Theravance Biopharma, Inc.
Form 10-Q
November 08, 2018
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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 September 30, 2018

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 every Interactive Data File required to be submitted 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, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Smaller reporting company
Non-accelerated filer	Emerging growth company
Accelerated filer	

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

Exchange Act.

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

As of October 31, 2018, the number of the registrant's outstanding ordinary shares was 55,411,264.

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THERAVANCE BIOPHARMA, INC.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

THERAVANCE BIOPHARMA, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except per share data)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 101,202	$ 88,980
Short-term marketable securities	199,207	259,586
Accounts receivable, net of allowances of $1,062 and $992 at September 30, 2018		
and December 31, 2017, respectively	3,024	2,253
Receivables from collaborative arrangements	3,907	7,109
Prepaid taxes	314	291
Other prepaid and current assets	7,029	3,700
Inventories	17,923	16,830
Total current assets	332,606	378,749
Property and equipment, net	12,415	10,157
Long-term marketable securities	20,217	41,587
Tax receivable	3,131	8,191
Restricted cash	833	833
Other assets	1,762	1,883
Total assets	$ 370,964	$ 441,400
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 3,745	$ 5,924
Accrued personnel-related expenses	15,893	24,136
Accrued clinical and development expenses	14,100	20,657
Other accrued liabilities	11,052	11,710
Deferred revenue	57,239	125
Total current liabilities	102,029	62,552
Convertible senior notes, net	224,550	223,746

Deferred rent	7,038	3,668
Long-term deferred revenue	22,469	1,436
Other long-term liabilities	28,323	34,820
Commitments and contingencies		
Shareholders' equity (deficit)		
Preferred shares, $0.00001 par value: 230 shares authorized, no shares issued or outstanding	—	—
Ordinary shares, $0.00001 par value: 200,000 shares authorized; 55,410 and 54,381 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	1	1
Additional paid-in capital	948,844	913,650
Accumulated other comprehensive loss	(331)	(733)
Accumulated deficit	(961,959)	(797,740)
Total shareholders' equity (deficit)	(13,445)	115,178
Total liabilities and shareholders' equity (deficit)	$ 370,964	$ 441,400

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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue:				
Product sales	$ 3,849	$ 4,140	$ 12,889	$ 10,664
Revenue from collaborative arrangements	8,989	135	31,744	207
Total revenue	12,838	4,275	44,633	10,871
Costs and expenses:				
Cost of goods sold (Note 7)	705	985	83	2,914
Research and development (1)	52,693	39,343	149,079	122,835
Selling, general and administrative (1)	21,890	20,944	71,601	66,069
Total costs and expenses	75,288	61,272	220,763	191,818
Loss from operations	(62,450)	(56,997)	(176,130)	(180,947)
Income from investment in TRC, LLC (Note 6)	3,119	—	5,754	—
Interest expense	(2,137)	(2,136)	(6,411)	(6,410)
Other-than-temporary impairment loss	—	(8,000)	—	(8,000)
Interest and other income, net	1,376	1,124	4,144	3,579
Loss before income taxes	(60,092)	(66,009)	(172,643)	(191,778)
Provision for income tax (benefit) (Note 9)	(659)	868	(7,305)	6,705
Net loss	$ (59,433)	$ (66,877)	$ (165,338)	$ (198,483)
Net loss per share:				
Basic and diluted net loss per share	$ (1.10)	$ (1.27)	$ (3.07)	$ (3.80)
Shares used to compute basic and diluted net loss per share	54,248	52,611	53,771	52,165
Net unrealized gain (loss) on available-for-sale investments	194	(44)	402	(39)
Total comprehensive loss	$ (59,239)	$ (66,921)	$ (164,936)	$ (198,522)

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

	Three Months Ended	Nine Months Ended

	September 30,		September 30,	
(In thousands)	2018	2017	2018	2017
Research and development	$ 6,294	$ 5,005	$ 19,757	$ 15,023
Selling, general and administrative	5,452	5,680	19,842	16,329
Total share-based compensation expense	$ 11,746	$ 10,685	$ 39,599	$ 31,352

See accompanying notes to condensed consolidated financial statements.

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THERAVANCE BIOPHARMA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Nine Months Ended September 30, 2018	2017
Operating activities		
Net loss	$ (165,338)	$ (198,483)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,308	3,009
Share-based compensation	39,599	31,352
Other-than-temporary impairment loss	—	8,000
Reversal of inventory purchase commitment liability	(2,250)	—
Inventory write-down	—	643
Undistributed earnings from investment in TRC, LLC	(2,803)	—
Other	(68)	(3)
Changes in operating assets and liabilities:		
Accounts receivable	(771)	(930)
Receivables from collaborative arrangements	3,202	(2,471)
Other prepaid and current assets	(493)	1,537
Inventories	(552)	(2,963)
Tax receivable	5,092	(7,890)
Other assets	(115)	(349)
Accounts payable	(1,665)	3,540
Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued liabilities	(14,324)	(4,524)
Deferred rent	3,370	(678)
Deferred revenue	79,266	20
Other long-term liabilities	(5,147)	13,340
Net cash used in operating activities	(60,689)	(156,850)
Investing activities		
Purchases of property and equipment	(5,740)	(2,151)
Purchases of marketable securities	(166,412)	(285,821)
Maturities of marketable securities	249,450	190,389
Proceeds from the sales of fixed assets	17	—
Net cash provided by (used in) investing activities	77,315	(97,583)
Financing activities		
Proceeds from ESPP purchases	2,742	2,657
Proceeds from option exercises	1,306	5,693

Repurchase of shares to satisfy tax withholding	(8,452)	(7,325)
Net cash (used in) provided by financing activities	(4,404)	1,025
Net increase (decrease) in cash, cash equivalents, and restricted cash	12,222	(253,408)
Cash, cash equivalents, and restricted cash at beginning of period	89,813	345,542
Cash, cash equivalents, and restricted cash at end of period	$ 102,035	$ 92,134
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 3,738	$ 3,717
Cash (received) paid for income taxes, net	$ (5,027)	$ 4,927

See accompanying notes to condensed consolidated financial statements.

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THERAVANCE BIOPHARMA, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Organization and Summary of Significant Accounting Policies

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

Basis of Presentation

Our condensed consolidated financial information as of September 30, 2018, and the three and nine months ended September 30, 2018 and 2017 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 US 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, 2017 financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the Securities and Exchange Commission (“SEC”) on February 28, 2018.

Effective January 1, 2018, we adopted Accounting Standards Codification, Topic 606, Revenue from Contracts with Customers (“ASC 606”) using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018 and recognized the cumulative effect of ASC 606 at the date of initial application. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior period. We recorded a reduction to the opening balance of accumulated deficit of approximately $1.1 million and a corresponding reduction in deferred revenue as of January 1, 2018 due to ASC 606’s cumulative adoption impact on our collaborative arrangements. Our product sales revenue under ASC 606 would not have been materially different under the legacy Accounting Standards Codification, Topic 605, Revenue Recognition (“ASC 605”).

Effective January 1, 2018, we adopted Accounting Standards Update 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (“ASU 2016-18”) that changed the presentation of restricted cash and cash equivalents on the condensed consolidated statements of cash flows. Restricted cash balances are now included with cash and cash equivalents when reconciling the beginning of period and end of period total amounts shown on the condensed consolidated statements of cash flows. To conform to the presentation under ASU 2016-18, we revised the amounts previously reported on the condensed consolidated statements of cash flows for the comparable prior year period.

Significant Accounting Policies

Other than the policies below, there have been no material revisions in our significant accounting policies described in Note 1 to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2017.

Revenue Recognition

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

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At contract inception, once the contract is determined to be within the scope of ASC 606, we identify the performance obligations in the contract by assessing whether the goods or services promised within each contract are distinct. We then recognize revenue for the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Sales

We sell VIBATIV in the US market by making the drug product available through a limited number of distributors, who sell VIBATIV to healthcare providers. Title and risk of loss transfer upon receipt by these distributors. We recognize VIBATIV product sales and related cost of product sales when the distributors obtain control of the drug product, which is at the time title transfers to the distributors.

Product sales are recorded on a net sales basis which includes estimates of variable consideration. The variable consideration results from sales discounts, government mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions. We reflect such reductions in revenue as either an allowance to the related account receivable from the distributor, or as an accrued liability, depending on the nature of the sales deduction. Sales deductions are based on management's estimates that consider payor mix in target markets, industry benchmarks and experience to date. In general, these estimates take into consideration a range of possible outcomes which are probability-weighted in accordance with the expected value method in ASC 606. We monitor inventory levels in the distribution channel, as well as sales of VIBATIV by distributors to healthcare providers, using product specific data provided by the distributors. Product return allowances are based on amounts owed or to be claimed on related sales. These estimates take into consideration the terms of our agreements with customers, historical product returns of VIBATIV, rebates or discounts taken, estimated levels of inventory in the distribution channel, the shelf life of the product, and specific known market events, such as competitive pricing and new product introductions. We update our estimates and assumptions each quarter and if actual future results vary from our estimates, we may adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment.

Sales Discounts: We offer cash discounts to certain customers as an incentive for prompt payment. We expect our customers to comply with the prompt payment terms to earn the cash discount. In addition, we offer contract discounts to certain direct customers. We estimate sales discounts based on contractual terms, historical utilization rates, as available, and our expectations regarding future utilization rates. We account for sales discounts by reducing accounts receivable by the expected discount and recognizing the discount as a reduction of revenue in the same period the related revenue is recognized.

Chargebacks and Government Rebates: For VIBATIV sales in the US, we estimate reductions to product sales for qualifying federal and state government programs including discounted pricing offered to Public Health Service ("PHS"), as well as government managed Medicaid programs. Our reduction for PHS is based on actual chargebacks that distributors have claimed for reduced pricing offered to such healthcare providers and our expectation about future utilization rates. Our accrual for Medicaid is based upon statutorily defined discounts, estimated payor mix, expected sales to qualified healthcare providers, and our expectation about future utilization. The Medicaid accrual and government rebates that are invoiced directly to us are recorded in other accrued liabilities on the condensed consolidated balance sheets. For qualified programs that can purchase our products through distributors at a lower contractual government price, the distributors charge back to us the difference between their acquisition cost and the lower contractual government price, which we record as an allowance against accounts receivable.

Distribution Fees: We have contracts with our distributors in the US that include terms for distribution related fees. We determine distribution related fees based on a percentage of the product sales price, and we record the distribution fees as an allowance against accounts receivable.

Product Returns: We offer our distributors a right to return product purchased directly from us, which is principally based upon the product’s expiration date. Our policy is to accept product returns during the six months prior to and twelve months after the product expiration date on product that has been sold to our distributors. Product return allowances are based on amounts owed or to be claimed on related sales. These estimates take into consideration the terms of our agreements with customers, historical product returns of VIBATIV, rebates or discounts taken, estimated levels of inventory in the distribution

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channel, the shelf life of the product, and specific known market events, such as competitive pricing and new product introductions. We record our product return reserves as other accrued liabilities.

Allowance for Doubtful Accounts: We record allowances for potentially doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. As of September 30, 2018, there was no allowance for doubtful accounts related to customer payments.

The following table summarizes activity in each of the product revenue allowance and reserve categories for the nine months ended September 30, 2018.

(In thousands)	Chargebacks, Discounts and Fees	Government and Other Rebates	Returns	Total
Balance at December 31, 2017	$ 992	$ 352	$ 947	$ 2,291
Provision related to current period sales	5,277	560	365	6,202
Adjustment related to prior period sales	(81)	142	(449)	(388)
Credit or payments made during the period	(5,126)	(562)	(131)	(5,819)
Balance at September 30, 2018	$ 1,062	$ 492	$ 732	$ 2,286

We adopted ASC 606 on January 1, 2018 using the modified retrospective method. Our comparative prior period revenue remains reported under ASC 605. Our revenue recognition policy under ASC 605 for the comparative 2017 periods is included in our Annual Report on Form 10-K for the year ended December 31, 2017.

Collaborative Arrangements

We enter into collaborative arrangements with partners that fall under the scope of Accounting Standards Codification, Topic 808, Collaborative Arrangements ("ASC 808"). While these arrangements are in the scope of ASC 808, we may analogize to ASC 606 for some aspects of the arrangements. We analogize to ASC 606 for certain activities within the collaborative arrangement for the delivery of a good or service (i.e., a unit of account) that is part of our ongoing major or central operations.

The terms of our collaborative arrangements typically include one or more of the following: (i) up-front fees; (ii) milestone payments related to the achievement of development, regulatory, or commercial goals; (iii) royalties on net sales of licensed products; (iv) reimbursements or cost-sharing of R&D expenses; and (v) profit/loss sharing arising from co-promotion arrangements. Each of these payments results in collaboration revenues or an offset against R&D

expenses. Where a portion of non refundable up-front fees or other payments received are allocated to continuing performance obligations under the terms of a collaborative arrangement, they are recorded as deferred revenue and recognized as collaboration revenue when (or as) the underlying performance obligation is satisfied.

As part of the accounting for these arrangements, we must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation which determines how the transaction price is allocated among the performance obligations. The estimation of the stand-alone selling price may include such estimates as, forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. We evaluate each performance obligation to determine if they can be satisfied at a point in time or over time, and we measure the services delivered to our collaboration partner which are periodically reviewed based on the progress of the related program. The effect of any change made to an estimated input component and, therefore revenue or expense recognized, would be recorded as a change in estimate. In addition, variable consideration (e.g., milestone payments) must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

Up-front Fees: If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize collaboration revenues from the transaction price allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing collaboration revenue from the allocated transaction price. For example, when we receive up-front fees for the performance of research and development services, or when

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research and development services are not considered to be distinct from a license, we recognize collaboration revenue for those units of account over time using a measure of progress. We evaluate the measure of progress each at reporting period and, if necessary, adjust the measure of performance and related revenue or expense recognition as a change in estimate.

Milestone Payments: At the inception of each arrangement that includes milestone payments (variable consideration), we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our or the collaboration partner's control, such as non-operational developmental and regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, we re-evaluate the probability of achievement of milestones that are within our or the collaboration partner's control, such as operational developmental milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues and earnings in the period of adjustment. Revisions to our estimate of the transaction price may also result in negative collaboration revenues and earnings in the period of adjustment.

Royalties: For arrangements that include sales-based royalties, including commercial milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any material royalty revenue resulting from any of our collaborative arrangements.

Reimbursement, cost-sharing and profit-sharing payments: Under certain collaborative arrangements, we have been reimbursed for a portion of our R&D expenses or participate in the cost-sharing of such R&D expenses. Such reimbursements and cost-sharing arrangements have been reflected as a reduction of R&D expense in our condensed consolidated statements of operations, as we do not consider performing research and development services for reimbursement to be a part of our ongoing major or central operations. Therefore, the reimbursement or cost-sharing of research and development services are recorded as a reduction of R&D expense.

Under the terms of our collaboration agreement with Mylan Ireland Limited ("Mylan") for revefenacin, including YUPELRITM inhalation solution, we are also entitled to a share of US profits and losses (65% to Mylan/35% to Theravance Biopharma) received in connection with commercialization of YUPELRI, and we are entitled to low double-digit royalties on ex-US net sales (excluding China). If and when YUPELRI is approved, we expect that Mylan will be the principal in the sales transaction, and as a result, we will not reflect the product sales on our records. Until YUPELRI is approved and our collaboration activities are profitable, in accordance with GAAP, our share of the losses under a co-promote arrangement are recorded within R&D expense and selling, general and administrative expense on our condensed consolidated statements of operations. See "Note 3. Collaborative Arrangements" for additional information about our collaboration agreement with Mylan.

Theravance Respiratory Company, LLC (“TRC”)

Through our equity ownership of TRC, we are entitled to receive an 85% economic interest in any future payments that may be made by Glaxo Group or one of its affiliates (“GSK”) relating to the GSK-Partnered Respiratory Programs (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters). The GSK-Partnered Respiratory Programs consist primarily of the Trelegy Ellipta program and the inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist (“MABA”) program.

