

Theravance Biopharma, Inc.
Form 10-Q
May 10, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2016

OR

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

For the transition period from to

Commission file number: 001-36033

THERAVANCE BIOPHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Cayman Islands

(State or Other Jurisdiction of
Incorporation or Organization)

98-1226628

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

PO Box 309

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

KY1-1104

(Zip Code)

(650) 808-6000

(Registrant's Telephone Number, Including Area Code)

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

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

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

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐
(Do not check if a smaller reporting company)

Smaller reporting company ☐

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

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As of May 5, 2016, the number of the registrant's outstanding ordinary shares was 47,479,910.

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THERAVANCE BIOPHARMA, INC.

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THERAVANCE BIOPHARMA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except per share data)

	March 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 128,803	\$ 112,707
Short-term marketable securities	51,073	59,727
Accounts receivable, net of allowances of \$894 and \$758 at March 31, 2016 and December 31, 2015, respectively	1,527	1,922
Receivables from collaborative arrangements	37,536	35,232
Prepaid taxes	242	12,764
Other prepaid and current assets	10,165	5,115
Inventories	9,406	10,005
Total current assets	238,752	237,472
Property and equipment, net	10,119	9,873
Long-term marketable securities	34,598	42,860
Other investments	8,000	8,000
Restricted cash	833	833
Other assets	823	1,078
Total assets	\$ 293,125	\$ 300,116
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 9,092	\$ 18,804
Accrued personnel-related expenses	7,824	10,866
Accrued clinical and development expenses	23,640	14,709
Other accrued liabilities	4,725	4,947
Deferred revenue	1,120	144
Total current liabilities	46,401	49,470
Deferred rent	4,449	4,598
Other long-term liabilities	3,738	2,983

Commitments and contingencies (Note 9)

Shareholders' equity

Preferred shares, \$0.00001 par value: 230 shares authorized, no shares issued or outstanding at March 31, 2016 and December 31, 2015, respectively

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Ordinary shares, \$0.00001 par value: 200,000 shares authorized at March 31, 2016 and December 31, 2015; 41,452 and 37,981 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively

Additional paid-in capital	602,117	564,691
Accumulated other comprehensive income (loss)	126	(70)
Accumulated deficit	(363,706)	(321,556)
Total shareholders' equity	238,537	243,065
Total liabilities and shareholders' equity	\$ 293,125	\$ 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 March 31,	
	2016	2015
Revenue:		
Product sales	\$ 3,311	\$ 1,280
Revenue from collaborative arrangements	15,099	19,121
Total revenue	18,410	20,401
Costs and expenses:		
Cost of goods sold	778	371
Research and development (1)	35,678	36,019
Selling, general and administrative (1)	23,596	21,748
Total costs and expenses	60,052	58,138
Loss from operations	(41,642)	(37,737)
Interest and other income	186	211
Loss before income taxes	(41,456)	(37,526)
Provision for income taxes	694	4,948
Net loss	\$ (42,150)	\$ (42,474)
Net loss per share:		
Basic and diluted net loss per share	\$ (1.10)	\$ (1.29)
Shares used to compute basic and diluted net loss per share	38,326	32,830
Net unrealized gain on available-for-sale investments	196	113
Total comprehensive loss	\$ (41,954)	\$ (42,361)

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

	Three Months Ended March 31,	
	2016	2015
(In thousands)		
Research and development	\$ 5,160	\$ 7,482
Selling, general and administrative	6,170	8,144
Total share-based compensation expense	\$ 11,330	\$ 15,626

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2016	2015
Operating activities		
Net loss	\$ (42,150)	\$ (42,474)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	699	825
Share-based compensation	11,330	15,626
Inventory write-down	10	79
Excess tax benefits from share-based compensation		(391)
Changes in operating assets and liabilities:		
Accounts receivable	395	(276)
Receivables from collaborative arrangements	(2,304)	(17,820)
Prepaid taxes	12,522	(10)
Other prepaid and current assets	(5,050)	(664)
Inventories	134	(41)
Other assets	255	(180)
Accounts payable	(9,450)	(5,431)
Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued liabilities	5,718	(6,184)
Deferred rent	(149)	(106)
Deferred revenue	1,141	212
Other long-term liabilities	590	321
Net cash used in operating activities	(26,309)	(56,514)
Investing activities		
Purchases of property and equipment	(684)	(657)
Purchases of marketable securities		(10,659)
Maturities of marketable securities	17,069	53,470
Net cash provided by investing activities	16,385	42,154
Financing activities		
Net proceeds from sale of ordinary shares	27,802	25,753
Excess tax benefits from share-based compensation		391
Repurchase of shares to satisfy tax withholding	(1,782)	(100)
Net cash provided by financing activities	26,020	26,044
Net increase in cash and cash equivalents	16,096	11,684
Cash and cash equivalents at beginning of period	112,707	89,215
Cash and cash equivalents at end of period	\$ 128,803	\$ 100,899
Supplemental disclosure of cash flow information		
Cash paid for income taxes, net	\$ 9,494	\$ 765

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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, umecclidinium, and vilanterol), currently in development for the treatment of COPD and asthma.

