

---

---

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

---

**Form 10-Q**

---

(Mark One)

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

For the quarterly period ended June 30, 2017

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-36033

---

**THERAVANCE BIOPHARMA, INC.**

(Exact Name of Registrant as Specified in its Charter)

---

**Cayman Islands**

(State or Other Jurisdiction of  
Incorporation or Organization)

**98-1226628**

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

**PO Box 309**

**Ugland House, South Church Street  
George Town, Grand Cayman, Cayman Islands**  
(Address of Principal Executive Offices)

**KY1-1104**

(Zip Code)

**(650) 808-6000**

(Registrant's Telephone Number, Including Area Code)

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of August 1, 2017, the number of the registrant's outstanding ordinary shares was 53,829,472.



**THERAVANCE BIOPHARMA, INC.**  
**TABLE OF CONTENTS**

	<u>Page No.</u>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
<b><u>Item 1. Financial Statements</u></b>	
<u>Condensed Consolidated Balance Sheets as of June 30, 2017 and December 31, 2016 (unaudited)</u>	3
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2017 and 2016 (unaudited)</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2017 and 2016 (unaudited)</u>	5
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	6
<b><u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	13
<b><u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u></b>	25
<b><u>Item 4. Controls and Procedures</u></b>	25
<b><u>PART II. OTHER INFORMATION</u></b>	
<b><u>Item 1. Legal Proceedings</u></b>	25
<u>Item 1A. Risk Factors</u>	25
<b><u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u></b>	54
<b><u>Item 6. Exhibits</u></b>	55
<u>Signatures</u>	56
<u>Exhibit Index</u>	57

[Table of Contents](#)

## PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2017	December 31, 2016
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 139,626	\$ 344,709
Short-term marketable securities	222,194	156,387
Accounts receivable, net of allowances of \$757 and \$779 at June 30, 2017 and December 31, 2016, respectively	1,346	646
Receivables from collaborative arrangements	5,318	9,076
Prepaid taxes	242	3,060
Other prepaid and current assets	4,030	2,405
Inventories	12,126	12,220
Total current assets	384,882	528,503
Property and equipment, net	8,679	8,460
Long-term marketable securities	136,445	91,565
Other investments	8,000	8,000
Restricted cash	833	833
Other assets	5,047	1,893
Total assets	<u>\$ 543,886</u>	<u>\$ 639,254</u>
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 6,406	\$ 1,733
Accrued personnel-related expenses	15,800	14,021
Accrued clinical and development expenses	26,386	25,064
Other accrued liabilities	8,369	8,298
Deferred revenue	142	152
Total current liabilities	57,103	49,268
Convertible senior notes, net	223,210	222,676
Deferred rent	3,450	3,966
Other long-term liabilities	18,996	13,113
Commitments and contingencies		
Shareholders' equity		
Preferred shares, \$0.00001 par value: 230 shares authorized, no shares issued or outstanding at June 30, 2017 and December 31, 2016, respectively	—	—
Ordinary shares, \$0.00001 par value: 200,000 shares authorized at June 30, 2017 and December 31, 2016; 53,829 and 52,833 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	1	1
Additional paid-in capital	885,315	862,708
Accumulated other comprehensive loss	(248)	(253)
Accumulated deficit	(643,941)	(512,225)
Total shareholders' equity	241,127	350,231
Total liabilities and shareholders' equity	<u>\$ 543,886</u>	<u>\$ 639,254</u>

*See accompanying notes to condensed consolidated financial statements.*

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
<b>Revenue:</b>				
Product sales	\$ 3,474	\$ 5,359	\$ 6,524	\$ 8,670
Revenue from collaborative arrangements	35	112	72	15,211
Total revenue	<u>3,509</u>	<u>5,471</u>	<u>6,596</u>	<u>23,881</u>
<b>Costs and expenses:</b>				
Cost of goods sold	1,364	638	1,929	1,416
Research and development <sup>(1)</sup>	42,927	32,069	83,492	67,748
Selling, general and administrative <sup>(1)</sup>	24,339	20,261	45,125	43,857
Total costs and expenses	<u>68,630</u>	<u>52,968</u>	<u>130,546</u>	<u>113,021</u>
Loss from operations	(65,121)	(47,497)	(123,950)	(89,140)
Interest expense	(2,137)	—	(4,274)	—
Interest and other income (loss), net	1,425	308	2,455	495
Loss before income taxes	(65,833)	(47,189)	(125,769)	(88,645)
Provision for income taxes	454	36	5,837	730
Net loss	<u>\$ (66,287)</u>	<u>\$ (47,225)</u>	<u>\$ (131,606)</u>	<u>\$ (89,375)</u>
<b>Net loss per share:</b>				
Basic and diluted net loss per share	<u>\$ (1.27)</u>	<u>\$ (1.06)</u>	<u>\$ (2.53)</u>	<u>\$ (2.16)</u>
Shares used to compute basic and diluted net loss per share	<u>52,255</u>	<u>44,407</u>	<u>51,938</u>	<u>41,366</u>
Net unrealized gain (loss) on available-for-sale investments	24	55	5	251
Total comprehensive loss	<u>\$ (66,263)</u>	<u>\$ (47,170)</u>	<u>\$ (131,601)</u>	<u>\$ (89,124)</u>

<sup>(1)</sup> Amounts include share-based compensation expense as follows:

<b>(In thousands)</b>	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Research and development	\$ 4,917	\$ 4,959	\$ 10,018	\$ 10,119
Selling, general and administrative	5,481	4,945	10,649	11,115
Total share-based compensation expense	<u>\$ 10,398</u>	<u>\$ 9,904</u>	<u>\$ 20,667</u>	<u>\$ 21,234</u>

*See accompanying notes to condensed consolidated financial statements.*

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

	<u>Six Months Ended June 30,</u>	
	<u>2017</u>	<u>2016</u>
<b>Operating activities</b>		
Net loss	\$ (131,606)	\$ (89,375)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,059	1,153
Share-based compensation	20,667	21,234
Inventory write-down	642	119
Other	262	—
Changes in operating assets and liabilities:		
Accounts receivable	(700)	66
Receivables from collaborative arrangements	3,758	152
Prepaid taxes	(212)	9,614
Other prepaid and current assets	(1,857)	1,566
Inventories	(497)	157
Other assets	(128)	711
Accounts payable	4,798	(10,757)
Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued liabilities	2,905	5,732
Deferred rent	(516)	(229)
Deferred revenue	15	905
Other long-term liabilities	5,859	508
Net cash used in operating activities	<u>(94,551)</u>	<u>(58,444)</u>
<b>Investing activities</b>		
Purchases of property and equipment	(1,325)	(1,322)
Purchases of marketable securities	(231,991)	(91,382)
Maturities of marketable securities	120,970	40,514
Net cash used in investing activities	<u>(112,346)</u>	<u>(52,190)</u>
<b>Financing activities</b>		
Proceeds from sale of ordinary shares, net	—	145,224
Proceeds from ESPP purchases	2,657	1,944
Proceeds from option exercises	5,320	1,346
Repurchase of shares to satisfy tax withholding	(6,163)	(2,224)
Net cash provided by financing activities	<u>1,814</u>	<u>146,290</u>
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(205,083)</b>	<b>35,656</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>344,709</b>	<b>112,707</b>
<b>Cash and cash equivalents at end of period</b>	<b><u>\$ 139,626</u></b>	<b><u>\$ 148,363</u></b>
<b>Supplemental disclosure of cash flow information</b>		
Cash paid for interest	\$ 3,717	\$ —
Cash paid (received) for income taxes, net	\$ (2,985)	\$ (9,488)

*See accompanying notes to condensed consolidated financial statements.*

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

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

***Description of Operations***

Theravance Biopharma, Inc. (“Theravance Biopharma”, the “Company”, or “we” and other similar pronouns) is a diversified biopharmaceutical company with the core purpose of creating medicines that help improve the lives of patients suffering from serious illness.

Our pipeline of internally discovered product candidates includes potential best-in-class medicines to address the unmet needs of patients being treated for serious conditions primarily in the acute care setting. VIBATIV® (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the U.S., Europe and certain other countries for certain difficult-to-treat infections. Revefenacin (TD-4208) is a long-acting muscarinic antagonist (“LAMA”) being developed as a potential once-daily, nebulized treatment for chronic obstructive pulmonary disease (“COPD”). Our neprilysin (“NEP”) inhibitor program is designed to develop selective NEP inhibitors for the treatment of a range of major cardiovascular and renal diseases, including acute and chronic heart failure, hypertension and chronic kidney diseases such as diabetic nephropathy. Our research efforts are focused in the areas of inflammation and immunology, with the goal of designing medicines that provide targeted drug delivery to tissues in the lung and gastrointestinal tract in order to maximize patient benefit and minimize risk. The first program to emerge from this research is designed to develop intestinally restricted pan-Janus kinase (“JAK”) inhibitors for the treatment of a range of inflammatory intestinal diseases.

In addition, we have an economic interest in future payments that may be made by Glaxo Group Limited or one of its affiliates (“GSK”) pursuant to its agreements with Innoviva, Inc. (“Innoviva”) (known as Theravance, Inc. prior to January 7, 2016) relating to certain drug development programs, including the Closed Triple (the combination of fluticasone furoate, umeclidinium, and vilanterol), currently in development for the treatment of COPD and asthma.

***Basis of Presentation***

Our condensed consolidated financial information as of June 30, 2017, and the three and six months ended June 30, 2017 and 2016 are unaudited but include all adjustments (consisting only of normal recurring adjustments), which we consider necessary for a fair presentation of the financial position at such date and of the operating results and cash flows for those periods, and have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated December 31, 2016 financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2016, filed with the Securities and Exchange Commission (“SEC”) on March 1, 2017.

On January 1, 2017, we adopted ASU 2016-09, *Compensation—Stock Compensation (Topic 718)* (“ASU 2016-09”). Under ASU 2016-09, excess tax benefits from share-based compensation are now included on the Consolidated Statements of Cash Flows as an operating activity rather than a financing activity. This change has been applied prospectively as allowed under ASU 2016-09 and prior periods have not been adjusted on the Consolidated Statements of Cash Flows.

***Significant Accounting Policies***

Other than the below, there have been no material revisions in our significant accounting policies described in Note 1 to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2016.

***Share-Based Compensation***

In connection with the adoption of ASU 2016-09, we elected to change our accounting policy for recognizing share-based compensation expense by replacing the practice of estimating forfeitures to utilizing actual forfeitures as they occur. The change was applied on a modified retrospective basis, and the cumulative effect adjustment recorded to retained earnings, as of January 1, 2017, was immaterial.

**Recently Issued Accounting Pronouncements Not Yet Adopted**

In May 2014, the FASB issued Accounting Standards Update (“ASU”) 2014-09, *Revenue from Contracts with Customers (Topic 606)* (“ASU 2014-09” or “*Topic 606*”), which will replace most existing revenue recognition guidance in GAAP when it becomes effective. ASU 2014-09’s core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. ASU 2014-09 defines a five-step process to achieve this core principle and, in doing so, companies may need to use more judgment and make more estimates than under the currently effective guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price, and allocating the transaction price to each separate performance obligation. Since ASU 2014-09 was issued, several additional ASUs have been issued and incorporated within *Topic 606* to clarify various elements of the guidance.

*Topic 606* differs from the current accounting standard in many respects, such as in the accounting for variable consideration, including milestone payments. Since the separation from our former parent, Innoviva, in June 2014, our revenues have been derived primarily from collaboration agreements. The consideration we are eligible to receive under these agreements includes upfront payments, research and development funding, milestone payments, and royalties. Each collaboration agreement is unique and will need to be assessed separately under the five-step process under the new standard. Under our current accounting policy, we recognize milestone revenue using the milestone method specified in ASC 605-28, which generally results in the recognition of the milestone payment as revenue in the period that the milestone is achieved. However, under the new accounting standard, it is possible to start to recognize milestone revenue before the milestone is achieved, subject to management’s assessment of whether it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. This aspect of *Topic 606* may have a material effect on our financial statements. We also recognize revenues from product sales. Although we have not yet completed our final review of the impact of *Topic 606*, we currently do not anticipate a material impact on our revenue recognition practices for product sales.

We will adopt *Topic 606* in the first quarter of 2018 using the modified retrospective method which consists of applying and recognizing the cumulative effect of *Topic 606* at the date of initial application and providing certain additional disclosures as defined per *Topic 606*. We are in the process of reviewing variable consideration, potential disclosures, and our method of adoption to complete our evaluation of the impact on our consolidated financial statements prior to the end of 2017. In addition, we continue to monitor additional changes, modifications, clarifications or interpretations undertaken by the FASB, which may impact our current conclusions.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments — Overall (Subtopic 825-10)* (“ASU 2016-01”), which requires equity investments that are not accounted for under the equity method of accounting to be measured at fair value with changes recognized in net income, simplifies the impairment assessment of certain equity investments, and updates certain presentation and disclosure requirements. However, an entity may choose to measure equity investments that do not have readily determinable fair values at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. This guidance is effective for all interim and annual reporting periods beginning after December 15, 2017, and early adoption is not permitted. We have evaluated the potential impact of ASU 2016-01, and we do not believe the adoption of ASU 2016-01 will have a material impact on our consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* (“ASU 2016-02”). ASU 2016-02 is aimed at making leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. ASU 2016-02 is effective for all interim and annual reporting periods beginning after December 15, 2018 with early adoption permitted. We are currently evaluating the impact that the adoption of ASU 2016-02 will have on our consolidated financial statements and related disclosures.

In October 2016, the FASB issued ASU 2016-16, *Income Taxes (Topic 740)* (“ASU 2016-16”). ASU 2016-16 requires immediate recognition of income tax consequences of intra-company asset transfers, other than inventory transfers. Existing GAAP prohibits recognition of income tax consequences of intra-company asset transfers whereby the seller defers any net tax effect and the buyer is prohibited from recognizing a deferred tax asset on the difference between the newly created tax basis of the asset in its tax jurisdiction and its financial statement carrying amount as reported in the consolidated financial statements. ASU 2016-16 specifically excludes from its scope intra-company inventory transfers whereby the recognition of tax consequences will take place when the inventory is sold to third parties. Two common examples of assets included in ASU 2016-16’s scope are intellectual property and property, plant and equipment. ASU 2016-16 is effective for



[Table of Contents](#)

fiscal years beginning after December 15, 2017, and interim periods within those fiscal years with early adoption is permitted. We expect to adopt ASU 2016-16 in the first quarter of 2018 using the modified retrospective method. Currently, we do not anticipate a material impact on our consolidated financial statements and related disclosures upon adoption due to a full valuation allowance on our deferred tax assets. However, the ultimate impact of adopting ASU 2016-16 will depend on the balance of intercompany sales transactions, if any, between our subsidiaries as of the adoption date and our continued full valuation allowance position.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting* (“ASU 2017-09”). ASU 2017-09 provides clarity and reduces both diversity in practice and cost and complexity when applying the guidance in Topic 718 to a change to the terms and conditions of a share-based payment award. ASU 2017-09 also provides guidance about the types of changes to the terms or conditions of a share-based payment award that require an entity to apply modification accounting in accordance with Topic 718. The provisions of ASU 2017-09 are effective for all interim and annual reporting periods beginning after December 15, 2017, and early adoption is permitted. We plan to adopt ASU 2017-09 on its effective date and apply the new guidance to evaluate future changes, if any, to the terms and conditions of our share-based payment awards.

We have evaluated other recently issued accounting pronouncements and do not believe that any of these pronouncements will have a significant impact 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 outstanding, less ordinary shares subject to forfeiture. Diluted net loss per share is computed by dividing net loss by the weighted-average number of shares outstanding, less ordinary shares subject to forfeiture, plus all additional ordinary shares that would have been outstanding, assuming dilutive potential ordinary shares had been issued for other dilutive securities.

For the three and six months ended June 30, 2017 and 2016, diluted and basic net loss per share was identical since potential ordinary shares were excluded from the calculation, as their effect was anti-dilutive.

### *Anti-Dilutive Securities*

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

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Share issuances under equity incentive plan and ESPP	2,674	3,310	2,958	3,417
Restricted shares	26	1,488	26	1,488
Share issuances upon the conversion of convertible senior notes	6,676	—	6,676	—
	<u>9,376</u>	<u>4,798</u>	<u>9,660</u>	<u>4,905</u>

In addition, as of June 30, 2017 and 2016, there were 1,305,000 shares and 1,440,000 shares, respectively, which were subject to performance-based vesting criteria which have been excluded from the ordinary equivalent shares table above.

## 3. Collaborative Arrangements

### *Revenue from Collaborative Arrangements*

We recognized the following revenues from our collaborative arrangements:

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Mylan	\$ 26	\$ 25	\$ 52	\$ 15,051
Other	9	87	20	160
Total revenue from collaborative arrangements	<u>\$ 35</u>	<u>\$ 112</u>	<u>\$ 72</u>	<u>\$ 15,211</u>

[Table of Contents](#)

**Mylan**

*Development and Commercialization Agreement*

In January 2015, we established a strategic collaboration with Mylan Ireland Limited (“Mylan”) for the development and, subject to regulatory approval, commercialization of revefenacin (TD-4208), our investigational LAMA in development for the treatment of COPD. We entered into this collaboration to expand the breadth of our revefenacin development program and extend our commercial reach beyond the acute care setting where we currently market VIBATIV.

For the three and six months ended June 30, 2017, we recognized \$26,000 and \$52,000, respectively, in revenue primarily from the amortization of previously deferred revenue. For the three and six months ended June 30, 2016, we recognized \$25,000 and \$15.0 million of revenue, respectively. The \$25,000 resulted from amortization of previously deferred revenue and the \$15.0 million resulted from the achievement of 50% enrollment in the Phase 3 twelve-month safety study which triggered a milestone payment to Theravance Biopharma by Mylan.

As of June 30, 2017, we are eligible to receive from Mylan additional potential development, regulatory and sales milestone payments totaling up to \$205.0 million in the aggregate, with \$160.0 million associated with revefenacin monotherapy and \$45.0 million for future potential combination products. Of the \$160.0 million associated with monotherapy, \$150.0 million relates to commercialization and \$10.0 million relates to regulatory actions in the European Union (“EU”). Development and regulatory milestones are deemed to be substantive milestones and will be recognized as revenue in the period upon achievement of each respective milestone. Sales milestones are considered contingent payments and are not deemed to be substantive milestones due to the fact that the achievement of the event underlying the payment predominantly relates to Mylan’s performance of future commercial activities. We do not expect to earn any milestone payments from Mylan in 2017.

**Alfasigma (formerly Alfa Wassermann)**

*Development and Collaboration Agreement*

Under an October 2012 development and collaboration agreement for velusetrag, we and Alfasigma S.p.A (“Alfasigma”) (formerly Alfa Wassermann S.p.A.) agreed to collaborate in the execution of a two-part Phase 2 program to test the efficacy, safety and tolerability of velusetrag in the treatment of patients with gastroparesis (a medical condition consisting of a paresis (partial paralysis) of the stomach, resulting in food remaining in the stomach for a longer time than normal). Alfasigma has an exclusive option to develop and commercialize velusetrag in the EU, Russia, China, Mexico and certain other countries, while we retain full rights to velusetrag in the United States, Canada, Japan and certain other countries. As part of this agreement, Alfasigma funded the majority of the costs associated with the Phase 2 gastroparesis program, which consisted of a Phase 2 study focused on gastric emptying and a Phase 2 study focused on symptoms. If Alfasigma exercises its license option at the completion of the Phase 2 program, then we are entitled to receive a \$10.0 million option fee. If velusetrag is successfully developed and commercialized, we are entitled to receive potential future contingent payments totaling up to \$53.5 million, and royalties on net sales by Alfasigma ranging from the low teens to 20%.