We analyzed our ownership, contractual and other interests in TRC to determine if it is a variable interest entity (“VIE”), whether we have a variable interest in TRC and the nature and extent of that interest. We determined that TRC is a VIE. The party with the controlling financial interest, the primary beneficiary, is required to consolidate the entity determined to be a VIE. Therefore, we also assessed whether we are the primary beneficiary of TRC based on the power to direct its activities that most significantly impact its economic performance and our obligation to absorb its losses or the right to receive benefits from it that could potentially be significant to TRC. Based on our assessment, we determined that we are not the primary beneficiary of TRC, and, as a result, we do not consolidate TRC in our consolidated financial statements. TRC is recognized in our consolidated financial statements under the equity method of accounting. Income related to our equity ownership of TRC is reflected in our consolidated statement of operations as non-operating income.

Income Taxes

On January 1, 2018, we adopted ASU 2016-16, Income Taxes (Topic 740), Intra-Entity Transfers of Assets Other Than Inventory ("ASU 2016-16") using the modified retrospective approach. ASU 2016-16 requires immediate recognition of income tax consequences of intra-company asset transfers, other than inventory transfers. Legacy GAAP prohibited recognition of income tax consequences of intra-company asset transfers whereby the seller defers any net tax effect and the buyer is prohibited from recognizing a deferred tax asset on the difference between the newly created tax basis of the asset in its tax jurisdiction and its financial statement carrying amount as reported in the consolidated financial statements. An example of an inter-company asset transfers included in ASU 2016-16's scope is intellectual property. The adoption of ASU 2016-16 did not have a material impact on our balance sheet or statement of operations as our deferred tax assets are fully offset by a valuation allowance.

Recently Issued Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU 2016 02, Leases (Topic 842) ("ASU 2016 02"). ASU 2016 02 is aimed at making leasing activities more transparent and comparable, and requires leases with terms greater than one year to be recognized by lessees on their balance sheet as a right of use asset and corresponding lease liability. ASU 2016 02 is effective for all interim and annual reporting periods beginning after December 15, 2018, with early adoption permitted, and is required to be adopted using a modified retrospective approach. In July 2018, the FASB issued supplemental adoption guidance that allows for an optional transition method to initially account for the impact of the adoption with a cumulative adjustment to accumulated deficit on the effective date of ASU 2016-02, January 1, 2019, rather than applying the transition provisions in the earliest period presented.

Based on our assessment of ASU 2016-02, we plan to elect the optional transition method described above and other practical expedients that allows entities to not (i) reassess whether any expired or existing contracts are considered or contain leases; (ii) reassess the lease classification for any expired or existing leases; and (iii) reassess initial direct costs for any existing leases.

We expect to adopt ASU 2016-02 in the first quarter of 2019, and we are in the process of evaluating our existing lease arrangements in order to determine the full impact that the adoption of ASU 2016 02 will have on our balance sheet, financial statement disclosures, and related internal controls. We currently believe that the most significant impact to our balance sheet upon adoption will be from recognizing a right-of-use asset and corresponding lease liability related to our office leases in South San Francisco and Dublin, Ireland. Based on the initial review of our existing lease arrangements, we do not expect ASU 2016-02 to have a material impact on our results of operations or cash flows.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. We anticipate its first presentation of changes in stockholders' equity as required under the new SEC guidance will be included in our Form 10-Q for the three month period ended March 31, 2019.

We have evaluated other recently issued accounting pronouncements and do not believe that any of these pronouncements will have a material impact on our consolidated financial statements and related disclosures.

2. Net Loss per Share

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

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For the three and nine months ended September 30, 2018 and 2017, diluted and basic net loss per share was identical since potential ordinary shares were excluded from the calculation, as their effect was anti-dilutive.

Anti-dilutive Securities

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2018	2017	2018	2017
Share issuances under equity incentive plans and ESPP	3,783	3,069	4,741	3,075
Restricted shares	4	26	4	26
Share issuances upon the conversion of convertible senior notes	6,676	6,676	6,676	6,676
Total	10,463	9,771	11,421	9,777

In addition, there were 978,750 and 1,305,000 shares that are subject to performance based vesting criteria which have been excluded from the ordinary equivalent shares table above as of September 30, 2018 and 2017, respectively.

3. Collaborative Arrangements

Revenue from Collaborative Arrangements

We recognized revenues from our collaborative arrangements as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2018	2017	2018	2017

Janssen	$ 8,866	$ —	$ 21,044	$ —
Alfasigma	117	—	10,650	—
Other	6	135	50	207
Total revenue from collaborative arrangements	$ 8,989	$ 135	$ 31,744	$ 207

Under the legacy revenue guidance ASC 605, our collaboration revenue for the three and nine months ended September 30, 2018, would not have differed materially.

Changes in Deferred Revenue Balances

We recognized the following revenue from collaborative arrangements as a result of changes in our deferred revenue balance during the periods below:

(In thousands)	Three Months Ended September 30, 2018
Collaboration revenue recognized in the period from:	
Amounts included in deferred revenue at the beginning of the period	$ 7
Performance obligations satisfied in previous period	—

(In thousands)	Nine Months Ended September 30, 2018
Collaboration revenue recognized in the period from:	
Amounts included in deferred revenue at the beginning of the period	$ 39
Performance obligations satisfied in previous period	—

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Mylan

Development and Commercialization Agreement

In January 2015, Mylan Ireland Limited ("Mylan") and we established a strategic collaboration (the "Mylan Agreement") for the development and, subject to regulatory approval, commercialization of revefenacin, our investigational LAMA in development under the proposed brand name YUPELRITM inhalation solution as a nebulized, once-daily single-agent 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.

Under the Mylan Agreement, Mylan paid us an up-front fee of $15.0 million for the delivery of the revefenacin license in 2015 and, in 2016, Mylan paid us a milestone payment $15.0 million for the achievement of 50% enrollment in the Phase 3 twelve-month safety study. Separately, pursuant to an ordinary share purchase agreement entered into on January 30, 2015, Mylan Inc., a subsidiary of Mylan N.V., made a $30.0 million equity investment in us, buying 1,585,790 ordinary shares from us in February 2015 in a private placement transaction at a price of approximately $18.918 per share, which represented a 10% premium, equal to $4.2 million, over the volume weighted average price per share of our ordinary shares for the five trading days ending on January 30, 2015.

As of September 30, 2018, we are eligible to receive from Mylan additional potential development, regulatory and sales milestone payments totaling up to $205.0 million in the aggregate, with $160.0 million associated with YUPELRI monotherapy, and $45.0 million associated with future potential combination products. Of the $160.0 million associated with monotherapy, $150.0 million relates to sales milestones based on achieving certain levels of net sales and $10.0 million relates to regulatory actions in the European Union ("EU").

The Mylan Agreement is considered to be within the scope of ASC 808, as the parties are active participants and exposed to the risks and rewards of the collaborative activity. Under the terms of the Mylan Agreement, Mylan is responsible for reimbursement of our costs related to the registrational program up until the approval of the first new drug application. Performing R&D services for reimbursement is considered to be a collaborative activity under the scope of ASC 808. Reimbursable program costs are recognized proportionately with the performance of the underlying services and accounted for as reductions to R&D expense. For this unit of account, we do not recognize revenue or analogize to ASC 606 and, as such, the reimbursable program costs are excluded from the transaction price.

We analogized to ASC 606 for the accounting for two performance obligations: (1) delivery of the license to develop and commercialize revefenacin; and (2) joint steering committee participation. We determined the license to be distinct from the joint steering committee participation. We further determined that the transaction price under the arrangement was comprised of the following: (1) $15.0 million up-front license fee received in 2015; (2) $4.2 million premium related to the ordinary share purchase agreement received in 2015; and (3) $15.0 million milestone for 50% enrollment in the Phase 3 twelve-month safety study received in 2016. The total transaction price of $34.2 million was allocated to the two performance obligations based on our best estimate of the relative stand-alone selling price. For the delivery of the license, we based the stand-alone selling price on a discounted cash flow approach and considered several factors including, but not limited to: discount rate, development timeline, regulatory risks, estimated market demand and future revenue potential. For the committee participation, we based the stand-alone selling price on the average compensation of our committee members estimated to be incurred over the performance period. We expect to recognize collaboration revenue from the committee participation ratably over the performance period of approximately seventeen years.

The future potential milestone amounts were not included in the transaction price, as they were all determined to be fully constrained following the concepts of ASC 606. As part of our evaluation of the development and regulatory milestones constraint, we determined that the achievement of such milestones are contingent upon success in future clinical trials and regulatory approvals which are not within our control and uncertain at this stage. We expect that the sales-based milestone payments and royalty arrangements will be recognized when the sales occur or the milestone is achieved. We will re-evaluate the transaction price each quarter and as uncertain events are resolved or other changes in circumstances occur.

We are also entitled to a share of US profits and losses (65% to Mylan/35% to Theravance Biopharma) received in connection with commercialization of YUPELRI, and we are entitled to low double-digit royalties on ex-US net sales (excluding China). We expect that Mylan will be the principal in the sales transaction, and as a result, we will not reflect the

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product sales on our records. Under a co-promote arrangement with Mylan, we record our 35% share of expenses based on collaboration activities to prepare for a potential product launch. Until, and unless, YUPELRI is approved and our collaboration activities are profitable, in accordance with GAAP, collaboration expenses are recognized within R&D expense and selling, general and administrative expense on our condensed consolidated statements of operations. If our collaboration activities are profitable, our 35% share of profits related to the commercialization of YUPELRI will be recognized as collaboration revenue. For the cost-sharing and profit-sharing activities, we do not analogize to ASC 606. We consider these activities to be collaborative activities under the scope of ASC 808, and we will recognize the shared profits (if any) and expenses in the periods that such profits and expenses occur, following the implementation guidance in ASC 808. For the three and nine months ended September 30, 2018, we recognized $1.5 million and $3.3 million, respectively, in collaboration expense under the YUPELRI co-promote arrangement with Mylan.

As of September 30, 2018, $0.3 million was recorded in deferred revenue on the condensed consolidated balance sheets under the Mylan Agreement. This amount reflects revenue allocated to joint steering committee participation and will be recognized as collaboration revenue over the course of the remaining performance period of approximately fourteen years. For the three and nine months ended September 30, 2018, we recognized $6,000 and $18,000, respectively, in collaboration revenue from the recognition of previously deferred revenue under the Mylan collaborative arrangement.

Janssen Biotech

In February 2018, we entered into a global co-development and commercialization agreement with Janssen Biotech, Inc. (“Janssen”) for TD-1473 and related back-up compounds for inflammatory intestinal diseases, including ulcerative colitis and Crohn's disease (the “Janssen Agreement”). Under the terms of the Janssen Agreement, we received an upfront payment of $100.0 million. We are currently initiating a Phase 2 study in Crohn’s disease and plan to initiate a large, Phase 2b/3 adaptive design induction and maintenance study in ulcerative colitis with patient dosing expected to begin in late 2018 or early 2019. Following completion of the Phase 2 Crohn’s study and the Phase 2b induction portion of an ulcerative colitis study, Janssen can elect to obtain an exclusive license to develop and commercialize TD-1473 and certain related compounds by paying us a fee of $200.0 million. Upon any such election, we and Janssen will jointly develop and commercialize TD-1473 in inflammatory intestinal diseases and share profits in the US and expenses related to a potential Phase 3 program (67% to Janssen; 33% to Theravance Biopharma). We would receive royalties on ex-US sales at double-digit tiered percentage royalty rates, and we would be eligible to receive up to an additional $700.0 million in development and commercialization milestone payments from Janssen.

The Janssen Agreement is considered to be within the scope of ASC 808, as the parties are active participants and exposed to the risks and rewards of the collaborative activity. We evaluated the terms of the Janssen Agreement and have analogized to ASC 606 for the research and development activities to be performed through the initial Phase 2 development period of the collaborative arrangement that are considered to be part of our ongoing major or central operations. Using the concepts of ASC 606, we have identified research and development activities as our only performance obligation. We further determined that the transaction price under the arrangement was the $100.0 million upfront payment which was allocated to the single performance obligation.

The $900.0 million in future potential payments is considered variable consideration if Janssen elects to remain in the collaboration arrangement following completion of certain Phase 2 activities, as described above and, as such, was not included in the transaction price, as the potential payments were all determined to be fully constrained under ASC 606. As part of our evaluation of this variable consideration constraint, we determined that the potential payments are contingent upon developmental and regulatory milestones that are uncertain and are highly susceptible to factors outside of our control. We expect that any consideration related to royalties and sales-based milestones will be recognized when the subsequent sales occur.

For the three and nine months ended September 30, 2018, we recognized $8.9 million and $21.0 million, respectively, as revenue from collaboration arrangements related to the Janssen Agreement. The remaining transaction price of $79.0 million was recorded in deferred revenue on the condensed consolidated balance sheets and is expected to be recognized as collaboration revenue as the research and development services are delivered over the Phase 2 development period. Collaboration revenue is recognized for the research and development services based on a measure of our efforts toward satisfying a performance obligation relative to the total expected efforts or inputs to satisfy the performance obligation (e.g., costs incurred compared to total budget). For the three and nine months ended September 30, 2018, we incurred $10.5 million and $28.1 million, respectively, in research and development costs related to the Janssen Agreement. In future reporting periods, we will reevaluate our estimates related to our efforts towards satisfying the performance obligation and may record a change in estimate if deemed necessary.

Alfasigma

Development and Collaboration Agreement

Under an October 2012 development and collaboration agreement for velusetrag, we and Alfasigma S.p.A ("Alfasigma") agreed to collaborate in the execution of a two-part Phase 2 program to test the efficacy, safety and tolerability of velusetrag in the treatment of patients with gastroparesis (a medical condition consisting of a paresis (partial paralysis) of the stomach, resulting in food remaining in the stomach for a longer time than normal) (the "Alfasigma Agreement"). As part of the Alfasigma Agreement, Alfasigma funded the majority of the costs associated with the Phase 2 gastroparesis program, which consisted of a Phase 2 study focused on gastric emptying and a Phase 2 study focused on symptoms. Alfasigma had an exclusive option to develop and commercialize velusetrag in the EU, Russia, China, Mexico and certain other countries, while we retained full rights to velusetrag in the US, Canada, Japan and certain other countries.

In April 2018, Alfasigma exercised its exclusive option to develop and commercialize velusetrag, and we elected not to pursue further development of velusetrag. As a result, we will transfer global rights for velusetrag to Alfasigma under the terms of the existing collaboration agreement. We received a $10.0 million option exercise fee and a $1.0 million non-refundable reimbursement from Alfasigma, and we are eligible to receive future potential development, regulatory and sales milestone payments of up to $26.8 million, and tiered royalties on global net sales ranging from high single digits to the mid-teens.

The Alfasigma Agreement is considered to be within the scope of ASC 808, as the parties are active participants and exposed to the risks and rewards of the collaborative activity. We have historically received reimbursements related to R&D services performed under the Alfasigma Agreement. Performing R&D services for reimbursement is considered to be a collaborative activity under the scope of ASC 808. Reimbursable program costs are accounted for as reductions to R&D expense. For this unit of account, we do not recognize revenue or analogize to ASC 606 and, as such, the reimbursable program costs are excluded from the transaction price.

As a result of Alfasigma's election to exercise its exclusive option to develop and commercialize velusetrag in April 2018, Alfasigma paid us a total of $11.0 million, comprised of the $10.0 million option exercise fee and a $1.0 million non-refundable reimbursement. We analogized to ASC 606 for the delivery of the following identified performance obligations: (i) delivery of the velusetrag license; (ii) transfer of technical know-how; (iii) delivery of clinical study reports ("CSRs"); (iv) delivery of registration batches, including drug substances; and (v) joint steering committee participation. We determined that all of the five performance obligations were distinct, and we allocated the transaction price based on the estimated stand-alone selling prices of each of the performance obligations. The stand-alone selling price of the license was based on a discounted cash flow approach and considered several factors including, but not limited to: discount rate, development timeline, regulatory risks, estimated market demand and future revenue potential.