Basis of Presentation

The Company's condensed consolidated financial information as of March 31, 2016, and the three months ended March 31, 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 February 2016, the FASB issued Accounting Standards Update No. 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 Accounting Standards Update No. 2016-08, *Revenue from Contracts with Customers (Topic 606)* (ASU 2016-08) which clarifies whether an entity is a principal or an agent in a transaction in which another party is involved in providing goods or services to a customer. ASU 2016-08 also clarifies (i) how an entity should

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identify the unit of accounting for the principal versus agent evaluation and (ii) how the control principle applies to transactions, and reframes the indicators to focus on evidence that an entity is acting as a principal rather than as an agent. ASU 2016-08 is effective for all interim and annual reporting periods beginning after December 15, 2017, and early adoption is permitted for interim and annual reporting periods beginning after December 15, 2016. We are currently evaluating the impact that the adoption of ASU 2016-08 will have on our consolidated financial statements and related disclosures.

In March 2016, the FASB also issued Accounting Standards Update No. 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.

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 months ended March 31, 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.

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:

(In thousands)	Three Months Ended March 31,	
	2016	2015
Share issuances under equity incentive plan and ESPP	4,136	4,353
Restricted shares	1,497	395
	5,633	4,748

3. Collaborative Arrangements

Revenue from Collaborative Arrangements

We recognized the following revenues from our collaborative arrangements:

(In thousands)	Three Months Ended March 31,			
	2016		2015	
Mylan	\$	15,025	\$	19,099
Other		74		22
Total revenue from collaborative arrangements	\$	15,099	\$	19,121

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.

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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 three months ended March 31, 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 March 31, 2016, we recognized \$15.0 million in revenue from the Mylan collaborative arrangement for the achievement of 50% enrollment in the Phase 3 twelve-month safety study, which triggered a milestone payment to Theravance Biopharma by Mylan.

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 March 31,	
	2016	2015
Mylan	\$ 31,173	\$ 4,132
Alfa Wassermann	1,185	422
R-Pharm	14	
Total reduction to R&D costs	\$ 32,372	\$ 4,554

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

Our available-for-sale securities include:

(In thousands)	Fair Value Hierarchy Level	Estimated Fair Value	
		March 31, 2016	December 31, 2015
U.S. government securities	Level 1	\$ 42,150	\$ 47,043
U.S. government agency securities	Level 2	26,014	31,465
Corporate notes	Level 2	12,511	19,089
Commercial paper	Level 2	4,996	4,990
Marketable securities		85,671	102,587
Money market funds	Level 1	75,514	69,126
Total		\$ 161,185	\$ 171,713

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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. Gross unrealized gains and losses were not significant at either March 31, 2016 or December 31, 2015.

At March 31, 2016, all of the marketable securities had contractual maturities within two years and the weighted average maturity of the marketable securities was approximately nine 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 months ended March 31, 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

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that the gross unrealized losses on our marketable securities at March 31, 2016 were temporary in nature. All marketable securities with unrealized losses at March 31, 2016 have been in a loss position for less than twelve months.

At March 31, 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 months ended March 31, 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.

5. Inventories

Inventory consists of the following:

(In thousands)	March 31, 2016	December 31, 2015
Raw materials	\$ 5,270	\$ 6,869
Work-in-process	1,758	
Finished goods	2,378	3,136
Total inventories	\$ 9,406	\$ 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 March 31, 2016	2015
Research and development	\$ 5,160	\$ 7,482
Selling, general and administrative	6,170	8,144
Total share-based compensation expense	\$ 11,330	\$ 15,626

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 approved the grant of 1,575,000 performance-contingent restricted stock 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. The maximum potential expense associated with the awards could be up to approximately \$26.7 million (allocated as \$11.4 million for research and development expense and \$15.3 million for selling, general and administrative expense) if all of the performance conditions are achieved on time. 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 each reporting period. As of March 31, 2016, we determined that the achievement of the requisite performance conditions was not probable and, as a result, no compensation expense related to these awards has been recognized.

