

**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, 2019

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 (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit 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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class
Ordinary Share \$0.00001 Par Value

Trading Symbol
TBPH

Name of each exchange on which registered
The Nasdaq Global Market

As of October 25, 2019, the number of the registrant's outstanding ordinary shares was 56,762,307.

[Table of Contents](#)

THERAVANCE BIOPHARMA, INC.
TABLE OF CONTENTS

	<u>Page No.</u>
PART I. FINANCIAL INFORMATION	
<u>Item 1. Financial Statements</u>	
<u>Condensed Consolidated Balance Sheets as of September 30, 2019 and December 31, 2018 (unaudited)</u>	3
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2019 and 2018 (unaudited)</u>	4
<u>Condensed Consolidated Statements of Shareholders' Equity (Deficit) for the three and nine months ended September 30, 2019 and 2018 (unaudited)</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2019 and 2018 (unaudited)</u>	6
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	7
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	21
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	34
<u>Item 4. Controls and Procedures</u>	35
PART II. OTHER INFORMATION	
<u>Item 1. Legal Proceedings</u>	35
<u>Item 1A. Risk Factors</u>	36
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	68
<u>Item 6. Exhibits</u>	69
<u>Signatures</u>	70

[Table of Contents](#)

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 102,403	\$ 378,021
Short-term marketable securities	217,278	127,255
Accounts receivable, net of allowances of \$0 at September 30, 2019 and December 31, 2018	87	620
Receivables from collaborative arrangements	4,595	10,053
Amounts due from TRC, LLC	16,661	5,422
Short-term restricted cash	7,496	—
Other prepaid and current assets	7,132	11,452
Total current assets	<u>355,652</u>	<u>532,823</u>
Property and equipment, net	12,189	13,176
Long-term marketable securities	24,939	11,869
Operating lease assets	46,755	—
Tax receivable	3,664	—
Restricted cash	833	833
Other assets	1,305	1,534
Total assets	<u>\$ 445,337</u>	<u>\$ 560,235</u>
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accounts payable	\$ 8,713	\$ 9,028
Accrued personnel-related expenses	25,801	23,803
Accrued clinical and development expenses	10,907	11,876
Accrued interest payable	7,568	3,086
Non-recourse notes due 2033, net	8,701	—
Operating lease liabilities	6,833	—
Deferred revenue	33,751	43,402
Other accrued liabilities	6,549	7,359
Total current liabilities	<u>108,823</u>	<u>98,554</u>
Convertible senior notes due 2023, net	225,622	224,818
Non-recourse notes due 2033, net	222,008	229,535
Deferred rent	—	7,976
Long-term operating lease liabilities	48,620	—
Long-term deferred revenue	14,169	26,179
Other long-term liabilities	8,900	24,762
Commitments and contingencies		
Shareholders' 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; 56,762 and 55,681 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	1	1
Additional paid-in capital	1,000,094	960,721
Accumulated other comprehensive income (loss)	94	(166)
Accumulated deficit	<u>(1,182,994)</u>	<u>(1,012,145)</u>
Total shareholders' deficit	<u>(182,805)</u>	<u>(51,589)</u>
Total liabilities and shareholders' deficit	<u>\$ 445,337</u>	<u>\$ 560,235</u>

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue:				
Product sales	\$ —	\$ 3,849	\$ —	\$ 12,889
Collaboration revenue	8,836	8,989	21,666	31,744
Licensing revenue	—	—	18,500	—
Mylan collaboration agreement	3,591	—	3,749	—
Total revenue	12,427	12,838	43,915	44,633
Costs and expenses:				
Cost of goods sold	—	705	—	83
Research and development (1)	52,006	52,693	152,223	149,079
Selling, general and administrative (1)	25,622	21,890	73,035	71,601
Total costs and expenses	77,628	75,288	225,258	220,763
Loss from operations	(65,201)	(62,450)	(181,343)	(176,130)
Income from investment in TRC, LLC	7,197	3,119	21,792	5,754
Interest expense	(8,068)	(2,137)	(23,827)	(6,411)
Interest and other income, net	2,089	1,376	7,258	4,144
Loss before income taxes	(63,983)	(60,092)	(176,120)	(172,643)
Provision for income tax benefit	5,552	659	5,271	7,305
Net loss	<u>\$ (58,431)</u>	<u>\$ (59,433)</u>	<u>\$ (170,849)</u>	<u>\$ (165,338)</u>
Net unrealized (loss) gain on available-for-sale investments	(35)	194	260	402
Total comprehensive loss	<u>\$ (58,466)</u>	<u>\$ (59,239)</u>	<u>\$ (170,589)</u>	<u>\$ (164,936)</u>
Net loss per share:				
Basic and diluted net loss per share	\$ (1.05)	\$ (1.10)	\$ (3.08)	\$ (3.07)
Shares used to compute basic and diluted net loss per share	<u>55,858</u>	<u>54,248</u>	<u>55,445</u>	<u>53,771</u>

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

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	\$ 6,458	\$ 6,294	\$ 18,338	\$ 19,757
Selling, general and administrative	6,561	5,452	18,200	19,842
Total share-based compensation expense	<u>\$ 13,019</u>	<u>\$ 11,746</u>	<u>\$ 36,538</u>	<u>\$ 39,599</u>

See accompanying notes to condensed consolidated financial statements.

[Table of Contents](#)

THERAVANCE BIOPHARMA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)
(Unaudited)
(In thousands)

	<u>Ordinary Shares</u>	<u>Additional Paid-In Capital</u>	<u>Accumulated Other Comprehensive Income (Loss)</u>	<u>Accumulated Deficit</u>	<u>Total Shareholders' Deficit</u>
	Shares	Amount			
Balances at June 30, 2019	56,637	\$ 1	\$ 987,209	\$ (1,124,563)	\$ (137,224)
Proceeds from ESPP purchases	—	—	—	—	—
Employee share-based compensation expense	—	—	13,019	—	13,019
Issuance of restricted shares	209	—	—	—	—
Option exercises	29	—	428	—	428
Repurchase of shares to satisfy tax withholding	(113)	—	(562)	—	(562)
Net unrealized loss on marketable securities	—	—	(35)	—	(35)
Net loss	—	—	—	(58,431)	(58,431)
Balances at September 30, 2019	<u>56,762</u>	<u>\$ 1</u>	<u>\$ 1,000,094</u>	<u>\$ 94</u>	<u>\$ (1,182,994)</u>
					<u>\$ (182,805)</u>

	<u>Ordinary Shares</u>	<u>Additional Paid-In Capital</u>	<u>Accumulated Other Comprehensive Income (Loss)</u>	<u>Accumulated Deficit</u>	<u>Total Shareholders' Deficit</u>
	Shares	Amount			
Balances at December 31, 2018	55,681	\$ 1	\$ 960,721	\$ (166)	\$ (51,589)
Proceeds from ESPP purchases	145	—	2,605	—	2,605
Employee share-based compensation expense	—	—	36,538	—	36,538
Issuance of restricted shares	898	—	—	—	—
Option exercises	151	—	2,973	—	2,973
Repurchase of shares to satisfy tax withholding	(113)	—	(2,743)	—	(2,743)
Net unrealized gain on marketable securities	—	—	260	—	260
Net loss	—	—	—	(170,849)	(170,849)
Balances at September 30, 2019	<u>56,762</u>	<u>\$ 1</u>	<u>\$ 1,000,094</u>	<u>\$ 94</u>	<u>\$ (1,182,994)</u>
					<u>\$ (182,805)</u>

	<u>Ordinary Shares</u>	<u>Additional Paid-In Capital</u>	<u>Accumulated Other Comprehensive Income (Loss)</u>	<u>Accumulated Deficit</u>	<u>Total Shareholders' Deficit</u>
	Shares	Amount			
Balances at June 30, 2018	55,104	\$ 1	\$ 937,437	\$ (525)	\$ (902,526)
Proceeds from ESPP purchases	—	—	—	—	—
Employee share-based compensation expense	—	—	11,730	—	11,730
Issuance of restricted shares	242	—	—	—	—
Option exercises	64	—	1,225	—	1,225
Repurchase of shares to satisfy tax withholding	—	—	(1,548)	—	(1,548)
Net unrealized gain on marketable securities	—	—	194	—	194
Net loss	—	—	—	(59,433)	(59,433)
Balances at September 30, 2018	<u>55,410</u>	<u>\$ 1</u>	<u>\$ 948,844</u>	<u>\$ (331)</u>	<u>\$ (961,959)</u>
					<u>\$ (13,445)</u>

	<u>Ordinary Shares</u>	<u>Additional Paid-In Capital</u>	<u>Accumulated Other Comprehensive Income (Loss)</u>	<u>Accumulated Deficit</u>	<u>Total Shareholders' Deficit</u>
	Shares	Amount			
Balances at December 31, 2017	54,381	\$ 1	\$ 913,650	\$ (733)	\$ (797,740)
Proceeds from ESPP purchases	135	—	2,742	—	2,742
Employee share-based compensation expense	—	—	39,599	—	39,599
Issuance of restricted shares	971	—	—	—	—
Option exercises	69	—	1,306	—	1,306
Cumulative effect upon the adoption of ASC 606	—	—	—	1,119	1,119
Repurchase of shares to satisfy tax withholding	(146)	—	(8,453)	—	(8,453)
Net unrealized gain on marketable securities	—	—	402	—	402
Net loss	—	—	—	(165,338)	(165,338)
Balances at September 30, 2018	<u>55,410</u>	<u>\$ 1</u>	<u>\$ 948,844</u>	<u>\$ (331)</u>	<u>\$ (961,959)</u>
					<u>\$ (13,445)</u>

See accompanying notes to condensed consolidated financial statements.

[Table of Contents](#)

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

	Nine Months Ended September 30,	
	2019	2018
Operating activities		
Net loss	\$ (170,849)	\$ (165,338)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,676	3,195
Amortization and accretion income, net	(2,599)	(887)
Share-based compensation	36,538	39,599
Reversal of inventory purchase commitment liability	—	(2,250)
Amortization of right-of-use assets	3,029	—
Undistributed earnings from investment in TRC, LLC	(11,239)	(2,803)
Other	148	(68)
Changes in operating assets and liabilities:		
Accounts receivable	534	(771)
Receivables from collaborative arrangements	5,458	3,202
Other prepaid and current assets	(681)	(493)
Inventories	—	(552)
Tax receivable	(3,700)	5,092
Other assets	3	(115)
Accounts payable	(543)	(1,665)
Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued liabilities	(9,846)	(14,324)
Accrued interest payable	4,482	—
Deferred rent	—	3,370
Deferred revenue	(21,661)	79,266
Operating lease liabilities	(2,307)	—
Other long-term liabilities	(5,288)	(5,147)
Net cash used in operating activities	(173,845)	(60,689)
Investing activities		
Purchases of property and equipment	(1,873)	(5,740)
Purchases of marketable securities	(366,412)	(166,412)
Maturities of marketable securities	266,168	249,450
Proceeds from the sale of VIBATIV business, net	5,000	—
Proceeds from the sale of fixed assets	5	17
Net cash (used in) provided by investing activities	(97,112)	77,315
Financing activities		
Proceeds from ESPP purchases	2,605	2,742
Proceeds from option exercises	2,973	1,306
Repurchase of shares to satisfy tax withholding	(2,743)	(8,452)
Net cash provided by (used in) financing activities	2,835	(4,404)
Net (decrease) increase in cash, cash equivalents, and restricted cash	(268,122)	12,222
Cash, cash equivalents, and restricted cash at beginning of period	378,854	89,813
Cash, cash equivalents, and restricted cash at end of period	\$ 110,732	\$ 102,035
Supplemental disclosure of cash flow information		
Cash paid for interest	\$ 17,097	\$ 3,738
Cash paid (received) for income taxes, net	\$ 22	\$ (5,027)
Right-of-use assets obtained in exchange for lease obligations (1)	\$ 49,847	\$ —

(1) Amounts for the nine months ended September 30, 2019 include the transition adjustment for the adoption of ASC 842.

See accompanying notes to condensed consolidated financial statements.

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

1. Organization and Summary of Significant Accounting Policies

Theravance Biopharma, Inc. (“Theravance Biopharma” or the “Company”) is a diversified biopharmaceutical company primarily focused on the discovery, development and commercialization of organ-selective medicines. The Company’s purpose is to create transformational medicines to improve the lives of patients suffering from serious illnesses. The Company’s research is focused in the areas of inflammation and immunology.

Basis of Presentation

The Company’s condensed consolidated financial information as of September 30, 2019, and the three and nine months ended September 30, 2019 and 2018 is unaudited but includes all adjustments (consisting only of normal recurring adjustments), which are considered 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 United States 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, 2018 financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission (“SEC”) on February 28, 2019.

The results for the three and nine months ended September 30, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019, or for any other interim period or for any future period. These condensed consolidated financial statements include the accounts of the Company and its subsidiaries, and intercompany transactions and balances have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures in the condensed consolidated financial statements and accompanying notes. Management bases its estimates on historical experience and on assumptions believed to be reasonable under the circumstances. Actual results could differ materially from those estimates.

Significant Accounting Policies

Other than the recently adopted accounting pronouncements below, there have been no material revisions in the Company’s significant accounting policies described in Note 1 to the consolidated financial statements included in its Annual Report on Form 10-K for the year ended December 31, 2018.

Recently Adopted Accounting Pronouncements

Effective January 1, 2019, the Company adopted Accounting Standards Update (“ASU”) 2016-02, *Leases (Topic 842)* (“ASU 2016-02”) under the required modified retrospective approach. ASU 2016-02 was 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.

The Company elected the optional transition method to initially account for the impact of the adoption with a cumulative adjustment to accumulated deficit, if any, on the effective date of ASU 2016-02 of January 1, 2019, rather than applying the transition provisions in the earliest period presented, and the Company elected a package of practical expedients that allowed 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. In addition, the Company elected other practical expedients that allowed entities to: (i) use hindsight in determining the term

[Table of Contents](#)

of a lease when the lease includes an option to extend the lease term; (ii) exclude all leases, on a go forward basis, that have a lease term of 12-months or less; and (iii) combine lease and non-lease components (e.g., office common area maintenance expenses) when recognizing a lease on an entity's balance sheet on a go forward basis.

