quarterly beginning November 15, 2014. The 2029 Notes may be redeemed at any time prior to maturity, in whole or in part, at specified redemption premiums. Prior to May 15, 2016, in the event that the specified portion of royalties received in a quarter is less than the interest accrued for the quarter, the principal amount of the 2029 Notes will increase by the interest shortfall amount for that period. Since the principal and interest payments on the 2029 Notes are based on royalties from product sales, which will vary from quarter to quarter, the 2029 Notes may be repaid prior to the final maturity date in 2029.

From the net proceeds of the offering of approximately \$434.7 million, we established a \$32.0 million milestone payment reserve account to fund 40% of any future milestone payments that could become payable under the LABA Collaboration with GSK. This milestone reserve account is a segregated bank account and at June 30, 2014, the balance of this account is \$14.0 million. The milestone reserve account and collection account is classified as current restricted cash on our condensed consolidated balance sheet.

As part of this sale, we incurred approximately \$15.3 million in transaction costs, which will be amortized to interest expense over the estimated life of the 2029 Notes.

As of June 30, 2014, the future minimum principal payments under the 2029 Notes (1) were as follows:

Years Ending December 31: Amount

2015	_
2016	10,831
2017	52,935
2018	101,779
Thereafter	337,964
Total payments	\$ 503,509

<sup>(1)</sup> Repayment of the 2029 Notes is based on anticipated future royalties to be received from GSK and the anticipated final payment date in November 2020.

# 11. Spin-Off of Theravance Biopharma, Inc.

On June 1, 2014, we separated our late-stage partnered respiratory assets from our biopharmaceutical research and drug development operations. We contributed the assets and certain liabilities from the research and drug development operations and \$393.0 million of cash, cash equivalents and marketable securities to Theravance Biopharma. All outstanding shares of Theravance Biopharma were then distributed to our stockholders of record on May 15, 2014 as a pro-rata dividend distribution of one ordinary share of Theravance Biopharma for every 3.5 shares held of our common stock.

On June 1, 2014, we entered into a Separation and Distribution Agreement with Theravance Biopharma that set forth the terms and conditions of the separation of Theravance Biopharma from us. The Separation and Distribution Agreement sets forth a framework for the relationship between us and Theravance Biopharma following the separation regarding principal transactions necessary to separate Theravance Biopharma from us. This agreement also sets forth other provisions that govern certain aspects of our relationship with Theravance Biopharma after the completion of the separation from us and provides for the allocation of assets, liabilities and obligations between Theravance Biopharma and us in connection with the Spin-Off.

In addition, we entered into other definitive agreements in connection with the Spin-Off, including (1) a Transition Services Agreement pursuant to which Theravance Biopharma and we will provide each other with a variety of administrative services, including financial, tax, accounting, information technology, legal and human resources services, for a period of time of up to 12 months following the Spin-Off, (2) a Tax Matters Agreement that generally governs the parties' respective rights, responsibilities and obligations after the separation with respect to taxes, (3) a Sublease Agreement that provides for the sublease from Theravance Biopharma to us for certain office space to be utilized in our operations and (4) an Employee Matters Agreement that allocates liabilities and responsibilities relating to employee compensation, benefit plans, programs and other related matters in connection with the separation, including the treatment of outstanding incentive awards and certain retirement and welfare benefit obligations. These arrangements contain the provisions related to the Spin-Off of Theravance Biopharma and the distribution of Theravance Biopharma's ordinary shares to our stockholders.

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The total amount of the Theravance Biopharma share dividend of \$402.9 million was based on the net book value of the net assets that were contributed to Theravance Biopharma in connection with the Spin-Off, as follows:

(In thousands)	June 30, 2014
Cash and cash equivalents	\$ 277,541
Marketable investment securities	115,129
Accounts receivable	125
Reimbursement of certain liabilities	16,983
Prepaid and other current assets	3,172
Inventories	14,328
Fixed assets, net	9,580
Accrued liabilities	(22,342)
Deferred revenue	(6,694)
Other liabilities	(4,944)
Net book value of assets contributed	\$ 402,878

Theravance Biopharma's historical results of operations have been presented as discontinued operations in our condensed consolidated statement of operations for the three and six months ended June 30, 2014 and 2013. See Note 12, "Discontinued Operations," for further information.

# 12. Discontinued Operations

On June 1, 2014, we separated our research and drug development businesses from our late-stage partnered respiratory assets. For further information on the Spin-Off, refer to Notes 1 and 11, "Description of Operations and Summary of Significant Accounting Policies" and "Spin-Off of Theravance Biopharma, Inc.". The significant components of the research and drug development operations, which are presented as discontinued operations on the condensed consolidated statements of operations, were as follows:

	Three Months Ended June 30,				Six Months Ended June 30,				
(In thousands)	2014		2013		2014		2013		
Net revenues (1)	\$ 2,184	\$	5	\$	3,129	\$	27		
Loss from discontinued operations (2)	\$ (43,413)	\$	(34,888)	\$	(94,934)	\$	(61,502)		

<sup>(1)</sup> Net revenues primarily consist of revenue from collaborative arrangements and product sales. Revenue from collaborative arrangements was recognized from our agreement with R-Pharm CJSC, which was transferred to Theravance Biopharma as a part of the Spin-Off. Products sales were generated from sales of VIBATIV® in the U.S. through a limited number of distributors, and title and risk of loss transfer upon receipt by these distributors. Healthcare providers ordered VIBATIV® through these distributors. Commencing in the first quarter of 2014, revenue on the sale of VIBATIV® was recorded on a sell-through basis, once the distributors

sold the product to healthcare providers. Product sales were recorded net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions.

(2) Loss from discontinued operations before income taxes includes the reimbursement of research and development costs from our former collaborative arrangements, excluding GSK, which we accounted for as reductions to research and development expense. Reimbursement of research and development costs from discontinued operations from our collaborative arrangements was \$22,000 and \$2.1 million for the three months ended June 30, 2014 and 2013, and \$0.1 million and \$3.9 million for the six months ended June 30, 2014 and 2013.

In addition, the loss from discontinued operations before income taxes for the six months ended June 30, 2014 includes the special long-term retention and incentive cash awards program. In 2011, we granted special long-term retention and incentive cash bonus awards to certain employees. The awards have dual triggers of vesting based upon the achievement of certain performance conditions over a six-year timeframe from 2011 through December 31, 2016 and continued employment.

As of March 31, 2014, we determined that the achievement of the requisite performance conditions for the first tranche of these awards was probable and, as a result, \$9.1 million of cash bonus expense was recognized in the first quarter of 2014, the majority of which is included in discontinued operations. In May 2014, the total cash bonus of \$9.5 million for the first tranche was paid.

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#### 13. Subsequent Events

#### **Declaration of Cash Dividends**

On July 25, 2014, Theravance's Board of Directors declared a \$0.25 per share dividend for the third quarter of 2014. The dividend will be paid on September 18, 2014 to all stockholders of record as of the close of business on August 28, 2014. The dividend was publicly announced by Theravance on August 6, 2014.

#### Conversion of 2023 Notes

On July 15, 2014, certain holders of the 2023 Notes converted their notes into 1,519,367 shares of our common stock at the conversion price of \$21.32 per share. In connection with the partial conversion of the 2023 Notes, we will receive 149,645 shares of our common stock from our hedge counterparty.

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

# **OVERVIEW**

#### **Executive Summary**

Theravance, Inc (Theravance) is a royalty management company focused on maximizing the potential value of the respiratory assets partnered with Glaxo Group Limited (GSK), including RELVAR®/BREO® ELLIPTA® (fluticasone furoate/ vilanterol, "FF/VI") and ANORO® ELLIPTA® (umeclidinium bromide/ vilanterol, "UMEC/VI"), with the intention of providing capital returns to stockholders. Under the Long-Acting Beta² Agonist (LABA) Collaboration Agreement and the Strategic Alliance Agreement with GSK (referred to herein as the GSK Agreements), Theravance is eligible to receive the associated royalty revenues from RELVAR®/BREO® ELLIPTA® , ANORO® ELLIPTA® and if approved and commercialized, VI monotherapy. Theravance is also entitled to 15% of any future payments made by GSK under its agreements originally entered into with us, and since assigned to Theravance Respiratory Company, LLC ("TRC"), relating to the combination UMEC/VI/FF and the Bifunctional Muscarinic Antagonist-Beta² Agonist (MABA) program, as monotherapy and in combination with other therapeutically active components, such as an inhaled corticosteroid, and any other product or combination of products that may be discovered and developed in the future under the LABA Collaboration Agreement, which has been assigned to TRC other than RELVAR®/BREO®ELLIPTA®, ANORO® ELLIPTA® and VI monotherapy.

On June 1, 2014, we separated our late-stage partnered respiratory assets from our biopharmaceutical research ("Spin-Off") and drug development operations by contributing our research and drug development operations into our then wholly-owned subsidiary Theravance Biopharma. We contributed

\$393.0 million of cash, cash equivalents and marketable securities to Theravance Biopharma and all outstanding shares of Theravance Biopharma were then distributed to Theravance stockholders as a pro-rata dividend distribution on June 2, 2014 by issuing one ordinary share of Theravance Biopharma for every 3.5 shares held of our common stock to stockholders of record on May 15, 2014. The separation resulted in Theravance Biopharma operating as an independent publicly-traded company. The results of operations for the former research and drug development operations conducted by us and by Theravance Biopharma until June 1, 2014 are included as part of this report as discontinued operations.

Pursuant to a three-way master agreement entered into by and among us, Theravance Biopharma and GSK in connection with the Spin-Off, we agreed to sell that number of Theravance Biopharma shares withheld from a taxable dividend of Theravance Biopharma shares to GSK. After such Theravance Biopharma shares were sent to the transfer agent, we agreed to purchase the Theravance Biopharma shares from the transfer agent, rather than have them sold on the open market, in order to satisfy tax withholdings. GSK had an option to purchase these shares of Theravance Biopharma from us, but this option expired unexercised. Accordingly, at June 30, 2014, we own 436,802 ordinary shares of Theravance Biopharma.

Since the Spin-Off of Theravance Biopharma, we have significantly downsized our operations and currently have twelve employees managing our intellectual property, licensing operations, late-stage partnered respiratory assets with GSK as well as providing for certain essential reporting and management functions of a public company. Our revenues consist of royalties from our respiratory partnership agreements with GSK.

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For the first six months of 2014, our net loss from our continuing operations was \$36.3 million, an increase of \$24.0 million from \$12.3 million for the first six months of 2013 primarily due to higher employee-related expenses, including stock-based compensation expense, and an increase in interest expense from our non-recourse notes due 2029. Cash, cash equivalents, and marketable securities totaled \$368.8 million on June 30, 2014, a decrease of \$151.7 million from December 31, 2013 primarily due to the contribution of \$393.0 million to Theravance Biopharma in connection with the Spin-Off, registrational and launch-related milestone payments to GSK of \$100.0 million and cash used in operations of \$105.0 million. These outflows were partially offset by net proceeds of \$434.7 million from the issuance of our non-recourse notes due 2029 and net proceeds of \$23.8 million received from issuances of our common stock.

#### **Recent Developments**

#### **Declaration of Cash Dividends**

On July 25, 2014, Theravance's Board of Directors declared a \$0.25 per share dividend for the third quarter of 2014. The dividend will be paid on September 18, 2014 to all stockholders of record as of the close of business on August 28, 2014. The dividend was publicly announced by Theravance on August 6, 2014.

# **Program Highlights**

# Program Highlights — Respiratory Programs Partnered with GlaxoSmithKline plc

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

RELVAR®/BREO® ELLIPTA® product sales by GSK in the second quarter of 2014 were \$18.2 million.

RELVAR®/BREO® ELLIPTA® has been approved in 46 countries for marketing and has been launched in 19 countries, including the U.S., Canada, Japan and U.K., as of July 30, 2014.

In July 2014, GSK announced that BREO® ELLIPTA® for chronic obstructive pulmonary disease (COPD) is steadily improving insurance coverage in the U.S. Approximately 70 percent of people with Medicare Part D coverage currently have some degree of reimbursement for prescriptions of BREO® ELLIPTA® and approximately 50 percent of patients insured through commercial plans also have access to the product.

In June 2014, GSK and Theravance announced the submission of a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for a fixed dose combination of fluticasone furoate (FF)/vilanterol (VI) as a once-daily treatment for asthma in patients aged 12 years and older, with the brand name of BREO® ELLIPTA®. GSK is seeking approval for two dose regimens, 100/25mcg and 200/25mcg, administered once daily using the ELLIPTA® dry powder inhaler.

BREO® ELLIPTA® is the proprietary name in the U.S., Canada and Australia for the once-daily combination medicine of an inhaled corticosteroid (ICS), FF, and a long-acting beta<sub>2</sub>-agonist (LABA), VI (FF/VI) administered using the ELLIPTA® dry powder inhaler (DPI). RELVAR® ELLIPTA® is the proprietary name for FF/VI outside of the U.S., Canada and Australia. BREO® ELLIPTA® is not indicated for the relief of acute bronchospasm or for the treatment of asthma in the U.S. or Canada.

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

ANORO® ELLIPTA® product sales by GSK in the second quarter of 2014 were \$8.2 million which includes initial stocking of the U.S. wholesaler channel.

ANORO® ELLIPTA® has been approved in 39 countries for marketing and has been launched in 4 countries, including the U.S., Canada, U.K. and Germany, as of July 30, 2014.

In July 2014, GSK announced that ANORO® ELLIPTA® now is reimbursed to some extent for 30 percent of the population with Medicare Part D insurance and that 75 percent of patients insured through commercial plans have some degree of access following approval in late April 2014.

In July 2014, GSK and Theravance announced that ANORO® became available in the European Union following the May 2014 receipt of the marketing authorization as a once-daily, maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD.

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In July 2014, GSK and Theravance announced that the Japanese Ministry of Health, Labour and Welfare approved ANORO® ELLIPTA® for the relief of various symptoms due to airway obstruction with COPD (chronic bronchitis, pulmonary emphysema) in the case where concurrent use of long-acting inhaled muscarinic antagonist and long-acting inhaled beta2 agonist is required. Following this approval, it is expected that launch will take place in Japan in the third quarter of 2014.

In July 2014, GSK and Theravance announced that the Therapeutic Goods Administration in Australia approved ANORO® ELLIPTA® as a long-term oncedaily, maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD.

ANORO® ELLIPTA® is the proprietary name in the U.S., Canada, Japan and Australia for UMEC/VI and ANORO® is the proprietary name in Europe. ANORO® is a once-daily combination treatment comprising two bronchodilators, UMEC, a long-acting muscarinic antagonist (LAMA), and VI, a LABA, in a single inhaler, the ELLIPTA®. ANORO® ELLIPTA® is not indicated for the relief of acute bronchospasm or for the treatment of asthma.

#### **Triple Therapy**

#### 'Open Triple' Combination

In June 2014, GSK and Theravance announced positive results from two Phase 3 studies, which showed that patients with COPD who received the 'open triple' therapy, the anticholinergic, GSK's INCRUSE<sup>TM</sup> ELLIPTA® (UMEC 62.5mcg), or UMEC 125mcg (an unlicensed dose) in addition to RELVAR®/BREO® ELLIPTA®, achieved an additional improvement in lung function (FEV<sub>1</sub>) compared to patients receiving FF/VI plus placebo. The studies showed that for the primary endpoint of trough FEV<sub>1</sub> at day 85, the addition of UMEC 62.5mcg or UMEC 125mcg to FF/VI 100/25mcg resulted in a statistically significant improvement in lung function when compared with FF/VI 100/25mcg plus placebo in patients with COPD.

### 'Closed Triple' Combination

In July 2014, GSK and Theravance announced the start of a global Phase 3 study, known as IMPACT (InforMing the PAthway of COPD Treatment), to evaluate the efficacy and safety of the 'closed triple' combination of FF/UMEC/VI in patients with COPD. IMPACT is the first pivotal Phase 3 study in a program to evaluate a once-daily 'closed triple' combination treatment of an ICS; a LAMA; and a LABA in patients with COPD. The IMPACT study will enroll approximately 10,000 patients and assess whether the combination of FF, UMEC and VI, all delivered in the ELLIPTA® DPI, can reduce the annual rate of moderate and severe exacerbations compared with two approved once daily COPD treatments, RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®.

#### Combination MABA/ICS

GSK961081 ('081) is an investigational, single molecule bifunctional bronchodilator discovered by Theravance with both muscarinic antagonist and beta<sub>2</sub> receptor agonist (MABA) activities. Preclinical Phase 3-enabling studies and a Phase 1 study with healthy volunteers of the MABA/ICS combination '081/FF are ongoing to explore its potential as a once-daily medicine delivered in the ELLIPTA® DPI.

# **Collaborative Arrangement with GSK**

#### LABA Collaboration

In November 2002, we entered into our Long-Acting Beta<sub>2</sub> Agonist (LABA) collaboration with GSK to develop and commercialize once-daily LABA products for the treatment of COPD and asthma. For the treatment of COPD, the collaboration has developed two combination products: (1) RELVAR®/BREO® ELLIPTA® (FF/VI) (BREO® ELLIPTA® is the proprietary name in the U.S. and Canada and RELVAR® ELLIPTA® is the proprietary name outside the U.S. and Canada), a once-daily combination medicine consisting of a LABA, vilanterol (VI), and an inhaled corticosteroid (ICS), fluticasone furoate (FF) and (2) ANORO® ELLIPTA® (UMEC/VI), a once-daily medicine combining a long-acting muscarinic antagonist (LAMA), umeclidinium bromide (UMEC), with a LABA, VI. Under the collaboration agreements between the parties, GSK and Theravance are exploring various paths to create triple therapy medications. The use of triple therapy is supported by the GOLD (Global initiative for chronic Obstructive Lung Disease) guidelines in high-risk patients with severe COPD and a high risk of exacerbations. One potential triple therapy path is the combination of UMEC/VI (two bronchodilators) and FF (an inhaled corticosteroid), to be administered via the ELLIPTA® investigational dry powder inhaler, which triple therapy program GSK has referred to as Diamond. GSK recently announced its goal of advancing Diamond into Phase 3 in either 2014 or 2015. For the treatment of asthma, RELVAR® ELLIPTA® is approved in multiple regions outside of North America and the collaboration is further developing FF/VI for the U.S. The FF/VI program is aimed at developing a once-daily combination LABA/ICS to succeed GSK's Advair ® /Seretide™ (salmeterol and fluticasone as a combination) franchise, which had reported 2013 sales of approximately \$8.3 billion, and to compete with Symbicort® (formoterol and budesonide as a combination), which had reported 2013 sales of approximately \$3.5 billion. ANORO® ELLIPTA®, which is also a combination product, is targeted as an alternative treatment op

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In the event that a product containing VI is successfully developed and commercialized, we are 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. As of June 30, 2014, we have paid a total of \$185.0 million of these milestones and have an accrued a liability of \$15.0 million. In July 2014, we recorded an additional \$10.0 million accrued liability. These milestone fees paid or owed to GSK were capitalized as finite-lived intangible assets, which are being amortized over their estimated useful lives commencing upon the commercial launch of the product. We estimate the remaining potential milestone payments of \$10.0 million could be payable by the end of 2014.

- · In May 2013, the FDA approved BREO® ELLIPTA® as an inhaled long-term, once-daily maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. It is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations.
- In September 2013, the Japanese Ministry of Health, Labour and Welfare (MHLW) approved RELVAR® ELLIPTA® for the treatment of bronchial asthma in cases where concurrent use of inhaled corticosteroid and long-acting inhaled beta2 agonist is required.
- · In October 2013, BREO® ELLIPTA® was launched in the U.S. for the treatment of COPD.
- · In November 2013, the European Commission granted marketing authorization for RELVAR® ELLIPTA® for the regular treatment of asthma and the systematic treatment of COPD.
- · In December 2013, RELVAR® ELLIPTA® was launched in Japan for the treatment of bronchial asthma.
- · In December 2013, the FDA approved ANORO® ELLIPTA® as a combination anticholinergic/long-acting beta2-adrenergic agonist (LABA) indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema.
- · In January 2014, RELVAR® ELLIPTA® was launched in the European Union.
- · In April 2014, ANORO® ELLIPTA® became available in the U.S. for the treatment of COPD.
- · In May 2014, the European Commission granted marketing authorization for ANORO(R) (umeclidinium/vilanterol) as a once-daily, maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD.
- · In June 2014, ANORO® ELLIPTA® became available in the European Union.

Total milestone fees recorded of \$10.0 million in July 2014 resulted from the following:

· In July 2014, the Japanese MHLW approved ANORO® ELLIPTA® for the relief of various symptoms due to airway obstruction with COPD in cases where concurrent use of long-acting inhaled muscarinic antagonist and long-acting inhaled beta² agonist is required.

We are entitled to receive annual royalties from GSK on sales of RELVAR\*/BREO\* ELLIPTA\* as follows: 15% on the first \$3.0 billion of annual global net sales and 5% for all annual global net sales above \$3.0 billion. Sales of single-agent LABA medicines and combination medicines would be combined for the purposes of this royalty calculation. For other products combined with a LABA from the LABA Collaboration Agreement, such as ANORO\* ELLIPTA\*, royalties are upward tiering and range from 6.5% to 10%.

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

#### 2004 Strategic Alliance

In March 2004, we entered into our strategic alliance with GSK (the Strategic Alliance Agreement and the LABA Collaboration Agreement are together referred to herein as the GSK Agreements). Under this alliance, GSK received an option to license exclusive development and commercialization rights to product candidates from certain of our discovery programs on pre-determined terms and on an exclusive, worldwide basis. Upon GSK's decision to license a program, GSK is responsible for funding all future development, manufacturing and commercialization activities for product candidates in that program. In addition, GSK is obligated to use diligent efforts to develop and commercialize product candidates from any program that it licenses. If the program is successfully advanced through development by GSK, we are entitled to receive clinical, regulatory and commercial milestone payments and royalties on any sales of medicines developed from the program. If GSK chooses not to license a program, we retain all rights to the program and may continue the program alone or with a third party. GSK has no further option rights on any of our research or development programs under the strategic alliance.

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In 2005, GSK licensed our MABA program for the treatment of COPD, and in October 2011, we and GSK expanded the MABA program by adding six additional Theravance-discovered preclinical MABA compounds (the "Additional MABAs"). GSK's development, commercialization, milestone and royalty obligations under the strategic alliance remain the same with respect to GSK961081 ('081), the lead compound in the MABA program. GSK is obligated to use diligent efforts to develop and commercialize at least one MABA within the MABA program, but may terminate progression of any or all Additional MABAs at any time and return them to us, at which point we may develop and commercialize such Additional MABAs alone or with a third party. Both GSK and we have agreed not to conduct any MABA clinical studies outside of the strategic alliance so long as GSK is in possession of the Additional MABAs. If a single-agent MABA medicine containing '081 is successfully developed and commercialized, we are entitled to receive royalties from GSK of between 10% and 20% of annual global net sales up to \$3.5 billion, and 7.5% for all annual global net sales above \$3.5 billion. If a MABA medicine containing '081 is commercialized as a combination product, such as a '081/FF, the royalty rate is 70% of the rate applicable to sales of the single-agent MABA medicine. For single-agent MABA medicines containing an Additional MABA, we are entitled to receive royalties from GSK of between 10% and 15% of annual global net sales up to \$3.5 billion, and 10% for all annual global net sales above \$3.5 billion. For combination products containing an Additional MABA, such as a MABA/ICS combination, the royalty rate is 50% of the rate applicable to sales of the single-agent MABA medicine. If a MABA medicine containing '081 is successfully developed and commercialized in multiple regions of the world, we could earn total contingent payments of up to \$125.0 million for a single-agent medicine and up to \$250.0 million for both a single-agent and a combination medicine. If a MABA medicine containing an Additional MABA is successfully developed and commercialized in multiple regions of the world, we could earn total contingent payments of up to \$129.0 million.

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

On March 3, 2014, in contemplation of the Spin-Off of Theravance Biopharma, we, Theravance Biopharma and GSK entered into a series of agreements clarifying how the companies would implement the Spin-Off and operate following the Spin-Off. We, Theravance Biopharma and GSK entered into a three-way master agreement providing for GSK's consent to the Spin-Off provided certain conditions are met. In addition, we and GSK also entered into amendments to the GSK Agreements, and Theravance Biopharma and GSK entered into a governance agreement, a registration rights agreement and an extension agreement. The three-way master agreement GSK entered into a governance agreement, a registration rights agreement and an extension agreement. The three-way master agreement is effective on June 1, 2014 when we transferred our research and drug development operations to Theravance Biopharma. Pursuant to a three-way master agreement entered into by and among us, Theravance Biopharma and GSK in connection with the Spin-Off, we agreed to sell that number of Theravance Biopharma shares withheld from a taxable dividend of Theravance Biopharma shares to GSK. After such

Theravance Biopharma shares were sent to the transfer agent, we agreed to purchase the Theravance Biopharma shares from the transfer agent, rather than have them sold on the open market, in order to satisfy tax withholdings. GSK had an option to purchase these shares of Theravance Biopharma from us, but this option expired unexercised. Accordingly, at June 30, 2014, we owned 436,802 ordinary shares of Theravance Biopharma.

The amendments to the GSK Agreements do not change the economics or royalty rates under the GSK Agreements, though the assignment of the Strategic Alliance Agreement and portions of the LABA Collaboration Agreement to TRC do change how the economics are allocated between Theravance Biopharma and us. The amendments to the GSK Agreements do provide that GSK's diligent efforts obligations regarding commercialization matters under both agreements will change upon regulatory approval in either the United States or the European Union of UMEC/VI/FF or a MABA in combination with FF. Upon such regulatory approval, GSK's diligent efforts obligations as to commercialization matters under the GSK Agreements will have the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK Agreements. Since GSK's commercialization efforts following such regulatory approval will be guided by a portfolio approach across products in which we will retain our full interests upon the Spin-Off and also products in which we will have retained only a portion of our interests upon the planned Spin-Off transaction, GSK's commercialization efforts may have the effect of reducing the overall value of our remaining interests in the GSK Agreements after the Spin-Off.

### Purchases of Common Stock by GSK

During the first six months of 2014, GSK purchased 659,999 shares of our common stock pursuant to its periodic "top-up" rights under our Amended and Restated Governance Agreement, dated as of June 4, 2004, as amended, among us, GSK and certain GSK affiliates, for an aggregate purchase price of \$21.4 million.

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#### **GSK Contingent Payments and Revenue**

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

Net revenue recognized from GSK under the GSK Agreements was as follows:

	Three Months Ended June 30,				Six Months Ended June 30,			
(In thousands)		2014		2013		2014		2013
Royalty revenue	\$	3,261	\$		\$	3,991	\$	
Amortization of intangible assets		(2,598)		_		(4,378)		_
Net royalty revenue		663				(387)		
LABA collaboration		_		907		_		1,814
Strategic alliance—MABA program license		271		415		541		830
Total net revenue from GSK	\$	934	\$	1,322	\$	154	\$	2,644

Amortization expense for intangible assets, which is a reduction to royalty revenue, exceeded amounts recognized for royalty revenues under the LABA Collaboration Agreement with GSK, resulting in negative net royalty revenue in the six month ended June 30, 2014. Estimated annual amortization expense of intangible assets is \$10.9 million for 2014.

Under the GSK Agreements, we are reimbursed for research and development expenses. These reimbursements have been reflected as a reduction of research and development expense and were not material for the second quarter and first six months of 2014. The reimbursement of research and development expense was \$0.2 million and \$0.3 million for the second quarter and first six months of 2013.

# **Critical Accounting Policies and Estimates**

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

# Revenue Recognition

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

# Collaborative Arrangements and Multiple Element Arrangements

We generate revenue from collaboration and license agreements for the development and commercialization of product candidates. Collaboration and license agreements may include non-refundable upfront payments, partial or complete reimbursement of research and development costs, supply arrangement, contingent payments based on the occurrence of specified events under our collaborative arrangements, license fees and royalties on sales of product candidates if they are successfully approved and commercialized. Our performance obligations under the collaborations may include the transfer of intellectual property rights in the form of licenses, obligations to provide research and development services and related materials, supply of active

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

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

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

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

Under the GSK Agreements we recognized revenue of \$0.2 million and \$2.6 million for the six months ended June 30, 2014 and 2013. The remaining deferred revenue under the GSK Strategic Alliance Agreement is \$5.4 million at June 30, 2014. Any change in the estimated performance period, which is predominantly based on GSK's development timeline, will not have a significant impact on the results of operations, except for a change in estimated performance period resulting from the termination of the MABA program that would result in immediate recognition of the deferred revenue.

On January 1, 2011, we also adopted an accounting standards update that provides guidance on revenue recognition using the milestone method. Payments that are contingent upon achievement of a substantive milestone are recognized in their entirety in the period in which the milestone is achieved. Milestones are defined as events that can be achieved based only on our performance and as to which, at the inception of the arrangement, there is substantive uncertainty about whether the milestone will be achieved. Events that are contingent only on the passage of time or only on third-party performance are not considered milestones subject to this guidance. Further, the amounts received must relate solely to prior performance, be reasonable relative to all of the deliverables and payment terms in the agreement and commensurate with our performance to achieve the milestone after commencement of the agreement. Total contingent payments that may become payable to us under our collaborative agreements were up to \$363.0 million at June 30, 2014 and are considered non-substantive.

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

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

# Royalties

We recognize royalty revenue on licensee net sales of products with respect to which we have royalty rights in the period in which the royalties are earned and reported to us and collectability is reasonably assured. Royalties are recognized net of amortization of intangible assets associated with any approval and launch milestone payments made to GSK.

# **Intangible Assets**

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

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

Our gross intangible assets of \$200.0 million at June 30, 2014 consist of registrational and launch-related to milestone fees paid or owed to GSK (see "Collaborative Arrangements with GSK" above for more information). These intangible assets are considered finite-lived intangible assets, which will be amortized over their estimated useful lives using the straight-line method commencing upon commercial launch.