7. Income Taxes

The income tax provision was \$0.7 million for the three months ended March 31, 2016. The provision for income tax was primarily due to uncertain tax positions taken with respect to transfer pricing and tax credits. No provision for income taxes has been recognized on undistributed earnings of our foreign subsidiaries because we consider such earnings to be indefinitely reinvested.

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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 March 31, 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

Purchases of Ordinary Shares by GSK

On March 17, 2016, GSK purchased 1,301,015 of our unregistered ordinary shares at a per share price of \$17.70 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. As of March 31, 2016, GSK beneficially owned approximately 23.3% of our outstanding ordinary shares.

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.

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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 price of \$19.53 per share, resulting in aggregate net proceeds of approximately \$14.6 million. For the three months ended March 31, 2016, we sold approximately 280,000 shares at an average price of \$18.48 per share, resulting in aggregate net proceeds of approximately \$5.0 million.

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 March 31, 2016.

10. Subsequent Events

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 \$107.7 million after deducting the underwriting discount and estimated offering expenses.

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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, 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, umecclidinium, and vilanterol), currently in development for the treatment of COPD and asthma.

Program Highlights

VIBATIV® (telavancin)

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

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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. 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 Europe, Canada, Middle East, North Africa, Israel, Russia, China and India.

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.

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

In September 2015, we announced that the Food and Drug Administration (FDA) accepted for filing our sNDA to expand the VIBATIV label to include concurrent *Staphylococcus aureus* bacteremia. 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. In May 2016, we announced approval of our sNDA allowing for the addition of new clinical data to the VIBATIV label concerning concurrent bacteremia in cases of HABP/VABP and cSSSI. 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 2017 or 2018.

Telavancin Observational Use Registry (TOUR)

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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.

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.

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Phase 3 Study in COPD

In September 2015, we announced, with our partner Mylan Ireland Limited ("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 moderate to severe patients with 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. We expect to complete the efficacy studies late-third quarter or 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.

Mylan Collaboration

In January 2015, 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.

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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.

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.

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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. 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, an HCV protease inhibitor, combined with TD-6450 and ribavirin in patients infected with HCV genotype 4.

Neprilysin (NEP) Inhibitor Program

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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

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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. 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 exclusively to the tissues of the GI tract and minimize systemic exposure to treat ulcerative colitis and potentially other inflammatory intestinal disorders.

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

In December 2015, we initiated a Phase 1 clinical study of TD-1473. The Phase 1 trial is a randomized, double-blind, placebo-controlled, single ascending dose and multiple ascending dose study in healthy subjects. The primary objective of the study will be evaluation of the safety and tolerability of single ascending doses and multiple ascending doses of TD-1473 in healthy subjects. A key secondary objective of the trial will be the characterization of pharmacokinetics related to TD-1473, which will help determine the amount of TD-1473 that enters systemic circulation following oral administration. We expect to complete the Phase 1 trial in the second quarter of 2016.

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 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 Theravance Respiratory Company, LLC (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. 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%. Innoviva and GSK are conducting two global Phase 3 studies for the Closed Triple, which will enroll approximately 11,800 patients with COPD.

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.

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

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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 our Board of Directors approved the grant of 1,575,000 performance-contingent RSAs and 135,000 performance-contingent 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. The maximum potential expense associated with the awards could be up to approximately \$26.7 million (allocated as \$11.4 million for research and development expense and \$15.3 million for

selling, general and administrative expense) if all of the performance conditions are achieved on time. 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 each reporting period. As of March 31, 2016, we determined that the achievement of the requisite performance conditions was not probable and, as a result, no compensation expense related to these awards has been recognized.

Results of Operations

Product Sales and Revenue from Collaborative Arrangements

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

(In thousands)	Three Months Ended March 31,		Change	
	2016	2015	\$	%
Product sales	\$ 3,311	\$ 1,280	\$ 2,031	159%
Revenue from collaborative arrangements	15,099	19,121	(4,022)	(21)
Total revenue	\$ 18,410	\$ 20,401	\$ (1,991)	(10)%

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Revenue from product sales increased to \$3.3 million for the three months ended March 31, 2016 compared to \$1.3 million for the same period in 2015. The \$2.0 million growth in product sales was due to an increase in the number of customer accounts and in sales volume. Both increases resulted primarily from the expansion of our sales infrastructure in the fourth quarter of 2015.