As a result of the adoption of ASU 2016-02, on January 1, 2019, the Company recorded a right-of-use operating lease asset of \$48.3 million and an operating lease liability of \$56.3 million related to its office leases in South San Francisco, California and Dublin, Ireland. The lease liability included \$8.0 million related to deferred rent liabilities. The adoption of ASU 2016-02 did not have an impact on the Company's consolidated results of operations, lease expense, or cash flows.

Effective January 1, 2019, the Company adopted ASU 2017-09, *Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"). ASU 2017-09 was issued to provide clarity and reduce both (i) diversity in practice and (ii) cost and complexity when applying the guidance in Topic 718, Compensation—Stock Compensation, to a change to the terms or conditions of a share-based payment award. The amendments in ASU 2017-09 provided guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. Essentially, an entity will not have to account for the effects of a modification if: (i) the fair value of the modified award is the same immediately before and after the modification; (ii) the vesting conditions of the modified award are the same immediately before and after the modification; and (iii) the classification of the modified award as either an equity instrument or liability instrument is the same immediately before and after the modification. The adoption of ASU 2017-09 did not have a material impact on the Company's consolidated financial statements and related disclosures as of January 1, 2019.

Effective January 1, 2019, the Company adopted the new 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. The Company has included condensed consolidated statements of shareholders' equity (deficit) in this Form 10-Q for the three and nine months ended September 30, 2019 and 2018.

Recently Issued Accounting Pronouncements Not Yet Adopted

In June 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). This guidance requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. The measurement of expected credit losses is based on historical experience, current conditions, and reasonable and supportable forecasts that affect collectability. ASU 2016-13 also eliminates the concept of "other-than-temporary" impairment when evaluating available-for-sale debt securities and instead focuses on determining whether any impairment is a result of a credit loss or other factors. An entity will recognize an allowance for credit losses on available-for-sale debt securities rather than an other-than-temporary impairment that reduces the cost basis of the investment. ASU 2016-13 is effective for annual reporting periods and interim periods within those years beginning after December 15, 2019. The Company does not currently expect ASU 2016-13 to have a material impact on its consolidated financial statements and related disclosures based on the historically high credit quality of the Company's financial instruments.

In August 2018, the FASB issued ASU 2018-15, *Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* ("ASU 2018-15"). ASU 2018-15 aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. Accordingly, ASU 2018-15 requires a customer in a hosting arrangement that is a service contract to follow the guidance in Subtopic 350-40 to determine which implementation costs to capitalize as an asset related to the service contract and which costs to expense. ASU 2018-15 is effective for annual reporting periods and interim periods within those years beginning after December 15, 2019. The Company is currently evaluating the impact of adopting ASU 2018-15 on its consolidated financial statements and related disclosures.

[Table of Contents](#)

In November 2018, the FASB issued ASU 2018-18, *Collaboration Arrangements: Clarifying the Interaction between Topic 808 and Topic 606* (“ASU 2018-18”). The issuance of Topic 606 raised questions about the interaction between the guidance on collaborative arrangements and revenue recognition. ASU 2018-18 addresses this uncertainty by: (i) clarifying that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606 when the collaboration arrangement participant is a customer; (ii) adding unit of account guidance to assess whether the collaboration arrangement or a part of the arrangement is with a customer; and (iii) precluding a company from presenting transactions with collaboration arrangement participants that are not directly related to sales to third parties together with revenue from contracts with customers. ASU 2018-18 is effective for annual reporting periods and interim periods within those years beginning after December 15, 2019. Early adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2018-18 on its consolidated financial statements and related disclosures.

The Company is currently evaluating other recently issued accounting pronouncements and does not currently believe that any of those pronouncements will have a material impact on its 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.

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Numerator:				
Net loss				
Weighted-average common shares outstanding	56,690	55,230	56,308	54,920
Less: weighted-average common shares subject to forfeiture	(832)	(982)	(863)	(1,149)
Weighted-average common shares used to compute basic and diluted net loss per share	55,858	54,248	55,445	53,771
Basic and diluted net loss per share	<u><u>\$ (1.05)</u></u>	<u><u>\$ (1.10)</u></u>	<u><u>\$ (3.08)</u></u>	<u><u>\$ (3.07)</u></u>

For the three and nine months ended September 30, 2019 and 2018, diluted and basic net loss per share was identical since potential ordinary shares were excluded from the calculation, as their effect was anti-dilutive.

Anti-dilutive Securities

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

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Share issuances under equity incentive plans and ESPP				
Share issuances upon the conversion of convertible senior notes	7,340	3,783	6,491	4,741
Restricted shares	—	4	—	4
Total	<u><u>14,016</u></u>	<u><u>10,463</u></u>	<u><u>13,167</u></u>	<u><u>11,421</u></u>

As of September 30, 2019 and 2018, there were 414,000 and 978,750 shares, respectively, subject to performance-based vesting criteria which have been excluded from the anti-dilutive securities table above.

3. Revenue

Revenue from Collaborative Arrangements

The Company recognized revenues from its collaborative arrangements as follows:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Janssen	\$ 8,807	\$ 8,866	\$ 21,522	\$ 21,044
Alfasigma	23	117	121	10,650
Other	6	6	23	50
Total collaboration revenue	\$ 8,836	\$ 8,989	\$ 21,666	\$ 31,744

Changes in Deferred Revenue Balances

The changes in the deferred revenue balances arose as a result of the Company recognizing the following revenue from collaborative arrangements during the periods below:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Collaboration revenue recognized in the period from:				
Amounts included in deferred revenue at the beginning of the period	\$ 8,836	\$ 7	\$ 21,661	\$ 39
Performance obligations satisfied in previous period	—	—	—	—

Janssen Biotech

In February 2018, the Company 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, the Company received an upfront payment of \$100.0 million. The Company is conducting a Phase 2 (DIONE) study of TD-1473 in Crohn’s disease and a Phase 2b/3 (RHEA) induction and maintenance study of TD-1473 in ulcerative colitis. Following the initial Phase 2 development period, including the 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 back-up compounds by paying us a fee of \$200.0 million. Upon any such election, the Company and Janssen will jointly develop and commercialize TD-1473 in inflammatory intestinal diseases and share profits in the United States (“US”) and expenses related to Phase 3 development and registration activities (67% to Janssen; 33% to Theravance Biopharma). The Company would receive royalties on ex-US sales at double-digit tiered percentage royalty rates, and the Company 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 Accounting Standards Codification, Topic 808, *Collaborative Arrangements* (“ASC 808”), as the parties are active participants and exposed to the risks and rewards of the collaborative activity. The Company evaluated the terms of the Janssen Agreement and have analogized to Accounting Standards Codification, Topic 606, *Revenue from Contracts with Customers* (“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 the Company’s ongoing major or central operations. Using the concepts of ASC 606, the Company has identified research and development activities as its only performance obligation. The Company 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, inclusive of the \$200.0 million opt-in fee and \$700.0 million future development and commercialization milestones, is considered variable consideration if Janssen elects to remain in the collaboration arrangement following completion of the initial Phase 2 development period, 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 the Company’s evaluation of this variable consideration constraint, it determined that the potential payments

[Table of Contents](#)

are contingent upon developmental and regulatory milestones that are uncertain and are highly susceptible to factors outside of its control. The Company expects 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, 2019, the Company recognized \$8.8 million and \$21.5 million, respectively, as revenue from collaboration arrangements related to the Janssen Agreement. The remaining transaction price of \$47.4 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 initial Phase 2 development period. Collaboration revenue is recognized for the research and development services based on a measure of the Company's efforts toward satisfying the 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, 2019, the Company incurred \$11.5 million and \$29.1 million, respectively, in research and development costs related to the Janssen Agreement, and for the three and nine months ended September 30, 2018, the Company incurred \$10.5 million and \$28.1 million, respectively, in research and development costs related to the Janssen Agreement. In future reporting periods, the Company will reevaluate the estimates related to its efforts towards satisfying the performance obligation and may record a change in estimate if deemed necessary.

Mylan

In January 2015, the Company and Mylan Ireland Limited ("Mylan") established a strategic collaboration (the "Mylan Agreement") for the development and commercialization of rевefenacin, including YUPELRI® (revefenacin) inhalation solution. The Company entered into the collaboration to expand the breadth of its revefenacin development program and extend its commercial reach beyond the hospital setting.

Under the Mylan Agreement, Mylan paid the Company an upfront fee of \$15.0 million for the delivery of the revefenacin license in 2015 and, in 2016, Mylan paid the Company a milestone payment \$15.0 million for the achievement of 50% enrollment in the Phase 3 twelve-month safety study. Separately, pursuant to an agreement to purchase ordinary shares entered into on January 30, 2015, Mylan Inc., a subsidiary of Mylan N.V., made a \$30.0 million equity investment in the Company, buying 1,585,790 ordinary shares from the Company 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 the Company's ordinary shares for the five trading days ending on January 30, 2015.

Under the Mylan Agreement, as of September 30, 2019, the Company is eligible to receive from Mylan potential global (ex-China and adjacent territories) 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 \$45.0 million associated with future potential combination products relates solely to development and regulatory actions.

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 was responsible for reimbursement of the Company's costs related to the registrational program up until the approval of the first new drug application in November 2018, thereafter, research and development ("R&D") expenses are shared. 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, the Company did not recognize revenue or analogize to ASC 606 and, as such, the reimbursable program costs are excluded from the transaction price.

The Company 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. The Company determined the license to be distinct from the joint steering committee participation. The Company further determined that the transaction price under the arrangement was comprised of the following: (1) \$15.0 million upfront 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

[Table of Contents](#)

allocated to the two performance obligations based on the Company's best estimate of the relative stand-alone selling price. For the delivery of the license, the Company 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, the Company based the stand-alone selling price on the average compensation of its committee members estimated to be incurred over the performance period. The Company expects to recognize collaboration revenue from the committee participation ratably over the performance period of approximately seventeen years.

The future potential milestone amounts for the Mylan Agreement 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 the Company's evaluation of the development and regulatory milestones constraint, the Company determined that the achievement of such milestones are contingent upon success in future clinical trials and regulatory approvals which are not within its control and uncertain at this stage. The Company expects that the sales-based milestone payments and royalty arrangements will be recognized when the sales occur or the milestone is achieved. The Company will re-evaluate the transaction price each quarter and as uncertain events are resolved or other changes in circumstances occur.

As of September 30, 2019, \$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 which will be recognized as collaboration revenue over the course of the remaining performance period of approximately twelve years.

The Company is 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 the Company is entitled to low double-digit tiered royalties on ex-US net sales. Mylan is the principal in the sales transactions, and as a result, the Company does not reflect the product sales in its financial statements.

Following the US Food and Drug Administration ("FDA") approval of YUPELRI in November 2018, net amounts payable to or receivable from Mylan each quarter under the profit sharing structure are disaggregated according to their individual components. Any reimbursement received from Mylan for the Company's R&D expense is characterized as a reduction of R&D expense, as the Company does not consider performing research and development services for reimbursement to be a part of its ongoing major or central operations. All other amounts receivable from, or payable to, Mylan in connection with the commercialization of YUPELRI are recorded within the condensed consolidated statements of operations as revenue from "Mylan collaboration agreement" or as a collaboration loss within selling, general and administrative expenses, respectively. The following YUPLERI-related amounts were recognized in the Company's condensed consolidated statements of operations:

(In thousands)	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2019
	\$ 3,591	\$ 3,749
Mylan collaboration agreement - <i>Amounts receivable from Mylan</i>		
Collaboration loss - <i>Amounts payable to Mylan</i>	\$ —	\$ 1,582

Prior to the FDA approval of YUPELRI in late 2018, the Company recognized its 35% share of expenses within R&D expense and selling, general and administrative expense on its condensed consolidated statements of operations. For the three and nine months ended September 30, 2018, the arrangement resulted in total collaboration expense, net of reimbursements from Mylan, of \$1.5 million and \$3.3 million, respectively.

Reimbursement of R&D Expense

Under certain collaborative arrangements, the Company is entitled to reimbursement of certain R&D expenses. Activities under collaborative arrangements for which the Company is entitled to reimbursement are considered to be collaborative activities under the scope of ASC 808. For these units of account, the Company does not analogize to ASC 606 or recognize revenue. The Company records reimbursement payments received from its collaboration partners as reductions to R&D expense.

[Table of Contents](#)

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

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Janssen	\$ 930	\$ 610	\$ 3,125	\$ 610
Mylan	53	2,598	287	5,843
Total reduction to R&D expense	<u>\$ 983</u>	<u>\$ 3,208</u>	<u>\$ 3,412</u>	<u>\$ 6,453</u>

Revenue from Licensing Arrangements

In June 2019, the Company announced the expansion of the Mylan Agreement (the “Mylan Amendment”) to grant Mylan exclusive development and commercialization rights to nebulized revefenacin in China and adjacent territories. In exchange, the Company received an upfront payment of \$18.5 million (before a required tax withholding) and will be eligible to receive potential development and sales milestones totaling \$54.0 million together with low double-digit tiered royalties on net sales of nebulized revefenacin, if approved. Of the \$54.0 million in potential milestones, \$9.0 million is associated with the development of YUPELRI monotherapy, \$7.5 million associated with the development of future potential combination products, and \$37.5 million is associated with sales milestones. Mylan will be responsible for all aspects of development and commercialization in the partnered regions, including pre- and post-launch activities and product registration and all associated costs.

The Mylan Amendment is accounted for under ASC 606 as a separate contract from the original Mylan Agreement that was entered into in January 2015. The Company identified a single performance obligation comprising of the delivery of the license to develop and commercialize revefenacin in China and adjacent territories. The transaction price was determined to be the upfront payment of \$18.5 million which the Company recognized as licensing revenue following the completion of the performance obligation in June 2019.

