Theravance Biopharma, Inc.
Form 10-Q
August 09, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2016

OR

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

For the transition period from to

Commission file number: 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 x No o

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See 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 o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

As of August 1, 2016, the number of the registrant s outstanding ordinary shares was 47,851,848.

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THERAVANCE BIOPHARMA, INC.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

THERAVANCE BIOPHARMA, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except per share data)

	June 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 148,363	$ 112,707
Short-term marketable securities	101,316	59,727
Accounts receivable, net of allowances of $1,238 and $758 at June 30, 2016 and December 31, 2015, respectively	1,856	1,922
Receivables from collaborative arrangements	35,080	35,232
Prepaid taxes	3,150	12,764
Other prepaid and current assets	3,550	5,115
Inventories	9,810	10,005
Total current assets	303,125	237,472
Property and equipment, net	8,811	9,873
Long-term marketable securities	52,316	42,860
Other investments	8,000	8,000
Restricted cash	833	833
Other assets	1,403	1,078
Total assets	$ 374,488	$ 300,116
Liabilities and Shareholders Equity		
Current liabilities:		
Accounts payable	$ 7,412	$ 18,804
Accrued personnel-related expenses	9,020	10,866
Accrued clinical and development expenses	22,650	14,709
Other accrued liabilities	4,913	4,947
Deferred revenue	662	144
Total current liabilities	44,657	49,470
Deferred rent	4,369	4,598
Other long-term liabilities	3,878	2,983
Commitments and contingencies (Note 9)		
Shareholders equity		
Preferred shares, $0.00001 par value: 230 shares authorized, no shares issued or outstanding at June 30, 2016 and December 31, 2015, respectively		

Ordinary shares, $0.00001 par value: 200,000 shares authorized at June 30, 2016 and December 31, 2015; 47,853 and 37,981 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively				
Additional paid-in capital		732,334		564,691
Accumulated other comprehensive income (loss)		181		(70)
Accumulated deficit		(410,931)		(321,556)
Total shareholders equity		321,584		243,065
Total liabilities and shareholders equity	$	374,488	$	300,116

See accompanying notes to condensed consolidated financial statements.

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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,	
	2016	2015	2016	2015
Revenue:				
Product sales	$ 5,359	$ 2,124	$ 8,670	$ 3,404
Revenue from collaborative arrangements	112	5,010	15,211	24,131
Total revenue	5,471	7,134	23,881	27,535
Costs and expenses:				
Cost of goods sold	638	505	1,416	875
Research and development (1)	32,069	30,377	67,748	66,396
Selling, general and administrative (1)	20,261	21,545	43,857	43,293
Total costs and expenses	52,968	52,427	113,021	110,564
Loss from operations	(47,497)	(45,293)	(89,140)	(83,029)
Interest and other income	308	204	495	414
Loss before income taxes	(47,189)	(45,089)	(88,645)	(82,615)
Provision for income taxes	36	2,514	730	7,463
Net loss	$ (47,225)	$ (47,603)	$ (89,375)	$ (90,078)
Net loss per share:				
Basic and diluted net loss per share	$ (1.06)	$ (1.42)	$ (2.16)	$ (2.71)
Shares used to compute basic and diluted net loss per share	44,407	33,532	41,366	33,183
Net unrealized gain (loss) on available-for-sale investments	55	(7)	251	107
Total comprehensive loss	$ (47,170)	$ (47,610)	$ (89,124)	$ (89,971)

(1) Amounts include share-based compensation expense as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	2016	2015	2016	2015
Research and development	$ 4,959	$ 6,817	$ 10,119	$ 14,299
Selling, general and administrative	4,945	7,845	11,115	15,989
Total share-based compensation expense	$ 9,904	$ 14,662	$ 21,234	$ 30,288

See accompanying notes to condensed consolidated financial statements.

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THERAVANCE BIOPHARMA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Six Months Ended June 30,	
	2016	**2015**
Operating activities		
Net loss	$ (89,375)	$ (90,078)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,153	1,572
Share-based compensation	21,234	30,289
Inventory write-down	119	79
Excess tax benefits from share-based compensation		(240)
Changes in operating assets and liabilities:		
Accounts receivable	66	(516)
Receivables from collaborative arrangements	152	(23,647)
Prepaid taxes	9,614	(3,024)
Other prepaid and current assets	1,566	(1,286)
Inventories	157	359
Other assets	711	(511)
Accounts payable	(10,757)	(3,770)
Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued liabilities	5,732	(13,208)
Deferred rent	(229)	(255)
Deferred revenue	905	385
Other long-term liabilities	508	723
Net cash used in operating activities	(58,444)	(103,128)
Investing activities		
Purchases of property and equipment	(1,322)	(1,367)
Purchases of marketable securities	(91,382)	(11,059)
Maturities of marketable securities	40,514	95,879
Net cash (used in) provided by investing activities	(52,190)	83,453
Financing activities		
Net proceeds from sale of ordinary shares	145,224	27,310
Proceeds from ESPP purchases	1,944	
Proceeds from option exercise	1,346	
Excess tax benefits from share-based compensation		240
Repurchase of shares to satisfy tax withholding	(2,224)	
Net cash provided by financing activities	146,290	27,550
Net increase in cash and cash equivalents	35,656	7,875
Cash and cash equivalents at beginning of period	112,707	89,215
Cash and cash equivalents at end of period	$ 148,363	$ 97,090
Supplemental disclosure of cash flow information		

Cash (received) paid for income taxes, net	$	(9,488)	$	7,273

See accompanying notes to condensed consolidated financial statements.

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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 make a difference in 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 GI-targeted pan-Janus kinases (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

The Company s condensed consolidated financial information as of June 30, 2016, and the three and six months ended June 30, 2016 and 2015 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, 2015 financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission (SEC) on March 11, 2016.

Significant Accounting Policies

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, 2015.

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), which will replace most existing revenue recognition guidance in GAAP when it becomes effective. ASU 2014-19 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. In doing so, companies will 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. ASU 2014-09 was initially to be effective for interim and annual reporting periods beginning after December 15, 2016. In August 2015, the FASB issued ASU 2015-14 which delays the effective date of ASU 2014-09 by one year and allows for early adoption as of the original effective date. In March 2016, the FASB issued ASU 2016-08 which clarifies

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certain principal versus agent considerations under *Topic 606*. In April 2016, the FASB issued ASU 2016-10 which clarifies *Topic 606 s* implementation guidance on identifying performance obligations in a contract and determining whether an entity s promise to grant a license provides a customer with either a right to use the entity s intellectual property (which is satisfied at a point in time) or a right to access the entity s intellectual property (which is satisfied over time). In May 2016, the FASB issued ASU 2016-12 which amends the guidance on transition, collectability, noncash consideration and the presentation of sales and other similar taxes. ASU 2016-12 clarifies that, for a contract to be considered completed at transition, all (or substantially all) of the revenue must have been recognized under legacy GAAP. In addition, ASU 2016-12 clarifies how an entity should evaluate the collectability threshold and when an entity can recognize nonrefundable consideration received as revenue if an arrangement does not meet the standard s contract criteria.