## **Results of Operations**

# Net Revenue

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

	Three Mor	nths En	nded	Chan	ıge		Six Mont June	nded	Char	ıge	
(In thousands)	2014		2013	\$		%	2014	2013	\$	%	
Royalty revenue	\$ 3,261	\$	_	\$ 3,261		*%	\$ 3,991	\$ _	\$ 3,991		*%
Amortization of intangible											
assets	(2,598)		_	(2,598)		*	(4,378)	_	(4,378)		*
Net royalty revenue	663			663		*	(387)		(387)		*
Net revenue from											
collaborative arrangements	271		1,322	(1,051)		(80)%	541	2,644	(2,103)		(80)%
Total net revenue	\$ 934	\$	1,322	\$ (388)		(29)%	\$ 154	\$ 2,644	\$ (2,490)		(94)%

<sup>\*</sup>Not meaningful

Total net revenue decreased for the second quarter and first six months of 2014 compared to the same periods a year ago. Revenue for the second quarter and first six months of 2014 includes net royalty revenue and revenue from collaborative arrangements compared to the same periods in 2013, which only includes revenue from collaborative arrangements. Royalty revenue recognized under the LABA Collaboration Agreement with GSK is reduced by amortization expense for intangible assets, which in the first six months of 2014 exceeded amounts recognized for royalty revenues. Revenue from collaborative arrangements decreased for the second quarter and first six months of 2014 compared to the same periods in 2013 primarily as a result of deferred revenue under the LABA Collaboration Agreement with GSK being fully recognized in 2013.

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# Research & Development

Research and development expenses from our continuing operations, as compared to the prior year periods, were as follows:

	Three Mor	ıths E	Ended			Six Mont	hs Er	ıded			
	June	e 30,		Chan	ge	Jun	e 30,		Cha	nge	
(In thousands)	2014		2013	\$	%	2014		2013	\$	%	
Research and development expenses	\$ 2,125	\$	2,412	\$ (287)	(12)% \$	4,812	\$	4,451	361	8%	

Research and development expenses decreased in the second quarter of 2014 compared to the same period a year ago primarily due to our ongoing operations being significantly smaller as a result of the Spin-Off.

Research and development expenses increased in the first six months of 2014 compared to the same period a year ago primarily due to an increase in stock-based compensation expense, partially offset by our ongoing operations is significantly smaller as a result of the Spin-Off. The increase in stock-based compensation expense primarily resulted from the achievement of performance conditions under a special long-term retention and incentive equity awarded to certain employees in 2011, the majority of which was recognized in the first quarter of 2014.

# **General & Administrative**

General and administrative expenses from our continuing operations, as compared to the prior year periods, were as follows:

	Three Moi	nths E	nded			Six Mont	hs Eı	nded		
	Jun	e 30,		Cha	nge	June	e 30,		Cha	nge
(In thousands)	2014		2013	\$	%	2014		2013	\$	%
General and administrative expenses	\$ 8,603	\$	5,808	\$ 2,795	48%	\$ 19,859	\$	11,864	\$ 7,995	67%

General and administrative expenses increased in the second quarter and first six months of 2014 compared to the same periods a year ago primarily due to higher stock-based compensation expense and employee-related costs. Stock-based compensation expense and employee-related costs increased primarily due to the probable achievement of performance conditions under a special long-term retention and incentive equity and cash bonus awarded to certain employees in 2011, which resulted in additional stock-based compensation and cash bonus expense.

# Interest Income and Other Income (Expense), net

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

	Three Moi	nths I	Ended			Six Months	s Ended		
	Jun	e 30,		Chan	ige	June 3	30,	Chang	ge
(In thousands)	2014		2013	\$	%	2014	2013	\$	%
Interest income	\$ 165	\$	190	\$ (25)	(13)%	\$ 353	375	(22)	(6)%
Other income, (expense), net	83		8,192	(8,109)	(99)	80	6,770	(6,690)	(99)

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

The decrease in the other income (expense), net for the second quarter and first six months of 2014 is due to the net cash received from the termination of the royalty participation agreement with Elan Corporation, plc in 2013. The decrease for the first six months of 2014 was partially offset by \$1.4 million from the change in the fair value of the capped call instruments related to our convertible subordinated notes issued in 2013.

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#### Interest Expense

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

	Three Mor	ıths I	∃nded				Six month	ıs Ended		
	June	30,		 Cha	nge		 June	30,	 Cha	nge
(In thousands)	2014		2013	\$	%		2014	2013	\$	%
Interest expense	\$ 10,327	\$	3,025	\$ 7,302	24	11%	\$ 11,971	5,761	\$ 6,210	108%

Interest expense increased in the second quarter and first six months of 2014 compared to the same periods a year ago primarily due to the interest expense associated with the issuance in April 2014 of our non-recourse notes due 2029.

# **Discontinued Operations**

On June 1, 2014, we separated our research and drug development businesses from our late-stage partnered respiratory assets. The significant components of the research and drug development operations, which are presented as discontinued operations on the condensed consolidated statements of operations, were as follows:

	Three mor	ıths	Ended				Six mont	hs E	nded			
	Jun	e 30,		Cha	nge		Jun	e 30,		Cha	nge	
(In thousands)	2014		2013	\$		%	2014		2013	\$		%
Net revenue	\$ 2,184	\$	5	\$ 2,179		*%	\$ 3,129	\$	27	\$ 3,102		*%
Loss from discontinued operations	43,413		34,888	8,525		24	94,934		61,502	33,432		54

<sup>\*</sup>Not Meaningful

Net revenues primarily consist of revenue from collaborative arrangements and product sales. Revenue from collaborative arrangements was recognized from our agreement with R-Pharm CJSC, which was transferred to Theravance Biopharma as a part of the Spin-Off. Products sales were generated from sales of VIBATIV® in the U.S. through a limited number of distributors, and title and risk of loss transfer upon receipt by these distributors. Healthcare providers ordered VIBATIV® through these distributors. Commencing in the first quarter of 2014, revenue on the sale of VIBATIV® was recorded on a sell-through basis, once the distributors sold the product to healthcare providers. Product sales were recorded net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions.

Loss from discontinued operations increased in the second quarter and first six months of 2014 compared to the same periods a year ago primarily due to an increase in external legal and accounting fees in connection with our separation strategy. Included in the loss from operations in the first six months of 2014 is the additional stock-based compensation and cash bonus expense recognized due to the achievement of performance conditions under a special long-term retention and incentive equity and cash bonus awarded to certain employees in 2011.

# **Liquidity and Capital Resources**

# Liquidity

Since our inception, we have financed our operations primarily through private placements and public offerings of equity and debt securities and payments received under collaborative arrangements. At June 30, 2014, we had \$368.8 million in cash, cash equivalents and marketable securities, excluding amounts classified as restricted cash.

On June 1, 2014 we contributed \$393.0 million of cash, cash equivalents and marketable securities to Theravance Biopharma as initial funds for their operations, based on anticipated operating plans and financial forecasts at the separation date. Although our cash on hand was reduced as a result of the Spin-Off, we expect that going forward our operating expenses will decrease significantly as our ongoing operations will be significantly smaller due to the Spin-Off. As a result of the reduction in our operations, we believe that cash from future royalty revenues, net of operating expenses, debt service and cash on hand, will be sufficient to fund our operations for at least the next twelve months.

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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. In May 2014, the Compensation Committee of the Board of Directors approved the modification of the remaining tranches related to these awards contingent upon the Spin-Off as the performance conditions associated with these awards were unlikely to be consistent with the new strategies of each company following the separation. The modification acknowledged the Spin-Off and permitted recognition of achievement of the original performance conditions that were met prior to the Spin-Off, triggering service-based vesting for a portion of the cash awards. The remaining tranches of the cash awards were forfeited. The remaining potential cash bonus expense associated with these cash bonus awards after the modification is \$11.2 million, the majority of which is expected to be recognized by Theravance Biopharma over a twelve-month service period commencing in June 2014.

In April 2014, we entered into certain note purchase agreements relating to the private placement of \$450.0 million aggregate principal amount of 2029 Notes. The 2029 Notes are secured by a security interest in a segregated bank account established to receive 40% of royalties from global net sales occurring on or after April 1, 2014 and ending upon the earlier of full repayment of principal or May 15, 2029 due to us under the LABA Collaboration Agreement with GSK. Prior to May 15, 2016, in the event that the specified portion of royalties received in a quarter is less than the interest accrued for the quarter, the principal amount of the 2029 Notes will increase by the interest shortfall amount for that period. From the net proceeds of the offering of approximately \$434.7 million, we established a milestone payment reserve account to fund 40% of any future milestone payments that could become payable under the LABA Collaboration Agreement with GSK. This milestone reserve account is a segregated bank account and at June 30, 2014, the balance of this account is \$14.0 million. During the second quarter of 2014, we received \$0.2 million in a segregated bank account, which represents 40% royalties from global net sales. The milestone reserve account and collection account is classified as current restricted cash on our condensed consolidated balance sheets. We incurred approximately \$15.3 million in debt issuance costs, which are being amortized to interest expense over the estimated life of the 2029 Notes.

Adequacy of cash resources to meet future needs

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

# Cash Flows

Cash flows, as compared to the prior years, were as follows:

	Six Montl		ed .	
	 June	30,		
(In thousands)	 2014		2013	Change
Net cash used in operating activities	\$ (105,042)	\$	(48,317)	\$ (56,725)
Net cash provided by (used in) investing activities	2,896		(118,545)	121,441
Net cash provided by financing activities	166,688		271,256	(104,568)

#### Cash Flows from Operating Activities

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

Net cash used in operating activities in the first six months of 2014 of \$105.0 million was primarily due to:

- \$102.4 million used in operating expenses, after adjusting for non-cash related items of: \$28.9 million consisting of stock- based compensation expense of \$21.3 million, depreciation and amortization expense of \$6.2 million and amortization on premium of short-term investment of \$1.4 million:
- \$8.2 million increase in interest payments on convertible subordinated notes payable;
- \$1.9 million used to increase inventories;
- \$1.9 million used to decrease accrued personnel-related expenses and other accrued liabilities, and \$5.8 million decrease in accounts payable primarily due to the timing of payments and our ongoing operations being significantly smaller due to the Spin-Off; and
- \$2.6 million provided by decrease in deferred revenue.

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Net cash used in operating activities in the first six months of 2013 of \$48.3 million was primarily due to:

• \$55.2 million used in operating expenses, after adjusting for non-cash related items of \$18.6 million consisting of stock- based compensation expense of \$13.3 million, and depreciation and amortization expense of \$3.9 million;

- \$2.9 million used to decrease accrued liabilities primarily due to a \$2.9 million decrease in accrued personnel-related expenses, accrued clinical
  and development expense;
- \$2.6 million used for interest payments on convertible subordinated notes payable;
- \$2.5 million used to increase inventories;
- \$1.2 million used to increase receivable from collaborative arrangements related to reimbursement of research and development services; and
- \$0.4 million used to increase prepaid expenses and other current assets.

## Cash Flows from Investing Activities

Net cash provided by investing activities in the first six months of 2014 of \$2.9 million was due to \$103.3 million from the sale and maturities in available-for sale securities, net of purchases, partially offset by \$100.0 million used for intangible assets for the payments to GSK for registrational and launch-related milestone fees and \$0.6 million used for purchases of property and equipment.

Net cash used in investing activities in the six-months ended June 30, 2013 was \$118.5 million, which was primarily due to \$87.2 million in cash balances being invested in short-term investments and long-term marketable securities and \$30.0 million used for a registrational milestone payment to GSK.

#### Cash Flows from Financing Activities

Net cash provided by financing activities in the first six months of 2014 of \$166.7 million was due to net proceeds of \$434.7 million received from the private placement of our 9% non-recourse notes and \$23.8 million received from the issuance of our common stock, partially offset by \$277.5 million of cash and cash equivalents contributed to Theravance Biopharma as a result of the Spin-Off.

Net cash provided by financing activities in the first six months of 2013 of \$271.3 million was due to net proceeds of \$281.6 million received from the January 2013 issuance of 2.125% convertible subordinated notes due in 2023, partially offset by \$36.8 million of payments on privately-negotiated capped call option transactions in connection with the issuance of the notes.

# **Off-Balance Sheet Arrangements**

Due to the Spin-Off of Theravance Biopharma, the leases for the facilities in South San Francisco, California, which formerly served as our headquarters, were assigned to Theravance Biopharma. We would be held liable by the landlord if Theravance Biopharma default under its lease obligations, and thus, we have in substance guaranteed the payments under the lease agreements for the South San Francisco facilities. As of June 30, 2014, the total lease payments for the duration of the lease, which runs through May 2020, are approximately \$35.8 million. We would be also responsible for lease related payments including utilities, property taxes, and common area maintenance, which may be as much as the actual lease payments. We recorded a long-term liability of \$1.3 million on our condensed consolidated balance sheet as of June 30, 2014 related to the estimated fair value of this guarantee.

# **Commitments and Contingencies**

Special Long-Term Retention and Incentive Cash Awards Program

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.

In May 2014, the Compensation Committee approved the modification of the remaining tranches related to these awards contingent upon the Spin-Off as the performance conditions associated with these awards were unlikely to be consistent with the new strategies of each company following the separation. The modification acknowledged the Spin-Off and permitted recognition of achievement of the original performance conditions that were met prior to the Spin-Off, triggering service-based vesting for a portion of the cash and equity awards. The remaining tranches of the cash awards were forfeited, and the remaining tranches of the equity awards remain subject to performance and service conditions. The maximum remaining potential cash bonus expense associated with these cash bonus awards after the modification is \$11.2 million, the majority of which is expected to be recognized by Theravance Biopharma over a twelve-month service period commencing in June 2014. The remaining potential stock-based compensation expense associated with these awards after the modification is \$24.5 million, of which \$10.7 million is expected to be recognized by either us or Theravance Biopharma, based on which company employs the individuals who hold these awards during the twelve-month service period commencing in June 2014.

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#### **Contractual Obligations and Commercial Commitments**

Pursuant to our LABA Collaboration Agreement with GSK, we are 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. As of June 30, 2014, we have paid a total of \$185.0 million of these milestones, and have an accrued liability of \$15.0 million. In July 2014, we recorded an additional \$10.0 million accrued liability. These milestone fees paid or owed to GSK were capitalized as finite-lived intangible assets, which are being amortized over their estimated useful lives commencing upon commercial launch. We estimate the remaining potential milestone payments of \$10.0 million could become payable by the end of 2014.

In April 2014, we entered into certain note purchase agreements relating to the private placement of \$450.0 million aggregate principal amount of non-recourse 9% fixed rate term notes due 2029 issued by our wholly-owned subsidiary. As of June 30, 2014, our contractual obligations under the non-recourse notes for the next five years and thereafter are as follows:

Years Ending December 31:	Principal and interest payments
Six months remaining in 2014	\$ 1,550
2015	17,495
2016	50,108

2017	95,932
2018	138,324
Thereafter	371,017
Total payments	\$ 674,426

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

# **Equity Market Risk**

As of June 30, 2014, we hold ordinary shares of Theravance Biopharma with a fair value of \$13.9 million. These equity securities are restricted securities and can only be resold pursuant to a registration statement or an exemption from registration under the Securities Act of 1933, as amended (the "Securities Act"). We expect to be able to sell these shares pursuant to Rule 144 promulgated under the Securities Act after the satisfaction of a six-month holding period. The fair value of the marketable securities could be adversely affected as common stocks are susceptible to stock market fluctuations and to volatile increases and decreases in value. A 10% decrease in the fair value of this equity security would result in a loss in fair value of approximately \$1.4 million.

#### **Interest Rate Risk**

As of June 30, 2014, the fair value of our convertible notes due in 2023 was estimated to be \$417.1 million, based on available pricing information. The 2023 Notes bear interest at a fixed rate of 2.125% and are subject to interest rate risk because the fixed interest rates under this obligation may exceed current interest rates.

As of June 30, 2014, the fair value of our non-recourse notes due 2029 was estimated to be \$454.5 million, based on available pricing information. The 2029 Notes bear interest at a fixed rate of 9% per annum. This obligation is subject to interest rate risk because the fixed interest rates under this obligation may exceed current interest rates.

The following table presents information about our material debt obligations that are sensitive to changes in interest rates. The table presents principal amounts and the effective interest rates by year of expected maturity for our debt obligations or the earliest in which the note holders may put the debt to us. Our convertible notes may be converted to common stock prior to the maturity date.

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(In thousands) Convertible notes due 2023	20	014 (1)		2015		2016		2017		2018		hereafter	_	Total		Value (2)
Fixed rate	\$	3,055	\$	6,109	\$	6,109	\$	6,109	\$	6,109	\$	314,992	\$	342,483	\$	417,148
Average interest rate		2.39%	6	2.39%	ó	2.39%	ó	2.39%	ó	2.39%	)	2.39%	)	2.39%	)	
(In thousands) Non recourse notes due 2029	20	014 (1)	_	2015		2016		2017	_	2018		Thereafter_		Total		Fair Value (2)
<u>,                                     </u>	\$	)14 (1) —	\$	2015	\$	2016 10,831	\$	<b>2017</b> 52,935	\$	2018 101,779	\$	Thereafter 337,964	\$	<b>Total</b> 503,509	\$	

- (1) Principal amounts from July 1 2014 to December 31, 2014
- (2) Fair value is as of June 30, 2014
- (3) Repayment of the 2029 notes is based on anticipated future royalties to be received from GSK and the anticipated final payment date in November 2020.

# Item 4. Controls and Procedures.

# Evaluation of Disclosure Controls and Procedures

We conducted an evaluation as of June 30, 2014, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, which are defined under SEC rules as controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Securities Exchange Act of 1934 (Exchange Act) (i) is recorded, processed, summarized and reported within required time periods and (ii) is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

# Limitations on the Effectiveness of Controls

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

On June 2, 2014, we completed the Spin-Off of Theravance Biopharma, Inc. Since the Spin-Off of Theravance Biopharma, Inc., we have significantly downsized our operations and currently have twelve employees managing our intellectual property, licensing operations and late-stage partnered respiratory assets with GSK as well as providing for certain essential reporting and management functions of a public company. Under a transition services agreement, Theravance Biopharma, Inc. continues to support the financial reporting function for Theravance, Inc. during a transition period. There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act, which occurred during our most recent fiscal quarter which has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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# PART II. OTHER INFORMATION

#### ITEM 1A. RISK FACTORS

#### **Risks Related to our Business**

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

Under our agreements with our collaborative partner GlaxoSmithKline plc (GSK), GSK has full responsibility for commercialization of BREO® ELLIPTA® and RELVAR® ELLIPTA®. GSK launched BREO® ELLIPTA® into the U.S. and Canadian markets in October 2013 and January 2014, respectively. GSK launched RELVAR® ELLIPTA® in Japan during December 2013 and in the United Kingdom, Germany and Denmark during January 2014. It has since been launched in other countries. BREO® ELLIPTA® is the proprietary name in the United States (U.S.) and Canada and RELVAR® ELLIPTA® is the proprietary name outside the U.S. and Canada. The initial launch of BREO® ELLIPTA® has been relatively slow, as this is a primary care product and we believe it will take time to obtain payor coverage and increase physician awareness. In addition, GSK recently indicated publicly that it is experiencing price pressure with Advair®, its largest selling respiratory product, which may indicate broader weakness in the respiratory markets targeted by BREO® ELLIPTA® and RELVAR® ELLIPTA®. As a result, we believe some analysts have adjusted their sales forecasts downward from previous projections. Any further delays or adverse developments or perceived additional delays or adverse developments with respect to the commercialization of RELVAR®/BREO® ELLIPTA® in the countries in which RELVAR®/BREO® ELLIPTA® has received regulatory approval, including if sales or payor coverage do not meet investor expectations, will significantly harm our business and the price of our securities could fall.

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

ANORO® ELLIPTA® (UMEC/VI) was launched by GSK in the U.S. in April 2014 and made available for purchase in Canada in April 2014 and in the European Union (EU) in June 2014. ANORO® ELLIPTA® is the proprietary name in the U.S. and Canada and Japan and ANORO® is the proprietary name in Europe. Although it is still early in the launch cycle, the ANORO® ELLIPTA® launch has also been slow, as this is also a primary care product and we believe it will take time to obtain payor coverage and increase physician awareness. Any delays or adverse developments or perceived delays or adverse developments with respect to the commercialization of ANORO® ELLIPTA® in countries in which ANORO® ELLIPTA® has received regulatory approval, including if sales or payor coverage do not meet investor expectations, will significantly harm our business and the price of our securities could fall.

Any adverse developments or results or perceived adverse developments or results with respect to the Phase 3 programs for FF/VI in asthma or chronic obstructive pulmonary disease (COPD), for UMEC/VI in COPD, the FF/VI supplemental New Drug Application (sNDA) for asthma submitted to the U.S. Food and Drug Administration (FDA) in June 2014, or any future studies will significantly harm our business and the price of our securities could fall, and if regulatory authorities in those countries in which approval has not yet been granted determine that the Phase 3 programs for FF/VI in asthma or COPD or the Phase 3 programs for UMEC/VI for COPD do not demonstrate adequate safety and efficacy, the continued development of FF/VI or UMEC/VI or both may be significantly delayed, they may not be approved by these regulatory authorities, and even if approved it may be subject to restrictive labeling, any of which will harm our business, and the price of our securities could fall.

Although we have announced the completion of, and reported certain top-line data from, the Phase 3 registrational program for FF/VI in COPD and asthma, additional studies of FF/VI are underway. In June 2014, we and GSK announced the submission of a sNDA to the FDA for a fixed dose combination of FF/VI as a once-daily treatment for asthma in patients aged 12 years and older. The Phase 3b program for FF/VI in COPD commenced in February 2011. Any adverse developments or perceived adverse developments with respect to the asthma sNDA, the COPD Phase 3b program or any future studies in these programs will significantly harm our business and the price of our securities could fall.

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Although the FDA, the European Medicines Agency, the Japanese Ministry of Health, Labour and Welfare and Health Canada have approved ANORO® ELLIPTA®, it has not yet been approved in other countries. Any adverse developments or results or perceived adverse developments or results with respect to other pending or future regulatory submissions for the FF/VI program or the UMEC/VI program will significantly harm our business and the price of our securities could fall. Examples of such adverse developments include, but are not limited to:

- · not every study, nor every dose in every study, in the Phase 3 programs for FF/VI achieved its primary endpoint and regulatory authorities may determine that additional clinical studies are required;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in these programs having to do with the LABA VI, which is a component of FF/VI and UMEC/VI;

- · safety, efficacy or other concerns arising from clinical or non-clinical studies in these programs;
- · regulatory authorities determining that the Phase 3 programs in asthma or in COPD raise safety concerns or do not demonstrate adequate efficacy; or
- · any change in FDA policy or guidance regarding the use of LABAs to treat asthma or the use of LABAs combined with a LAMA to treat COPD.

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

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

GSK has responsibility for obtaining regulatory approval, launching and commercializing RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® for their intended uses in the targeted markets around the world. While these products have received regulatory approval and been launched and commercialized in the United States and certain other targeted markets, the products face substantial competition from existing products previously developed and commercialized both by GSK and by other competing pharmaceutical companies and can expect to face additional competition from new products that are discovered, developed and commercialized by the same pharmaceutical companies and other competitors going forward. For example, sales of Advair®, GSK's approved medicine for both COPD and asthma, continue to be significantly greater than sales of RELVAR®/BREO® ELLIPTA®, and GSK has indicated publicly that it intends to continue commercializing Advair®.

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

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

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In July 2014 we and GSK announced the initiation of a large, global Phase 3 study for the fixed dose triple combination treatment UMEC/VI/FF (LABA/LAMA/ICS) in patients with COPD. As a result of the spin-off and the associated assignment of most of our economic rights in this program, if this Phase 3 study is successful and GSK and the respiratory market in general view this triple combination therapy as significantly more beneficial than existing therapies, including RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®, our business could be harmed, and the price of our securities could fall.

Under our LABA collaboration agreement with GSK, we and GSK are exploring various paths to create triple therapy respiratory medications. The use of triple therapy is supported by the GOLD (Global initiative for chronic Obstructive Lung Disease) guidelines in high-risk patients with severe COPD and a high risk of exacerbations. One potential triple therapy path is the combination of UMEC/VI (two separate bronchodilators) and FF (an inhaled corticosteroid), to be administered via the ELLIPTA® dry powder inhaler, referred to as UMEC/VI/FF or the "closed triple." Prior to our spin-off of Theravance Biopharma, we were entitled to receive 100% of any royalties payable under the GSK Agreements arising from sales of UMEC/VI/FF (as well as MABA and MABA/FF) if such products were successfully developed, approved and commercialized. As a result of the transactions effected by the spin-off, however, we are now only entitled to receive 15% of the royalties payable by GSK from sales of UMEC/VI/FF (and MABA, and MABA/FF). In July 2014, we and GSK announced the initiation of a large, global Phase 3 study for the closed triple in patients with COPD. If this Phase 3 study (or any other closed triple Phase 3 studies that may be initiated in the future) is successful, GSK and the respiratory market in general may view this triple combination therapy as significantly more beneficial than existing therapies, including RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®. In such event the commercialization of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® could be adversely affected, which in turn could result in lower royalties to us. Furthermore, if the closed triple (or MABA /FF) receives regulatory approval in either the United States or the European Union, GSK's diligent efforts obligations regarding commercialization matters will have the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK Agreements. Since GSK's commercialization efforts following such regulatory approval will be guided by a portfolio approach across products in which we have retained our full interest and also products in which we now have only a small portion of our former interest, GSK's commercialization efforts may have the effect of reducing the overall value of our remaining interests in the GSK Agreements in the future

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

The lead compound, GSK961081 ('081), in the bifunctional muscarinic antagonist-beta2 agonist (MABA) program with GSK, has completed a Phase 2b study, a Phase 1 study in combination with the inhaled corticosteroid, fluticasone propionate ("FP"), and a number of Phase 3-enabling non-clinical studies. '081 is now being progressed as a combination with FF delivered once-daily in the ELLIPTA® inhaler which requires additional work on non-clinical studies, manufacturing and a Phase 1 bioequivalence study. As a result, it is unlikely that a Phase 3 study with '081 will commence in 2014. Any further delays or adverse developments or results or perceived adverse developments or results with respect to the MABA program will harm our business and the price of our securities could fall. Examples of such adverse developments include, but are not limited to:

- · GSK deciding to further delay or halt development of '081 monotherapy or the combination '081/FF;
- the FDA and/or other regulatory authorities determining that any of the '081 studies do not demonstrate adequate safety or efficacy, or that additional non-clinical or clinical studies are required with respect to the MABA program;
- · safety, efficacy or other concerns arising from clinical or non-clinical studies in this program; or
- · any change in FDA policy or guidance regarding the use of MABAs to treat COPD.

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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 royalites under the GSK Agreements.

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:

- GSK's ability to set a price we believe is fair for our partnered products, if approved; and
- · GSK's ability to generate revenues and the resulting royalties owed to us.

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 partnered products. This could harm GSK's ability to market our partnered products 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 have and are expected to emerge in connection with this act could significantly reduce potential revenues from the sale of our partnered products. For example, while GSK launched BREO® ELLIPTA® for the treatment of COPD in the United States in October 2013 and launched RELVAR® ELLIPTA® in certain countries in the European Union in early 2014, GSK has experienced significant challenges in gaining acceptance for RELVAR®/BREO® ELLIPTA® for treatment of COPD by some of the largest healthcare payors and providers. Further, if the ongoing Phase 3b studies with FF/VI do not show improved outcomes relative to the standard of care, obtaining payor coverage for RELVAR®/BREO® ELLIPTA® could become more difficult. 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 GSK to sell our partnered products that have been or may be approved in the future at a price acceptable to us or GSK, which may cause the price of our securities to fall.

We are relying significantly upon Theravance Biopharma for a variety of services during a six to nine-month post-separation transition period during which time we are required to establish our own separate administrative infrastructure, systems and controls to enable us to function as an independent public company and, if we fail to do so in timely manner, our business will be harmed and the price of our securities could fall.

Under the terms of a transition services agreement entered into between us and Theravance Biopharma, Theravance Biopharma will provide us with a variety of administrative services for a period of approximately six to nine-months following the spin-off, including (i) record keeping support, (ii) finance, tax and accounting support to assist us in a secondary capacity to our own personnel, (iii) legal support, (iv) human resources support and (v) facilities support to the extent we continue to occupy separate space at our current South San Francisco, California facilities. We will be relying on Theravance Biopharma for execution of these administrative activities through this transition period, which is a period when Theravance Biopharma personnel will be highly focused on supporting its own newly public company operations. If there is any disruption in the provision of these services to us, or if the services provided to us are not provided in a timely or satisfactory manner, our business operations could be adversely affected. Further, we must design, build, test and implement our own stand-alone (i) finance, tax, accounting and IT systems, controls and capabilities, and (ii) legal, human resources and administrative functions that are properly suited to our new post-spin business operations. All of these will need to be sufficiently rigorous to support our ongoing operations as an independent public company. Failure to do so could cause us to be unable to comply with the accounting and legal standards required of publicly traded companies, which would harm our business and our reputation and could cause the price of our securities to fall.

On June 2, 2014, we completed the separation of our businesses into two independent, publicly traded companies by separating our late-stage partnered respiratory assets from our biopharmaceutical operations; the lengthy, complicated and ongoing process to separate the two businesses has and will continue to divert the attention of our management and employees, may disrupt our operations, and has and will continue to increase our professional services expenses through the balance of 2014.