The future potential milestone amounts for the Mylan Amendment 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 the Company’s evaluation of the development milestones constraint, the Company determined that the achievement of such milestones is contingent upon success in future clinical trials and regulatory approvals which are not within its control and uncertain at this stage. The Company expects that the sales-based milestone payments and royalty arrangements will be recognized when the sales occur or the milestone is achieved. The Company will re-evaluate the transaction price each quarter and as uncertain events are resolved or other changes in circumstances occur.

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.

(In thousands)	September 30,	
	2019	2018
Cash and cash equivalents	\$ 102,403	\$ 101,202
Restricted cash	8,329	833
Total cash, cash equivalents, and restricted cash shown on the condensed consolidated statements of cash flows	<u>\$ 110,732</u>	<u>\$ 102,035</u>

As of September 30, 2019, the Company maintained restricted cash to secure a line of credit and debt servicing of its 9.0% non-recourse notes, due on or before 2033. See “Note 6. Long-Term Debt” for further information regarding the Company’s 9.0% non-recourse notes, due on or before 2033.

5. Investments and Fair Value Measurements

Available-for-Sale Securities

The estimated fair value of marketable securities is based on quoted market prices for these or similar investments obtained from a commercial pricing service. The fair market value of marketable securities classified within Level 1 is based on quoted prices for identical instruments in active markets. The fair value of marketable securities classified within Level 2 is based on quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; or model-driven valuations whose inputs are observable or whose significant value drivers are observable. 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:

(In thousands)	September 30, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
US government securities	Level 1 \$ 132,492	\$ 61	\$ (15)	\$ 132,538
Corporate notes	Level 2 32,227	41	(1)	32,267
Commercial paper	Level 2 122,328	17	(7)	122,338
Marketable securities	287,047	119	(23)	287,143
Money market funds	Level 1 47,626	—	—	47,626
Total	<u>\$ 334,673</u>	<u>\$ 119</u>	<u>\$ (23)</u>	<u>\$ 334,769</u>

(In thousands)	December 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
US government securities	Level 1 \$ 48,807	\$ —	\$ (86)	\$ 48,721
US government agency securities	Level 2 9,852	2	—	9,854
Corporate notes	Level 2 57,508	6	(88)	57,426
Commercial paper	Level 2 90,919	—	—	90,919
Marketable securities	207,086	8	(174)	206,920
Money market funds	Level 1 294,751	—	—	294,751
Total	<u>\$ 501,837</u>	<u>\$ 8</u>	<u>\$ (174)</u>	<u>\$ 501,671</u>

As of September 30, 2019, all of the available-for-sale securities had contractual maturities within 19 months and the weighted-average maturity of marketable securities was approximately six months. There were no transfers between Level 1 and Level 2 during the periods presented, and there have been no changes to the Company's valuation techniques during the three and nine months ended September 30, 2019.

In general, the Company invests in debt securities with the intent to hold such securities until maturity at par value. The Company does not intend to sell the investments that are currently in an unrealized loss position, and it is unlikely that it will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. The Company has determined that the gross unrealized losses on its marketable securities, as of September 30, 2019, were temporary in nature, and there were no material unrealized losses on investments which have been in a loss position for more than twelve months as of September 30, 2019.

As of September 30, 2019, the Company's accumulated other comprehensive income (loss) on its condensed consolidated balance sheets consisted of unrealized gains or losses on available-for-sale investments. During the three and nine months ended September 30, 2019 and 2018, the Company did not sell any of its marketable securities.

6. Long-Term Debt

9.0% Non-Recourse Notes Due 2033

In November 2018, the Company entered into note purchase agreements relating to the private placement of \$250.0 million aggregate principal amount of 9.0% non-recourse notes, due on or before 2033 (the "Non-Recourse 2033 Notes") issued by the Company's wholly-owned subsidiary, Triple Royalty Sub LLC (the "Issuer").

The Non-Recourse 2033 Notes are secured by all of the Issuer's rights, title and interest as a holder of certain membership interests (the "Issuer Class C Units") in Theravance Respiratory Company, LLC ("TRC"). The primary source of funds to make payments on the Non-Recourse 2033 Notes will be the 63.75% economic interest of the Issuer (evidenced by the Issuer Class C Units) in any future payments made by the Glaxo Group or one of its affiliates ("GSK") under the collaboration agreement, dated as of November 14, 2002, by and between Innoviva, Inc. ("Innoviva") and GSK, as amended from time to time (net of the amount of cash, if any, expected to be used in TRC pursuant to the TRC LLC Agreement ("LLC Agreement") over the next four fiscal quarters) relating to the TRELEGY ELLIPTA program. The sole source of principal and interest payments for the Non-Recourse 2033 Notes are the future royalty payments generated from the TRELEGY ELLIPTA program, and as a result, the holders of the Non-Recourse 2033 Notes have no recourse against the Company even if the TRELEGY ELLIPTA payments are insufficient to cover the principal and interest payments for the Non-Recourse 2033 Notes.

The Non-Recourse 2033 Notes are not convertible into Company equity and have no security interest in nor rights under any agreement with GSK. The Non-Recourse 2033 Notes may be redeemed at any time prior to maturity, in whole or in part, at specified redemption premiums. The Non-Recourse 2033 Notes bear an annual interest rate of 9.0%, with interest and principal paid quarterly beginning April 15, 2019. Prior to October 15, 2020, in the event that the distributions received by the Issuer from TRC in a quarter are less than the interest accrued for the quarter, the principal amount of the Non-Recourse 2033 Notes will increase by the interest shortfall amount for that period without a default or event of default occurring. The terms of the Notes also provide that the Company, at its option, may satisfy the quarterly interest payment obligations by making a capital contribution to the Issuer, but not for more than four (4) consecutive quarterly interest payment dates or for more than six (6) quarterly interest payment dates during the term of the Notes. Since the principal and interest payments on the Non-Recourse 2033 Notes are ultimately based on royalties from TRELEGY ELLIPTA product sales, which will vary from quarter to quarter, the Non-Recourse 2033 Notes may be repaid prior to the final maturity date in 2033. The portion of the Non-Recourse 2033 Notes classified as a current liability is based on the amount of royalties received, or receivable, as of September 30, 2019, that are expected to be used to make a principal repayment on the Non-Recourse 2033 Notes within the next 12 months. Please refer to "*Note 8. Theravance Respiratory Company, LLC*" for information regarding the results of the arbitration against Innoviva and TRC that the Company initiated in May 2019.

In order to comply with Regulation RR – Credit Risk Retention (17 C.F.R. Part 246), 5.0% of the principal amount of the Non-Recourse 2033 Notes were retained by Theravance Biopharma R&D, Inc. and eliminated in the Company's condensed consolidated financial statements.

As of September 30, 2019, the net principal and estimated fair value of the Non-Recourse 2033 Notes were \$237.5 million and \$225.6 million, respectively. The inputs to determine fair value of the Non-Recourse 2033 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.

3.25% Convertible Senior Notes Due 2023

The Company has \$230.0 million of 3.250% convertible senior notes due in 2023 ("Convertible Senior 2023 Notes") outstanding as of September 30, 2019 with an estimated fair value of \$212.3 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, 2019. The inputs to determine fair value of the Convertible Senior 2023 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.

7. Leases

The Company leases approximately 170,000 square feet of office and laboratory space in two buildings in South San Francisco, California, under a non-cancelable operating lease that ends in May 2030 (“SSF Lease”) and includes a tenant improvement allowance with a remaining balance of \$15.7 million, as of September 30, 2019, that expires in May 2022. The Company’s Irish subsidiary leases approximately 6,100 square feet of office space in Dublin, Ireland under a lease that expires in April 2027 (“Dublin Lease”). In addition, the Company leases equipment for clinical research studies with an estimated lease period ending in September 2020.

The SSF Lease contains two options to extend the term of the lease for successive periods of five years each, and the Dublin Lease contains a lease termination option in April 2024 at the Company’s discretion. The two options to extend the SSF Lease and the option to terminate the Dublin Lease were not recognized in the determination of the Company’s right-of-use assets and lease liabilities below.

The Company has evaluated its leases and determined that they were all operating leases. The present values of the remaining lease payments and corresponding right-of-use assets were as follows, and the difference between the right-of-use assets and lease liabilities amounts was due to deferred rent payments that are payable in future periods.

<u>(In thousands)</u>	<u>Classification</u>	<u>September 30, 2019</u>
Assets		
Operating lease assets	Operating lease assets	\$ <u>46,755</u>
Liabilities		
<i>Current:</i>		
Operating lease liabilities	Operating lease liabilities	\$ 6,833
<i>Non-current:</i>		
Operating lease liabilities	Long-term operating lease liabilities	48,620
Total operating lease liabilities		<u>\$ 55,453</u>

Lease expense was included within operating expenses in the condensed consolidated statements of operations as follows:

<u>(In thousands)</u>	<u>Classification</u>	<u>Three Months Ended September 30, 2019</u>	<u>Nine Months Ended September 30, 2019</u>
Operating lease expense	Selling, general and administrative expenses	\$ 2,512	\$ 7,431
Operating lease expense	Research and development expenses	238	715
Total operating lease expense (1)		<u>\$ 2,750</u>	<u>\$ 8,146</u>

(1) Includes short-term leases which were immaterial.

As of September 30, 2019, the maturities of the Company’s lease liabilities were as follows:

<u>(In thousands)</u>	
Three months ending December 31, 2019	\$ 2,201
Years ending December 31:	
2020	7,242
2021	9,481
2022	9,746
2023	10,024
Thereafter	70,172
Total operating lease payments	\$ 108,866
Less: Estimated tenant improvement allowance	(15,721)
Less: Imputed interest	(37,692)
Present value of operating lease liabilities	<u>\$ 55,453</u>

Cash paid for amounts included in the measurement of lease liabilities for the three and nine months ended September 30, 2019 was \$2.1 million and \$6.0 million, respectively, and is included in net cash used in operating activities in the condensed consolidated statements of cash flows. As of September 30, 2019, the weighted-average remaining lease term was 10.4 years, and the weighted-average discount rate used to determine the lease liabilities was 8.65%. The Company's discount rate was primarily derived from the 9.0% interest rate on its Non-Recourse 2033 Notes issued in November 2018 and did not involve any significant assumptions.

8. Theravance Respiratory Company, LLC

Prior to the June 2014 spin-off from Innoviva, the Company's former parent company, 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 the Company's 85% equity interests in TRC, the Company is 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 inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist ("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, the Company 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 and operation of TRC complies with applicable law and partner agreements. The Company is responsible for its proportionate share of TRC's administrative expenses incurred, and communicated to the Company, by Innoviva.

The Company analyzed its ownership, contractual and other interests in TRC to determine if it is a variable-interest entity ("VIE"), whether the Company has a variable interest in TRC and the nature and extent of that interest. The Company 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, the Company also assessed whether it is the primary beneficiary of TRC based on the power to direct TRC's activities that most significantly impact TRC's economic performance and its obligation to absorb TRC's losses or the right to receive benefits from TRC that could potentially be significant to TRC. Based on the Company's assessment, the Company determined that it is not the primary beneficiary of TRC, and, as a result, the Company does not consolidate TRC in its condensed consolidated financial statements. TRC is recognized in the Company's condensed consolidated financial statements under the equity method of accounting, and the value of the Company's equity investment in TRC was \$16.7 million and \$5.4 million as of September 30, 2019 and December 31, 2018, respectively. This amount includes undistributed earnings from the Company's investment in TRC which are recorded on the condensed consolidated balance sheets as "Amounts due from TRC, LLC" and are net of the Company's proportionate share of TRC's administrative expenses incurred, and communicated to the Company, by Innoviva. Pursuant to the TRC operating agreement, the cash from the TRELEGY ELLIPTA royalties, net of any expenses, is distributed to the equity holders quarterly.

For the three and nine months ended September 30, 2019, the Company recognized net royalty income of \$7.2 million and \$21.8 million within the condensed consolidated statements of operations within "Income from investment in TRC, LLC". These amounts were recorded net of the Company's share of TRC's expenses of \$2.3 million for the three and nine months ended September 30, 2019, which was primarily comprised of TRC's legal and related fees associated with the arbitration between Innoviva and TRC and the Company. For the three and nine months ended September 30, 2018, the Company recognized net royalty income of \$3.1 million and \$5.8 million, respectively. There were minimal TRC expenses for the three and nine months ended September 30, 2018.

In May 2019, the Company announced that it had initiated an arbitration against Innoviva and TRC because Innoviva, as manager of TRC, had caused TRC to withhold certain distributions owed to the Company with respect to the

[Table of Contents](#)

Company's 85% economic interest in TRC since the quarter ended December 31, 2018, and Innoviva's previous statement to the Company that it intended to prevent TRC from making cash distributions during 2019. The arbitration hearing commenced on July 23, 2019.

In September 2019, the arbitrator issued a final decision. The arbitrator ruled that, while Innoviva breached the LLC Agreement by failing to provide quarterly financial plans to the Company as required, the withholding of funds by Innoviva with respect to certain TRELEGY ELLIPTA development and commercialization initiatives proposed by Innoviva was not in breach of the LLC Agreement. The arbitrator also found that Innoviva had not breached its fiduciary duties to the Company. The arbitrator awarded injunctive relief to give more certainty to future dealings between the parties and to clarify certain terms of the LLC Agreement, and imposed additional obligations on Innoviva to obtain the consent of GSK for any proposed investment of TRC funds that requires the consent of GSK under the collaboration agreement dated November 14, 2002, as amended. Under the arbitrator's ruling, Innoviva is currently permitted to continue to withhold \$8.0 million of TRC funds for certain TRELEGY ELLIPTA development and commercialization initiatives proposed by Innoviva. These initiatives must be presented to GSK in the fourth quarter of 2019 and they cannot be implemented without GSK's approval, which approval must be obtained no later than during the first quarter of 2020. To the extent GSK's approval is not received, the Company expects distribution to the TRC members of the withheld funds. To the extent the initiatives are timely approved by GSK and proceed, TRC may withhold additional amounts in subsequent quarters through to the completion of these initiatives.