The effective dates of ASU 2016-08, ASU 2016-10, and ASU 2016-12 are the same as the new effective date of ASU 2014-09 which is for all interim and annual reporting periods beginning after December 15, 2017, and early adoption is permitted as of the original effective date of ASU 2014-09. We currently do not anticipate an early adoption of the new revenue standards, and we are currently evaluating the impact that the adoption of the new revenue standards will have on our consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU 2016-02, *Leases* (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 March 2016, the FASB issued ASU 2016-09, *Compensation Stock Compensation (Topic 718)* (ASU 2016-09). ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as equity or liabilities, an option to recognize gross share compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. ASU 2016-09 is effective for all interim and annual reporting periods beginning after December 15, 2016 with early adoption permitted. We are currently evaluating the potential impact that the adoption of ASU 2016-09 will have on our consolidated financial statements and related disclosures.

In May 2016, the FASB issued ASU 2016-11, *Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815)* (ASU 2016-11). With respect to *Revenue Recognition* (*Topic 605),* ASU 2016-11 rescinds various standards codified as part of *Revenue Recognition (Topic 605)* in relation to the future adoption of ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. These rescissions include changes to topics pertaining to revenue and expense recognition for freight services in process, accounting for shipping and handling fees and costs and accounting for consideration given by a vendor to a customer. ASU 2016-11 was effective immediately upon issuance and will be adopted when we adopt ASU 2014-09. We are currently evaluating the impact that the adoption of ASU 2016-11, specific to *Topic 605*, will have on our consolidated financial statements and related disclosures. We do not believe ASU 2016-11, specific to *Topic 815*, will have any material 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 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 common shares had been issued for other dilutive securities.

For the three and six months ended June 30, 2016 and 2015, diluted and basic net loss per share was identical since potential common shares were excluded from the calculation, as their effect was anti-dilutive.

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Anti-Dilutive Securities

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	**2016**	**2015**	**2016**	**2015**
Share issuances under equity incentive plan and ESPP	3,310	6,684	3,417	4,404
Restricted shares	1,488	260	1,488	260
	4,798	6,944	4,905	4,664

3. Collaborative Arrangements

Revenue from Collaborative Arrangements

We recognized the following revenues from our collaborative arrangements:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	**2016**	**2015**	**2016**	**2015**
Mylan	$ 25	$ 25	$ 15,051	$ 19,124
R-Pharm	18	2,009	27	2,031
SciClone Pharmaceuticals	2	2,950	4	2,950
Other	67	26	129	26
Total revenue from collaborative arrangements	$ 112	$ 5,010	$ 15,211	$ 24,131

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.

In the first quarter of 2015, upfront payments totaling $19.2 million from Mylan were allocated to the license and committee participation deliverables based on the relative selling price method. The $19.2 million consisted of the initial payment of $15.0 million in cash and the $4.2 million premium related to the equity investment, which represents the difference between the closing price on January 30, 2015 and the issued price of $18.918 per share. For the six months ended June 30, 2015, we recognized $19.1 million in revenue from the Mylan collaborative arrangement related primarily to the license and technological know-how delivered in the first quarter of 2015.

For the three months ended June 30, 2016, we recognized $25,000 for the amortization of previously deferred revenue. For the six months ended June 30, 2016, we recognized $15.1 million in revenue, primarily related to the $15.0 million milestone payment received from Mylan for the achievement of 50% enrollment in the Phase 3 twelve-month safety study.

Takeda Collaborative Arrangement

In June 2016, we entered into a License and Collaboration Agreement (the Takeda Agreement) with Millennium Pharmaceuticals, Inc. (Millennium), in order to establish a collaboration for the development and commercialization of TD-8954, a selective 5-HT4 receptor agonist. Prior to the Takeda Agreement, the Company has developed TD-8954 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 U.S. Food and Drug Administration (FDA) Fast Track Designation. Millennium is an indirect wholly-owned subsidiary of Takeda Pharmaceutical Company Limited (TSE: 4502) (collectively with Millennium, Takeda). Under the terms of the Takeda Agreement, Takeda will be responsible for worldwide development and commercialization of TD-8954. We will receive an upfront cash payment of $15 million and will be eligible to receive success based development, regulatory and sales milestone payments by Takeda. The first $110 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.

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The transactions contemplated by the Takeda Agreement closed in the third quarter, following the expiration of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act (HSR Act). Upon closing and the subsequent transfer of the license and technical know-how, we have the right to receive an upfront payment of $15 million.

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, 2016	2015	Six Months Ended June 30, 2016	2015
Mylan	$ 25,971	$ 11,610	$ 57,144	$ 15,742
Alfa Wassermann	2,601	367	3,786	789
SciClone	98		98	
R-Pharm	12	277	25	277
Total reduction to R&D expense	$ 28,682	$ 12,254	$ 61,053	$ 16,808

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, 2016	December 31, 2015
U.S. government securities	Level 1	$ 52,227	$ 47,043
U.S. government agency securities	Level 2	44,381	31,465
Corporate notes	Level 2	24,173	19,089
Commercial paper	Level 2	91,927	4,990
Marketable securities (including commercial paper classified as cash equivalents)		212,708	102,587
Money market funds	Level 1	71,273	69,126
Total		$ 283,981	$ 171,713

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 gains and losses were $0.2 million at June 30, 2016 and immaterial at December 31, 2015.

At June 30, 2016, all of the marketable securities had contractual maturities within two years and the weighted average maturity of the marketable securities was approximately eight 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, 2016.

We do not intend to sell the investments that are in an unrealized loss position, and it is unlikely that we will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. We have determined that the gross unrealized losses on our marketable securities at June 30, 2016 were temporary in nature. All marketable securities with unrealized losses at June 30, 2016 have been in a loss position for less than twelve months.

At June 30, 2016, our accumulated other comprehensive income (loss) on our condensed consolidated balance sheets consisted of net unrealized gains on available-for-sale investments. During the three and six months ended June 30, 2016, 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.

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5. Inventories

Inventory consists of the following:

(In thousands)	June 30, 2016	December 31, 2015
Raw materials	$ 5,811	$ 6,869
Work-in-process	1,838	
Finished goods	2,161	3,136
Total inventories	$ 9,810	$ 10,005

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:

(In thousands)	Three Months Ended June 30, 2016	2015	Six Months Ended June 30, 2016	2015
Research and development	$ 4,959	$ 6,817	$ 10,119	$ 14,299
Selling, general and administrative	4,945	7,845	11,115	15,989
Total share-based compensation expense	$ 9,904	$ 14,662	$ 21,234	$ 30,288

Total share-based compensation expense capitalized to inventory was not material for any of the periods presented.

Performance-Contingent Awards

In the first quarter of 2016, the Compensation Committee of the Company s 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. These grants have dual triggers of vesting based upon the achievement of certain performance conditions over a five-year timeframe from 2016 to 2020 and continued employment, both of which must be satisfied in order for the awards to vest.

Expense associated with these awards would 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 will be reassessed at each reporting period.

In August 2016, the Compensation Committee determined not to award credit for a performance condition that occurred in the second quarter of 2016, which for accounting purposes is treated as a modification of the vesting conditions of all outstanding awards. As a result of the modification, the vesting of the first tranche of the awards changed from probable of achievement to improbable. The vesting of the second and third tranches of the awards is still considered improbable of achievement. As a result of the modification, there is a new measurement date for the second and third tranches of the awards as of the modification date. While the total number of shares under the award did not change, the remeasurement of the awards results in a higher potential compensation charge for the awards because our share price had increased since the original measurement date. The revised maximum potential expense associated with the awards could be up to approximately $38.9 million (allocated as $16.7 million for research and development expense and $22.2 million for selling, general and administrative expense) if all of the performance conditions are achieved. In the second quarter of 2016, we recognized $0.7 million in share-based compensation expense related to our assessment of the probability that the performance conditions associated with the first tranche of these awards were considered to be probable of vesting. As of June 30, 2016, we determined that the remaining second and third tranches were improbable of vesting and, as a result, no compensation expense related to these tranches has been recognized for the quarter.