We determined that any potential development or regulatory milestones were to be fully constrained as prescribed under ASC 606. As part of our evaluation of this variable consideration constraint, we determined that the potential payments are contingent upon developmental and regulatory milestones that are uncertain and are highly susceptible to factors outside of our control. In addition, we expect that any consideration related to sales-based milestones would be recognized when the subsequent sales occur.

For the three and nine months ended September 30, 2018, we recognized $0.1 million and $10.6 million, respectively, as revenue from collaboration arrangements related to the Alfasigma Agreement. As of September 30, 2018, $0.4 million was recorded in deferred revenue on the condensed consolidated balance sheet and is expected to be recognized as collaboration revenue over approximately the next four years.

Reimbursement of R&D Expense

Under certain collaborative arrangements, we are entitled to reimbursement of certain R&D expense. Activities under collaborative arrangements for which we are entitled to reimbursement are considered to be collaborative activities

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under the scope of ASC 808. For these units of account, we do not analogize to ASC 606 or recognize revenue. We record reimbursement payments received from our collaboration partners as reductions to R&D expense.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2018	2017	2018	2017
Mylan	$ 2,598	$ 5,839	$ 5,843	$ 17,737
Janssen	610	—	610	—
Other	—	—	—	41
Total reduction to R&D expense	$ 3,208	$ 5,839	$ 6,453	$ 17,778

4. Cash, Cash Equivalents, and Restricted Cash

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same such amount shown on the condensed consolidated statements of cash flows.

	September 30,	
(In thousands)	2018	2017
Cash and cash equivalents	$ 101,202	$ 91,301
Restricted cash	833	833
Total cash, cash equivalents, and restricted cash shown on the condensed consolidated statements of cash flows	$ 102,035	$ 92,134

Restricted cash pertained to certain lease agreements and letters of credit where we have pledged cash and cash equivalents as collateral. The cash-related amounts reported in the table above exclude our investments in short and long-term marketable securities that are reported separately on the condensed consolidated balance sheets.

5. Investments and Fair Value Measurements

Available for Sale Securities

The estimated fair value of investments 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 investments 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.

Available for sale securities are summarized below:

		September 30, 2018			
(In thousands)		Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
US government securities	Level 1	$ 91,607	$ —	$ (196)	$ 91,411
US government agency securities	Level 2	6,625	—	(3)	6,622
Corporate notes	Level 2	72,602	3	(137)	72,468
Commercial paper	Level 2	68,876	—	—	68,876
Classified as marketable securities		239,710	3	(336)	239,377
Money market funds	Level 1	68,864	—	—	68,864
Total		$ 308,574	$ 3	$ (336)	$ 308,241

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		December 31, 2017			
(In thousands)		Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
US government securities	Level 1	$ 89,896	$ —	$ (342)	$ 89,554
US government agency securities	Level 2	50,891	—	(113)	50,778
Corporate notes	Level 2	141,226	2	(280)	140,948
Commercial paper	Level 2	19,893	—	—	19,893
Classified as marketable securities		301,906	2	(735)	301,173
Money market funds	Level 1	69,055	—	—	69,055
Total		$ 370,961	$ 2	$ (735)	$ 370,228

As of September 30, 2018, all of the investments had contractual maturities within two years and the weighted average maturity of the marketable securities was approximately five months. There were no transfers between Level 1 and Level 2 during the periods presented, and there have been no changes to our valuation techniques during the three and nine months ended September 30, 2018.

In general, we invest in debt securities with the intent to hold such securities until maturity at par value. We do not intend to sell the investments that are currently in an unrealized loss position, and it is unlikely that we will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. We have determined that the gross unrealized losses on our marketable securities, as of September 30, 2018, were temporary in nature and primarily due to increases in short-term interest rates in the capital markets. There were no material unrealized losses on investments which have been in a loss position for more than twelve months as of September 30, 2018.

As of September 30, 2018, our accumulated other comprehensive loss on our condensed consolidated balance sheets consisted of net unrealized losses on available-for-sale investments. During the three and nine months ended September 30, 2018, we did not sell any of our marketable securities.

Long-term Debt Fair Value

We have $230.0 million of 3.250% convertible senior notes (“Notes”) outstanding as of September 30, 2018 with an estimated fair value of $271.1 million. The estimated fair value was primarily based upon the underlying price of Theravance Biopharma’s publicly traded shares and other observable inputs as of September 30, 2018. The inputs to determine fair value of the Notes are categorized as Level 2 inputs. Level 2 inputs include quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

6. Theravance Respiratory Company, LLC (“TRC”)

Prior to the June 2014 spin-off from Innoviva, Inc. (the “Spin-Off”), our former parent company, Innoviva, Inc. (“Innoviva”), assigned to TRC, a Delaware limited liability company formed by Innoviva, its strategic alliance agreement with GSK and all of its rights and obligations under its collaboration agreement with GSK other than with respect to RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO® ELLIPTA® and vilanterol monotherapy. Through our 85% equity interests in TRC, we are entitled to receive 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 (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters). The drug programs assigned to TRC include Trelegy Ellipta 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.

In May 2014, we entered into the TRC LLC Agreement with Innoviva that governs the operation of TRC. Under the TRC LLC Agreement, Innoviva is the manager of TRC, and the business and affairs of TRC are managed exclusively by the manager, including (i) day to day management of the drug programs in accordance with the existing GSK agreements; (ii) preparing an annual operating plan for TRC; and (iii) taking all actions necessary to ensure that the formation, structure

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and operation of TRC complies with applicable law and partner agreements. We are responsible for our proportionate share of TRC's administrative expenses incurred by Innoviva.

We analyzed our ownership, contractual and other interests in TRC to determine if it is a variable interest entity ("VIE"), whether we have a variable interest in TRC and the nature and extent of that interest. We determined that TRC is a VIE. The party with the controlling financial interest, the primary beneficiary, is required to consolidate the entity determined to be a VIE. Therefore, we also assessed whether we are the primary beneficiary of TRC based on the power to direct its activities that most significantly impact its economic performance and our obligation to absorb its losses or the right to receive benefits from it that could potentially be significant to TRC. Based on our assessment, we determined that we are not the primary beneficiary of TRC, and, as a result, we do not consolidate TRC in our consolidated financial statements. TRC is recognized in our consolidated financial statements under the equity method of accounting, and the value of our equity investment in TRC was $3.1 million as of September 30, 2018.

For the three and nine months ended September 30, 2018, we recognized $3.1 million and $5.8 million, respectively, in income from our investment in TRC which was generated by royalty payments from GSK to TRC arising from the net sales of Trelegy Ellipta. There was no income from TRC in the comparable prior year periods.

7. Inventories

Inventory consists of the following:

(In thousands)	September 30, 2018	December 31, 2017
Raw materials	$ 10,785	$ 11,729
Work-in-process	3,628	66
Finished goods	3,510	5,035
Total inventories	$ 17,923	$ 16,830

We assess our inventory levels each reporting period in consideration of the risk of product expiration. In evaluating the sufficiency of our inventory reserves or liabilities for firm purchase commitments, we also take into consideration our firm purchase commitments for future inventory production. In the fourth quarter of 2017, we accrued a $2.3 million liability related to excess inventory purchase commitments based on our expected purchase obligations at the time. In the second quarter of 2018, we reversed the expense related to the $2.3 million purchase commitment liability due to the waiver of our minimum purchase commitment by our third-party manufacturer, and the $2.3 million adjustment is included within cost of goods sold for the nine months ended September 30, 2018 on the condensed consolidated statements of operations.

8. 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2018	2017	2018	2017
Research and development	$ 6,294	$ 5,005	$ 19,757	$ 15,023
Selling, general and administrative	5,452	5,680	19,842	16,329
Total share-based compensation expense	$ 11,746	$ 10,685	$ 39,599	$ 31,352

Performance-Contingent Awards

In the first quarter of 2016, the Compensation Committee of our Board of Directors (“Compensation Committee”) approved the grant of 1,575,000 performance-contingent restricted share awards (“RSAs”) and 135,000 performance-contingent restricted share units (“RSUs”) to senior management. The vesting of such awards is dependent on the Company meeting its critical operating goals and objectives during a five-year period from 2016 to December 31, 2020. The goals that must be met in order for the performance-contingent RSAs and RSUs to vest are strategically important for the Company,

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and the Compensation Committee believes the goals, if achieved, will increase shareholder value. The awards have dual triggers of vesting based upon the achievement of these goals and continued employment. As of September 30, 2018, there were 978,750 performance-contingent RSAs and 101,250 performance-contingent RSUs outstanding. As of September 30, 2017, there were 1,305,000 performance-contingent RSAs and 135,000 performance-contingent RSUs outstanding.

Expense associated with these awards is broken into three separate tranches and may be recognized during the years 2016 to 2020 depending on the probability of meeting the performance conditions. Compensation expense relating to awards subject to performance conditions is recognized if it is considered probable that the performance goals will be achieved. The probability of achievement is reassessed at each quarter-end reporting period.

The performance conditions associated with the first tranche of these awards were completed in the second quarter of 2018, and we recognized $1.8 million of share-based compensation expense for the nine months ended September 30, 2018 associated with these awards. For the three and nine months ended September 30, 2017, we recognized $0.5 million and $1.4 million, respectively, of share-based compensation expense related to the first tranche of these awards.

For the three and nine months ended September 30, 2018, we recognized $47,000 and $1.8 million, respectively, of share-based compensation expense related to our assessment of the probability that the performance conditions associated with the second tranche of these awards was considered to be probable of vesting. The $47,000 recognized in the third quarter of 2018 was a significant decrease from the $0.9 million recognized in the second quarter of 2018 due to the reversal of expenses resulting from employee forfeitures. As of September 30, 2017, the second tranche was not considered probable of vesting, and as of September 30, 2018 and 2017, we determined that the remaining third tranche was not probable of vesting and, as a result, no compensation expense related to the third tranche has been recognized to date.

The maximum potential expense associated with the remaining second and third tranches could be up to $18.6 million (allocated as $7.7 million for research and development expense and $10.9 million for selling, general and administrative expense) if the performance conditions for the second and third tranches are achieved.

In the third quarter of 2017, the Compensation Committee approved the grant of 50,000 performance-contingent RSUs to a newly appointed member of senior management. The RSUs have dual triggers of vesting based upon the achievement of certain corporate operating milestones in specified timelines, as well as a requirement for continued employment. Share-based compensation expense related to this grant is broken into two separate tranches and recognized when the associated performance goals are deemed to be probable of achievement. The maximum expense associated with the first tranche was $0.8 million. In 2017, we recognized $0.4 million in share-based compensation expense as we determined that the performance conditions associated with the first tranche was probable of vesting, and in the first quarter of 2018, we recognized the remaining $0.4 million of share-based compensation expense as the performance conditions associated with the first tranche of this award were met. We have determined that the second tranche was not probable of vesting as of September 30, 2018 and, as a result, no compensation expense related to the second tranche has been recognized to date.

9. Income Taxes

The income tax provision was $0.7 million benefit and a $7.3 million benefit for the three and nine months ended September 30, 2018, respectively. The benefit for the three months ended September 30, 2018 was primarily attributed to the reversal of previously accrued contingent tax liabilities of $0.8 million due to a lapse of the statute of limitations. The year-to-date benefit recorded in the income tax provision was primarily due to recording contingent tax liabilities pertaining primarily to uncertain tax positions taken with respect to transfer pricing and tax credits, offset by a tax benefit arising from an updated estimate of a tax filing position to be reported in our tax returns filed in 2018 and the benefit recorded in the current quarter. No provision for income taxes has been recognized on undistributed earnings of our foreign subsidiaries because we consider such earnings to be indefinitely reinvested.

We follow the accounting guidance related to accounting for income taxes which requires that a company reduce its deferred tax assets by a valuation allowance if, based on the weight of available evidence, it is more likely than not that some portion or all of its deferred tax assets will not be realized. As of September 30, 2018, our deferred tax assets were offset in full by a valuation allowance.

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

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

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

US Tax Reform

On December 22, 2017, the US government enacted the Tax Cuts and Jobs Acts (the "Tax Act"). The Tax Act significantly revises the US corporate income tax laws by, amongst other things, reducing the corporate income tax rate from 35% to 21% and implementing a modified territorial tax system that includes a one-time repatriation tax on accumulated undistributed foreign earnings.

Based on provisions of the Tax Act, we remeasured our deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21%. The estimated amount of the remeasurement of our federal deferred tax balance was $12.4 million. However, as we recognize a valuation allowance on deferred tax assets, if it is more likely than not that the assets will not be realized in future years, there is no impact to our effective tax rate, as any change to deferred taxes would be offset by valuation allowances.

The changes included in the Tax Act are broad and complex. The final transition impact of the Tax Act may differ from the above estimate, possibly materially, due to, among other things, changes in interpretations of the Tax Act, any legislative action to address questions that arise because of the Tax Act, any changes in accounting standards for income taxes or related interpretations in response to the Tax Act, or any updates or changes to estimates the Company has utilized to calculate the transition impact, including impact from changes to current year earnings estimates and foreign exchange rates of foreign subsidiaries. For example, one area where we are waiting on further guidance before finalizing our conclusion as to the impact of the Tax Act on our deferred tax assets and liabilities is the transition rules with respect to the tax deductibility of executive compensation. The SEC has issued rules that would allow for a measurement period of up to one year after the enactment date of the Tax Act to finalize the recording of the related tax impacts. For the three and nine months ended September 30, 2018, we did not adjust or include any previously assessed Tax Act effect in our quarterly tax provision. We currently anticipate finalizing and recording any resulting adjustments by December 22, 2018.

10. Subsequent Events

Cumberland Pharmaceuticals Inc. Asset Purchase Agreement

On November 1, 2018, we entered into an Asset Purchase Agreement (the “Agreement”) with Cumberland Pharmaceuticals Inc. (“Cumberland”) pursuant to which Cumberland will acquire from us assets related to the manufacture, marketing and sale of VIBATIV (telavancin) (“VIBATIV” or the “Product”).

Upon the consummation of the transaction contemplated by the Agreement (the “Transaction”), Cumberland will pay us (i) \$20.0 million at the closing of the Transaction, (ii) \$5.0 million on or before April 1, 2019 and (iii) tiered royalties of up to 20% of US net sales of the Product until such time as royalties cumulatively total \$100.0 million.

In connection with the Transaction, Cumberland will acquire, among other things, (i) intellectual property rights relating to the Product, (ii) active pharmaceutical ingredient for the Product, work-in-process and finished drug product, (iii)

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the US marketing authorization for the Product, (iv) certain assigned contracts relating to the manufacture and commercialization of the Product, and (v) books and records related to the Product. Cumberland will also assume certain clinical study obligations related to the Product and post-closing liabilities and obligations relating to the Product as described in the Agreement. The Company has agreed to provide transition services to Cumberland for limited periods of time following the consummation of the Transaction. The Transaction is expected to close in mid-November 2018, subject to customary closing conditions.

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

Forward-Looking Statements

You should read the following discussion in conjunction with our condensed financial statements (unaudited) and related notes included elsewhere in this report. This report includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 (the "Securities Act"), as amended, and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"), as amended, that involve risks and uncertainties. All statements in this report, other than statements of historical facts, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans, intentions, expectations and objectives are forward-looking statements. The words "anticipate," "assume," "believe," "contemplate," "continue," "could," "designed," "developed," "drive," "estimate," "expect," "forecast," "goal," "intend," "may," "mission," "opportunities," "plan," "potential," "pursue," "seek," "should," "target," "will," "would," and similar expressions (including the negatives thereof) are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These statements reflect our current views with respect to future events or our future financial performance, are based on assumptions, and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We may not actually achieve the plans, intentions, expectations or objectives disclosed in our forward-looking statements and the assumptions underlying our forward-looking statements may prove incorrect. Therefore, you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and objectives disclosed in the forward-looking statements that we make. Factors that we believe could cause actual results or events to differ materially from our forward-looking statements include, but are not limited to, those discussed in "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report and in our Annual Report on Form 10-K for the year ended December 31, 2017. Our forward-looking statements in this report are based on current expectations and we do not assume any obligation to update any forward-looking statements for any reason, even if new information becomes available in the future.