As of June 30, 2019, the Company was owed, under the LLC Agreement, \$20.0 million in net royalty income payments for the period from the fourth quarter of 2018 through the second quarter of 2019. After initiation of the arbitration and prior to the final decision being issued in the third quarter of 2019, Innoviva caused TRC to make a partial distribution of funds to the Company of \$10.6 million against these amounts due. Innoviva withheld \$6.9 million, representing the Company's share of the \$8.0 million of total TRC funds earmarked for certain TRELEGY ELLIPTA development and commercialization initiatives proposed by Innoviva, pursuant to the arbitrator's final decision. The amount due to the Company as of September 30, 2019 was \$16.7 million and includes the \$6.9 million currently being withheld by Innoviva. The Company believes the \$16.7 million will be received by early 2020. In the event GSK agrees to the TRELEGY ELLIPTA development and commercialization initiatives proposed by Innoviva, the Company will reclassify the \$6.9 million from "Amounts due from TRC, LLC" within total current assets to "Investment in TRC, LLC" within long-term assets on its condensed consolidated balance sheets.

9. Share-Based Compensation

Share-Based Compensation Expense Allocation

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

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	\$ 6,458	\$ 6,294	\$ 18,338	\$ 19,757
Selling, general and administrative	6,561	5,452	18,200	19,842
Total share-based compensation expense	<u>\$ 13,019</u>	<u>\$ 11,746</u>	<u>\$ 36,538</u>	<u>\$ 39,599</u>

Performance-Contingent Awards

In the first quarter of 2016, the Compensation Committee of the Company's board of directors ("Compensation Committee") approved the grant of 1,575,000 performance-contingent restricted share awards ("RSAs") and 135,000 performance-contingent restricted share units ("RSUs") to senior management. The vesting of such awards is dependent on the Company meeting its critical operating goals and objectives during the five-year period from 2016 to December 31, 2020, as well as, continued employment. The goals that must be met in order for the performance-contingent RSAs and RSUs to vest are strategically important for the Company, 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, 2019, there were 776,250 of these performance-contingent RSAs and 101,250 of these performance-contingent RSUs outstanding, and as of September 30, 2018, there were 978,750 of these performance-contingent RSAs and 101,250 of these performance-contingent RSUs outstanding.

[Table of Contents](#)

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. Previously recognized expense is reversed in the period in which it becomes probable that the requisite service period will not be rendered.

The performance conditions associated with the first tranche of these awards were completed in the second quarter of 2018, and the Company recognized \$1.8 million of share-based compensation expense for the nine months ended September 30, 2018 associated with the first tranche of these awards.

The performance conditions associated with the second tranche of these awards were completed in the first quarter of 2019. For the three and nine months ended September 30, 2019, the Company recognized \$0.7 million and \$1.2 million, respectively, of share-based compensation expense related to the second tranche of these awards. The maximum remaining expense associated with the second tranche is \$1.1 million (allocated as \$0.4 million for research and development expense and \$0.7 million for selling, general and administrative expense). For the three and nine months ended September 30, 2018, the Company recognized \$47,000 and \$1.8 million, respectively, of share-based compensation expense related to the second tranche of these awards.

As of September 30, 2019, the Company 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 third tranche could be up to \$12.8 million (allocated as \$4.4 million for research and development expense and \$8.4 million for selling, general and administrative expense) if the performance conditions are achieved.

In the fourth quarter of 2018, the Compensation Committee approved a grant of 3,000 performance-contingent RSUs to an employee. These RSUs expire by December 31, 2020 and have a maximum share-based compensation expense of \$75,000 which will be recognized when its single performance milestone is deemed to be probable of achievement. As of September 30, 2019, the Company determined that the performance milestone was not probable of achievement and, as a result, no compensation expense related to these RSUs has been recognized to date.

In the first quarter of 2019, the Compensation Committee approved a grant of 60,000 performance-contingent RSUs to an employee. These RSUs have dual triggers of vesting based upon the achievement of certain performance milestones in specified timeframes, as well as a requirement for continued employment. The compensation expense related to these awards is broken into two separate performance milestones and recognized when the associated performance milestones are deemed to be probable of achievement. The maximum share-based compensation expense associated with the 60,000 performance-contingent RSUs' first and second performance milestones are \$0.8 million each for a total of \$1.6 million, and the RSUs expire by December 31, 2021. In the third quarter of 2019, the Company determined that a portion of performance milestone associated with the first tranche was probable of achievement and recognized \$0.3 million of share-based compensation expense. The Company determined that the second tranche was not probable as of September 30, 2019 and, as a result, no compensation expense related to these RSUs has been recognized to date.

In the third quarter of 2019, the Compensation Committee approved a grant of 60,000 performance-contingent RSUs to an employee. These RSUs have dual triggers of vesting based upon the achievement of certain performance milestones in specified timeframes, as well as a requirement for continued employment. The compensation expense related to these RSUs is broken into three separate performance milestones and will be recognized when the associated performance milestones are deemed to be probable of achievement. The maximum share-based compensation expense associated with the 60,000 performance-contingent RSUs' three performance milestones are approximately \$0.3 million each for a total of \$1.0 million, and the 60,000 performance-contingent RSUs expire by June 30, 2022. As of September 30, 2019, the Company determined that the performance milestones were not probable of achievement and, as a result, no compensation expense related to these RSUs has been recognized to date.

[Table of Contents](#)

10. Income Taxes

The income tax provision was a \$5.6 million net benefit and \$5.3 million net benefit for the three and nine months ended September 30, 2019, respectively. The net income tax benefit was primarily attributed to a reversal of previously accrued contingent tax liabilities for uncertain tax positions due to a lapse of the statute of limitations and current year US research and development credits. No provision for income taxes has been recognized on undistributed earnings of the Company's foreign subsidiaries because it considers such earnings to be indefinitely reinvested.

The Company follows 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, 2019, the Company's deferred tax assets were offset in full by a valuation allowance.

The Company records 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. The Company includes any applicable interest and penalties within the provision for income taxes in the condensed consolidated statements of operations.

The Company's future income tax expense may be affected by such factors as changes in tax laws, its 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, its 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.

New United Kingdom ("UK") tax legislation was introduced by the *Finance Act 2019* ("FA 2019") and came into effect on April 6, 2019 that subjects UK-derived income earned by offshore recipients with respect to intangible property ("ORIP") to UK income tax at 20% on the gross receipts, where the intangible property is held offshore in a jurisdiction with which the UK does not have a double taxation treaty. FA 2019 also included a power for amendments to the ORIP legislation to be made by regulation by December 31, 2019.

On October 15, 2019, the UK published further guidance intended to facilitate the administration of the ORIP regime. However, a number of issues and areas of uncertainty remain. The Company has reviewed the original legislation in conjunction with the guidance and believes that the ORIP regime may apply to certain cash receipts. Based on this analysis, the Company believes that the ORIP charge on UK-derived cash receipts through the third quarter of 2019 is not material, but the Company will continue to refine its ORIP conclusions as guidance evolves.

11. Reduction in Workforce

In January 2019, the Company announced a reduction in workforce to align with its focus on continued execution of key strategic programs and advancement of selected late-stage research programs toward clinical development. The Company reduced its overall headcount by 51 individuals, with the affected employees primarily focused on early research or the infrastructure in support of VIBATIV, which was sold by the Company to Cumberland Pharmaceuticals Inc. in November 2018.

The workforce reduction was substantially completed in the first quarter of 2019, and the Company recorded and paid severance related charges totaling \$3.5 million for the nine months ended September 30, 2019, including compensation expense made to affected employees through any minimum statutory notice periods. The severance related charges are presented on the condensed consolidated statements of operations within research and development expenses and selling, general and administrative expenses.

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, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that involve risks and uncertainties. All statements in this report, other than statements of historical facts, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans, intentions, expectations and objectives are forward-looking statements. The words "anticipate," "assume," "believe," "contemplate," "continue," "could," "designed," "developed," "drive," "estimate," "expect," "forecast," "goal," "intend," "may," "mission," "opportunities," "plan," "potential," "predict," "project," "pursue," "seek," "should," "target," "will," "would," and similar expressions (including the negatives thereof) are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These statements reflect our current views with respect to future events or our future financial performance, are based on assumptions, and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We may not actually achieve the plans, intentions, expectations or objectives disclosed in our forward-looking statements and the assumptions underlying our forward-looking statements may prove incorrect. Therefore, you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and objectives disclosed in the forward-looking statements that we make. Factors that we believe could cause actual results or events to differ materially from our forward-looking statements include, but are not limited to, those discussed in "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report and in our Annual Report on Form 10-K for the year ended December 31, 2018. 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. ("we," "our" or "Theravance Biopharma") is a diversified biopharmaceutical company primarily focused on the discovery, development and commercialization of organ-selective medicines. Our purpose is to create transformational medicines to improve the lives of patients suffering from serious illnesses. Our research is focused in the areas of inflammation and immunology.

In pursuit of our purpose, we apply insights and innovation at each stage of our business and utilize our internal capabilities and those of partners around the world. We apply organ-selective expertise to biologically compelling targets to discover and develop medicines designed to treat underserved localized diseases and to limit systemic exposure, in order to maximize patient benefit and minimize risk. These efforts leverage years of experience in developing lung-selective medicines to treat respiratory disease, including the United States ("US") Food and Drug Administration (the "FDA") approved YUPELRI® (reverfenacin) inhalation solution indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease ("COPD"). Our pipeline of internally discovered programs is targeted to address significant patient needs.

We have an economic interest in potential future payments from Glaxo Group or one of its affiliates ("GSK") pursuant to its agreements with Innoviva, Inc. ("Innoviva") relating to certain programs, including TRELEGY ELLIPTA.

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

[Table of Contents](#)

systemic exposure. In TD-1473, our program 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. TD-1473 is in development as a potential treatment for a range of inflammatory intestinal diseases, including ulcerative colitis and Crohn's disease.

Based on positive results from a Phase 1b exploratory study in ulcerative colitis and following dialogues with the FDA and European Medicines Agency ("EMA") regarding study design, we advanced TD-1473 into two clinical studies in inflammatory intestinal diseases. The Phase 2 (DIONE) study is a twelve-week randomized, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of patients with Crohn's disease, which began dosing patients in late 2018. The Phase 2b/3 (RHEA) study is a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of eight weeks induction and 44 weeks maintenance therapy in patients with ulcerative colitis, which began dosing patients in early 2019. We anticipate results from the Phase 2b portion of the ulcerative colitis study and Phase 2 Crohn's disease study in late-2020.

Irreversible Janus-Kinase 3 (JAK3) Inhibitor (TD-5202)

TD-5202 is an investigational, orally administered, gut-selective, irreversible JAK3 inhibitor that has demonstrated a high affinity for the JAK3 enzyme. Through the selective inhibition of JAK3, TD-5202 interferes with the JAK/STAT signaling pathway and, in turn, modulates the activity of select pro-inflammatory cytokines, including IL-2, IL-15, and IL-21 which play a central role in the pathogenesis of T-cell mediated disease, including inflammatory intestinal disease, such as celiac disease. Importantly, TD-5202 is specifically designed to act locally within the intestinal wall thereby limiting systemic exposure.

In September 2019, we announced the initiation of a Phase 1 single ascending dose and multiple ascending dose trial designed to evaluate the safety and tolerability of TD-5202 in healthy subjects, plus assess plasma pharmacokinetics of TD-5202 to confirm circulating levels are low, consistent with a gut-selective approach. Data from the study is expected in the first half of 2020.

We are developing TD-1473 and TD-5202 in collaboration with Janssen Biotech, Inc., ("Janssen") as part of the companies' global co-development and commercialization agreement for novel, gut-selective JAK inhibitors.

Janssen Biotech Collaboration

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. 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, inclusive of a potential opt-in payment following completion of the Phase 2 Crohn's study and the Phase 2b induction portion of the ulcerative colitis study. At that time, 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 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.

The closing of the opt-in 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 an election. We will lead development of TD-1473 in ulcerative colitis through completion of the Phase 2b/3 study. 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.

Ampreloxytine (TD-9855)

Ampreloxytine is an investigational, once-daily norepinephrine reuptake inhibitor ("NRI") being developed for the treatment of patients with symptomatic neurogenic orthostatic hypotension ("nOH"). nOH is caused by primary autonomic failure conditions, including multiple system atrophy, Parkinson's disease and pure autonomic failure. The compound has

[Table of Contents](#)

high affinity for binding to norepinephrine transporters. By blocking the action of these transporters, amprexetine causes an increase in extracellular concentrations of norepinephrine.

Based on positive top-line four-week results from a small exploratory Phase 2 study in nOH and discussions with the FDA, we advanced amprexetine into a Phase 3 program. The Phase 3 program includes two studies. The first study (SEQUOIA) is a four-week, randomized double-blind, placebo-controlled study designed to evaluate the efficacy and safety of amprexetine in patients with symptomatic nOH. The second study (REDWOOD) is a four-month open label study followed by a six-week randomized withdrawal phase to evaluate the durability of patient response of amprexetine. We announced the initiation of patient dosing in each Phase 3 study in early 2019. We anticipate results from the Phase 3 four-week efficacy study in the second half of 2020.

In a poster presentation at the International Congress of Parkinson's Disease and Movement Disorders® ("MDS") in September 2019, we announced supplemental data from the Phase 2 study of amprexetine in nOH. Data suggest mechanistic association between symptom improvement and increases in circulating norepinephrine levels over four weeks of amprexetine therapy.

YUPELRI® (revefenacin) Inhalation Solution

YUPELRI (revefenacin) inhalation solution is a once-daily, nebulized long-acting muscarinic antagonist ("LAMA") approved for the maintenance treatment of COPD in the US. LAMAs are recognized by international COPD treatment guidelines as a cornerstone of maintenance therapy for COPD, regardless of severity of disease. 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. The stability of YUPELRI in both metered dose inhaler and dry powder inhaler ("MDI/DPI") formulations suggest that this LAMA could also serve as a foundation for novel handheld combination products.