7. Income Taxes

The income tax provision was $36,000 and $0.7 million for the three and six months ended June 30, 2016, respectively, although we incurred operating losses on a consolidated basis. The provision for income tax was primarily due to uncertain tax positions taken with respect to transfer pricing. No provision for income taxes has been recognized on undistributed earnings of our foreign subsidiaries because we consider such earnings to be indefinitely reinvested.

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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. At June 30, 2016, 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 is 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, and changes in overall levels of income before tax.

8. Shareholders Equity

Ordinary Shares Issuance under At-the-Market Agreement

Pursuant to a sales agreement with Cantor Fitzgerald & Co. (Cantor Fitzgerald), we may issue and sell up to $50 million of our ordinary shares pursuant to an at-the-market offering program (ATM Agreement), under our shelf registration statement on Form S-3 effective in July 2015. Under the ATM Agreement, we pay Cantor Fitzgerald a commission rate of up to 3.0% of the gross proceeds from the sale of our ordinary shares.

We engaged in sales of our ordinary shares under the ATM Agreement from March 17, 2016 to April 8, 2016. During this period, we sold approximately 770,000 shares at an average market price of $19.53 per share, resulting in aggregate net proceeds after offering costs of approximately $14.3 million. For the three and six months ended June 30, 2016, we sold approximately 490,000 and 770,000 shares, respectively.

Public Offering of Ordinary Shares

On May 4, 2016, we closed the sale of an aggregate of 5,479,750 of our ordinary shares, $0.00001 par value, at a public offering price of $21.00 per share. The shares were issued pursuant to a prospectus supplement filed with the SEC on April 28, 2016, in connection with a takedown from our shelf registration statement on Form S-3. We received net offering proceeds of approximately $107.9 million after deducting the underwriting discount and estimated offering expenses.

9. Commitments and Contingencies

Guarantees and Indemnifications

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, 2016.

10. Subsequent Events

Takeda Collaborative Arrangement

The transactions contemplated by the Takeda Agreement closed in the third quarter, following the expiration of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act (HSR Act). Upon closing and the subsequent transfer of the license and technical know-how, we have the right to receive an upfront payment of $15 million.

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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, e forecast, goal, intend, may, mission, opportunities, plan, potential, predict, project, pursue, seek, should, target, 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, 2015. 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 make a difference in 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 GI-targeted pan-Janus kinases (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.

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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 alternative treatments are not suitable. VIBATIV is indicated in the European Union 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 complicated skin and skin structure infections and HABP and VABP caused by Gram-positive bacteria, including MRSA.

Commercial Program Expansion

In 2014 and early 2015, we implemented a phased launch strategy for VIBATIV in the U.S. that focused on a limited number of targeted geographic territories across the country. In the second quarter of 2015, we announced our intention to expand our sales force to 50 representatives with the goal of further strengthening our commercial infrastructure comprised of experienced sales representatives and a significant medical information component focused on the acute care market. We achieved our goal of hiring and training additional sales representatives by the end of the third quarter of 2015, and the newly expanded field force was fully deployed by the beginning of the fourth quarter of 2015.

We plan to market VIBATIV outside the U.S. through a network of partners. To date, we have secured partners for VIBATIV in the following geographies Canada, Middle East, North Africa, Israel, Russia, China and India. In August 2016, we and Clinigen Group (Clinigen) reached a mutual decision that Clinigen will return commercial rights to market and distribute VIBATIV in the European Union to Theravance Biopharma. Both companies are collaborating to transition the EU-focused commercial rights and activities for VIBATIV to ensure the product remains accessible to physicians and patients. Theravance Biopharma is 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.

Telavancin Observational Use Registry (TOUR)

Initiated in February 2015, the 1,000-patient TOUR observational use registry 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 and safety outcomes in the real world, we aim to create an expansive knowledge base to guide future development and optimal use of the drug.

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Long-Acting Muscarinic Antagonist Revefenacin (TD-4208)

Revefenacin is an investigational long acting muscarinic antagonist (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. 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 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 strengthens 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 will co-develop 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 for that program up until the approval of the first new drug application, 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. Although China is not included in the ex-U.S. territory, Mylan has a right of first negotiation with respect to the development and commercialization of nebulized revefenacin in China.

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. As of December 31, 2015, we are eligible to receive from Mylan potential development and sales milestone payments totaling $220.0 million in the aggregate, with $175.0 million associated with revefenacin monotherapy and $45.0 million for future potential combination products. In February 2016, we earned a $15.0 million development milestone payment for achieving 50% enrollment in the Phase 3 twelve-month safety study. We do not anticipate earning any new milestone payments from Mylan for the remainder of 2016.

We retain worldwide rights to revefenacin delivered through other dosage forms, such as a metered dose inhaler or dry powder inhaler (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.

Phase 3 Study 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 will examine 2 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 are 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 is an open-label, active comparator study of 12 months duration. Together, the three studies will enroll approximately 2,300 patients. In February 2016, we announced the achievement of 50% enrollment in all three of the Phase 3 clinical studies for revefenacin. The achievement of 50% enrollment in the twelve-month safety study triggered a $15.0 million milestone payment to Theravance Biopharma by Mylan. In June 2016, we completed enrollment for all three studies. We expect to complete the efficacy studies early-fourth quarter of 2016, and the twelve-month safety study in 2017. If the Phase 3 program is successful, our goal would be to submit a regulatory filing in the U.S. in late-2017.

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Oral Peripherally-Acting Mu Opioid Receptor Antagonist Axelopran (TD-1211)

OIC Program

Axelopran is an investigational, once-daily, oral peripherally-active mu opioid receptor antagonist for opioid- induced constipation (OIC). The axelopran Phase 2 program demonstrated a clinically meaningful treatment effect in OIC patients compared to placebo. The goal for this program is to demonstrate the ability to normalize bowel function without impacting analgesia and improve a variety of GI symptoms associated with constipation, which could provide axelopran with a competitive advantage in the OIC market if demonstrated in Phase 3 studies and approved by regulatory authorities. We have developed a patient reported outcomes tool designed to measure patient symptoms which would be used in a Phase 3 registrational program and potentially generate data that could differentiate the product from the competition. We are currently refining our development and commercial strategy for axelopran.

Fixed Dose Combination

In December 2014, we completed a Phase 1 study to determine the relative bioavailability of OxyContin® (oxycodone) and axelopran after oral administration as a fixed dose combination (FDC) relative to the individual components administered together. The study examined a spray-coat application of axelopran to an opioid, OxyContin, to determine the effect of axelopran on OxyContin exposure. The study compared exposure of OxyContin alone, axelopran alone, OxyContin and axelopran administered as two separate tablets, and OxyContin spray-coated with axelopran in a FDC. Study results demonstrated that axelopran does not significantly alter systemic exposure to OxyContin when delivered as a FDC relative to when co-administered as individual tablets. A FDC of axelopran and an opioid could present an important market opportunity, as it has the potential to provide pain relief without constipation in a single abuse-deterrent pill for patients using opioids on a chronic basis.