On April 25, 2013 we announced our intention to separate our businesses into two independent, publicly traded companies. On August 1, 2013, the company to be spun-off, Theravance Biopharma, Inc. (Theravance Biopharma), filed a preliminary Form 10 with the SEC, and subsequent amendments throughout 2013 and the Spring of 2014. The spin-off was completed on June 2, 2014. Theravance continues to be responsible for all development and commercial activities under the LABA Collaboration agreement and the Strategic Alliance agreement with GSK (collectively, the "GSK Agreements"). Theravance is eligible to receive the associated royalty revenues from FF/VI (RELVAR®/BREO® ELLIPTA®), UMEC/VI (ANORO® ELLIPTA®) and potentially VI monotherapy and 15% of the aggregate potential royalty revenues payable to Theravance Respiratory Company, LLC from UMEC/VI/FF, MABA, and MABA/FF and other products that may be developed under the GSK Agreements. Theravance Biopharma is now a separate and independent

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In conjunction with the spin-off of Theravance Biopharma, on March 3, 2014, we, Theravance Biopharma and GSK entered into a series of agreements clarifying how the companies would implement the separation and operate following the spin-off. We, Theravance Biopharma and GSK entered into a three-way master agreement providing for GSK's consent to the spin-off provided certain conditions were met. We and GSK also entered into amendments of the GSK Agreements. The master agreement is currently effective and the other agreements became effective upon the spin-off.

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

The process of planning for and effecting the business separation demanded a significant amount of time and effort from our management and certain employees, and we anticipate that it will continue to do so for the balance of 2014. The diversion of our management's and employees' attention to the business separation process and the post-separation transition has disrupted and may continue to disrupt our operations and may adversely impact our relationship with GSK and increase employee turnover.

We cannot assure you that we will not undertake additional restructuring activities, that the business separation will succeed in meeting our objectives and increasing stockholder value, or that the actual results will not differ materially from the results that we anticipate.

We have incurred and will continue to incur significant expenditures for professional services in connection with the business separation and our post-separation operations, including financial advisory, accounting and legal fees.

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

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

As a part of the overall spin-off transaction, the transfer of certain assets by us to Theravance Biopharma and our distribution of Theravance Biopharma ordinary shares resulted in taxable transfers pursuant to applicable provisions of the Internal Revenue Code of 1986, as amended (the "Code") and Treasury Regulations. The taxable gain recognized by us attributable to the transfer of certain assets to Theravance Biopharma will generally equal the excess of the fair market value of each asset transferred over our adjusted tax basis in such asset. Although we will not recognized any gain with respect to the cash we transferred to Theravance Biopharma, we may recognize substantial gain based on the fair market value of the other assets (other than cash) transferred to Theravance Biopharma. The determination of the fair market value of these assets is subjective and could be subject to adjustments or future challenge by the Internal Revenue Service ("IRS"), which could result in an increase in the amount of gain realized by us as a result of the transfer. Our U.S. federal income tax resulting from any gain recognized upon the transfer of our assets to Theravance Biopharma (including any increased U.S. federal income tax that may result from a subsequent determination of higher fair market values for the transferred assets), may be reduced by our net operating loss carryforward. As federal and state tax laws impose restrictions on the utilization of net operating losses in the event of an ownership change, as defined in Section 382 of the Code, we conducted an analysis to determine whether an ownership change had occurred since inception through December 31, 2013, and concluded that we had undergone two ownership changes in prior years. We had approximately \$1.1 billion of net operating loss carryforward as of June 30, 2014. We expect our net operating loss carryforward and current projected losses for the 2014 taxable year will generally fully offset the U.S. federal income tax resulting from the gains we will realize in connection with the pre spin-off restructuring and distribution of Theravance Biopharma ordinary shares. There may be alternative minimum tax federal tax liability to the extent such gains are offset with net operating loss carryforwards from prior years. However, the amount of our net operating loss carryforward that will be used is uncertain in part due to subjective nature of a valuation of the transferred assets as described above.

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Our stockholders who received ordinary shares of Theravance Biopharma in the spin-off could incur significant U.S. federal income tax liabilities as a result of the distribution.

All or a portion of the Theravance Biopharma ordinary shares received by our stockholders in the spin-off is expected be taxable to them as a dividend. An amount equal to the fair market value of Theravance Biopharma ordinary shares received (including any fractional shares deemed to be received) on the distribution date will be treated as a taxable dividend to the extent of each Theravance stockholder's ratable share of any current and accumulated earnings and profits of Theravance, measured as of the end of 2014, with the excess treated as a non-taxable return of capital to the extent of such stockholder's tax basis in our common stock and any remaining excess treated as a capital gain. Accordingly, Theravance stockholders who received ordinary shares of Theravance Biopharma in the spin-off could incur significant U.S. federal income tax liabilities as a result of the distribution.

Since the spin-off, our Chief Executive Officer has worked part time for us and part time for Theravance Biopharma and this arrangement is expected to last until the earlier of recruitment and transition of a new chief executive officer for Theravance or nine months following the spin-off. Although we will benefit from his deep knowledge of our business, as well as his familiarity with our systems, policies, procedures and mode of operation, the lack of his full time focus on our business may dilute his effectiveness on our behalf and therefore hurt our business. In addition, we also anticipate that most, if not all, of the other senior officers remaining at Theravance will become officers of Theravance Biopharma in the future as we recruit and integrate new officers for our royalty management business. Some of these senior officer transitions may occur quickly after the spin-off (i.e. in the third quarter of 2014) depending in part on our success in recruiting and integrating new officers into our management. Following the completion of the spin-off Catherine J. Friedman, Paul Pepe and James L. Tyree became members of our Board of Directors and Henrietta H. Fore, Robert V. Gunderson, Jr., Burton G. Malkiel, Peter S. Ringrose, George M. Whitesides and William D. Young resigned as members of our Board of Directors. These senior officer and board level changes could be disruptive to our operations, present significant management challenges and could harm our business.

If any product candidates in any respiratory program partnered with GSK are not approved by regulatory authorities or are determined to be unsafe or ineffective in humans, our business will be adversely affected and the price of our securities could fall.

The FDA must approve any new medicine before it can be marketed and sold in the United States. Our partner GSK must provide the FDA and similar foreign regulatory authorities with data from preclinical and clinical studies that demonstrate that the product candidates are safe and effective for a defined indication before they can be approved for commercial distribution. GSK will not obtain this approval for a partnered 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 medicines in foreign countries, separate regulatory approvals must be obtained 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 or by the FDA. Conversely, failure to obtain approval in one or more country may make approval in other countries more difficult.

Clinical studies involving product candidates partnered with GSK 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 product candidates in development partnered with GSK, GSK may not receive regulatory approval for such product candidates and our business and financial condition will be materially harmed and the price of our securities may fall.

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

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Even if product candidates in any respiratory program partnered with GSK receive regulatory approval, as is the case with RELVAR\*/BREO\* ELLIPTA\* and ANORO\* ELLIPTA\*, commercialization of such products may be adversely affected by regulatory actions and oversight.

Even if GSK receives regulatory approval for product candidates in any respiratory program partnered with GSK, this approval may include limitations on the indicated uses for which GSK can market the medicines or the patient population that may utilize the medicines, which may limit the market for the medicines or put GSK at a competitive disadvantage relative to alternative therapies. These restrictions make it more difficult to market the approved products.

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 or GSK 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 GSK, including requiring it 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. GSK is 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 as well as governmental authorities in those foreign countries in which any of the product candidates in any respiratory program partnered with GSK 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. Any failure to maintain regulatory approval will limit GSK's ability to commercialize the product candidates in any respiratory program partnered with GSK, which would materially and adversely affect our business and financial condition and which may cause the price of our securities to fall.

We have incurred operating losses in each year since our inception and will continue to incur losses until royalties from the sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® exceed total expenses, including interest expenses, and our revenues and operating results will likely fluctuate in future periods.

From mid-1997 until the spin-off, we were engaged in discovering and developing compounds and product candidates and we never generated sufficient revenue from the sale of medicines or royalties on sales by our partners to achieve sustained profitability. As of June 30, 2014, we had an

accumulated deficit of approximately \$1.6 billion. Although we expect to have a substantial reduction in our expenses in future periods as a result of the spin-off, we will continue to incur losses until royalties from the sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® exceed total expenses, including interest expenses, and our revenues and operating results will likely fluctuate from period to period. 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, our ability to return capital to stockholders and continue operations.

For the foreseeable future we will derive all of our royalty revenues from GSK and our future success depends on GSK's ability to successfully develop and commercialize the products in the respiratory programs partnered with GSK.

Pursuant to the GSK Agreements, GSK is responsible for the development and commercialization of products in the partnered respiratory programs. Our future revenues will consist almost entirely of royalties from the sale of products in the respiratory programs partnered with GSK, although we may receive milestone payments from GSK if certain development milestones are achieved in our MABA program licensed to GSK. Our future success depends primarily upon the performance by GSK of its obligations under the GSK Agreements. We have no control over GSK's marketing and sales efforts, and GSK might not be successful, which would harm our business and the price of our securities could fall.

The amount of any royalties we receive will depend on many factors, including the following:

- the competitive landscape for approved products and developing therapies that compete with our partnered products, including other products owned by GSK (such as Advair®) but which are not partnered with us and pricing pressure in the respiratory markets targeted by our partnered products;
- the ability of patients to be able to afford our partnered products or obtain health care coverage that covers our partnered products;

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- · acceptance of, and ongoing satisfaction with, our partnered products by the medical community, patients receiving therapy and third party payors;
- a satisfactory efficacy and safety profile as demonstrated in a broad patient population;
- the size of the market for our partnered products;
- the extent and effectiveness of the sales and marketing and distribution support GSK provides our partnered products;
- · safety concerns in the marketplace for respiratory therapies in general and with our partnered products in particular;
- · regulatory developments relating to the manufacture or continued use of our partnered products;
- decisions as to the timing of product launches, pricing and discounts; GSK's ability to expand the indications for which our partnered products can be marketed;
- · GSK's ability to obtain regulatory approval of our partnered products in additional countries; or
- the unfavorable outcome of any potential litigation relating to our partnered products.

We intend to reserve from time to time a certain amount of cash in order to satisfy the obligations relating to our debt, which could adversely affect the amount or timing of distributions to our stockholders.

As of June 30, 2014 we had approximately \$737.5 million in total long-term liabilities outstanding, comprised of \$287.5 million in principal that remains outstanding under our 2.125% Convertible Subordinated Notes due 2023 (the "2023 Notes") and \$450.0 million in principal that remains outstanding under our 9% fixed rate term notes due 2029 (the "2029 Notes"). The 2023 Notes are unsecured debt and are not redeemable by us prior to the maturity date. Holders of the Notes may require us to purchase all or any portion of their Notes at 100% of their principal amount, plus any unpaid interest, upon a fundamental change. A fundamental change is generally defined to include a merger involving us, an acquisition of a majority of our outstanding common stock, and the change of a majority of our board without the approval of the board. In addition, to the extent we pursue and complete a monetization transaction, the structure of such transaction may qualify as a fundamental change under the Notes, which could trigger the put rights of the holders of the Notes, in which case we would be required to use a portion of the net proceeds from such transaction to repurchase any Notes put to us. This could adversely affect the amount or timing of any distributions to our stockholders.

We intend to reserve from time to time a certain amount of cash in order to satisfy these obligations relating to Notes, which could materially affect the amount or timing of any distribution to our stockholders. We may also finance such repurchase through public or private equity or debt financings if we deem such financings available on favorable terms. If any or all of Notes are not converted into shares of our common stock before the maturity date, we will have to pay the holders the full aggregate principal amount of the Notes then outstanding. Any of the above payments could have a material adverse effect on our cash position. If we fail to satisfy these obligations, it may result in a default under the indenture, which could result in a default under certain of our other debt instruments, if any. Any such default would harm our business and the price of our securities could fall.

If we lose key management personnel, or if we fail to retain our key employees, our ability to manage our business will be impaired.

Following the spin-off, we have a much smaller management team and very few employees. We are highly dependent on principal members of our management team and a small group of key employees 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 business operations, which may cause the price of our securities to fall.

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#### Risks Related to our Alliance with GSK

Because all our current and projected revenues are derived from products under the GSK Agreements, disputes with GSK could harm our business and cause the price of our securities to fall.

All of our current and projected revenues are derived from products under the GSK Agreements. Any action or inaction by either GSK or us that results in a material dispute, allegation of breach, litigation, arbitration, or significant disagreement between the parties may be interpreted negatively by the market or by our investors, could harm our business and cause the price of our securities to fall. Examples of these kinds of issues include but are not limited to non-performance of contractual obligations and allegations of non-performance, disagreements over the relative marketing and sales efforts for our partnered products and other GSK respiratory products, disputes over public statements, and similar matters. In addition, while we obtained GSK's consent to the spin off as structured, GSK could decide to challenge various aspects of our post spin off operation of Theravance Respiratory Company, LLC ("TRC"), the limited liability company jointly owned by us and Theravance Biopharma as violating or allowing it to terminate the GSK Agreements. Although we believe our operation of TRC fully complies with the GSK Agreements and applicable law, there can be no assurance that we would prevail against any such claims by GSK. Moreover, regardless of the merit of any claims by GSK, we may incur significant cost and diversion of resources in defending them. In addition, any market or investor uncertainty about the respiratory programs partnered with GSK or the enforceability of the GSK Agreements could result in significant reduction in the market price of our securities and other material harm to our business.

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

Although GSK beneficially owns approximately 26.6% of our outstanding capital stock as of July 31, 2014, it is also a strategic partner with rights and obligations under the GSK Agreements that cause its interests to differ from the interests of us and our other stockholders. In particular, GSK has a substantial respiratory product portfolio in addition to its products that are covered by the GSK Agreements. GSK may make respiratory product portfolio decisions or statements about its portfolio which may be, or may be perceived to be, harmful to the respiratory products partnered with us. For example, GSK could promote its own respiratory products and/or delay or terminate the development or commercialization of the respiratory programs covered by the GSK Agreements. In this regard and by way of example, sales of Advair®, GSK's approved medicine for both COPD and asthma, continue to be significantly greater than sales of RELVAR®/BREO® ELLIPTA®, and GSK has indicated publicly that it intends to continue commercializing Advair®. Also, given the potential future royalty payments GSK may be obligated to pay under the GSK Agreements, GSK may seek to acquire us to reduce those payment obligations. The timing of when GSK may seek to acquire us could potentially be when it possesses information regarding the status of drug programs covered by the GSK Agreements that has not been publicly disclosed and is not otherwise known to us. As a result of these differing interests, GSK may take actions that it believes are in its best interest but which might not be in the best interests of either us or our other stockholders. In addition, upon regulatory approval of UMEC/VI/FF or a MABA/ICS in either the U.S. or the European Union, GSK's diligent efforts obligations as to commercialization matters under the GSK Agreements will have the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK Agreements. Since GSK's commercialization efforts following such regulatory approval will be guided by a portfolio approach across products in which we have retained our full interest and also products in which we now have only a portion of our former interest, GSK's commercialization efforts may have the effect of reducing the overall value of our remaining interests in the products covered by the GSK Agreements in the future.

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

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

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

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

As of July 31, 2014, GSK beneficially owned approximately 26.6% of our outstanding capital stock, and GSK has the right to acquire stock from us to maintain its percentage ownership of our capital stock in certain circumstances. GSK could have substantial influence in the election of our directors, delay or prevent a transaction in which stockholders might receive a premium over the prevailing market price for their shares and have significant control over certain changes in our business.

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

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

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

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

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

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

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

As of July 31, 2014, GSK beneficially owned approximately 26.6% 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.

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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. Sales by GSK of a substantial number of shares, or the expectation of such sales, could cause a significant reduction in the market price of our common stock.

# Risks Related to Legal and Regulatory Uncertainty

If the efforts of our partner, GSK, to protect the proprietary nature of the intellectual property related to products in any respiratory program partnered with GSK are not adequate, the future commercialization of any such product could be delayed, limited or prevented, which would materially harm our business and the price of our securities could fall.

To the extent the intellectual property protection of products in any respiratory program partnered with GSK are successfully challenged or encounter problems with the United States Patent and Trademark Office or other comparable agencies throughout the world, the commercialization of these products could be delayed, limited or prevented. Any challenge to the intellectual property protection of a late-stage development asset or approved product arising from any respiratory program partnered with GSK could harm our business and cause the price of our securities to fall.

Our commercial success depends in part on products in any respiratory program partnered with GSK not infringing the patents and proprietary rights of third parties. Third parties may assert that these products are using their proprietary rights without authorization. In addition, third parties may obtain patents in the future and claim that use of GSK's technologies infringes upon these patents. Furthermore, parties making claims against GSK may obtain injunctive or other equitable relief, which could effectively block GSK's ability to further develop or commercialize one or more of the product candidates or products in any respiratory program partnered with GSK.

In the event of a successful claim of infringement against GSK, it 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, GSK may need to obtain licenses from third parties to advance its research or allow commercialization of the products. GSK may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, GSK would be unable to further develop and commercialize one or more of the products, which could harm our business significantly. In addition, in the future GSK could be required to initiate litigation to enforce its proprietary rights against infringement by third parties. Prosecution of these claims to enforce its rights against others would involve substantial litigation expenses. If GSK fails to effectively enforce its proprietary rights related to our partnered respiratory programs against others, our business will be harmed, and the price of our securities could fall.

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

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

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

any adverse developments or results or perceived adverse developments or results with respect to the commercialization of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® with GSK, including, without limitation, if payor coverage is lower than anticipated or if sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® are less than

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anticipated because of pricing pressure in the respiratory markets targeted by our partnered products or existing or future competition in the markets in which they are commercialized, including competition from existing and new products that are perceived as lower cost or more effective, and our royalty payments are less than anticipated;

- Any positive developments or results or perceived positive developments or results with respect to the development of UMEC/VI/FF with GSK, including, without limitation if the new Phase 3 study (or any other closed triple Phase 3 studies that may be initiated in the future) is successful and GSK and the respiratory market in general view this triple combination therapy as significantly more beneficial than existing therapies, including RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®;
  - 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 or does not sufficiently differentiate itself from alternative therapies;
  - any adverse developments or results or perceived adverse developments or results with respect to the development of UMEC/VI with GSK, including, without limitation, any difficulties or delays encountered with regard to the regulatory path for UMEC/VI, any indication from clinical or non-clinical studies that UMEC/VI is not safe or efficacious;
  - any adverse developments or results or perceived adverse developments or results with respect to the MABA program with GSK, including, without limitation, any further delays encountered in progressing '081 and/or '081/FF or a decision by GSK to halt the program or any further development of certain drug candidates in the program, any difficulties or delays encountered with regard to the regulatory path for '081, either alone or in combination with other therapeutically active ingredients, or any indication from non-clinical studies of '081 that the compound is not safe or efficacious;
  - any adverse developments or results or perceived adverse developments or results with respect to the sNDA submitted to the FDA for a fixed dose combination of FF/VI as a once-daily treatment for asthma in patients aged 12 years and older;
  - any adverse developments or perceived adverse developments in the field of LABAs, including any change in FDA policy or guidance (such as
    the pronouncement in February 2010 warning that LABAs should not be used alone in the treatment of asthma and related labeling
    requirements, the impact of the March 2010 FDA Advisory Committee discussing LABA clinical trial design to evaluate serious asthma
    outcomes or the FDA's April 2011 announcement that manufacturers of currently marketed LABAs conduct additional clinical studies
    comparing the addition of LABAs to inhaled corticosteroids versus inhaled corticosteroids alone);
  - GSK's decisions whether or not to purchase, on a quarterly basis, sufficient shares of our common stock to maintain its ownership percentage taking into account our preceding quarter's option exercise, equity vesting and debt conversion activity;
  - the occurrence of a fundamental change triggering a put right of the holders of the Notes or our inability, or perceived inability, to satisfy the obligations under the Notes when they become due;
  - · 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;
- announcements regarding GSK generally;
- · announcements of patent issuances or denials, technological innovations or new commercial products by GSK;
- · publicity regarding actual or potential study results or the outcome of regulatory review relating to products under development by GSK;
- · regulatory developments in the United States and foreign countries;
- · economic and other external factors beyond our control;
- sales of stock by us or by our stockholders, including sales by certain of our employees and directors whether or not pursuant to selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934;
- · relative illiquidity in the public market for our common stock (our three largest stockholders other than GSK collectively owned approximately 35.8% of our outstanding capital stock as of July 31, 2014 based on our review of publicly available filings);

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- $\cdot$  any adverse developments or perceived adverse developments with respect to the 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 July 31, 2014, GSK beneficially owned approximately 26.6% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 3.6% of our outstanding capital stock. Based on our review of publicly available filings as of July 31, 2014, our three largest stockholders other than GSK collectively owned approximately 35.8% 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 May 9, 2014, we completed the sale of 317,770 shares of our common stock to Glaxo Group Limited, an affiliate of GSK, at a price of \$26.89 per share, resulting in aggregate gross proceeds of \$8.5 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.

#### **Item 3. Defaults Upon Senior Securities**

None

#### **Item 4. Mine Safety Disclosures**

None

#### **Item 5. Other Information**

None

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#### Item 6. Exhibits.

#### (a) Index to Exhibits

Exhibit			Incorporated by Reference Filing Date/Period
Number 3.3	Description Amended and Restated Certificate of Incorporation	Form S-1	End Date 7/26/04
5.5	Amended and Restated Certificate of incorporation	3-1	7/20/04
3.4	Certificate of Amendment of Restated Certificate of Incorporation	10-Q	3/31/07
3.5	Amended and Restated Bylaws (as amended by the board of directors April 25, 2007)	10-Q	9/30/08
4.1	Specimen certificate representing the common stock of the registrant	10-K	12/31/06
4.2	Amended and Restated Rights Agreement between Theravance, Inc. and The Bank of New York, as Rights Agent, dated as of June 22, 2007	10-Q	6/30/07
4.3	Amendment to Amended and Restated Rights Agreement between the registrant and The Bank of New York Mellon Corporation, as Rights Agent, dated November 21, 2008	8-K	11/25/08
4.4	Indenture dated as of January 24, 2013 by and between Theravance, Inc. and The Bank of New York Mellon Trust Company, N.A., as trustee	8-K	1/25/13
4.5	Form of 2.125% Convertible Subordinated Note Due 2023 (included in Exhibit 4.4)		
10.1	Collaboration Agreement between the registrant and Glaxo Group Limited, dated as of November 14, 2002		
10.2+	Equity Award Amendments for Employees VP Level or above remaining at Theravance, Inc.		
10.3+	Policy for Non-Employee Director Stock Options (effective June 2, 2014)		
10.4+	Offer Letter with Ted Witek dated May 2, 2014		
10.5+	Offer Letter with George Abercrombie dated May 30, 2014		
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended		
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended		
32	Certifications Pursuant to 18 U.S.C. Section 1350		
101	Financial statements from the quarterly report on Form 10-Q of the Company for the three months and six months ended June 30, 2014, formatted in XBRL: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Comprehensive Loss, (iv) the Condensed Consolidated Statements of Cash Flows and (iv) the Notes to the Condensed Consolidated Financial Statements		

<sup>+</sup> Management contract or compensatory plan or arrangement.

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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.

Date: August 7, 2014 /s/ Rick E Winningham

Rick E Winningham
Chief Executive Officer

Date: August 7, 2014 /s/ Michael W. Aguiar

Michael W. Aguiar

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#### COLLABORATION AGREEMENT

by and between

#### THERAVANCE, INC.

and

#### GLAXO GROUP LIMITED

Dated: November 14, 2002

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#### **COLLABORATION AGREEMENT**

This COLLABORATION AGREEMENT ("Agreement") dated November 14, 2002, is made by and between THERAVANCE, INC., a Delaware corporation, and having its principal office at 901 Gateway Boulevard, South San Francisco, California 94080 ("Theravance"), and GLAXO GROUP LIMITED, a United Kingdom corporation, and having its principal office at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB6 0NN, United Kingdom ("GSK"). Theravance and GSK may be referred to as a "Party" or together, the "Parties".

#### **RECITALS**

WHEREAS, Theravance is currently developing Long-Acting  $\beta$ 2 Adrenoceptor Agonists such as but not limited to TD-3327 and AMI-15471 for the treatment and/or prophylaxis of asthma and other respiratory diseases;

WHEREAS, GSK is also currently developing Long-Acting β2 Adrenoceptor Agonists such as but not limited to GW 597901, GW 678007, GW 642444 and GW 774419, as well as other anti-inflammatory compounds, for the treatment and/or prophylaxis of respiratory disease;

WHEREAS, GSK and Theravance desire to pool certain of their respective development compounds on an exclusive, worldwide basis to commercialize at least one Long-Acting  $\beta$ 2 Adrenoceptor Agonist that can be used as a single agent and/or in combination with a Long-Acting Inhaled Corticosteroid and potentially other compounds for treatment and/or prophylaxis of respiratory disease;

WHEREAS, GSK and Theravance are willing to undertake research and development activities and investment and to coordinate such activities and investment as provided by this Agreement with respect to the Collaboration Products; and

WHEREAS, GSK and Theravance believe that a collaboration pursuant to this Agreement for the development and commercialization of Collaboration Products 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 GSK, intending to be legally bound, hereby agree as follows:

## ARTICLE 1 DEFINITIONS

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

- 1.1 "AMI-15471" means the Long-Acting  $\beta 2$  Adrenoceptor Agonist designated as such by Theravance and all pharmaceutically acceptable salts and solvates thereof.
- 1.2 "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.
- 1.3 "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.
- 1.4 "API Compound" means bulk quantities of active pharmaceutical ingredient compound prior to the commencement of secondary manufacturing resulting in a Collaboration Product.
  - 1.5 "Breaching Party" shall have the meaning set forth in Section 14.2.
- 1.6 "Business Day" means any day on which banking institutions in both New York City, New York, United States and London, England are open for business.
  - 1.7 "Calendar Month" means for each Calendar Year, each of the one-month periods.
- 1.8 "Calendar Quarter" means for each Calendar Year, each of the 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.
- 1.9 "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 "Change in Control" means, with respect to a Party, any transaction or series of related transactions following which continuing stockholders of such Party hold less than 50% of the outstanding voting securities of either such Party or the entity surviving such transaction.
  - 1.11 "Claim" means all charges, complaints, actions, suits, proceedings, hearings, investigations, claims and demands.

"Collaboration Product" shall also include any formulation of excipients, stabilizers, propellants, or other components necessary to prepare and deliver a pharmaceutically effective dose of the Pooled Compound and any other therapeutically active component together with any delivery device.

- 1.13 "Commercial Conflict" means a situation where Theravance determines that GSK's decision related to Development or Commercialization of a Collaboration Product is likely to result in a materially reduced financial return to Theravance from such Collaboration Product, and that such decision is not based on the technical profile of the Collaboration Product but primarily on commercial factors whereby GSK is likely to achieve an increased financial return from a Competing Product owned by GSK.
- 1.14 "Commercial Failure" means failure of a Collaboration Product for reasons other than Technical Failure, based on the determination that such product will result in a net present value that is materially worse than the net present value for GSK's other prescription pharmaceutical products, based on GSK's normal and customary procedures for determining net present value for its own portfolio products. The net present value of a Collaboration Product will be based on forecasted cash flow from such product not taking into account the cannibalization of sales or profit from any other GSK product.
- 1.15 "Commercialization" means any and all activities directed to marketing, promoting, distributing, offering for sale and selling a Collaboration Product, importing a Collaboration Product (to the extent applicable) and conducting Phase IV Studies. When used as a verb, "Commercialize" means to engage in Commercialization.
  - 1.16 "Competing Product" means a product that is intended for the treatment and/or prophylaxis of respiratory diseases.
- 1.17 "Confidential Information" means all secret, confidential or proprietary information, data or Know-How (including GSK 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:
- 1.17.1 were already known to the Receiving Party (other than under an obligation of confidentiality), at the time of disclosure by the Disclosing Party;
  - 1.17.2 were generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;
- 1.17.3 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;

- 1.17.4 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
- 1.17.5 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.
  - 1.18 "Country" means any generally recognized sovereign entity.
- 1.19 "Criteria" means the requirements set forth in Schedule 1.19 that the Replacement Compounds and Theravance New Compounds must meet to become a Pooled Compound. These requirements may be amended after the Effective Date by written agreement of the Parties (such agreement not to be unreasonably withheld by either Party) to take account of any newly established data or knowledge that has or have arisen since the Effective Date that affect or is likely to affect same.
  - 1.20 "Designated Foreign Filing" shall have the meaning set forth in Section 13.1.2(b).
- 1.21 "Development" or "Develop" means preclinical and clinical drug development activities, including, among other things: test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, current Good Manufacturing 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, preclinical and clinical studies, regulatory filing submission and approval, and regulatory affairs related to the foregoing. When used as a verb, "Develop" means to engage in Development.
- 1.22 "Development Expenses" means the cost of all studies or activities performed by or on behalf of GSK or any of its Affiliates pursuant to this Agreement.
  - 1.23 "Development Milestone" shall have the meaning set forth in Section 6.2.1.

- 1.24 "Development Plan" means the outline plan for each Collaboration Product designed to achieve the Development for such Collaboration Product, including, without limitation, the nature, number and schedule of Development activities as well as the estimated resources necessary to implement such activities as such may be amended in accordance with the terms of this Agreement.
- 1.25 "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 resulting from its own research efforts, based on conditions then prevailing and as if there were no Competing Product owned by such Party, with the objective of launching a single agent Collaboration Product and a combination agent Collaboration Product in accordance with the Development principles more specifically outlined in Section 4.2.4. 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.