In November 2018, YUPELRI was approved by the FDA for the maintenance treatment of patients with COPD. Following shipments into commercial channel in late 2018, we and Mylan formally launched our sales and marketing efforts in early 2019. The launch is progressing well in partnership with Mylan. We are tracking several key performance metrics to gauge success in building early market acceptance, including formulary reviews, formulary wins and market access. Since launch, YUPELRI has been accepted on 70 formularies that account for a total of 196 institutional accounts. With respect to market access, we have made important gains with confirmed commercial coverage of approximately 50% and Medicare Part B coverage for patients with supplement insurance of 100%. In May 2019, we announced that YUPELRI had been assigned a permanent unique Healthcare Common Procedure Coding System ("J-CODE") nearly six months ahead of schedule. The permanent J-CODE allows for full automation of prescription adjudication, simplifying the process for pharmacists and patients.

Mylan Collaboration

In January 2015, Mylan Ireland Limited ("Mylan") and we established a strategic collaboration for the development and 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. 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 co-develop revefenacin for COPD and other respiratory diseases. We led the US Phase 3 development program for YUPELRI in COPD, and Mylan was 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 are shared. With YUPELRI approved in the US, Mylan is leading commercialization, and we co-promote the product in the US under a profit and loss sharing arrangement (65% to Mylan; 35% to Theravance Biopharma). Outside the US, 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 agreement to purchase ordinary shares entered into on January 30, 2015, Mylan Inc., the indirect

[Table of Contents](#)

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.

In June 2019, we announced the expansion of the Mylan Agreement to grant Mylan exclusive development and commercialization rights to nebulized revefenacin in China and adjacent territories, which include Hong Kong SAR, the Macau SAR, and Taiwan. In exchange, we received an upfront payment of \$18.5 million (before a required tax withholding) and will be eligible to receive additional potential development and sales milestones totaling \$54.0 million together with low double-digit tiered royalties on net sales of nebulized revefenacin, if approved. Mylan will be responsible for all aspects of development and commercialization in the partnered regions, including pre- and post-launch activities and product registration and all associated costs.

Under the Mylan Agreement, as of September 30, 2019, we are eligible to receive from Mylan potential global development, regulatory and sales milestone payments totaling up to \$259.0 million in the aggregate, with \$206.5 million associated with YUPELRI monotherapy, and \$52.5 million associated with future potential combination products. Of the \$206.5 million associated with monotherapy, \$187.5 million relates to sales milestones based on achieving certain levels of net sales and \$19.0 million relates to global development and regulatory actions. The \$52.5 million associated with future potential combination products relates solely to global development and regulatory actions. We do not expect to earn any significant milestone payments from Mylan for the remainder of 2019.

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.

Lung-selective Pan-Janus Kinase (JAK) Inhibitor Program (TD-8236)

TD-8236 is an investigational, lung-selective inhaled pan-JAK inhibitor that has demonstrated a high affinity for each of the JAK family of enzymes (JAK1, JAK2, JAK3 and TYK2) that play a key role in cytokine signalling. Inhibiting these JAK enzymes interferes with the JAK/STAT signalling pathway and, in turn, modulates the activity of a wide range of pro-inflammatory cytokines. While orally-administered JAK inhibitors are currently approved for the treatment of a range of inflammatory diseases, no inhaled JAK inhibitor is approved for the treatment of airway disease, including asthma. The pan-JAK activity of TD-8236 suggests that it may impact a broad range of cytokines that have been associated both Th2-high and Th2-low asthma. Many moderate to severe asthma patients comprising these phenotypes remain symptomatic with currently available therapies. Importantly, TD-8236 is designed to distribute adequately and predominantly within the lungs following dry powder inhalation, with the potential to treat inflammation within that organ while minimizing systemic exposure. In pre-clinical assessments, TD-8236 has shown to potently inhibit targeted mediators of Th2-high and Th2-low asthma in human cells.

In September 2019, we announced positive results from a Phase 1 single-ascending dose and multiple-ascending dose clinical trial of TD-8236. Data from the study demonstrated TD-8236 to be generally well tolerated as a single dose (up to 4500 mcg) in healthy volunteers and as a once-daily dose (up to 4000 mcg) given for seven consecutive days in patients with mild asthma. There were no severe or serious adverse events reported and no subject discontinued due to adverse events. Pharmacokinetic results from the trial showed that plasma levels of TD-8236 in study subjects were several orders of magnitude below the levels predicted to cause systemic pharmacological activity, which is consistent with data from preclinical studies and the organ-selective design of the compound. Additionally, evidence of the biological activity of TD-8236 in the lung was demonstrated in the repeat dose portion of the study, which recruited patients with mild asthma who had elevated levels of fractional exhaled nitric oxide (“FeNO”). FeNO is an established disease activity biomarker in asthma, and reductions in FeNO are associated with a decrease in airway inflammation. Over the seven days of TD-8236 administration once daily by inhalation, patients experienced reductions in both pre-dose and six-hour post-dose FeNO compared to placebo at all doses above 150mcg. Importantly, this included >10ppb reduction in pre-dose FeNO on Day 7 for all doses above 150mcg. The Phase 1 clinical trial also includes a biomarker cohort designed to evaluate multiple doses of TD-8236 in patients with moderate-to-severe asthma. Data from the biomarker cohort is expected in the first half of 2020. Also in

[Table of Contents](#)

September of 2019, we announced plans to initiate a lung allergen challenge study of TD-8236 in asthma patients in the fourth quarter of 2019, and we expect data from the study in 2020.

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.

Alfasigma S.p.A. Collaboration

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 2018, Alfasigma exercised its option to develop and commercialize velusetrag, and we elected not to pursue further development due to our planned pipeline investments and in light of an 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 been transferred to Alfasigma under the terms of the 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, discovered and developed by Theravance Biopharma. 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 authorized new clinical data into 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.

In November 2018, we sold VIBATIV to Cumberland Pharmaceuticals Inc. (“Cumberland”) pursuant to an Asset Purchase Agreement (the “Agreement”). Under the Agreement, Cumberland paid us \$20.0 million at the closing of the transaction and \$5.0 million in April 2019. In addition, Cumberland will pay us tiered royalties of up to 20% of US net sales of VIBATIV until such time as royalties cumulatively total \$100.0 million.

Selective 5-HT4 Agonist (TD-8954)

TD-8954 is a selective 5-HT4 receptor agonist being developed for potential use in the treatment of gastrointestinal motility disorders.

Takeda Collaborative Arrangement

In June 2016, we entered into a License and Collaboration Agreement (the “Takeda Agreement”) with Millennium Pharmaceuticals, Inc., a Delaware corporation (“Millennium”), in order to establish a collaboration for the development and commercialization of TD-8954 (TAK-954). Millennium is an indirect wholly-owned subsidiary of Takeda Pharmaceutical Company Limited (“Takeda”). TD-8954 is currently in a Phase 2 study as a potential treatment for post-operative gastrointestinal dysfunction. Under the terms of the Takeda Agreement, Takeda is 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 from Takeda. 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.

Research Projects

Our research goal is to design organ-selective medicines that target diseased tissues, without systemic exposure, in order to maximize patient benefit and minimize risk. The intention is to expand the therapeutic index of our potential medicines compared to conventional systemic therapies. Our efforts leverage years of experience in developing lung-

[Table of Contents](#)

selective medicines, such as YUPELRI, to treat respiratory diseases, and have led to the discovery of the gut-selective pan-JAK inhibitor TD-1473 in inflammatory intestinal diseases and the lung-selective inhaled JAK inhibitor TD-8236 in serious respiratory disease. We plan to advance towards the clinic other research projects with various mechanisms of action, each specifically tailored for the organ of interest, as we identify and validate potentially appropriate compounds. Our research is focused in the areas of inflammation and immunology, and our pipeline of internally discovered programs is targeted to address significant patient needs.

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 in TRC 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.

In May 2019, we announced that we had initiated an arbitration against Innoviva and TRC because Innoviva had caused TRC to not make certain distributions owed to us with respect to our 85% economic interest in TRC. A final decision was issued in September 2019. See Part II, Item 1 “Legal Proceedings” for further information.

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 (UMECA, 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 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 of GSK’s costs related to the development or commercialization of TRELEGY ELLIPTA.

GSK and Innoviva conducted two global pivotal Phase 3 studies of TRELEGY ELLIPTA in COPD, the IMPACT study and the FULFIL study. In September 2017, GSK and Innoviva announced that the FDA approved TRELEGY ELLIPTA for the long-term, once-daily, maintenance treatment of appropriate patients with COPD. TRELEGY ELLIPTA is currently approved in 36 markets with additional approvals expected in 2019, including a potential approval in China in the fourth quarter of 2019. In August 2019, GSK announced that it had filed a supplemental new drug application (“sNDA”) to the FDA supporting revised labelling for TRELEGY ELLIPTA on reduction in risk of all-cause mortality compared with ANORO ELLIPTA in patients with COPD.

Additionally, GSK and Innoviva conducted a Phase 3 (CAPTAIN) study of TRELEGY ELLIPTA in patients with asthma. In May 2019, GSK and Innoviva announced that the study had met its primary endpoint and in October 2019, GSK announced it had filed a sNDA with the FDA seeking an additional indication for the use of once-daily, single-inhaler triple therapy, TRELEGY ELLIPTA, for the treatment of asthma in adults.

Theravance Respiratory Company, LLC

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 in TRC over the

[Table of Contents](#)

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 within “Income from investment in TRC, LLC” and is classified as non-operating income. Seventy-five percent of the “Income from investment in TRC, LLC,” as evidenced by the Issuer Class C Units, is available only for payment of the \$250.0 million aggregate amount of 9.0% fixed-rate non-recourse term notes due 2033 (the “Non-Recourse 2033 Notes”) and is not available to pay our other obligations or the claims of our other creditors. 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.

Our special purpose subsidiary Triple Royalty Sub LLC (the “Issuer”) issued the Non-Recourse 2033 Notes in November 2018, which are secured by all of the Issuer’s rights, title and interest as a holder of certain membership interests (the “Issuer Class C Units”) in TRC. The Issuer Class C Units entitle the Issuer to receive 63.75% of the economic interest that TRC receives in any future payments made by GSK under the agreements described above, or 75% of the income from our ownership interest in TRC. The primary source of funds to make payments on the Non-Recourse 2033 Notes will be 75% of the income from our ownership interest in TRC, as evidenced by the Issuer Class C Units. Since the principal and interest payments on the Non-Recourse 2033 Notes are ultimately based on royalties from TRELEGY ELLIPTA product sales, which will vary from quarter to quarter, the Non-Recourse 2033 Notes may be repaid prior to the final maturity date in 2033. In order to comply with Regulation RR – Credit Risk Retention (17 C.F.R. Part 246), 5.0% of the original principal amount (equal to \$12.5 million) of the Non-Recourse 2033 Notes were retained by Theravance Biopharma R&D, Inc., our wholly-owned subsidiary, and is eliminated in our condensed consolidated financial statements.

Through October 15, 2020, the terms of the Non-Recourse 2033 Notes provide that to the extent there are insufficient funds to satisfy the Issuer’s scheduled quarterly interest obligations, the shortfall shall be added to the principal amount of the Non-Recourse 2033 Notes without a default or event of default occurring. The terms of the Non-Recourse 2033 Notes also provide that, at Theravance Biopharma’s option, the quarterly interest payment obligations can be satisfied by making a capital contribution to the Issuer, but not for more than four (4) consecutive quarterly interest payment dates or for more than six (6) quarterly interest payment dates during the term of the notes. For the April 15, 2019 and July 15, 2019 interest payment dates, Theravance Biopharma R&D, Inc. (parent entity of Issuer) made a capital contribution to satisfy the interest payment obligations for these two scheduled payments while we arbitrated the dispute with Innoviva discussed below in Part II, Item 1 “Legal Proceedings.”

2020 Annual General Meeting of Shareholders

The Company will hold its 2020 Annual General Meeting of Shareholders on Tuesday, April 28, 2020 in Dublin, Ireland. Further information regarding the Annual General Meeting will be provided in the Company’s proxy materials, which will be filed with the SEC and made available to shareholders prior to the Annual General Meeting.

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. 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, 2018.

[Table of Contents](#)

Results of Operations

Revenue

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

(In thousands)	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2019	2018	\$	%	2019	2018	\$	%
Product sales	\$ —	\$ 3,849	\$ (3,849)	NM %	\$ —	\$ 12,889	\$ (12,889)	NM %
Collaboration revenue	8,836	8,989	(153)	(2)	21,666	31,744	(10,078)	(32)
Licensing revenue	—	—	—	NM	18,500	—	18,500	NM
Mylan collaboration agreement	3,591	—	3,591	NM	3,749	—	3,749	NM
Total revenue	<u>\$ 12,427</u>	<u>\$ 12,838</u>	<u>\$ (411)</u>	<u>(3)%</u>	<u>\$ 43,915</u>	<u>\$ 44,633</u>	<u>\$ (718)</u>	<u>(2)%</u>

NM: Not Meaningful

As a result of the sale of our VIBATIV business to Cumberland in November 2018, no product sales were recognized for the three and nine months ended September 30, 2019.

Collaboration revenue decreased by \$0.2 million and \$10.1 million for the three and nine months ended September 30, 2019, respectively, compared to the same periods in 2018. The \$0.2 million decrease for the three month period ended September 30, 2019 was primarily attributed to a lower 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 \$10.1 million decrease for the nine month period ended September 30, 2019 was primarily attributed to the April 2018 exercise by Alfasigma of its option to develop and commercialize velusetrag.

Licensing revenue was \$18.5 million for the nine months ended September 30, 2019 and represented an \$18.5 million upfront payment (before a required tax withholding) from Mylan associated with the amendment signed in June 2019 for the commercialization and development rights to nebulized refefenacin in China and adjacent territories.