Velusetrag

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-HT4 receptor. Velusetrag is being developed in collaboration with Alfa Wassermann S.p.A. (Alfa Wassermann) in a two-part Phase 2 program to test the efficacy, safety and tolerability of velusetrag in the treatment of patients with gastroparesis. 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 March 2015, we initiated a Phase 2b study of velusetrag for the treatment of patients with gastroparesis and other gastrointestinal motility disorders. The 200-patient study is a multi-center, double-blind, randomized, placebo-controlled, parallel-group trial which will explore the efficacy and safety of multiple doses of velusetrag in patients with diabetic or idiopathic gastroparesis. The twelve-week study will test three doses: 5, 15, and 30 mg administered once-daily. The primary endpoint will be the effect of velusetrag on symptoms in subjects with gastroparesis. The study will also evaluate the effect of velusetrag on gastric emptying, and the psychometric properties of the Gastroparesis Rating Scale, a daily patient-reported outcome measure. We currently expect to complete the Phase 2b study in 2017. Pursuant to our agreement with Alfa Wassermann, the first Phase 2 study was, and the bulk of the Phase 2b study is, funded by Alfa Wassermann.

NS5A Inhibitor TD-6450

TD-6450 is an internally discovered multivalent NS5A inhibitor designed to have improved antiviral activity against GT-1 resistance-associated variants resistant to first generation NS5A inhibitors. 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. In October 2015, TREKtx and we announced that TREKtx had initiated a 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. In June 2016, TREKtx announced interim results from its Phase 2a study evaluating FDV plus TD-6450 and RBV in patients will HCV genotype 4, as well as, the initiation of a second Phase 2a study of FDV and TD-6450, with and without RBV in patients with HCV genotype 1.

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Neprilysin (NEP) Inhibitor Program

Neprilysin (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 intend to create a platform for multiple combination products with our NEP inhibitor with features that are differentiated from currently available products. Specifically, compounds that are non-renally cleared, dosed once-daily, dosed alone or in combination with other medicines and that may be dosed orally or intravenously.

Phase 1 Single Ascending Dose (SAD) Study

In March 2016, we completed a Phase 1 clinical study of our most advanced NEP inhibitor compound, TD-0714. The Phase 1 trial was a randomized, double-blind, placebo-controlled, single ascending dose study in healthy volunteers. 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 safety and tolerability profile. These results met the Company s target product profile and provide confidence for future efficacy studies of TD-0714 in a broad range of cardiovascular and renal diseases, including in patients with compromised renal function. Theravance Biopharma is now conducting a Phase 1 multiple ascending dose (MAD) study of TD-0714 that is designed to supplement the findings of the SAD study and support the ongoing clinical development of the molecule. We expect to complete the MAD study in the second half of 2016.

Gastrointestinal (GI)-Targeted Pan-Janus Kinase (JAK) Inhibitor Program

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, myelofibrosis and psoriasis. However, these products are known to have side effects based on their systemic exposure. This mechanism has previously demonstrated therapeutic benefit for patients with ulcerative colitis. Currently available treatments for ulcerative colitis have systemic safety liabilities and limited efficacy. Our goal is to develop an orally administered GI-targeted pan-JAK inhibitor designed to distribute adequately and predominantly to the tissues of the GI tract, treating inflammation in those tissues while minimizing systemic exposure. We are focused on utilizing targeted JAK inhibitors for potential treatment of inflammatory intestinal disease including ulcerative colitis.

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 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, to determine 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 at daily doses of 30 mg and 100 mg were approximately 75-fold and 15-fold lower, respectively, as compared to the plasma exposure of tofacitinib at twice daily doses of 10 mg.

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 progression into a Phase 1b trial in ulcerative colitis patients later this year, with data expected in 2017.

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.

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Selective 5-HT4 Agonist (TD-8954)

Takeda Collaborative Arrangement

In June 2016, we entered into a License and Collaboration Agreement (the Takeda Agreement) with Millennium Pharmaceuticals, Inc., a Delaware corporation (Millennium), in order to establish a collaboration for the development and commercialization of TD-8954, a selective 5-HT4 receptor agonist. Prior to the Takeda Agreement, the Company has developed TD-8954 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 U.S. Food and Drug Administration (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 will receive an upfront cash payment of $15 million and will be eligible to receive success based development, regulatory and sales milestone payments by Takeda. The first $110 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.

The transactions contemplated by the Takeda Agreement closed in the third quarter, following the expiration of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act (HSR Act). Upon closing and the subsequent transfer of the license and technical know-how, we have the right to receive an upfront payment of $15 million.

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 that Innoviva partnered with GSK and assigned to Theravance Respiratory Company, LLC (TRC) in connection with the Spin-Off (the GSK-Partnered Respiratory Programs) consisting 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. Also in June 2016, GSK and Innoviva announced plans to accelerate the timeline for filing the New Drug Application (NDA) in the U.S. for the Closed Triple from first half 2018 to end of 2016. In June 2016, GSK and Innoviva confirmed previously communicated plans to file an EU regulatory submission by the end of 2016.

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. Innoviva and GSK are conducting two Phase 2 clinical trials for batefenterol and batefenterol/FF, which will enroll approximately 380 patients with COPD.

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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, GSK will pay TRC contingent milestone payments of up to $125.0 million for a single-agent medicine and up to $250.0 million for both a single-agent and a combination medicine, and in each case we would be entitled to receive an 85% economic interest in any such payments.

Theravance Respiratory Company, LLC

Prior to the June 1, 2014 separation of its biopharmaceutical operations into its then wholly-owned subsidiary Theravance Biopharma (the Spin-Off), Innoviva assigned to TRC its strategic alliance agreement with GSK and all of its rights and obligations under its LABA collaboration agreement with GSK other than with respect to RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO® ELLIPTA® and vilanterol monotherapy. 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. 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 the 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, 2015.

In the first quarter of 2016, the Compensation Committee of the Company s 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. These grants have dual triggers of vesting based upon the achievement of certain performance conditions over a five-year timeframe from 2016 to 2020 and continued employment, both of which must be satisfied in order for the awards to vest.

Expense associated with these awards would 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 will be reassessed at each reporting period.

In August 2016, the Compensation Committee determined not to award credit for a performance condition that occurred in the second quarter of 2016, which for accounting purposes is treated as a modification of the vesting conditions of all outstanding awards. As a result of the modification, the vesting of the first tranche of the awards changed from probable of achievement to improbable. The vesting of the second and third tranches of the awards is still considered improbable of achievement. As a result of the modification, there is a new measurement date for the second and third tranches of the awards as of the modification date. While the total number of shares under the award did not change, the remeasurement of the awards results in a higher potential compensation charge for the awards because our share price had increased since the original measurement date. The revised maximum potential expense associated with the awards could be up to approximately $38.9 million (allocated as $16.7 million for research and development expense and $22.2 million for selling, general and administrative expense) if all of the performance conditions are achieved. In the second quarter of 2016, we recognized $0.7 million in share-based compensation expense related to our assessment of the probability that the performance conditions associated with the first tranche of these awards were considered to be probable of vesting. As of June 30, 2016, we determined that the remaining second and third tranches were improbable of vesting and, as a result, no compensation expense related to these tranches has been recognized for the quarter.