- 1.26 "Disclosing Party" shall have the meaning set forth in Section 1.17.
- 1.27 "Effective Date" means the first business day following the date on which the last of the conditions contained in Section 16.15 of this Agreement has been satisfied.
  - 1.28 "Exchange Act" shall have the meaning set forth in Section 15.1.1.
  - 1.29 "FDA" means the United States Food and Drug Administration and any successor agency thereto.
- 1.30 "Field" means human pharmaceutical use of Long-Acting  $\beta$ 2 Adrenoceptor Agonists for the treatment and/or prophylaxis of respiratory diseases.
- 1.31 "First Commercial Sale" means the first shipment of commercial quantities of any Collaboration Product sold to a Third Party by a Party or its sublicensees in any Country after receipt of Marketing Authorization Approval for such Collaboration Product in such Country. Sales for test marketing, sampling and promotional uses, clinical trial purposes or compassionate or similar uses shall not be considered to constitute a First Commercial Sale.
  - 1.32 "Force Majeure Event" shall have the meaning set forth in Section 16.3.
- 1.33 "Governmental Authority" means any court, tribunal, arbitrator, agency, legislative body, commission, official or other instrumentality of (i) any government of any Country, (ii) a federal, state, province, county, city or other political subdivision thereof or (iii) any supranational body, including without limitation the European Agency for the Evaluation of Medicinal Products.
- 1.34 "GSK Compound" means a GSK Initially Pooled Compound, any Replacement Compound offered up to the collaboration by GSK or a GSK non-LABA Compound utilised by GSK for Development purposes in relation to combination product activity under this Agreement currently owned or subsequently discovered by GSK and/or its predecessors in title or in-licensed from a Third Party by GSK and/or its predecessors in title.
- 1.35 "GSK Initially Pooled Compound" shall mean the chemical entities individually identified as GW 597901, GW 678007, GW 642444 and GW 774419 and all pharmaceutically acceptable salts and solvates thereof.
  - 1.36 "GSK Invention" means an Invention that is invented by an employee or agent of GSK solely or jointly with a Third Party.
- 1.37 "GSK Know-How" means all present and future information directly relating to the Collaboration Products, a GSK Compound or the GSK Inventions, including without limitation all data, records, and regulatory filings relating to Collaboration Products, that is required for Theravance to perform its obligations or exercise it rights under this Agreement, and which during the Term are in GSK's or any of its Affiliates' possession or control and are or become owned by, or otherwise may be licensed to (provided there is no restriction on GSK thereof), GSK. GSK Know-How does not include any GSK Patents.

- 1.38 "GSK non-LABA Compound" means any other compound contributed to the collaboration by GSK pursuant to Section 4.2.1 for the purpose of developing a combination product.
- 1.39 "GSK Patents" means all present and future patents and patent applications including United States provisional applications and any continuations, continuations, registrations, confirmations, revalidations, reissues, Patent Cooperation Treaty applications, certificates of addition, utility models, design patents, petty patents as well as all other intellectual property related to the application or patent including extensions or restorations of terms thereof, pediatric use extensions, supplementary protection certificates or any other such right covering the Pooled Compounds, Collaboration Products, a GSK Compound or the GSK Inventions which are or become owned by GSK or GSK's Affiliates, or as to which GSK or GSK's Affiliates otherwise are or become licensed, now or in the future, where GSK has the right to grant the sublicense rights granted to Theravance under this Agreement, which such patent rights cover the making, having made, use, offer for sale, sale or importation of the Collaboration Products.
  - 1.40 "Hatch-Waxman Certification" shall have the meaning set forth in Section 13.3.
  - 1.41 "Hostile Tender Offer" shall have the meaning set forth in Section 15.2.6.
  - 1.42 "Indemnified Party" shall have the meaning set forth in Section 12.3.1.
  - 1.43 "Indemnifying Party" shall have the meaning set forth in Section 12.3.1.

- 1.44 "Invention" means any discovery (whether patentable or not) invented during the Term as a result of research, Development or manufacturing activities and specifically related to a Pooled Compound or Collaboration Product hereunder.
- 1.45 "Investigational Authorization" means, with respect to a Country, the regulatory authorization required to investigate a Collaboration Product in such Country as granted by the relevant Governmental Authority.
- 1.46 "Joint Invention" means an Invention that is invented jointly by employees and/or agents of both Theravance and GSK hereunder and the patent rights in such Invention.
  - 1.47 "Joint Project Committee" shall have the meaning set forth in Section 3.2.
  - 1.48 "Joint Steering Committee" shall have the meaning set forth in Section 3.1.
- 1.49 "LABA/ICS Combination Product" means a product that contains a Pooled Compound and a Long-Acting Inhaled Corticosteroid for the treatment and/or prophylaxis of respiratory diseases. A LABA/ICS Combination Product shall also be considered a Collaboration Product.
- 1.50 "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; 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), ordinances and other pronouncements having the binding effect of law of any Governmental Authority.

- 1.51 "Litigation Condition" shall have the meaning set forth in Section 12.3.2.
- 1.52 "Long-Acting  $\beta_2$  Adrenoceptor Agonist" or "LABA" means a chemical entity that (i) selectively binds to human  $\beta_2$  adrenoceptors and activates human  $\beta_2$  adrenoceptors at concentrations less than 100 nanomolar and (ii) has significantly longer activity than salmeterol after inhalation dosing as determined in a guinea pig acetylcholine bronchoprotection model or similar animal model.
- 1.53 "Long-Acting Inhaled Corticosteroid" or "ICS" means a corticosteroid that has duration of action of at least 24 hours demonstrated in clinical testing.
- 1.54 "Losses" means any and all damages (including all incidental, consequential, statutory an treble 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.
  - 1.55 "Major Market Country" means each of the United States, Canada, Japan, France, United Kingdom, Italy, Germany and Spain.
- 1.56 "Marketing Authorization" means, with respect to a Country, the regulatory authorization required to market and sell a Collaboration Product in such Country as granted by the relevant Governmental Authority.
- 1.57 "Marketing Authorization Approval" shall mean approval by a Governmental Authority for sale of a Collaboration Product, including any applicable pricing, final labeling or reimbursement approvals.
- 1.58 "Marketing Plan" means for each relevant Collaboration Product the global plan prepared by GSK identifying the core strategic, commercial and promotional claims and objectives for the specific Collaboration Product as reviewed and approved under Section 5.1.1.
- 1.59 "NDA" means a new drug application or supplemental new drug application or any amendments thereto submitted to the FDA in the United States.
- 1.60 "NDA Acceptance" shall mean the written notification by the FDA that the NDA has met all the criteria for filing acceptance pursuant to 21 C.F.R.(S)314.101.
- 1.61 "Net Sales" means the gross sales price of a Collaboration Product sold by GSK, 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 such as Medicare or Medicaid provided in the United States or any similar organization elsewhere in the world; and

- (c) credits and allowances for product returns actually made. Net Sales shall exclude Samples distributed in the usual course of business.
  - 1.62 "Net Sales Report" shall have the meaning set forth in Section 6.4.2.
  - 1.63 "Officers" shall have the meaning set forth in Section 3.1.5(b).
- 1.64 "Other Combination Product" means any product developed pursuant to this Agreement for the treatment and/or prophylaxis of respiratory disease that contains a Long-Acting  $\beta_2$  Adrenoceptor Agonist and another active agent which is a GSK Compound other than a Long-Acting Inhaled

- 1.65 "Patent Infringement Claim" shall have the meaning set forth in Section 13.2.1.
- 1.66 "Patent Infringement Notice" shall have the meaning set forth in Section 13.2.2.
- 1.67 "Person" means any natural person, corporation, general partnership, limited partnership, limited liability company, joint venture, proprietorship or other business organization.
- 1.68 "Phase I Studies" means that portion of the Development Plan or Development relating to each Collaboration Product which provides for the first introduction into humans of such Collaboration Product including small scale clinical studies conducted in normal volunteers to obtain information on such Collaboration Product's safety, tolerability, pharmacological activity, pharmacokinetics, drug metabolism and mechanism of action, as well as early evidence of effectiveness, as more fully defined in 21 C.F.R. (S) 312.21(a).
- 1.69 "Phase II Studies" means, subject to Section 6.2.2, that portion of the Development Plan or Development relating to each Collaboration Product which provides for well controlled clinical trials of such Collaboration Product in patients, including clinical studies conducted in patients with the condition, and designed to evaluate clinical efficacy and safety for such Collaboration Product for one or more indications, as well as to obtain an indication of the dosage regimen required, as more fully defined in 21 C.F.R. (S) 312.21(b).
- 1.70 "Phase III Studies" means that portion of the Development Plan or Development relating to each Collaboration Product which provides for large scale, pivotal, clinical studies conducted in a sufficient number of patients and whose primary objective is to obtain a definitive evaluation of the therapeutic efficacy and safety of the Collaboration Product in patients for the particular indication in question that is needed to evaluate the overall risk-benefit profile of the Collaboration Product and to provide adequate basis for obtaining requisite regulatory approval(s) and product labeling, as more fully defined in 21 C.F.R. (S) 312.21(c).
- 1.71 "Phase IV Studies" means a study for a Collaboration Product that is initiated after receipt of a Marketing Authorization for a Collaboration Product and is principally intended to support the marketing and Commercialization of such Collaboration Product, including without limitation investigator initiated trials, clinical experience trials and studies conducted to fulfill local commitments made as a condition of any Marketing Authorization.
- 1.72 "Pooled Compounds" means (i) the four Long-Acting Beta-2 Adrenoceptor Agonists provided by GSK as of the Effective Date (identified as GW 597901, GW 678007, GW 642444 and GW 774419), (ii) the two Long-Acting Beta-2 Adrenoceptor Agonists provided by

Theravance as of the Effective Date (identified as TD-3327 and AMI-15471), (iii) the Theravance New Compounds provided by Theravance pursuant to Section 4.1, and any Replacement Compounds provided by Theravance or GSK.

- 1.73 "Product Supplier" means any manufacturer, packager or processor of a Collaboration Product for development, marketing and sale.
- 1.74 "Promotional Materials" means the core written, printed, video or graphic advertising, promotional, educational and communication materials (other than Collaboration Product labeling) for marketing, advertising and promotion of the Collaboration Products.
  - 1.75 "Receiving Party" shall have the meaning set forth in Section 1.17.
- 1.76 "Replacement Compound" means a Long-Acting β2 Adrenoceptor Agonist that meets the Criteria and is provided by Theravance or GSK, as applicable, (and "GSK Replacement Compound" and "Theravance Replacement Compound" shall be interpreted accordingly) after the Effective Date to replace a Pooled Compound for which Development has been discontinued due to Technical Failure.
  - 1.77 "ROW" means Countries other than the Major Market Countries.
  - 1.78 "Samples" means Collaboration Product packaged and distributed as a complimentary trial for use by patients in the Territory.
  - 1.79 "SEC" shall have the meaning set forth in Section 15.1.2.
- 1.80 "Selectively" means the chemical entity binds human  $\beta_2$  adrenoceptors (a) with more than 100 fold greater affinity than it binds other protein targets in the human body as determined by receptor binding, radioligand displacement or functional *in vitro* assays, and (b) more than 5 fold greater than the other human  $\beta$  adrenoceptor subtypes.
- 1.81 "TD-3327" means the Long-Acting  $\beta$ 2 Adrenoceptor Agonist so designated by Theravance and all pharmaceutically acceptable salts and solvates thereof contributed to the collaboration by Theravance.
  - 1.82 "Taxes" shall have the meaning set forth in Section 6.9.1.
- 1.83 "Technical Failure" means the discontinuation of Development of a Collaboration Product for technical, scientific, medical or regulatory reasons, such as but not limited to unacceptable preclinical toxicity, or the inability to demonstrate sufficient Long-Acting  $\beta_2$  Adrenoceptor Agonist effect in humans, or demonstration of a side effect profile significantly worse than currently marketed products, or inability to manufacture API in an acceptable purity or crystalline form, or inability to produce a metered dose inhaler or dry powder inhaler formulation with acceptable aerosol performance and stability.
- 1.84 "Term" means, on a Country-by-Country and Collaboration Product-by-Collaboration Product basis, the period from the Effective Date until the later of (a) the expiration or termination of the last Valid Claim of a Patent Right covering the Pooled Compound in such Collaboration Product in such Country, and (b) fifteen (15) years from First Commercial Sale in such Country, unless this Agreement is terminated earlier in accordance with Article 14.

- 1.85 "Terminated Collaboration Product" shall mean a Terminated Development Collaboration Product or a Terminated Commercialized Collaboration Product.
  - 1.86 "Terminated Commercialized Collaboration Product" shall have the meaning set forth in Section 14.4.
  - 1.87 "Terminated Development Collaboration Product" shall have the meaning set forth in Section 14.3.
  - 1.88 "Territory" means worldwide.
- 1.89 "Theravance Compound" means TD-3327 and AMI-15471, (together the "Theravance Initially Pooled Compounds"), the two Theravance New Compounds and any Replacement Compound that is offered up to the collaboration by Theravance.
- 1.90 "Theravance New Compound" means each of the two chemical entities meeting the Criteria and provided by Theravance to the collaboration as Pooled Compounds after the Effective Date pursuant to Section 4.1.
- 1.91 "Housemark" means the name and logo of GSK or Theravance or any of their respective Affiliates as identified by one Party to the other from time to time.
  - 1.92 "Theravance Invention" means an Invention that is invented by an employee or agent of Theravance solely or jointly with a Third Party.
- 1.93 "Theravance Know-How" means all present and future information directly relating to the Collaboration Products, a Theravance Compound or the Theravance Inventions that is required for GSK to perform its obligations or exercise its rights under this Agreement, 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.
- 1.94 "Theravance Patents" means all present and future patents and patent applications including United States provisional applications and any continuations, continuations, continuations, registrations, confirmations, revalidations, reissues, Patent Cooperation Treaty applications, certificates of addition, utility models, design patents, petty patents as well as all other intellectual property related to the application or patent including extensions or restorations of terms thereof, pediatric use extensions, supplementary protection certificates or any other such right covering the Pooled Compounds, the Collaboration Products, a Theravance Compound or the Theravance Inventions which are or become owned by Theravance or Theravance's Affiliates, or as to which Theravance or Theravance's Affiliates are or become licensed, now or in the future, with the right to grant the sublicense rights granted to GSK under this Agreement, which patent rights cover the making, having made, use, offer for sale, sale or importation of Collaboration Products.
  - 1.95 "Third Party" means a Person who is not a Party or an Affiliate of a Party.
  - 1.96 "Third Party Claim" shall have the meaning set forth in Section 12.3.1.
  - 1.97 "United States" means the United States, its territories and possessions.

- 1.98 "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.
  - $1.99 \qquad \hbox{``Withholding Party'' shall have the meaning set forth in Section 6.9.1.}$

## ARTICLE 2 RIGHTS AND OBLIGATIONS

- 2.1 <u>License Grants from Theravance to GSK.</u>
- 2.1.1 <u>Development License</u>. Subject to the terms of this Agreement, including without limitation Section 2.2, Theravance grants to GSK, and GSK accepts, an exclusive (except as to Theravance and its Affiliates) license in the Field under the Theravance Patents, Theravance Know-How and Theravance's rights in the Joint Inventions to make, have made, use and Develop Collaboration Products for Commercialization in the Territory.
- 2.1.2 <u>Commercialization License</u>. Subject to the terms of this Agreement, including without limitation Section 2.2, Theravance hereby grants to GSK, and GSK accepts, an exclusive license in the Field under the Theravance Patents, Theravance Know-How and Theravance's rights in the Joint Inventions to make, have made use, sell, offer for sale and import Collaboration Products in the Territory.
- 2.1.3 <u>Manufacturing License</u>. Subject to the terms of this Agreement, including without limitation Section 2.2, Theravance grants to GSK an exclusive license in the Field under the Theravance Patents, Theravance Know-How and Theravance's rights in the Joint Inventions to make and have made API Compound or formulated Collaboration Product in the Territory.
- 2.2 <u>Sublicensing and Subcontracting</u>. GSK may sublicense or subcontract its rights to Develop, Manufacture or Commercialize the Collaboration Products 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 GSK. GSK may also sublicense or subcontract any of GSK's rights to Develop or Manufacture the Collaboration Products, in whole or in part, to one or more Third Parties. In the

event GSK wishes to sublicense or subcontract any of GSK's rights to Commercialize the Collaboration Products, in whole or in part, to one or more Third Parties, GSK shall obtain the prior written consent of Theravance, such consent not to be unreasonably withheld, provided always that no such restriction shall apply in respect of those countries of the Territory wherein GSK is or has been required under applicable local laws to appoint a Third Party as its distributor or marketing partner. GSK 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

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comply with all of GSK's covenants and obligations to Theravance under this Agreement. GSK's rights to sublicense, subcontract or otherwise transfer its rights granted under Section 2.1 are limited to those expressly set forth in this Section 2.2.

#### 2.3 <u>Trademarks and Housemarks</u>.

- 2.3.1 <u>Trademarks</u>. The Collaboration Products shall be Commercialized under trademarks (the "Trademarks") and trade dress selected by the Joint Project Committee and approved by the Joint Steering Committee. Prior to any such proposed Trademark(s) being submitted to the Joint Project Committee, GSK shall be responsible for undertaking their preliminary selection. GSK shall exclusively own all Trademarks, and shall be responsible for the procurement, filing and maintenance of trademark registrations for such Trademarks and all costs and expenses related thereto. GSK shall also exclusively own all trade dress and copyrights associated with the Collaboration Products. Nothing herein shall create any ownership rights of Theravance in and to the Trademarks or the copyrights and trade dress associated with the Collaboration Products.
- 2.3.2 <u>Housemarks</u>. 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.
- 2.3.3 Ownership of Inventions. Each Party shall promptly disclose to the other Party all Inventions made by it during the Term; provided that GSK will be allowed a reasonable time to file patent applications covering GSK Inventions prior to disclosing the GSK Invention to Theravance, and Theravance will be allowed a reasonable time to file patent applications covering Theravance Inventions prior to disclosing the Theravance Invention to GSK. Theravance shall own all Theravance Inventions and GSK shall own all GSK Inventions. All Joint Inventions shall be owned jointly by Theravance and GSK, and each Party hereby consents to the assignment or license or other disposition by the other Party of its joint interests in Joint Inventions without the need to seek the consent of the other Party to such assignment or license or other disposition; provided that any such assignment, license or other disposition shall at all times be subject to the grant of rights and accompanying conditions under Sections 2.1 and 2.2 and Article 14. The determination of inventorship for Inventions shall be made in accordance with applicable laws relating to inventorship set forth in the patent laws of the United States (Title 35, United States Code).

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## ARTICLE 3 GOVERNANCE OF DEVELOPMENT AND COMMERCIALIZATION OF PRODUCTS

#### 3.1 <u>Joint Steering Committee</u>.

- 3.1.1 <u>Purpose</u>. 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.
- 3.1.2 Members; Officers. 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 GSK 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. Each of GSK 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 any meeting of the Joint Steering Committee. GSK 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. The Joint Steering Committee shall be chaired on an annual rotating basis by a representative of either Theravance or GSK, as applicable, on the Joint Steering Committee, with Theravance providing the first such chairperson. The chairperson shall appoint a secretary of the Joint Steering Committee, who shall be a representative of the other Party and who shall serve for the same annual term as such chairperson.
  - 3.1.3 <u>Responsibilities</u>. The Joint Steering Committee shall perform the following functions:
  - (a) Manage and oversee the Development and Commercialization of the Collaboration Products pursuant to the terms of this Agreement;
- (b) Review and approve the Development Plans and the Marketing Plans for Collaboration Products and any material amendments to the Development Plans and Marketing Plans;
  - (c) At each meeting of the Joint Steering Committee, review Net Sales for the year-to-date as available;
  - (d) Review and approve the progress of the Joint Project Committee;
  - (e) Review and approve the Trademarks selected under Section 2.3;

- (f) Review and approve "go/no-go" decisions and other matters referred to the Joint Steering Committee, including, without limitation, the continued Development of a particular Collaboration Product or the inclusion of Replacement Compounds;
  - (g) Life cycle management of, and intellectual property protection for, the Collaboration Products;

- (h) In accordance with the procedures established in Section 3.1.5, resolve disputes, disagreements and deadlocks unresolved by the Joint Project Committee; and
- (i) 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.
- 3.1.4 Meetings. The Joint Steering Committee shall meet in person at least once during every Calendar Year, and more frequently (i) as mutually agreed by the Parties or (ii) as required to resolve disputes, disagreements or deadlocks in the Joint Project Committee, 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. The Joint Steering Committee shall arrange to meet in person or convene otherwise to assess and approve any Development Plans or Marketing Plans, if any, submitted to the Joint Steering Committee in each Calendar Year so that such plans will be reviewed and approved within thirty (30) days following submission to the Joint Steering Committee. To the extent any such Development Plans or Marketing Plans are not approved and need to be reformulated by the Joint Project Committee, such plans shall be reviewed by the Joint Steering Committee as soon as reasonably practicable after resubmission of same. Meetings of the Joint Steering Committee that are held in person shall alternate between offices of GSK and Theravance, or such other place as the Parties may agree. In addition to the annual face to face meetings the Joint Steering Committee may also be held by means of telecommunications or, video conferences as deemed appropriate by the Parties.

#### 3.1.5 Decision-Making.

- (a) 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 3.1.3. Except as specified in Section 3.1.5(b), 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.
- (b) With respect to any 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 Chairman of R&D of GSK (collectively, the "Officers") for resolution. The Parties accept that the use of the Officers for resolution of any unresolved issues will be on an exceptional basis. In the event that the use of the Officers occurs on more than two occasions in any consecutive twelve (12) month period and such disputes are not related to Commercial Conflict issues, then GSK will from then on retain the final vote within the Joint Steering Committee for all issues other than Commercial Conflict. If the Officers are unable to reach consensus within thirty (30) days after the matter has been referred to them, the final decision on such disputed issue will reside with GSK; provided, however, that if the disputed issue involves a Commercial Conflict, then the final decision will be made by a mutually acceptable Third Party mediator. Either Party can initiate such mediation on 30 days written notice to the other Party. The Parties will use best efforts to agree on a mediator within such 30-day period. Such mediation will occur as promptly as practicable following selection of the mediator and will be held in New York, New York. The decision of the mediator will be final and binding on the Parties; provided that either party shall retain all rights to bring an action against the other for damages and other monetary relief related to or arising out of the issue decided by the mediator.

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#### 3.2 <u>Joint Project Committee</u>.

- 3.2.1 Purpose. The purposes of the Joint Project Committee shall be to manage the Parties' day-to-day activities hereunder.
- 3.2.2 Members; Officers. Within thirty (30) days after the Effective Date, the Parties shall establish a Project Committee (the "Joint Project Committee"), and GSK and Theravance shall designate an equal number of representatives, up to a maximum total of eight (8) members on such Joint Project Committee, with a maximum of four (4) from each Party. Each of GSK and Theravance may replace any or all of its representatives on the Joint Project Committee at any time upon written notice to the other Party. Such representatives shall include individuals who have the relevant experience and expertise for the next twelve months as included in the Development Plan for the Collaboration Products. A Party may designate a substitute to temporarily attend and perform the functions of such Party's designee at any meeting of the Joint Project Committee. GSK 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 Project Committee. The Joint Project Committee shall be chaired by a representative of GSK. The chairperson shall appoint a secretary of the Joint Project Committee, who shall be a representative of Theravance.
  - $3.2.3\ \underline{Responsibilities}.\ The\ Joint\ Project\ Committee\ shall\ perform\ the\ following\ functions:$
  - (a) Review the Development Plans as prepared by GSK;
- (b) On an annual rolling basis beginning within six months of the Effective Date, update and amend any initial Development Plan and review the Development Plan for each Collaboration Product for the following Calendar Year so that it can immediately thereafter submit such proposed Development Plan to the Joint Steering Committee for review and approval;
  - (c) At each meeting of the Joint Project Committee, review the Development strategy for the Collaboration Products in the Territory;
- (d) At each meeting of the Joint Project Committee, review and recommend to the Joint Steering Committee any material amendments or modifications to the Development Plans;
  - (e) Coordinate and monitor regulatory strategy and activities for the Collaboration Products in accordance with Article 8;

- (f) Review and recommend to the Joint Steering Committee "go/no-go" decisions for the Development of Collaboration Products;
  - (g) Review the Marketing Plans where appropriate;
  - (h) Review and recommend to the Joint Steering Committee any material amendments or modifications to the Marketing Plans;

- (j) Discuss the state of the markets for Collaboration Products and opportunities and issues concerning the Commercialization of the Collaboration Products, including consideration of marketing and promotional strategy, marketing research plans, labeling, Collaboration Product positioning and Collaboration Product profile issues;
- (k) At each meeting of the Joint Project Committee, review the status of all Studies conducted on Collaboration Products and any results therefrom;
  - (1) At each meeting of the Joint Project Committee, review Net Sales for the year-to-date, as available; and
- (m) Have such other responsibilities as may be assigned to the Joint Project Committee pursuant to this Agreement or as may be mutually agreed upon by the Parties through the Joint Steering Committee from time to time.
- 3.2.4 Meetings. The Joint Project Committee shall meet at least once during every Calendar Quarter, and more frequently as GSK and Theravance mutually agree 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 Project Committee as a face to face meeting within thirty (30) days after the establishment of the Joint Project Committee. Meetings of the Joint Project Committee that are held in person shall alternate between the offices of GSK and Theravance, or such other place as the Parties may agree and such face to face meetings shall occur no less than twice a year. The remaining meetings may be held by means of telecommunications or video conferences as deemed appropriate. Following Commercialization of a Collaboration Product in the first Major Market, the Joint Project Committee shall meet twice a year with only one annual face to face meeting required.
- 3.2.5 <u>Decision-Making</u>. The Joint Project Committee may make decisions with respect to any subject matter that is subject to the Joint Project Committee's decision-making authority and functions as set forth in Section 3.2.3. All decisions of the Joint Project Committee shall be made by consensus, with the representatives from each Party presenting a unified position on behalf of such Party. If the Joint Project Committee cannot reach consensus within ten (10) Business Days after it has first met and attempted to reach such consensus, the matter shall be referred on the eleventh (11<sup>th</sup>) Business Day to the Joint Steering Committee for resolution.
- 3.3 <u>Minutes of Committee Meetings</u>. Definitive minutes of all committee meetings shall be finalized no later than thirty (30) days after the meeting to which the minutes pertain as follows:
- 3.3.1 <u>Distribution of Minutes</u>. Within ten (10) days after a 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.
- 3.3.2 <u>Review of Minutes</u>. The Party members of each committee shall have ten (10) days after receiving such draft minutes to collect comments thereon and provide them to the secretary of such committee.
- 3.3.3 <u>Discussion of Comments</u>. Upon the expiration of such second ten (10) day period, the Parties shall have an additional ten (10) days to discuss each other's comments and finalize the minutes. The secretary and chairperson(s) of such committee shall each sign and date

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the final minutes. The signature of such chairperson(s) and secretary upon the final minutes shall indicate each Party's assent to the minutes.

- 3.4 <u>Expenses</u>. 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, a committee.
- 3.5 <u>General Guidelines and Initial Coordination Efforts</u>. In all matters related to the 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 realize the economic potential of Collaboration Products. In all matters relating to this Agreement, the Parties shall seek to comply with good pharmaceutical and environmental practices. 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 Development and Commercialization of the Collaboration Products.

## ARTICLE 4 DEVELOPMENT OF PRODUCTS

4.1. <u>Pooling of Compounds</u>. Subject to and consistent with the further Development principles outlined herein, each Party will offer a minimum of four (4) identified LABA compounds to this collaboration, with the intention of commercializing at least one Long-Acting β2 Adrenoceptor Agonist as a single agent and/or as a LABA/ICS Combination Product. Upon commencement of the collaboration pursuant to this Agreement, GSK and Theravance will contribute the following LABA compounds as Pooled Compounds to the collaboration:

For the avoidance of doubt, it is agreed and hereby acknowledged by both Parties that the compounds GW 597901, GW 678007, GW 642444 and GW 774419, TD-3327 and AMI-15471 are hereby accepted as Pooled Compounds.

Theravance will provide two (2) Theravance New Compounds to the collaboration within eighteen (18) months of the Effective Date in order to meet the requirement that Theravance contribute a total of four (4) LABA compounds to the Pooled Compounds. Without prejudice to the foregoing, GSK will endeavor to provide Theravance, upon Theravance's request and at GSK's expense and discretion, such assistance as may be reasonably required by Theravance to achieve this objective, including providing directly or through GSK's vendors, assistance in (i) chemical process development, (ii) salt selection, (iii) pharmaceutical formulation, (iv) toxicological evaluation, and (v) API preparation.

#### 4.2 <u>Obligations for Development</u>.

4.2.1 <u>General</u>; <u>GSK</u>. Under the direction of the Joint Project Committee, specific Pooled Compounds will be identified from time to time and, as applicable, selected for Development as a Collaboration Product. The Joint Project Committee will determine the number and extent of Development of the Pooled Compounds and the criteria to be used for selecting among the eight Pooled Compounds and, subject to the other terms of this Agreement, will endeavor to move one or more such Collaboration Products forward in Development. In

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relation to the foregoing, GSK shall have the overall responsibility for, and use Diligent Efforts in, the performance of all such Development activities which shall include, where applicable, relevant regulatory filings (as contemplated under Article 8) for any such Collaboration Product moved forward in Development. Further, GSK shall use Diligent Efforts to advance such Collaboration Product through Development in accordance with the Go/No-Go checkpoints identified in the then current Development Plan for such Collaboration Product. GSK shall also use Diligent Efforts to contribute at least one ICS and/or other non-LABA compound to the collaboration for the purpose of developing a combination product and Diligent Efforts to develop an optimal inhaled formulation of Collaboration Product in a device which may be either/or a dry powder inhaler formulation and/or a metered dose inhaler formulation of the Collaboration Compound and Development activities of such may continue in parallel.

4.2.2 <u>GSK Funding Responsibility</u>. GSK shall bear all costs and expenses associated with the Development of Collaboration Products for Commercialization including those incurred by Theravance (or to which it has become obligated) after the signature date of this Agreement and which previously have been discussed with and agreed to by GSK and, so far as the aforementioned Theravance costs are concerned, for the avoidance of doubt, the maximum amount shall not exceed U.S. \$2,940,000.