**Reimbursement of R&D Costs**

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

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

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Mylan	\$ 4,768	\$ 25,971	\$ 11,857	\$ 57,144
Alfasigma	—	2,601	—	3,786
Other	4	110	41	123
Total reduction to R&D expense	<u>\$ 4,772</u>	<u>\$ 28,682</u>	<u>\$ 11,898</u>	<u>\$ 61,053</u>

[Table of Contents](#)

#### 4. Available-for-Sale Securities and Fair Value Measurements

Our available-for-sale securities include:

(In thousands)	Fair Value Hierarchy Level	Estimated Fair Value	
		June 30, 2017	December 31, 2016
U.S. government securities	Level 1	\$ 84,884	\$ 69,955
U.S. government agency securities	Level 2	69,200	60,747
Corporate notes	Level 2	181,593	98,313
Commercial paper	Level 2	35,953	18,937
Marketable securities		371,630	247,952
Money market funds	Level 1	92,493	323,602
Total		\$ 464,123	\$ 571,554

The estimated fair value of marketable securities is based on quoted market prices for these or similar investments that were based on prices obtained from a commercial pricing service. The fair value of our marketable securities classified within Level 2 is based upon observable inputs that may include benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data including market research publications. Net unrealized losses were \$0.4 million as of June 30, 2017 and \$0.3 million as of December 31, 2016.

As of June 30, 2017, all of the marketable securities had contractual maturities within two years and the weighted average maturity of the marketable securities was approximately 10 months. There were no transfers between Level 1 and Level 2 during the periods presented and there have been no changes to our valuation techniques during the three and six months ended June 30, 2017.

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 as of June 30, 2017 were temporary in nature. The gross unrealized loss on marketable securities held for greater than twelve months was immaterial, as of June 30, 2017.

As of June 30, 2017, our accumulated other comprehensive loss on our condensed consolidated balance sheets consisted of net unrealized losses on available-for-sale investments. During the three and six months ended June 30, 2017, we did not sell any of our marketable securities.

Restricted cash pertained to certain lease agreements and letters of credit where we have pledged cash and cash equivalents as collateral.

In November 2016, we completed an underwritten public offering of \$230.0 million of 3.250% convertible senior notes, due 2023 (the "Notes"). The estimated fair value of our Notes was \$310.2 million as of June 30, 2017 and was primarily based upon the underlying price of Theravance Biopharma's publicly traded shares and other observable inputs. The inputs to determine fair value of the Notes are categorized as Level 2 inputs. Level 2 inputs include 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.

As of June 30, 2017, we reviewed our \$8.0 million investment in Trek Therapeutics, PBC ("TREKtx"), a non-marketable equity security that we acquired in September 2015, for impairment and believe the current liquidity of TREKtx is an indicator of impairment in our investment. However, based on TREKtx's current financing plans, we believe that the impairment is temporary. The realization of the value in TREKtx is dependent upon TREKtx's ability to continue to raise capital to pursue their business plan. TREKtx faces development risks and the outcome of the development is inherently uncertain, and the ultimate commercialization of their product is further dependent upon regulatory approvals, product pricing and reimbursements. As a result of these risks, it is possible that impairments of the carrying value of TREKtx can arise in future reporting periods.

**5. Inventories**

Inventory consists of the following:

<u>(In thousands)</u>	<u>June 30,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Raw materials	\$ 6,749	\$ 6,067
Work-in-process	3,384	2,627
Finished goods	1,993	3,526
Total inventories	<u>\$ 12,126</u>	<u>\$ 12,220</u>

**6. Share-Based Compensation*****Share-Based Compensation Expense Allocation***

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

<u>(In thousands)</u>	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Research and development	\$ 4,917	\$ 4,959	\$ 10,018	\$ 10,119
Selling, general and administrative	5,481	4,945	10,649	11,115
Total share-based compensation expense	<u>\$ 10,398</u>	<u>\$ 9,904</u>	<u>\$ 20,667</u>	<u>\$ 21,234</u>

***Performance-Contingent Awards***

In the first quarter of 2016, the Compensation Committee of our Board of Directors (“Compensation Committee”) approved the grant of 1,575,000 performance-contingent restricted share awards (“RSAs”) and 135,000 performance-contingent restricted share units (“RSUs”) to senior management. The vesting of such awards is dependent on the Company meeting its critical operating goals and objectives during a five-year period from 2016 to December 31, 2020. These goals are strategically important for the Company, and management believes the goals, if achieved, will increase shareholder value. The awards have dual triggers of vesting based upon the achievement of these goals and continued employment. As of June 30, 2017, there were 1,305,000 performance-contingent RSAs and 135,000 performance-contingent RSUs outstanding, and as of June 30, 2016, there were 1,440,000 performance-contingent RSAs and 135,000 performance-contingent RSUs outstanding.

Expense associated with these awards is broken into three separate tranches and may be recognized during the years 2016 to 2020 depending on the probability of meeting the performance conditions. Compensation expense relating to awards subject to performance conditions is recognized if it is considered probable that the performance goals will be achieved. The probability of achievement is reassessed at each quarter-end reporting period. The maximum potential expense associated with the awards could be up to \$35.5 million (allocated as \$13.3 million for research and development expense and \$22.2 million for selling, general and administrative expense) if all of the performance conditions are achieved.

As of June 30, 2017, we determined that the achievement of the requisite performance conditions for the first tranche of the awards is probable due to multiple advancements of programs within our development pipeline over the course of 2017. For the three and six months ended June 30, 2017, we recognized \$0.5 million and \$0.9 million of share-based compensation expense from the first tranche of the awards, respectively.

We have determined that the remaining second and third tranches are not probable of vesting and, as a result, no compensation expense related to these tranches has been recognized as of June 30, 2017.

**7. Income Taxes**

The income tax provision was \$0.5 million and \$5.8 million for the three and six months ended June 30, 2017, respectively, although we incurred operating losses on a consolidated basis. The provision for income tax was primarily due to recording contingent tax liabilities pertaining primarily to uncertain tax positions taken with respect to transfer pricing and tax credits. No provision for income taxes has been recognized on undistributed earnings of our foreign subsidiaries because we consider such earnings to be indefinitely reinvested.

[Table of Contents](#)

We follow the accounting guidance related to accounting for income taxes which requires that a company reduce its deferred tax assets by a valuation allowance if, based on the weight of available evidence, it is more likely than not that some portion or all of its deferred tax assets will not be realized. As of June 30, 2017, our deferred tax assets were offset in full by a valuation allowance.

We record liabilities related to uncertain tax positions in accordance with the income tax guidance which clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Resolution of one or more of these uncertain tax positions in any period may have a material impact on the results of operations for that period. We include any applicable interest and penalties within the provision for income taxes in the condensed consolidated statements of operations.

The difference between the Irish statutory rate and our effective tax rate was primarily due to the valuation allowance on deferred tax assets and the liabilities recorded for the uncertain tax position related to transfer pricing and tax credits.

Our future income tax expense may be affected by such factors as changes in tax laws, our business, regulations, tax rates, interpretation of existing laws or regulations, the impact of accounting for share-based compensation, the impact of accounting for business combinations, our international organization, shifts in the amount of income before tax earned in the U.S. as compared with other regions in the world, the timing and amounts of releases of our valuation allowance and changes in overall levels of income before tax.

## 8. Operating Leases

We lease approximately 150,000 square feet of office and laboratory space in two buildings in South San Francisco, California, under a non-cancelable operating lease that ends in May 2020. We have the right to extend the terms of this lease for two additional five-year periods. In April 2017, we entered into a 10-year lease for an office space in Connaught House, Dublin, Ireland ("Connaught House"). The Connaught House replaces our previously leased Dublin office space and allows us to accommodate future personnel growth. Under the terms of the Connaught House lease, we are leasing approximately 6,100 square feet at an initial base rent of approximately \$443,000 per year. Future minimum lease payments under the leases, exclusive of executory costs, as of June 30, 2017, are as follows:

<u>(In thousands)</u>	
Six months ending December 31, 2017	\$ 3,305
<u>Years ending December 31:</u>	
2018	6,748
2019	6,937
2020	3,201
2021	443
Thereafter	2,333
Total	<u>\$ 22,967</u>

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### Forward-Looking Statements

You should read the following discussion in conjunction with our condensed financial statements (unaudited) and related notes included elsewhere in this report. This report includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 (the "Securities Act"), as amended, and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"), as amended, that involve risks and uncertainties. All statements in this report, other than statements of historical facts, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans, intentions, expectations and objectives are forward-looking statements. The words "anticipate," "assume," "believe," "contemplate," "continue," "could," "designed," "developed," "drive," "estimate," "expect," "forecast," "goal," "intend," "may," "mission," "opportunities," "plan," "potential," "predict," "project," "pursue," "seek," "should," "target," "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. These statements reflect our current views with respect to future events or our future financial performance, are based on assumptions, and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. 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 differ materially 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 in "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report and in our Annual Report on Form 10-K for the year ended December 31, 2016. Our forward-looking statements in this report are based on current expectations and we do not assume any obligation to update any forward-looking statements for any reason, even if new information becomes available in the future.

### Management Overview

Theravance Biopharma, Inc. ("Theravance Biopharma") is a diversified biopharmaceutical company with the core purpose of creating medicines that help improve the lives of patients suffering from serious illness.

Our pipeline of internally discovered product candidates includes potential best-in-class medicines to address the unmet needs of patients being treated for serious conditions primarily in the acute care setting. VIBATIV® (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the U.S., Europe and certain other countries for certain difficult-to-treat infections. Revefenacin (TD-4208) is a long-acting muscarinic antagonist ("LAMA") being developed as a potential once-daily, nebulized treatment for chronic obstructive pulmonary disease ("COPD"). Our neprilysin ("NEP") inhibitor program is designed to develop selective NEP inhibitors for the treatment of a range of major cardiovascular and renal diseases, including acute and chronic heart failure, hypertension and chronic kidney diseases such as diabetic nephropathy. Our research efforts are focused in the areas of inflammation and immunology, with the goal of designing medicines that provide targeted drug delivery to tissues in the lung and gastrointestinal tract in order to maximize patient benefit and minimize risk. The first program to emerge from this research is designed to develop intestinally restricted pan-Janus kinase ("JAK") inhibitors for the treatment of a range of inflammatory intestinal diseases.

In addition, we have an economic interest in future payments that may be made by Glaxo Group Limited or one of its affiliates ("GSK") pursuant to its agreements with Innoviva, Inc. ("Innoviva") (known as Theravance, Inc. prior to January 7, 2016) relating to certain drug development programs, including the combination of fluticasone furoate, umeclidinium, and vilanterol (the "Closed Triple"), currently in development for the treatment of COPD and asthma.

### Program Highlights

#### *VIBATIV® (telavancin)*

VIBATIV is a bactericidal, once-daily injectable antibiotic to treat patients with serious, life-threatening infections due to *Staphylococcus aureus* and other Gram-positive bacteria, including methicillin-resistant ("MRSA") strains. VIBATIV is approved in the U.S. for the treatment of adult patients with complicated skin and skin structure infections ("cSSSI") caused by susceptible Gram-positive bacteria and for the treatment of adult patients with hospital-acquired and ventilator-associated bacterial pneumonia ("HABP"/ "VABP") caused by susceptible isolates of *Staphylococcus aureus* when

## [Table of Contents](#)

alternative treatments are not suitable. VIBATIV is indicated in the European Union (“EU”) for the treatment of adults with nosocomial pneumonia, including ventilator-associated pneumonia, known or suspected to be caused by MRSA when other alternatives are not suitable. VIBATIV is also indicated in Canada and Russia for cSSSI and HABP and VABP caused by Gram-positive bacteria, including MRSA.

Our acute care sales force currently markets VIBATIV in the U.S., and we maintain an independent marketing and medical affairs team. Outside of the U.S., our strategy is to market VIBATIV through a network of partners. To date, we have secured partners for VIBATIV in the following geographies—Canada, Middle East and North Africa, Israel, Russia, China and India. In August 2016, we and Clinigen Group (“Clinigen”) reached a mutual decision for Clinigen to return commercial rights to market and distribute VIBATIV in the EU to Theravance Biopharma. On November 4, 2016, the European Commission approved the transfer of the centralized marketing authorization for VIBATIV from Clinigen to our wholly-owned Irish subsidiary, Theravance Biopharma Ireland Limited. We are in discussion with potential collaborators with the goal of establishing a new strategic commercial partnership in the EU.

### *Supplemental New Drug Application (sNDA) for Concurrent Staphylococcus aureus Bacteremia*

In May 2016, we announced approval of our sNDA by the Food and Drug Administration (“FDA”) allowing for the addition of new clinical data to the VIBATIV label concerning concurrent bacteremia in cases of HABP/VABP and cSSSI. The sNDA submission was based on the combined data from our previously conducted pivotal trials of VIBATIV in its two approved indications—cSSSI (ATLAS I and ATLAS II) and HABP/VABP (ATTAIN I and ATTAIN II). The trials were large, multi-center, multi-national, double-blind, randomized Phase 3 clinical studies enrolling and treating 3,370 adult patients, including a portion of patients with concurrent bacteremia. Importantly, these studies involved two of the largest cohorts of patients ever studied in these diseases and included one of the largest cohorts of patients with MRSA infections studied to date. Separately, we are conducting a Phase 3 registrational study in patients with *Staphylococcus aureus* bacteremia.

### *Phase 3 Registrational Study in Staphylococcus aureus Bacteremia*

As part of our effort to explore additional settings in which VIBATIV may offer patients therapeutic benefit, in February 2015, we initiated a Phase 3 registrational study for the treatment of patients with *Staphylococcus aureus* bacteremia. The 250-patient registrational study is a multi-center, randomized, open-label study designed to evaluate the non-inferiority of telavancin in treating *Staphylococcus aureus* bacteremia as compared to standard therapy. Key secondary outcome measures of the study include an assessment of the duration of bacteremia post-randomization and the incidence of development of metastatic complications, as compared to standard therapy. We expect to complete the study in 2018 or 2019.

### *Telavancin Observational Use Registry (“TOUR<sup>TM</sup>”) Study*

Initiated in February 2015, the 1,000-patient TOUR<sup>TM</sup> study is designed to assess the manner in which VIBATIV is used by healthcare practitioners to treat patients. By broadly collecting and examining data related to VIBATIV treatment patterns, as well as clinical effectiveness and safety outcomes in medical practice, we aim to create an expansive knowledge base to guide optimal clinical use and future development of the drug. In February 2017, we announced that enrollment in the TOUR<sup>TM</sup> study was complete. Final results from the study will be available once all patient data is collected, verified and analyzed. This study is providing information about the use of VIBATIV in real-world clinical settings, including reports of positive clinical responses in patients with bacteremia, endocarditis, osteomyelitis, skin and respiratory infections. We expect future TOUR<sup>TM</sup> analyses to be updated as additional data becomes available.

### *Janssen Pharmaceutica License Agreement*

In 2002, we entered into a License Agreement with Janssen Pharmaceutica N.V. (“Janssen”) pursuant to which we have licensed rights under certain patents owned by Janssen covering an excipient used in the formulation of telavancin. Pursuant to the terms of this license agreement, we are obligated to pay royalties to Janssen of 2.5-5% of any net commercial sales of VIBATIV (telavancin). The license will terminate in 2019. The license is terminable by us upon prior written notice to Janssen or upon an uncured breach or a liquidation event of one of the parties.

### *Long-Acting Muscarinic Antagonist—Revefenacin (TD-4208)*

Revefenacin is an investigational LAMA in development for the treatment of COPD. We believe that revefenacin may become a valuable addition to the COPD treatment regimen and that it represents a significant commercial opportunity.

## [Table of Contents](#)

Our market research indicates there is an enduring population of COPD patients in the U.S. that either need or prefer nebulized delivery for maintenance therapy. LAMAs are a cornerstone of maintenance therapy for COPD, but existing LAMAs are only available in handheld devices that may not be suitable for every patient. Revefenacin has the potential to be a best-in-class once-daily single-agent product for COPD patients who require, or prefer, nebulized therapy. The therapeutic profile of revefenacin, together with its physical characteristics, suggest that this LAMA could serve as a foundation for combination products and for delivery in metered dose inhaler and dry powder inhaler (“MDI”/“DPI”) products.

### *Mylan Collaboration*

In January 2015, Mylan Ireland Limited (“Mylan”) and we established a strategic collaboration for the development and, subject to regulatory approval, commercialization of revefenacin. Partnering with a world leader in nebulized respiratory therapies enables us to expand the breadth of our revefenacin development program and extend our commercial reach beyond the acute care setting where we currently market VIBATIV. Funding of the Phase 3 development program by Mylan preserves our capital position and enhances our financial flexibility to advance other high-value pipeline assets alongside revefenacin.

Under the terms of the Mylan Development and Commercialization Agreement (the “Mylan Agreement”), Mylan and we are co-developing nebulized revefenacin for COPD and other respiratory diseases. We are leading the U.S. Phase 3 development program and Mylan is responsible for reimbursement of our costs related to the registrational program up until the approval of the first new drug application (“NDA”), after which costs will be shared. If a product developed under the collaboration is approved in the U.S., Mylan will lead commercialization and we will retain the right to co-promote the product in the U.S. under a profit-sharing arrangement (65% Mylan/35% Theravance Biopharma). Outside the U.S. (excluding China), Mylan will be responsible for development and commercialization and will pay us a tiered royalty on net sales at percentage royalty rates ranging from low double-digits to mid-teens.

Under the Mylan Agreement, Mylan paid us an initial payment of \$15.0 million in cash in the second quarter of 2015. Also, pursuant to an ordinary share purchase agreement entered into on January 30, 2015, Mylan Inc., the indirect parent corporation of Mylan, made a \$30.0 million equity investment in us, buying 1,585,790 ordinary shares from us in early February 2015 in a private placement transaction at a price of approximately \$18.918 per share, which represented a 10% premium over the volume weighted average price per share of our ordinary shares for the five trading days ending on January 30, 2015. In February 2016, we earned a \$15.0 million development milestone payment for achieving 50% enrollment in the Phase 3 twelve-month safety study. As of June 30, 2017, we are eligible to receive from Mylan additional potential development, regulatory and sales milestone payments totaling up to \$205.0 million in the aggregate, with \$160.0 million associated with revefenacin monotherapy and \$45.0 million for future potential combination products. Of the \$160.0 million associated with monotherapy, \$150.0 million relates to commercialization and \$10.0 million relates to regulatory actions in the EU. We do not expect to earn any milestone payments from Mylan in 2017.

We retain worldwide rights to revefenacin delivered through other dosage forms, such as a MDI/DPI, while Mylan has certain rights of first negotiation with respect to our development and commercialization of revefenacin delivered other than via a nebulized inhalation product. In China, we retain all rights to revefenacin in any dosage form.

### *Phase 3 Program in COPD*

In September 2015, we announced, with our partner Mylan, the initiation of the Phase 3 development program for revefenacin for the treatment of COPD. The Phase 3 development program, designed to support the registration of the product in the U.S., includes two replicate three-month efficacy studies and a single twelve-month safety study. The two efficacy studies examined two doses (88 mcg and 175 mcg) of revefenacin inhalation solution administered once-daily via nebulizer in patients with moderate to severe COPD. The Phase 3 efficacy studies were replicate, randomized, double-blind, placebo-controlled, parallel-group trials designed to provide pivotal efficacy and safety data for once-daily revefenacin over a dosing period of 12 weeks, with a primary endpoint of trough forced expiratory volume in one second (FEV1) on day 85. The Phase 3 safety study was an open-label, active comparator study of 12 months duration.