Revenue from collaborative arrangements decreased to \$15.1 million for the three months ended March 31, 2016 compared to \$19.1 million for the same period in 2015. The revenue in both periods was primarily attributed to our collaborative arrangement with Mylan that was established in January 2015. In the first quarter of 2015, we recognized \$19.1 million of upfront payments related to the delivery of the license and technological know-how to Mylan, and in the first quarter of 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.

Cost of Goods Sold

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

(In thousands)	Three Months Ended March 31,				Change	
	2016		2015		\$	%
Costs of goods sold	\$	778	\$	371	\$ 407	110%

Costs of goods sold was \$0.8 million for the three months ended March 31, 2016 compared to \$0.4 million for the same period in 2015. The increase was primarily due to the increase in sales of VIBATIV.

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;

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3) External-related costs, which include clinical trial related expenses, other contract research fees, consulting fees, and contract manufacturing fees; and

4) Facilities and other, which include laboratory and office supplies, depreciation and other allocated expenses, which include general and administrative support functions, insurance and general supplies.

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

(In thousands)	Three Months Ended March 31,				Change	
	2016	2015	\$		\$	%
Employee-related	\$ 10,518	\$ 12,949	\$	(2,431)		(19)%
Share-based compensation	5,160	7,482		(2,322)		(31)
External-related	13,103	8,936		4,167		47
Facilities, depreciation and other allocated	6,897	6,652		245		4
Total Research & Development	\$ 35,678	\$ 36,019	\$	(341)		(1)%

R&D expenses decreased slightly by \$0.3 million for the three months ended March 31, 2016 compared to the same period in 2015 primarily due to decreases in employee-related costs and share-based compensation. The decrease in employee-related costs was primarily due to expense reimbursements from Mylan related to our revefenacin program, and the decrease in share-based compensation was primarily due to lower costs associated with the long-term retention and incentive awards granted to certain employees in 2011. These decreases were offset by an increase in external-related costs primarily driven by the progression of our key programs, such as our NEP and GI-JAK inhibitor programs.

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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 \$32.4 million and \$4.6 million for three months ended March 31, 2016 and 2015, respectively. The increase was primarily due to expense reimbursements received from Mylan's 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 March 31,		Change	
	2016	2015	\$	%
Selling, general and administrative	\$ 23,596	\$ 21,748	\$ 1,848	8%

Selling, general and administrative expenses increased to \$23.6 million for three months ended March 31, 2016 compared to \$21.7 million the same period in 2015. The \$1.8 million increase was primarily due to the expansion of our internal sales and marketing organization supporting VIBATIV. The increase was partially offset by a 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 2011.

Provision for Income Taxes

(In thousands)	Three Months Ended March 31,		Change	
	2016	2015	\$	%
Provision for income taxes	\$ 694	\$ 4,948	\$ (4,254)	(86)%

Our effective tax rate for the three months ended March 31, 2016 was (1.7)%, which compares to an effective tax rate of (1.0)% 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 and tax credits. The provision for income taxes decreased to \$0.7 million for the three months ended March 31, 2016 compared to \$4.9 million for the same period 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

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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

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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 would act as our sales agent and underwriter.

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, \$0.00001 par value, 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, we commenced selling shares under the ATM Agreement, and through April 8, 2016, we sold approximately 770,000 shares of our ordinary shares at an average price of \$19.53 per share, resulting in aggregate net proceeds of approximately \$14.6 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.

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.

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 \$107.7 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:

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(In thousands)	Three Months Ended March 31,				
	2016		2015		Change
Net cash used in operating activities	\$	(26,309)	\$	(56,514)	
Net cash provided by investing activities		16,385		42,154	(25,769)
Net cash provided by financing activities		26,020		26,044	(24)

Cash flows used in operating activities

Net cash used in operating activities was \$26.3 million for the three months ended March 31, 2016, consisting primarily of net loss of \$42.2 million, adjusted for non-cash items such as \$11.3 million for share-based compensation expense, and \$3.8 million of net cash inflow related to changes in operating assets and liabilities. The \$3.8 million net cash inflow related to changes in operating assets and liabilities was primarily attributable to a \$7.5 million net decrease in prepaid and other current assets partially offset by a \$3.7 million net decrease in accounts payables and accrued expenses for the three months ended March 31, 2015.

Net cash used in operating activities was \$56.5 million for the comparable period in 2015, consisting primarily of net loss of \$42.5 million, adjusted for non-cash items such as \$15.6 million for share-based compensation expense, and \$30.2 million of net cash outflow related to changes in operating assets and liabilities. The \$30.2 million net cash outflow

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related to changes in operating assets and liabilities was primarily attributable to an increase in receivables from collaborative arrangements and a decrease in accounts payable and accrued expenses for the three months ended March 31, 2015.