Management Overview

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

In our relentless pursuit of this objective, we strive to apply insight and innovation at each stage of our business, including research, development and commercialization, and utilize both internal capabilities and those of partners around the world. Our research efforts are focused in the areas of inflammation and immunology. Our research goal is to design localized medicines that target diseased tissues, without systemic exposure, in order to maximize patient benefit and minimize risk. These efforts leverage years of experience in developing localized medicines for the lungs to treat respiratory disease. The first potential medicine to emerge from our research focus on immunology and localized treatments is an oral, gut-selective pan-Janus kinase (JAK) inhibitor, currently in development to treat a range of inflammatory intestinal diseases. Our pipeline of internally discovered product candidates will continue to evolve with the goal of creating transformational medicines to address the significant needs of patients.

In addition, we have an economic interest in future payments that may be made by Glaxo Group or one of its affiliates ("GSK") pursuant to its agreements with Innoviva, Inc. relating to certain programs, including Trelegy Ellipta.

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Program Highlights

Gut-selective Pan-Janus Kinase (JAK) Inhibitor Program (TD-1473)

JAK inhibitors function by inhibiting the activity of one or more of the Janus kinase family of enzymes (JAK1, JAK2, JAK3, TYK2) that play a key role in cytokine signaling. Inhibiting these JAK enzymes interferes with the JAK/STAT signaling pathway and, in turn, modulates the activity of a wide range of pro-inflammatory cytokines. JAK inhibitors are currently approved for the treatment of rheumatoid arthritis, myelofibrosis, and ulcerative colitis and have demonstrated therapeutic benefit for patients with Crohn's disease. However, these products are known to have side effects based on their systemic exposure. Our goal is to develop an orally administered, gut-selective pan-JAK inhibitor specifically designed to distribute adequately and predominantly to the tissues of the intestinal tract, treating inflammation in those tissues while minimizing systemic exposure. We are focused on utilizing targeted JAK inhibitors for potential treatment of a range of inflammatory intestinal diseases, including ulcerative colitis and Crohn's disease. TD-1473 is our lead gut-selective pan-JAK inhibitor that is progressing into multiple clinical studies in 2018 and early 2019, as further described below. TD-3504 is a back-up compound that has successfully completed Phase 1 studies in healthy volunteers. Development of TD-3504 has been paused, consistent with the strategy we generally apply to back-up compounds and due to our significant investments in TD-1473.

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

In June 2016, we completed a Phase 1 clinical study of TD-1473, an internally-discovered JAK inhibitor that has demonstrated a high affinity for each of the JAK family of enzymes. The primary objective of the study was to evaluate the safety and tolerability of single ascending and multiple ascending doses of TD-1473 in healthy volunteers. A key secondary objective of the trial was to characterize the pharmacokinetics of TD-1473, including the determination of the amount of TD-1473 that entered systemic circulation following oral administration. Data from the study demonstrated TD-1473 to be generally well tolerated. Study results also demonstrated that systemic exposures of TD-1473 were low relative to that reported for tofacitinib, a JAK inhibitor currently in development for ulcerative colitis. At steady state, the plasma exposures of TD-1473 were significantly lower than the plasma exposure of tofacitinib.

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

Previously announced findings from a preclinical model of colitis evaluating TD-1473 and tofacitinib demonstrated that both compounds significantly reduced disease activity scores. However, at doses providing similar preclinical efficacy, the systemic exposure of TD-1473 was much lower than that of tofacitinib and, in contrast to tofacitinib, TD-1473 did not reduce systemic immune cell counts. Also, we completed six and nine month toxicology studies of TD-1473 and demonstrated favorable safety margins in these studies, in support of the dose ranges planned in the Phase 3 registrational program. Based on these preclinical findings, we believe that TD-1473 represents a potential breakthrough approach to treating inflammatory intestinal diseases without the risk generally associated with systemically active therapies.

Phase 1b Study

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

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

In August 2018, we announced top-line results from the Phase 1b study of TD-1473 in ulcerative colitis. Full results were shared as an oral late-breaker presentation at the United European Gastroenterology Week (“UEGW”) in October 2018.

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Data from the Phase 1b study demonstrated that four weeks of TD-1473 treatment led to signals of biological activity and localized target engagement with low systemic exposures and no evidence of systemic immunosuppression or opportunistic infections in patients with moderately to severely active ulcerative colitis. More specifically, rates of clinical response were higher on all active doses (20, 80, 270 mg) compared with placebo using both partial and total Mayo endpoints, with greatest effect seen at the 270 mg dose. Rectal bleeding scores improved above placebo at the 80 and 270 mg doses. Endoscopic improvements and mucosal healing were reported in all active arms, and none were reported in the placebo arm. Additionally, plasma levels were low and consistent with data from healthy volunteers, and TD-1473 was generally well tolerated at all doses.

Following positive results from the Phase 1b study and completed dialogues with the US Food and Drug Administration ("FDA") and European Medicines Agency ("EMA") regarding study design, we plan to initiate a Phase 2b/3 induction and maintenance study in ulcerative colitis with patient dosing expected to begin in late 2018 or early 2019. In addition, we are currently initiating a Phase 2 induction study of TD-1473 in Crohn's disease.

Janssen Biotech Collaboration

In February 2018, we announced a global co-development and commercialization agreement with Janssen Biotech, Inc. ("Janssen") for TD-1473 and related back-up compounds for inflammatory intestinal diseases, including ulcerative colitis and Crohn's disease. Under the terms of the agreement, we received an upfront payment of $100.0 million and will be eligible to receive up to an additional $900.0 million in potential payments, if Janssen elects to remain in the collaboration following the completion of certain Phase 2 activities. Upon such election, we and Janssen will jointly develop and commercialize TD-1473 in inflammatory intestinal diseases, and we and Janssen will share profits and losses in the US and expenses related to a potential Phase 3 program (67% to Janssen; 33% to Theravance Biopharma). In addition, we would receive royalties on ex-US sales at double-digit tiered percentage royalty rates.

Following completion of the Phase 2 Crohn's study and the Phase 2b induction portion of the ulcerative colitis study, Janssen can elect to obtain an exclusive license to develop and commercialize TD-1473 and certain related compounds by paying us a fee of $200.0 million. The closing of this portion of the transaction is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act ("HSR Act"). After Phase 2, Janssen would lead subsequent development of TD-1473 in Crohn's disease if it makes such election. We will lead development of TD-1473 in ulcerative colitis through completion of the Phase 2b/3 program. If TD-1473 is commercialized, we have the option to co-commercialize in the US, and Janssen would have sole commercialization responsibilities outside the US.

TD 9855

TD-9855 is an investigational, once-daily norepinephrine and serotonin reuptake inhibitor ("NSRI") being developed for the treatment of patients with symptomatic neurogenic orthostatic hypotension ("nOH"). The compound has high affinity for binding to norepinephrine and serotonin transporters. By blocking the action of these transporters, TD-9855 causes an increase in extracellular concentrations of norepinephrine and serotonin.

In May 2016, we initiated a Phase 2 study of TD-9855 in nOH. The initial study design of the Phase 2 trial consisted of two parts. Part A, a single ascending dose study, with doses ranging from 1 mg up to 20 mg based on patient response, was designed to evaluate impact on blood pressure and standing time for TD-9855 as compared to placebo. Part B, a double-blind, single dose study was designed to evaluate impact on blood pressure and standing time for TD-9855 as compared to placebo. Based on encouraging treatment responses in the first part of the study, we amended the study design to allow responders to continue dosing for up to 20 weeks to assess the durability of their response (Part C). Part C, an open label extension to Part A, was designed to evaluate improvement in patients' symptoms and impact on blood pressure. Responders in Part A were eligible to enroll in Part C at up to their highest tolerated Part A dose, which included 5 mg, 10 mg and 20 mg. The primary endpoint of the study was measured after four weeks, although patients can continue to receive medication for up to five months. We believe the ability to demonstrate a durable effect in nOH with TD-9855 could lead to significant benefits for patients over existing therapy.

In August 2018, we announced positive top-line four week data from the Phase 2 trial of TD-9855 for the treatment of nOH. Top-line results from the study included durable improvements in patients' disease symptom severity after four weeks of treatment with TD-9855, as measured by Orthostatic Hypotension Symptom Assessment Question #1 ("OHSA

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#1”). OSHA #1 is a measure of dizziness, lightheadedness, or the sensation of being about to black out. Patients treated in the extension phase of the study showed a mean symptom improvement of 2.4 points at four weeks. Importantly, mean symptom improvement was greatest (3.8 points) in nOH patients who reported dizziness symptoms (OHSA #1 > 4) at baseline. Additionally, TD-9855 consistently increased systolic blood pressure (“SBP”), including clinically meaningful increases in standing SBP at the three-minute assessment on all weekly clinic visits. TD-9855 was generally well tolerated, with no new safety findings attributable to drug observed in the study. Full results will be shared at a future medical meeting. Based on positive top-line four-week results from the Phase 2 study and completed discussions with the FDA regarding the Phase 3 clinical design, we plan to progress TD-9855 into a registrational Phase 3 program in nOH in late 2018 or early 2019.

YUPELRITM (revefenacin) Inhalation Solution

Revefenacin is an investigational long-acting muscarinic antagonist (“LAMA”) under regulatory review as a nebulized, once-daily single-agent for the treatment of COPD under the proposed brand name YUPELRITM inhalation solution, with an FDA PDUFA target action date of November 13, 2018. We believe that YUPELRI 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 US 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. If approved, YUPELRI would be the first and only once-daily, long-acting single-agent product for COPD patients who require, or prefer, nebulized therapy. The therapeutic profile of YUPELRI, together with its physical characteristics, suggest that this LAMA could also serve as a foundation for combination products and for delivery in metered dose inhaler and dry powder inhaler (“MDI/DPI”) products.

Mylan Collaboration

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

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

Under the Mylan Agreement, Mylan paid us an initial payment of $15.0 million in cash in the second quarter of 2015. Also, pursuant to an ordinary share purchase agreement entered into on January 30, 2015, Mylan Inc., the indirect parent corporation of Mylan, made a $30.0 million equity investment in us, buying 1,585,790 ordinary shares from us in February 2015 in a private placement transaction at a price of approximately $18.918 per share, which represented a 10% premium over the volume weighted average price per share of our ordinary shares for the five trading days ending on January 30, 2015. In February 2016, we earned a $15.0 million development milestone payment for achieving 50% enrollment in the Phase 3 twelve-month safety study. As of September 30, 2018, we are eligible to receive from Mylan additional potential development, regulatory and sales milestone payments totaling up to $205.0 million in the aggregate, with $160.0 million associated with YUPELRI monotherapy, and $45.0 million associated with future potential combination products. Of the $160.0 million associated with monotherapy, $150.0 million relates to sales milestones based on achieving certain levels of net sales and $10.0 million relates to regulatory actions in the European Union ("EU"). We do not expect to earn any milestone payments from Mylan in 2018.

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

Phase 3 Study in COPD and NDA Submission

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

In October 2016, we announced positive top-line results from the two replicate Phase 3 efficacy studies of YUPELRI in more than 1,200 moderate to very severe COPD patients, and in May and November 2017 we reported additional data from these studies. Both Phase 3 efficacy studies met their primary endpoints, demonstrating statistically significant improvements over placebo in trough FEV1 after 12 weeks of dosing for each of the YUPELRI doses studied (88 mcg once daily and 175 mcg once daily). The studies also demonstrated that the 88 mcg and 175 mcg doses of YUPELRI were generally well tolerated, with comparable rates of adverse events and serious adverse events across all treatment groups (active and placebo). In July 2017, we announced positive top-line results from the twelve-month safety study in more than 1,000 COPD patients. Data demonstrated that both the 88 mcg and 175 mcg doses of YUPELRI were generally well tolerated, with low rates of adverse events (AEs) and serious adverse events (SAEs), comparable to those seen with the active comparator. Together, the three studies enrolled approximately 2,280 patients.

In November 2017, we submitted to the FDA for filing a NDA for YUPELRI supported by data from the two replicate Phase 3 efficacy studies and twelve-month safety study. In January 2018, the FDA accepted the NDA for filing and assigned a PDUFA target action date of November 13, 2018.

Phase 3b PIFR Study

In March 2017, we initiated a Phase 3b study of YUPELRI in patients with suboptimal peak inspiratory flow rate (“PIFR”). This study is not required for NDA approval and was designed to support commercialization, if YUPELRI is approved. The purpose of the study was to assess whether nebulized YUPELRI was superior to handheld tiotropium (dosed via the Handihaler® device) in a broad population of COPD patients with suboptimal PIFR. The primary endpoint was improvement in lung function, as measured by trough forced expiratory volume in one second (FEV_1) after 4 weeks of treatment.

The PIFR study was completed in the first quarter of 2018. In the overall population of approximately 200 moderate to very severe (GOLD Stage 2/3/4) COPD patients, we saw numerical improvements for YUPELRI over tiotropium, but these improvements were not statistically significant, and as a result the study failed to meet the predefined threshold for superiority. In the pre specified subgroup of severe and very severe (GOLD 3/4) COPD patients, which represented approximately 80% of the patients in the study, YUPELRI demonstrated nominally statistically significant and clinically relevant improvements in trough FEV1 versus tiotropium. Data generated in the study provide important insights to inform future potential studies of YUPELRI in COPD patients with suboptimal PIFR. YUPELRI was well tolerated in this study, with no new safety issues identified. The Company plans to publish the results from this study in a future medical meeting or publication.

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TD-8236

TD-8236 is an internally-discovered inhaled JAK inhibitor that has demonstrated a high affinity and selectivity for each of the JAK family enzymes (JAK1, JAK2, JAK3 and TYK2). Through the inhibition of these kinases, TD-8236 interferes with the JAK/STAT signaling pathway and, in turn, modulates the activity of a wide range of pro-inflammatory cytokines. TD-8236 is an inhaled treatment specifically designed to be delivered exclusively to the lungs with a dry-powder inhaler with minimal systemic exposure. With multiple JAK-dependent pathways clinically validated in asthma and COPD, we believe it offers potentially broad activity across a range of serious respiratory diseases. We plan to initiate a first-in-human Phase 1 study of TD-8236 by the end of 2018.

Velusetrag (TD 5108)

Velusetrag is an oral, investigational medicine developed for gastrointestinal motility disorders. It is a highly selective agonist with high intrinsic activity at the human 5-HT4 receptor. In 2012, we partnered with Alfasigma S.p.A. (“Alfasigma”) (formerly Alfa Wassermann S.p.A.) in the development of velusetrag and its commercialization in certain countries. In April 2014, we announced 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.

In August 2017, we announced positive top-line results from a 12-week, Phase 2b study of velusetrag characterizing the impact on symptoms and gastric emptying of three oral doses of velusetrag (5, 15 and 30 mg) compared to placebo administered once daily over 12 weeks of therapy. Results from the study demonstrated statistically significant improvements in gastroparesis symptoms and gastric emptying for patients receiving 5 mg of velusetrag as compared to placebo. Patients in the 15 and 30 mg velusetrag study arms demonstrated statistically significant improvements in gastric emptying, but they did not experience statistically significant improvements in gastroparesis symptoms. Velusetrag was shown to be generally well tolerated, with 5 mg and placebo having comparable rates of adverse events and serious adverse events. Completion of the Phase 2b study was followed by dialogue with regulatory authorities in the US and EU regarding further development of velusetrag.

In late April 2018, Alfasigma exercised its exclusive option to develop and commercialize velusetrag. As a result, Alfasigma paid us a total of $11.0 million, comprised of the $10.0 million option exercise fee and a $1.0 million non-refundable reimbursement. Additionally, we elected not to pursue further development of velusetrag, based on our planned pipeline investments and in light of the current FDA requirement that a chronically administered gastroparesis product in this class complete a large Phase 3 safety study. Global rights to develop, manufacture and commercialize velusetrag have transferred to Alfasigma under the terms of the existing collaboration agreement. Also under the terms of the collaboration with Alfasigma, we are entitled to receive future potential development, regulatory and commercial milestone payments of up to $26.8 million, and tiered royalties on global net sales ranging from high single digits to the mid-teens.