In October 2016, we announced positive top-line results from the two replicate Phase 3 efficacy studies of revefenacin in more than 1,250 moderate to very severe COPD patients, and in May 2017 we reported additional data from these studies. Both Phase 3 efficacy studies met their primary endpoints, demonstrating statistically significant improvements over placebo in trough FEV1 after 12 weeks of dosing for each of the revefenacin doses studied (88 mcg once daily and 175 mcg once daily). The studies also demonstrated that the 88 mcg and 175 mcg doses of revefenacin were generally well-tolerated, with comparable rates of adverse events and serious adverse events across all treatment groups (active and placebo). In July 2017, we announced positive top-line results from the twelve-month safety study in 1,055 COPD patients.



## [Table of Contents](#)

Data demonstrated that both the 88 mcg and 175 mcg doses of revefenacin were generally well-tolerated, with low rates of adverse events (AEs) and serious adverse events (SAEs), comparable to those seen with the active comparator. Together, the three studies enrolled approximately 2,305 patients. We expect to file a NDA for revefenacin with the FDA in the fourth quarter of 2017, supported by data from the two replicate Phase 3 efficacy studies and twelve-month safety study.

In March 2017, we initiated a Phase 3b study of revefenacin in patients with low peak inspiratory flow rate (“PIFR”), designed to support commercialization if revefenacin is approved. The study is not required for the planned NDA submission for revefenacin in COPD in the fourth quarter of 2017. We expect results from this study in the first quarter of 2018.

### ***Velusetrag (TD-5108)***

Velusetrag is an oral, investigational medicine developed for gastrointestinal motility disorders. It is a highly selective agonist with high intrinsic activity at the human 5-HT<sub>4</sub> receptor. Velusetrag, which was granted Fast Track designation by the FDA for the treatment of symptoms associated with idiopathic and diabetic gastroparesis, is being developed in collaboration with Alfasigma S.p.A. (“Alfasigma”) (formerly Alfa Wassermann S.p.A.). Positive top-line results from the initial Phase 2 proof-of-concept study under this partnership, which evaluated gastric emptying, safety and tolerability of multiple doses of velusetrag, were announced in April 2014.

In early August 2017, we announced positive top-line results from a 12-week, Phase 2b study of velusetrag characterizing the impact on symptoms and gastric emptying of three oral doses of velusetrag (5, 15 and 30 mg) compared to placebo administered once daily over 12 weeks of therapy. Results from the study demonstrated statistically significant improvements in gastroparesis symptoms and gastric emptying for patients receiving 5 mg of velusetrag as compared to placebo. Patients in the 15 and 30 mg velusetrag study arms demonstrated an inverse dose response in symptom improvement and did not experience statistically significant improvements in gastroparesis symptoms. Velusetrag was shown to be generally well-tolerated, with 5 mg and placebo having comparable rates of adverse events and serious adverse events.

### ***TD-9855***

TD-9855 is an investigational norepinephrine and serotonin reuptake inhibitor (“NSRI”). TD-9855 completed a Phase 2 study in patients with fibromyalgia, demonstrating statistically significant and clinically meaningful improvements in pain and core symptoms at the highest dose tested compared to placebo. We are assessing the potential use of TD-9855 in neurogenic orthostatic hypotension (“nOH”), and in May 2016, we initiated a Phase 2a study of TD-9855 in this indication. The Phase 2a study is designed to evaluate postural changes in blood pressure, symptom reduction, and safety and tolerability of single ascending doses in patients with nOH. Based on encouraging treatment responses in the majority of patients enrolled to date, we announced in February 2017 our plan to amend the study design to allow those patients who respond to continue dosing for up to 20 weeks to assess the durability of their response. We expect to complete the extended Phase 2a study by the first half of 2018. In parallel with the Phase 2a study, we plan to seek regulatory support for an orphan drug designation and an expedited development pathway for TD-9855 in nOH.

### ***Intestinally Restricted Pan-Janus Kinase (JAK) Inhibitor Program (TD-1473 and TD-3504)***

JAK inhibitors function by inhibiting the activity of one or more of the Janus kinase family of enzymes (JAK1, JAK2, JAK3, TYK2) that play a key role in cytokine signaling. Inhibiting these JAK enzymes interferes with the JAK/STAT signaling pathway and, in turn, modulates the activity of a wide range of pro-inflammatory cytokines. JAK inhibitors are currently approved for the treatment of rheumatoid arthritis and myelofibrosis and have demonstrated therapeutic benefit for patients with ulcerative colitis. However, these products are known to have side effects based on their systemic exposure. Our goal is to develop an orally administered, intestinally restricted pan-JAK inhibitor specifically designed to distribute adequately and predominantly to the tissues of the intestinal tract, treating inflammation in those tissues while minimizing systemic exposure. We are focused on utilizing targeted JAK inhibitors for potential treatment of a range of inflammatory intestinal diseases, including ulcerative colitis.

### ***TD-1473***

#### ***Phase 1 Single Ascending Dose (SAD) and Multiple Ascending Dose (MAD) Studies***

In June 2016, we completed a Phase 1 clinical study of TD-1473, an internally-discovered JAK inhibitor that has demonstrated a high affinity for each of the JAK family of enzymes. The primary objective of the study was to evaluate the

## [Table of Contents](#)

safety and tolerability of single ascending and multiple ascending doses of TD-1473 in healthy volunteers. A key secondary objective of the trial was to characterize the pharmacokinetics of TD-1473, including the determination of the amount of TD-1473 that entered systemic circulation following oral administration. Data from the study demonstrated TD-1473 to be generally well tolerated. Study results also demonstrated that systemic exposures of TD-1473 were low relative to that reported for tofacitinib, a JAK inhibitor currently in development for ulcerative colitis. At steady state, the plasma exposures of TD-1473 were significantly lower than the plasma exposure of tofacitinib.

Furthermore, subjects exhibited high stool concentrations of TD-1473, which were comparable to concentrations associated with efficacy in preclinical colitis models. Preclinical studies also demonstrated penetration of TD-1473 into the intestinal wall and membrane. The data generated from the study met our target pharmacokinetic profile and support clinical progression of the compound.

Previously announced findings from a preclinical model of colitis evaluating TD-1473 and tofacitinib demonstrated that both compounds significantly reduced disease activity scores. However, at doses providing similar preclinical efficacy, the systemic exposure of TD-1473 was much lower than that of tofacitinib and TD-1473 did not reduce systemic immune cell counts, in contrast to tofacitinib. Based on these preclinical findings, we believe that TD-1473 represents a potential breakthrough approach to treating ulcerative colitis without the risk generally associated with systemically active therapies.

### *Phase 1b Study*

In late 2016, we announced dosing of the first patient in a Phase 1b clinical study of TD-1473 in patients with moderate to severe ulcerative colitis. The Phase 1b exploratory study in 40 patients is designed to evaluate the safety, tolerability, and pharmacokinetics (PK) of TD-1473 over a 28-day treatment period. In addition, the study incorporates biomarker analysis and clinical, endoscopic, and histologic assessments to evaluate biological effect.

In early August 2017, we announced encouraging data from the first cohort of patients in the Phase 1b study. Data from the first cohort demonstrated evidence of localized biological activity for TD-1473 after four weeks of treatment, based on a compilation of clinical, endoscopic, and biomarker assessments. Pharmacokinetic data demonstrated minimal systemic exposure and there was no evidence of systemic immunosuppression. We expect data from the remaining two cohorts in the Phase 1b study in 2018.

### *TD-3504*

In September 2016, we announced plans to progress a second compound, TD-3504, from our JAK inhibitor program. TD-3504 is an innovative prodrug of tofacitinib, an investigational JAK inhibitor in development for ulcerative colitis. TD-3504 is chemically distinct from TD-1473 and is designed to release active tofacitinib into the intestinal tract. In preclinical studies, TD-3504 demonstrated rapid formation of tofacitinib in the intestinal tract, reduction in disease activity score comparable to tofacitinib, and low systemic exposure in contrast to tofacitinib.

### ***Nepilysin (NEP) Inhibitor Program (TD-0714 and TD-1439)***

Nepilysin ("NEP") is an enzyme that degrades natriuretic peptides. These peptides play a protective role in controlling blood pressure and preventing cardiovascular tissue remodeling. Inhibiting NEP may result in clinical benefit for patients, including diuresis, control of blood pressure, and reversing maladaptive changes in the heart and vascular tissue in patients with congestive heart failure. Our primary objective is to develop a NEP inhibitor that could be used across a broad population of patients with cardiovascular and renal diseases, including acute and chronic heart failure and chronic kidney disease, including diabetic nephropathy. We aim to create a platform for multiple combination products with our NEP inhibitor with features that are differentiated from currently available products. Specifically, we intend to develop compounds that are non-renal cleared, dosed once-daily, dosed alone or in combination with other medicines and that may be dosed orally or intravenously.

## [Table of Contents](#)

### *TD-0714*

#### *Phase 1 Single Ascending Dose (SAD) and Multiple Ascending Dose (MAD) Studies*

In March 2016, we completed a Phase 1 randomized, double-blind, placebo-controlled, single ascending dose (“SAD”) study in healthy volunteers of our most advanced NEP inhibitor compound, TD-0714. The study was designed to assess the safety, tolerability and pharmacokinetics of TD-0714, as well as measure biomarker evidence of target engagement and the amount of the drug that is eliminated via the kidneys. Results from the SAD study of TD-0714 demonstrate that the compound achieved maximal and sustained levels of target engagement for 24 hours after a single-dose, supporting the drug’s potential for once-daily dosing. Target engagement was measured by dose-related increases in the levels of cyclic GMP (cGMP, a well-precedented biomarker of NEP engagement). TD-0714 also demonstrated very low levels of renal elimination, as evidenced by intravenous microtracer testing technology, and a favorable tolerability profile.

In October 2016, we completed a Phase 1 randomized, double-blind, placebo-controlled, multiple ascending dose (“MAD”) study in healthy volunteers of TD-0714. The findings from the MAD study were consistent with the Phase 1 randomized, double-blind, placebo-controlled, SAD study in healthy volunteers we completed in March 2016, demonstrating sustained target engagement, low levels of renal elimination, and a favorable tolerability profile.

### *TD-1439*

TD-1439 is a second NEP inhibitor compound, which is structurally distinct from TD-0714. In the first half of 2017, we announced favorable results from Phase 1 SAD and a Phase 1 MAD studies of TD-1439. In both Phase 1 studies, TD-1439 demonstrated characteristics which met our target product profile, including sustained 24-hour target engagement, low levels of renal elimination and a favorable tolerability profile.

We are currently evaluating next steps for both compounds in our NEPi clinical program, including compound and formulation selection, potential combinations, study population, and timing. The results from the Phase 1 programs provide confidence for future efficacy studies of either compound in a broad range of cardiovascular and renal diseases, including in patients with compromised renal function.

#### ***Selective 5-HT<sub>4</sub> Agonist (TD-8954)***

##### *Takeda Collaborative Arrangement*

In June 2016, we entered into a License and Collaboration Agreement with Millennium Pharmaceuticals, Inc., a Delaware corporation (“Millennium”) (the “Takeda Agreement”), in order to establish a collaboration for the development and commercialization of TD-8954 (TAK-954), a selective 5-HT<sub>4</sub> receptor agonist. TD-8954 is being developed for potential use in the treatment of gastrointestinal motility disorders, including short-term intravenous use for enteral feeding intolerance (“EFI”) to achieve early nutritional adequacy in critically ill patients at high nutritional risk, an indication for which the compound received FDA Fast Track designation. Millennium is an indirect wholly-owned subsidiary of Takeda Pharmaceutical Company Limited (TSE: 4502), a publicly-traded Japanese corporation listed on the Tokyo Stock Exchange (collectively with Millennium, “Takeda”). Under the terms of the Takeda Agreement, Takeda will be responsible for worldwide development and commercialization of TD-8954. We received an upfront cash payment of \$15.0 million and will be eligible to receive success-based development, regulatory and sales milestone payments by Takeda. The first \$110.0 million of potential milestones are associated with the development, regulatory and commercial launch milestones for EFI or other intravenously dosed indications. We will also be eligible to receive a tiered royalty on worldwide net sales by Takeda at percentage royalty rates ranging from low double-digits to mid-teens.

#### ***NS5A Inhibitor—TD-6450***

TD-6450 is a multivalent NS5A inhibitor. TD-6450 has successfully completed Phase 1 studies in both healthy volunteers and hepatitis C virus (“HCV”) patients. In September 2015, we entered into a licensing agreement with Trek Therapeutics, PBC (“TREKtx”) (the “TREKtx Agreement”) granting TREKtx an exclusive worldwide license for the development, manufacturing, use, marketing and sale of TD-6450 as a component in combination HCV products (the “HCV Products”). Pursuant to the TREKtx Agreement, we received an upfront payment of \$8.0 million in the form of TREKtx’s Series A preferred stock and will be eligible to receive future royalties based on net sales of the HCV Products.

## [Table of Contents](#)

In October 2015, TREKtx initiated an open-label Phase 2a clinical trial to evaluate faldaprevir (“FDV”), an HCV protease inhibitor, combined with TD-6450 and ribavirin (“RBV”) in patients infected with HCV genotype 4 (GT4). In September 2016, TREKtx announced interim data from the study that showed the sustained viral response (“SVR”) rate four weeks after the completion of treatment (SVR4) was 100% (16 of 16) in treatment naïve patients with chronic GT4 HCV who received 120 mg of FDV and RBV in combination with 60 mg or 120 mg of TD-6450 for 12 weeks. In February 2017, TREKtx announced that 100% of these patients (16 of 16) had maintained SVR at twelve weeks after the completion of treatment (SVR12) as well.

In July 2017, TREKtx reported that dosing was complete in a second Phase 2a study of FDV and TD-6450, with and without RBV in patients with HCV genotype 1b (GT1b). In the study arm containing RBV, 14 of 15 patients achieved SVR12 and in the study arm without ribavirin, 6 of 8 patients achieved SVR. A summary of safety results revealed no SAEs, discontinuations due to AEs, and no significant safety issues.

### **Other Programs**

#### ***Economic Interest in GSK-Partnered Respiratory Programs***

We are entitled to receive an 85% economic interest in any future payments that may be made by GSK (pursuant to its agreements with Innoviva) relating to certain of the respiratory programs (the “GSK-Partnered Respiratory Programs”) that Innoviva partnered with GSK and assigned to Theravance Respiratory Company, LLC (“TRC”) in connection with Innoviva’s separation of its biopharmaceutical operations into its then wholly-owned subsidiary Theravance Biopharma. The GSK-Partnered Respiratory Programs consist primarily of the Closed Triple program and the Inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist (“MABA”) program, each of which are described in more detail below. We are entitled to this economic interest through our equity ownership in TRC. Our economic interest will not include any payments associated with RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO® ELLIPTA® or vilanterol monotherapy. The following information regarding the Closed Triple and the MABA program is based solely upon publicly available information and may not reflect the most recent developments under the programs.

#### *“Closed Triple” or FF/UMEC/VI (fluticasone furoate/umeclidinium bromide/vilanterol)*

The Closed Triple program seeks to provide the activity of an inhaled corticosteroid (FF) plus two bronchodilators (UMEC, a LAMA, and VI, a long-acting beta2 agonist, or LABA) in a single delivery device administered once-daily. If the Closed Triple is successfully developed and commercialized, we are entitled to receive an 85% economic interest in the royalties payable by GSK to TRC on worldwide net sales, which royalties are upward-tiering from 6.5% to 10%. Previously, Innoviva and GSK announced the initiation of two global pivotal Phase 3 studies of the Closed Triple. The IMPACT study, which will enroll approximately 10,000 COPD patients, was initiated in July 2014. The IMPACT study will assess whether the Closed Triple can reduce the rate of moderate and severe exacerbations compared with two approved once-daily COPD treatments, RELVAR® ELLIPTA®/BREO® ELLIPTA® (FF/VI), an ICS/LABA combination, and ANORO® ELLIPTA® (UMEC/VI), a LAMA/LABA combination. The IMPACT study is ongoing and is expected to read out in 2017. The FULFIL study, which enrolled approximately 1,800 COPD patients was initiated in February 2015. In June 2016, GSK and Innoviva disclosed positive top-line results from the FULFIL study, in which data demonstrated superiority of the Closed Triple as compared to twice-daily SYMBICORT® TURBOHALER® (budesonide/formoterol) in improving lung function and health-related quality of life in COPD patients. In November 2016, GSK and Innoviva announced the filing of a NDA in the U.S. for the Closed Triple for patients with COPD. In December 2016, GSK and Innoviva announced the filing of a Marketing Authorization Application (“MAA”) in the EU for the Closed Triple for patients with COPD. In December 2016, GSK and Innoviva announced the initiation of the Phase 3 (CAPTAIN) study of the Closed Triple in patients with asthma. The CAPTAIN study is expected to read out in 2018.

#### *Inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist (MABA)*

GSK961081 (‘081), also known as batefenterol, is an investigational, single-molecule bifunctional bronchodilator with both muscarinic antagonist and beta2 receptor agonist activity that was discovered by us when we were part of Innoviva.

## [Table of Contents](#)

If a single-agent MABA medicine containing '081 is successfully developed and commercialized, we are entitled to receive an 85% economic interest in the royalties payable by GSK to TRC on worldwide net sales, which royalties range between 10% and 20% of annual global net sales up to \$3.5 billion, and 7.5% for all annual global net sales above \$3.5 billion. If a MABA medicine containing '081 is commercialized only as a combination product, such as '081/FF, the royalty rate is 70% 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, TRC is eligible to receive contingent milestone payments from GSK. The agreements allow for total milestones of up to \$125.0 million for a single-agent medicine and an incremental \$125.0 million for a combination medicine. Of these amounts, \$112.0 million in potential milestones remain for a single-agent medicine, and \$122.0 million remain for a combination medicine. In each case, we would be entitled to receive an 85% economic interest in any such payments.

### *Theravance Respiratory Company, LLC ("TRC")*

Our equity interest in TRC is the mechanism by which we are entitled to the 85% economic interest in any future payments made by GSK under the strategic alliance agreement and under the portion of the collaboration agreement assigned to TRC by Innoviva. The drug programs assigned to TRC include the Closed Triple and the MABA program, as monotherapy and in combination with other therapeutically active components, such as an inhaled corticosteroid ("ICS"), as well as any other product or combination of products that may be discovered and developed in the future under these GSK agreements.

### **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. Other than below, there have been no material changes to the critical accounting policies and estimates discussed in our Annual Report on Form 10-K for the year ended December 31, 2016.

### *Investments in Non-Marketable Equity Securities*

Non-marketable equity securities are recorded at cost in long-term assets, and we periodically review our non-marketable equity securities for impairment by determining whether impairment indicators are present. Common impairment indicators include a significant adverse change in the regulatory or economic environment in which the investee entity operates, inadequacies in the ability of the investee to raise cash to fund operating activities, or other working capital deficiencies.

If we conclude that a non-marketable equity security is impaired, we determine whether such impairment is other-than-temporary. The term "other-than-temporary" is not intended to indicate that the decline in value is permanent, but indicates that the prospect for a near-term recovery of value is not necessarily favorable and that there is a lack of evidence to support a realizable value equal to or greater than the carrying value of the investment. Factors we consider to make such determination include the duration and severity of the impairment, the reason for the decline in value and the potential recovery period and our intent to sell. If any impairment is considered other-than-temporary, we will write-down the asset to its fair value and record the corresponding charge as interest and other income (loss).

As of June 30, 2017, we reviewed our \$8.0 million investment in TREKtx for impairment. We believe that the current liquidity of TREKtx is an indicator of impairment in our investment. However, based on TREKtx's current financing plans, we believe that the impairment is temporary. The realization of the value of our investment in TREKtx is dependent upon TREKtx's ability to continue to raise capital to pursue their business plan. TREKtx faces development risks and the outcome of the development is inherently uncertain, and the ultimate commercialization of their product is further dependent upon regulatory approvals, product pricing and reimbursements. As a result of these risks, it is possible that impairments of the carrying value of TREKtx can arise in future reporting periods.