#### 4.2.3 <u>Decisions with Respect to Products</u>.

- (a) GSK shall have the sole discretion with respect to Development decisions for Collaboration Products subject to and in accordance with Sections 3.1.5, 3.2.5, and 4.3.
- (b) Notwithstanding the foregoing, the Parties acknowledge that Theravance is about to initiate a Phase I Study in two parts, on TD-3327. The initiation of this study will be approved via the Joint Project Committee in accordance with all other Development activities. Theravance shall be responsible for the routine monitoring of this study and will transfer remaining clinical development responsibility for TD-3327 to the Joint Project Committee on completion of the TD-3327 Phase Ia and Phase Ib Studies.
- (c) GSK shall provide the Joint Project Committee with an update report within thirty days of (i) the initiation (i.e., first person dosed) of any Study involving a Collaboration Product, and (ii) the last person dosed/last visit in any Study relating to a Collaboration Product. GSK will provide the Joint Project Committee with a reasonably detailed "top line results" report within sixty days following the last person dosed/last visit in any Study involving a Collaboration Product.
- 4.2.4 <u>Development Timelines</u>. It is hereby acknowledged that GSK's strategic objective is to move one or more of the Collaboration Products into Development at the earliest opportunity. GSK will consult with the Joint Project Committee and will share, modify and further develop all applicable Development Plans and timelines in that forum. It is recognised that success can be optimised by pursuing a number of Collaboration Products through various phases of clinical Development up to the point of Technical or Commercial Failure, and/or until the first Collaboration Product for both single agent and combination therapy achieves regulatory agency approval. At a strategic level, GSK is committed to this objective. However, at an operational level it is recognised that internal and external resources will be constrained from time to time, resulting in the need to prioritise individual studies and activities relating to Collaboration Products. GSK will use Diligent Efforts to secure the necessary resource and will keep the Joint Project Committee informed on the progress of individual studies and activities relating to Collaboration Products as part of any changes to Development Plans and timelines.

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The current objective of the Collaboration is to achieve Marketing Authorization Approval in the US and other Major Markets for a Collaboration Product from one of the eight Pooled Compounds which can be used as a single agent and/or in combination with other therapeutically active components (including but not limited to a Long Acting Inhaled Corticosteroid) for the treatment and/or prophylaxis of one or more respiratory diseases by end 2009 for the single agent and 2010 for the first combination product and Development Plans and timelines will be developed and/or refined in an effort to achieve this objective.

4.3 Replacement Compounds. If within two years after the Effective Date, the Development of Collaboration Products containing any two of the Pooled Compounds contributed by a Party is discontinued due to Technical Failure, it will be the option of the Party who contributed the discontinued compounds to discover and offer up to the collaboration two Replacement Compounds as replacements for the discontinued compounds within twelve months following the discontinuation of the second failed compound. For the avoidance of doubt, any such new compound that satisfies the Criteria will automatically be accepted as a Pooled Compound in place of the relevant Party's discontinued compound, subject to Joint Steering Committee approval pursuant to Section 3.1.3(f). Nothing in the foregoing shall preclude either Party from having the option of offering up a Replacement Compound for a Pooled Compound at any time during the period referred to in Section 14.5 (subject to the Criteria being met and Joint Steering Committee approval pursuant to Section 3.1.3(f)).

- 4.4 <u>Transfer of Data</u>. As soon as practicable but in no event more than thirty (30) days after the Effective Date, the Parties shall determine what data and materials relating to TD-3327 and AMI-15471 are necessary for GSK's Development obligations pursuant to this Article 4, including any technology transfer required for API Compound manufacturing activities contemplated by Article 9, and establish a process for transferring copies of such data and material to GSK (including, to the extent available, in appropriate electronic format) or provide means of access thereto reasonably acceptable to GSK.
  - 4.5 <u>LABA Activity Inside and Outside of the Collaboration.</u>
- 4.5.1 The intent of the Parties in respect of the Pooled Compounds is that such Pooled Compounds remain exclusive to this Collaboration and, subject to Sections 4.5.2 4.5.4 and Article 14 below, no activity in respect of such Pooled Compounds shall be permitted outside of this Agreement.
- 4.5.2 Subject to Article 14 and to Section 4.5.4, if prior to First Commercial Sale of a GSK Initially Pooled Compound or a GSK Replacement Compound, Development of such compound is discontinued under this Agreement ("GSK Discontinued Compound"), all rights in respect of such GSK Discontinued Compound shall revert in full to GSK and such GSK Discontinued Compound shall automatically fall outside of this Agreement except that (i) GSK shall thereafter be prohibited from carrying out any further clinical Development work or clinical activity in respect of such GSK Discontinued Compound inside the Field for at least four (4) years after the termination of this Agreement, and (ii) for the avoidance of doubt, GSK shall pay to Theravance a royalty on Net Sales of any such GSK Discontinued Compound in accordance with Section 14.9.
- 4.5.3 Subject to Article 14 and Section 4.5.4, if prior to First Commercial Sale of a Theravance Compound, Development of such compound is discontinued under this Agreement ("Theravance Discontinued Compound"), all rights in respect of such Theravance Discontinued Compound shall revert in full to Theravance and such Theravance Discontinued Compound shall

automatically fall outside of this Agreement except that (i) Theravance thereafter shall be prohibited from carrying out any further clinical Development work or clinical activity in respect of such Theravance Discontinued Compound inside the Field until after the termination of this Agreement, and (ii) for the avoidance of doubt, Theravance shall pay to GSK a royalty on Net Sales of any such Theravance Discontinued Compound in accordance with Section 14.9.

4.5.4 Notwithstanding Sections 4.5.2 and 4.5.3, for so long as there is one Collaboration Product being Developed under this Agreement, neither Party shall carry out clinical Development inside the Field with any Long Acting B2 Adrenoceptor Agonist that is not a Pooled Compound under this Agreement; provided, however, that this restriction shall not apply to any compound or product (including new product line extensions and/or re-formulation work) where the original compound or product is, as of the date of signature of this Agreement, already Commercialized.

## ARTICLE 5 COMMERCIALIZATION

- 5.1 <u>Global Marketing Plans</u>.
- 5.1.1 <u>General</u>. The Joint Project Committee shall be responsible for reviewing and approving a Global Marketing Plan for each Collaboration Product ("Marketing Plan"). Each Marketing Plan shall define the goals and objectives for Commercializing the Collaboration Products in the pertinent Calendar Year consistent with the applicable Development Plan.
- 5.1.2 <u>Contents of Each Marketing Plan</u>. The Marketing Plan for each Collaboration Product shall be prepared during the Calendar Year wherein, and where applicable, Phase III Studies for such Collaboration Product have commenced and shall be a rolling, three year plan, updated annually and shall contain at a minimum and as appropriate to current knowledge:
- (a) Results of market research and strategy, including market size, dynamics, growth, customer segmentation, customer targeting, competitive analysis and global Collaboration Product positioning;
  - (b) Annual sales forecasts for Major Market Countries;
- (c) For each major Market Country (as available): sales plans which will include target number of sales representatives, detail order and target number of details
  - (d) Core, global advertising and promotion programs and strategies, including literature, media plans, symposia and speaker programs; and
  - (e) Core Phase III/Phase IV Studies to be conducted
  - 5.2 Obligations for Commercialization. GSK shall use Diligent Efforts to Commercialize the Collaboration Products.
  - 5.3 <u>Commercialization</u>.
- 5.3.1 <u>GSK Responsibility</u>. GSK shall have the sole right and responsibility for Commercialization of Collaboration Products for distribution and sale. GSK shall bear all costs

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and expenses associated with the Commercialization of Collaboration Products for sale or distribution.

- (a) GSK shall have the sole right and responsibility to distribute, sell, record sales and collect payments for Collaboration Products.
- (b) GSK shall have the sole right and responsibility for establishing and modifying the terms and conditions with respect to the sale of Collaboration Products, including, without limitation, the price or prices at which the Collaboration Products will be sold, any discount applicable to

payments or receivables, and similar matters.

(c) GSK will be responsible for storage, order receipt, order fulfillment, shipping and invoicing of Collaboration Products.

#### 5.3.2 Semi-Annual Reports.

GSK shall provide the Joint Project Committee reports semi-annually. Such reports shall set forth in summary form the results of GSK's Commercialization activities performed during such semi-annual period in the Major Markets.

5.3.3 <u>Exports to the United States</u>. To the extent permitted by Law, the Parties shall use Diligent Efforts to prevent the Collaboration Products distributed for sale in a particular Country other than the United States from being exported to the United States for sale.

## ARTICLE 6 FINANCIAL PROVISIONS

#### 6.1 <u>Signing Payment; Equity Investment; One-Time Fee</u>.

- 6.1.1 <u>Signing Payment</u>. In partial consideration for the acquisition of license rights under the Theravance Patents and the Theravance Know-How by GSK under this Agreement, GSK shall on the Effective Date, pay to Theravance a non-creditable, non-refundable amount of Ten Million United States Dollars (U.S. \$10,000,000).
- 6.1.2 <u>Stock Purchase</u>. On the Effective Date, GSK will purchase 4,000,000 shares of Theravance Series E Preferred Stock at a price of U.S.\$10.00 per share for total consideration of Forty Million United States Dollars (U.S. \$40,000,000). Such purchase will be made pursuant to the Preferred Stock Purchase Agreement attached hereto as Schedule 6.1.2.
- 6.1.3 One-Time Fee for AMI-15471. Within thirty days following receipt by GSK of Theravance's written notification of the decision by Theravance to nominate AMI-15471 as a "development candidate," and in further partial consideration for the acquisition of license rights under the Theravance Patents and the Theravance Know-How by GSK under this Agreement, GSK shall pay to Theravance a non-creditable, non-refundable amount of Five Million United States Dollars (U.S.\$5,000,000). AMI-15471 will be declared a development candidate when Theravance (a) completes a study demonstrating lack of activity in the hERG assay (as per the Criteria in Schedule 1.19), and (b) establishes AMI-15471 in a stable crystalline form.

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6.1.4 One-Time Fee for Each Theravance New Compound. Within thirty days following the acceptance by the Joint Project Committee or the Joint Steering Committee of each of the two Theravance New Compounds to be contributed to the collaboration pursuant to Section 4.1, and in further partial consideration for the acquisition of license rights under the Theravance Patents and the Theravance Know-How by GSK under this Agreement, GSK shall pay to Theravance a non-creditable, non-refundable amount of Five Million United States Dollars (U.S.\$5,000,000) for each such Theravance New Compound.

#### 6.2 <u>Milestone Payments</u>.

6.2.1 General. In further consideration of the covenants and agreements contained herein, the Parties shall also pay to each other the payments set forth below for each such Development milestone referred to therein (each, a "Development Milestone"); provided always that each such payment shall be made only one time for each Collaboration Product regardless of how many times such Development Milestones are achieved for such Collaboration Product, and no payment shall be owed for a Development Milestone which is not reached (except that, upon achievement of a Development Milestone for a particular Collaboration Product, any previous Development Milestone for that Collaboration Product for which payment was not made shall be deemed achieved and payment therefore shall be made); provided further that, in the event that more than one Development Milestone is achieved with respect to the same Collaboration Product at one time, then all applicable payments under Section 6.2 shall be made. For example, if TD-3327 as a single-agent Collaboration Product and a LABA/ICS Combination Product that contains TD-3327 are approved in the same Marketing Authorization Approval, then in addition to the relevant milestone for the single-agent TD-3327 Collaboration Product, the relevant milestone for the LABA/ICS Combination Product shall be paid simultaneously. In the event of termination of development of a particular Collaboration Product and an alternative Collaboration Product replaces such Terminated Collaboration Product then milestone payments for such replacement compound shall not be paid in respect of milestones already achieved by the Terminated Collaboration Product. For example, if development of TD-3327 is terminated and TD-3327 is replaced by a another Collaboration Product which contains a Theravance compound, milestone payments for such replacement compound will only commence for milestones achieved that have not already been achieved by TD-3327.

 $6.2.2~\underline{GSK}$  to Theravance. GSK shall make the following milestone payments to Theravance upon the achievement of the indicated Development Milestone for the first Collaboration Product in which the Long-Acting  $\beta 2$  Adrenoceptor Agonist is a Theravance Compound, and for the first LABA/ICS Combination Product in which the Long-Acting  $\beta 2$  Adrenoceptor Agonist is a Theravance Compound:

Milestone	Amount	
Initiation of Phase I *	U.S.\$10 Million	
Initiation of Phase IIa**	U.S.\$10 Million	
Initiation of Phase IIb**	U.S.\$5 Million	
Initiation of Phase III	U.S.\$25 Million	
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Milestone	Amount

<u>Registration</u>	
U.S.	U.S.\$30 Million
Europe	U.S.\$15 Million
Japan	U.S.\$10 Million
<u>Launch</u>	
U.S.	U.S.\$30 Million
Europe	U.S.\$15 Million
Japan	U.S.\$10 Million
Annual Worldwide Net Sales over	U.S.\$10 Million per year for first five years for single agent
U.S.\$500 Million for single agent	Collaboration Product
Collaboration Product	
Annual Worldwide Net Sales over	U.S.\$20 Million per year for first five years for LABA/ICS
U.S.\$500 Million for LABA/ICS	Combination Product
Combination Product	

<sup>\*</sup> GSK will make a Phase I milestone payment for both TD-3327 and AMI-15471. The Phase I milestone for TD-3327 is defined as initiation of the methacholine challenge portion of the Phase I Study in normal volunteers and will trigger a payment of U.S. \$10 Million. The Phase I milestone for AMI-15471 is defined as initiation of the first Phase I Study in normal volunteers and will trigger a payment of U.S. \$10 Million.

Other Combination Products that contain a Long-Acting  $\beta 2$  Adrenoceptor Agonist that is a Theravance Compound are not subject to milestone payments by GSK <u>only</u> if all milestone payments through launch have otherwise been made to Theravance from any Collaboration Product as both a single-agent and as a combination product. The Parties intend that if the collaboration is successful in launching at least two Collaboration Products that contain a Theravance Compound, Theravance be paid the applicable milestones through launch for two products.

If GSK, either individually or as a member of the Joint Steering Committee or Joint Project Committee, discontinues the Development of a single agent Collaboration Product that is a Theravance Compound for reasons other than Technical Failure, and such compound is the LABA in a LABA/ICS Combination Product or in an Other Combination Product, it will compensate Theravance for the unpaid milestone payments otherwise due to Theravance under Section 6.2.2 by adding the unpaid milestone amounts for such discontinued single agent product onto the corresponding milestone payments for the relevant Combination Product.

 $6.2.3 \, \underline{\text{Theravance to GSK}}$ . Theravance shall make the following milestone payments to GSK upon the achievement of the indicated Development Milestone for the first Collaboration Product in which the Long-Acting  $\beta 2$  Adrenoceptor Agonist is a GSK Compound

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and for the first LABA/ICS Combination Product in which the Long-Acting  $\beta 2$  Adrenoceptor Agonist is a GSK Compound:

Milestone	Amount
<u>Registration</u>	
US	U.S.\$30 Million
Europe	U.S.\$15 Million
Japan	U.S.\$10 Million
<u>Launch</u>	
US	U.S.\$30 Million
Europe	U.S.\$15 Million
Japan	U.S.\$10 Million
Japan	U.S.\$10 Million

Other Combination Products that contain a Long-Acting  $\beta 2$  Adrenoceptor Agonist that is a GSK Compound are not subject to milestone payments by Theravance <u>only</u> if all milestone payments through launch have otherwise been made to GSK from any Collaboration Product as both a single-agent and as a combination product. The Parties intend that if the collaboration is successful in launching at least two Collaboration Products that contain a GSK Compound, GSK be paid the applicable milestones through launch for two products.

6.2.4 <u>Notification and Payment</u>. In the event a Party achieves a Development Milestone, such Party shall promptly, but in no event more than ten (10) days after the achievement of each such Development Milestone, notify the other Party in writing of the achievement of same. For all Development Milestones achieved, each Party shall promptly, but in no event more than thirty (30) days after notification of the achievement of each such Development Milestone, remit payment to the other Party for such Development Milestone.

#### 6.3 <u>Payment of Royalties on Net Sales.</u>

6.3.1 Royalty on Single-Agent Collaboration Products and LABA/ICS Combination Products.

Within twenty (20) days after the end of each Calendar Quarter , GSK shall pay Theravance royalty payments based on Net Sales in such Calendar Quarter during the Term as follows:

<sup>\*\*</sup>Phase IIa is defined as initiation of the first single dose study in patients where such study is statistically powered for efficacy based on FEV<sub>1</sub>. Phase IIb is defined as initiation of the first four (4) week dosing, safety and efficacy study in patients.

it being understood that Net Sales of a single agent Collaboration Product will be combined with Net Sales of a LABA/ICS Combination Product for purposes of the foregoing royalty calculation.

The quarterly royalty payments made under this Section 6.3.1 may be based on estimated Net Sales. Within thirty (30) days after the end of each Calendar Quarter, GSK shall calculate the actual amount of Net Sales for the previous Calendar Quarter and either credit or debit the difference between such actual and projected amount on the succeeding Calendar Quarter's royalty payment to Theravance. As soon as practical following the end of each Calendar Month, but in no event later than the 10<sup>th</sup> business day of the following month, GSK will provide Theravance with an estimate of Net Sales for such Calendar Month.

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The royalties payable under this Section 6.3 shall be paid on a Country-by-Country basis from the date of first commercial sale of each Collaboration Product in a particular Country for the Term of the Collaboration.

6.3.2 <u>Royalty Adjustment.</u> The 15% royalty payable on the first U.S. \$3 Billion of total annual worldwide Net Sales under this Section 6.3 shall be reduced to 12% if all of the following occur: (i) all Theravance Compounds are discontinued by the collaboration for Technical Failure; (ii) Theravance only contributes one Theravance New Compound to the collaboration within 18 months following the Effective Date; and (iii) the Collaboration Product upon which the royalty is payable contains a LABA that is one of the GSK Initially Pooled Compounds. The 15% royalty payable on the first U.S. \$3 Billion of total annual worldwide Net Sales under this Section 6.3 shall be reduced to 10% if all of the following occur: (i) all Theravance Compounds are discontinued by the collaboration for Technical Failure; (ii) Theravance fails to contribute any Theravance New Compound to the collaboration within 18 months following the Effective Date; and (iii) the Collaboration Product upon which the royalty is payable contains a LABA that is one of the GSK Initially Pooled Compounds. Nothing in the foregoing shall affect other royalties owed under this Agreement.

6.3.3 <u>Royalties on Other Collaboration Products Launched After the LABA/ICS Combination Product</u>. For any Other Collaboration Product launched after the LABA/ICS Combination Product, GSK shall within twenty (20) days after the end of each Calendar Quarter, pay Theravance royalty payments based on Net Sales in such Calendar Quarter during the Term as follows:

Annual Net Sales	Percentage Royalty
Up to U.S.\$750 Million	6.5%
_	
Additional Net Sales up to U.S.\$1.25 Billion	8.0%
<u>.</u>	
Additional Net Sales up to U.S.\$2.25 Billion	9.0%
·	
Net Sales exceeding U.S.\$2.25 Billion	10.0%

For the avoidance of doubt, the Parties agree that the royalty set forth in this Section 6.3.3 shall only be effective if GSK has launched and is selling a LABA/ICS Combination Product that is subject to the royalties under Section 6.3.1. If GSK is not selling a LABA/ICS Combination Product, then the royalty set forth in Section 6.3.1 shall apply to the first Other Combination Product launched by GSK, provided such Other Combination Product does not contain a product in-licensed by GSK; if such Other Combination Product contains a product in-licensed by GSK, then the royalty payable to Theravance will be reduced by 50% of any running royalties paid to a Third Party, provided that in no case will the royalty payable to Theravance be less than set forth in this Section 6.3.3.

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#### 6.4 Royalty Responsibilities; Net Sales Reports.

#### 6.4.1 Payments to Third Parties.

(a) If, as a result of a settlement approved by both Parties or as a result of a final non-appealable judgment, GSK is required to pay any amounts to a Third Party directly because using or selling a Theravance Compound is found to infringe the rights of such Third Party, GSK shall deduct fifty percent (50%) of any such amount paid to such Third Party from the royalties otherwise due Theravance for the Collaboration Product containing such Theravance Compound, provided in no event shall such reduction reduce the royalties otherwise payable to Theravance during any Calendar Year by more than fifty percent (50%); provided, further, that any excess deduction shall be carried over into subsequent years of this Agreement until the full deduction is taken.

(b) GSK shall pay any amounts owed to a Third Party as a result of the use of GSK Patents or GSK Know-How with respect to sales of Collaboration Products and shall not deduct any of such amounts from the royalties due Theravance. The foregoing is subject to Section 6.3.3.

6.4.2 Net Sales Report. Within thirty (30) days after the end of each Calendar Quarter, GSK shall submit to Theravance a written report setting forth Net Sales in the Territory on a Country-by-Country and Collaboration Product-by-Collaboration Product basis during such Calendar Quarter, total royalty payments due Theravance, relevant market share data and any payments made to any Third Party pursuant to Section 6.4.1(a) (each a "Net Sales Report").

6.5 <u>GAAP</u>. All financial terms and standards defined or used in this Agreement for sales or activities occurring in the United States shall be governed by and determined in accordance with United States generally accepted accounting principles, consistently applied. Except as otherwise set forth herein, all financial terms and standards defined or used in this Agreement for sales or activities occurring outside the United States shall be governed by and determined in accordance with United Kingdom generally accepted accounting principles, consistently applied.

- Currencies. Monetary conversion from the currency of a foreign country in which Collaboration Product is sold into US Dollars shall be calculated in accordance with either (a) the methodology referred to in GSK's then current Corporate Finance Reporting Policy or (b) as otherwise may be mutually agreed by the Parties. The following summarizes GSK's current methodology applied in accordance with its current Corporate Finance Reporting System: the cumulative year-to-date Average Rates are calculated by determining the average of (i) the preceding 31st December Spot Rate plus (ii) the Closing Spot Rates of the relevant months to date using the exact figures provided by the Reuters 2000 download. (By way of example, the Average Rate for the five months from January, 2002 to May, 2002 would be computed by taking the sum of the Spot Rates for the preceding 31st December, 2001, plus the month-end Spot Rates for the five months to May, 2002, divided by six).
- 6.7 <u>Manner of Payments</u>. All sums due to either Party under this Section 6 shall be payable in United States Dollars by bank wire transfer in immediately available funds to such bank account(s) as each of GSK and Theravance shall designate. GSK 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. Theravance shall notify GSK as to the date and amount of any such wire transfer to GSK at least five (5) Business Days prior to such transfer.

6.8 <u>Interest on Late Payments</u>. If either Theravance or GSK shall fail to make a timely payment pursuant to this Article 6, 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 law, 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.

#### 6.9 <u>Tax Withholding.</u>

6.9.1 Any taxes, levies or other duties ("Taxes") paid or required to be withheld under the appropriate local tax laws by one of the Parties ("Withholding Party") on account of monies payable to the other Party under this Agreement shall, subject to Sections 6.9.2 and 6.9.3, be deducted from the amount of monies otherwise payable to the other Party under this Agreement. The Withholding Party shall secure and send to the other Party within a reasonable period of time proof of any such Taxes paid or required to be withheld by Withholding Party for the benefit of the other Party.

6.9.2 If GSK or any GSK Affiliate is or becomes liable to withhold any taxes from payments made to Theravance under Sections 6.1 and 6.2 of this Agreement, then GSK shall pay to Theravance an amount equal to the amount GSK or the applicable GSK Affiliate owes to the relevant tax authority provided always that if Theravance is able to obtain credit for any taxes withheld ("Creditable Taxes") against any liability to tax either in the year in which the receipt is taxable or any preceding years, Theravance shall reimburse to GSK an amount equivalent to the Creditable Taxes. Theravance shall provide GSK with such reasonable evidence as GSK may reasonably request to determine whether the taxes are creditable against taxes payable by Theravance.

6.9.3 If GSK or any GSK Affiliate is or becomes liable to withhold any taxes from payments made to Theravance under Section 6.3, then such taxes may be withheld by GSK or the applicable GSK Affiliate up to a limit of five percent (5%) of the relevant payment. GSK shall pay to Theravance an amount equal to the amount GSK owes to the relevant tax authority in excess of such five percent (5%) provided always that if Theravance is able to obtain credit for any taxes withheld ("Creditable Taxes") against any liability to tax either in the year in which the receipt is taxable or any preceding years, Theravance shall reimburse to GSK an amount equivalent to the Creditable Taxes. Theravance shall provide GSK with such reasonable evidence as GSK may reasonably request to determine whether the taxes are creditable against taxes payable by Theravance.

6.10 <u>Financial Records; Audits.</u> GSK shall keep, and shall cause its Affiliates and sublicensees 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 GSK or any of its Affiliates or sublicensees (in such capacity, the "Recording Party") for at least the three preceding Calendar Years to which the Net Sales relate. 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

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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 its 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 6.8, 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 6 shall be retained by the relevant Party during the Term.

## ARTICLE 7 PROMOTIONAL MATERIALS AND SAMPLES

#### 7.1 <u>Promotional Materials</u>.

7.1.1 <u>Review of Core Promotional Materials</u>. Subject to applicable Law, in accordance with the direction of the Joint Project Committee, the Parties will jointly, through consultation and with the assistance of each other, review the core Promotional Materials. The relevant legal or regulatory

personnel of each Party shall have the opportunity to review and comment on all such core Promotional Materials prior to use and such comments shall be considered by the Joint Project Committee in the review of such core Promotional Materials.

- 7.1.2 <u>Markings of Promotional Materials</u>. To the extent required by applicable Law, and further to the extent reasonably practicable, all Promotional Materials will indicate the contribution of the license from Theravance for the Collaboration Products. Subject to the foregoing, the Theravance Housemark and the GSK Housemark shall both be given exposure and prominence on all promotional materials, labelling, package inserts or outserts and packaging for the Collaboration Products.
- 5.2 Samples. Packaging, package inserts and outserts, Sample labels and labeling shall each contain reference to Theravance and GSK indicating, in the case of Theravance, the contribution of the license from Theravance for the Collaboration Products, if appropriate, and as may be required under applicable FDA rules and regulations.
- 7.3 <u>Statements Consistent with Labeling</u>. GSK shall ensure that its sales representatives detail the Collaboration Products in a fair and balanced manner and consistent with the requirements of the Federal Food, Drug and Cosmetic Act of the United States, as amended, including, but not limited to, the regulations at 21 C.F.R. (S) 202 in the United States.
- 7.4 <u>Implications of Change in Control in Theravance.</u> In the event that there is a Change in Control of Theravance and the references contemplated in Sections 7.1.2 and 7.2 are no longer made to "Theravance,", then other than to the extent required by applicable Law, GSK

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shall have the right, not to be unreasonably exercised, to terminate its obligations under Sections 7.1 and 7.2.

## ARTICLE 8 REGULATORY MATTERS

- 8.1 <u>Governmental Authorities</u>. GSK shall be solely responsible for communicating with Governmental Authorities and will keep Theravance informed, through the Joint Project Committee and Joint Steering Committee, of any significant issue or issues arising therefrom.
- 8.2 <u>Filings.</u> GSK shall also be solely responsible for filing drug approval applications for Collaboration Products and will use Diligent Efforts in seeking appropriate approvals in those Countries of the Territory for Collaboration Products as GSK reasonably determines and sees fit. Such regulatory documents for each filing shall be centralized and held at the offices of GSK. Theravance shall provide such reasonable assistance as may be required by GSK where liaison between the Parties is, or may be, necessary to enable GSK to fulfill its responsibilities hereunder. GSK shall be responsible for maintaining the Approvals obtained under this Section and shall solely own all such Approvals in the Territory. GSK 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 Approvals and fees payable to regulatory agencies in obtaining and maintaining same.
- 8.3 Exchange of Drug Safety Information. Subject to the second sentence of this Section 8.3, GSK shall be responsible for recording, investigating, summarizing, notifying, reporting and reviewing all Adverse Drug Experiences in accordance with Law and shall require that its Affiliates (i) adhere to all requirements of applicable Laws which relate to the reporting and investigation of Adverse Drug Experiences, and (ii) keep the Joint Project Committee apprised on a regular basis of such matters arising therefrom. The foregoing shall be subject to any of Theravance's own clinical safety obligations mandated by Law as a result of its ongoing Development activity related to TD-3327 (as such activity is more specifically referred to in Article 4) and, in acknowledgement of this, it is thereby contemplated that the Parties' respective clinical safety groups may need to discuss and agree, at the appropriate time after the Effective Date, appropriate safety data exchange procedures related to same.
- 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. GSK shall promptly notify Theravance of any material actions to be taken by GSK with respect to any recall or market withdrawal or other corrective action related to a Collaboration Product prior to such action to permit Theravance a reasonable opportunity to consult with GSK with respect thereto. All costs and expenses with respect to a recall, market withdrawal or other corrective action was due solely to the negligence, willful misconduct or breach of this Agreement by Theravance. GSK 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 Collaboration Products.
- 8.5 <u>Events Affecting Integrity or Reputation</u>. During the Term, 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 Collaboration Products or if a Party is threatened by the

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unlawful activity of any Third Party in relation to the Collaboration Products, which circumstances shall include, by way of illustration, deliberate tampering with or contamination of the Collaboration Products by any Third Party as a means of extorting payment from the Parties or another Third Party. In any such circumstances, the Parties shall use Diligent Efforts to limit any damage to the Parties and/or to the Collaboration Products. The Parties shall promptly call a Joint Steering Committee meeting to discuss and resolve such circumstances.