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 US for the treatment of adult patients with complicated skin and skin structure infections (“cSSSI”) caused by susceptible Gram-positive bacteria and for the treatment of adult patients with hospital-acquired and ventilator-associated bacterial pneumonia (“HABP”/“VABP”) caused by susceptible isolates of Staphylococcus aureus when alternative treatments are not suitable. In addition, in 2016, the FDA allowed us to add new clinical data to the VIBATIV label concerning concurrent bacteremia in cases of HABP/VABP and cSSSI. VIBATIV is also indicated in Canada and Russia for cSSSI and HABP and VABP caused by Gram-positive bacteria, including MRSA.

Our acute care sales force currently markets VIBATIV in the US, and we maintain an independent marketing and medical affairs team. This same organization will support YUPELRI, if approved in the US, alongside our partner for the program. Outside of the US, we market VIBATIV through a network of partners. To date, we have secured partners for VIBATIV in the following geographies: Canada, Middle East and North Africa, Israel, Russia, China and India.

Given the challenges we faced commercializing VIBATIV in the US in a highly competitive environment against a variety of generic drugs, we reduced and closely managed our overall spending in 2018 related to the product while preparing for and investing in the potential commercial launch of YUPELRI as a treatment for COPD. We continue to view VIBATIV as an important medicine to treat serious infections in very sick patients.

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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.

In February 2018, the study stopped enrolling new patients following an interim analysis conducted by an independent review committee and company-wide review of investment priorities. The committee concluded the study was underpowered and therefore unlikely to achieve the primary study objective, without a significant increase in study size beyond the planned sample size of approximately 250 patients. Given the incremental investment required, we elected to close the study. No new safety issues were identified in the study, and as a result, patients previously enrolled were allowed to complete dosing.

Telavancin Observational Use Registry (“TOURTM”) Study

Initiated in February 2015, the 1,000-patient TOURTM study is designed to assess the manner in which VIBATIV is used by healthcare practitioners to treat patients. By broadly collecting and examining data related to VIBATIV treatment patterns, as well as clinical effectiveness and safety outcomes in medical practice, we aim to create an expansive knowledge base to guide clinical use and future development of the drug. Data from this study is providing information about the use of VIBATIV in real-world clinical settings, including reports of positive clinical responses in patients with bacteremia, endocarditis, osteomyelitis, skin and respiratory infections. During 2017, we concluded the TOURTM registry study and completed the data base.

Janssen Pharmaceutica License Agreement

In 2002, we entered into a License Agreement with Janssen Pharmaceutica N.V. (“Janssen Pharmaceutica”) pursuant to which we have licensed rights under certain patents owned by Janssen Pharmaceutica covering an excipient used in the formulation of telavancin. Pursuant to the terms of this license agreement, we are obligated to pay royalties to Janssen Pharmaceutica of 2.5% to 5% of any net commercial sales of VIBATIV (telavancin). The license will terminate in 2019 on the later of 10 years from first commercial sale of VIBATIV and the date of expiration of the last applicable Janssen Pharmaceutica patent covering VIBATIV. The license is terminable by us upon prior written notice to Janssen Pharmaceutica or upon an uncured breach or a liquidation event of one of the parties.

Cumberland Pharmaceuticals Inc. Asset Purchase Agreement

On November 1, 2018, we entered into an Asset Purchase Agreement (the “Agreement”) with Cumberland Pharmaceuticals Inc. (“Cumberland”) pursuant to which Cumberland will acquire from us assets related to the manufacture, marketing and sale of VIBATIV (telavancin) (“VIBATIV” or the “Product”).

Upon the consummation of the transaction contemplated by the Agreement (the “Transaction”), Cumberland will pay us (i) $20.0 million at the closing of the Transaction, (ii) $5.0 million on or before April 1, 2019 and (iii) tiered royalties of up to 20% of US net sales of the Product until such time as royalties cumulatively total $100.0 million.

In connection with the Transaction, Cumberland will acquire, among other things, (i) intellectual property rights relating to the Product, (ii) active pharmaceutical ingredient for the Product, work-in-process and finished drug product, (iii) the US marketing authorization for the Product, (iv) certain assigned contracts relating to the manufacture and commercialization of the Product, and (v) books and records related to the Product. Cumberland will also assume certain clinical study obligations related to the Product and post-closing liabilities and obligations relating to the Product as described in the Agreement. The Company has agreed to provide transition services to Cumberland for limited periods of time following the consummation of the Transaction. The Transaction is expected to close in mid-November 2018, subject to customary closing conditions.

Neprilysin (NEP) Inhibitor Program (TD-0714 and TD-1439)

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 for this program is to develop a NEP inhibitor that could be used across a broad population of patients with cardiovascular and renal diseases, including acute and chronic heart failure and chronic kidney disease, including diabetic nephropathy. We aim to create a platform for multiple combination products with our NEP inhibitor with features that are differentiated from currently available products. Our NEP inhibitor program consists of two compounds (TD-0714 and TD-1439), each of which demonstrated characteristics in line with our target product profile in Phase 1 studies in healthy volunteers.

TD-0714

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

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

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

TD-1439

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

We are evaluating next steps for both compounds in our NEP inhibitor program clinical program. The results from the Phase 1 programs provide confidence for pursuing future efficacy studies of either compound in a broad range of cardiovascular and renal diseases, including in patients with compromised renal function.

Selective 5-HT4 Agonist (TD-8954)

Takeda Collaborative Arrangement

In June 2016, we entered into a License and Collaboration Agreement with Millennium Pharmaceuticals, Inc., a Delaware corporation (“Millennium”) (the “Takeda Agreement”), in order to establish a collaboration for the development and commercialization of TD-8954 (TAK-954), a selective 5-HT4 receptor agonist. Millennium is an indirect wholly-owned subsidiary of Takeda Pharmaceutical Company Limited (TSE: 4502), a publicly-traded Japanese corporation listed on the Tokyo Stock Exchange (collectively with Millennium, “Takeda”). TD-8954 is being developed for potential use in the treatment of gastrointestinal motility disorders. Under the terms of the Takeda Agreement, Takeda will be responsible for worldwide development and commercialization of TD-8954. We received an upfront cash payment of $15.0 million and will be eligible to receive success-based development, regulatory and sales milestone payments by Takeda. The first $110.0 million of potential milestones are associated with the development, regulatory and commercial launch milestones for EFI or other intravenously dosed indications. We will also be eligible to receive a tiered royalty on worldwide net sales by Takeda at percentage royalty rates ranging from low double-digits to mid-teens.

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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 to Theravance Respiratory Company, LLC ("TRC") pursuant to its agreements with Innoviva (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters) relating to the GSK-Partnered Respiratory Programs, which Innoviva partnered with GSK and assigned to TRC in connection with Innoviva's separation of its biopharmaceutical operations into its then wholly-owned subsidiary Theravance Biopharma in June 2014. The GSK-Partnered Respiratory Programs consist primarily of the Trelegy Ellipta program and the inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist ("MABA") program, each of which are described in more detail below. We are entitled to this economic interest through our equity ownership in TRC. Our economic interest does not include any payments associated with RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO® ELLIPTA® or vilanterol monotherapy. The following information regarding the Trelegy Ellipta and MABA programs is based solely upon publicly available information and may not reflect the most recent developments under the programs.

Trelegy Ellipta (the combination of fluticasone furoate/umeclidinium bromide/vilanterol)

Trelegy Ellipta is the first treatment to provide the activity of an inhaled corticosteroid (FF) plus two bronchodilators (UMEC, a LAMA, and VI, a long-acting beta2 agonist, or LABA) in a single delivery device administered once-daily. Trelegy Ellipta is approved for use in the US and EU for the long-term, once-daily, maintenance treatment of appropriate patients with COPD. We are entitled to receive an 85% economic interest in the royalties payable by GSK to TRC on worldwide net sales (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters). Those royalties are upward-tiering from 6.5% to 10%, resulting in cash flows to Theravance Biopharma of approximately 5.5% to 8.5% of worldwide net sales of Trelegy Ellipta. Theravance Biopharma is not responsible for any costs related to Trelegy Ellipta.

Innoviva and GSK conducted two global pivotal Phase 3 studies of Trelegy Ellipta in COPD, the IMPACT study and the FULFIL study.

The IMPACT study, which enrolled 10,355 COPD patients, was initiated in July 2014. In September 2017, GSK and Innoviva disclosed positive headline results from the IMPACT study, in which data demonstrated statistically significant reductions in the annual rate of on-treatment moderate/severe exacerbations for Trelegy Ellipta (100/62.5/25mcg) when compared with two, once-daily dual COPD therapies RELVAR® ELLIPTA®/BREO®

ELLIPTA® (FF/VI), an ICS/LABA combination, and ANORO® ELLIPTA® (UMEC/VI), a LAMA/LABA combination. In addition, statistically significant improvements were observed across all pre-specified key secondary endpoints and associated treatment comparisons.

The FULFIL study, which enrolled 1,810 COPD patients, was initiated in February 2015. In June 2016, GSK and Innoviva disclosed positive top line results from the FULFIL study, in which data demonstrated superiority of Trelegy Ellipta as compared to twice daily SYMBICORT® TURBOHALER® (budesonide/formoterol) in improving lung function and health related quality of life, as well as reducing exacerbations in COPD patients.

In September 2017, GSK and Innoviva announced that the US FDA approved Trelegy Ellipta for the long-term, once-daily, maintenance treatment of appropriate patients with COPD. In April 2018, GSK and Innoviva announced the FDA approved a sNDA containing data from the IMPACT study, resulting in an expanded indication for the product. The updated indication is for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. It is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations. In addition, the FDA removed a boxed warning from Trelegy Ellipta prescribing information.

In December 2017, GSK and Innoviva announced that the European Commission granted marketing authorization for Trelegy Ellipta as a maintenance treatment for appropriate patients with COPD.

In February 2018, GSK and Innoviva announced the submission of the IMPACT data to the EMA as part of a type II variation to support an expanded label for Trelegy Ellipta in Europe for the maintenance treatment of moderate to severe COPD. Approval of the submission would mean Trelegy Ellipta, the only once-daily single inhalation triple therapy for the

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treatment of COPD, could be used by physicians to treat a wider population of patients with the condition who are at risk of an exacerbation and require triple therapy. In September 2018, GSK and Innoviva announced the EMA Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion supporting the submission and that labelling, if approved, will be updated to further reflect its effect on exacerbations of COPD.

Additionally, in December 2016, GSK and Innoviva announced the initiation of the Phase 3 (CAPTAIN) study of Trelegy Ellipta in patients with asthma. The CAPTAIN study is expected to be completed in 2019.

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.

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 (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters), which royalties range between 10% and 20% of annual global net sales up to $3.5 billion, and 7.5% for all annual global net sales above $3.5 billion. If a MABA medicine containing ‘081 is commercialized only as a combination product, such as ‘081/FF, the royalty rate is 70% of the rate applicable to sales of the single-agent MABA medicine. If a MABA medicine containing ‘081 is successfully developed and commercialized in multiple regions of the world, TRC is eligible to receive contingent milestone payments from GSK. The agreements allow for total milestones of up to $125.0 million for a single-agent medicine and an incremental $125.0 million for a combination medicine. Of these amounts, $112.0 million in potential milestones remain for a single-agent medicine, and $122.0 million remain for a combination medicine. In each case, we would be entitled to receive an 85% economic interest in any such payments (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters).

Theravance Respiratory Company, LLC (“TRC”)

Our equity interest in TRC is the mechanism by which we are entitled to the 85% economic interest in any future payments made by GSK under the strategic alliance agreement and under the portion of the collaboration agreement assigned to TRC by Innoviva (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters). The royalty payments from GSK to TRC arising from the net sales of Trelegy Ellipta are presented on our condensed consolidated statements of operations under “Income from investment in TRC, LLC” and is considered non-operating income. The drug programs assigned to TRC include all Trelegy Ellipta products 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 US 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 policies 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, 2017.

Revenue Recognition

Effective January 1, 2018, we adopted Accounting Standards Codification, Topic 606, Revenue from Contracts with Customers (“ASC 606”) using the modified retrospective method. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects

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to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

At contract inception, once the contract is determined to be within the scope of ASC 606, we identify the performance obligations in the contract by assessing whether the goods or services promised within each contract are distinct. We then recognize revenue for the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Sales

We sell VIBATIV in the US market by making the drug product available through a limited number of distributors, who sell VIBATIV to healthcare providers. Title and risk of loss transfer upon receipt by these distributors. We recognize VIBATIV product sales and related cost of product sales when the distributors obtain control of the drug product, which is at the time title transfers to the distributors.

Product sales are recorded on a net sales basis which includes estimates of variable consideration. The variable consideration results from sales discounts, government mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions. We reflect such reductions in revenue as either an allowance to the related account receivable from the distributor, or as an accrued liability, depending on the nature of the sales deduction. Sales deductions are based on management's estimates that consider payor mix in target markets, industry benchmarks and experience to date. In general, these estimates take into consideration a range of possible outcomes which are probability-weighted in accordance with the expected value method in ASC 606. We monitor inventory levels in the distribution channel, as well as sales of VIBATIV by distributors to healthcare providers, using product specific data provided by the distributors. Product return allowances are based on amounts owed or to be claimed on related sales. These estimates take into consideration the terms of our agreements with customers, historical product returns of VIBATIV, rebates or discounts taken, estimated levels of inventory in the distribution channel, the shelf life of the product, and specific known market events, such as competitive pricing and new product introductions. We update our estimates and assumptions each quarter and if actual future results vary from our estimates, we may adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment.

Sales Discounts: We offer cash discounts to certain customers as an incentive for prompt payment. We expect our customers to comply with the prompt payment terms to earn the cash discount. In addition, we offer contract discounts to certain direct customers. We estimate sales discounts based on contractual terms, historical utilization rates, as available, and our expectations regarding future utilization rates. We account for sales discounts by reducing accounts receivable by the expected discount and recognizing the discount as a reduction of revenue in the same period the related revenue is recognized.

Chargebacks and Government Rebates: For VIBATIV sales in the US, we estimate reductions to product sales for qualifying federal and state government programs including discounted pricing offered to Public Health Service ("PHS"), as well as government managed Medicaid programs. Our reduction for PHS is based on actual chargebacks that distributors have claimed for reduced pricing offered to such healthcare providers and our expectation about future utilization rates. Our accrual for Medicaid is based upon statutorily defined discounts, estimated payor mix, expected sales to qualified healthcare providers, and our expectation about future utilization. The Medicaid accrual and government rebates that are invoiced directly to us are recorded in other accrued liabilities on the condensed consolidated balance sheets. For qualified programs that can purchase our products through distributors at a lower contractual government price, the distributors charge back to us the difference between their acquisition cost and the lower contractual government price, which we record as an allowance against accounts receivable.

Distribution Fees: We have contracts with our distributors in the US that include terms for distribution related fees. We determine distribution related fees based on a percentage of the product sales price, and we record the distribution fees as an allowance against accounts receivable.

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Product Returns: We offer our distributors a right to return product purchased directly from us, which is principally based upon the product's expiration date. Our policy is to accept product returns during the six months prior to and twelve months after the product expiration date on product that has been sold to our distributors. Product return allowances are based on amounts owed or to be claimed on related sales. These estimates take into consideration the terms of our agreements with customers, historical product returns of VIBATIV, rebates or discounts taken, estimated levels of inventory in the distribution channel, the shelf life of the product, and specific known market events, such as competitive pricing and new product introductions. We record our product return reserves as other accrued liabilities.

Allowance for Doubtful Accounts: We record allowances for potentially doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. As of September 30, 2018, there was no allowance for doubtful accounts related to customer payments.

The following table summarizes activity in each of the product revenue allowance and reserve categories for the nine months ended September 30, 2018.