**Results of Operations**

**Product Sales and Revenue from Collaborative Arrangements**

Product sales and revenue from collaborative arrangements, as compared to the comparable period in the prior year, were as follows:

(In thousands)	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2017	2016	\$	%	2017	2016	\$	%
Product sales	\$ 3,474	\$ 5,359	\$ (1,885)	(35)%	\$ 6,524	\$ 8,670	\$ (2,146)	(25)%
Revenue from collaborative arrangements	35	112	(77)	(69)	72	15,211	(15,139)	(100)
Total revenue	\$ 3,509	\$ 5,471	\$ (1,962)	(36)%	\$ 6,596	\$ 23,881	\$ (17,285)	(72)%

Revenue from product sales decreased by \$1.9 million and \$2.1 million for the three and six months ended June 30, 2017, respectively, compared to the same periods in 2016. Both decreases resulted primarily from reduced volume attributed to the impact of generic daptomycin in the outpatient market.

Revenue from collaborative arrangements for the six months ended June 30, 2017 decreased by \$15.1 million from the same period in the prior year primarily due to a \$15.0 million milestone payment from Mylan in the first half of 2016 for the achievement of 50% enrollment in the Phase 3 twelve-month safety study. There were no milestone payments in the current quarter.

**Cost of Goods Sold**

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

(In thousands)	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2017	2016	\$	%	2017	2016	\$	%
Cost of goods sold	\$ 1,364	\$ 638	\$ 726	114%	\$ 1,929	\$ 1,416	\$ 513	36%

Costs of goods sold increased by \$0.7 million and \$0.5 million for the three and six months ended June 30, 2017, respectively, compared to the same periods in 2016 primarily due to the write-off of certain inventory.

**Research and Development**

Our research and development (“R&D”) expenses consist primarily of employee-related costs, external costs, and various allocable expenses. We budget total R&D expenses on an internal department level basis, and we manage and report our R&D activities across the following four cost categories:

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

The following table summarizes our R&D expenses incurred, net of reimbursements from collaboration partners, during the periods presented:

(In thousands)	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2017	2016	\$	%	2017	2016	\$	%
Employee-related	\$ 14,669	\$ 8,881	\$ 5,788	65%	\$ 26,822	\$ 19,400	\$ 7,422	38%
Share-based compensation	4,917	4,959	(42)	(1)	10,018	10,119	(101)	(1)
External-related	15,799	11,510	4,289	37	32,055	24,613	7,442	30
Facilities, depreciation and other allocated expenses	7,542	6,719	823	12	14,597	13,616	981	7
Total research and development expenses	\$ 42,927	\$ 32,069	\$ 10,858	34%	\$ 83,492	\$ 67,748	\$ 15,744	23%

[Table of Contents](#)

R&D expenses increased by \$10.9 million and \$15.7 million for the three and six months ended June 30, 2017, respectively, compared to the same periods in 2016. The increases were primarily related to increases in employee-related and external-related costs as we continue to fund advancement across all stages of our development pipeline. For the three and six months ended June 30, 2017, the employee-related costs increased \$5.8 million and \$7.4 million, respectively, and were primarily attributed to the accrual of long-term retention and cash bonus awards granted to certain employees in 2016. The payout of such awards is dependent on the company meeting its critical operating goals and objectives during a five-year period from 2016 to December 31, 2020. For the three and six months ended June 30, 2017, external-related costs increased by \$4.3 million and \$7.4 million, respectively, primarily due to the progression in our key programs, including the ongoing enrollment of the Phase 3b PIFR study of revefenacin and the Phase 3 registrational study of telavancin for bacteremia.

Under certain of our collaborative arrangements, we receive partial reimbursement of employee-related costs and external costs, which have been reflected as a reduction of R&D expenses of \$4.8 million and \$28.7 million for the three months ended June 30, 2017 and 2016, respectively, and \$11.9 million and \$61.1 million for the six months ended June 30, 2017 and 2016, respectively. The decrease in expense reimbursements for both periods was primarily attributed to the completion of the two replicate three-month efficacy studies and the long term safety study for revefenacin, a program we are co-developing with Mylan.

### ***Selling, General and Administrative Expenses***

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

(In thousands)	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2017	2016	\$	%	2017	2016	\$	%
Selling, general and administrative	\$ 24,339	\$ 20,261	\$ 4,078	20%	\$ 45,125	\$ 43,857	\$ 1,268	3%

Selling, general and administrative expenses increased by \$4.1 million for three months ended June 30, 2017 compared to the same period in 2016 primarily due to an increase in employee-related costs associated with the accrual of our long-term retention and incentive cash bonus awards granted to certain employees in 2016, an increase in other general and administrative costs, and share-based compensation. This increase was partially offset by a reduction in external expenses related to our commercialization activities. Share-based compensation within selling, general and administrative expenses was \$5.5 million and \$4.9 million for the three months ended June 30, 2017 and 2016, respectively.

Selling, general and administrative expenses increased by \$1.3 million for six months ended June 30, 2017 compared to the same period in 2016 primarily due to an increase in employee-related costs associated with the accrual of long-term retention and incentive cash bonus awards granted to certain employees in 2016. The payout of such awards is dependent on the company meeting its critical operating goals and objectives during a five-year period from 2016 to December 31, 2020. This increase was partially offset by reductions in external general and administrative expenses and a reduction in external expenses related to our commercialization activities. Share-based compensation within selling, general and administrative expenses was \$10.6 million and \$11.1 million for the six months ended June 30, 2017 and 2016, respectively.

### ***Interest Expense***

(In thousands)	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2017	2016	\$	%	2017	2016	\$	%
Interest expense	\$ 2,137	\$ —	\$ 2,137	NM	\$ 4,274	\$ —	\$ 4,274	NM

NM: Not Meaningful

Interest expense for the three and six months ended June 30, 2017 increased to \$2.1 million and \$4.3 million, respectively, due to the November 2016 issuance of \$230.0 million principal amount of 3.250% convertible senior notes due 2023. We had no interest-bearing debt for the comparable periods in 2016.

[Table of Contents](#)

**Provision for Income Taxes**

(In thousands)	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2017	2016	\$	%	2017	2016	\$	%
Provision for income taxes	\$ 454	\$ 36	\$ 418	1,161%	\$ 5,837	\$ 730	\$ 5,107	700%

Our effective tax rate for the six months ended June 30, 2017 was approximately (4.6)%. Although we incurred operating losses on a consolidated basis, the provision for income taxes was due to the uncertain tax positions taken with respect to transfer pricing and tax credits.

**Liquidity and Capital Resources**

We have financed our operations primarily through public offering of equity and debt securities, private placements of equity, revenue from collaboration arrangements and revenue from product sales. As of June 30, 2017, we had approximately \$498.3 million in cash and investments in marketable securities. Also, as of June 30, 2017, we had outstanding \$230.0 million in aggregate principal amount of 3.250% convertible senior notes due 2023.

We expect to continue to incur net losses over the next several years as we continue our drug discovery efforts and incur significant preclinical and clinical development costs related to our current product candidates and commercialization and development costs relating to VIBATIV. In particular, to the extent we advance our product candidates into and through later-stage clinical studies without a partner, we will incur substantial expenses. We expect the clinical development of our key development programs will require significant investment in order to continue to advance in clinical development. In the past, we have received a number of significant payments from collaboration agreements and other significant transactions. In the future, we expect to receive revenues from product sales and potential substantial payments from future collaboration transactions if the drug candidates in our pipeline achieve positive clinical or regulatory outcomes. Our current business plan is also subject to significant uncertainties and risks as a result of, among other factors, the sales levels of VIBATIV, clinical program outcomes, whether, when and on what terms we are able to enter into new collaboration arrangements, expenses being higher than anticipated, unplanned expenses, cash receipts being lower than anticipated, and the need to satisfy contingent liabilities, including litigation matters and indemnification obligations.

*Adequacy of cash resources to meet future needs*

We expect our cash and cash equivalents and marketable securities will fund our operations for at least the next 12 months based on current operating plans and financial forecasts.

If our current operating plans or financial forecasts change, we may require additional funding sooner in the form of public or private equity offerings, debt financings or additional collaborations and licensing arrangements. However, future financing may not be available in amounts or on terms acceptable to us, if at all.

Without adequate financial resources to fund our operations as presently conducted, we may be required to relinquish rights to our technologies, product candidates or territories, or grant licenses on terms that are not favorable to us, in order to raise additional funds through collaborations or licensing arrangements. We may also have to sequence pre-clinical and clinical studies as opposed to conducting them concomitantly in order to conserve resources, or delay, reduce or eliminate one or more of our research or development programs and reduce overall overhead expenses. In addition, we may have to make reductions in our workforce and may be prevented from continuing our discovery, development and commercialization efforts and exploiting other corporate opportunities.

**Cash Flows**

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

(In thousands)	Six Months Ended June 30,		Change
	2017	2016	
Net cash used in operating activities	\$ (94,551)	\$ (58,444)	\$ (36,107)
Net cash used in investing activities	(112,346)	(52,190)	(60,156)
Net cash provided by financing activities	1,814	146,290	(144,476)

*Cash flows used in operating activities*

Net cash used in operating activities was \$94.6 million for the six months ended June 30, 2017, consisting primarily of net loss of \$131.6 million, adjusted for non-cash items such as \$20.7 million for share-based compensation expense and \$13.4 million of net cash inflow related to changes in operating assets and liabilities for the six months ended June 30, 2017.

Net cash used in operating activities was \$58.4 million for the six months ended June 30, 2016, consisting primarily of net loss of \$89.4 million, adjusted for non-cash items such as \$21.2 million for share-based compensation expense, and \$8.4 million of net cash inflow related to changes in operating assets and liabilities. The \$8.4 million net cash inflow related to changes in operating assets and liabilities was primarily attributable to \$9.6 million in net tax refunds during the six months period ended June 30, 2016.



## [Table of Contents](#)

### *Cash flows used in provided by investing activities*

Net cash used in investing activities was \$112.3 million for the six months ended June 30, 2017, consisting primarily of net cash outflows resulting from the purchases and maturities of marketable securities of \$111.0 million.

Net cash used in investing activities was \$52.2 million for the six months ended June 30, 2016, consisting of outflows related to net purchases and maturities of marketable securities of \$50.9 million and by purchases of property and equipment of \$1.3 million.

### *Cash flows provided by financing activities*

Net cash provided by financing activities was \$1.8 million for the six months ended June 30, 2017, consisting of net cash inflows of \$8.0 million from the proceeds from employee option exercises and employee stock plan purchases which was partially offset by the sale of shares to satisfy tax withholding obligations of \$6.2 million.

Net cash provided by financing activities was \$146.3 million for the six months ended June 30, 2016, consisting primarily of \$107.9 million related to the sale of ordinary shares through our public equity offering, \$23.0 million related to the sale of ordinary shares to GSK, and \$14.3 million through our at-the-market offering program.

### *Commitments and Contingencies*

We indemnify our officers and directors for certain events or occurrences, subject to certain limits. We believe the fair value of these indemnification agreements is minimal. Accordingly, we have not recognized any liabilities relating to these agreements as of June 30, 2017.

In 2016, we granted a long-term retention and incentive restricted share awards (“RSAs”) and restricted share units (“RSUs”) to members of senior management and a long-term retention and incentive cash bonus awards to certain employees. The vesting and payout of such awards is dependent on the company meeting its critical operating goals and objectives during a five-year period from 2016 to December 31, 2020. These goals are strategically important for the company, and we believe the goals, if achieved, will increase shareholder value. The awards have dual triggers of vesting based upon the achievement of these goals and continued employment, and they are broken into three separate tranches. The maximum potential expense associated with all three tranches of this program is \$35.5 million related to share-based compensation expense and \$54.2 million related to cash bonus expense, which would be recognized in increments based on achievement of the performance conditions. The maximum potential expense associated with the first tranche of the program is \$6.1 million in share-based compensation expense and \$13.6 million in cash bonus expense. We have determined that achievement of the requisite performance conditions for the first tranche of the awards is probable due to multiple advancements of programs within our development pipeline, and as a result, we have recognized \$2.7 million in share-based compensation and \$6.2 million in cash bonus expense, as of June 30, 2017.

### *Off-Balance Sheet Arrangements*

There have been no material changes in our off-balance sheet arrangements from those set forth in our Annual Report on Form 10-K for the year ended December 31, 2016, filed with the SEC on March 1, 2017.

### *Contractual Obligations and Commercial Commitments*

In the table below, we set forth our enforceable and legally binding, significant obligations and future commitments, as well as obligations related to all contracts that we are likely to continue, regardless of the fact that they were cancelable as of June 30, 2017. Some of the figures that we include in this table are based on management’s estimate and assumptions about these obligations, including their duration. Because these estimates and assumptions are necessarily subjective, the obligations we will actually pay in future periods may vary from those reflected in the table.

(In thousands)	Years				
	Total	Within 1	Over 1 to 3	Over 3 to 5	After 5
3.250% Convertible senior notes due 2023	\$ 277,362	\$ 7,475	\$ 14,950	\$ 14,950	\$ 239,987
Facility operating leases <sup>(1)</sup>	22,967	6,656	13,315	885	2,111
Purchase obligations <sup>(2)</sup>	83,864	71,275	10,409	2,180	—
Total	<u>\$ 384,193</u>	<u>\$ 85,406</u>	<u>\$ 38,674</u>	<u>\$ 18,016</u>	<u>\$ 242,098</u>

(1) As security for performance of certain obligations under the operating leases for our principal physical properties, we issued a letter of credit in the amount of \$0.8 million, collateralized by an equal amount of restricted cash.

(2) Substantially all of this amount was subject to open purchase orders, as of June 30, 2017, that were issued under existing contracts. This amount does not represent any minimum contract termination liabilities for our existing contracts.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our market risks as of June 30, 2017 have not changed materially from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2016, filed with the SEC on March 1, 2017.

### **ITEM 4. CONTROLS AND PROCEDURES**

#### *Evaluation of Disclosure Controls and Procedures*

We conducted an evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act as of June 30, 2017, 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 (as defined under Rule 13a-15(e) of the Exchange Act), which are 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 Exchange Act is recorded, processed, summarized and reported within required time periods. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective 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 Biopharma have been detected. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

#### *Changes in Internal Control over Financial Reporting*

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act, which occurred during the second quarter of the year ending December 31, 2017 which has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

We are not currently a party to any material litigation or other material legal proceedings.

### **ITEM 1A. RISK FACTORS**

#### **RISKS RELATING TO THE COMPANY**

The risks described below and elsewhere in this Quarterly Report on Form 10-Q and in our other public filings with the SEC are not the only risks facing the Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

***We anticipate that we will incur losses for the foreseeable future. We may never achieve or sustain profitability.***

First as part of Innoviva, Inc. (known as Theravance, Inc. prior to January 7, 2016), and since June 2, 2014 as Theravance Biopharma, we have been engaged in discovery and development of compounds and product candidates since mid-1997. We may never generate sufficient revenue from the sale of medicines, royalties on sales by our partners or from our interest in Theravance Respiratory Company, LLC (“TRC”) to achieve profitability. During six months ended June 30, 2017 and the years ended December 31, 2016 and 2015, we recognized losses of \$131.6 million, \$190.7 million and \$182.2 million, respectively, which are reflected in the Shareholders’ Equity on our consolidated balance sheets. We reflect cumulative net loss incurred after June 2, 2014, the effective date of the Spin-Off, as accumulated deficit on our consolidated balance sheets. We expect to continue to incur net losses at least over the next several years as we continue our drug discovery and development efforts and incur significant preclinical and clinical development costs related to our current product candidates and commercialization and development costs relating to VIBATIV® (telavancin) and, in anticipation of potential approval, revefenacin. In particular, to the extent we advance our product candidates into and through additional clinical studies without a partner, we will incur substantial expenses. For example, in August 2017, we announced our decision to accelerate funding associated with the next phase of development of our intestinally restricted pan-Janus kinase (“JAK”) inhibitor program. We are also making additional investments in telavancin, our antibiotic that has been approved for certain difficult-to-treat infections. For example, we are conducting a Phase 3 registrational study of telavancin for bacteremia. We are incurring all of the costs and expenses associated with the commercialization of VIBATIV in the U.S., including the maintenance of an independent sales and marketing organization with appropriate technical expertise, supporting infrastructure and distribution capabilities, expanded medical affairs presence, manufacturing and third-party vendor logistics and consultant support, and post-marketing studies. We are also making additional investments in revefenacin in anticipation of potential approval. Our commitment of resources to VIBATIV, to the continued development of our existing product candidates and to our discovery programs will require significant additional funding. Our operating expenses also will increase if, among other things:

- our earlier stage potential products move into later-stage clinical development, which is generally more expensive than early stage development;
- additional preclinical product candidates are selected for clinical development;
- we pursue clinical development of our potential or current products in new indications;
- we increase the number of patents we are prosecuting or otherwise expend additional resources on patent prosecution or defense; or
- we acquire or in-license additional technologies, product candidates, products or businesses.

Other than revenues from sales of VIBATIV, our only approved medicine and potential payments under collaboration agreements, we do not expect to generate revenues from our programs in the immediate future. Since we or our collaborators or licensees may not successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost or with appropriate quality, or successfully market and sell such products with desired margins, our expenses may continue to exceed any revenues we may receive.

In the absence of substantial licensing payments, contingent payments or other revenues from third-party collaborators, royalties on sales of products licensed under our intellectual property rights, future revenues from VIBATIV and product candidates in development that receive regulatory approval or other sources of revenues, we will continue to incur operating losses and will require additional capital to execute our business strategy. The likelihood of reaching, and the time required to reach, and then to sustain, profitability are highly uncertain. As a result, we expect to continue to incur substantial losses for the foreseeable future. We are uncertain when or if we will ever be able to achieve or sustain profitability. Failure to become and remain profitable would adversely affect the price of our securities and our ability to raise capital and continue operations.

***If additional capital is not available, we may have to curtail or cease operations or we could be forced to share our rights to commercialize our product candidates with third parties on terms that may not be favorable to us.***

Based on our current operating plans and financial forecasts, 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. If our current operating plans or financial forecasts change, we may require or seek additional funding sooner in the form of public or private equity or equity-linked offerings, debt financings or additional collaborations and licensing arrangements. For example, if we choose to progress any additional product candidates into later-stage development on our own, our capital needs would increase substantially. We also are making significant investments in telavancin, our approved antibiotic. For example, we are conducting a Phase 3 registrational study of telavancin for bacteremia.

## [Table of Contents](#)

In addition, we maintain an independent sales and marketing organization and medical affairs team focused on the acute care setting and VIBATIV. We are also making additional investments in revefenacin in anticipation of potential approval. In 2016, we increased our anticipated operating loss, primarily because of accelerated enrollment in TOUR, increased funding for the development of our JAK inhibitors and increased investment in our neprilysin (“NEP”) inhibitor program. In August 2017, we announced an increase in our anticipated operating loss for 2017, primarily driven by our decision to accelerate funding associated with the next phase of development of our JAK inhibitor program.

We may need to raise additional capital in the future to, among other things:

- fund our discovery efforts and research and development programs;
- fund our commercialization strategies for VIBATIV and any additional approved products;
- progress mid-to-late stage product candidates into later-stage development, if warranted;
- respond to competitive pressures; and
- acquire complementary businesses or technologies.