We are entitled to a share of US profits and losses (65% to Mylan; 35% to Theravance Biopharma) received in connection with commercialization of YUPELRI. Any reimbursement from Mylan attributed to the 65% cost sharing of our R&D expenses is characterized as a reduction of R&D expense. All other amounts receivable from, or payable to, Mylan in connection with the commercialization of YUPELRI are recorded within the condensed consolidated statements of operations as revenue from “Mylan collaboration agreement” or as a collaboration loss within operating expenses, respectively. Revenue from the Mylan collaboration agreement was \$3.6 million and \$3.7 million for the three and nine months ended September 30, 2019, respectively, and represented the receivables due from Mylan during the periods.

Cost of Goods Sold

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

(In thousands)	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2019	2018	\$	%	2019	2018	\$	%
Cost of goods sold	\$ —	\$ 705	\$ (705)	NM %	\$ —	\$ 83	\$ (83)	NM %

NM: Not Meaningful

As a result of the sale of our VIBATIV business to Cumberland in November 2018, no cost of goods sold was recognized for the three and nine months ended September 30, 2019.

Reduction in Workforce

In January 2019, we announced a reduction in workforce to align with our focus on continued execution of key strategic programs and advancement of selected late-stage research programs toward clinical development. We reduced our

[Table of Contents](#)

overall headcount by 51 individuals, with the affected employees primarily focused on early research or the infrastructure in support of VIBATIV which was sold by us to Cumberland in November 2018.

The workforce reduction was substantially completed in the first quarter of 2019. We recorded and paid severance related charges totaling approximately \$3.5 million including compensation expense made to affected employees through any minimum statutory notice periods. The severance related charges are presented on the condensed consolidated statements of operations within research and development expenses and selling, general and administrative expenses.

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 any reimbursements from collaboration partners, as compared to the comparable periods in the prior year:

(In thousands)	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2019	2018	\$	%	2019	2018	\$	%
Employee-related	\$ 12,469	\$ 14,591	\$ (2,122)	(15)%	\$ 43,273	\$ 46,977	\$ (3,704)	(8)%
Share-based compensation	6,458	6,294	164	3	18,338	19,757	(1,419)	(7)
External-related	25,592	23,340	2,252	10	66,175	55,673	10,502	19
Facilities, depreciation and other allocated expenses	7,487	8,468	(981)	(12)	24,437	26,672	(2,235)	(8)
Total research & development	<u>\$ 52,006</u>	<u>\$ 52,693</u>	<u>\$ (687)</u>	<u>(1)%</u>	<u>\$ 152,223</u>	<u>\$ 149,079</u>	<u>\$ 3,144</u>	<u>2 %</u>

R&D expenses decreased by \$0.7 million for the three months ended September 30, 2019 compared to same period in 2018. The decrease was primarily attributed to a \$2.1 million decrease in employee-related expenses and a \$1.0 million decrease in other expenses resulting from our workforce reduction in the first quarter of 2019. The decrease was partially offset by a \$2.3 million increase in external-related expenses related to our ongoing late-stage clinical programs in TD-1473 (our gut-selective pan-JAK inhibitor), amprexetine (a norepinephrine serotonin reuptake inhibitor (“NSRI”)) in neurogenic orthostatic hypotension (“nOH”), as well as continued investment in our early-stage programs, and partially offset by the termination of the Phase 3 Bacteremia study of VIBATIV in 2018.

R&D expenses increased by \$3.1 million for the nine months ended September 30, 2019 compared to the same period in 2018. The increase was primarily due to a \$10.5 million increase in external-related expenses related to our ongoing late-stage clinical programs in TD-1473, amprexetine, as well as continued investment in our early-stage programs and partially offset by the termination of the Phase 3 Bacteremia study of VIBATIV in 2018. The external-related expense increase was partially offset by a \$3.7 million decrease in employee-related expenses, a \$1.4 million decrease related to share-based compensation expense, and a \$2.2 million decrease in other expenses resulting primarily from our workforce reduction in the first quarter of 2019.

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 \$1.0 million and \$3.2 million for the three

[Table of Contents](#)

months ended September 30, 2019 and 2018, respectively, and \$3.4 million and \$6.5 million for the nine months ended September 30, 2019 and 2018, respectively. The decreases in expense reimbursements were primarily attributed to the wind down of the rевefenac development program following our submission of the NDA in November 2017.

Selling, General and Administrative Expenses

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

(In thousands)	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2019	2018	\$	%	2019	2018	\$	%
Selling, general and administrative	\$ 25,622	\$ 21,890	\$ 3,732	17 %	\$ 73,035	\$ 71,601	\$ 1,434	2 %

Selling, general and administrative expenses increased by \$3.7 million for the three months ended September 30, 2019 compared to the same period in 2018. The increase was primarily due to increases in external-related expenses and share-based compensation expense. External-related expenses increased \$3.4 million primarily due to legal costs associated with the Innoviva arbitration, partially offset by a decrease in VIBATIV-related external services as a result of the sale of VIBATIV to Cumberland in November 2018, and share-based compensation expense increased by \$1.1 million. These increases were partially offset by a decrease of \$1.3 million in employee-related expenses primarily due to our workforce reduction in the first quarter of 2019.

Selling, general and administrative expenses increased by \$1.4 million for the nine months ended September 30, 2019 compared to the same period in 2018. The increase was primarily due to increases in external-related expenses, collaboration loss, and facilities and other allocable expenses. External-related expenses increased \$0.4 million primarily due to legal costs associated with the Innoviva arbitration, partially offset by a decrease in VIBATIV-related external services as a result of the sale of VIBATIV to Cumberland in November 2018. Collaboration loss increased by \$1.6 million due to the launch of YUPELRI late-2018, and facilities and other allocable expenses increased by \$2.0 million. These increases were partially offset by decreases in share-based compensation of \$1.6 million and employee-related expenses of \$1.1 million. The decrease in employee-related expenses was primarily due to our workforce reduction in the first quarter of 2019.

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,		Change		Nine Months Ended September 30,		Change	
	2019	2018	\$	%	2019	2018	\$	%
Income from investment in TRC, LLC	\$ 7,197	\$ 3,119	\$ 4,078	131%	\$ 21,792	\$ 5,754	\$ 16,038	279%

The income from investment in TRC, LLC represents our share of the royalty payments from GSK to TRC on the net sales of TRELEGY ELLIPTA (net of our share 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). Income from investment in TRC increased by \$4.1 million and \$16.0 million for the three and nine months ended September 30, 2019, respectively, compared to the same periods in 2018. Our share of TRC expenses for the three and nine months ended September 30, 2019 was \$2.3 million, which was primarily comprised of TRC's legal and related fees associated with the arbitration between Innoviva and TRC and us. There were minimal TRC expenses for the three and nine months ended September 30, 2018.

In connection with the issuance of our \$237.5 million net principal amount Non-Recourse 2033 Notes in November 2018, 75% of the income from our investment in TRC is available only for payment of the Non-Recourse 2033 Notes and is not available to pay other creditor obligations or claims. In May 2019, we announced that we had initiated arbitration against Innoviva and TRC in connection with Innoviva's failure to disburse certain royalties to us. Please refer to "Legal Proceedings" under Part II, Item 1 of these financial statements for further details regarding the arbitrator's final decision issued in September 2019.

[Table of Contents](#)

Interest Expense

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

(In thousands)	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2019	2018	\$	%	2019	2018	\$	%
Interest expense	\$ (8,068)	\$ (2,137)	\$ (5,931)	278 %	\$ (23,827)	\$ (6,411)	\$ (17,416)	272 %

Interest expense increased by \$5.9 million and \$17.4 million for the three and nine months ended September 30, 2019, respectively, compared to the same periods in 2018 due to additional interest expense related to the issuance of the Non-Recourse 2033 Notes in November 2018.

Interest and Other Income, net

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

(In thousands)	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2019	2018	\$	%	2019	2018	\$	%
Interest and other income, net	\$ 2,089	\$ 1,376	\$ 713	52 %	\$ 7,258	\$ 4,144	\$ 3,114	75 %

Interest and other income increased by \$0.7 million and \$3.1 million for the three and nine months ended September 30, 2019, respectively, compared to the same periods in 2018 primarily due to the additional income earned from higher investment balances following the issuance of the Non-Recourse 2033 Notes in November 2018. We also recognized \$0.2 million and \$0.6 million for the three and nine months ended September 30, 2019, respectively, as royalty income generated from sales of VIBATIV by Cumberland.

Provision for Income Tax Benefit

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

(In thousands)	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2019	2018	\$	%	2019	2018	\$	%
Provision for income tax benefit	\$ 5,552	\$ 659	\$ 4,893	742 %	\$ 5,271	\$ 7,305	\$ (2,034)	(28)%

For the three months ended September 30, 2019, the benefit for income taxes increased by \$4.9 million compared to the same period in 2018. The increase was primarily attributed to a reversal of previously accrued contingent tax liabilities for uncertain tax positions due to a lapse of the statute of limitations and current year US research and development credits.

For the nine months ended September 30, 2019, the benefit for income taxes decreased by \$2.0 million compared to the same period in 2018. The decrease was primarily due to higher tax benefits recorded in 2018 resulting from the finalization of our transfer pricing policy included in the US tax return filed in 2018. Our effective tax rate for the nine months ended September 30, 2019 was 3.0%.

Liquidity and Capital Resources

We have financed our operations primarily through public offering of equity and debt securities, private placements of equity and debt, revenue from collaboration arrangements and, to a lesser extent, revenue from product sales. As of September 30, 2019, we had approximately \$344.6 million in cash, cash equivalents, and investments in marketable securities (excluding restricted cash). Also, as of September 30, 2019, we had outstanding (i) \$230.0 million in aggregate principal Convertible Senior 2023 Notes and (ii) \$237.5 million in net principal Non-Recourse 2033 Notes stated net of a 5.0% retention by us as discussed in the *Economic Interest in GSK-Partnered Respiratory Programs—Theravance Respiratory Company, LLC* section above.

[Table of Contents](#)

The Non-Recourse 2033 Notes are secured by all of the Issuer's rights, title and interest as a holder of the Issuer Class C Units in TRC. The primary source of funds to make payments on the Non-Recourse 2033 Notes will be the 63.75% economic interest of the issuer (evidenced by the Issuer Class C Units) in any future payments that may be made by GSK to TRC 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) relating to the GSK-Partnered Respiratory Programs, including the TRELEGY ELLIPTA program. As a result, the holders of the Non-Recourse 2033 Notes have no recourse against Theravance Biopharma even if the TRELEGY ELLIPTA payments are insufficient to cover the principal and interest payments for the Non-Recourse 2033 Notes.

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 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 may continue to receive potential substantial payments from future collaboration transactions if the drug candidates in our pipeline achieve positive clinical or regulatory outcomes or if our product candidates are approved and meet certain milestones. 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 be sufficient to 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:

(In thousands)	Nine Months Ended September 30,		
	2019	2018	Change
Net cash used in operating activities	\$ (173,845)	\$ (60,689)	\$ (113,156)
Net cash (used in) provided by investing activities	(97,112)	77,315	(174,427)
Net cash provided by (used in) financing activities	2,835	(4,404)	7,239

[Table of Contents](#)

Cash flows used in operating activities

Net cash used in operating activities was \$173.8 million for the nine months ended September 30, 2019. The \$173.8 million used in operating activities consisted primarily of net loss of \$170.8 million, adjusted for non-cash items such as \$36.5 million for share-based compensation expense and \$33.5 million of net cash outflow related to changes in operating assets and liabilities. Overall, net cash used in operating activities increased by \$113.2 million, compared to the same period in 2018, primarily driven by our receipt of the \$100.0 million upfront payment from our collaborative arrangement from Janssen in February 2018.

Net cash used in operating activities was \$60.7 million 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 upfront payment in February 2018 from the Janssen collaborative agreement.

Cash flows (used in) provided by investing activities

Net cash used in investing activities was \$97.1 million for the nine months ended September 30, 2019, consisting primarily of net cash outflows resulting from net purchases and maturities of marketable securities of \$100.2 million which was partially offset by \$5.0 million in cash inflows related to final installment proceeds from the sale of the VIBATIV product to Cumberland in November 2018.

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 net 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.

Cash flows provided by (used in) financing activities

Net cash provided by financing activities was \$2.8 million for the nine months ended September 30, 2019, consisting of \$5.6 million of cash inflows from employee share plan purchase proceeds and share option exercises which was partially offset by \$2.7 million of net cash outflows related to the repurchase of shares to satisfy tax withholding obligations.

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.

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, 2019.

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 meeting certain operating goals and objectives during the five-year period from 2016 to December 31, 2020. These goals are strategically important for us, 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 recognize compensation expense relating to awards subject to performance conditions if it is considered probable that the performance goals will be achieved. The probability of achievement is reassessed at each quarter-end reporting period. Previously recognized expense is reversed in the period in which it becomes probable that the requisite service period will not be rendered.

We determined that achievement of the requisite performance conditions for the first tranche were completed as of June 2018, and the expense associated with this first tranche has been fully recognized. We determined that achievement of the requisite performance conditions for the second tranche were completed as of February 2019. For the nine months ended

[Table of Contents](#)

September 30, 2019, we recognized \$1.2 million and \$1.9 million of share-based compensation expense and cash bonus expense, respectively, related to the second tranche of these awards. The maximum remaining share-based compensation expense and cash bonus expense associated with the second tranche is \$1.1 million and \$1.3 million, respectively.

The maximum potential remaining expense associated with the third tranche of this program is \$12.8 million related to share-based compensation expense and \$15.7 million related to cash bonus expense, which would be recognized in increments based on achievement of the performance conditions. 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.

In the fourth quarter of 2018, we granted 3,000 performance-contingent RSUs to an employee. These RSUs expire by December 31, 2020 and have a maximum share-based compensation expense of \$75,000 which will be recognized when its single performance milestone is deemed to be probable of achievement.