(In thousands)	Chargebacks, Discounts and Fees	Government and Other Rebates	Returns	Total
Balance at December 31, 2017	$ 992	$ 352	$ 947	$ 2,291
Provision related to current period sales	5,277	560	365	6,202
Adjustment related to prior period sales	(81)	142	(449)	(388)
Credit or payments made during the period	(5,126)	(562)	(131)	(5,819)
Balance at September 30, 2018	$ 1,062	$ 492	$ 732	$ 2,286

We adopted ASC 606 on January 1, 2018 using the modified retrospective method. Our comparative prior period revenue remains reported under Accounting Standards Codification, Topic 605, Revenue Recognition ("ASC 605"). Our revenue recognition policy under ASC 605 for the comparative 2017 periods is included in our Annual Report on Form 10-K for the year ended December 31, 2017.

Collaborative Arrangements

We enter into collaborative arrangements with partners that fall under the scope of Accounting Standards Codification, Topic 808, Collaborative Arrangements ("ASC 808"). While these arrangements are in the scope of ASC 808, we may analogize to ASC 606 for some aspects of the arrangements. We analogize to ASC 606 for certain activities within the collaborative arrangement for the delivery of a good or service (i.e., a unit of account) that is part of our ongoing major or central operations.

The terms of our collaborative arrangements typically include one or more of the following: (i) up-front fees; (ii) milestone payments related to the achievement of development, regulatory, or commercial goals; (iii) royalties on net sales of licensed products; (iv) reimbursements or cost-sharing of R&D expenses; and (v) profit/loss sharing arising from co-promotion arrangements. Each of these payments results in collaboration revenues or an offset against R&D expense. Where a portion of non refundable up-front fees or other payments received are allocated to continuing performance obligations under the terms of a collaborative arrangement, they are recorded as deferred revenue and recognized as collaboration revenue when (or as) the underlying performance obligation is satisfied.

As part of the accounting for these arrangements, we must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation which determines how the transaction price is allocated among the performance obligations. The estimation of the stand-alone selling price may include such estimates as, forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. We evaluate each performance obligation to determine if they can be satisfied at a point in time or over time, and we measure the services delivered to our collaborative partner which are periodically reviewed based on the progress of the related program. The effect of any change made to an estimated input component and, therefore revenue or expense recognized, would be recorded as a change in estimate. In addition, variable consideration (e.g., milestone payments) must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

Up-front Fees: If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize collaboration revenues from transaction price allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from the allocated transaction price. For example, when we receive up-front fees for the performance of research and development services, or when research and development services are not considered to be distinct from a license, we recognize collaboration revenue for those units of account over time using a measure of progress. We evaluate the measure of progress each at reporting period and, if necessary, adjust the measure of performance and related revenue or expense recognition as a change in estimate.

Milestone Payments: At the inception of each arrangement that includes milestone payments (variable consideration), we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our or the collaboration partner’s control, such as non-operational developmental and regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, we re-evaluate the probability of achievement of milestones that are within our or the collaboration partner’s control, such as operational developmental milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues and earnings in the period of adjustment. Revisions to our estimate of the transaction price may also result in negative collaboration revenues and earnings in the period of adjustment.

Royalties: For arrangements that include sales-based royalties, including commercial milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any material royalty revenue resulting from any of our collaborative arrangements.

Reimbursement, cost-sharing and profit-sharing payments: Under certain collaborative arrangements, we have been reimbursed for a portion of our R&D expenses or participate in the cost-sharing of such R&D expenses. Such reimbursements and cost-sharing arrangements have been reflected as a reduction of R&D expense in our condensed consolidated statements of operations, as we do not consider performing research and development services for reimbursement to be a part of our ongoing major or central operations. Therefore, the reimbursement or cost-sharing of research and development services are recorded as a reduction of R&D expense.

Under the terms of our collaboration agreement with Mylan for revefenacin, including YUPELRITM inhalation solution, we are also entitled to a share of US profits and losses (65% to Mylan/35% to Theravance Biopharma) received in connection with commercialization of YUPELRITM, and we are entitled to low double-digit royalties on ex-US net sales (excluding China). If and when YUPELRI is approved, we expect that Mylan will be the principal in the sales transaction, and as a result, we will not reflect the product sales on our records. Until YUPELRI is approved and our collaboration activities are profitable, our share of the expenses under a co-promote arrangement are recorded within R&D expense and selling, general and administrative expense on our condensed consolidated statements of operations. See “Note 3. Collaborative Arrangements” in the notes to the condensed consolidated financial statements for additional information about our collaboration agreement with Mylan.

Theravance Respiratory Company, LLC (“TRC”)

Through our equity ownership of TRC, we are entitled to receive an 85% economic interest in any future payments that may be made by Glaxo Group or one of its affiliates (“GSK”) relating to the GSK-Partnered Respiratory Programs (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters). The GSK-Partnered Respiratory Programs consist primarily of the Trelegy Ellipta program and the inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist (“MABA”) program.

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We analyzed our ownership, contractual and other interests in TRC to determine if it is a variable interest entity ("VIE"), whether we have a variable interest in TRC and the nature and extent of that interest. We determined that TRC is a VIE. The party with the controlling financial interest, the primary beneficiary, is required to consolidate the entity determined to be a VIE. Therefore, we also assessed whether we are the primary beneficiary of TRC based on the power to direct its activities that most significantly impact its economic performance and our obligation to absorb its losses or the right to receive benefits from it that could potentially be significant to TRC. Based on our assessment, we determined that we are not the primary beneficiary of TRC, and, as a result, we do not consolidate TRC in our consolidated financial statements. TRC is recognized in our consolidated financial statements under the equity method of accounting. Income related to our equity ownership of TRC is reflected in our consolidated statement of operations as non-operating income.

Results of Operations

Product Sales and Revenue from Collaborative Arrangements

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

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
(In thousands)	2018	2017	$	%	2018	2017	$	%
Product sales	$ 3,849	$ 4,140	$ (291)	(7) %	$ 12,889	$ 10,664	$ 2,225	21 %
Revenue from collaborative arrangements	8,989	135	8,854	NM	31,744	207	31,537	NM
Total revenue	$ 12,838	$ 4,275	$ 8,563	200 %	$ 44,633	$ 10,871	$ 33,762	311 %

NM: Not Meaningful

Revenue from product sales decreased by $0.3 million and increased $2.2 million for the three and nine months ended September 30, 2018, respectively, compared to the same periods in 2017. The $0.3 million decrease for the three months ended September 30, 2018 was primarily due to a decrease in VIBATIV sales volume outside of the US. The $2.2 million increase for the nine months ended September 30, 2018 was primarily due to an increase in VIBATIV sales volume and pricing.

Revenue from collaborative arrangements increased by $8.9 million and $31.5 million for the three and nine months ended September 30, 2018, respectively, compared to the same periods in 2017. The $8.9 million increase for the three months ended September 30, 2018 was primarily attributed to the portion of recognized revenue related to the $100.0 million upfront payment from the Janssen collaboration agreement that was entered into in February 2018. The $31.5 million increase for the nine months ended September 30, 2018 was primarily comprised of $10.0 million attributed to the April 2018 exercise by Alfasigma of its option to develop and commercialize velusetrag and $21.0 million related to the Janssen collaboration agreement as noted above.

Cost of Goods Sold

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

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
(In thousands)	2018	2017	$	%	2018	2017	$	%
Cost of goods sold	$ 705	$ 985	$ (280)	(28) %	$ 83	$ 2,914	$ (2,831)	(97) %

Cost of goods sold decreased by $0.3 million and $2.8 million for the three and nine months ended September 30, 2018, respectively, compared to the same periods in 2017. The $0.3 million decrease for the three months ended September 30, 2018 was primarily due to a decrease in global sales volume. The $2.8 million decrease for the nine months ended September 30, 2018 was primarily due to a reversal of a $2.3 million charge taken in 2017 related to inventory purchase commitments. In the fourth quarter of 2017, we accrued a $2.3 million liability related to excess inventory purchase commitments based on our expected purchase obligations at the time. For the second quarter of 2018, we reversed the expense related to the $2.3 million purchase commitment liability due to the waiver of our minimum purchase commitment by our third-party manufacturer. In addition to the inventory charge reversal noted above, costs of goods sold also decreased for the three and nine months ended September 30, 2018 due to a $0.6 million write-off of inventory taken in the second quarter of 2017.

Research and Development

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

1) Employee-related costs, which include salaries, wages and benefits;

2) Share-based compensation, which includes expenses associated with our equity plans;

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

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

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

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
(In thousands)	2018	2017	$	%	2018	2017	$	%
Employee-related	$ 14,591	$ 11,333	$ 3,258	29 %	$ 46,977	$ 38,155	$ 8,822	23 %
Share-based compensation	6,294	5,005	1,289	26	19,757	15,023	4,734	32
External-related	23,340	15,170	8,170	54	55,673	47,225	8,448	18
Facilities, depreciation and other allocated expenses	8,468	7,835	633	8	26,672	22,432	4,240	19
	$ 52,693	$ 39,343	$ 13,350	34 %	$ 149,079	$ 122,835	$ 26,244	21 %

Total research &
development

R&D expenses increased by $13.4 million for the three months ended September 30, 2018 compared to same period in 2017. The increase was primarily due to a $3.3 million increase in employee-related expenses, a $1.3 million increase in share-based compensation, and an $8.2 million increase in external-related expenses. The increase in employee-related expenses was primarily due to a $1.6 million increase in compensation and benefits associated with incremental headcount hired to support our key programs, and a $1.6 million decrease in employee-related expense reimbursements under certain collaborative arrangements. The increase in share-based compensation was primarily due to the issuance of new share-based awards. The increase in external-related expenses was primarily due to the advancement of TD-1473 (our gut-selective pan-JAK inhibitor) into a Phase 2 study in Crohn's disease and a Phase 2b/3 study in ulcerative colitis, continued development of TD-9855 (a norepinephrine serotonin reuptake inhibitor ("NSRI")) in neurogenic orthostatic hypotension ("nOH"), and continued investment in our research and preclinical programs.

R&D expenses increased by $26.2 million for the nine months ended September 30, 2018, compared to the same period in 2017. The increase was primarily attributed to an $8.8 million increase in employee-related expenses, a $4.7 million increase in share-based compensation, an $8.4 million increase in external-related expenses, and a $4.2 million increase in facilities and other allocated expenses. The increase in employee-related expenses was primarily due to a $5.0 million increase in compensation, benefits, and headcount, and a $3.8 million decrease in employee-related expense reimbursements under certain collaborative arrangements. The increase in share-based compensation was comprised of $4.7 million related to the issuance of new share-based awards, $1.2 million related to our long-term retention and incentive bonus awards granted to certain employees in 2016 which are dependent on the Company meeting its critical operating goals and objectives during a five-year period from 2016 to December 31, 2020, and a $1.2 million partial offset related to the phase-out of long-term retention and incentive awards granted to certain employees in 2011 and terminations. As described above, the increase in

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external-related expenses was primarily driven by the advancement of TD-1473 into later stage clinical development and the continued investment in our research and preclinical programs. The increase in facilities and other allocated expenses was primarily due to the extension of our office and laboratory lease in South San Francisco and an increase in other allocable expenses.

Under certain of our collaborative arrangements, we receive partial reimbursement of employee-related costs and external costs, which have been reflected as a reduction of R&D expenses of $3.2 million and $5.8 million for the three months ended September 30, 2018 and 2017, respectively, and $6.5 million and $17.8 million for the nine months ended September 30, 2018 and 2017, respectively. The decreases in expense reimbursements were primarily attributed to the completion of the Phase 3 program and submission of the NDA for YUPELRI, a program we are co-developing with Mylan.

Selling, General and Administrative Expenses

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

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
(In thousands)	2018	2017	$	%	2018	2017	$	%
Selling, general and administrative	$ 21,890	$ 20,944	$ 946	5 %	$ 71,601	$ 66,069	$ 5,532	8 %

For the three months ended September 30, 2018, selling, general and administrative expenses increased by $0.9 million, relatively unchanged compared to the same period in 2017. For the nine months ended September 30, 2018, selling, general and administrative expenses increased by $5.5 million, compared to the same period in 2017. The increase was primarily attributed to a $3.3 million increase in share-based compensation, a $2.8 million increase in employee-related expenses associated with incremental headcount hired to support our key programs, a $2.7 million increase in external-related expenses, and a partial offset by a $3.6 million decrease in facilities and other allocated expenses. The increase in share-based compensation was primarily comprised of $4.3 million related to the issuance of new share-based awards, $1.0 million related to our long-term retention and incentive bonus awards granted to certain employees in 2016 which are dependent on the Company meeting its critical operating goals and objectives during a five-year period from 2016 to December 31, 2020, and a $2.1 million partial offset related to the phase-out of long-term retention and incentive awards granted to certain employees in 2011 and terminations. The increase in employee-related expenses was primarily due to a $2.8 million increase in compensation, benefits, and headcount, and the increase in external-related expenses was primarily due to $2.6 million in non-recurring legal-related expenses. The decrease in facilities and other allocated expenses was primarily due to decreases in other allocable expenses and a partial offset by increases related to the extension of our office and laboratory lease in South San Francisco.

Income from Investment in TRC, LLC

Income from investment in TRC, as compared to the comparable periods in the prior year, was as follows:

(In thousands)	Three Months Ended September 30, 2018	2017	Change $	%	Nine Months Ended September 30, 2018	2017	Change $	%
Income from investment in TRC, LLC	$ 3,119	$ —	$ 3,119	NM %	$ 5,754	$ —	$ 5,754	NM %

NM: Not Meaningful

Income from investment in TRC was $3.1 million and $5.8 million for the three and nine months ended September 30, 2018, respectively. The investment income in TRC was generated by royalty payments from GSK to TRC arising from the net sales of Trelegy Ellipta which was launched in the fourth quarter of 2017. There was no income from TRC in the comparable prior year periods.

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Interest Expense

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

(In thousands)	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Change $	Change %	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017	Change $	Change %
Interest expense	$ 2,137	$ 2,136	$ 1	0 %	$ 6,411	$ 6,410	$ 1	0 %

Interest expense for the three and nine months ended September 30, 2018 was largely unchanged compared to the same periods in 2017 and was attributed to the November 2016 issuance of $230.0 million principal amount of 3.250% convertible senior notes due 2023.

Other-Than-Temporary Impairment Loss

Other-than-temporary impairment loss, as compared to the comparable periods in the prior year, was as follows:

(In thousands)	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Change $	Change %	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017	Change $	Change %
Other-than-temporary impairment loss	$ —	$ 8,000	$ (8,000)	NM %	$ —	$ 8,000	$ (8,000)	NM %

NM: Not Meaningful

For the three and nine months ended September 30, 2017, we recognized an impairment loss of $8.0 million on our investment in Trek Therapeutics, PBC, a non-marketable equity security, which we determined to be other-than-temporary. We had no such loss recorded in the comparable periods in 2018.

Interest and Other Income, net

Interest and other income, as compared to the comparable periods in the prior year, was as follows:

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
(In thousands)	2018	2017	$	%	2018	2017	$	%
Interest and other income, net	$ 1,376	$ 1,124	$ 252	22 %	$ 4,144	$ 3,579	$ 565	16 %

Interest and other income for the three and nine months ended September 30, 2018 increased by $0.3 million and $0.6 million, respectively, compared to the same periods in 2017. The increases for both periods were primarily due to increases in interest income related to higher interest rates earned on our investments.

Provision for Income Tax (Benefit)

The provision for income taxes, as compared to the comparable periods in the prior year, was as follows:

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
(In thousands)	2018	2017	$	%	2018	2017	$	%
Provision for income tax (benefit)	$ (659)	$ 868	$ (1,527)	(176) %	$ (7,305)	$ 6,705	$ (14,010)	(209) %

The net benefit for income taxes for the nine months ended September 30, 2018 was due to the uncertain tax positions taken with respect to transfer pricing and tax credits, offset by tax benefits arising from an updated estimate of a tax filing position to be reported in our tax returns filed in 2018 and the reversal of previously accrued contingent tax liabilities due to a lapse of the statute of limitations. The provision for income taxes decreased by $1.5 million and $14.0 million for the three and nine months ended September 30, 2018, respectively, compared to the same period in 2017. The differences were primarily attributed to the aforementioned tax benefits, in addition to incrementally lower estimates of uncertain tax positions for 2018.