Our future capital needs depend on many factors, including:

- the scope, duration and expenditures associated with our discovery efforts and research and development programs;
- continued scientific progress in these programs;
- the extent to which we encounter technical obstacles in our research and development programs;
- the outcome of potential licensing or partnering transactions, if any;
- competing technological developments;
- the extent of our proprietary patent position in telavancin and our product candidates;
- our facilities expenses, which will vary depending on the time and terms of any facility lease or sublease we may enter into, and other operating expenses;
- the scope and extent of the expansion of our sales and marketing efforts;
- potential litigation and other contingencies; and
- the regulatory approval process for our product candidates.

We may seek to raise additional capital or obtain future funding through public or private equity offerings, debt financings or additional collaborations and licensing arrangements. We may not be able to obtain additional financing on terms favorable to us, if at all. General market conditions may make it difficult for us to seek financing from the capital markets. We may be required to relinquish rights to our technologies, product candidates or territories, or grant licenses on terms that are not favorable to us, in order to raise additional funds through collaborations or licensing arrangements. We may sequence pre-clinical and clinical studies as opposed to conducting them concomitantly in order to conserve resources, or delay, reduce or eliminate one or more of our research or development programs and reduce overall overhead expenses. If we are unable to raise additional capital or obtain future funding in sufficient amounts or on terms acceptable to us, we may have to make reductions in our workforce and may be prevented from continuing our discovery, development and commercialization efforts and exploiting other corporate opportunities. This would likely harm our business, prospects and financial condition and cause the price of our securities to fall.

[Table of Contents](#)

***We may seek to obtain future financing through the issuance of debt or equity, which may have an adverse effect on our shareholders or may otherwise adversely affect our business.***

If we raise funds through the issuance of additional debt, including convertible debt or equity, any debt securities or preferred shares issued will have rights, preferences and privileges senior to those of holders of our ordinary shares in the event of liquidation. The terms of our existing convertible senior notes do not restrict our ability to issue additional debt. In such event, there is a possibility that once all senior claims are settled, there may be no assets remaining to pay out to the holders of ordinary shares. In addition, if we raise funds through the issuance of additional equity, whether through private placements or public offerings, such an issuance would dilute ownership of our current shareholders that do not participate in the issuance. For example, since our Spin-Off in June 2014, we have raised an aggregate of \$583.9 million through the sale of approximately 17.5 million shares and \$230.0 million aggregate principal amount of 3.250% convertible senior notes due 2023 in a combination of private sale, public offerings and pursuant to our at-the-market offering program. If we are unable to obtain any needed additional funding, we may be required to reduce the scope of, delay, or eliminate some or all of, our planned research, development and commercialization activities or to license to third parties the rights to develop and/or commercialize products or technologies that we would otherwise seek to develop and/or commercialize ourselves or on terms that are less attractive than they might otherwise be, any of which could materially harm our business.

Furthermore, the terms of any additional debt securities we may issue in the future may impose restrictions on our operations, which may include limiting our ability to incur additional indebtedness, pay dividends on or repurchase our share capital, or make certain acquisitions or investments. In addition, we may be subject to covenants requiring us to satisfy certain financial tests and ratios, and our ability to satisfy such covenants may be affected by events outside of our control.

***Servicing our convertible senior notes requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our debt. Additionally, holders may require us to repurchase our convertible senior notes under certain circumstances, and we may not have sufficient cash to do so.***

Our ability to make interest or principal payments when due or to refinance the Notes depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations sufficient to satisfy our obligations under the Notes and any future indebtedness we may incur and to make necessary capital expenditures. We may be required to adopt one or more alternatives, such as reducing or delaying investments or capital expenditures, selling assets, refinancing or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance the Notes or future indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities on desirable terms or at all, which could result in a default on the Notes or future indebtedness.

Additionally, holders of the Notes may have the right to require us to repurchase the Notes upon the occurrence of a “fundamental change” such as a change of control of our Company or the termination of trading of our ordinary shares, as defined in the indenture, as amended, governing the Notes. We may not have sufficient funds to repurchase the Notes in cash or have the ability to arrange necessary financing on acceptable terms. Our failure to repurchase the Notes when required would result in an event of default with respect to the Notes. Any acceleration of the repayment of the Notes or future indebtedness after any applicable notice or grace periods could have a material adverse effect on our business, results of operations and financial condition.

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

We have collaborations with a number of third parties including Mylan for the development and commercialization of a nebulized formulation of revefenacin (TD-4208), our LAMA compound, Alfasigma S.p.A. (“Alfasigma”) (formerly Alfa Wassermann S.p.A.) for velusetrag, Millennium Pharmaceuticals, Inc., an indirect wholly-owned subsidiary of Takeda Pharmaceutical Company Limited (collectively with Millennium, “Takeda”) for the development and commercialization of a selective 5-HT<sub>4</sub> receptor agonist (TD-8954) and other companies for regional development and commercialization of VIBATIV. Also, through our interest in TRC we may participate economically in Innoviva’s collaborations with GSK with respect to the GSK-Partnered Respiratory Programs and we received non-marketable equity securities in connection with our September 2015 licensing agreement with Trek Therapeutics, PBC. Additional collaborations will likely be needed to fund later-stage development of certain programs that have not been licensed to a collaborator, such as our NEP inhibitor program and axelopran (TD-1211) for opioid-induced constipation and to commercialize the product candidates in our programs if approved by the necessary regulatory authorities. We are in discussion with potential collaborators with the goal of establishing a new strategic commercial partnership in the EU and we may also seek collaboration arrangements with additional third parties to pursue the future commercialization of VIBATIV. Collaborations with third parties regarding our programs may require us to relinquish material rights, including revenue from commercialization of our medicines, or to assume material ongoing development obligations that we would have to fund. These collaboration arrangements are

## [Table of Contents](#)

complex and time-consuming to negotiate, and if we are unable to reach agreements with third-party collaborators, we may fail to meet our business objectives and our financial condition may be adversely affected. We face significant competition in seeking third-party collaborators. We may be unable to find third parties to pursue product collaborations on a timely basis or on acceptable terms. Furthermore, for any collaboration, we may not be able to control the amount of time and resources that our partners devote to our product candidates and our partners may choose to prioritize alternative programs or otherwise be unsuccessful in their efforts with respect to our products or product candidates. Our inability to successfully collaborate with third parties would increase our development costs and may cause us to choose not to continue development of certain product candidates, would limit the likelihood of successful commercialization of some of our product candidates and could cause the price of our securities to fall.

***We do not control TRC and, in particular, have no control over or access to non-public information about the GSK-Partnered Respiratory Programs.***

Innoviva has assigned to TRC its strategic alliance agreement with GSK and all of its rights and obligations under its LABA collaboration agreement other than with respect to RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO® ELLIPTA® and vilanterol monotherapy. Our equity interest in TRC entitles us to an 85% economic interest in any future payments made by GSK under the strategic alliance agreement and under the portion of the collaboration agreement assigned to TRC (the “GSK Agreements”). Our equity interest covers various drug programs including the Closed Triple combination of fluticasone furoate (FF)/umeclidinium (UMEC)/vilanterol (VI) (ICS/LAMA/LABA) and the MABA program, as monotherapy and in combination with other therapeutically active components, such as an inhaled corticosteroid (“ICS”), and any other product or combination of products that may be discovered and developed in the future under the GSK Agreements. Our economic interest does not include any payments by GSK associated with RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO® ELLIPTA® or vilanterol monotherapy. Innoviva controls TRC and, except for certain limited consent rights, we have no right to participate in the business and affairs of TRC. Innoviva has the exclusive right to appoint TRC’s manager who, among other things, is responsible for the day-to-day management of the GSK-Partnered Respiratory Programs and exercises the rights relating to the GSK-Partnered Respiratory Programs. As a result, we have no rights to participate in, or access to non-public information about, the development and commercialization of the GSK-Partnered Respiratory Programs and no right to enforce rights under the GSK Agreements assigned to TRC. Moreover, we have many of the same risks with respect to our and TRC’s dependence on GSK as we have with respect to our dependence on our own partners.

***If the GSK-Partnered Respiratory Programs in which we have a substantial economic interest, including the Closed Triple program and MABA program, encounter delays, do not demonstrate safety and efficacy, are terminated, or if there are any adverse developments or perceived adverse developments with respect to these programs, our business will be harmed, and the price of our securities could fall.***

We have no access to confidential information regarding the progress of, or plans for, the GSK-Partnered Respiratory Programs, including the Closed Triple program and the MABA program, and we have little, if any, ability to influence the progress of those programs because our interest in these programs is only through our economic interest in TRC, which is controlled by Innoviva. However, if any of the GSK-Partnered Respiratory Programs in which we have a substantial economic interest, including the Closed Triple program and MABA program, encounter delays, do not demonstrate safety and efficacy, are terminated, or if there are any adverse developments or perceived adverse developments with respect to such programs, our business will be harmed, and the price of our securities could fall. Examples of such adverse developments include, but are not limited to:

- GSK deciding to delay or halt development of any of the GSK-Partnered Respiratory Programs in which we have a substantial economic interest, including the Closed Triple or GSK961081 (‘081), the lead compound in the MABA program;
- the U.S. Food and Drug Administration (“FDA”) and/or other regulatory authorities determining that any of the studies under these programs do not demonstrate adequate safety or efficacy, or that additional non-clinical or clinical studies are required with respect to such programs;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in these programs;
- any particular FDA requirements or changes in FDA policy or guidance regarding these programs; or
- the emergence of new closed triple or other alternative therapies or any developments regarding these potentially competitive therapies, comparative price or efficacy of such potentially competitive therapies.

[Table of Contents](#)

*VIBATIV may not be broadly accepted by physicians, patients, third-party payors, or the medical community in general, which would have a material, adverse effect on our business.*

The commercial success of VIBATIV depends upon its acceptance by physicians, patients, third-party payors and the medical community in general. VIBATIV may not be sufficiently accepted by these parties. VIBATIV competes with vancomycin (which accounts for a substantial majority of patient treatment days), linezolid and daptomycin, all relatively inexpensive generic drugs that are manufactured by a variety of companies, and a number of existing antibacterials manufactured and marketed by major pharmaceutical companies and others, and may compete against new antibacterials that are not yet on the market. If we are unable to demonstrate to physicians that, based on experience, clinical data, side effect profiles and other factors, VIBATIV is a preferred injectable treatment for treating the infections for which it is indicated, we may never generate significant revenue or profits from VIBATIV. In that case we may in the future reassess the VIBATIV business and respond in a number of ways which could include, for example, materially reducing our spending on commercialization and development efforts or other actions, any of which could cause the price of our securities to fall. Responding to ongoing challenges in the branded antibiotics market, we scaled back the size of our sales force in early 2017 and are allocating our resources with a focus on promotionally sensitive territories. In addition, if we fail to meet expectations about our net sales of VIBATIV and our VIBATIV commercialization strategy, the price of our securities could fall. For example, we reduced our projected U.S. net sales target for VIBATIV for 2015 more than once.

The degree of market acceptance of VIBATIV, the rate of our VIBATIV sales and our ability to generate revenues through sales of VIBATIV depends on a number of factors, including, but not limited to:

- the market price of VIBATIV relative to competing therapies, including generic therapies;
- the experiences of physicians, patients and payors with the use of VIBATIV;
- the occurrence of unexpected serious adverse reactions in relation to VIBATIV;
- the timing, frequency and impact of price changes or changes to pricing programs;
- our customer mix;
- any adverse developments or perceived adverse developments with respect to Pfizer, Inc. which may adversely impact our single source of supply for VIBATIV drug product;
- any developments with, or comments by, the FDA or other regulatory agencies with respect to the manufacture, use or sale of VIBATIV;
- our ability to complete our ongoing Phase 3 registrational study for use of telavancin in the treatment of patients with *Staphylococcus aureus* bacteremia, the timing of any such completion, and the results of this study;
- the advantages and disadvantages of VIBATIV compared to alternative therapies;
- our ability to find an EU commercialization partner for VIBATIV, which we have not had since August 2016;
- our ability to educate the medical community about the appropriate circumstances for use of VIBATIV;
- the acceptance of VIBATIV onto formulary by hospitals and healthcare systems;
- our ability to attract, train and retain appropriate numbers of sales and marketing personnel in the U.S.;
- our ability to attract, train and retain medical science liaisons in the U.S. supporting physician education on the proper usage of VIBATIV;
- the effectiveness of sales personnel in obtaining access to and educating adequate numbers of physicians about prescribing VIBATIV in appropriate clinical situations;
- the lack of complementary products offered by our sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- the reimbursement policies of government and third-party payors, including the amount of chargebacks and government rebates.

[Table of Contents](#)

***We market, sell and distribute VIBATIV in the U.S. without a partner and we may bear similar costs with respect to additional products in the future, which subjects us to certain risks.***

We evaluate commercial strategy on a product by product basis either to engage pharmaceutical or other healthcare companies with an existing sales and marketing organization and distribution system to market, sell and distribute our products or to commercialize a product ourselves. However, we may not be able to establish these sales and distribution relationships on acceptable terms, or at all, or may encounter difficulties in commercializing a product ourselves. For any of our product candidates that receive regulatory approval in the future and are not covered by our current collaboration agreements, we will need a partner in order to commercialize such products unless we establish independent sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure.

Astellas Pharma Inc. (“Astellas”), our former VIBATIV collaboration partner is entitled to a ten-year, 1% royalty on future net sales of VIBATIV. We have built and now maintain a VIBATIV sales force in the U.S. The risks of commercializing VIBATIV in the U.S. without a partner and commercializing any future products that we may choose to commercialize without a partner include:

- costs and expenses associated with creating and maintaining an independent sales and marketing organization with appropriate technical expertise and supporting infrastructure and distribution capability, including third-party vendor logistics and consultant support, which costs and expenses could, depending on the scope and method of the marketing effort, exceed any product revenue from VIBATIV or any future products for several years;
- our ability to retain effective sales and marketing personnel and medical science liaisons in the U.S.;
- the ability of our sales and marketing personnel to obtain access to and educate adequate numbers of physicians about prescribing VIBATIV, or any future products, in appropriate clinical situations;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- bearing the full costs of further U.S. development of telavancin, the compound that is the basis of VIBATIV.

If we are not successful in maintaining an internal sales and marketing organization with appropriate experience, technical expertise, supporting infrastructure, distribution capability and the ability to obtain access to and educate adequate numbers of physicians about prescribing VIBATIV, or any future products, in appropriate clinical situations, we will have difficulty commercializing VIBATIV, or any future products, in the U.S., which would adversely affect our business and financial condition and the price of our securities could fall.

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

Each of our product candidates must undergo extensive non-clinical and clinical studies as a condition to regulatory approval. Non-clinical and clinical studies are expensive, take many years to complete and study results may lead to delays in further studies, new requirements for conducting future studies or decisions to terminate programs. The commencement and completion of clinical studies for our product candidates may be delayed and programs may be terminated due to many factors, including, but not limited to:

- lack of effectiveness of product candidates during clinical studies;
- adverse events, safety issues or side effects relating to the product candidates or their formulation into medicines;
- inability to raise additional capital in sufficient amounts to continue our development programs, which are very expensive;



## [Table of Contents](#)

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

### ***Our ongoing drug discovery and development efforts might not generate additional successful product candidates or approvable drugs.***

Our compounds in clinical trials and our future leads for potential drug compounds are subject to the risks and failures inherent in the development of pharmaceutical products. These risks include, but are not limited to, the inherent difficulty in selecting the right drug and drug target and avoiding unwanted side effects, as well as unanticipated problems relating to product development, testing, enrollment, obtaining regulatory approvals, maintaining regulatory compliance, manufacturing, competition and costs and expenses that may exceed current estimates.

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

Frequently, product candidates that have shown promising results in early preclinical or clinical studies have subsequently suffered significant setbacks or failed in later non-clinical or clinical studies. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, varying levels of adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Clinical and non-clinical studies of product candidates often reveal that it is not possible or practical to continue development efforts for these product candidates. In addition, the design of a clinical trial can determine whether its results will support regulatory approval and flaws in the design of a clinical trial may not become apparent until the clinical trial is well underway or completed. If our ongoing clinical studies for our current product candidates, such as the early stage clinical studies for our JAK inhibitor program or TD-9855 in patients with nOH, are substantially delayed or suggest that our product candidate may not be efficacious or well tolerated, we could choose to cease development of these product candidates. In addition, our product candidates may have undesirable side effects or other unexpected characteristics that could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restricted label or the delay or denial of regulatory approval by regulatory authorities.

### ***If our product candidates are not approved by regulatory authorities, including the FDA, we will be unable to commercialize them.***

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

## [Table of Contents](#)

FDA or foreign regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. The processes by which regulatory approvals are obtained from the FDA and foreign regulatory authorities to market and sell a new product are complex, require a number of years, depend upon the type, complexity and novelty of the product candidate and involve the expenditure of substantial resources for research, development and testing. The FDA has substantial discretion in the drug approval process and may require us to conduct additional nonclinical and clinical testing or to perform post-marketing studies. Further, the implementation of new laws and regulations, and revisions to FDA clinical trial design guidance may lead to increased uncertainty regarding the approvability of new drugs. In addition, over the past decade, the FDA has implemented additional standards for approval of new drugs, including recommended advisory committee meetings for certain new molecular entities, and formal risk evaluation and mitigation requirements at the FDA's discretion. Even if we receive regulatory approval of a product, the approval may limit the indicated uses for which the drug may be marketed or impose significant restrictions or limitations on the use and/or distribution of such product.

In addition, in order to market our medicines in foreign jurisdictions, we, or our collaborative partners, must obtain separate regulatory approvals in each country. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Conversely, failure to obtain approval in one or more jurisdictions may make approval in other jurisdictions more difficult. These laws, regulations, additional requirements and changes in interpretation could cause non-approval or further delays in the FDA's review and approval of our and our collaborative partner's product candidates, which would materially harm our business and financial condition and could cause the price of our securities to fall.

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

We have a single source of supply of API for telavancin and another, separate single source of supply of VIBATIV drug product. If, for any reason, either single-source third-party manufacturer of telavancin API or of VIBATIV drug product is unable or unwilling to perform, or if the performance of either does not meet regulatory requirements, including maintaining current Good Manufacturing Practice ("cGMP") compliance, we may not be able to locate alternative manufacturers, enter into acceptable agreements with them or obtain sufficient quantities of API or drug product in a timely manner. We expect it would take approximately 24 months for an alternative manufacturer to be qualified by us and begin producing drug product for us. We currently have sufficient quantities of VIBATIV drug product on hand to meet our anticipated needs through approximately December 2018. We have released certain lots manufactured in 2017 and we have manufactured additional VIBATIV drug product supply which is currently undergoing our internal quality review prior to release. We will not know whether this supply is suitable for release until we complete our internal quality review. If we are able to release this additional supply we would have sufficient quantities of VIBATIV drug product available to meet our anticipated needs through mid-2019. This supply was manufactured by Pfizer, our single source manufacturer for VIBATIV, at its McPherson, Kansas facility. As publicly reported in early 2017, Pfizer has received an FDA warning letter relating to a 2016 inspection of this facility. None of the lots cited in the warning letter are manufactured VIBATIV drug product. We are also having additional VIBATIV drug product manufactured for us at this facility in 2017. Given the time required to locate and qualify another acceptable drug product manufacturer, any supply delay, suspension or cessation in the manufacture and release of VIBATIV drug product would adversely affect the commercialization of VIBATIV and our obligations to our partners, as well as our Phase 3 registrational study for the treatment of patients with *Staphylococcus aureus* bacteremia. Similarly, any inability to acquire sufficient quantities of API in a timely manner from current or future sources would adversely affect the commercialization of VIBATIV and our ability to satisfy our obligations to our partners. If either of these were to occur, our business would be harmed.