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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:

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
(In thousands)	**2016**	**2015**	**$**	**%**	**2016**	**2015**	**$**	**%**
Product sales	$ 5,359	$ 2,124	$ 3,235	152%	$ 8,670	$ 3,404	$ 5,266	155%
Revenue from collaborative arrangements	112	5,010	(4,898)	(98)	15,211	24,131	(8,920)	(37)
Total revenue	$ 5,471	$ 7,134	$ (1,663)	(23)%	$ 23,881	$ 27,535	$ (3,654)	(13)%

Revenue from product sales increased by $3.2 million and $5.3 million for the three months and six months ended June 30, 2016, respectively, compared to the same periods in 2015. Both increases resulted primarily from the expansion of our VIBATIV sales infrastructure that was completed in the fourth quarter of 2015.

Revenue from collaborative arrangements decreased by $4.9 million for the three months ended June 30, 2016 compared to the same period in 2015. The decrease was attributed to a $2.95 million upfront payment from a new collaboration arrangement with SciClone Pharmaceutical International Holding Ltd. (SciClone) and a $2.0 million VIBATIV development milestone payment from R-Pharm both recorded in the second quarter of 2015.

Revenue from collaborative arrangements decreased by $8.9 million for the six months ended June 30, 2016 compared to the same period in 2015. For the six months ended June 30, 2016, we recognized a $15.0 million milestone payment from Mylan for the achievement of 50% enrollment in the Phase 3 twelve-month safety study. Comparatively for the same period in 2015, we recognized $19.1 million of upfront payments related to the delivery of the license and technological know-how to Mylan and $4.95 million related to the SciClone upfront and R-Pharm milestone payments described above.

Cost of Goods Sold

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

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
(In thousands)	**2016**	**2015**	**$**	**%**	**2016**	**2015**	**$**	**%**
Cost of goods sold	$ 638	$ 505	$ 133	26%	$ 1,416	$ 875	$ 541	62%

Costs of goods sold increased by by $0.1 million for the three months ended June 30, 2016 compared to the same period in 2015. The increase was due to $0.2 million in royalty payments related to the increase in VIBATIV sales and a $0.1 million charge for the write-down of short-dated VIBATIV inventory. These increases were partially offset by a $0.2 million decrease in cost of goods sold due to the sale of VIBATIV vials that were previously written off.

Costs of goods sold increased by $0.5 million for the six months ended June 30, 2016 compared to the same period in 2015. The increase was primarily attributed to the increase in the sales of VIBATIV, including a $0.2 million increase in royalty payments.

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.

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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, 2016	2015	Change $	Change %	Six Months Ended June 30, 2016	2015	Change $	Change %
Employee-related	$ 8,881	$ 10,016	$ (1,135)	(11)%	$ 19,400	$ 22,965	$ (3,565)	(16)%
Share-based compensation	4,959	6,817	(1,858)	(27)	10,119	14,299	(4,180)	(29)
External-related	11,510	6,879	4,631	67	24,613	15,815	8,798	56
Facilities, depreciation and other allocated	6,719	6,665	54	1	13,616	13,317	299	2
Total research and development expenses	$ 32,069	$ 30,377	$ 1,692	6%	$ 67,748	$ 66,396	$ 1,352	2%

R&D expenses increased by $1.7 million for the three months ended June 30, 2016 compared to the same period in 2015. The increase was attributed to a $4.6 million increase in external-related costs that was primarily driven by costs associated with the progression of our priority programs. This increase was offset by decreases in our employee-related and share-based compensation expenses of $1.1 million and $1.9 million, respectively, primarily due to lower costs associated with the long-term retention and incentive awards granted to certain employees in 2012 and 2011.

R&D expenses increased by $1.4 million for the six months ended June 30, 2016 compared to the same period in 2015. The increase was attributed to an $8.8 million increase in external-related costs that was primarily driven by costs associated with the progression of our priority programs. This increase was offset by decreases in our employee-related and share-based compensation expenses of $3.6 million and $4.2 million, respectively, primarily due to lower costs associated with the long-term retention and incentive awards granted to certain employees in 2012 and 2011.

Under certain of our collaborative arrangements we receive partial reimbursement of external costs and employee-related costs, which have been reflected as a reduction of R&D expenses of $28.7 million and $61.1 million for three and six months ended June 30, 2016, respectively, and $12.3 million and $16.8 million for the three and six months ended June 30, 2015, respectively. The increases were primarily due to expense reimbursements received from Mylan related to the progression of our revefenacin program.

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, 2016	2015	Change $	Change %	Six Months Ended June 30, 2016	2015	Change $	Change %
Selling, general and administrative	$ 20,261	$ 21,545	$ (1,284)	(6)%	$ 43,857	$ 43,293	$ 564	1%

Selling, general and administrative expenses decreased by $1.3 million for three months ended June 30, 2016 compared to the same period in 2015. The $1.3 million decrease was primarily due to a $2.9 million decrease in share-based compensation expense primarily due to costs incurred in the second quarter of 2015 associated with long-term retention and incentive awards granted to certain employees in 2012 and 2011.

The decrease was partially offset by a $1.5 million increase related to the expansion of our internal sales and marketing organization supporting VIBATIV.

Selling, general and administrative expenses increased by $0.6 million for six months ended June 30, 2016 compared to the same period in 2015. The $0.6 million increase was primarily attributed to a $4.6 million increase related to the expansion of our internal sales and marketing organization supporting VIBATIV and a $0.8 million increase related to consulting services. These increases were partially offset by a $4.9 million decrease in share-based compensation expense primarily due to lower costs associated with the long-term retention and incentive awards granted to certain employees in 2012 and 2011.

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Provision for Income Taxes

(In thousands)	Three Months Ended June 30, 2016	2015	Change $	Change %	Six Months Ended June 30, 2016	2015	Change $	Change %
Provision for income taxes	$ 36	$ 2,514	$ (2,478)	(99)%	$ 730	$ 7,463	$ (6,733)	(90)%

Our effective tax rate for the six months ended June 30, 2016 was approximately (1.0)% which was consistent with the effective tax rate for the year ended December 31, 2015. The provision for income taxes for all periods presented reflect primarily the U.S. federal taxes associated with the intercompany services that the Company s U.S. subsidiary performs for the Company. 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. The provision for income taxes decreased to $36,000 and $0.7 million for the three and six months ended June 30, 2016, respectively, compared to $2.5 million and $7.4 million for the respective periods in 2015 due to changes in our transfer pricing.

Liquidity and Capital Resources

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. In 2015, we made additional investments in telavancin, our approved antibiotic. For example, in February 2015, we initiated a Phase 3 registrational study for bacteremia and a patient registry study. In addition, we increased the number of VIBATIV sales representatives and medical science liaisons in the U.S. supporting physician education on the proper usage of VIBATIV. We are incurring all of the costs and expenses associated with the commercialization of VIBATIV in the U.S., including the creation of an independent sales and marketing organization with appropriate technical expertise, supporting infrastructure and distribution capabilities, expansion of medical affairs presence, manufacturing and third-party vendor logistics and consultant support, and post-marketing studies.

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.