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Liquidity and Capital Resources

We have financed our operations primarily through public offering of equity and debt securities, private placements of equity, revenue from collaboration arrangements and revenue from product sales. As of September 30, 2018, we had approximately $320.6 million in cash, cash equivalents, and investments in marketable securities. Also, as of September 30, 2018, we had outstanding $230.0 million in aggregate principal amount of 3.250% convertible senior notes due 2023.

We expect to continue to incur net losses over at least the next several years due to significant expenditures relating to our continuing drug discovery efforts, preclinical and clinical development of our current product candidates and, if YUPELRI is approved, commercialization costs relating to YUPELRI. In particular, to the extent we advance our product candidates into and through later stage clinical studies without a partner, we will incur substantial expenses. We expect the clinical development of our key development programs will require significant investment in order to continue to advance in clinical development. In addition, we expect to invest strategically in our research efforts to continue to grow our development pipeline. In the past, we have received a number of significant payments from collaboration agreements and other significant transactions. In the future, we expect to receive revenues from product sales and potential substantial payments from future collaboration transactions if the drug candidates in our pipeline achieve positive clinical or regulatory outcomes. In addition, we recently began recognizing investment income arising from our economic interest in royalties payable by GSK to TRC. Our current business plan is subject to significant uncertainties and risks as a result of, among other factors, clinical program outcomes, whether, when and on what terms we are able to enter into new collaboration arrangements, expenses being higher than anticipated, the sales levels of any approved products, unplanned expenses, cash receipts being lower than anticipated, and the need to satisfy contingent liabilities, including litigation matters and indemnification obligations.

Adequacy of cash resources to meet future needs

We expect our cash and cash equivalents and marketable securities will fund our operations for at least the next 12 months from the issuance date of these condensed consolidated financial statements based on current operating plans and financial forecasts.

We may seek to obtain additional financing in the form of public or private equity offerings, debt financing or additional collaborations and licensing arrangements. However, future financing may not be available in amounts or on terms acceptable to us, if at all.

Without adequate financial resources to fund our operations as presently conducted, we may be required to relinquish rights to our technologies, product candidates or territories, or grant licenses on terms that are not favorable to us, in order to raise additional funds through collaborations or licensing arrangements. We may also have to sequence preclinical 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:

	Nine Months Ended September 30,		
(In thousands)	2018	2017	Change
Net cash used in operating activities	$ (60,689)	$ (156,850)	$ 96,161
Net cash provided by (used in) investing activities	77,315	(97,583)	174,898
Net cash (used in) provided by financing activities	(4,404)	1,025	(5,429)

Cash flows used in operating activities

For the nine months ended September 30, 2018, the $60.7 million used in operating activities consisted primarily of net loss of $165.3 million, adjusted for non-cash items such as $39.6 million for share-based compensation expense, and $67.9 million of net cash inflow related to changes in operating assets and liabilities primarily driven by the $100.0 million

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upfront payment in February 2018 from the Janssen collaborative agreement. Overall, net cash used in operating activities decreased by $96.2 million, compared to the same period in 2017, primarily driven by the upfront payment from Janssen.

Net cash used in operating activities was $156.9 million for the nine months ended September 30, 2017, consisting primarily of net loss of $198.5 million, adjusted for non cash items such as $31.4 million for share based compensation expense, $8.0 million for other-than-temporary impairment loss on our non-marketable equity securities and $1.4 million of net cash outflow related to changes in operating assets and liabilities for the nine months ended September 30, 2017.

Cash flows provided by (used in) investing activities

Net cash provided by investing activities was $77.3 million for the nine months ended September 30, 2018, consisting primarily of net cash inflow resulting from the purchases and maturities of marketable securities of $83.0 million which was partially offset by $5.7 million in cash outflow related to the acquisition of property and equipment.

Net cash used in investing activities was $97.6 million for the nine months ended September 30, 2017, consisting primarily of net cash outflows resulting from the purchases and maturities of marketable securities of $95.4 million.

Cash flows (used in) provided by financing activities

Net cash used in financing activities was $4.4 million for the nine months ended September 30, 2018, primarily consisting of $8.5 million of cash outflow for the repurchase of shares to satisfy tax withholding obligations which was partially offset by $4.0 million of cash inflow from employee share plan purchases and share option exercises.

Net cash provided by financing activities was $1.0 million for the nine months ended September 30, 2017, consisting of net cash inflows of $8.4 million from the proceeds from employee option exercises and employee stock plan purchases which was partially offset by the sale of shares to satisfy tax withholding obligations of $7.3 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 September 30, 2018.

Performance-Contingent Awards

In 2016, we granted long-term retention and incentive restricted share awards (“RSAs”) and restricted share units (“RSUs”) to members of senior management and long-term retention and incentive cash bonus awards to certain employees. The vesting and payout of such awards is dependent on the Company meeting its critical operating goals and objectives during a five-year period from 2016 to December 31, 2020. These goals are strategically important for the Company, and we believe the goals, if achieved, will increase shareholder value. The awards have dual triggers of vesting based upon the achievement of these goals and continued employment, and they are broken into three separate tranches. We determined that achievement of the requisite performance conditions for the first tranche were completed as of June 30, 2018. The maximum potential remaining expense associated with the second and third tranches of this program is $18.6 million related to share-based compensation expense and $24.7 million related to cash bonus expense, which would be recognized in increments based on achievement of the performance conditions. With the completed achievement of the first tranche’s requisite performance conditions and the second tranche being probable due to achievement of certain performance conditions and multiple advancements of programs within our development pipeline, we have recognized $47,000 and $3.5 million in share-based compensation expense and $0.7 million and $5.7 million in cash bonus expense for the three and nine months ended September 30, 2018, respectively. We determined that the remaining third tranche was not probable of vesting and, as a result, no compensation expense related to this tranche has been recognized to date.

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, 2017, filed with the SEC on February 28, 2018.

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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, 2017, filed with the SEC on February 28, 2018.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks as of September 30, 2018 have not changed materially from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on February 28, 2018.

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 September 30, 2018, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined under Rule 13a-15(e) of the Exchange Act), which are controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Exchange Act is recorded, processed, summarized and reported within required time periods. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Limitations on the Effectiveness of Controls

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

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act, which occurred during the third quarter of the year ending December 31, 2018 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 Annual Report on Form 10 K 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., 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 and nine months ended September 30, 2018 and the years ended December 31, 2017 and 2016, we recognized losses of $59.4 million, $165.3 million, $285.4 million and $190.7 million, respectively, which are reflected in the shareholders’ equity (deficit) on our consolidated balance sheets. We reflect cumulative net loss incurred after June 2, 2014, the effective date of our spin-off from Innoviva, Inc. (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 our approved products (if any). In particular, to the extent we continue to advance our product candidates into and through additional clinical studies, we will incur substantial expenses. For example, in August 2017, we announced our decision to accelerate funding associated with the next phase of development of our gut-selective pan-Janus kinase (“JAK”) inhibitor program, and in August 2018 we announced that we intend to progress TD-9855 into a Phase 3 registrational program. We are also making additional investments in YUPELRI in anticipation of potential approval. We currently incur all of the costs and expenses associated with the commercialization of VIBATIV in the US, including the maintenance of an independent sales and marketing organization with appropriate technical expertise, supporting infrastructure and distribution capabilities, a medical affairs presence, manufacturing and third-party vendor logistics and consultant support, and post-marketing studies. We plan to continue to incur commercialization expenses on similar investments if YUPELRI is approved for sale in the US. Our commitment of resources to the continued development of our existing product candidates, our discovery programs, and our products (if any) 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 (i) potential revenues from sales of YUPELRI, if it is approved, (ii) our economic interest in royalties from net sales of Trelegy Ellipta paid to TRC, and (iii) potential payments under collaboration agreements, we do not expect to generate revenues in the immediate future. Since we or our collaborators or licensees may not successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost or with appropriate

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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 those product candidates in development that receive regulatory approval or other sources of revenues, we will continue to incur operating losses and will require additional capital to execute our business strategy. The likelihood of reaching, and the time required to reach, and then to sustain, profitability are highly uncertain. As a result, we expect to continue to incur substantial losses for the foreseeable future. We are uncertain when or if we will ever be able to achieve or sustain profitability. Failure to become and remain profitable would adversely affect the price of our securities and our ability to raise capital and continue operations.

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

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

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

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Any adverse developments or results or perceived adverse developments or results with respect to our clinical programs including, without limitation, any delays in development in our programs, any halting of development in our programs, any difficulties or delays encountered with regard to the FDA or other regulatory authorities with respect to our programs, or any indication from clinical or non-clinical studies that the compounds in our programs are not safe or efficacious, could have a material adverse effect on our business and cause the price of our securities to fall.

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

The FDA must approve any new medicine before it can be marketed and sold in the US. We will not obtain this approval for a product candidate unless and until the FDA approves an NDA. We, or our collaborative partners, must provide the FDA and similar foreign regulatory authorities with data from preclinical and clinical studies that demonstrate that our product candidates are safe and effective for a defined indication before they can be approved for commercial distribution. FDA or foreign regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. The processes by which regulatory approvals are obtained from the FDA and foreign regulatory authorities to market and sell a new product are complex, require a number of years, depend upon the type, complexity and novelty of the product candidate and involve the expenditure of substantial resources for research, development and testing. The FDA has substantial discretion in the drug approval process and may require us to conduct additional nonclinical and clinical testing or to perform post-marketing studies. Further, the implementation of new laws and regulations, and revisions to FDA clinical trial design guidance may lead to increased uncertainty regarding the approvability of new drugs. In addition, the FDA has additional standards for approval of new drugs, including recommended advisory committee meetings for certain new molecular entities, and formal risk evaluation and mitigation requirements at the FDA's discretion. Even if we receive regulatory approval of a product, the approval may limit the indicated uses for which the drug may be marketed or impose significant restrictions or limitations on the use and/or distribution of such product.

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

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. However, our current operating plans or financial forecasts occasionally change. For example, in 2016, our actual operating loss exceeded our anticipated operating loss, primarily because of accelerated enrollment in TOUR, increased funding for the development of our JAK inhibitors and increased investment in our neprilysin ("NEP") inhibitor program. In August 2017, we announced an increase in our anticipated operating loss for 2017, primarily driven by our decision to accelerate funding associated with the next phase of development of our JAK inhibitor program. 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.

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 any approved products and to prepare for potential product approvals;
- support our independent sales and marketing organization and medical affairs team;

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- support our additional investments in YUPELRI in anticipation of potential approval;
- progress any additional product candidates into later-stage development without funding from a collaboration partner;
- 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 any approved products and our product candidates;
- our facilities expenses, which will vary depending on the time and terms of any facility lease or sublease we may enter into, and other operating expenses;
- the scope and extent of the expansion of our sales and marketing efforts;
- potential litigation and other contingencies; and
- the regulatory approval process for our product candidates.

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

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

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

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

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

We have an exclusive development and commercialization agreement with Alfasigma S.p.A. (“Alfasigma”) (formerly Alfa Wassermann S.p.A.) for velusetrag, our internally discovered 5-HT4 agonist for the treatment of gastromotility disorders, under which we are transferring to Alfasigma global rights for velusetrag. In January 2015, we entered into a collaboration agreement with Mylan for the development and commercialization of a nebulized formulation of our LAMA revefenacin, including YUPELRI. Under the terms of the agreement, we and Mylan will co-develop nebulized revefenacin, including YUPELRI, for COPD and other respiratory diseases. In June 2016, we entered into a License and Collaboration Agreement with Millennium Pharmaceuticals, Inc., an indirect wholly-owned subsidiary of Takeda Pharmaceutical Company Limited (collectively with Millennium, “Takeda”) in order to establish a collaboration for the development and commercialization of TD-8954, a selective 5-HT4 receptor agonist. Under the terms of the Agreement, Takeda is responsible for worldwide development and commercialization of TD-8954. In February 2018, we announced a global co-development and commercialization agreement with Janssen for TD-1473 and related back-up compounds for inflammatory intestinal diseases, including ulcerative colitis and Crohn's disease. On November 1, 2018, we entered into an Asset Purchase Agreement with Cumberland Pharmaceuticals Inc. (“Cumberland”) pursuant to which Cumberland will acquire from us assets related to the manufacture, marketing and sale of VIBATIV (telavancin) as contemplated by the Agreement (the “Transaction”). The Transaction is expected to close in mid-November 2018, subject to customary closing conditions. In connection with these agreements, these parties have certain rights regarding the use of patents and technology with respect to the compounds in our development programs, including development and marketing rights.

We also currently have commercialization agreements with various partners for the commercialization of VIBATIV outside of the US, including Canada, Middle East, North Africa, Israel, Russia, China and India. In August 2016, we and Clinigen reached a mutual decision that Clinigen will return commercial rights to market and distribute VIBATIV in the EU to Theravance Biopharma and, since we do not intend to commercialize VIBATIV in the EU without a partner and have been unable to secure another partner to commercialize VIBATIV in the EU, in early 2018 we withdrew VIBATIV's EU marketing authorization.

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

We do not control TRC and, in particular, have no control over the GSK-Partnered Respiratory Programs or access to non-public information regarding the development of 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") (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters), which agreements govern Innoviva's and GSK's respective interests in the GSK-Partnered Respiratory Programs. Our equity interest covers various drug programs including all Trelegy Ellipta (the combination of fluticasone furoate, umeclidinium, and vilanterol in a single ELLIPTA® inhaler, previously referred to as the Closed Triple) products 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 work GSK and Innoviva are undertaking with respect to the GSK-Partnered Respiratory Programs and no right to enforce rights under the GSK Agreements assigned to TRC. Moreover, we have many of the same risks with respect to our and TRC's dependence on GSK as we have with respect to our dependence on our own partners.

If there are any adverse developments or perceived adverse developments with respect to the GSK-Partnered Respiratory Programs in which we have a substantial economic interest, including Trelegy Ellipta and the MABA program, our business will be harmed, and the price of our securities could fall.

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

- GSK deciding to delay or halt of any of the GSK-Partnered Respiratory Programs in which we have a substantial economic interest;
- the FDA and/or other regulatory authorities determining that any of the studies under these programs do not demonstrate adequate safety or efficacy, or that additional non-clinical or clinical studies are required with respect to such programs;
- any safety, efficacy or other concerns regarding any of the GSK-Partnered Respiratory Programs in which we have a substantial economic interest;
- any particular FDA requirements or changes in FDA policy or guidance regarding these programs;

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- the emergence of new closed triple or other alternative therapies or any developments regarding these potentially competitive therapies, comparative price or efficacy of such potentially competitive therapies;
- disappointing or lower than expected sales of Trelegy Ellipta; or
- disputes between GSK and Innoviva or between us and Innoviva.