Our previous VIBATIV commercialization partner (at the time with Innoviva) failed to maintain a reliable source of drug product supply which resulted in critical product shortages and, eventually, suspension of commercialization for well over a year. Our current agreement with Pfizer to supply VIBATIV drug product was entered into May 2012. In June 2013, the FDA approved Pfizer as a VIBATIV drug product manufacturer. On September 29, 2016, we amended our agreement with Pfizer to extend the term of the agreement to December 31, 2020. If our supply relationship with Pfizer terminates for any reason, we would need to arrange for the advance manufacture and purchase of drug product in order to manage the transition to a new supplier and such advance manufacturing and purchasing entails significant uncertainties, including the risk of purchasing excess or insufficient quantities relative to our future needs and the possible expiration of excess inventories. Any difficulties in continuing or transitioning our single source suppliers would adversely affect the commercialization of VIBATIV and our ability to satisfy our obligations to our partners and the price of our securities could fall.

[Table of Contents](#)

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

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

Our manufacturing strategy presents the following additional risks:

- because of the complex nature of many of our compounds, our manufacturers may not be able to successfully manufacture our APIs and/or drug products in a cost effective and/or timely manner and changing manufacturers for our APIs or drug products could involve lengthy technology transfer, validation and regulatory qualification activities for the new manufacturer;
- the processes required to manufacture certain of our APIs and drug products are specialized and available only from a limited number of third-party manufacturers;
- some of the manufacturing processes for our APIs and drug products have not been scaled to quantities needed for continued clinical studies or commercial sales, and delays in scale-up to higher quantities could delay clinical studies, regulatory submissions and commercialization of our product candidates; and
- because some of the third-party manufacturers are located outside of the U.S., there may be difficulties in importing our APIs and drug products or their components into the U.S. as a result of, among other things, FDA import inspections, incomplete or inaccurate import documentation or defective packaging.

***We are subject to extensive and ongoing regulation, oversight and other requirements by the FDA with respect to VIBATIV and failure to comply with these regulations and requirements may subject us to penalties that may adversely affect our financial condition or our ability to commercialize VIBATIV.***

With VIBATIV approved in certain countries, we are subject to continuing regulatory obligations, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of promotion and marketing. Prescription drug advertising and promotion are closely scrutinized by the FDA, including substantiation of promotional claims, disclosure of risks and safety information, and the use themes and imagery in advertising and promotional materials. As with all companies selling and marketing products regulated by the FDA in the U.S., we are prohibited from promoting any uses of VIBATIV that are outside the scope of use that has been expressly approved by the FDA as safe and effective on the VIBATIV label.

The U.S. labeling for VIBATIV contains a boxed warning. Products with boxed warnings are subject to more restrictive advertising regulations than products without such warnings and FDA regulations prohibit the use of reminder advertising for VIBATIV.

In addition, patients receive a medication guide with each course of antibiotic use in connection with the approved labelling for VIBATIV. Further, the VIBATIV labeling for hospital-acquired and ventilator associated bacterial pneumonia ("HABP/VABP") in the U.S. and the European Union ("EU") specifies that VIBATIV should be reserved for use when alternative treatments are not suitable. These restrictions add complexity to the marketing of VIBATIV.

The FDA has also required that we evaluate the safety of VIBATIV use during pregnancy by developing and maintaining a prospective, observational pregnancy exposure registry study conducted in the United States. This postmarketing study remains ongoing and will continue through the end of 2019.

## [Table of Contents](#)

The manufacturing, labeling, packaging, adverse event reporting, advertising, promotion and recordkeeping for the approved product remain subject to extensive and ongoing regulatory requirements. If we become aware of previously unknown problems with an approved product in the U.S. or overseas or at a contract manufacturer's facilities, a regulatory authority may impose restrictions on the product, the contract manufacturers or on us, including requiring us to reformulate the product, conduct additional clinical studies, change the labeling of the product, withdraw the product from the market or require the contract manufacturer to implement changes to its facilities.

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

Regulatory approval for our product candidates, if any, may include similar or other limitations on the indicated uses for which we can market our medicines or the patient population that may utilize our medicines, which may limit the market for our medicines or put us at a competitive disadvantage relative to alternative therapies.

Failure to satisfy required post-approval requirements and/or commitments may have implications for a product's approval and may carry civil monetary penalties. Any failure to maintain regulatory approval will limit our ability to commercialize VIBATIV or our product candidates and if we fail to comply with FDA regulations and requirements regarding VIBATIV or any of our product candidates, the FDA could potentially take a number of enforcement actions against us, including the issuance of untitled letters, warning letters, preventing the introduction or delivery of VIBATIV into interstate commerce in the United States, misbranding charges, product seizures, injunctions, and civil monetary penalties, which would materially and adversely affect our business and financial condition and may cause the price of our securities to fall.

The risks identified in this risk factor relating to regulatory actions and oversight by agencies in the U.S. and throughout the world also apply to the commercialization of any partnered products by our collaboration partners, and such regulatory actions and oversight may limit our collaboration partners' ability to commercialize such products, which could materially and adversely affect our business and financial condition, and which may cause the price of our securities to fall.

### ***We may face competition from companies seeking to market generic versions of VIBATIV.***

For a discussion of the risk of generic competition to VIBATIV, please see the following risk factor below "*If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our current or future markets.*"

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

We have an exclusive development and commercialization agreement with Alfasigma for velusetrag, our lead compound in the 5-HT<sub>4</sub> program, covering the EU, Russia, China, Mexico and certain other countries. The Alfasigma agreement was assigned to us in the Spin-Off and provides some research and development funding for the program under license. In October 2012, we (at the time with Innoviva) also entered into a research collaboration and license agreement with Merck & Co., Inc. ("Merck") to discover, develop and commercialize novel small molecule therapeutics for the treatment of cardiovascular disease, which Merck terminated in September 2013. In January 2015, we entered into a collaboration agreement with Mylan for the development and commercialization of a nebulized formulation of our LAMA revefenacin (TD-4208). Under the terms of the agreement, we and Mylan will co-develop nebulized revefenacin for COPD and other respiratory diseases. In June 2016, we entered into a License and Collaboration Agreement with an indirect wholly-owned subsidiary of Takeda, in order to establish a collaboration for the development and commercialization of TD-8954, a selective 5-HT<sub>4</sub> receptor agonist. Under the terms of the Agreement, Takeda will be responsible for worldwide development and commercialization of TD-8954. In connection with these agreements, these parties have certain rights regarding the use of patents and technology with respect to the compounds in our development programs, including development and marketing rights.

## [Table of Contents](#)

We also have commercialization agreements with various partners for the commercialization of VIBATIV outside of the United States, including Canada, Middle East, North Africa, Israel, Russia, China and India. In August 2016, we and Clinigen reached a mutual decision that Clinigen will return commercial rights to market and distribute VIBATIV in the EU to Theravance Biopharma. On November 4, 2016, the European Commission authorized the transfer of the centralized marketing authorization for VIBATIV to our wholly-owned Irish subsidiary, Theravance Biopharma Ireland Limited. Therefore, we are now subject to all applicable EU regulatory obligations as the new marketing authorization holder of VIBATIV in the EU. We do not intend to commercialize VIBATIV in the EU without a partner. Therefore, if we fail to find a suitable partner to commercialize VIBATIV in the EU, we will not receive any product revenue from that region.

Our partners might not fulfill all of their obligations under these agreements, and, in certain circumstances, they or we may terminate our partnership with them as Astellas did in January 2012 with its VIBATIV agreement, as Merck did in September 2013 with the cardiovascular disease collaboration and as we and Clinigen did in August 2016 with the commercialization agreement for VIBATIV in the EU and certain other European countries. In either event, we may be unable to assume the development and commercialization responsibilities covered by the agreements or enter into alternative arrangements with a third-party to develop and commercialize such product candidates. If a partner elected to promote alternative products and product candidates such as its own products and product candidates in preference to those licensed from us, does not devote an adequate amount of time and resources to our product candidates or is otherwise unsuccessful in its efforts with respect to our products or product candidates, the development and commercialization of product candidates covered by the agreements could be delayed or terminated, and future payments to us could be delayed, reduced or eliminated and our business and financial condition could be materially and adversely affected. Accordingly, our ability to receive any revenue from the product candidates covered by these agreements is dependent on the efforts of our partners. If a partner terminates or breaches its agreements with us, otherwise fails to complete its obligations in a timely manner or alleges that we have breached our contractual obligations under these agreements, the chances of successfully developing or commercializing product candidates under the collaboration could be materially and adversely affected. We could also become involved in disputes with a partner, which could lead to delays in or termination of our development and commercialization programs and time-consuming and expensive litigation or arbitration. Furthermore, termination of an agreement by a partner could have an adverse effect on the price of our ordinary shares or other securities even if not material to our business.

***Because GSK is a strategic partner of Innoviva, a strategic partner of TRC and a significant shareholder of us, it may take actions that in certain cases are materially harmful to our business and to our other shareholders.***

Based on our review of publicly available filings, as of June 30, 2017, GSK beneficially owned approximately 17.9% of our outstanding ordinary shares. GSK is also a strategic partner to Innoviva with rights and obligations under the strategic alliance agreement and under the collaboration agreement assigned to TRC (the “GSK-Innoviva Agreements”) that may cause GSK’s interests to differ from our interests and those of our other shareholders. In particular, if the Closed Triple or a MABA/ICS in either the U.S. or the EU is approved, GSK’s diligent efforts obligations under the GSK-Innoviva Agreements with regard to 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-Innoviva Agreements. Following such regulatory approval, GSK’s commercialization efforts will be guided by a portfolio approach across products in which we have an indirect interest through TRC and products in which we have no interest. Accordingly, GSK’s commercialization efforts may have the effect of reducing the value of our interest in TRC. Furthermore, GSK has a substantial respiratory product portfolio in addition to the products covered by the GSK-Innoviva 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 Innoviva and TRC. 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-Innoviva Agreements. Also, given the potential future royalty payments GSK may be obligated to pay under the GSK-Innoviva Agreements, GSK may seek to acquire us or acquire our interests in TRC in order to effectively reduce those payment obligations and the price at which GSK might seek to acquire us may not reflect our true value. Although the actions GSK may take to acquire us are limited under our governance agreement with GSK (the “Governance Agreement”), this agreement will expire on December 31, 2017. 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-Innoviva 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 shareholders. In addition, GSK could also seek to challenge our or Innoviva’s post-Spin-Off operations as violating or allowing it to terminate the GSK-Innoviva Agreements, including by violating the confidentiality provisions of those agreements or the master agreement between GSK, Innoviva and us entered into in connection with the Spin-Off, or otherwise violating its legal rights. While we believe our operations fully comply with the GSK-Innoviva Agreements, the master agreement and applicable law, there can be no assurance that

## [Table of Contents](#)

we or Innoviva will prevail against any such claims by GSK. Moreover, regardless of the merit of any claims by GSK, we may incur significant cost and diversion of resources in defending them. In addition, any other action or inaction by either GSK or Innoviva that results in a material dispute, allegation of breach, litigation, arbitration, or significant disagreement between those 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 Innoviva's partnered products and other GSK respiratory products, disputes over public statements, and similar matters. In general, any uncertainty about the respiratory programs partnered with GSK, the enforceability of the GSK-Innoviva Agreements or the relationship/partnership between Innoviva and GSK could result in significant reduction in the market price of our securities and other material harm to our business.

### ***Agreements entered into with or for the benefit of GSK in connection with the Spin-Off may significantly restrict our business and affairs.***

On March 3, 2014, in connection with the Spin-Off, we, Innoviva and GSK entered into a number of agreements that may significantly restrict our business and affairs. In particular, we, Innoviva and GSK entered into a three-way master agreement (the "Master Agreement") that, among other things, requires GSK's consent to make any changes to (A) a Separation and Distribution Agreement and ancillary agreements that would, individually or in the aggregate, reasonably be expected to adversely affect GSK in any material respect or (B) the TRC Limited Liability Company Agreement, which consent is not to be unreasonably withheld, conditioned or delayed, provided that GSK may withhold, condition or delay such consent in its sole discretion with respect to certain sections of the TRC Limited Liability Company Agreement and any changes to the governance structure of TRC, the confidentiality restrictions, the consent rights, and the transfer restrictions in the TRC Limited Liability Company Agreement. We and GSK also entered into (i) the Governance Agreement that, among other things, provides share purchase rights to GSK and exempts GSK from triggering our Rights Agreement until December 31, 2017, (ii) a registration rights agreement that gives GSK certain registration rights with respect to our ordinary shares held by GSK and (iii) an extension agreement that extends to us certain restrictive covenants similar to those applicable to Innoviva under the GSK-Innoviva Agreements. There can be no assurance that these restrictions will not materially harm our business, particularly given that GSK's interests may not be aligned with the interests of our business or our other shareholders.

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

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

The FDA, and equivalent authorities in other countries, enforces GxPs and other regulations through periodic inspections of trial sponsors, clinical research organizations ("CROs"), principal investigators and trial sites. If we or any of the third parties on which we have relied to conduct our clinical studies are determined to have failed to comply with GxPs (or other equivalent regulations outside the United States), the study protocol or applicable regulations, the clinical data generated in our studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or equivalent authorities in other countries, or we, the FDA, or equivalent authorities in other countries may decide to conduct additional audits or require additional clinical studies, which would delay our development programs, could result in significant additional costs and the price of our securities could fall.

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

Our ability to succeed in the future depends on our ability to demonstrate and maintain a competitive advantage with respect to our approach to the discovery, development and commercialization of medicines. Our objective is to discover, develop and commercialize new small molecule medicines with superior efficacy, convenience, tolerability and/or safety using our proprietary insight in chemistry, biology and multivalency, where applicable. We expect that any medicines that we commercialize with or without our collaborative partners will compete with existing or future market-leading medicines.

## [Table of Contents](#)

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

- discover and develop medicines that are superior to other products in the market;
- attract and retain qualified personnel;
- obtain patent and/or other proprietary protection for our medicines and technologies;
- obtain required regulatory approvals;
- develop and effectively implement commercialization strategies, with or without collaborative partners; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicines.

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

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

***Certain of our directors and officers may have actual or potential conflicts of interest because of their equity ownership in Innoviva, which actual or potential conflicts may harm our business, prospects and financial condition and result in the diversion of corporate opportunities to Innoviva.***

Certain of our directors and executive officers hold shares of Innoviva's common stock or rights to acquire such shares, and these holdings may be significant for some of these individuals compared to their total assets. This ownership of Innoviva common stock by our officers and most of our directors may create, or may create the appearance of, conflicts of interest when these directors and officers are faced with decisions that could have different implications for Innoviva and for us. For example, potential or actual conflicts could arise relating to: our relationship with Innoviva, including Innoviva's and our respective rights and obligations under agreements entered into in connection with the Spin-Off; Innoviva's management of TRC, particularly given that we and Innoviva have different economic interests in TRC; and corporate opportunities that may be available to both companies in the future. Although we and Innoviva have implemented policies and procedures to identify and properly address such potential and actual conflicts of interest, there can be no assurance that, when such conflicts are resolved in accordance with applicable laws, such conflicts of interest will not harm our business, prospects and financial condition and result in the diversion of corporate opportunities to Innoviva.

***If we lose key management or scientific personnel, or if we fail to attract and retain key employees, our ability to discover and develop our product candidates and commercialize VIBATIV and any other products that may be approved in the future will be impaired.***

We are highly dependent on principal members of our management team and scientific staff, and in particular, our Chief Executive Officer, Rick E. Winningham, to operate our business. Mr. Winningham has significant pharmaceutical industry experience. The loss of Mr. Winningham's services could impair our ability to discover, develop and commercialize new medicines.

[Table of Contents](#)

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

In addition, our U.S. operating subsidiary's facility and most of its employees are located in northern California, 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 is intense. None of our employees have employment commitments for any fixed period of time and they all may leave our employment at will. If we fail to retain our qualified personnel or replace them when they leave, we may be unable to continue our development and commercialization activities and the price of our securities could fall.

***Our business and operations would suffer in the event of significant disruptions of information technology systems or security breaches.***

We rely extensively on computer systems to maintain information and manage our finances and business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including but not limited to trade secrets or other intellectual property, proprietary business information and personal information) and it is critical that we maintain the confidentiality and integrity of such confidential information. Although we have security measures in place, our internal information technology systems and those of our CROs and other service providers, including cloud-based and hosted applications, data and services, are vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, service providers and/or business partners, from cyber-attacks by malicious third parties, and/or from, natural disasters, terrorism, war and telecommunication and electrical failures. Cyber-attacks are increasing in their frequency, sophistication, and intensity, and have become increasingly difficult to detect. Significant disruptions of information technology systems or security breaches could adversely affect our business operations and result in financial, legal, business and reputational harm to us, including significant liability and/or significant disruption to our business. If a disruption of information technology systems or security breach results in a loss of or damage to our data or regulatory applications, unauthorized access, use, or disclosure of, or the prevention of access to, confidential information, or other harm to our business, we could incur liability and reputational harm, we could be required to comply with federal and/or state breach notification laws and foreign law equivalents, the further development of our product candidates could be delayed and the price of our securities could fall. For example, the loss of clinical trial data from completed or ongoing clinical trials of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Although we have security and fraud prevention measures in place, we have been subject to immaterial payment fraud activity. Moreover, there can be no assurance that such security measures will prevent service interruptions or security breaches that could adversely affect our business.

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

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

***Global health and economic, political and social conditions may harm our ability to do business, increase our costs and negatively affect our stock price.***

Worldwide economic conditions remain uncertain due to the election by the United Kingdom to withdraw from the European Union (often referred to as "Brexit"), new political leadership in the United States, current economic challenges in Asia and other disruptions to global and regional economies and markets.



[Table of Contents](#)

Brexit has created significant uncertainty about the future relationship between the United Kingdom and the EU, including with respect to the laws and regulations that will apply as the United Kingdom determines which EU laws to replace or replicate in the event of a withdrawal. From a regulatory perspective, the United Kingdom's withdrawal could bear significant complexity and risks. A basic requirement related to the grant of a marketing authorization for a medicinal product in the EU is that the applicant is established in the EU. Depending upon the exact terms of the United Kingdom's withdrawal, there is a potential risk that the scope of a marketing authorization for a medicinal product granted by the European Commission pursuant to the centralized procedure would not, in the future, include the United Kingdom. In these circumstances, an authorization granted by the United Kingdom's competent authorities would always be required to market medicinal products on the United Kingdom market. In addition, the exact terms of the United Kingdom's withdrawal and the laws and regulations that will apply after the United Kingdom withdraws from the EU would affect manufacturing sites that hold an EU manufacturing authorization issued by the United Kingdom competent authorities. The referendum has also given rise to calls for the governments of other EU Member States to consider withdrawal from the EU.

Our operations also depend upon favorable trade relations between the U.S. and those foreign countries in which our materials suppliers have operations. A protectionist trade environment in either the U.S. or those foreign countries in which we do business, such as a change in the current tariff structures, export compliance or other trade policies, may materially and adversely affect our operations. External factors, such as potential terrorist attacks, acts of war, geopolitical and social turmoil or epidemics and other similar outbreaks in many parts of the world, could also prevent or hinder our ability to do business, increase our costs and negatively affect our stock price. These geopolitical, social and economic conditions could harm our business.

***If we are unable to maintain effective internal controls, our business, financial position and results of operations could be adversely affected.***

If we are unable to maintain effective internal controls, our business, financial position and results of operations could be adversely affected. We are subject to the reporting and other obligations under the Exchange Act, including the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, which require annual management assessments of the effectiveness of our internal control over financial reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States. Any failure to achieve and maintain effective internal controls could have an adverse effect on our business, financial position and results of operations. In addition, since we are a "large accelerated filer" rather than an "emerging growth company" (each as defined in the Exchange Act) as of December 31, 2016 our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting annually. If our independent registered public accounting firm is unable to attest to the effectiveness of our internal control over financial reporting, investor confidence in our reported results will be harmed and the price of our securities may fall. These reporting and other obligations place significant demands on our management and administrative and operational resources, including accounting resources.