## ARTICLE 9 ORDERS; SUPPLY AND RETURNS

9.1 Orders and Terms of Sale. Except as otherwise expressly stated in this Agreement, GSK shall have the sole right to (i) receive, accept and fill orders for the Collaboration Products, (ii) control invoicing, order processing and collection of accounts receivable for the Collaboration Products sales, (iii) record the Collaboration Products sales in its books of account, and (iv) establish and modify the commercial terms and conditions with respect to the sale and distribution of the Collaboration Products, including without limitation matters such as the price at which the Collaboration Products will be sold and whether any discounts, rebates or other deductions should be made, paid or allowed.

- 9.2 Supply of API Compound and Formulated Collaboration Product for Development.
- 9.2.1 <u>Supply of API Compound for Development</u>. Subject to the terms and conditions of this Agreement, GSK shall conduct or have conducted any chemical process development required to develop a commercially acceptable process for making API Compound and obtain supply for worldwide requirements of API Compound. Notwithstanding the foregoing, Theravance may transfer to GSK, at cost, whatever supply it has on hand of TD-3327 API and/or AMI-15471 API and/or intermediate materials for API manufacture, within specification as of the Effective Date, such cost not to exceed U.S. \$1,230,000. API Compound requirements for Development activities shall be set forth in the relevant Development Plan and shall be periodically updated by the Joint Project Committee.
- 9.2.2 <u>Supply of Formulated Collaboration Products for Development</u>. Subject to the terms and conditions of this Agreement, GSK shall obtain supply for worldwide requirements of formulated Collaboration Products. Notwithstanding the foregoing, Theravance agrees to transfer to GSK whatever supply it has on hand of formulated TD-3327, within specification, at cost as of the Effective Date, such cost not to exceed U.S. \$175,000. Formulated Collaboration Product requirements for Development activities shall be set forth in the relevant Development Plan and shall be periodically updated by the Joint Project Committee.
- 9.3 <u>Supply of API Compound for Commercial Requirements</u>. Subject to the terms and conditions of this Agreement, GSK shall obtain supply of API Compound. A forecast for API Compound requirements for Commercialization of the Collaboration Products shall be prepared and periodically updated by the Joint Project Committee and coordinated with the applicable Marketing Plans for Collaboration Products.
- 9.4 <u>Supply of Collaboration Products for Commercialization</u>. Subject to the terms and conditions of this Agreement, GSK shall obtain supply of the commercial requirements of formulated, packaged and labeled Collaboration Products. Such formulated, packaged and labeled Collaboration Products shall be manufactured and supplied in accordance with all

applicable Laws and current Good Manufacturing Practices. GSK shall be solely responsible for secondary manufacture, packaging and labeling of the Collaboration Product.

9.5 <u>Inventories</u>. GSK and its Product Suppliers shall maintain an inventory of API Compound and Collaboration Products in accordance with their normal practices and so as to ensure fulfillment of its respective supply obligations herein.

#### ARTICLE 10 CONFIDENTIAL INFORMATION

- Confidential Information. Each of GSK and Theravance 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, Neither Party shall use such Confidential Information for any purpose other than in performance of this Agreement or disclose the same to any other Person other than to such of its agents 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 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. Upon termination of this Agreement, the Receiving Party shall return or destroy all documents, tapes or other media containing Confidential Information of the Disclosing Party that remain in the Receiving Party's or its agents' 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 10. Notwithstanding anything to the contrary in this Agreement, the Receiving Party shall have the right to disclose this Agreement or Confidential Information provided hereunder if, in the reasonable opinion of the Receiving Party's legal counsel, such disclosure is necessary to comply with the terms of this Agreement, or the requirements of any Law. Where possible, the Receiving Party shall notify the Disclosing Party of the Receiving Party's intent to make such disclosure pursuant to the provision of the preceding sentence sufficiently prior to making such disclosure so as to allow the Disclosing Party adequate time to take whatever action the Disclosing Party may deem to be appropriate to protect the confidentiality of the information. The Receiving Party will cooperate reasonably with the Disclosing Party's efforts to protect the confidentiality of the information. Each Party will be liable for breach of this Article 10 by any of its Affiliates.
- 10.2 <u>Permitted Disclosure and Use</u>. Notwithstanding Section 10.1, 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 a Collaboration Product; (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 10.2, such Party shall give reasonable advance notice of such disclosure to the other Party to permit such other Party sufficient opportunity to object to such disclosure or to take measures to ensure confidential treatment of such information. The Receiving Party will cooperate reasonably with the Disclosing Party's efforts to protect the confidentiality of the information.
- 10.3 <u>Publications</u>. Subject to any Third Party rights existing as of the Effective Date, each Party shall submit to the Joint Project Committee for review and approval all proposed academic, scientific and medical publications and public presentations relating to a Collaboration Product or any research or Development activities under this Agreement for review in connection

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with preservation of Patent Rights, and trade secrets and/or to determine whether Confidential Information should be modified or deleted from the proposed publication or public presentation. Written copies of such proposed publications and presentations shall be submitted to the Joint Project Committee no later than sixty (60) days before submission for publication or presentation and the Joint Project Committee shall provide its comments with respect to such publications and presentations within ten (10) Business Days of 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 Project 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 Collaboration Products or any research or Development activities under this Agreement.

- 10.4 Public Announcements. Except as may be expressly permitted under Section 10.3 or required by applicable Laws and subject to the final two sentences of this Section 10.4, neither Party will make any public announcement of any information regarding this Agreement, the Collaboration Products 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 Collaboration Products or any research and Development activities under this Agreement.
- 10.5 <u>Confidentiality of This Agreement</u>. The terms of this Agreement shall be Confidential Information of each Party and, as such, shall be subject to the provisions of this Article 10. Either party may disclose the terms of this Agreement if, in the opinion of its counsel, such disclosure is required by Law. In such event, the disclosing Party will seek appropriate confidentiality of those portions of the Agreement for which confidential treatment is typically permitted by the relevant Governmental Authority.
- 10.6 Termination of Prior Confidentiality Agreements. Except as expressly provided in this Section 10.6, this Agreement supercedes the Mutual Confidential Disclosure Agreement (the "MCDA") between the Parties dated April 10, 2002. Except as expressly provided in this Section 10.6 and in Paragraph 8 of the Confidentiality Agreement between the Parties dated October 2, 2002 (the "Patent CDA"), this Agreement supersedes the Patent CDA. Except as set forth in Paragraph 8 of the Patent CDA, all information disclosed pursuant to the MCDA and the Patent CDA shall be subject to the provisions of this Article 10.
- 10.7 <u>Survival</u>. The obligations and prohibitions contained in this Article 10 shall survive the expiration or termination of this Agreement for a period of ten (10) years.

## ARTICLE 11 REPRESENTATIONS AND WARRANTIES; COVENANTS

- 11.1 <u>Mutual Representations and Warranties</u>. Theravance and GSK each represents and warrants to the other as of the Effective Date that:
- 11.1.1 Such Party (a) is a company duly organized, validly existing, and in good standing under the Laws of its incorporation; (b) 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; (c) has the requisite corporate power and authority and the legal right to conduct its business as now conducted and hereafter contemplated to be conducted; (d) 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 (e) is in compliance with its charter documents;
- 11.1.2 The execution, delivery and performance of this Agreement by such Party and all instruments and documents to be delivered by such Party hereunder (a) are within the corporate power of such Party; (b) have been duly authorized by all necessary or proper corporate action; (c) do not conflict with any provision of the charter documents of such Party; (d) will not, to the best of such Party's knowledge, violate any law or regulation or any order or decree of any court of governmental instrumentality; (e) will not violate or conflict with any terms of any indenture, mortgage, deed of trust, lease, agreement, or other 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;
- 11.1.3 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
- 11.1.4 All of its employees, officers, and consultants have executed agreements or have existing obligations under law 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.
- 11.1.5 Nothing contained in this Agreement shall give a Party the right to use the Confidential Information received from the other Party in connection with any activity other than Development and Commercialization of a Pooled Compound or Collaboration Product consistent with this Agreement.
- 11.1.6 As soon as practicably possible after the Effective Date, the Parties will each deliver to each other a schedule listing (i) in the case of GSK, GSK Patents as of the date of signature of this Agreement and (ii) in the case of Theravance, Theravance Patents as of the date of signature of this Agreement.

- 11.2 Additional GSK Representations and Warranties. GSK further represents, warrants and covenants to Theravance that:
- 11.2.1 It 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 has solely relied on such analysis and evaluations in deciding to enter into this Agreement;
- 11.2.2 Neither GSK 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 GSK's rights granted under

this Agreement;

- 11.2.3 There is no claim or demand of any person or entity pertaining to, or any proceeding which is pending or, to the knowledge of GSK, threatened, that challenges the rights of Theravance in respect of any GSK Know-How or GSK Patents, or that claims that any default exists under any license with respect to any GSK Know-How or GSK Patents to which GSK is a party, except where such claim, demand or proceeding would not materially and adversely affect the ability of GSK to carry out its obligations under this Agreement; and
- 11.2.4 Having carried out and completed diligent searches in relation to the GSK Patents, and other than as disclosed to Theravance's counsel by GSK's counsel, GSK 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 GSK Patents.
  - 11.3 Additional Theravance Representations and Warranties. Theravance further represents and warrants to GSK as of the Effective Date that:
- 11.3.1 Having carried out and completed diligent searches in relation to the Theravance Patents, and other than as disclosed to GSK's counsel by Theravance's counsel, 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 has not received notice from any Third Party of a claim that an issued patent of such Third Party would be infringed by the manufacture, distribution, marketing or sale of the Collaboration Products under this Agreement;

- 11.3.2 To Theravance's knowledge, the Theravance Patents are not subject to any pending or any threatened re-examination, opposition, interference or litigation proceedings;
- 11.3.3 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 or the Theravance Know-How, or making any adverse claim of ownership thereof;
- 11.3.4 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 Patents and Theravance Know-How; and

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- 11.3.5 Theravance has, up to and including the Effective Date, furnished GSK with all material information requested by GSK concerning the quality, toxicity, safety and/or efficacy concerns that may materially impair the utility and/or safety of the Compound or Collaboration Products.
- 11.4 <u>Covenants</u>. 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.
- 11.5 <u>Disclaimer of Warranty.</u> Subject to the specific warranties and representations given under Sections 11.1 through and including 11.3, nothing in this Agreement shall be construed as a warranty or representation by either Party (i) that any Collaboration 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 Collaboration Products or any information or results provided by either Party pursuant to this Agreement or (iii) that any Collaboration Product will obtain Marketing Authorization or appropriate pricing approval. 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.

## ARTICLE 12 INDEMNIFICATION

- 12.1 <u>Indemnification by GSK</u>. Subject to Sections 12.4 and 13.2, GSK shall defend, indemnify and hold harmless Theravance and its Affiliates and each of their officers, directors, shareholders, employees, successors and assigns from and against all Claims of Third Parties, and all associated Losses, to the extent arising out of (a) GSK's negligence or willful misconduct in performing any of its obligations under this Agreement, (b) a breach by GSK of any of its representations, warranties, covenants or agreements under this Agreement, or (c) the manufacture, use, handling, storage, marketing, sale, distribution or other disposition of Collaboration Products by GSK, its Affiliates, agents or sublicensees, except to the extent such losses result from the negligence or willful misconduct of Theravance.
- 12.2 <u>Indemnification by Theravance</u>. Subject to Sections 12.4 and 13.2, Theravance shall defend, indemnify and hold harmless GSK and its Affiliates and each of their officers, directors, shareholders, 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, or (b) a breach by Theravance of any of its representations, warranties, covenants or agreements under this Agreement.

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#### 12.3 <u>Procedure for Indemnification</u>.

12.3.1 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 12.1 or 12.2, 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.

12.3.2 <u>Defense of Claim</u>. 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 fortyfive (45) days after the receipt of the written notice from the Indemnified Party of the potentially indemnifiable Third Party Claim (the "Litigation Condition"). 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 law 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 Litigation Condition, 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 Litigation Condition is not met, 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 satisfy the Litigation Condition, 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

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the inception of the Third Party Claim until the date the Indemnifying Party assumes the defense or control thereof.

- 12.4 <u>Assumption of Defense</u>. 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 12.4, in which case the Indemnifying Party shall be relieved of liability under Section 12.1 or 12.2, as applicable, solely for such Third Party Claim and related Losses.
- Insurance. During the Term of this Agreement and for a period of one (1) year after the termination or expiration of this Agreement, GSK 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 U.S. pharmaceutical industry for companies of comparable size and activities. Such product liability insurance or self-insured arrangements shall insure against all liability, including without limitation personal injury, physical injury, or property damage arising out of the manufacture, sale, distribution, or marketing of the Collaboration Products. GSK shall provide written proof of the existence of such insurance to Theravance upon request.

#### ARTICLE 13 PATENTS

#### 13.1 Prosecution and Maintenance of Patents.

13.1.1 Prosecution and Maintenance of Theravance Patents. Theravance shall have the exclusive right and the obligation to (subject to Theravance's election not to file, prosecute, or maintain pursuant to Section 13.1.4) or to cause its licensors 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 costs required under applicable Laws) and extend all Theravance Patents and related applications. Theravance shall consult with GSK prior to abandoning any Theravance Patents or related applications that are material to the matters contemplated in this Agreement. Theravance shall regularly advise GSK of the status of all pending applications, including with respect to any hearings or other proceedings before any Governmental Authority, and, at GSK's request, shall provide GSK with copies of all documentation concerning such applications, including all correspondence to and from any Governmental Authority. Subject to Section 2.3.3, Theravance shall solicit GSK's advice and review of the nature and text of such patent applications and important prosecution matters related thereto in reasonably sufficient time prior to filing thereof, and Theravance shall take into account GSK's reasonable comments related thereto; provided, however, Theravance shall have the final decision authority with respect to any action relating to any Theravance Patent. Within the priority period, Theravance shall agree with GSK regarding the countries outside the United States in which corresponding applications should be filed ("OUS Filings"). It is presumed that a corresponding Patent Cooperation Treaty ("PCT") application will be filed unless otherwise agreed by the Parties. Theravance shall effect filing of all such applications within the priority period.

Subject to Section 13.1.4, Theravance shall be responsible for all costs incurred in the United States in connection with procuring Theravance Patents, including applications preparation, filing fees, prosecution, maintenance and all costs associated with reexamination and

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interference proceedings in the United States Patent and Trademark Office and United States Courts. GSK shall be responsible for all out-of-pocket costs and expenses incurred by Theravance after the Effective Date that are associated with procuring corresponding OUS patents, including without limitation PCT and individual country filing fees, translations, maintenance, annuities, and protest proceedings. For all such OUS patent applications, Theravance will invoice GSK on a quarterly basis beginning April 1, 2003, 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 GSK. GSK will within thirty (30) days following the Effective Date identify the GSK representative that should receive such invoices from Theravance. GSK's obligations hereunder are in addition to any obligations of GSK under Section 13.1.2(b)

#### 13.1.2 Prosecution and Maintenance of Patents Covering Joint Inventions.

(a) For Patents covering Joint Inventions, the Parties shall agree, without prejudice to ownership, which Party shall have the right to prepare and file a priority patent application, and prosecute such application(s) and maintain any patents derived therefrom, with the Parties equally sharing the reasonable out-of-pocket costs for the preparation, filing, prosecution and maintenance of such priority patent application. The Parties will reasonably cooperate to obtain any export licenses that might be required for such activities. Should the agreed upon Party elect not to prepare and/or file any such priority patent application, it shall (i) provide the other Party with written notice as soon as reasonably possible after making such election but in any event no later than sixty (60) days before the other Party would be faced with a possible loss of rights, (ii) give the other Party the right, at the other Party's discretion and sole expense, to prepare and file the priority application(s), and (iii) offer reasonable assistance in connection with such preparation and filing at no cost to the other Party except for reimbursement of reasonable out-of-pocket expenses incurred by the agreed upon Party in rendering such assistance. The other Party, at its discretion and cost, shall prosecute such application(s) and maintain sole ownership of any patents derived therefrom.

(b) Within nine (9) months after the filing date of a priority application directed to an Invention, the Party filing the priority application shall request that the other Party identify those non-priority, non-PCT ("foreign") Countries in which the other Party desires that the Party filing the priority application file corresponding patent applications. Within thirty (30) days after receipt by the other Party of such request from the Party filing the priority application, the other Party shall provide to the Party filing the priority application a written list of such foreign countries in which the other Party wishes to effect corresponding foreign patent applications filings. The Parties will then attempt to agree on the particular countries in which such applications will be filed, provided that in the event agreement is not reached, the application will be filed in the disputed as well as the non-disputed countries (all such filings referred to hereinafter as "Designated Foreign Filings"). Thereafter, within twelve (12) months after the filing date of the priority application, the Party filing the priority application shall effect all such Designated Foreign Filings. It is presumed unless otherwise agreed in writing by the Parties, that a corresponding PCT application will be filed designating all PCT member countries. As to each Designated Foreign Filing and PCT application, GSK shall bear the costs for the filing and prosecutions of such Designated Foreign Filing and PCT application (including entering national phase in all agreed countries). Should the Party filing the priority application not agree to file or cause to be filed a Designated Foreign Filing, the other Party will have the right to effect such Designated Foreign Filing in its name.

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- (c) Should the filing Party pursuant to Section 13.1.2(a) or 13.1.2(b) no longer wish to prosecute and/or maintain any patent application or patent resulting from such application, the filing Party shall (i) provide the non-filing Party with written notice of its wish no later than sixty (60) days before the patent or patent applications would otherwise become abandoned, (ii) give the non-filing Party the right, at the non-filing Party's election and sole expense, to prosecute and/or maintain such patent or patent application, and (iii) offer reasonable assistance to the non-filing Party in connection with such prosecution and/or maintenance at no cost to the non-filing Party except for reimbursement of the filing Party's reasonable out-of-pocket expenses incurred by the filing Party in rendering such assistance.
- (d) Should the non-filing Party pursuant to Section 13.1.2(c) not wish to incur its share of preparation, filing, prosecution and/or maintenance costs for a patent application filed pursuant to Section 13.1.2(a) or 13.1.2(b) or patents derived therefrom, it shall (i) provide the filing Party with written notice of its wish, and (ii) continue to offer reasonable assistance to the filing Party in connection with such prosecution or maintenance at no cost to the filing Party except for reimbursement of the non-filing Party's reasonable out-of-pocket expenses incurred by the non-filing Party in rendering such assistance.
- (e) The Parties agree to cooperate in the preparation and prosecution of all patent applications filed under Section 13.1.2(a) and 13.1.2(b), including 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 such patent application, obtaining execution of such other documents which shall be needed in the filing and prosecution of such patent applications, and, as requested, updating each other regarding the status of such patent applications.
- 13.1.3 Prosecution and Maintenance of GSK Patents. GSK shall have the exclusive right and obligation to (subject to GSK's election not to file, prosecute or maintain pursuant to Section 13.1.5) or to cause its licensors to, prepare, file and 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 costs required under applicable Laws) and extend all GSK Patents and related applications. Consistent with Section 2.3.3, GSK will consult with Theravance within the priority period for any patent application that is material to this Agreement concerning Countries in which corresponding applications will be filed. In the event the Parties can not agree, GSK shall make the final decision. GSK shall consult with Theravance prior to abandoning any GSK Patents or related applications that are material to the matters contemplated in this Agreement. GSK shall regularly advise Theravance of the status of all pending applications, including with respect to any hearings or other proceedings before any Governmental Authority, and, at Theravance's request, shall provide Theravance with copies of documentation relating to such applications, including all correspondence to and from any Governmental Authority. Subject to Section 2.3.3, GSK shall solicit Theravance's advice and review of the nature and text of such patent applications and important prosecution matters related thereto in reasonably sufficient time prior to filing thereof, and GSK shall take into account Theravance's reasonable comments relating thereto; provided that GSK shall have the final decision authority with respect to any action relating to a GSK Patent.
- 13.1.4 <u>GSK Step-In Rights</u>. If Theravance elects not to file, prosecute or maintain the Theravance Patents or claims encompassed by such Theravance Patents necessary for GSK to exercise its rights hereunder in any Country, Theravance shall give GSK notice thereof within a reasonable period prior to allowing such Theravance Patents, or such claims encompassed by

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such Theravance Patents, to lapse or become abandoned or unenforceable, and GSK shall thereafter have the right, at its sole expense, to prepare, file, prosecute and maintain such Theravance Patents in such Country.

13.1.5 <u>Theravance Step-In Rights</u>. If GSK elects not to file, prosecute or maintain the GSK Patents or claims encompassed by such GSK Patents necessary for Theravance to exercise its license rights hereunder in any Country, GSK shall give Theravance notice thereof within a reasonable period prior to allowing such GSK Patents, or such claims encompassed by such GSK Patents, to lapse or become abandoned or unenforceable, and Theravance shall thereafter have the right, at its sole expense, to prepare, file, prosecute and maintain such GSK Patents in such Country. In the event that GSK elects not to

file, prosecute or maintain GSK Patents or claims that would affect the royalty owed Theravance pursuant to Section 6.3, GSK shall reimburse Theravance for all out-of-pocket expenses incurred by Theravance in connection with Theravance exercising its Step-In Rights under this Section.

- 13.1.6 Execution of Documents by Agents. Each of the Parties shall execute or have executed by its appropriate agents such documents as may be necessary to obtain, perfect or maintain any Patent Rights filed or to be filed pursuant to this Agreement, and 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 obtain or maintain such Patent Rights.
- 13.1.7 <u>Patent Term Extensions</u>. The Parties shall cooperate with each other in gaining patent term extension where applicable to Collaboration Products. The Joint Steering Committee shall determine which patents the Parties shall endeavor to have extended. All filings for such extension will be made by the Party to whom the patent is assigned after consultation with the other Party. In the event the Joint Steering Committee can not agree, the Party who is assigned the compound patent covering the LABA in the Collaboration Product will make the decision.

#### 13.2 Patent Infringement.

- 13.2.1 <u>Infringement Claims</u>. With respect to any and all Claims instituted by Third Parties against Theravance or GSK or any of their respective Affiliates for patent infringement involving the manufacture, use, license, marketing or sale of a Collaboration Product in the United States during the Term (each, a "Patent Infringement Claim") as applicable, Theravance and GSK will assist one another and cooperate in the defense and settlement of such Patent Infringement Claims at the other Party's request.
- 13.2.2 <u>Infringement of Theravance Patents</u>. In the event that Theravance or GSK becomes aware of actual or threatened infringement of a Theravance Patent during the Term, that Party will promptly notify the other Party in writing (a "Patent Infringement Notice"). Theravance will have the right but not the obligation to bring an infringement action against any Third Party. If Theravance elects to pursue such infringement action, Theravance shall be solely responsible for the costs and expenses associated with such action and retain all recoveries. During the Term, in the event that Theravance does not undertake such an infringement action, upon Theravance's written consent, which shall not be unreasonably withheld, refused, conditioned or delayed, GSK shall be permitted to do so in Theravance's or the relevant Theravance Affiliate's name and on Theravance's or the relevant Theravance Affiliate's behalf. If Theravance has consented to an infringement action but GSK is not recognized by the applicable court or other relevant body as having the requisite standing to pursue such action, then GSK may join Theravance as party-plaintiff. If GSK elects to pursue such infringement action, Theravance may be represented in

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such action by attorneys of its own choice and its own expense with GSK taking the lead in such action.

- 13.2.3 <u>Infringement of GSK Patents</u>. In the event that GSK or Theravance becomes aware of actual or threatened infringement of a GSK Patent during the Term, that Party will promptly notify the other Party in writing. GSK will have the right but not the obligation to bring an infringement action against any Third Party. If GSK elects to pursue such infringement action, GSK shall be solely responsible for the costs and expenses associated with such action and retain all recoveries. During the Term, in the event that GSK does not undertake such an infringement action, upon GSK's written consent, which shall not be unreasonably withheld, refused, conditioned or delayed, Theravance shall be permitted to do so in GSK's or the relevant GSK Affiliate's name and on GSK's or the relevant GSK Affiliate's behalf. If GSK has consented to an infringement action but Theravance is not recognized by the applicable court or other relevant body as having the requisite standing to pursue such action, then Theravance may join GSK as a party-plaintiff. If Theravance elects to pursue such infringement action, GSK may be represented in such action by attorneys of its own choice and at its own expense, with Theravance taking the lead in such action.
- 13.3 <u>Notice of Certification</u>. GSK and Theravance each shall immediately give notice to the other of any certification filed under the "U.S. Drug Price Competition and Patent Term Restoration Act of 1984" (or its foreign equivalent) claiming that a GSK Patent or a Theravance Patent is invalid or that infringement will not arise from the manufacture, use or sale of any Collaboration Product by a Third Party ("Hatch-Waxman Certification").
- 13.3.1 <u>Notice</u>. If a Party decides not to bring infringement proceedings against the entity making such a certification, such Party shall give notice to the other Party of its decision not to bring suit within twenty-one (21) days after receipt of notice of such certification.
  - 13.3.2 Option. Such other Party then may, but is not required to, bring suit against the entity that filed the certification.
- 13.3.3 Name of Party. Any suit by Theravance or GSK shall either be in the name of Theravance or in the name of GSK, (or any Affiliate) or jointly in the name of Theravance and GSK (or any Affiliate), as may be required by law.
- Assistance. For purposes of this Article 13, the Party not bringing suit shall execute such legal papers necessary for the prosecution of such suit as may be reasonably requested by the Party bringing suit. The out-of-pocket costs and expenses of the Party bringing suit shall be reimbursed first out of any damages or other monetary awards recovered in favor of GSK or Theravance. The documented out-of-pocket costs and expenses of the other Party shall then be reimbursed out of any remaining damages or other monetary awards. The Party initiating and prosecuting the action to completion will retain any remaining damages or other monetary awards following such reimbursements.
- 13.5 <u>Settlement</u>. No settlement or consent judgment or other voluntary final disposition of a suit under this Article may be entered into without the joint written consent of GSK and Theravance (which consent will not be withheld unreasonably).

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## ARTICLE 14 TERM AND TERMINATION

14.1 <u>Term and Expiration of Term</u>. 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 14, the licenses granted by Theravance to GSK pursuant to Section 2.1 with respect to the Collaboration Products shall be considered fully-paid and shall become non-exclusive upon expiration of the Term.

- 14.2 <u>Termination for Material Breach</u>. Either Party may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement subject to Section 14.10 in the event that the other Party (as used in this subsection, 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).
- 14.3 <u>GSK Right to Terminate Development of a Collaboration Product.</u> On a Collaboration Product-by-Collaboration Product basis, and at any time during Development and prior to First Commercial Sale of the applicable Collaboration Product, GSK shall have the right to terminate Development of such Collaboration Product (upon the provision of ninety (90) days written notice) for reasons of Technical Failure or Commercial Failure following communication to, and assessment of such proposed termination by, the Joint Project Committee and Joint Steering Committee (in which case such Collaboration Product shall be referred to as a "Terminated Development Collaboration Product"). For the avoidance of doubt, a "Terminated Development Collaboration Product" can be any of the following: (i) a Pooled Compound and/or (ii) a Replacement Compound and/or (iii) a single agent LABA Collaboration Product and/or (iv) a LABA/ICS Combination Product and/or (v) an Other Combination Product.
- GSK Right to Terminate Commercialization of a Collaboration Product Following First Commercial Sale. On a Collaboration Product-by-Collaboration Product basis, and on a Country-by-Country basis, at any time after First Commercial Sale of the applicable Collaboration Product in such country, GSK shall have the right to terminate Commercialization of such Collaboration Product (upon the provision of one hundred and eighty (180) days written notice) for reasons of Commercial Failure or Technical Failure and following communication to, and assessment of such proposed termination by, the Joint Project Committee and Joint Steering Committee (in which case, such Collaboration Product shall be referred to as a "Terminated Commercialized Collaboration Product"). For the avoidance of doubt, a Terminated Commercialized Collaboration Product can be any of the following: (i) a single agent LABA Collaboration Product and/or (ii) a LABA/ICS Combination Product and/or (iii) an Other Combination Product.

14.5 <u>Termination of the Agreement Due to Discontinuation of Development of All Collaboration Products and All Pooled Compounds</u>. Any time following the third anniversary of the Effective Date, either Party may terminate this Agreement, subject to Section 14.10, upon the provision of ninety (90) days written notice if Development of all Collaboration Products and all Pooled Compounds have been discontinued for Technical Failure and/or Commercial Failure. Notwithstanding the foregoing, in the event that (i) Development of all Collaboration Products and all Pooled Compounds (including any Replacement Compounds) has ceased for at least three (3) months, (ii) all such termination and/or discontinuance decisions have been validly approved by the Joint Steering Committee, and (iii) both parties have provided written notice to the other that such party does not intend to contribute any additional Replacement Compounds to the collaboration, then either Party shall be entitled to terminate this Agreement, subject to Section 14.10, upon the provision of ninety (90) days written notice.

#### 14.6 <u>Effects of Termination</u>.

GSK:

#### 14.6.1 Effect of Termination for Material Breach.

(a) Material Breach by Theravance. In the event this Agreement is terminated by GSK pursuant to Section 14.2 for material breach by Theravance, all licenses granted by Theravance to GSK under this Agreement shall survive, subject to GSK's continued obligation to pay milestones and royalties to Theravance hereunder. In such event, GSK shall retain all of its rights to bring an action against Theravance for damages and any other available remedies in law or equity, and shall be entitled to set-off against any monies payable to Theravance hereunder all amounts GSK reasonably believes constitute its damages incurred by such breach, subject to final judicial resolution or settlement. Also, Theravance shall, at its sole expense, promptly transfer to GSK copies of all data, reports, records and materials in its possession or control that relate to the Collaboration Products that contain a GSK Compound and return to GSK, or destroy at GSK's request, all relevant records and materials in its possession or control containing Confidential Information of GSK (provided that Theravance may keep one copy of such Confidential Information of GSK for archival purposes only in accordance with Section 10.1).