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

Based on our review of publicly available filings, as of September 30, 2018 GSK beneficially owned approximately 17.4% of our outstanding ordinary shares. GSK is also a strategic partner to Innoviva with rights and obligations under the GSK Agreements, which include the strategic alliance agreement and the collaboration agreement assigned to TRC, that may cause GSK's interests to differ from our interests and those of our other shareholders. In particular, following the approval of Trelegy Ellipta in the US and if a MABA/ICS is approved in either the US or the EU, GSK's diligent efforts obligations under the GSK Agreements with regard to commercialization matters will have the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK Agreements. GSK's commercialization efforts will be guided by a portfolio approach across products in which we have an indirect interest through TRC and products in which we have no interest. Accordingly, GSK's commercialization efforts may have the effect of reducing the value of our interest in TRC. Furthermore, GSK has a substantial respiratory product portfolio in addition to the products covered by the GSK Agreements. GSK may make respiratory product portfolio decisions or statements about its portfolio which may be, or may be perceived to be, harmful to the respiratory products partnered with Innoviva and TRC. For example, GSK could promote its own respiratory products and/or delay or terminate the development or commercialization of the respiratory programs covered by the GSK Agreements. Also, given the potential future royalty payments GSK may be obligated to pay under the GSK Agreements, GSK may seek to acquire us or acquire our interests in TRC in order to effectively reduce those payment obligations and the price at which GSK might seek to acquire us may not reflect our true value. Before 2018, the actions GSK could have taken to acquire us were limited under our governance agreement with GSK (the "Governance Agreement"), but this agreement expired on December 31, 2017. In May 2018, our shareholders approved a resolution authorizing our board of directors to adopt a shareholder rights plan in the future which may deter GSK from acquiring more than 19.9% of our outstanding ordinary shares. However, our board of directors might not adopt such shareholder rights plan, and we otherwise might not be able to respond successfully to a takeover attempt. The timing of when GSK may seek to acquire us could potentially be when it possesses information regarding the status of drug programs covered by the GSK Agreements that has not been publicly disclosed and is not otherwise known to us. As a result of these differing interests, GSK may take actions that it believes are in its best interest but which might not be in the best interests of either us or our other shareholders. In addition, GSK could also seek to challenge our or Innoviva's post-Spin-Off operations as violating or allowing it to terminate the GSK Agreements, including by violating the confidentiality provisions of those agreements or the master agreement between GSK, Innoviva and us entered into in connection with the Spin-Off (the "Master Agreement"), or otherwise violating its legal rights. While we believe our operations fully comply with the GSK Agreements, the Master Agreement and applicable law, there can be no assurance that we or Innoviva will prevail against any such claims by GSK. Moreover, regardless of the merit of any claims by GSK, we may incur significant cost and diversion of resources in defending them. In addition, any other action or inaction by either GSK or Innoviva that results in a material dispute, allegation of breach, litigation, arbitration, or significant disagreement between those parties or between us and either of those parties may be interpreted negatively by the market or by our investors, could harm our business and cause the price of our securities to fall. Examples of these kinds of issues include but are not limited to non-performance of contractual obligations and allegations of non-performance, disagreements over the relative marketing and sales efforts for Innoviva's partnered products and other GSK respiratory products, disputes over public statements, and similar matters. In general, any uncertainty about the respiratory programs partnered with GSK, the enforceability of the GSK Agreements or the relationship/partnership between Innoviva and GSK could result in significant reduction in the market price of our securities and other material harm to our business.

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

Our compounds in clinical trials and our future leads for potential drug compounds are subject to the risks and failures inherent in the development of pharmaceutical products. These risks include, but are not limited to, the inherent

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difficulty in selecting the right drug and drug target and avoiding unwanted side effects, as well as unanticipated problems relating to product development, testing, enrollment, obtaining regulatory approvals, maintaining regulatory compliance, manufacturing, competition and costs and expenses that may exceed current estimates.

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

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

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

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

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

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

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

Any new medicine that competes with a generic or proprietary market leading medicine must demonstrate compelling advantages in efficacy, convenience, tolerability and/or safety in order to overcome severe price competition and be commercially successful. For example, VIBATIV must demonstrate these advantages in certain circumstances, as it competes with vancomycin, linezolid and daptomycin, relatively inexpensive generic drugs that are manufactured by a number of companies, and a number of existing antibacterial drugs marketed by major and other pharmaceutical companies. If approved as the first once daily nebulized LAMA, YUPELRI would be expected to compete predominantly with short acting nebulized bronchodilators used three to four times per day and the nebulized LAMA LonhalaTM MagnairTM (SUN-101/eFlow®) used twice per day. If we are not able to compete effectively against our current and future competitors, our business will not grow, our financial condition and operations will suffer and the price of our securities could fall.

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 Janssen for TD-1473 and related back-up compounds for inflammatory intestinal diseases, including ulcerative colitis and Crohn's disease, Mylan for the development and commercialization of a nebulized formulation of revefenacin, our LAMA compound (including YUPELRI), Alfasigma for velusetrag, Takeda for the development and commercialization of a selective 5-HT4 receptor agonist (TD-8954) and, if the Transaction is successfully consummated, Cumberland for 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. 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 to commercialize the product candidates in our programs if approved by the necessary regulatory authorities. We evaluate commercial strategy on a product by product basis either to engage pharmaceutical or other healthcare companies with an existing sales and marketing organization and distribution system to market, sell and distribute our products or to commercialize a product ourselves. However, we may not be able to establish these sales and distribution relationships on acceptable terms, or at all, or may encounter difficulties in commercializing a product ourselves. For any of our product candidates that receive regulatory approval in the future and are not covered by our current collaboration agreements, we will need a partner in order to commercialize such products unless we establish independent sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure.

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

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

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

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

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

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

Our manufacturing strategy presents the following additional risks:

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

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

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

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capital markets and our financial condition at such time. We may not be able to engage in any of these activities on desirable terms or at all, which could result in a default on the Notes or future indebtedness.

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

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

We rely extensively on computer systems to maintain information and manage our finances and business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including but not limited to trade secrets or other intellectual property, proprietary business information and personal information) and it is critical that we maintain the confidentiality and integrity of such confidential information. Although we have security measures in place, our internal information technology systems and those of our CROs and other service providers, including cloud-based and hosted applications, data and services, are vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, service providers and/or business partners, from cyber-attacks by malicious third parties, and/or from, natural disasters, terrorism, war and telecommunication and electrical failures. Cyber-attacks are increasing in their frequency, sophistication, and intensity, and have become increasingly difficult to detect. Significant disruptions of information technology systems or security breaches could adversely affect our business operations and result in financial, legal, business and reputational harm to us, including significant liability and/or significant disruption to our business. If a disruption of information technology systems or security breach results in a loss of or damage to our data or regulatory applications, unauthorized access, use, or disclosure of, or the prevention of access to, confidential information, or other harm to our business, we could incur liability and reputational harm, we could be required to comply with federal and/or state breach notification laws and foreign law equivalents, we may incur legal expenses to protect our confidential information, the further development of our product candidates could be delayed and the price of our securities could fall. For example, the loss of clinical trial data from completed or ongoing clinical trials of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Although we have security and fraud prevention measures in place, we have been subject to immaterial payment fraud activity. In 2017, we filed a lawsuit (which has since been resolved) against a former employee for misappropriation of our confidential, proprietary and trade secret information. Moreover, there can be no assurance that such security measures will prevent service interruptions or security breaches that could adversely affect our business.

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

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

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

In addition, our US operating subsidiary's facility and most of its employees are located in northern California, headquarters to many other biotechnology and biopharmaceutical companies and many academic and research institutions. As a result, competition for certain skilled personnel in our market is intense. None of our employees have employment commitments for any fixed period of time and they all may leave our employment at will. If we fail to retain our qualified personnel or replace them when they leave, we may be unable to continue our development and commercialization activities and the price of our securities could fall.

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

Worldwide economic conditions remain uncertain due to the decision by the United Kingdom to initiate the formal procedure of withdrawal from the EU (often referred to as “Brexit”), current economic challenges in Asia and other disruptions to global and regional economies and markets.

Brexit has created significant uncertainty about the future relationship between the United Kingdom and the EU, including with respect to the laws and regulations that will apply as the United Kingdom determines which EU laws to replace or replicate in the event of a withdrawal. From a regulatory perspective, the United Kingdom's withdrawal could bear significant complexity and risks. In addition, the exact terms of the United Kingdom's withdrawal and the laws and regulations that will apply after the United Kingdom withdraws from the EU would affect manufacturing sites that hold an EU manufacturing authorization issued by the United Kingdom competent authorities. The referendum has also given rise to calls for the governments of other EU Member States to consider withdrawal from the EU.

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

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

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

The Transaction with Cumberland may not be successfully consummated and, as VIBATIV has not been broadly accepted by physicians, patients, third-party payors, or the medical community in general, and we may never generate significant revenue or profits from VIBATIV.

The Transaction with Cumberland may not be successfully consummated as it currently remains subject to closing conditions. The commercial success of VIBATIV depends upon its acceptance by physicians, patients, third-party payors and the medical community in general. VIBATIV may not be sufficiently accepted by these parties. VIBATIV competes with vancomycin (which accounts for a substantial majority of patient treatment days), linezolid and daptomycin, all relatively inexpensive generic drugs that are manufactured by a variety of companies, and a number of existing antibacterials manufactured and marketed by major pharmaceutical companies and others, and may compete against new antibacterials that are not yet on the market. To date, VIBATIV has not been broadly accepted by physicians, patients, third-party payors, or the medical community in general, we believe primarily due to the availability of low cost generic antibiotic products such as vancomycin and daptomycin. If VIBATIV is not accepted as a preferred injectable treatment for treating the infections for which it is indicated, we may never generate significant revenue or profits from VIBATIV.

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Unless and until the Transaction with Cumberland is consummated, we are responsible for marketing, sales and distribution of VIBATIV in the US and we may bear similar costs with respect to additional products in the future, including YUPELRI if approved, which subjects us to certain risks.

We currently maintain a limited sales force in the US and plan to continue to augment our sales and marketing personnel to support our co-promotion obligations under our agreement with Mylan should YUPELRI be approved. The risks of continuing to support VIBATIV in the US without a partner if the Transaction is not consummated and fulfilling our US co-promotion obligations to Mylan if YUPELRI is approved include:

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

If we are not successful in maintaining an internal sales and marketing organization with appropriate experience, technical expertise, supporting infrastructure, distribution capability and the ability to obtain access to and educate adequate numbers of physicians about prescribing YUPELRI (if approved) and VIBATIV (if the Transaction with Cumberland is not consummated), in appropriate clinical situations, we will have difficulty commercializing these products, which would adversely affect our business and financial condition and the price of our securities could fall.

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

We currently have a single source of supply of API for telavancin and another, separate single source of supply of VIBATIV drug product. If, for any reason, either single-source third-party manufacturer of telavancin API or of VIBATIV drug product is unable or unwilling to perform, or if the performance of either does not meet regulatory requirements, including maintaining cGMP compliance, we may not be able to obtain sufficient quantities of API or drug product in a timely manner. We expect it would take approximately 24 months for an alternative manufacturer to be qualified by us and begin producing drug product for us. We have sufficient quantities of VIBATIV drug product on hand to meet the currently anticipated needs until approximately the first quarter of 2020. This supply was manufactured by Pfizer, our single source manufacturer for VIBATIV, at its McPherson, Kansas facility. Pfizer received an FDA warning letter relating to a 2016 inspection of this facility and was notified that the FDA closed out the warning letter for the facility in June 2018. We have manufactured additional VIBATIV drug product at this facility in 2018, which is in the process of being released. Given the time required to locate and qualify another acceptable drug product manufacturer, any supply delay, suspension or cessation in the manufacture and release of

VIBATIV drug product could adversely affect the commercialization of VIBATIV and our current obligations to our partners. Similarly, any inability to acquire sufficient quantities of API in a timely manner from current or future sources would adversely affect the commercialization of VIBATIV and our ability to satisfy our current obligations to our partners. If either of these were to occur, our business would be harmed.

Our current agreement with Pfizer to supply VIBATIV drug product was entered into May 2012. In June 2013, the FDA approved Pfizer as a VIBATIV drug product manufacturer. In September 2016, we amended our agreement with Pfizer to extend the term of the agreement to December 31, 2020. In July 2018, Pfizer notified us that it will not renew our agreement after it expires at the end of 2020, though it remains committed to manufacturing under our agreement until the end of the contract's term. We are currently in the process of qualifying another manufacturer to supply VIBATIV drug product for us. Although we believe that our new supplier will be qualified and able to manufacture VIBATIV drug product for us after 2020, there can be no assurance in this regard. We may need to arrange for the advance manufacture and purchase of VIBATIV drug product in order to manage the transition to a new supplier and such advance manufacturing and purchasing entails significant uncertainties, including the risk of purchasing excess or insufficient quantities relative to our future needs and the possible expiration of excess inventories. Any difficulties in continuing or transitioning our single source suppliers would adversely affect the commercialization of VIBATIV and our ability to satisfy our obligations to our partners and the price of our securities could fall.

We are subject to extensive and ongoing regulation, oversight and other requirements by the FDA with respect to VIBATIV and failure to comply with these regulations and requirements may subject us to penalties that may adversely affect our financial condition or our ability to commercialize VIBATIV, if the Transaction with Cumberland is not consummated and we continue to commercialize VIBATIV, and, if approved, YUPELRI will be subject to similar FDA regulations, oversight and requirements. .

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

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

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

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

Under the Pediatric Research Equity Act (PREA), the FDA also requires that we conduct two pediatric pharmacokinetic studies, one Phase 3 randomized, comparator-controlled study in pediatric patients with

Gram-positive infections, as well as a study gathering data regarding the treatment of cSSSI in pediatric patients. If we are unable to meet the applicable deadlines for any of these studies, FDA may issue us a non-compliance letter, to which will be required to respond within 45 days. FDA's non-compliance letter and our response will be posted publicly on the FDA website. If we continue to be unable to meet our deadlines, FDA may deem VIBATIV to be misbranded and, on that basis, VIBATIV could be subject to injunction proceedings or seizure by FDA.

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

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

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

Failure to satisfy required post-approval requirements and/or commitments may have implications for a product's approval and may carry civil monetary penalties. Any failure to maintain regulatory approval will limit our ability to commercialize VIBATIV (if the Transaction is not consummated), YUPELRI (if approved) or any future product candidates and if we fail to comply with FDA regulations and requirements regarding VIBATIV (if the Transaction is not consummated), YUPELRI (if approved) or any future product candidates, the FDA could potentially take a number of enforcement actions against us, including the issuance of untitled letters, warning letters, preventing the introduction or delivery of the product into interstate commerce in the United States, misbranding charges, product seizures, injunctions, and civil monetary penalties, which would materially and adversely affect our business and financial condition and may cause the price of our securities to fall.

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

We and/or our collaboration partners may face competition from companies seeking to market generic versions of any approved products in which we have an interest, such as VIBATIV or, if approved, YUPELRI.

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

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

We may be treated as a US corporation for US federal income tax purposes.

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

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

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

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

Taxing authorities may challenge our structure and transfer pricing arrangements.

We are incorporated in the Cayman Islands, maintain subsidiaries in the Cayman Islands, the United States, the United Kingdom and Ireland, and effective July 1, 2015, we migrated our tax residency from the Cayman Islands to Ireland. Due to economic and political conditions, various countries are actively considering changes to existing tax laws. We cannot predict the form or timing of potential legislative changes that could have a material adverse impact on our results of operations. We are aware that Ireland is expected to implement certain tax law changes to comply with the European Union Anti-Tax Avoidance Directives. These changes will include the first ever Irish controlled foreign company (CFC) rules which will be effective on January 1, 2019. It is also expected that Ireland will implement certain transfer pricing rule changes, most likely with effect from 2020. We are currently evaluating the applicability of the CFC rules published in Finance Bill 2018. Until these rules are enacted, they remain subject to possible change, but our current assessment is that the rules are unlikely to have a material impact on our operations. Proposed statutory language has not yet been provided for transfer pricing rule changes and, as a result, we have not yet been able to determine the impact, if any, of such future legislation on our operations.

In addition, significant judgment is required in determining our worldwide provision for income taxes. Various factors may have favorable or unfavorable effects on our income tax rate including, but not limited to the performance of certain functions and ownership of certain assets in tax-efficient jurisdictions such as the Cayman Islands and Ireland, together with intra-group transfer pricing agreements. Taxing authorities may challenge our structure and transfer pricing arrangements through an audit or lawsuit. Responding to or defending such a challenge could be expensive and consume time and other resources, and divert management's time and focus from operating our business. We cannot predict whether taxing authorities will conduct an audit or file a lawsuit challenging this structure, the cost involved in responding to any such audit or lawsuit, or the outcome. We may be required to pay taxes for prior periods, interest, fines or penalties, and may be obligated to pay increased taxes in the future which could result in reduced cash flows a