***We have only been operating as a stand-alone entity since June 2, 2014 and therefore we have a limited history operating as an independent company upon which you can evaluate us.***

We have only been operating as a stand-alone entity since June 2, 2014 and therefore we have a limited operating history as an independent company upon which you can evaluate us. While our biopharmaceutical business has constituted a substantial part of the historic operations of Innoviva, we did not operate as a stand-alone company.

In addition, our historical financial information prior to the Spin-Off does not necessarily reflect what our financial position, results of operations or cash flows would have been as a stand-alone company during the periods presented and is not necessarily indicative of our future financial position, future results of operations or future cash flows.

***We may be treated as a U.S. corporation for U.S. federal income tax purposes.***

For U.S. federal income tax purposes, a corporation generally is considered tax resident in the place of its incorporation. Theravance Biopharma is incorporated under Cayman Islands law and established tax residency in Ireland effective July 1, 2015. Therefore, it should be a non-U.S. corporation under this general rule. However, Section 7874 of the Internal Revenue Code of 1986, as amended (the "Code"), contains rules that may result in a foreign corporation being treated as a U.S. corporation for U.S. federal income tax purposes. The application of these rules is complex and there is little guidance regarding certain aspects of their application.

## [Table of Contents](#)

Under Section 7874 of the Code, a corporation created or organized outside the U.S. will be treated as a U.S. corporation for U.S. federal tax purposes if (i) the foreign corporation directly or indirectly acquires substantially all of the properties held directly or indirectly by a U.S. corporation, (ii) the former shareholders of the acquired U.S. corporation hold at least 80% of the vote or value of the shares of the foreign acquiring corporation by reason of holding stock in the U.S. acquired corporation, and (iii) the foreign corporation's "expanded affiliated group" does not have "substantial business activities" in the foreign corporation's country of incorporation relative to its expanded affiliated group's worldwide activities. For this purpose, "expanded affiliated group" generally means the foreign corporation and all subsidiaries in which the foreign corporation, directly or indirectly, owns more than 50% of the stock by vote and value, and "substantial business activities" generally means at least 25% of employees (by number and compensation), assets and gross income of our expanded affiliated group are based, located and derived, respectively, in the country of incorporation.

We do not expect to be treated as a U.S. corporation under Section 7874 of the Code, because we do not believe that the assets contributed to us by Innoviva constituted "substantially all" of the properties of Innoviva (as determined on both a gross and net fair market value basis). However, the Internal Revenue Service ("IRS") may disagree with our conclusion on this point and assert that, in its view, the assets contributed to us by Innoviva did constitute "substantially all" of the properties of Innoviva. In addition, there could be legislative proposals to expand the scope of U.S. corporate tax residence and there could be changes to Section 7874 of the Code or the Treasury Regulations promulgated thereunder that could apply retroactively and could result in Theravance Biopharma being treated as a U.S. corporation.

If it were determined that we should be treated as a U.S. corporation for U.S. federal income tax purposes, we could be liable for substantial additional U.S. federal income tax on our post-Spin-Off taxable income. In addition, though we have no current plans to pay any dividends, payments of any dividends to non-U.S. holders may be subject to U.S. withholding tax.

### ***Taxing authorities may challenge our structure and transfer pricing arrangements.***

We are incorporated in the Cayman Islands, maintain subsidiaries in the Cayman Islands, the United States, the United Kingdom and Ireland, and effective July 1, 2015, we migrated our tax residency from the Cayman Islands to Ireland. Due to economic and political conditions various countries are actively considering changes to existing tax laws. We cannot predict the form or timing of potential legislative changes that could have a material adverse impact on our results of operations. In addition, significant judgment is required in determining our worldwide provision for income taxes. Various factors may have favorable or unfavorable effects on our income tax rate including, but not limited to the performance of certain functions and ownership of certain assets in tax-efficient jurisdictions such as the Cayman Islands and Ireland, together with intra-group transfer pricing agreements. Taxing authorities may challenge our structure and transfer pricing arrangements through an audit or lawsuit. Responding to or defending such a challenge could be expensive and consume time and other resources, and divert management's time and focus from operating our business. We cannot predict whether taxing authorities will conduct an audit or file a lawsuit challenging this structure, the cost involved in responding to any such audit or lawsuit, or the outcome. We may be required to pay taxes for prior periods, interest, fines or penalties, and may be obligated to pay increased taxes in the future which could result in reduced cash flows and have a material adverse effect on our business, financial condition and growth prospects.

### ***We were a passive foreign investment company, or "PFIC," for 2014 but we were not a PFIC for 2015 and 2016, and we do not expect to be a PFIC for the foreseeable future.***

For U.S. federal income tax purposes, we generally would be classified as a PFIC for any taxable year if either (i) 75% or more of our gross income (including gross income of certain 25% or more owned corporate subsidiaries) is "passive income" (as defined for such purposes) or (ii) the average percentage of our assets (including the assets of certain 25% or more owned corporate subsidiaries) that produce passive income or that are held for the production of passive income is at least 50%. In addition, whether our company will be a PFIC for any taxable year depends on our assets and income over the course of each such taxable year and, as a result, cannot be predicted with certainty until after the end of the year.

Based upon our assets and income during the course of 2014, we believe that our company and one of our company's wholly owned subsidiaries, Theravance Biopharma R&D, Inc. was a PFIC for 2014. Based upon our assets and income during the course of 2015 and 2016, we do not believe that our company is a PFIC for 2015 or 2016. We do not expect to be a PFIC for the foreseeable future based on our current business plans and current business model. For any taxable year (or portion thereof) in which our company is a PFIC that is included in the holding period of a U.S. holder, the U.S. holder is generally subject to additional U.S. federal income taxes plus an interest charge with respect to certain distributions from Theravance Biopharma or gain recognized on a sale of Theravance Biopharma shares. Similar rules would apply with respect to distributions from or gain recognized on an indirect sale of Theravance Biopharma R&D, Inc. U.S. holders of our ordinary shares may have filed an election with respect to company shares held at any time during 2014 to be treated as owning an interest in a "qualified electing fund" ("QEF") or to "mark to market" their ordinary shares to avoid the

[Table of Contents](#)

otherwise applicable interest charge consequences of PFIC treatment with respect to our ordinary shares. A foreign corporation will not be treated as a QEF for any taxable year in which such foreign corporation is not treated as a PFIC. QEF and mark to market elections generally apply to the taxable year for which the election is made and all subsequent taxable years unless the election is revoked with consent of the Secretary of Treasury. U.S. holders of our ordinary shares should consult their tax advisers regarding the tax reporting implications with respect to any QEF and mark to market elections made with respect to our company and with respect to their indirect interests in Theravance Biopharma R&D, Inc.

***If we are required to indemnify Innoviva, or if we are not able to collect on indemnification rights from Innoviva, our business prospects and financial condition may be harmed.***

We agreed to indemnify Innoviva from and after the Spin-Off with respect to (i) all debts, liabilities and obligations transferred to us in connection with the Spin-Off (including our 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 resulting in a misleading statement in our Information Statement distributed to Innoviva stockholders in connection with the Spin-Off and (iii) any breach by us of certain agreements entered into with Innoviva in connection with the Spin-Off (namely, the Separation and Distribution Agreement, a Transition Services Agreement, a Employee Matters Agreement, a Tax Matters Agreement, and a Facility Sublease Agreement). We are not aware of any existing indemnification obligations at this time, but any such indemnification obligations that may arise could be significant. Under the terms of the Separation and Distribution Agreement, Innoviva agreed to indemnify us from and after the Spin-Off with respect to (i) all debts, liabilities and obligations retained by Innoviva after the Spin-Off (including its failure to pay, perform or otherwise promptly discharge any such debts, liabilities or obligations after the Spin-Off) and (ii) any breach by Innoviva of the Separation and Distribution Agreement, the Transition Services Agreement, the Employee Matters Agreement, the Tax Matters Agreement, and the Facility Sublease Agreement. Our and Innoviva's ability to satisfy these indemnities, if called upon to do so, will depend upon our and Innoviva's future financial strength. If we are required to indemnify Innoviva, or if we are not able to collect on indemnification rights from Innoviva, our business prospects and financial condition may be harmed.

#### **RISKS RELATED TO LEGAL AND REGULATORY UNCERTAINTY**

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

We rely upon a combination of patents, patent applications, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any involuntary disclosure to or misappropriation by third parties of this proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. The status of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and is very uncertain. As of June 30, 2017, we or one of our wholly-owned subsidiaries owned 449 issued United States patents and 1,903 granted foreign patents, as well as additional pending United States and foreign patent applications. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be invalidated or be too narrow to prevent third parties from developing or designing around these patents. If the sufficiency of the breadth or strength of protection provided by our patents with respect to a product candidate is threatened, it could dissuade companies from collaborating with us to develop product candidates and threaten our ability to commercialize products. Further, if we encounter delays in our clinical trials or in obtaining regulatory approval of our product candidates, the patent lives of the related product candidates would be reduced.

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

[Table of Contents](#)

Under the Drug Price Competition and Patent Term Restoration Act of 1984, a company may submit an abbreviated new drug application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to market a generic version of an approved drug. Because a generic applicant does not conduct its own clinical studies, but instead relies on the FDA's finding of safety and effectiveness for the approved drug, it is able to introduce a competing product into the market at a cost significantly below that of the original drug. Although we have multiple patents protecting VIBATIV until at least 2027 that are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, generic applicants could potentially submit "paragraph IV certifications" to FDA stating that such patents are invalid or will not be infringed by the applicant's product. We have not received any such paragraph IV notifications but if any competitors successfully challenge our patents, we would face substantial competition. If we are not able to compete effectively against such future competition, our business will not grow, our financial condition and operations will suffer and the price of our securities could fall.

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

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

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

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

The risks identified in the two preceding risk factors may also apply to the intellectual property protection efforts of our partners or future partners and to GSK with respect to the GSK-Partnered Respiratory Programs in which we hold an economic interest. To the extent the intellectual property protection of any partnered assets are successfully challenged or encounter problems with the United States Patent and Trademark Office or other comparable agencies throughout the world, the future commercialization of these potential medicines could be delayed or prevented. Any challenge to the intellectual property protection of a late-stage development asset, particularly those of the GSK-Partnered Respiratory Programs in which we hold an economic interest, could harm our business and cause the price of our securities to fall.

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

The risk that we may be sued on product liability claims is inherent in the development and commercialization of pharmaceutical products. Side effects of, or manufacturing defects in, products that we or our partners develop or commercialize could result in the deterioration of a patient's condition, injury or even death. The VIBATIV prescribing information describes several potential adverse effects observed during clinical trials, including increased mortality versus vancomycin in patients with HAP/VABP who had pre-existing moderate to severe renal impairment, decreased clinical response in patients with cSSSI who had pre-existing moderate/severe renal impairment, and other renal adverse events. The prescribing information includes a black box warning regarding increased mortality in patients with pre-existing moderate/severe renal impairment who were treated with VIBATIV for HAP/VABP, new onset or worsening renal impairment, use in women of childbearing potential or during pregnancy and adverse developmental outcomes observed in 3 animal species. Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits tends to

## [Table of Contents](#)

increase. Claims may be brought by individuals seeking relief for themselves or by individuals or groups seeking to represent a class, asserting injuries based both on potential adverse effects described in the label as well as adverse events not yet observed. Also, changes in laws outside the U.S. are expanding our potential liability for injuries that occur during clinical trials. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forgo further commercialization of the applicable products.

Although we maintain general liability and product liability insurance, this insurance may not fully cover potential liabilities and we cannot be sure that our insurer will not disclaim coverage as to a future claim. In addition, inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercial production and sale of our products, which could adversely affect our business. The cost of defending any product liability litigation or other proceeding, even if resolved in our favor, could be substantial and uncertainties resulting from the initiation and continuation of product liability litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Product liability claims could also harm our reputation, which may adversely affect our and our partners' ability to commercialize our products successfully and the price of our securities could fall.

### ***Changes in healthcare law and implementing regulations, including government restrictions on pricing and reimbursement, as well as healthcare policy and other healthcare payor cost-containment initiatives, may negatively impact our ability to generate revenues.***

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

- our or our collaborators' ability to set and collect a price we believe is reasonable for our product;
- our ability to generate revenues and achieve profitability; and
- the availability of capital.

The pricing and reimbursement environment for VIBATIV and any future products may change in the future and become more challenging due to, among other reasons, policies advanced by the new presidential administration, federal agencies, new healthcare legislation passed by Congress or fiscal challenges faced by all levels of government health administration authorities. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been and may in the future be significantly affected by major legislative initiatives. We expect to experience pricing pressures in connection with the sale of VIBATIV and other products we may bring to market, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative enactments.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (together the "Healthcare Reform Act"), is a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. This law substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions that impact our business and operations, including those governing enrollment in federal healthcare programs, reimbursement changes, benefits for patients within a coverage gap in the Medicare Part D prescription drug program (commonly known as the "donut hole"), rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicare Drug Rebate program, expansion of the Public Health Service's 340B drug pricing program, fraud and abuse and enforcement. These changes impact existing government healthcare programs and are resulting in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Details of the changes to the Medicaid Drug Rebate program and the 340B program are discussed below under the risk factor "*If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.*" In particular, on February 1, 2016, the Centers for Medicare and Medicaid Services ("CMS"), the federal agency that administers the Medicare and Medicaid programs, issued final regulations to implement the changes to the Medicaid

## [Table of Contents](#)

Drug Rebate program under the Healthcare Reform Act. These regulations became effective on April 1, 2016. Congress could enact additional legislation that further increases Medicaid drug rebates or other costs and charges associated with participating in the Medicaid Drug Rebate program. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program has and will continue to increase our costs and the complexity of compliance, has been and will be time-consuming, and could have a material adverse effect on our results of operations.

Some states have elected not to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level, as is permitted under the Healthcare Reform Act. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales, business and financial condition. Where Medicaid patients receive insurance coverage under any of the new options made available through the Healthcare Reform Act, manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, which could impact manufacturer revenues. In addition, the federal government has also announced delays in the implementation of key provisions of the Healthcare Reform Act. The implications of these delays for our sales, business and financial condition, if any, are not yet clear.

Moreover, legislative and regulatory changes to the Healthcare Reform Act and its implementation remain possible in the 115th U.S. Congress and under the Trump Administration. The nature and extent of any legislative or regulatory changes to the Healthcare Reform Act are uncertain at this time. We expect that the Healthcare Reform Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products or to successfully commercialize our product candidates, if approved.

In addition, there have been proposals to impose federal rebates on Medicare Part D drugs, requiring federally-mandated rebates on all drugs dispensed to Medicare Part D enrollees or on only those drugs dispensed to certain groups of lower income beneficiaries. If any of these proposals are adopted they could result in Theravance owing additional rebates, which could have a negative impact on revenues from sales of our products.

Beginning on April 1, 2013, Medicare payments for all items and services under Part A and B, including drugs and biologicals, were reduced by 2% under the sequestration (i.e., automatic spending reductions) as required by federal law, which requires sequestration for most federal programs, excluding Medicaid, Social Security, and certain other programs. The law caps the cuts to Medicare payments for items and services at 2% and this will continue to 2025. As long as these cuts remain in effect, they could adversely impact payment for VIBATIV and, if approved, our product candidates. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

***If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.***

We participate in and have certain price reporting obligations to the Medicaid Drug Rebate program and other governmental pricing programs, and we have obligations to report average sales price under the Medicare program.

Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the United States in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions.

The Healthcare Reform Act made significant changes to the Medicaid Drug Rebate program, such as expanding rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well and changing the definition of average manufacturer price. The Healthcare Reform Act also increased the minimum Medicaid rebate; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount at 100% of the average manufacturer price. Finally, the Healthcare Reform Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government.

## [Table of Contents](#)

On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate program under the Healthcare Reform Act. These regulations became effective on April 1, 2016. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program has and will continue to increase our costs and the complexity of compliance, has been and will be time-consuming, and could have a material adverse effect on our results of operations.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs to a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The Healthcare Reform Act expanded the list of covered entities to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals. The 340B ceiling price is calculated using a statutory formula based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. Changes to the definition of average manufacturer price and the Medicaid rebate amount under the Healthcare Reform Act and CMS's final regulations implementing those changes also could affect our 340B ceiling price calculations and negatively impact our results of operations.

The Healthcare Reform Act obligates the Secretary of the HHS to update the agreement that manufacturers must sign to participate in the 340B program to obligate a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. The Health Resources and Services Administration ("HRSA"), the federal agency that administers the 340B program, recently updated the agreement with participating manufacturers. The Healthcare Reform Act also obligates the Secretary of the HHS to create regulations and processes to improve the integrity of the 340B program. In August 2016, HRSA issued a proposed regulation regarding an administrative dispute resolution process to resolve claims by covered entities that they have been overcharged by manufacturers and claims by manufacturers of program violations by covered entities. It is unclear when or whether the regulation will be released in final form under the Trump Administration. On January 5, 2017, HRSA issued a final regulation regarding the calculation of 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. The effective date of the regulation has been delayed until October 1, 2017. Implementation of this final rule and the issuance of any other final regulations and guidance could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

Federal law also requires that a company that participates in the Medicaid Drug Rebate program report average sales price information each quarter to CMS for certain categories of drugs that are paid under the Medicare Part B program. Manufacturers calculate the average sales price based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. CMS uses these submissions to determine payment rates for drugs under Medicare Part B. Statutory or regulatory changes or CMS guidance could affect the average sales price calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations. Also, the Medicare Part B drug payment methodology is subject to change based on potential demonstration projects undertaken by CMS or potential legislation enacted by Congress.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program.

We are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted any false price information to the government, we may be liable for civil monetary penalties in the amount of \$178,156 per item of false information. If we are found to have made a misrepresentation in the reporting of our average sales price, the Medicare statute provides for civil

## [Table of Contents](#)

monetary penalties of up to \$12,856 for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit the required price data on a timely basis could result in a civil monetary penalty of \$17,816 per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs.

CMS and the OIG have pursued manufacturers that were alleged to have failed to report these data to the government in a timely manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by the VA, Department of Defense, Public Health Service, and Coast Guard (the “Big Four agencies”) and certain federal grantees, we are required to participate in the Department of Veterans Affairs (“VA”) Federal Supply Schedule (“FSS”) pricing program, established under Section 603 of the Veterans Health Care Act of 1992. Under this program, we are obligated to make VIBATIV available for procurement on an FSS contract and charge a price to the Big Four agencies that is no higher than the Federal Ceiling Price (“FCP”), which is a price calculated pursuant to a statutory formula. The FCP is derived from a calculated price point called the “non-federal average manufacturer price” (“Non-FAMP”), which we calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to penalties of \$178,156 for each item of false information. The FSS contract also contains extensive disclosure and certification requirements.

Under Section 703 of the National Defense Authorization Act for FY 2008, we are required to pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare network pharmacies to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP. If we overcharge the government in connection with the FSS contract or Tricare Retail Pharmacy Rebate Program, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and any response to government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

***If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity, which could negatively affect our operating results and business.***

We are subject to data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the U.S., numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the FTC Act), govern the collection, use, disclosure, and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions and create liability for us (which could include civil and/or criminal penalties), private litigation and/or adverse publicity that could negatively affect our operating results and business. In addition, we may obtain health information from third parties (e.g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (“HIPAA”). Although we are not directly subject to HIPAA—other than potentially with respect to providing certain employee benefits—we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. HIPAA generally requires that healthcare providers and other covered entities obtain written authorizations from patients prior to disclosing protected health information of the patient (unless an exception to the authorization requirement applies). If authorization is required and the patient fails to execute an authorization or the authorization fails to contain all required provisions, then we may not be allowed access to and use of the patient’s information and our research efforts could be impaired or delayed. Furthermore, use of protected health information that is provided to us pursuant to a valid patient authorization is subject to the limits set forth in the authorization (e.g., for use in research and in submissions to regulatory authorities for product approvals). In addition, HIPAA does not replace federal, state, international or other laws that may grant individuals even greater privacy protections.