In the first quarter of 2019, we granted 60,000 performance-contingent RSUs to an employee. These RSUs have dual triggers of vesting based upon the achievement of certain performance milestones in specified timeframes, as well as a requirement for continued employment. The compensation expense related to these awards is broken into two separate performance milestones and recognized when the associated performance milestones are deemed to be probable of achievement. The maximum share-based compensation expense associated with the 60,000 performance-contingent RSUs' first and second performance milestones are \$0.8 million each for a total of \$1.6 million, and the RSUs expire by December 31, 2021. In the third quarter of 2019, we determined that a portion of the performance milestone associated with the first tranche was probable of achievement and recognized \$0.3 million of share-based compensation expense. We determined that the second tranche was not probable as of September 30, 2019, and, as a result, no compensation expense related to these RSUs has been recognized to date.

In the third quarter of 2019, we granted 60,000 performance-contingent RSUs to an employee. These RSUs have dual triggers of vesting based upon the achievement of certain performance milestones in specified timeframes, as well as a requirement for continued employment. The compensation expense related to these RSUs is broken into three separate performance milestones and will be recognized when the associated performance milestones are deemed to be probable of achievement. The maximum share-based compensation expense associated with the 60,000 performance-contingent RSUs' three performance milestones are approximately \$0.3 million each for a total of \$1.0 million. The 60,000 performance-contingent RSUs expire by June 30, 2022. As of September 30, 2019, we determined that the performance milestones were not probable of achievement and, as a result, no compensation expense related to these RSUs has been recognized to date.

Equity Compensation Plans

We have three equity compensation plans — our 2013 Equity Incentive Plan (the “2013 EIP”), our 2013 Employee Share Purchase Plan (the “2013 ESPP”), and our 2014 New Employee Equity Incentive Plan (the “2014 NEEIP”). As of December 31, 2018, (i) 5,324,287 securities remained available for future issuance under our shareholder approved equity compensation plans, consisting of 3,642,602 ordinary shares available under the 2013 EIP and 1,681,685 ordinary shares available under the 2013 ESPP, and (ii) 132,415 securities remained available for future issuance under the 2014 NEEIP, an equity compensation plan not approved by shareholders.

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, 2018, filed with the SEC on February 28, 2019.

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, 2018, filed with the SEC on February 28, 2019.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks, as of September 30, 2019, have not changed materially from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on February 28, 2019.

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, 2019, 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, 2019 which has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are 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 in TRC 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 above. We are entitled to this economic interest through our equity ownership in TRC.

In May 2019, the Company announced that it had initiated an arbitration against Innoviva and TRC because Innoviva, as manager of TRC, had caused TRC to withhold certain distributions owed to the Company with respect to the Company’s 85% economic interest in TRC since the quarter ended December 31, 2018, and Innoviva’s previous statement to the Company that it intended to prevent TRC from making cash distributions during 2019. The arbitration hearing commenced on July 23, 2019. After initiation of the arbitration and prior to the final decision being issued, in the third quarter of 2019 Innoviva caused TRC to make a partial distribution of funds due and owing to the Company of \$10.6 million. This distribution represented a portion of the Company’s share of the royalty payments received by TRC from GSK for sales of TRELEGY ELLIPTA from the fourth quarter of 2018 through the second quarter of 2019.

In September 2019, the arbitrator issued a final decision. The arbitrator ruled that, while Innoviva breached the TRC LLC Agreement by failing to provide quarterly financial plans to the Company as required, the withholding of funds by Innoviva with respect to certain TRELEGY ELLIPTA development and commercialization initiatives proposed by Innoviva was not in breach of the TRC LLC Agreement. The arbitrator also found that Innoviva had not breached its fiduciary duties to the Company. The arbitrator awarded injunctive relief to give more certainty to future dealings between the parties and to clarify certain terms of the TRC LLC Agreement, and imposed additional obligations on Innoviva to obtain the consent of GSK for any proposed investment of TRC funds that requires the consent of GSK under the collaboration agreement dated November 14, 2002, as amended. Under the arbitrator's ruling, Innoviva is currently permitted to continue to withhold \$8.0 million of TRC funds for certain TRELEGY ELLIPTA development and commercialization initiatives proposed by Innoviva. These initiatives must be presented to GSK in the fourth quarter of 2019 and they cannot be implemented without GSK's approval, which approval must be obtained no later than during the first quarter of 2020. To the extent GSK's approval is not received, the Company expects distribution to the TRC members of the withheld funds. To the extent the initiatives are timely approved by GSK and proceed, TRC may withhold additional amounts in subsequent quarters through to the completion of these initiatives.

ITEM 1A. RISK FACTORS

RISKS RELATING TO THE COMPANY

The risks described below and elsewhere in the Annual Report for the year ended December 31, 2018 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, 2019 and years ended December 31, 2018 and 2017, we recognized net losses of \$58.4 million, \$170.8 million, \$215.5 million and \$285.4 million, respectively, which are reflected in the shareholders' (deficit) equity 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, which was \$1.2 billion as of September 30, 2019. 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 YUPELRI. 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: we initiated a Phase 2b/3 induction and maintenance study of TD-1473 in ulcerative colitis, we initiated a Phase 2 induction study of TD-1473 in Crohn's disease; and we have progressed ampreloxetine (TD-9855) into a Phase 3 registrational program. The expenses associated with these clinical studies are very significant. We will incur costs and expenses associated with our co-promotion agreement with Mylan for commercialization of YUPELRI in the US, including the maintenance of an independent sales and marketing organization with appropriate technical expertise, a medical affairs presence and consultant support, and post-marketing studies. In late 2018 we sold our VIBATIV product, and therefore will not recognize revenue from future product sales, other than through royalties from sales by Cumberland Pharmaceuticals Inc. ("Cumberland"), the purchaser of the product. Our commitment of resources to the continued development of our existing product candidates, our discovery programs, and YUPELRI 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;

[Table of Contents](#)

- 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, (ii) our economic interest in royalties from net sales of TRELEGY ELLIPTA paid to TRC (63.75% of which amounts are used to make payments on the Non-Recourse 2033 Notes), (iii) potential payments under collaboration agreements, and (iv) minor royalties from the net sales of VIBATIV, 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 quality, or successfully market and sell such products with desired margins, our expenses will continue to exceed any revenues we may receive for the foreseeable future.

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 (or perceived adverse developments or results) 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;
- delays in patient enrollment and variability in the number and types of patients available for clinical studies;
- 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 or suspensions of the conduct of the clinical trials and changes in regulatory requirements, policy and guidelines, including as a result of any class-based risks that emerge as an area of FDA or other regulatory agency focus;

[Table of Contents](#)

- failure of our partners to advance our product candidates through clinical development;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- varying regulatory requirements or interpretations of data among the FDA and foreign regulatory authorities; and
- a regional disturbance where we or our collaborative partners are enrolling patients in clinical trials, such as a pandemic, terrorist activities or war, political unrest or a natural disaster.

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.

In July 2019, the FDA issued a Boxed Warning for a systemically active pan-JAK inhibitor, calling out an increased risk of pulmonary embolism and death following the results of a safety study in patients with rheumatoid arthritis. Theravance Biopharma is focused on developing pan-JAK inhibitors that are designed to remain organ-selective so that they do not become systemically active in order to minimize the risk of side effects. It is unknown at this time what, if any, additional requirements the FDA may put in place with respect to the development of JAK inhibitors generally or what other future FDA actions may have on the prospects for JAK inhibitors. Delays or adverse developments or results or perceived adverse developments or results relating to JAK inhibitors could harm our business and could cause the price of our securities to fall. Examples of such adverse developments include, but are not limited to:

- the FDA and/or other regulatory authorities determining that additional non-clinical or clinical studies are required with respect to our JAK inhibitor programs;
- safety, efficacy or other concerns relating to our JAK inhibitor programs or JAK inhibitors under development or commercialized by other companies; or
- any change in FDA policy or guidance regarding JAK inhibitors.

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 comply with the regulatory requirements for the quality of medicinal products and 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. See the risk factor entitled “*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*” above for additional information. 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.

[Table of Contents](#)

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 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 TD-1473 in 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;
- support our additional investments in YUPELRI, including potential post-marketing clinical studies;
- 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;

[Table of Contents](#)

- 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 intend to seek to raise additional capital or obtain future funding through public or private equity offerings, debt financings or additional collaborations and licensing arrangements to meet our capital needs or to take advantage of opportunistic market conditions. 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. Neither the terms of our \$230.0 million of 3.25% convertible senior notes, due 2023 (the "Convertible Senior 2023 Notes") nor the terms of the Issuer's 9.0% non-recourse notes due in or before 2033 ("Non-Recourse 2033 Notes") restrict our ability to issue additional debt. If additional debt is issued, 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. Moreover, 75% of the income from our investment in TRC, as evidenced by the Issuer Class C Units, is available only for payment of the Non-Recourse 2033 Notes and is not available to pay our other obligations or the claims of our other creditors. 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. Since our Spin-Off in June 2014, we have raised an aggregate of \$583.9 million in a combination of (i) the sale of approximately 17.5 million ordinary shares, and (ii) \$480.0 million aggregate principal amount of notes. 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 for velusetrag, our internally discovered 5-HT4 agonist for the treatment of gastromotility disorders, under which we have transferred to Alfasigma global rights for velusetrag. In January 2015, we entered into a collaboration agreement with Mylan for the development and

[Table of Contents](#)

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 in development for gastrointestinal motility disorders. 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. 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.

Our partners have in the past and may in the future 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. In addition, effective collaboration with a partner requires coordination to achieve complex and detail-intensive goals between entities that potentially have different priorities, capabilities and processes and successful navigation of the challenges such coordination entails. 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

[Table of Contents](#)

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 ownership 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 required quality, 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:

- disappointing or lower than expected sales of TRELEGY ELLIPTA;
- any regulatory difficulty in seeking approval of an asthma indication for TRELEGY ELLIPTA, which GSK will be undertaking following its successful Phase 3 clinical program in asthma patients;
- disputes between GSK and Innoviva or between us and Innoviva, such as our recent dispute with Innoviva described in Part II, Item 1 "Legal Proceedings" concerning the withholding of royalty payments due to us under the TRC LLC Agreement;
- 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;
- GSK deciding to delay or halt any of the GSK-Partnered Respiratory Programs in which we have a substantial economic interest;
- the FDA and/or other national or foreign regulatory authorities determining that any of the studies under these programs do not demonstrate the required quality, 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; or
- any particular FDA requirements or changes in FDA policy or guidance regarding these programs or any particular regulatory requirements in other jurisdictions or changes in the policies or guidance adopted by foreign regulatory authorities.

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, 2019 GSK beneficially owned approximately 17.0% 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. For example, GSK's commercialization efforts are 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

[Table of Contents](#)

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. See Part II, Item 1 “Legal Proceedings.” Other examples of these kinds of issues include but are not limited to non-performance of other 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 or between us and Innoviva could result in significant reduction in the market price of our securities and other material harm to our business.

We do not control the commercialization of TRELEGY ELLIPTA and we do not control TRC; accordingly the amount of royalties we receive will depend, among other factors, on GSK's ability to further commercialize TRELEGY ELLIPTA and TRC's decisions concerning use of cash in accordance with the TRC LLC Agreement.

We only receive revenues from TRELEGY ELLIPTA based on the amount of sales of this product by GSK in the form of our economic interest in the royalties paid by GSK to TRC, which is managed by Innoviva. There are no required minimum future payments associated with the product and any royalties we receive will depend on GSK’s ability to commercialize the product, the future payments, if any, made by GSK under the strategic alliance agreement and under the portion of the collaboration agreement assigned to TRC, TRC’s expenses, and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement. Following our recent arbitration with Innoviva concerning its withholding of certain royalty distributions to the TRC members, the arbitrator ruled that in the future if Innoviva desires to invest TRC funds in any initiatives that require the consent of GSK under the collaboration agreement, Innoviva must first obtain the consent of GSK. The timeframe for seeking GSK’s consent for these initiatives and the associated dates by which GSK’s consent must be received means that royalty distributions could be delayed for several quarters (if GSK ultimately does not consent) or perhaps not made at all until the completion of the initiatives (to the extent that GSK does consent and agrees with TRC that TRC funding will be used for such initiatives). This involves a number of risks and uncertainties, including:

- GSK’s ability to have an adequate supply of their respective product;
- Ongoing compliance by GSK or its suppliers with the FDA’s current Good Manufacturing Practice;
- Compliance with other applicable FDA and other regulatory requirements in the US or other foreign jurisdictions, including those described elsewhere in this report;
- Competition, whether from current competitors or new products developed by others in the future;
- Claims relating to intellectual property;

[Table of Contents](#)

- Any future disruptions in GSK's business which would affect its ability to commercialize the product;
- The ability of TRELEGY ELLIPTA to achieve wider acceptance among physicians, patients, third-party payors, or the medical community in general;
- The amount of cash associated with any additional future TRELEGY ELLIPTA commercialization initiatives that Innoviva proposes to GSK for TRC to pursue beyond those for which Innoviva is withholding \$8.0 million at present, the time it may take to present those initiatives to GSK for approval and the time it takes for GSK to consent or not consent;
- Any future withholding by Innoviva or TRC of royalty distributions not in accordance with the TRC LLC Agreement;
- Global economic conditions; and
- Any of the other risks relating to commercialization of products described elsewhere in this section.

These risks and uncertainties could materially impact the amount and timing of future royalties or other revenues we may receive from sales of TRELEGY ELLIPTA, which could have a material adverse effect on our future revenues, other financial results and our financial position and cause the price of our securities to fall.

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

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

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

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

[Table of Contents](#)

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 US 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, YUPELRI competes predominantly with short-acting nebulized bronchodilators used three to four times per day and the nebulized LAMA Lonhaler™ Magnair™ (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 and Mylan for the development and commercialization of a nebulized formulation of rевefenacin, our LAMA compound (including YUPELRI). 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,

[Table of Contents](#)

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. In addition, effective collaboration with a partner requires coordination to achieve complex and detail-intensive goals between entities that potentially have different priorities, capabilities and processes and successful navigation of the challenges such coordination entails. For example, Mylan has a substantial existing product portfolio and other considerations that influence its resource allocation, and other priorities and internal organizational processes that differ from our own. As a result of these differing interests and processes, Mylan 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. 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 US), 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

[Table of Contents](#)

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.