(b) Material Breach By GSK. In the event that this Agreement is terminated by Theravance pursuant to Section 14.2 for material breach by

- (i) GSK shall, at its sole expense, promptly transfer to Theravance copies of all data, reports, records and materials in its possession or control that relate to the Theravance Compounds and return to Theravance, or destroy at Theravance's request, all relevant records and materials in its possession or control containing Confidential Information of Theravance (provided that GSK may keep one copy of such Confidential Information of Theravance for archival purposes only in accordance with Section 10.1).
- (ii) GSK shall, at its sole expense, transfer to Theravance, or shall cause its designee(s) to transfer to Theravance, ownership of all regulatory filings made or filed for any Collaboration Product that contains a LABA as a single agent (to the extent that any are held in GSK's or such designee(s)'s name), and such transfer to be as permitted by applicable Laws and regulations; otherwise GSK shall cooperate as necessary to permit Theravance to exercise its rights hereunder.
- (iii) Theravance shall have the non-exclusive right to access, use and cite in any regulatory filing any data relating to formulation of a LABA/ICS Combination Product or Other Combination Product.

- (iv) All of the provisions of Section 14.6.2 shall apply for the benefit of Theravance for any Collaboration Product for which the first Phase III Study has been initiated at the effective date of such termination, subject to the limitations set forth in Section 14.6.2.
- (v) All the provisions of Section 14.6.3 shall apply for any Collaboration Product that has been Commercialized at the effective date of such termination.

- (vi) All licenses granted by Theravance to GSK with respect to the applicable Theravance Compounds under this Agreement shall terminate
- (vii) Theravance shall retain all of its rights to bring an action against GSK for damages and any other available remedies in law or equity, and shall be entitled to set-off against any monies payable to GSK hereunder all amounts Theravance reasonably believes constitute its damages incurred by such breach, subject to final judicial resolution or settlement.

14.6.2 Effect of Termination by GSK of Certain Terminated Development Collaboration Product(s). If GSK terminates a Collaboration Product at any time after initiation of the first Phase III Study concerning such Collaboration Product, and Development of all other Collaboration Products and Pooled Compounds have been discontinued for Technical Failure and/or Commercial Failure, then at the sole election of Theravance, the following shall apply:

- (a) GSK shall, at its sole expense, promptly transfer to Theravance copies of all data, reports, records and materials in its possession or control that relate to the Theravance Compounds and return to Theravance, or destroy at Theravance's request, all relevant records and materials in its possession or control containing Confidential Information of Theravance (provided that GSK may keep one copy of such Confidential Information of Theravance for archival purposes only in accordance with Section 10.1).
- (b) GSK shall, at its sole expense, transfer to Theravance, or shall cause its designee(s) to transfer to Theravance, ownership of all regulatory filings made or filed for the Terminated Development Collaboration Product that contains a LABA as a single agent (to the extent that any are held in GSK's or such designee(s)'s name), such transfer to be as permitted by any Third Party licenses or other such prior rights and applicable Laws and regulations, otherwise GSK shall cooperate as necessary to permit Theravance to exercise its rights hereunder.
- (c) Theravance shall have the non-exclusive right to access, use and cite in any regulatory filing any data relating to formulation of a LABA/ICS Combination Product or Other Combination Product.
- (d) For such Terminated Development Collaboration Product (excluding the non-LABA component of a LABA/ICS Combination Product and/or Other Combination Product and GSK's Diskus delivery device and any information directed thereto), GSK shall grant to Theravance the appropriate licenses in the Territory under the GSK Patents, GSK Inventions and GSK Know-How related to the LABA compound, dry powder inhaler formulation, metered dose inhaler formulation, and metered dose inhaler device, as applicable, to enable Theravance to Develop and Commercialize the Terminated Development Collaboration Product in the Field.

- (e) In the event of a Change in Control of Theravance prior to termination by GSK under Section 14.3, none of the provisions under this Section 14.6.2 shall survive as they pertain to any Collaboration Product other than a Theravance compound as a single agent LABA.
- 14.6.3 Effect of Termination by GSK of a Terminated Commercialized Collaboration Product. The provisions of this Section 14.6.3 shall apply only where a Terminated Commercialised Collaboration Product is not been replaced by an alternative Collaboration Product under this Agreement and provided that, in GSK's reasonable good faith judgment, exercise by Theravance alone or with a Third Party of any of the rights or activities contemplated by this Section 14.6.3 (which such rights or activities shall include access to a GSK compound and/or GSK proprietary formulations or devices including Diskus, (collectively "GSK Property")) will not materially damage GSK's continued development, regulatory or commercial use of such GSK Property. GSK will use reasonable efforts to assist Theravance in locating a mutually acceptable Third Party to carry out the rights and activities contemplated by this Section 14.6.3. Subject to the foregoing:
  - (a) If GSK terminates a Collaboration Product after First Commercial Sale of such Collaboration Product in one or more of the Major Market Countries, Theravance shall have the right in its sole discretion and at its sole expense, for its own benefit or together with a Third Party, to commercialize such Terminated Commercialized Collaboration Product in any of such Major Market Countries where it has been terminated.
  - (b) If GSK terminates Commercialization of a Collaboration Product in all Countries of the Territory following the first commercial sale in any Country of the Territory, Theravance shall have the right in its sole discretion and at it sole expense, for its own benefit or together with a Third Party, to Commercialise such Terminated Commercialized Collaboration Product in the Territory.
  - (c) Subject to Section 14.6.3(a), GSK shall grant to Theravance the appropriate licenses in the Territory (or in the case of a Country-by-Country termination, in the relevant Countries) under the GSK Patents, GSK Inventions and GSK Know-How to enable Theravance by itself and/or through one or more Third Party sublicensees, to Commercialize the Terminated Commercialized Collaboration Product. GSK shall also provide Theravance with all such information and data which GSK, or its sublicensees reasonably have available in such Country, for example access to drug master file, clinical data and the like, and shall execute such instruments as Theravance reasonably requests, to enable Theravance to obtain the appropriate regulatory approvals to market such Terminated Commercialized Collaboration Product in such Country and for any other lawful purpose related to Commercialization of such Terminated Commercialized Collaboration Product in such Country.
  - (d) In the event Theravance exercises its rights under Section 14.6.3(a) and (b) above, the Parties shall negotiate in good faith a separate commercialization and supply agreement for such Terminated Commercialized Collaboration Product which shall ensure that, based on commercially reasonable terms

- (e) In the event of a Change in Control of Theravance, prior to termination by GSK under Section 14.4, none of the provisions under this Section 14.6.3 shall survive as they pertain to any Collaboration Product other than to a single agent LABA, its dry powder inhaler formulation, metered dose inhaler formulation, and metered dose inhaler device, as applicable; and the Parties will meet in good faith to explore other potential commercial options e.g. use of one or more Third Parties for possible continued Commercialisation of such Terminated Commercialised Collaboration Product if it is a LABA/ICS Combination Product or Other Combination Product.
- (f) If GSK, in the exercise of its reasonable good faith judgment, determines that exercise by Theravance alone or with a Third Party of any of the rights or activities contemplated by this Section 14.6.3 will materially damage GSK's continued development, regulatory or commercial use of GSK Property, then GSK shall grant to Theravance, for such Terminated Commercialized Collaboration Product (excluding the non-LABA component of a Combination Product and/or Other Combination Product and GSK's Diskus delivery device and any information directed thereto), the appropriate licenses in the Territory under the GSK Patents, GSK Inventions and GSK Know-How related to the LABA compound, dry powder inhaler formulation, metered dose inhaler formulation, and metered dose inhaler device, as applicable, to enable Theravance to Commercialize a product containing the LABA Compound in the Field.

14.6.4 Effect of Termination of the Agreement Due to Discontinuation of Development Prior to First Commercial Sale of All Collaboration Products and All Pooled Compounds. In the event that the Agreement is terminated pursuant to Section 14.5, the following shall occur:

- (i) <u>Return of Materials</u>. GSK shall, at its sole expense, promptly transfer to Theravance copies of all data, reports, records and materials in its possession or control that relate to the Theravance Compounds and return to Theravance, or destroy at Theravance's request, all relevant records and materials in its possession or control containing Confidential Information of Theravance (provided that GSK may keep one copy of such Confidential Information of Theravance for archival purposes only in accordance with Section 10.1). Theravance shall, at its sole expense, promptly transfer to GSK copies of all data, reports, records and materials in its possession or control that relate to the GSK Compounds and return to GSK, or destroy at GSK's request, all relevant records and materials in its possession or control containing Confidential Information of GSK (provided that Theravance may keep one copy of such Confidential Information of GSK for archival purposes only in accordance with Section 10.1).
- (ii) <u>Transfer of Regulatory Filings</u>. GSK shall, at its sole expense, transfer to Theravance, or shall cause its designee(s) to transfer to Theravance, ownership of all regulatory filings made or filed for any Terminated Development Collaboration Product (to the extent that any are held in GSK's or such designee(s)'s name), but only where the Terminated Collaboration Product contains a Theravance Compound as a single agent and such transfer to be as permitted

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by applicable Laws and regulations. GSK, at its sole discretion, shall also give due consideration to transferring to Theravance any additional regulatory filings for a Terminated Development Collaboration Product which contains a Theravance Compound as a Combination Product.

- (iii) <u>License Rights</u>. All licenses granted by Theravance to GSK with respect to the Collaboration Products under this Agreement shall terminate.
- (iv) <u>Stock Return</u>. GSK shall return to Theravance all available formulated and API stocks that contain a Theravance Compound and which are then held by GSK or cause such API stocks to be provided to Theravance if held by a vendor or other Third Party on behalf of GSK.
- (v) <u>Limitations on Further Development by GSK.</u> GSK shall not be permitted to continue or re-initiate clinical Development of any GSK Compound that is both a Terminated Collaboration Product and a LABA in the Field for a period of four (4) years after the date of such termination.
- 14.7 <u>License Rights</u>. Except as otherwise provided herein in, all licenses granted hereunder relating to Terminated Collaboration Products shall terminate. Also the Parties accept that nothing provided for in this Article 14 or elsewhere in this Agreement, grants any licenses (whether exclusive, semi-exclusive or otherwise) from GSK to Theravance for any (i) GSK Compound (ii) GSK Invention (ii) GSK Know How and (iv) GSK Patents, except for those rights essential and specific to enable Theravance to exercise those rights and carry out those activities contemplated under Section 14.6 above.
- 14.8 <u>Milestone Payments</u>. Neither Party shall be obligated to make a Development Milestone payment under Section 6.2 which is triggered by an event occurring after the effective date of termination of this Agreement with respect to a Collaboration Product.
- Subsequent Royalties. If after termination of this Agreement either Party subsequently Develops and Commercializes any Long-Acting  $\beta 2$  Adrenoceptor Agonist for the treatment / prophylaxis of respiratory diseases which (i) was never a Pooled Compound or Collaboration Product or (ii) was a GSK Discontinued Compound or a Theravance Discontinued Compound, it will pay to the other Party a royalty on Net Sales of any such products at the rate of 3% for a single-agent product and 2% for the first combination product for a period of 15 years from the date of launch on a Country-by-Country basis; provided, however, that this royalty shall not apply to any compound or product (including new product line extensions and/or re-formulation work) where the original compound or product is, as of the date of signature of this Agreement, already Commercialized.
- 14.10 <u>Accrued Rights; Surviving Obligations</u>. 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 10, 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.

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## ARTICLE 15 LIMITATIONS RELATING TO THERAVANCE EQUITY SECURITIES

15.1 <u>Purchases of Equity Securities</u>. So long as this Agreement remains in effect and for a period of one (1) year thereafter, except as permitted by Section 15.2, or as otherwise agreed in writing by Theravance, GSK and its Affiliates will not (and will not assist or encourage others to) directly or

indirectly in any manner:

- 15.1.1 acquire, or agree to acquire, directly or indirectly, alone or in concert with others, by purchase, gift or otherwise, any direct or indirect beneficial ownership (within the meaning of Rule l3d-3 under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) or interest in any securities or direct or indirect rights, warrants or options to acquire, or securities convertible into or exchangeable for, any securities of Theravance;
- 15.1.2 make, or in any way participate in, directly or indirectly, alone or in concert with others, any "solicitation" of "proxies" to vote (as such terms are used in the proxy rules of the Securities and Exchange Commission (the "SEC") promulgated pursuant to Section 14 of the Exchange Act); provided, however, that the prohibition in this Section 15.1.2 shall not apply to solicitations exempted from the proxy solicitation rules by Rule 14a-2 under the Exchange Act as such Rule 14a-2 is in effect as of the date hereof;
- 15.1.3 form, join or in any way participate in a "group" within the meaning of Section 13(d)(3) of the Exchange Act with respect to any voting securities of Theravance;
- 15.1.4 acquire or agree to acquire, directly or indirectly, alone or in concert with others, by purchase, exchange or otherwise, (i) any of the assets, tangible or intangible, of Theravance or (ii) direct or indirect rights, warrants or options to acquire any assets of Theravance, except for such assets as are then being offered for sale by Theravance;
- 15.1.5 enter into any arrangement or understanding with others to do any of the actions restricted or prohibited under Sections 15.1.1, 15.1.2, 15.1.3, or 15.1.4.
- 15.1.6 otherwise act in concert with others, to seek to offer to Theravance or any of its stockholders any business combination, restructuring, recapitalization or similar transaction to or with Theravance or otherwise seek in concert with others, to control, change or influence the management, board of directors or policies of Theravance or nominate any person as a director of Theravance who is not nominated by the then incumbent directors, or propose any matter to be voted upon by the stockholders of Theravance.
- 15.2 <u>Exceptions for Purchasing Securities of Theravance</u>. Nothing herein shall prevent GSK or its Affiliates (or in the case of Section 15.2.4, their employees) from:
  - 15.2.1 purchasing the Series E Preferred Stock of Theravance on the Effective Date as contemplated herein.
- 15.2.2 purchasing additional equity securities of Theravance after the Effective Date if after such purchase GSK and its Affiliates would own in the aggregate no greater percent of the total voting power of all voting securities of Theravance then outstanding than GSK together with its Affiliates owned immediately after purchase of the Series E Preferred Stock on the Effective Date.

- 15.2.3 acquiring securities of Theravance issued in connection with stock splits or recapitalizations or on exercise of pre-emptive rights afforded to Theravance stockholders generally.
- 15.2.4 purchasing securities of Theravance pursuant to (i) a pension plan established for the benefit of GSK's employees, (ii) any employee benefit plan of GSK, (iii) any stock portfolios not controlled by GSK or any of its Affiliates that invest in Theravance among other companies, or (iv) following an initial public offering of Theravance common stock, for the account of a GSK employee in such employee's personal capacity.
  - 15.2.5 acquiring securities of another biotechnology or pharmaceutical company that beneficially owns any of Theravance's securities.
- 15.2.6 acquiring equity securities of Theravance without any limitation following initiation by a third party of an unsolicited tender offer to purchase twenty percent (20%) or more of any class or service of Theravance's publicly traded voting securities (a "Hostile Tender Offer"); provided that the exception provided by this Section 15.2.6 shall be limited to the classes or series of Theravance's securities that are the subject of the Hostile Tender Offer; provided, further, that, in the event that either (a) such Hostile Tender Offer is terminated or expires without the purchase of at least ten percent (10%) of any class or series of Theravance's publicly traded voting securities by such third party, or (b) the Theravance Board of Directors subsequently recommends that such offer be accepted, then following the date of such termination, expiration or recommendation the acquisitions by GSK and/or its Affiliates under this Section 15.2.6 prior to the events described in clauses (a) and (b) above shall not be considered a breach by GSK of the provisions of Section 15.2 as long as GSK, at its option, either:
- (i) divests (or cause to be divested) in one or more open-market transactions such number of shares of Theravance's securities acquired by it and its Affiliates pursuant to this Section 15.2.6 such that after such divestiture GSK and its Affiliates would own in the aggregate no greater percent of the total voting power of all voting securities of Theravance then outstanding than GSK together with its Affiliates owned immediately prior to the commencement of such Hostile Tender Offer, any such divestiture to be completed as expeditiously as possible consistent with applicable securities laws and regulations and in a manner intended to shield GSK and its Affiliates from liability for recovery of short swing profits under Section 16 of the Exchange Act and the rules promulgated thereunder; or
- (ii) enters into a voting agreement, proxy or similar arrangement pursuant to which (A) all Theravance voting securities acquired pursuant to this Section 15.2.6 are voted on all matters to be voted on by holders of Theravance voting securities, including, but not limited to, in favor of any transaction involving a proposed Change in Control (as defined below) of Theravance in the same proportion as the outstanding Theravance voting securities not held by GSK or any GSK Affiliate are voted, (B) no Theravance voting securities beneficially owned by GSK and/or any Affiliate abstain from such a vote, and (C) no dissenter or appraisal or similar rights are exercised with respect to any vote relating to a Change in Control of Theravance.
- 15.3 <u>Voting</u>. Until the date of an initial public offering of Theravance common stock, GSK shall ensure that all outstanding Theravance voting securities beneficially owned by GSK and/or any GSK Affiliate are voted for management's nominees to the Board of Directors of Theravance to the extent not inconsistent with Section 2.8 of the Investors' Rights Agreement.

#### 15.4 <u>Theravance Voting Securities Transfer Restrictions.</u>

- 15.4.1 So long as this Agreement remains in effect and for a period of one (1) year thereafter, neither GSK nor any of its Affiliates shall dispose of beneficial ownership of Theravance voting securities except (i) pursuant to a bona fide public offering registered under the Securities Act of either Theravance voting securities or securities exchangeable or exercisable for Theravance voting securities (in which the securities are broadly distributed and GSK does not select the purchasers); or (ii) pursuant to Rule 144 under the Securities Act (provided that if Rule 144(k) is available, such transfer nevertheless is within the volume limits and manner of sale requirements applicable to non-144(k) transfers under Rule 144); or (iii) in transactions that to the knowledge of GSK do not, directly or indirectly, result in any person or group owning or having the right to acquire or intent to acquire beneficial ownership of Theravance voting securities with aggregate voting power of five percent or more of the aggregate voting power of all outstanding Theravance voting securities.
- 15.4.2 Notwithstanding the foregoing, the restrictions on disposition under Section 15.4.1 shall not apply if, as a result of such disposition, (A) no filing by any Person (including, but not limited to GSK or any of its Affiliates) shall be required under any Law (including but not limited to the Exchange Act) that would identify GSK or any of its Affiliates as the seller of the securities, and (B) neither GSK nor any of its Affiliates (or any transferee thereof) would be required by Law (including without limitation the disclosure requirements of the Securities Act of 1933, as amended (the "Securities Act"), and the Exchange Act) to make any public announcement of the transfer or disposition.
- 15.4.3 So long as this Agreement remains in effect and for a period of one (1) year thereafter, neither GSK nor any of its Affiliates may make any public disclosure of any holdings of or disposition of beneficial ownership of Theravance voting securities unless such disclosure is approved in advance in writing by Theravance, such approval not to be unreasonably withheld or delayed. Notwithstanding the foregoing, no consent of Theravance shall be required for any filing that GSK or any of its Affiliates is required to make under applicable Law in any jurisdiction, including without limitation any Form 144 under the Securities Act, any Form 4 under the Exchange Act, or any Schedule 13D or 13G or any amendments thereto under the Exchange Act; provided that, prior to making any such filings, GSK shall use reasonable efforts to (i) to provide Theravance notice and a copy of such proposed filings and (ii) consult with Theravance on the content of such filings.
- 15.5 <u>Termination of Purchase Restrictions</u>. The limitations on purchase of equity securities set forth in Section 15.1 shall terminate immediately upon a transaction or series of related transactions following a Change in Control of Theravance.

#### ARTICLE 16 MISCELLANEOUS

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, GSK's legal

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relationship under this Agreement to Theravance shall be that of independent contractor. This Agreement is not a partnership agreement and nothing in this Agreement shall be construed to establish a relationship of co-partners or joint venturers between the Parties.

- 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 Competition Directorate of the Commission of the European Communities or the U.S. Federal Trade Commission, in accordance with Law, 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 Law. 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 there from on a timely basis.
- 16.3 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 or any of its Affiliates, not due to malfeasance by such Party or its Affiliates, 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, act of God, 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 termination thereof. The Party so affected shall use Diligent Efforts to avoid or remove such causes of nonperformance as soon as is reasonably practicable. Upon termination 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 16.3.
- Governing Law. This Agreement shall be construed, and the respective rights of the Parties determined, according to the substantive law of the State of Delaware notwithstanding the provisions governing conflict of laws under such Delaware law to the contrary, except matters of intellectual property law which shall be determined in accordance with the intellectual property laws relevant to the intellectual property in question.
- 16.5 <u>Attorneys' Fees and Related Costs</u>. In the event that any legal proceeding 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.

- 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.
- 16.7 <u>Notices</u>. 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 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: 650-827-8683

Attn: Senior Vice President, Commercial Development

GSK: Glaxo Group Limited

Glaxo Wellcome House Berkeley Avenue

Greenford Middlesex UB6 0NN

United Kingdom Attn: Company Secretary

Facsimile: 011 44 208-047-6912

GlaxoSmithKline plc

980 Great West Road

Brentford Middlesex TW8 9GS United Kingdom Attn: Corporate Law

Facsimile: 011 44 208-047-6912

and with a copy to: Brentford

With a copy to:

Middlesex TW8 9GS United Kingdom

Attn: Vice President, Worldwide Business Development

Facsimile: 011 44 208-990-8142

or to such other address as the addressee shall have last furnished in writing in accord with this provision to the addressor. All notices shall be deemed effective upon receipt by the addressee.

16.8 <u>Severability</u>. 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

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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.

- 16.9 <u>Headings</u>. The headings used in this Agreement have been inserted for convenience of reference only and do not define or limit the provisions hereof.
- Maiver. 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.
- 16.11 <u>Entire Agreement</u>. 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 GSK.

- 16.12 <u>No License</u>. 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 any Collaboration 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.
- 16.13 <u>Third Party Beneficiaries</u>. 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.
- 16.14 <u>Counterparts</u>. 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.

Single Closing Condition. The obligation of each Party to consummate the transaction contemplated hereby is subject to the satisfaction of the following condition (the "Closing Condition"): All filings under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and any other similar competition or merger control laws that are necessary in any jurisdiction with respect to the transaction contemplated hereby shall have been made and any required waiting period under such laws shall have expired or been terminated and any Governmental Authority that has power under or authority to enforce such laws shall have, if applicable, approved, cleared or decided neither to initiate proceedings or otherwise intervene in respect of the transaction contemplated hereby nor to refer the transaction to any other competent Governmental Authority. Each Party shall use good faith efforts to take, or cause to be taken, all actions, and to do, or cause to be done, and to assist and cooperate with the other party in doing, all things necessary, proper or advisable to consummate and make effective the transaction contemplated by this Agreement, including, but not limited to satisfaction of the Closing Condition and each Party shall keep the other Party reasonably apprised of the status of matters relating to the completion of same. In connection with the foregoing, the Parties hereby agree to negotiate in good faith to make as soon as practicable any modification or amendment to this Agreement or any agreement related hereto that is required by the United States Federal Trade Commission, Department of Justice or equivalent Governmental Authority, provided that no Party shall be required to agree to any modification or amendment that, in the reasonable opinion of such Party's external legal or financial counsel, would be adverse to such Party. This Agreement may be terminated by either Party upon written notice any time after June 1, 2003 if the transactions contemplated by this Agreement shall not have been consummated by June 1, 2003 due to failure to satisfy the Closing Condition; provided, however, that the terminating Party shall not have breached in any material respect its obligations under this Agreement in any manner that shall have been the proximate cause of, or resulted in, the failure to satisfy the Closing Condition or otherwise to consummate the transactions contemplated by this Agreement by such date.

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IN WITNESS WHEREOF, Theravance and GSK, by their duly authorized officers, have executed this Agreement on November 14, 2002.

THERAVANCE, INC.

GLAXO GROUP LIMITED

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

By: /s/ Jean-Pierre Garnier

Jean-Pierre Garnier

Chief Executive Officer

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#### Schedule 1.19

#### Criteria for Theravance New Compounds and Replacement Compounds

- 1. Single optical isomer, which is patentable.
- 2. Potency *in vitro* and *in vivo* compatible with potential to develop in a DPI device.
- 3. Intrinsic agonist activity not less than that of salmeterol.
- 4. Selectivity at  $\beta_2$  adrenoceptors, relative to  $\beta_1$  and  $\beta_3$  adrenoceptors, similar or superior to that of formoterol, assessed in assays determining equi-potent molar ratios relative to that of isoprenaline (isoproterenol).
- 5. Selectivity at non- $\beta_2$  adrenoceptors >100.
- 6. No significant inhibition of the hERG potassium channel at a concentration at least 30 fold greater than the anticipated therapeutic maximum concentration in plasma.
- 7. Duration of agonist activity *in vivo* to be clearly longer than that of salmeterol. This would be at least 72 hours in the Theravance model. The exact duration criterion for either the GSK or the Theravance model might be modified in the light of forthcoming clinical data from the program.
- 8. Stable compound suitable for formulation to pursue FTIM studies, with crystalline form identified.
- 9. Oral bioavailability to be less than 10% in the rat and less than 25% in the dog.
- 10. No significant generation of markedly active metabolite(s) in vitro.
- 11. Irritation to the respiratory tract no worse than salmeterol in a non-GLP 7-day inhaled rat study.

#### **EXHIBIT A**

#### Adjustments to Your Theravance Equity Awards in Connection with the Spin-Off

This Exhibit A sets forth adjustments to your outstanding options to purchase shares of Theravance common stock ("Theravance Options"), awards of Theravance restricted stock units ("Theravance RSU Awards") and Theravance restricted shares ("Theravance RSAs" and, together with Theravance Options and Theravance RSU Awards, "Theravance Equity Awards") granted to you by Theravance and the related stock option, restricted stock unit and restricted stock agreements (each, an "Award Agreement" and collectively the "Award Agreements") in connection with the Spin-Off. These adjustments will apply to your Theravance Equity Awards outstanding immediately prior to the effective time of the Spin-Off. For your reference, a list of your currently outstanding Theravance Equity Awards can be found by logging into your E\*Trade Theravance Stock Plan Account. The adjustments described on this Exhibit A are being made in connection with the Spin-Off. If the Spin-Off does not occur for any reason, the adjustments described below will not be made to your Theravance Equity Awards and they will continue to be governed by their existing terms.

The Theravance Equity Awards, as adjusted, are referred to as "<u>Adjusted Theravance Options</u>" (including Adjusted Theravance ISOs and Adjusted Theravance NSOs, as defined below), "<u>Adjusted Theravance RSAs</u>" [**For VPs with TFIO RSAs only:** (including Adjusted Time-Based TFIO RSAs and Adjusted Performance-Based TFIO RSAs, as defined below)] and "<u>Adjusted Theravance RSU Awards</u>," (collectively, "<u>Adjusted Theravance Awards</u>"). Except as described below, each of your Adjusted Theravance Awards will continue to be governed by (i) the applicable Award Agreement, as adjusted hereby, and (ii) the Theravance equity plan under which the Adjusted Theravance Award was granted.

You will <u>not</u> receive a new Award Agreement(s) to reflect the adjustments described below. Please keep a copy of this Exhibit A with the Award Agreement(s) applicable to your Adjusted Theravance Award(s) as evidence of the adjusted terms.

Following the Spin-Off, Theravance may delegate certain administrative responsibilities associated with the Adjusted Theravance Awards to Theravance Biopharma, Inc. ("<u>Biopharma</u>"). If you have any questions about your Adjusted Theravance Awards or how to effect a particular stock plan transaction, please contact Theravance's stock administrator.

#### **Adjustments to Theravance Incentive Stock Options**

The following adjustments apply to Theravance Options that are "incentive stock options" under the federal tax laws immediately prior to the Spin-Off (each, a "Theravance ISO"):

- The per share exercise price and number of Theravance shares subject to each outstanding Theravance ISO will be adjusted to account for the effect of the Spin-Off on the value of Theravance's common stock (as adjusted, the "<u>Adjusted Theravance ISOs</u>"). The adjusted exercise price and number of shares subject to each Adjusted Theravance
  - ISO can be found by logging into your E\*Trade Theravance Stock Plan Account following the Spin-Off. An announcement will be posted on the Company's Intranet and on the E\*Trade website when the adjustments have been completed.
- · Certain exercises of your Adjusted Theravance ISOs may be restricted following the Spin-Off if a blackout period at Theravance is in effect at the time of the Spin-Off. Additionally, the exercise of your Adjusted Theravance ISOs will be restricted completely for a short period of time immediately following the Spin-Off to allow the adjustments to be completed. You will be notified of any restrictions that are placed on your ability to exercise your Adjusted Theravance ISOs and when those restrictions will be lifted.
- · If your Award Agreement currently permits you to pay the exercise price of your Theravance ISOs by either (i) surrendering (or attesting to the ownership of) shares of Theravance common stock that you already own or (ii) having Theravance withhold shares of Theravance common stock that would otherwise be issued upon exercise of the option, you will no longer have the right to elect such forms of payment in the event you experience a Qualifying Transition (as defined below). Instead, if you choose to exercise your Adjusted Theravance ISOs after experiencing a Qualifying Transition, you will be required to pay the exercise price by means of another method permitted in the applicable Award Agreement.
- · No other changes will be made to Theravance ISOs. In the event your service with Theravance is terminated for any reason, including as a result of a Qualifying Transition, any Adjusted Theravance ISOs held by you will need to be exercised within the applicable post-termination exercise period (or, if sooner, prior to the expiration date applicable to the option). For avoidance of doubt, if you experience a Qualifying Transition, any subsequent provision of transition services to Theravance on behalf of Biopharma by you will not count as "service" for purpose of your Adjusted Theravance ISOs.