## [Table of Contents](#)

EU Member States and other jurisdictions where we operate have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU Data Protection Directive imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Switzerland has adopted similar restrictions. Data protection authorities from the different EU Member States may interpret the applicable laws differently, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in the EU. Although there are legal mechanisms to allow for the transfer of personal data from the EEA to the U.S., a decision of the European Court of Justice in the *Schrems* case (Case C-362/14 Maximilian Schrems v. Data Protection Commissioner) that invalidated the safe harbor framework has increased uncertainty around compliance with EU privacy law requirements. As a result of the decision, it was no longer possible to rely on the safe harbor certification as a legal basis for the transfer of personal data from the EU to entities in the U.S. On February 29, 2016, however, the European Commission announced an agreement with the United States Department of Commerce (DOC) to replace the invalidated Safe Harbor framework with a new EU-U.S. "Privacy Shield." On July 12, 2016, the European Commission adopted a decision on the adequacy of the protection provided by the Privacy Shield. The Privacy Shield is intended to address the requirements set out by the European Court of Justice in its ruling by imposing more stringent obligations on companies, providing stronger monitoring and enforcement by the DOC and Federal Trade Commission, and making commitments on the part of public authorities regarding access to information. U.S. companies have been able to certify to the U.S. Department of Commerce their compliance with the privacy principles of the Privacy Shield since August 1, 2016.

On September 16, 2016, the Irish privacy advocacy group Digital Rights Ireland brought an action for annulment of the EC decision on the adequacy of the Privacy Shield before the European Court of Justice (Case T-670/16). Case T-670/16 is still pending before the Court. If, however, the European Court of Justice invalidates the Privacy Shield, it will no longer be possible to rely on the Privacy Shield certification to support transfer of personal data from the EU to entities in the US. Adherence to the Privacy Shield is not, however, mandatory. U.S.-based companies are permitted to rely either on their adherence to the Privacy Shield or on the other authorized means and procedures to transfer personal data provided by the EU Data Protection Directive. If we or our vendors fail to comply with applicable data privacy laws, or if the legal mechanisms we or our vendors rely upon to allow for the transfer of personal data from the EEA or Switzerland to the U.S. (or other countries not considered by the European Commission to provide an adequate level of data protection) are not considered adequate, we could be subject to government enforcement actions and significant penalties against us, and our business could be adversely impacted if our ability to transfer personal data outside of the EEA or Switzerland is restricted, which could adversely impact our operating results. In December 2015, a proposal for an EU General Data Protection Regulation, intended to replace the current EU Data Protection Directive, was agreed between the European Parliament, the Council of the European Union and the European Commission. The EU General Data Protection Regulation entered into force on May 24, 2016 and will apply from May 25, 2018. The Regulation will introduce new data protection requirements in the EU, as well as substantial fines for breaches of the data protection rules. The EU General Data Protection Regulation will increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules.

***Our relationships with customers and third-party payors are subject to applicable anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians, distributors and third-party payors play a primary role in the distribution, recommendation and prescription of any pharmaceutical product for which we obtain marketing approval. Our arrangements with third-party payors and customers expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements through which we market, sell and distribute any products for which we have obtained or may obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- The federal healthcare Anti-Kickback Statute prohibits any person from, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchasing, leasing, ordering or arranging for or recommending of any good or service for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute is subject to evolving interpretation and has been applied by government enforcement officials to a number of common business arrangements in the pharmaceutical industry. The government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the statute or specific intent to violate it. There are a number of statutory exemptions and regulatory safe harbors protecting some common activities from prosecution; however, those exceptions and safe harbors are drawn narrowly. Failure to meet all of the requirements of a particular statutory exception or regulatory safe harbor does not make the conduct per se

illegal under the Anti-Kickback Statute, but the legality of the arrangement will be evaluated on a case-by-case basis based on the totality of the facts and circumstances. We seek to comply with the available statutory exemptions and safe harbors whenever possible, but our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants or patient assistance programs.

- The federal civil False Claims Act imposes civil penalties, and provides for whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent, or knowingly making, or using or causing to be made or used, a false record or statement material to a false or fraudulent claim to avoid, decrease, or conceal an obligation to pay money to the federal government. In recent years, several pharmaceutical and other healthcare companies have faced enforcement actions under the federal False Claims Act for, among other things, allegedly submitting false or misleading pricing information to government health care programs and providing free product to customers with the expectation that the customers would bill federal programs for the product. Federal enforcement agencies also have showed increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement and co-pay support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. Other companies have faced enforcement actions for causing false claims to be submitted because of the company's marketing the product for unapproved, and thus non-reimbursable, uses. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of \$5,500 to \$11,000 per false claim or statement. As a result of a recent interim final rule issued by the Department of Justice (DOJ), the penalties assessed after August 1, 2016 for violations occurring after November 2, 2015 will increase to per claim or statement penalties of \$10,781 to \$21,563. Because of the potential for large monetary exposure, healthcare and pharmaceutical companies often resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings. Companies may be required, however, to enter into corporate integrity agreements with the government, which may impose substantial costs on companies to ensure compliance. Criminal prosecution is also possible for making or presenting a false or fictitious or fraudulent claim to the federal government.
- HIPAA, among other things, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HIPAA also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services.
- The federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, imposes annual reporting requirements on certain manufacturers of drugs, devices, or biologics for payments and other transfers of value by them, directly or indirectly, to physicians (including physician family members) and teaching hospitals, as well as ownership and investment interests held by physicians. A manufacturer's failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties of up to an aggregate of \$150,000 per year, and up to an aggregate of \$1 million per year for "knowing failures." Manufacturers must submit reports by the 90th day of each calendar year.
- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Several states also require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing-related activities, including the provision of gifts, meals, or other items to certain health care providers. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes.

## [Table of Contents](#)

- Similar restrictions are imposed on the promotion and marketing of medicinal products in the EU Member States and other countries, including restrictions prohibiting the promotion of a compound prior to its approval. Laws (including those governing promotion, marketing and anti-kickback provisions), industry regulations and professional codes of conduct often are strictly enforced. Even in those countries where we may decide not to directly promote or market our products, inappropriate activity by our any international distribution partners could have implications for us.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that we or our partners may fail to comply fully with one or more of these requirements. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with applicable fraud and abuse or other healthcare laws and regulations or guidance. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we do or expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert resources and the attention of our management from operating our business.

### ***Our business and operations, including the use of hazardous and biological materials may result in liabilities with respect to environmental, health and safety matters.***

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

## **RISKS RELATING TO OUR ORDINARY SHARES**

### ***The market price for our shares has and may continue to fluctuate widely, and may result in substantial losses for purchasers of our ordinary shares.***

Our ordinary shares began trading on June 3, 2014, and the market price for our shares has and may continue to fluctuate widely, and may result in substantial losses for purchasers of our ordinary shares. To the extent that historically low trading volumes for our ordinary shares continues, our stock price may fluctuate significantly more than the stock market as a whole or the stock prices of similar companies. Without a larger public float of actively traded shares, our ordinary shares are likely to be more sensitive to changes in sales volumes, market fluctuations and events or perceived events with respect to our business, than the shares of common stock of companies with broader public ownership, and as a result, the trading prices for our ordinary shares may be more volatile. Among other things, trading of a relatively small volume of ordinary shares may have a greater effect on the trading price than would be the case if our public float of actively traded shares were larger. In addition, as further described below under the risk factor entitled “—*Concentration of ownership will limit your ability to influence corporate matters.*” a number of shareholders hold large concentrations of our shares which, if sold within a relatively short timeframe, could cause the price of our shares to drop significantly.

Market prices for securities of biotechnology and biopharmaceutical companies have been highly volatile, and we expect such volatility to continue for the foreseeable future, so that investment in our ordinary shares involves substantial risk. By separating from Innoviva, there is a risk that our company may be more susceptible to market fluctuations and other

[Table of Contents](#)

adverse events than we would have been were we still a part of Innoviva. Additionally, the stock market from time to time has experienced significant price and volume fluctuations unrelated to the operating performance of particular companies.

The following are some of the factors that may have a significant effect on the market price of our ordinary shares:

- any adverse developments or results or perceived adverse developments or results with respect to the GSK-Partnered Respiratory Programs, including, without limitation, any delays in development in these programs, any halting of development in these programs, any difficulties or delays encountered with regard to the FDA or other regulatory authorities in these programs, or any indication from clinical or non-clinical studies that the compounds in such programs are not safe or efficacious;
- any adverse developments or results or perceived adverse developments or results with respect to our key clinical programs (for example, revefenacin or our JAK inhibitor program), including, without limitation, any delays in development in these programs, any halting of development in these programs, any difficulties or delays encountered with regard to the FDA or other regulatory authorities in these programs, or any indication from clinical or non-clinical studies that the compounds in such programs are not safe or efficacious;
- any further adverse developments or perceived adverse developments with respect to the commercialization of VIBATIV;
- whether we achieve increased sales for VIBATIV;
- any announcements of developments with, or comments by, the FDA or other regulatory authorities with respect to products we or our partners have under development, are manufacturing or have commercialized;
- any adverse developments or agreements or perceived adverse developments or agreements with respect to the relationship of Innoviva or TRC, on the one hand, and GSK, on the other hand, including any such developments or agreements resulting from or relating to the Spin-Off;
- any adverse developments or perceived adverse developments with respect to our relationship with any of our research, development or commercialization partners, including, without limitation, disagreements that may arise between us and any of those partners;
- any adverse developments or perceived adverse developments in our programs with respect to partnering efforts or otherwise;
- announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors;
- publicity regarding actual or potential study results or the outcome of regulatory review relating to products under development by us, our partners or our competitors;
- regulatory developments in the United States and foreign countries;
- announcements with respect to governmental or private insurer reimbursement policies;
- announcements of equity or debt financings;
- possible impairment charges on non-marketable equity securities;
- economic and other external factors beyond our control;
- loss of key personnel;
- likelihood of our ordinary shares to be more sensitive to changes in sales volume, market fluctuations and events or perceived events with respect to our business due to our small public float;

[Table of Contents](#)

- low public market trading volumes for our ordinary shares related in part to the concentration of ownership of our shares;
- the sale of large concentrations of our shares;
- developments or disputes as to patent or other proprietary rights;
- approval or introduction of competing products and technologies;
- results of clinical trials;
- failures or unexpected delays in timelines for our potential products in development, including the obtaining of regulatory approvals;
- delays in manufacturing adversely affecting clinical or commercial operations;
- fluctuations in our operating results;
- market reaction to announcements by other biotechnology or pharmaceutical companies;
- initiation, termination or modification of agreements with our collaborators or disputes or disagreements with collaborators;
- litigation or the threat of litigation;
- public concern as to the safety of drugs developed by us; and
- comments and expectations of results made by securities analysts or investors.

If any of these factors causes us to fail to meet the expectations of securities analysts or investors, or if adverse conditions prevail or are perceived to prevail with respect to our business, the price of the ordinary shares would likely drop significantly. A significant drop in the price of a company's securities often leads to the filing of securities class action litigation against the company. This type of litigation against us could result in substantial costs and a diversion of management's attention and resources.

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

Based on our review of publicly available filings, as of June 30, 2017 GSK beneficially owned approximately 17.9% of our outstanding ordinary shares and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 6.4% of our outstanding ordinary shares. Based on our review of publicly available filings, as of June 30, 2017 our three largest shareholders other than GSK collectively owned approximately 49.1% of our outstanding ordinary shares. GSK also has a right to maintain its percentage ownership in our company under the Governance Agreement, including by participating in offerings of our ordinary shares or securities convertible into our shares. These shareholders and GSK could control the outcome of actions taken by us that require shareholder approval, including a transaction in which shareholders might receive a premium over the prevailing market price for their shares.

***Certain provisions in our constitutional documents may discourage our acquisition by a third-party, which could limit your opportunity to sell shares at a premium.***

Our constitutional documents include provisions that could limit the ability of others to acquire control of us, modify our structure or cause us to engage in change-of-control transactions, including, among other things, provisions that:

- require supermajority shareholder voting to effect certain amendments to our amended and restated memorandum and articles of association;
- establish a classified board of directors;
- restrict our shareholders from calling meetings or acting by written consent in lieu of a meeting;

[Table of Contents](#)

- limit the ability of our shareholders to propose actions at duly convened meetings; and
- authorize our board of directors, without action by our shareholders, to issue preferred shares and additional ordinary shares.

These provisions could have the effect of depriving you of an opportunity to sell your ordinary shares at a premium over prevailing market prices by discouraging third parties from seeking to acquire control of us in a tender offer or similar transaction.

***Our shareholders may face difficulties in protecting their interests because we are incorporated under Cayman Islands law.***

Our corporate affairs are governed by our amended and restated memorandum and articles of association, by the Companies Law (2016 Revision) of the Cayman Islands and by the common law of the Cayman Islands. The rights of our shareholders and the fiduciary responsibilities of our directors under the laws of the Cayman Islands are different from those under statutes or judicial precedent in existence in jurisdictions in the U.S. Therefore, you may have more difficulty in protecting your interests than would shareholders of a corporation incorporated in a jurisdiction in the U.S., due to the different nature of Cayman Islands law in this area.

Shareholders of Cayman Islands exempted companies such as our company have no general rights under Cayman Islands law to inspect corporate records and accounts or to obtain copies of lists of shareholders. Our directors have discretion under our amended and restated memorandum and articles of association to determine whether or not, and under what conditions, our corporate records may be inspected by our shareholders, but are not obliged to make them available to our shareholders. This may make it more difficult for you to obtain the information needed to establish any facts necessary for a shareholder motion or to solicit proxies from other shareholders in connection with a proxy contest.

Our Cayman Islands counsel, Maples and Calder, is not aware of any reported class action having been brought in a Cayman Islands court. Derivative actions have been brought in the Cayman Islands courts, and the Cayman Islands courts have confirmed the availability for such actions. In most cases, the company will be the proper plaintiff in any claim based on a breach of duty owed to it, and a claim against (for example) our officers or directors usually may not be brought by a shareholder. However, based on English authorities, which would in all likelihood be of persuasive authority and be applied by a court in the Cayman Islands, exceptions to the foregoing principle apply in circumstances in which:

- a company is acting, or proposing to act, illegally or beyond the scope of its authority;
- the act complained of, although not beyond the scope of the authority, could be effected if duly authorized by more than the number of votes which have actually been obtained; or
- those who control the company are perpetrating a “fraud on the minority.”

A shareholder may have a direct right of action against the company where the individual rights of that shareholder have been infringed or are about to be infringed.

***There is uncertainty as to shareholders’ ability to enforce certain foreign civil liabilities in the Cayman Islands.***

We are incorporated as an exempted company limited by shares with limited liability under the laws of the Cayman Islands. A material portion of our assets are located outside of the United States. As a result, it may be difficult for our shareholders to enforce judgments against us or judgments obtained in U.S. courts predicated upon the civil liability provisions of the federal securities laws of the United States or any state of the United States.

We have been advised by our Cayman Islands legal counsel, Maples and Calder, that the courts of the Cayman Islands are unlikely (i) to recognize or enforce against Theravance Biopharma judgments of courts of the United States predicated upon the civil liability provisions of the securities laws of the United States or any State; and (ii) in original actions brought in the Cayman Islands, to impose liabilities against Theravance Biopharma predicated upon the civil liability provisions of the securities laws of the United States or any State, on the grounds that such provisions are penal in nature. However, in the case of laws that are not penal in nature, although there is no statutory enforcement in the Cayman Islands of judgments obtained in the United States, the courts of the Cayman Islands will recognize and enforce a foreign money judgment of a foreign court of competent jurisdiction without retrial on the merits based on the principle that a judgment of a competent foreign court imposes upon the judgment debtor an obligation to pay the sum for which judgment has been given

[Table of Contents](#)

provided certain conditions are met. For a foreign judgment to be enforced in the Cayman Islands, such judgment must be final and conclusive and for a liquidated sum, and must not be in respect of taxes or a fine or penalty, inconsistent with a Cayman Islands' judgment in respect of the same matter, impeachable on the grounds of fraud or obtained in a manner, and or be of a kind the enforcement of which is, contrary to natural justice or the public policy of the Cayman Islands (awards of punitive or multiple damages may well be held to be contrary to public policy). A Cayman Islands court, including the Grand Court of the Cayman Islands, may stay proceedings if concurrent proceedings are being brought elsewhere, which would delay proceedings and make it more difficult for our shareholders to bring action against us.

*We do not anticipate paying any cash dividends on our capital shares in the foreseeable future; as a result, capital appreciation, if any, of our ordinary shares will be your sole source of gain for the foreseeable future.*

We have never declared or paid cash dividends on our capital shares. We do not anticipate paying any cash dividends on our capital shares in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. In addition, the terms of any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our ordinary shares. As a result, capital appreciation, if any, of our ordinary shares will be your sole source of gain for the foreseeable future.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None.

[Table of Contents](#)

**ITEM 6. EXHIBITS**

<b>Exhibit No.</b>	<b>Description of Exhibit</b>	<b>Filed Herewith</b>	<b>Incorporated by Reference</b>	
			<b>Form</b>	<b>Filing Date/Period End Date</b>
3.1	Amended and Restated Memorandum and Articles of Association		10-12B	April 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	X		
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended	X		
32 <sup>(1)</sup>	Certifications Pursuant to 18 U.S.C. Section 135	X		
101	Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended June 30, 2017, formatted in XBRL: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss, (iii) the Condensed Consolidated Statements of Cash Flows and (iv) the Notes to the Condensed Consolidated Financial Statements	X		

<sup>(1)</sup> The certifications provided as Exhibit 32 are being furnished to accompany the Report pursuant to 18 U.S.C. § 1350 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.



**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 Biopharma, Inc.

Date: August 8, 2017

/s/ Rick E Winningham

**Rick E Winningham**

Chairman of the Board and Chief Executive Officer  
(Principal Executive Officer)

Date: August 8, 2017

/s/ Renee D. Gala

**Renee D. Gala**

Senior Vice President and Chief Financial Officer  
(Principal Financial Officer)

**EXHIBIT INDEX**

Listed and indexed below are all Exhibits filed as part of this report.

Exhibit No.	Description of Exhibit	Filed Herewith	Incorporated by Reference	
			Form	Filing Date/Period End Date
3.1	Amended and Restated Memorandum and Articles of Association		10-12B	April 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	X		
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended	X		
32 <sup>(1)</sup>	Certifications Pursuant to 18 U.S.C. Section 135	X		
101	Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended June 30, 2017, formatted in XBRL: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss, (iii) the Condensed Consolidated Statements of Cash Flows and (iv) the Notes to the Condensed Consolidated Financial Statements	X		

<sup>(1)</sup> The certifications provided as Exhibit 32 are being furnished to accompany the Report pursuant to 18 U.S.C. § 1350 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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

Date: August 8, 2017

\_\_\_\_\_  
/s/ Rick E Winningham  
**Rick E Winningham**  
Chairman of the Board and Chief Executive Officer  
(Principal Executive Officer)

---

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

I, Renee D. Gala, certify that:

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

Date: August 8, 2017

/s/ Renee D. Gala  
**Renee D. Gala**  
Senior Vice President and Chief Financial Officer  
(Principal Financial Officer)

---