Cash flows provided by investing activities

Net cash provided by investing activities was \$16.4 million for the three months ended March 31, 2016, consisting of maturities of marketable securities of \$17.1 million partially offset by purchases of property and equipment of \$0.7 million.

Net cash provided by investing activities was \$42.2 million for the comparable period in 2015, consisting primarily of purchases of marketable securities of \$10.7 million and by maturities of marketable securities of \$53.5 million.

Cash flows provided by financing activities

Net cash provided by financing activities was \$26.0 million for the three months ended March 31, 2016, consisting primarily of \$23.0 million related to the sale of ordinary shares to GSK and \$5.0 million related to the sale of ordinary shares that were purchased by March 31, 2016 through our at-the-market offering program. The net proceeds were partially offset by \$1.8 million related to the repurchase of shares to satisfy tax withholdings in connection with our equity compensation plans.

Net cash provided by financing activities was \$26.0 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.

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 March 31, 2016.

In 2011, Innoviva granted special long-term retention and incentive restricted stock awards to members of senior management. The awards have dual triggers of vesting based upon the achievement of certain performance conditions over a six-year time frame from 2011 through December 31, 2016 and continued employment.

In May 2014, Innoviva's Compensation Committee approved the modification of the remaining tranches related to these awards contingent upon the Spin-Off. The modification acknowledged the Spin-Off and permitted recognition of achievement of the original performance conditions that

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were met prior to the Spin-Off, triggering 12-month service-based vesting for a portion of the equity awards. The share-based compensation expense of \$6.9 million associated with a portion of these awards after the modification was fully recognized as of June 30, 2015.

During the fourth quarter of 2014, we determined that it was probable that the performance conditions associated with the remaining Innoviva RSAs would be achieved. In addition, the remaining RSAs outstanding are entitled to the pro rata dividend distribution made by Innoviva on June 2, 2014 of one ordinary share of Theravance Biopharma for every three and one half shares of Innoviva common stock. The RSAs and pro rata dividend were subject to a twelve-month service period, which commenced in February 2015 and was completed in February 2016. As a result, for the three months ended March 31, 2016, we recognized the remaining \$1.0 million of the total share-based compensation expense of \$9.5 million related to these remaining RSAs and pro rata dividends.

In the first quarter of 2016, our Compensation Committee approved the grant of 1,575,000 performance-contingent RSAs and 135,000 performance-contingent 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 these years depending on the probability of meeting the performance conditions. The maximum potential expense associated with the awards could be up to approximately \$26.7 million (allocated as \$11.4 million for research and development expense and \$15.3 million for selling, general and administrative expense) if all of the performance conditions are achieved on time. 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 each reporting period. As of March 31, 2016, we determined that the achievement of the requisite performance conditions was not probable and, as a result, no compensation expense related to these awards has been recognized.

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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 March 31, 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 March 31, 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

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must reflect the fact that there are resource constraints, and the benefit of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within Theravance Biopharma have been detected. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act, which occurred during the first 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 three months ended March 31, 2016 and years ended December 31, 2015 and 2014, we recognized losses of \$42.2 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

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profitability. Failure to become and remain profitable would adversely affect the price of our securities and our ability to raise capital and continue operations.

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

Based on our current operating plans and financial forecasts, we believe that our cash, cash equivalents and marketable securities will be sufficient to meet our anticipated operating needs for at least the next twelve months. If our current operating plans or financial forecasts change, we may require or seek additional funding sooner in the form of public or private equity or equity-linked offerings, debt financings or additional collaborations and licensing arrangements. For example, if we choose to progress any 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 televancin 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 very 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

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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.

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, Clinigen Group plc ("Clinigen") for VIBATIV for the European Union, and with 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 in regions where it is not currently partnered. Collaborations with third parties regarding these programs or our other programs may require us to relinquish material rights, including revenue from commercialization of our medicines, or to assume material ongoing development obligations that we would have to fund. These collaboration arrangements are complex and time-consuming to negotiate, and if we are unable to reach agreements with third-party collaborators, we may fail to meet our business objectives and our financial condition may be adversely affected. We face significant competition in seeking third-party collaborators. We may be unable to find third parties to pursue product collaborations on a timely basis or on

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acceptable terms. Furthermore, for any collaboration, we may not be able to control the amount of time and resources that our partners devote to our product candidates and our partners may choose to prioritize alternative programs. Our inability to successfully collaborate with third parties would increase our development costs and 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 respiratory programs that Innoviva partnered with GSK and assigned to TRC in connection with the Spin-Off (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