#### **Adjustments to Theravance Nonstatutory Stock Options**

The following adjustments apply to Theravance Options that are nonstatutory stock options under the federal tax laws immediately prior to the Spin-Off (each, a "Theravance NSO"):

- The per share exercise price and number of Theravance shares subject to each outstanding Theravance NSO will be adjusted to account for the effect of the Spin-Off on the value of Theravance's common stock (as adjusted, the "Adjusted Theravance NSOs"). The adjusted exercise price and number of shares subject to each Adjusted Theravance NSO can be found by logging into your E\*Trade Theravance Stock Plan Account following the Spin-Off. An announcement will be posted on the Company's Intranet and on the E\*Trade website when the adjustments have been completed.
- · Certain exercises of your Adjusted Theravance NSOs may be restricted following the Spin-Off if a blackout period at Theravance is in effect at the time of the Spin-Off. Additionally, the exercise of your Adjusted Theravance NSOs will be restricted completely for a short period of time immediately following the Spin-Off to allow the adjustments to be completed. You will be notified of any restrictions that are placed on

- your ability to exercise your Adjusted Theravance NSOs and when those restrictions will be lifted.
- · In the event you experience a Qualifying Transition (as defined below), then for all purposes related to your Adjusted Theravance NSOs and the applicable stock option agreements (including vesting, exercisability and expiration of your Adjusted Theravance NSOs), your continuous service as an employee or consultant of Biopharma or any Parent, Subsidiary or Affiliate thereof will be treated as "service" with Theravance.
- Although you are currently eligible to participate in either the Theravance, Inc. Change in Control Severance Plan or the Theravance, Inc. 2009 Change in Control Severance Plan (each, a "Severance Plan"), your eligibility to participate in such plan will terminate in the event you experience a Qualifying Transition. As a result, your Adjusted Theravance NSOs would no longer be eligible for vesting acceleration if you are subject to an "involuntary termination" (as defined in the applicable Severance Plan) in connection with or following a "change in control" (as defined in the applicable Severance Plan) of Theravance. However, your Adjusted Theravance NSOs will vest and become exercisable in full if, after you experience a Qualifying Transition, Biopharma is subject to a "change in control" (as defined in the Biopharma 2013 Equity Incentive Plan as of the effective time of the Spin-Off) and you are subject to an "Involuntary Termination" (as defined below) within 3 months prior to or 24 months after that change in control.
- If your Award Agreement currently permits you to pay the exercise price of your Theravance NSOs by either (i) surrendering (or attesting to the ownership of) shares of Theravance common stock that you already own or (ii) having Theravance withhold shares of Theravance common stock that would otherwise be issued upon exercise of the option, you will no longer have the right to elect such forms of payment in the event you experience a Qualifying Transition. Instead, if you choose to exercise your Adjusted Theravance NSOs after experiencing a Qualifying Transition, you will be required to pay the exercise price by means of another method permitted in the applicable Award Agreement.

#### Adjustments to Theravance RSUs

- The number of Theravance restricted stock units subject to each outstanding Theravance RSU Award will be adjusted to account for the effect of the Spin-Off on the value of Theravance's common stock. The adjusted number of Theravance restricted stock units subject to each Adjusted Theravance RSU Award can be found by logging into your E\*Trade Theravance Stock Plan Account following the Spin-Off. An announcement will be posted on the Company's Intranet and on E\*Trade website when the adjustments have been completed.
- In the event you experience a Qualifying Transition (as defined below), then for all purposes related to your Adjusted Theravance RSU Awards and the applicable restricted stock unit agreements (including vesting and forfeiture of your Adjusted Theravance RSU Awards), your continuous service as an employee or consultant of Biopharma or any Parent, Subsidiary or Affiliate thereof will be treated as "service" with Theravance.
- · Although you are currently eligible to participate in a Severance Plan, your eligibility to participate in such plan will terminate in the event you experience a Qualifying Transition. As a result, your Adjusted Theravance RSU Awards would no longer be

eligible for vesting acceleration if you are subject to an "involuntary termination" (as defined in the applicable Severance Plan) in connection with or following a "change in control" (as defined in the applicable Severance Plan) of Theravance. However, your Adjusted Theravance RSU Awards will vest in full if, after you experience a Qualifying Transition, Biopharma is subject to a "change in control" (as defined in the Biopharma 2013 Equity Incentive Plan as of the effective time of the Spin-Off) and you are subject to an "Involuntary Termination" (as defined below) within 3 months prior to or 24 months after that change in control.

- [Non-Section 16 Officers: Regardless of whether you remain in continuous service with Theravance following the Spin-Off or experience a Qualifying Transition, the 10b5-1 Plans in the Award Agreements applicable to your Theravance RSU Awards will remain in effect following the Spin-Off.]
- [Section 16 Officers: You currently have the ability to satisfy withholding taxes due in connection with the settlement of your Theravance RSU Awards by having Theravance withhold a portion of the shares that would otherwise be released to you upon settlement of your Theravance RSU Awards (this method of satisfying withholding taxes is referred to as "stock withholding"). Pursuant to the terms of your Theravance RSU Awards, the Theravance Board of Directors or Compensation Committee, in their sole discretion, may withdraw consent for stock withholding at any time with respect to future vesting dates. Notwithstanding the foregoing, the Theravance Board of Directors and Compensation Committee will provide you with at least 90 days notice in the event that stock withholding will no longer be permitted. In the event the Theravance Board of Directors or Compensation Committee withdraws their consent for stock withholding, it will be necessary for you to satisfy the tax withholding obligations related to your Theravance RSU Awards by means of another method permitted by your Award Agreement.]

#### Adjustments to Theravance RSAs

- · No adjustment will be made in the number of outstanding Theravance RSAs in connection with the Spin-Off. However, as a Theravance stockholder, you will receive shares of Biopharma in the Spin-Off with respect to your Theravance RSAs that are outstanding on the record date for the Spin-Off. As provided in your applicable award agreements, the Biopharma shares distributed in respect of your Theravance RSAs will be subject to the same terms and conditions, including vesting and forfeiture, as apply to the applicable Adjusted Theravance RSAs.
- · In the event you experience a Qualifying Transition (as defined below), then for all purposes related to your Adjusted Theravance RSAs and the applicable restricted stock agreements (including vesting and forfeiture of your Adjusted Theravance RSAs and the related Biopharma shares distributed in respect of your Theravance RSAs), your continuous service as an employee (or, if the applicable Award Agreement currently permits it, as a consultant) of Biopharma or any Parent, Subsidiary or Affiliate thereof will be treated as "service" with Theravance.
- · Although you are currently eligible to participate in a Severance Plan, your eligibility to participate in such plan will terminate in the event you experience a Qualifying Transition. As a result, your Adjusted Theravance RSAs (and the related Biopharma shares distributed in respect of your Theravance RSAs) would no longer be eligible for

vesting acceleration if you are subject to an "involuntary termination" (as defined in the applicable Severance Plan) in connection with or following a "change in control" (as defined in the applicable Severance Plan) of Theravance. However, your Adjusted Theravance RSAs (including the related Biopharma shares distributed in respect of your Theravance RSAs) will vest in full if, after you experience a Qualifying Transition, Biopharma is subject to a "change in control" (as defined in the Biopharma 2013 Equity Incentive Plan as of the effective time of the Spin-Off) and you are subject to an "Involuntary Termination" (as defined below) within 3 months prior to or 24 months after the change in control (the "Biopharma CIC Protection").

· [Non-Section 16 Officers: Regardless of whether you remain in continuous service with Theravance following the Spin-Off or experience a Qualifying Transition, the 10b5-1 Plan(s) in your Award Agreement(s) will remain in effect following the Spin-Off for your Adjusted Theravance RSAs. After the Spin-Off, the "Withholding Taxes" section of your Award Agreement(s), including the 105b-1 plan instructions contained therein,

will apply to the Biopharma shares distributed in respect of your Theravance RSAs, but only to the extent necessary to meet your withholding tax obligations on such shares.

- In the event you experience a Qualifying Transition and you become an officer of Biopharma who is subject to Section 16(a) of the Securities Exchange Act of 1934 (a "Biopharma Section 16 Insider"), you may elect to satisfy the withholding taxes on any Biopharma shares distributed in respect of your Theravance RSAs that vest after the date you become a Biopharma Section 16 Insider by having Biopharma withhold a number of Biopharma shares that would otherwise be released to you upon vesting with a fair market value not in excess of the amount necessary to satisfy the minimum withholding amount on such shares (this method of satisfying withholding taxes is referred to as "stock withholding"), provided that the Biopharma Board of Directors or Compensation Committee, in their sole discretion, may withdraw consent for stock withholding at any time with respect to future vesting dates. Notwithstanding the foregoing, the Biopharma Board of Directors and Compensation Committee will provide you with at least 90 days notice in the event that stock withholding will no longer be permitted.]
- [Section 16 Officers: You currently have the ability to satisfy withholding taxes due in connection with the vesting of your Theravance RSAs by having Theravance withhold a portion of the shares that would otherwise be released to you upon vesting of your Theravance RSAs (this method of satisfying withholding taxes is referred to as "stock withholding"). However, pursuant to the terms of your Theravance RSAs, the Theravance Board of Directors or Compensation Committee, in their sole discretion, may withdraw consent for stock withholding at any time with respect to future vesting dates. Notwithstanding the foregoing, the Theravance Board of Directors and Compensation Committee will provide you with at least 90 days notice in the event that stock withholding will no longer be permitted.
- · Following the Spin-Off, you may elect to pay the withholding taxes due in connection with the vesting of the Biopharma shares distributed in respect of your Theravance RSAs by having Biopharma withhold a number of Biopharma shares that would otherwise be released to you upon vesting with a fair market value not in excess of the amount necessary to satisfy the minimum withholding amount on such shares, provided that the Biopharma Board of Directors or Compensation Committee, in their sole discretion, may withdraw consent for stock withholding at any time with respect to future vesting dates.

Notwithstanding the foregoing, the Biopharma Board of Directors and Compensation Committee will provide you with at least 90 days notice in the event that stock withholding will no longer be permitted.

• In the event that the Theravance and/or Biopharma Board of Directors or Compensation Committee withdraws consent for stock withholding, it will be necessary for you to satisfy the tax withholding obligations related to your Adjusted Theravance RSAs and the related Biopharma shares distributed in respect of your Theravance RSAs, as applicable, by means of another method permitted by your Award Agreement.]

#### [For VPs with TFIO RSAs only: Additional Adjustments to Theravance TFIO RSAs

In addition to the adjustments described above applicable to outstanding Theravance RSAs, the following additional adjustments will apply to outstanding performance-contingent Theravance RSAs that were granted on February 11, 2011 ("Theravance TFIO RSAs"):

- · <u>Tranche 1 Vesting</u>: All of the shares subject to Tranche 1 (as defined in the applicable Award Agreement) of your Theravance TFIO RSAs vested on May 9, 2014.
- Conversion to Time-Based Vesting: After taking into account the Tranche 1 Vesting, a portion of your Theravance TFIO RSAs that are outstanding immediately prior to the Spin-Off will be converted so that they vest solely based on your continuous service as an employee of Theravance (or, if you experience a Qualifying Transition, Biopharma or any Parent, Subsidiary or Affiliate thereof) for the 12 month period following the Spin-Off (as converted, the "Adjusted Time-Based TFIO RSAs"). 40% of the shares subject to Tranche 2 (as defined in the applicable Award Agreement) will be converted to Adjusted Time-Based TFIO RSAs). An additional portion of your remaining Theravance TFIO RSAs (after taking into account the Tranche 1 Vesting and the conversion of 40% of Tranche 2) will also be converted into Adjusted Time-Based TFIO RSAs. This portion will be determined by multiplying the remaining Theravance TFIO RSAs (after taking into account the Tranche 1 Vesting and the conversion of 40% of Tranche 2) by the Conversion Percentage (as defined below), which will be based on the average price of the Theravance shares and the average price of the Biopharma shares over a period of time following the Spin-Off, in relation to the Base Value (as defined in the applicable Award Agreement). The Biopharma shares distributed in respect of the Adjusted Time-Based TFIO RSAs will be subject to the same terms and conditions, including vesting and forfeiture, as the Adjusted Time-Based TFIO RSAs.
- Continued Performance-Based Vesting: Any remaining portion of your Theravance TFIO RSAs that are outstanding immediately prior to the Spin-Off (after taking into account both the Tranche 1 Vesting and the portion that are converted into Adjusted Time-Based TFIO RSAs) will become subject to new performance objectives that will be established by Theravance's Compensation Committee following the Spin-Off (the "Adjusted Performance-Based TFIO RSAs"). These goals will be communicated to you once they have been established. If you experience a Qualifying Transition following the Spin-Off and are still holding any outstanding Adjusted Performance-Based TFIO RSAs at such time (including the Biopharma shares distributed in relation thereto in the Spin-Off), then Biopharma's Compensation Committee will be responsible for establishing the performance objectives that will apply to such Adjusted Performance-Based TFIO RSAs
  - (including the Biopharma shares distributed in relation thereto in the Spin-Off) and determining whether such objectives have been satisfied. Pursuant to the Award Agreement governing your Theravance TFIO RSAs, the number of Theravance TFIO RSAs eligible for acceleration under a Severance Plan is subject to reduction based on the Change in Control Value (as defined in the applicable Award Agreement) (the "TFIO Acceleration Limitation"). Following the Spin-Off, the TFIO Acceleration Limitation will no longer apply to your Adjusted Time-Based TFIO RSAs and Adjusted Performance-Based TFIO RSAs (and the Biopharma shares distributed in respect thereof) for purposes of a Severance Plan or, if you experience a Qualifying Transition, for purposes of the Biopharma CIC Protection.
- · You will be notified of the number of your Adjusted Time-Based TFIO RSAs and the number of your Adjusted Performance-Based TFIO RSAs after the Spin-Off.

#### **Example of Treatment of Theravance TFIO RSAs**

The following example is for illustration purposes only and does not reflect the actual adjustments that may be made to the Theravance TFIO RSAs in connection with the Spin-Off.

For purposes of this example, assume Joe has 150,000 TFIO RSAs, that 37,500 of these are Tranche 1 TFIO RSAs and that 52,500 of these are Tranche 2 TFIO RSAs. Assume further that the Base Value is \$24.73 and the Spin-Off Value is \$35.

#### Based on these assumptions:

- · All 37,500 Tranche 1 TFIO RSAs vested on May 9, 2014, subject to Joe's continuous employment with Theravance through such date.
- The Conversion Percentage would be 41% (100 x ((35-24.73)/24.73)), rounded down to the nearest whole percentage.
- After the Tranche 1 Vesting, 112,500 TFIO RSAs will remain. 58,515 Theravance TFIO RSAs will be converted to Adjusted Time-Based TFIO RSAs ((52,500 x 40%) + ((112,500 (52,500 x 40%)) x 41%)).
- The remaining 53,985 Theravance TFIO RSAs (150,000 37,500 58,515) will become Adjusted Performance-Based TFIO RSAs.]

#### **Definitions**

The following definitions will apply to your Adjusted Theravance Awards:

- "Qualifying Transition" means you are offered, accept and commence an employment or consulting relationship with Biopharma or any Parent, Subsidiary or Affiliate thereof following the Spin-Off and your service with Theravance is terminated in connection with such commencement.
- "Subsidiary" means any corporation (other than Biopharma) in an unbroken chain of corporations beginning with the Biopharma, if each of the corporations other than the last corporation in the unbroken chain owns shares possessing 50% or more of the total combined voting power of all classes of shares in one of the other corporations in such chain.
- · "Affiliate" means any entity other than a Subsidiary, if Biopharma and/or one or more Subsidiaries own not less than 50% of such entity.
- "Parent" means any corporation (other than Biopharma) in an unbroken chain of corporations ending with Biopharma, if each of the corporations other than Biopharma owns stock possessing 50% or more of the total combined voting power of all classes of shares in one of the other corporations in such chain
- "Involuntary Termination" means a termination of your service by reason of (i) an involuntary dismissal or discharge by Biopharma (or the Parent, Subsidiary or Affiliate employing you) for reasons other than Cause or (ii) your voluntary resignation following one of the following that is effected by Biopharma (or the Parent, Subsidiary or Affiliate) employing you without your consent (A) a change in your position with Biopharma (or the Parent, Subsidiary or Affiliate employing you) which materially reduces your level of responsibility, (B) a material reduction in your base compensation or (C) a relocation of your workplace by more than fifty miles from your workplace immediately prior to the Change in Control (as defined in the Biopharma 2013 Equity Incentive Plan) that also materially increases your one-way commute, provided that in either case a "separation from service" (as defined in the regulations under Code Section 409A) occurs. In order for your resignation under clause (ii) to constitute an "Involuntary Termination," all of the following requirements must be satisfied: (1) you must provide notice to Biopharma of your intent to resign and assert an Involuntary Termination pursuant to clause (ii) within 90 days of the initial existence of one or more of the conditions set forth in subclauses (A) through (C), (2) Biopharma (or the Parent, Subsidiary or Affiliate employing you) will have 30 days from the date of such notice to remedy the condition and, if it does so, you may withdraw your resignation or resign without any vesting acceleration, and (3) any termination of service under clause (ii) must occur within two years of the initial existence of one or more of the conditions set forth in subclauses (A) through (C). Should Biopharma remedy the condition as set forth above and then one or more of the conditions set forth herein.
- "Cause" means (i) the unauthorized use or disclosure of the confidential information or trade secrets of Biopharma, a Parent, Subsidiary or Affiliate, which use causes material harm to Biopharma, a Parent, Subsidiary or Affiliate, (ii) conviction of a felony under the laws of the United States or any state thereof, (iii) gross negligence or (iv) repeated failure to perform lawful assigned duties for thirty days after receiving written notification from Biopharma's Board of Directors.
- · "Conversion Percentage" means the lesser of: (i) 100% and (ii) with rounding down to the nearest percentage, the product of 100 <u>multiplied</u> by the quotient of (a) the Spin-Off Value (as defined below) <u>minus</u> the Base Value, <u>divided</u> by (b) the Base Value.
- "Spin-Off Value" means the sum of: (i) the volume-weighted average price of one Biopharma common share for the first ten (10) trading days following the effective time of the Spin-Off divided by 3.5, <u>plus</u> (ii) the volume-weighted average price of one share of Theravance common stock for the first ten (10) trading days following the effective time of the Spin-Off; <u>provided</u>, that, if the ratio of shares of Theravance to Biopharma is greater than or less than 3.5:1, then the amount used in clause (i) shall be adjusted to reflect the actual ratio in the Spin-Off.

#### THERAVANCE, INC.

## POLICY FOR NON-EMPLOYEE DIRECTOR STOCK OPTIONS EFFECTIVE JUNE 2, 2014

This policy applies to stock options granted by Theravance, Inc. (the "<u>Company</u>") to its non-employee directors who resign from the Company's board of directors in connection with the Company's spin-off of Theravance Biopharma, Inc. ("<u>Biopharma</u>") and who continue to serve as non-employee members of the board of directors of Biopharma (each, a "<u>Biopharma Director</u>") to the extent such options are outstanding immediately prior to the spin-off ("<u>Eligible Theravance Options</u>").

Following the spin-off, the continued service by a former non-employee director of the Company as a Biopharma Director will constitute "service" for all purposes of the Biopharma Director's Eligible Theravance Options, other than with respect to the vesting of such stock options.

May 2, 2014

Ted Witek

Dear Ted:

Theravance, Inc. ("Theravance" or the "Company") is pleased to offer you the part-time exempt position of Senior Vice President, Clinical & Medical Affairs, Respiratory, reporting to the Chief Executive Officer. In accordance with your part-time status of 24 hours/week, you will be paid an annual salary of \$315,000. You will be eligible to receive an annual discretionary bonus of up to 50% of your annual salary, based on the Company's performance against its annual goals and a review of your individual performance. You must be an active employee in good standing at the time the bonus is paid in order to receive the bonus. The Company's bonus percentage targets may change from time-to-time at the sole discretion of the Board of Directors.

Subject to the approval by the appropriate committee of the Company's Board of Directors, you will be granted an option to purchase shares of Common Stock of the Company at a purchase price equal to the fair market value of our Common Stock on the date of grant, which we anticipate will be on or around the first business day of the month following your employment start date. Your option grant will be for 100,000 shares. The vesting and exercise details of your option grant will be set forth in your stock option paperwork, but in general your option will vest monthly over the first four years of your employment, with a one year "cliff" provision that prevents it from being exercised before the first anniversary of the grant date. The option shall be fully vested and exercisable on the 4-year anniversary of the date of grant provided you have remained in continuous service through such date. The option granted to you will be contingent on your execution of the Company's Stock Option Agreement and will be subject to all terms of the Company's 2012 Equity Incentive Plan. Performance and merit reviews will be conducted annually and will be calculated on a prorated basis, based on date of hire.

Subject to the approval of the appropriate committee of the Company's Board of Directors, you will also be granted a restricted stock award for 10,000 shares in consideration of services to be rendered by you. The shares will be subject to the terms and conditions applicable to shares awarded under the Plan, as described in the Plan and the applicable Restricted Stock Agreement. The shares vest in a series of installments as follows: 25% of the shares will vest on the first Company Vesting Date after the second anniversary of your employment start date (your "Start Date"); 25% of the shares will vest on the first Company Vesting Date after the third anniversary of your Start Date; 25% of the shares will vest on the first Company Vesting Date after the fourth anniversary of your Start Date; and 25% of the shares will vest on the first Company Vesting Date after the fifth anniversary of your Start Date provided you have remained in continuous service through each such vesting date. A "Company Vesting Date" means February 20, May 20, August 20 or November 20.

As a part-time employee, you will not be eligible to participate in the Company's paid-benefits plans when you begin your employment. Should your status change to full-time (30 hours or more per week), Theravance will provide a comprehensive company-paid benefits to you and your dependents at a minimal cost. Included are medical, vision and dental coverage, life insurance, long-term disability insurance and a flexible spending plan. Additionally, we offer a 401(k) plan.

You will abide by Theravance's strict company policy that prohibits any new employee from using or bringing with them from any prior employer any confidential information, trade secrets, proprietary materials or processes of such former employers. As a consideration of employment, you will be required to sign our Proprietary Information and Inventions Agreement. In addition, you will be required to present the documents establishing your legal right to work in the United States as required by the government's Form I-9.

While we hope that your employment with the Company will be mutually satisfactory, employment with Theravance is for no specific period of time. As a result, either you or the Company are free to terminate your employment relationship at any time for any reason, with or without cause. This is the full and complete agreement between us on this term. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures to which you will be subject, may change from time-to-time, the "at-will" nature of your employment may only be changed in an express writing signed by you and a Senior Officer of the Company.

This offer is contingent upon the successful completion of your background investigation.

There are two copies of this letter enclosed; if all of the foregoing is satisfactory, please sign and date each copy, and return one copy to me, saving the other copy for yourself.

We are very excited about the possibility of you joining our team and becoming a part of our company! We look forward to determining a mutually convenient start date as soon as possible.

If you have any questions, please don't hesitate to contact me at (650) 238-9600. We look forward to your favorable response.

Sincerely.

/s/ Dennis Driver

Dennis Driver Vice President, HR

Foregoing terms and conditions hereby accepted:

Signed: /s/ Ted Witek

Date: 13 May 2014

Start Date: 1 July 2014

May 30, 2014

George Abercrombie

#### **REVISED**

Dear George:

Theravance, Inc. ("Theravance" or the "Company") is pleased to offer you the part-time exempt position of Senior Vice President, Corporate Partnerships, reporting to the Chief Executive Officer. In accordance with your part-time status of 20 hours/week, you will be paid an annual salary of \$315,000. You will be based in North Carolina working from your home. You will be eligible to receive an annual discretionary bonus of up to 50% of your annual salary, based on the Company's performance against its annual goals and a review of your individual performance. You must be an active employee in good standing at the time the bonus is paid in order to receive the bonus. The Company's bonus percentage targets may change from time-to-time at the sole discretion of the Board of Directors. This offer will expire on June 2, 2014.

Subject to the approval by the appropriate committee of the Company's Board of Directors, you will be granted an option to purchase shares of Common Stock of the Company at a purchase price equal to the fair market value of our Common Stock on the date of grant, which we anticipate will be on or around the first business day of the month following your employment start date. Your option grant will be for 100,000 shares. The vesting and exercise details of your option grant will be set forth in your stock option paperwork, but in general your option will vest monthly over the first four years of your employment, with a one year "cliff" provision that prevents it from being exercised before the first anniversary of the grant date. The option shall be fully vested and exercisable on the 4-year anniversary of the date of grant provided you have remained in continuous service through such date. The option granted to you will be contingent on your execution of the Company's Stock Option Agreement and will be subject to all terms of the Company's 2012 Equity Incentive Plan (the "Plan"). Performance and merit reviews will be conducted annually and will be calculated on a prorated basis, based on date of hire.

Subject to the approval of the appropriate committee of the Company's Board of Directors, you will also be granted a restricted stock award for 10,000 shares in consideration of services to be rendered by you. The shares will be subject to the terms and conditions applicable to shares awarded under the Plan, as described in the Plan and the applicable Restricted Stock Agreement. The shares vest in a series of installments as follows: 25% of the shares will vest on the first Company Vesting Date after the second anniversary of your employment start date (your "Start Date"); 25% of the shares will vest on the first Company Vesting Date after the third anniversary of your Start Date; 25% of the shares will vest on the first Company Vesting Date after the fourth anniversary of your Start Date; and 25% of the shares will vest on the first Company Vesting Date after the fifth anniversary of your Start Date provided you have remained in continuous service through each such vesting date. A "Company Vesting Date" means February 20, May 20, August 20 or November 20.

As a part-time employee, you will not be eligible to participate in the Company's paid-benefits plans when you begin your employment. Should your status change to full-time (30 hours or more per week), Theravance will provide a comprehensive company-paid benefits to you and your dependents at a competitive cost. Included are medical, vision and dental coverage, life insurance, long-term disability insurance and a flexible spending plan. Additionally, we offer a 401(k) plan.

You will abide by Theravance's strict company policy that prohibits any new employee from using or bringing with them from any prior employer any confidential information, trade secrets, proprietary materials or

processes of such former employers. As a consideration of employment, you will be required to sign our Proprietary Information and Inventions Agreement. In addition, you will be required to present the documents establishing your legal right to work in the United States as required by the government's Form I-9.

Theravance acknowledges that, as a part-time employee, you will have the flexibility to maintain your other professional responsibilities as long as these do not conflict with your responsibilities to Theravance. Theravance will further endeavor to coordinate scheduling with you to reasonably accommodate the schedule of your other professional responsibilities.

You will be entitled to enter into the Company's standard form of Officer Indemnification Agreement. You shall be covered by directors and officers liability insurance while employed and while liability exists thereafter at the same level as other officers of Theravance.

Current Theravance travel policy allows you, as a Senior Vice President, to be reimbursed for business class travel. On flights without business class, you are entitled to fly first class. You are further entitled to reimbursement for Theravance-required cell phone and computer use.

While we hope that your employment with the Company will be mutually satisfactory, employment with Theravance is for no specific period of time. As a result, either you or the Company are free to terminate your employment relationship at any time for any reason, with or without cause. This is the full and complete agreement between us on this term. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures to which you will be subject, may change from time-to-time, the "at-will" nature of your employment may only be changed in an express writing signed by you and the Chief Executive Officer, Chairman of the Board or Lead Independent Director of the Company.

This offer is contingent upon the successful completion of your background investigation.

There are two copies of this letter enclosed; if all of the foregoing is satisfactory, please sign and date each copy, and return one copy to me, saving the other copy for yourself.

We are very excited about the possibility of you joining our team and becoming a part of our company! We look forward to determining a mutually convenient start date as soon as possible.

If you have any questions, please don't hesitate to contact me at (650) 238-9600. We look forward to your favorable response.

Sincerely,

/s/ Charissa Shaughnessy
Charissa Shaughnessy
Manager, Human Resources
Foregoing terms and conditions hereby accepted:

Signed: /s/ George B. Abercrombie

Date: 5-30-14

Start Date: 6-2-14

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

#### I, Rick E Winningham, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Theravance, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

financial reporting.	
Date: August 7, 2014	/s/ Rick E Winningham
	Rick E Winningham
	Chief Executive Officer
	(Principal Executive Officer)
	• • •

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

- I, Michael W. Aguiar, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Theravance, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

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Date: August 7, 2014	/s/ Michael W. Aguiar
	Michael W. Aguiar
	Senior Vice President, Finance and
	Chief Financial Officer
	(Principal Financial Officer)

# 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 and six months ended June 30, 2014 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition of Theravance, Inc. at the end of the periods covered by such Quarterly Report on Form 10-Q and results of operations of Theravance, Inc. for the periods covered by such Quarterly Report on Form 10-Q.

Date: August 7, 2014	By:	/s/ Rick E Winningham
2 att. 11 agast 1, 201 .		Rick E Winningham
		Chief Executive Officer
	CERTIFICATION OF CHIEF FINANCIAL C	OFFICER
	PURSUANT TO	
	18 U.S.C. SECTION 1350,	
	AS ADOPTED PURSUANT TO	
SE	CTION 906 OF THE SARBANES-OXLEY A	CT OF 2002
Report of Theravance, Inc. on Form 10-Q for the t the Securities Exchange Act of 1934, as amended	three and six months ended June 30, 2014 fully cand that information contained in such Quarterly at the end of the periods covered by such Quart	006 of the Sarbanes-Oxley Act of 2002, that the Quarterly omplies with the requirements of Section 13(a) or 15(d) of Report on Form 10-Q fairly presents in all material terly Report on Form 10-Q and results of operations of
Date: August 7, 2014	Ву:	/s/ Michael W. Aguiar
		Michael W. Aguiar
	Senior	Vice President, Finance and Chief Financial Officer