In July 2015, our shelf registration statement on Form S-3 for the potential offering, issuance and sale by us of up to a maximum aggregate offering price of $250.0 million of our debt securities, ordinary shares, and/or warrants was declared effective (the Form S-3). Up to $50.0 million of the maximum aggregate offering price under the registration statement may be issued and sold pursuant to an at-the-market

offering program for sales of our ordinary shares under a sales agreement with Cantor Fitzgerald & Co. (ATM Agreement), which acts as our sales agent and underwriter under the agreement.

In October 2015, we entered into an Ordinary Share Purchase Agreement (the Purchase Agreement) with funds managed by Woodford Investment Management LLP for the registered direct offering of an aggregate of 3,859,649 of our ordinary shares at a purchase price of $14.25 per share. The shares were issued pursuant to a prospectus supplement filed with the Securities and Exchange Commission (SEC) on October 26, 2015, in connection with a takedown from our shelf registration statement on Form S-3. The closing of the transaction occurred on October 29, 2015 and the net offering proceeds were approximately $53.0 million.

On March 17, 2016, GSK purchased 1,301,015 of our unregistered ordinary shares at a price of $17.70 per share pursuant to an Ordinary Share Purchase Agreement between the Company and GSK, dated as of March 14, 2016. The aggregate gross proceeds of the purchase were approximately $23.0 million and no underwriting discounts or commissions were paid in this transaction.

We commenced selling ordinary shares under the ATM Agreement from March 17, 2016. As of April 8, 2016, we sold approximately 770,000 of our ordinary shares at an average market price of $19.53 per share, resulting in aggregate net proceeds after offering costs of approximately $14.3 million. As favorable financing opportunities arise, we may seek to continue to raise capital under the ATM Agreement or through other debt or equity offerings to fund our operations. However, future financing may not be available in amounts or on terms acceptable to us, if at all.

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On May 4, 2016, we closed the sale of an aggregate of 5,479,750 of our ordinary shares at a public offering price of $21.00 per share. The shares were issued pursuant to a prospectus supplement filed with the SEC on April 28, 2016, in connection with a takedown from our shelf registration statement on Form S-3. We received net offering proceeds of approximately $107.9 million after deducting the underwriting discount and estimated offering expenses.

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:

	Six Months Ended June 30,		
(In thousands)	**2016**	**2015**	**Change**
Net cash used in operating activities	$ (58,444)	$ (103,128)	$ 44,684
Net cash (used in) provided by investing activities	(52,190)	83,453	(135,643)
Net cash provided by financing activities	146,290	27,550	118,740

Cash flows used in operating activities

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.

Net cash used in operating activities was $103.1 million for the comparable period in 2015, consisting primarily of net loss of $90.1 million, adjusted for non-cash items such as $30.3 million for share-based compensation expense, and $44.8 million of net cash outflow related to changes in operating assets and liabilities. The $44.8 million net cash outflow related to changes in operating assets and liabilities was primarily attributable to an increase in receivables from collaborative arrangements of $23.6 million and increases in accounts payable and accrued expenses of $17.0 million for the six months ended June 30, 2015.

Cash flows (used in) provided by investing activities

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.

Net cash provided by investing activities was $83.5 million for the comparable period in 2015, consisting of inflows related to net purchases and maturities of marketable securities of $84.8 million and by purchases of property and equipment of $1.4 million.

Cash flows provided by financing activities

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.

Net cash provided by financing activities was $27.6 million for the comparable period in 2015, consisting primarily of the sales of ordinary shares to Mylan for total net proceeds of $25.8 million.

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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, 2016.

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, 2015, filed with the Securities and Exchange Commission on March 11, 2016.

Contractual Obligations and Commercial Commitments

There have been no material changes in our contractual obligations and commercial commitments from those set forth in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission on March 11, 2016.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks as of June 30, 2016 have not changed materially from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2015.

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, 2016, 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

During the second quarter of 2016, we implemented a new enterprise resource planning (ERP) system. The new ERP system was designed and implemented, in part, to enhance the overall system of internal controls over financial reporting through further automation and integration of business processes. In connection with the ERP implementation, we updated the processes that constitute our internal control over financial reporting, as necessary, to accommodate related changes to our accounting procedures and business processes.

Other than the ERP implementation, 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, 2016 which has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 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 Report 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 the six months ended June 30, 2016 and years ended December 31, 2015 and 2014, we recognized losses of $89.4 million, $182.2 million and $237.0 million, respectively, which are reflected in the Shareholders Equity on our consolidated balance sheets. We reflect cumulative net loss incurred and retained 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). 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 are also making additional investments in telavancin, our antibiotic that has been approved for certain difficult-to-treat infections. For example, in February 2015 we initiated a Phase 3 registrational study of telavancin for bacteremia and a patient registry study. We are incurring all of the costs and expenses associated with the commercialization of VIBATIV in the U.S., including the creation of an independent sales and marketing organization with appropriate technical expertise, supporting infrastructure and distribution capabilities, expanded medical affairs presence, manufacturing and third-party vendor logistics and consultant support, and post-marketing studies. 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 sales revenues from our programs for the foreseeable 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 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.

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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 of our 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, which increases our operating expenses. For example, in February 2015 we announced initiation of a Phase 3 registrational study for bacteremia and initiation of a patient registry study. In addition, in 2015 we substantially increased the number of sales representatives and medical science liaisons supporting physician education on the proper usage of VIBATIV in the U.S. and at the end of 2015 we had approximately 50 sales representatives in the field.

Although we expect that we will have sufficient cash to fund our operations and working capital requirements for at least the next twelve months based on current operating plans and financial forecasts, 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;
- 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.

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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 debt, 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. 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, in connection with entering into a collaboration agreement with Mylan, Inc. (Mylan) for the development and commercialization of a nebulized formulation of our long-acting muscarinic antagonist (LAMA) revefenacin (TD-4208) in February 2015, Mylan made a $30.0 million equity investment in us by purchasing 1,585,790 newly issued ordinary shares, which issuance resulted in dilution of ownership to our shareholders. By way of further example, in October 2015, funds managed by Woodford Investment Management LLP (collectively, the Woodford Funds) made a $55.0 million equity investment in us by purchasing 3,859,649 newly issued ordinary shares, and in March 2016, GSK made an approximately $23.0 million equity investment in us by purchasing 1,301,015 newly issued ordinary shares, which issuances resulted in dilution of ownership to our shareholders. In addition, if we seek to raise funds and this becomes known publicly, the market price of our shares could decline upon the expectation of dilution, regardless of whether dilution actually occurs. In July 2015, our shelf registration statement on Form S-3 for the potential offering, issuance and sale by us of up to a maximum aggregate offering price of $250.0 million of our debt securities, ordinary shares, and/or warrants was declared effective. Up to $50.0 million of the maximum aggregate offering price of $250.0 million under the registration statement may be issued and sold pursuant to an at-the-market offering program for sales of our ordinary shares under a sales agreement with Cantor Fitzgerald & Co. (Cantor). In October 2015, we used approximately $55 million of the available financing capacity under the registration statement in the foregoing sale of ordinary shares to the Woodford Funds, in March and April of 2016, we used approximately $15 million of the available financing capacity under the registration statement pursuant to our at-the-market offering program for sales of approximately 770,000 ordinary shares under the foregoing sales agreement with Cantor, and in May of 2016, we used approximately $115 million of the available financing capacity under the registration statement pursuant to a public offering of 5,479,750 ordinary shares. 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 debt securities 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.

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, Alfa Wassermann S.p.A. (Alfa Wassermann) for velusetrag, Takeda for the development and commercialization of a selective 5-HT4 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 these programs if approved by the necessary regulatory authorities. We may also seek collaboration

arrangements with additional third parties to pursue the future commercialization of VIBATIV. Collaborations with third parties regarding these programs or our other programs may require us to relinquish material rights, including revenue from commercialization of our medicines, or to assume material ongoing development obligations that we would have to fund. These collaboration arrangements are complex and time-consuming to negotiate, and

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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, GSK961081 (081), the lead compound in the MABA program (081/FF);

- 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; or

- any particular FDA requirements or changes in FDA policy or guidance regarding these programs.

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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) and linezolid, both 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. In addition, sales of a generic version of daptomycin could begin in 2016. 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 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, reducing our investment in commercialization and development efforts or other actions, any of which could cause the price of our securities to fall. 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 experiences of physicians, patients and payors with the use of VIBATIV;
- the market price of VIBATIV relative to competing therapies;
- 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 Hospira, Inc. (now a subsidiary of Pfizer, Inc.) (Hospira) 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 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 to be 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.

We are developing the capability to 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.

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VIBATIV was returned by Astellas Pharma Inc. (Astellas), our former VIBATIV collaboration partner, in January 2012, and Astellas is entitled to a ten-year, 1% royalty on future net sales of VIBATIV. On August 14, 2013, we (at the time with Innoviva) announced the reintroduction of VIBATIV to the U.S. market with the commencement of shipments into the wholesaler channel and as of the end of 2015 we had approximately 50 VIBATIV sales representatives in the U.S. The risks of commercializing VIBATIV in the U.S. without a partner include:

- costs and expenses associated with creating an independent sales and marketing organization with appropriate technical expertise and supporting infrastructure and distribution capability, 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 for several years;

- our unproven ability to retain adequate numbers of effective sales and marketing personnel in the U.S.;

- our unproven ability to retain medical science liaisons in the U.S. supporting physician education on the proper usage of VIBATIV;

- the unproven ability of sales personnel to obtain access to and educate adequate numbers of physicians about prescribing VIBATIV 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.

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 in appropriate clinical situations, we will have difficulty commercializing VIBATIV in the U.S., which would adversely affect our business and financial condition and the price of our securities could fall. In the event we were to market, sell and distribute any additional products, we would face similar challenges and risks, which could 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 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;

- 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;

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- 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. If our ongoing clinical studies for our current product candidates, such as the Phase 3 development program for revefenacin for the treatment of COPD and the earlier stage clinical studies for our gastrointestinal (GI)-targeted JAK inhibitor program or our NEP inhibitor program, are substantially delayed or fail to meet their designated end points we may not receive regulatory approval of any 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 new drug application (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. 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 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 use of such product.

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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 and we currently have sufficient quantities of VIBATIV drug product on hand to meet our anticipated needs only through approximately December 2016. Currently we anticipate receipt of additional manufactured drug product supply during the third quarter of 2016 and plan to manufacture additional drug product. 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 by Hospira (whether or not resulting from the inability to release lots already manufactured or the inability to manufacture additional lots, or otherwise) would adversely affect the commercialization of VIBATIV and our obligations to our partners, and the price of our securities could fall. 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 and the price of our securities could fall.

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. We currently have an agreement with Hospira to supply VIBATIV drug product, which was entered into May 2012. In June 2013, the FDA approved Hospira as a VIBATIV drug product manufacturer. Pfizer acquired Hospira in 2015 and we cannot predict whether the acquisition will lead to changes in Hospira s operations which may adversely impact our single source of supply for VIBATIV drug product. We are currently in discussions with Hospira to extend the term of our agreement, which expires at the end of 2017. If we are unable to extend our supply relationship with Hospira, 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.

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 commercial quantities could delay clinical studies, regulatory submissions and commercialization of our product candidates; and

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

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 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 FDA as safe and effective on the VIBATIV label.

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Furthermore, 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, the VIBATIV labeling for hospital-acquired and ventilator associated bacterial pneumonia (HABP/VABP) in the U.S. and the European Union 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. In addition, the FDA has required that we comply with a risk evaluation and mitigation strategy (REMS) to inform healthcare providers and patients of key risks via a communication plan. Healthcare providers periodically receive letters reminding them of the major potential risks associated with VIBATIV and patients receive a medication guide with each course of antibiotic use. The healthcare provider letter is also available on the product website. The REMS stipulates that we make assessments of the efficacy of these educational efforts and provide reports to FDA at specified intervals.

In addition, the manufacturing, labeling, packaging, adverse event reporting, advertising, promotion and recordkeeping for the approved product remain subject to extensive and ongoing regulatory requirements. If we become aware of previously unknown problems with an approved product in the U.S. or overseas or at 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.

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, 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 market*.

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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 Alfa Wassermann for velusetrag, our lead compound in the 5 HT4 program, covering the European Union, Russia, China, Mexico and certain other countries. 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. 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 European Union to Theravance Biopharma. The Alfa Wassermann and Clinigen agreements were assigned to us in the Spin-Off. The Alfa Wassermann agreement provides research and development funding for the program under license. 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 Millennium Pharmaceuticals, Inc., an indirect wholly-owned subsidiary of Takeda Pharmaceutical Company Limited (collectively with Millennium, Takeda), in order to establish a collaboration for the development and commercialization of TD-8954, a selective 5-HT4 receptor agonist. Under the terms of the Agreement, Takeda will be responsible for worldwide development and commercialization of TD-8954. The closing of the transactions contemplated by the Agreement is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act (HSR Act). In connection with these agreements, these parties have certain rights regarding the use of its patents and technology with respect to the compounds in our development programs, including development and marketing rights.

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 European Union 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, 2016, GSK beneficially owned approximately 20.2% 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 the interests of us and our other shareholders. In particular, if the Closed Triple or a MABA/ICS in either the U.S. or the European Union 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

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

The FDA, and equivalent authorities in other countries, enforces GCPs and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators and trial sites. If we or any of the third parties on which we have relied to conduct our clinical studies are determined to have failed to comply with GCPs (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.

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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.

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 and linezolid, 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. In addition, sales of a generic version of daptomycin could begin in 2016. 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.

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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.

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 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 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.

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We are an emerging growth company and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our ordinary shares less attractive to investors.

We are an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. Where appropriate, we plan to avail ourselves of this exemption from new or revised accounting standards and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

For as long as we continue to be an emerging growth company, we also intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory shareholder vote on executive compensation and any golden parachute payments not previously approved, exemption from the requirement of auditor attestation in the assessment of our internal control over financial reporting and exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor s report providing additional information about the audit and the financial statements (auditor discussion and analysis). Therefore, the information that we intend to provide shareholders for as long as we continue to be an emerging growth company will be different than what is available with respect to some other public companies. We cannot predict if investors will find our ordinary shares less attractive because we rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile.

We were an emerging growth company for all of 2015 and will remain an emerging growth company until the earliest of (i) the end of the fiscal year in which the market value of our ordinary shares that is held by non-affiliates exceeds $700 million as of the end of the second fiscal quarter, (ii) the end of the fiscal year in which we have total annual gross revenues of $1 billion or more during such fiscal year, (iii) the date on which we issue more than $1 billion in non-convertible debt in a three-year period or (iv) December 31, 2019, the end of the fiscal year following the fifth anniversary of the date of the first sale of our ordinary shares pursuant to an effective registration statement filed under the Securities Act.

Our historical financial information prior to the Spin-Off may not 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.

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. This is primarily a result of the following factors:

- prior to the Spin-Off, our business was operated by Innoviva as part of its broader corporate organization rather than as a stand-alone company, and our business was able to leverage Innoviva s financial resources and creditworthiness;

- prior to the Spin-Off, certain general administrative functions were performed by Innoviva for the combined entity. Our historical consolidated financial statements reflect allocations of costs for services shared with Innoviva. These allocations may differ from the costs we will incur for these services as an independent company;

- holding other factors constant, our cost of capital as a stand-alone company is likely higher on average than Innoviva s cost of capital was as a combined business prior to the Spin-Off;

- following the Spin-Off, we are responsible for the additional costs associated with being an independent, public company, including costs related to corporate governance and listed and registered securities; and

- having separated from Innoviva, there is a risk that we may be more susceptible to market fluctuations and other adverse events than we would have been were we still a part of Innoviva.

Our accounting and other management systems and resources may not be adequately prepared to meet the financial reporting and other requirements to which we became subject following the Spin-Off. If we are unable to achieve and maintain effective internal controls, our business, financial position and results of operations could be adversely affected.

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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 will require annual management assessments of the effectiveness of our internal control over financial reporting. When and if we become a large accelerated filer and are no longer an emerging growth company, each as defined in the Exchange Act, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. These reporting and other obligations will place significant demands on our management and administrative and operational resources, including accounting resources.

In addition, during the second quarter of 2016, we implemented a new enterprise resource planning (ERP) system and continue to make modifications and enhancements to the ERP system. Our ERP system is critical to our ability to accurately maintain books and records, record transactions, provide important information to our management and prepare our financial statements. Such an implementation is complex and difficult and requires us to address a number of challenges including data conversion, system cutover and user training. As a result, it represents a major undertaking financially and from a management and personnel perspective. Our business and results of operations may be adversely affected if we experience operating problems and/or cost overruns relating to the ERP implementation (including subsequent modifications and enhancements), or if the ERP system and the associated process changes do not give rise to the benefits that we expect. Additionally, if we encounter problems with the ERP system (including all modifications and enhancements) as implemented or if the system does not operate as intended, it could be disruptive and adversely affect our operations and results of operations, including our ability to report accurate and timely financial results and 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.

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 without the right to receive potential royalty revenue derived from Innoviva s GSK-Partnered Respiratory Program (the Royalty Business) until the Spin-Off. As a new independent company, our ability to satisfy our obligations and achieve profitability will be primarily dependent upon the future performance of our biopharmaceutical business, and we do not rely upon the revenues, capital resources and cash flows of the Royalty Business remaining with Innoviva.

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.

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.

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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, payments of 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, 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.

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, the Transition Services Agreement, the Employee Matters Agreement, the Tax Matters Agreement, and the 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 market.

We rely upon a combination of patents, patent applications, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any involuntary disclosure to or misappropriation by third parties of this proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. The status of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and is very uncertain. As of June 30, 2016, we or one of our wholly-owned subsidiaries owned 423 issued United States patents and 1,571 granted foreign patents, as well as additional pending United

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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.

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 2021 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.

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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 and have likely increased with the commercial reintroduction of VIBATIV. Side effects of, or manufacturing defects in, products that we or our partners develop or commercialize could result in the deterioration of a patient s condition, injury or even death. The VIBATIV prescribing information describes several potential adverse effects observed during clinical trials, including increased mortality versus vancomycin in patients with HABP/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 HABP/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 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 current or any 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 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 proposals.

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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. Changes that may affect our business include 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 discount program, fraud and abuse and enforcement. These changes will impact existing government healthcare programs and will result 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 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 changes to the Healthcare Reform Act remain possible. 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.

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 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.

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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 for innovator drugs 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.

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 create regulations and processes to improve the integrity of the 340B program and 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) has issued a proposed regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, as well as proposed omnibus guidance that addresses many aspects of the 340B program. HRSA is expected to issue additional proposed regulations in 2016. Any 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 binding 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. For example, in March 2016, CMS proposed to conduct a demonstration project that would reduce the Medicare payment rates for most Part B drugs from average sales price plus 6% to average sales price plus 2.5% plus $16.80 per drug per day for approximately half of the country. CMS indicated that it intends to implement this project in 2016, followed by a second phase of the demonstration in 2017 that would apply value-based purchasing tools to make further adjustments to payment rates. A final decision on this proposal is expected later this year.

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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 drug discount 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 $100,000 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 monetary penalties of up to $10,000 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 $10,000 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 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 that is no higher than the Federal Ceiling Price (FCP), which is a price calculated pursuant to a statutory formula. The FCP keys off of 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 $100,000 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 (which could include civil and/or criminal penalties), private litigation and/or adverse publicity and 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

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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.

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 Maximillian 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 will be able to certify to the U.S. Department of Commerce their compliance with the privacy principles of the Privacy Shield starting on August 1, 2016. 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.

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- 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.

- Similar restrictions imposed on the promotion and marketing of medicinal products in the EU 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.

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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 date, there is limited securities analyst coverage of our company. Limited securities analyst coverage of our company and shares is likely to reduce demand for our shares from potential investors, which likely will reduce the market price for our 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.

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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 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 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, including any such developments resulting from or relating to the Spin-Off;

- 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;

- 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;

- low public market trading volumes for our ordinary shares related in part to the concentration of ownership 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;

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- 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, 2016 GSK beneficially owned approximately 20.2% of our outstanding ordinary shares and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 6.7% of our outstanding ordinary shares. Based on our review of publicly available filings, as of June 30, 2016 our three largest shareholders other than GSK collectively owned approximately 29.0% 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. 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;

- 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 (2013 Revision) (as amended) 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.

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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) the company s 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 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.

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

None.

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ITEM 6. EXHIBITS

Exhibit No.	Description of Exhibit	Filed Herewith	Incorporated by Reference Form	Incorporated by Reference Filing Date/Period End Date
3.1	Amended and Restated Memorandum and Articles of Association		10-12B	April 30, 2014
10.1*	License and Collaboration Agreement by and between Theravance Biopharma Ireland Limited and Millennium Pharmaceuticals, Inc. dated June 8, 2016	X		
10.2	Amendment No. 1 to the License, Development, and Commercialization Agreement by and between Theravance Biopharma Ireland Limited and Clinigen Group PLC dated August 4, 2016	X		
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(1)	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, 2016, 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		

* Confidential treatment has been requested for certain portions which are omitted in the copy of the exhibit electronically filed with the Securities and Exchange Commission. The omitted information has been filed separately with the Securities and Exchange Commission pursuant to Theravance Biopharma, Inc. s application for confidential treatment.

(1) The certifications provided as Exhibit 32.1 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.

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SIGNATURES

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

Theravance Biopharma, Inc.

Date: August 8, 2016

/s/ Rick E Winningham
Rick E Winningham
Chairman of the Board and Chief Executive Officer

(Principal Executive Officer)

Date: August 8, 2016

/s/ Renee D. Gala
Renee D. Gala
Senior Vice President and Chief Financial Officer

(Principal Financial Officer)

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EXHIBIT INDEX

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

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