We have a significant amount of debt, including our Non-Recourse 2033 Notes and Convertible Senior 2023 Notes, that are senior in capital structure and cash flow, respectively, to holders of our ordinary shares. Satisfying the obligations relating to our debt could adversely affect the amount or timing of distributions to our shareholders.

As of September 30, 2019, we had approximately \$519.3 million in total long-term liabilities outstanding, comprised primarily of \$237.5 million in net principal that remains outstanding under the Issuer’s Non-Recourse 2033 Notes and \$230.0 million in principal that remains outstanding under our Convertible Senior 2023 Notes (together with the Non-Recourse 2033 Notes, the “Notes”).

The Convertible Senior 2023 Notes are unsecured debt and are not redeemable by us prior to the maturity date except for certain changes in tax law. Holders of the Convertible Senior 2023 Notes may require us to purchase all or any portion of their notes at 100% of their principal amount, plus any unpaid interest, upon a fundamental change such as a change of control of us or the termination of trading of our ordinary shares in accordance with the indenture governing the Convertible Senior 2023 Notes.

Until the Non-Recourse 2033 Notes are paid in full, holders of the Non-Recourse 2033 Notes have a perfected security interest in the Issuer Class C Units that represent a 63.75% economic interest in any future payments that may be made by GSK to TRC 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 in over the next four fiscal quarters) relating to the GSK-Partnered Respiratory Programs, including the TRELEGY ELLIPTA program.

Through October 15, 2020, the terms of the Non-Recourse 2033 Notes provide that to the extent there are insufficient funds to satisfy the Issuer’s scheduled quarterly interest obligations, the shortfall shall be added to the principal amount of the Non-Recourse 2033 Notes without a default or event of default occurring. The terms of the Non-Recourse 2033 Notes also provide that, at Theravance Biopharma’s option, the quarterly interest payment obligations can be satisfied by making a capital contribution to the Issuer, but not for more than four (4) consecutive quarterly interest payment dates or for more than six (6) quarterly interest payment dates during the term of the notes. For the April 15, 2019 and July 15, 2019 interest payment dates, Theravance Biopharma R&D, Inc. (parent entity of Issuer) made a capital contribution to satisfy the interest payment obligations for these two scheduled payments while we arbitrated the dispute with Innoviva discussed above in Part II, Item 1 “Legal Proceedings.”

Satisfying the obligations of these Notes could adversely affect the amount or timing of any distributions to our shareholders. We may choose to satisfy, repurchase, or refinance these Notes through public or private equity or debt

[Table of Contents](#)

financings if we deem such financings are available on favorable terms. If any or all of the Convertible Senior 2023 Notes are not converted into our ordinary shares before the maturity date, we will have to pay the holders the full aggregate principal amount of the Convertible Senior 2023 Notes then outstanding. If the Non-Recourse 2033 Notes are not refinanced or paid in full, the holders of the Non-Recourse 2033 Notes will have the right to foreclose on the Issuer Class C Units that represent a 63.75% economic interest in future royalties due on net sales of TRELEGY ELLIPTA and related assets. If the Issuer Class C Units are foreclosed upon, we will lose any right to receive 75% of the future royalty payments made by GSK in connection with the net sales of TRELEGY ELLIPTA and related assets. Any of the above payments could have a material adverse effect on our cash position. Our failure to satisfy these obligations may result in a default under the applicable indenture governing these Notes, which could result in a default under certain of our other debt instruments, if any. Any such default would harm our business and the price of our securities could fall.

Servicing our Convertible Senior 2023 Notes requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our debt. Additionally, holders may require us to repurchase our Convertible Senior 2023 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 Convertible Senior 2023 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 Convertible Senior 2023 Notes and any future indebtedness we may incur and to make necessary capital expenditures. In addition, the issuance of the Non-Recourse 2033 Notes reduced the cash available for us to make interest or principal payments on, or to refinance, the Convertible Senior 2023 Notes. 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 Convertible Senior 2023 Notes or future indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities on desirable terms or at all, which could result in a default on the Convertible Senior 2023 Notes or future indebtedness.

The holders of the Convertible Senior 2023 Notes may have the right to require us to repurchase the Convertible Senior 2023 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 governing the Convertible Senior 2023 Notes. We may not have sufficient funds to repurchase the Convertible Senior 2023 Notes in cash or have the ability to arrange necessary financing on acceptable terms. Our failure to repurchase the Convertible Senior 2023 Notes when required would result in an event of default with respect to the Convertible Senior 2023 Notes. In addition, any acceleration of the repayment of the Convertible Senior 2023 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

[Table of Contents](#)

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. As another example, we may incur penalties imposed by the competent authorities in the EU Member States in case of breach of the EU rules governing the collection and processing of personal data, including unauthorized access to or disclosure of personal 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 Wintingham, to operate our business. Mr. Wintingham has significant pharmaceutical industry experience. The loss of Mr. Wintingham'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.

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 could also give rise to calls for the governments of other EU Member States to consider withdrawal from the EU.

Further, development of our product candidates and/or regulatory approval may be delayed for other political events beyond our control. For example, a US federal government shutdown or budget sequestration, such as ones that occurred during 2013, 2018, and 2019, may result in significant reductions to the FDA's budget, employees and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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,

[Table of Contents](#)

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.

If YUPELRI is not broadly accepted by physicians, patients, third-party payors, or the medical community in general, we may never receive significant revenues from sales of this product.

The commercial success of YUPELRI depends upon its acceptance by physicians, patients, third-party payors and the medical community in general. YUPELRI may not be sufficiently accepted by these parties. YUPELRI competes with predominantly with short-acting nebulized bronchodilators used three to four times per day and the nebulized LAMA Lonhala™ Magnair™ (SUN-101/eFlow®) used twice per day. If YUPELRI is not widely accepted, our business and financial results could be materially harmed.

In collaboration with Mylan, we are responsible for marketing and sales of YUPELRI in the US, which subjects us to certain risks.

We currently maintain a sales force in the US and plan to continue to augment our sales and marketing personnel to support our co-promotion obligations for YUPELRI under our agreement with Mylan. The risks of fulfilling our US co-promotion obligations to Mylan include:

- costs and expenses associated with creating and maintaining an independent sales and marketing organization with appropriate technical expertise and supporting infrastructure, 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 YUPELRI, 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 and the ability to obtain access to and educate adequate numbers of physicians about prescribing YUPELRI in appropriate clinical situations, we will have difficulty commercializing YUPELRI, which would adversely affect our business and financial condition and the price of our securities could fall.

[Table of Contents](#)

We are subject to extensive and ongoing regulation, oversight and other requirements by the FDA 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 any approved products.

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 an approved product, such as YUPELRI, 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 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 any approved product, such as YUPELRI, 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 materially limit the ability to commercialize a product or any future product candidates and if we fail to comply with FDA regulations and requirements, 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 US, 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 and those commercializing products with respect to which we have an economic interest or right to receive royalties, including GSK and Cumberland, and such regulatory actions and oversight may limit those parties' 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 and those commercializing products with respect to which we have an economic interest or right to receive royalties may face competition from companies seeking to market generic versions of any approved products in which we have an interest, such as TRELEGY ELLIPTA or 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

[Table of Contents](#)

a cost significantly below that of the original drug. Although we have multiple patents protecting YUPELRI until at least 2025 that are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, and those commercializing products with respect to which we have an economic interest or right to receive royalties similarly have patents protecting their products, such as TRELEGY ELLIPTA and VIBATIV, 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 nor are we aware of any with respect to products in which we have an economic interest or right to receive royalties, but if any competitors successfully challenge the patents related to these products, we and/or our collaboration partners and those commercializing products with respect to which we have an economic interest or right to receive royalties 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 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.

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 US, 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 has implemented certain tax law changes and is expected to implement additional tax law changes to

[Table of Contents](#)

comply with the European Union Anti-Tax Avoidance Directives. These changes include the first ever Irish controlled foreign company (“CFC”) rules which came into effect on January 1, 2019. Due to provisions in *Finance Bill 2019*, Ireland will also implement certain transfer pricing rule changes, with effect from 2020. We are continuing to evaluate and monitor the applicability of the CFC rules published in *Finance Act 2018*, but our current assessment, based on the rules and guidance published to date, is that the rules are unlikely to have a material impact on our operations. Proposed statutory language has been provided for transfer pricing rule changes, and we believe that the transfer pricing rules are unlikely to have a material impact on our operations. New United Kingdom tax legislation was introduced by the *Finance Act 2019* (“FA 2019”) that imposes a tax related to offshore receipts in respect of intangible property held in low tax jurisdictions (“ORIP”) and became effective in April 2019. FA 2019 also included a power for amendments to the ORIP legislation to be made by regulation by December 31, 2019. On October 15, 2019, the United Kingdom published further guidance intended to facilitate the administration of the ORIP regime. However, a number of issues and areas of uncertainty remain. We have reviewed the original legislation in conjunction with the guidance and believe that the ORIP regime may apply to certain cash receipts. Based on this analysis, we believe that the ORIP charge on UK-derived cash receipts through the third quarter of 2019 is not material, but we will continue to refine our ORIP conclusions as guidance evolves.

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

We were a passive foreign investment company, or “PFIC,” for 2014, but we were not a PFIC from 2015 through 2018, and we do not expect to be a PFIC for the foreseeable future.

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

Based upon our assets and income during the course of 2014, we believe that our Company and one of our Company’s wholly-owned subsidiaries, Theravance Biopharma R&D, Inc. was a PFIC for 2014. Based upon our assets and income from 2015 through 2018, we do not believe that our company is a PFIC during these four years. We do not expect to be a PFIC for the foreseeable future based on our current business plans and current business model. For any taxable year (or portion thereof) in which our Company is a PFIC that is included in the holding period of a US holder, the US holder is generally subject to additional US federal income taxes plus an interest charge with respect to certain distributions from Theravance Biopharma or gain recognized on a sale of Theravance Biopharma shares. Similar rules would apply with respect to distributions from or gain recognized on an indirect sale of Theravance Biopharma Ireland Limited. US holders of our ordinary shares may have filed an election with respect to Company shares held at any time during 2014 to be treated as owning an interest in a “qualified electing fund” (“QEF”) or to “mark to market” their ordinary shares to avoid the otherwise applicable interest charge consequences of PFIC treatment with respect to our ordinary shares. A foreign corporation will not be treated as a QEF for any taxable year in which such foreign corporation is not treated as a PFIC. QEF and mark to market elections generally apply to the taxable year for which the election is made and all subsequent taxable years unless the election is revoked with consent of the Secretary of Treasury. US holders of our ordinary shares should consult their tax advisers regarding the tax reporting implications with respect to any QEF and mark to market elections made with respect to our company and with respect to their indirect interests in Theravance Biopharma R&D, Inc.

[Table of Contents](#)

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

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

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

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

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

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

If we are required to indemnify Innoviva or Cumberland, or if we are not able to enforce our indemnification rights against Innoviva or Cumberland, our business prospects and financial condition may be harmed.

We agreed to indemnify Innoviva from and after the Spin-Off with respect to (i) all debts, liabilities and obligations transferred to us in connection with the Spin-Off (including our failure to pay, perform or otherwise promptly discharge any such debts, liabilities or obligations after the Spin-Off), (ii) any misstatement or omission of a material fact resulting in a

[Table of Contents](#)

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

In addition, the agreement relating to the sale of VIBATIV to Cumberland contains indemnification obligations of both us and Cumberland. If we are required to indemnify Cumberland or if we are unable to enforce our indemnification rights against Cumberland for any reason, our business and financial condition may be harmed.

We commenced a workforce restructuring during the first quarter of 2019 to focus our efforts on our key programs. Even after giving effect to this restructuring, we will not have sufficient cash to fully execute on our key programs, and the restructuring may impact our ability to execute our business plan.

During the first quarter of 2019, we commenced a workforce restructuring involving the reduction of our overall headcount by 51 individuals, with affected employees primarily focused on early research or the infrastructure in support of VIBATIV. There can be no assurance that we will be able to reduce spending as planned or that unanticipated costs will not occur. Our restructuring efforts to focus on key programs may not prove successful due to a variety of factors, including, without limitation, risks that a smaller workforce may have difficulty achieving our goals. In addition, we may in the future decide to restructure operations and reduce expenses further by taking such measures as additional reductions in our workforce and program spending. Any restructuring places a substantial strain on remaining management and employees and on operational resources and there is a risk that our business will be adversely affected by the diversion of management time to the restructuring efforts.

RISKS RELATED TO LEGAL AND REGULATORY UNCERTAINTY

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

We rely upon a combination of patents, patent applications, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any involuntary disclosure to or misappropriation by third parties of this proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. The status of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and is very uncertain. As of September 30, 2019, we owned 437 issued US patents and 1,576 granted foreign patents, as well as additional pending US and foreign patent applications. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be invalidated or be too narrow to prevent third parties from developing or designing around these patents. If the sufficiency of the breadth or strength of protection provided by our patents with respect to a product candidate is threatened, it could dissuade companies from collaborating with us to develop product candidates and threaten our ability to commercialize products. Further, if we encounter delays in our clinical trials or in obtaining regulatory approval of our product candidates, the patent lives of the related product candidates would be reduced.

In addition, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, for processes for which patents are difficult to enforce and for any other elements of our drug discovery and development processes that involve proprietary know-how, information and technology that is not covered by patent applications. Although we require our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be misappropriated, disclosed or used for unauthorized purposes or that

[Table of Contents](#)

competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the US. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the US and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or, if established, maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition and results of operations, which could cause the price of our securities to fall.

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

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

In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties or pay royalties. In addition, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

In addition, in the future we could be required to initiate litigation to enforce our proprietary rights against infringement by third parties, prevent the unauthorized use or disclosure of our trade secrets and confidential information, or defend the validity of our patents. For example, in 2017, we filed a lawsuit against a former employee for misappropriation of certain of our confidential, proprietary and trade secret information. While this litigation has since been resolved, prosecution of claims to enforce or defend our rights against others involve substantial litigation expenses and divert substantial employee resources from our business but may not result in adequate remedy to us or sufficiently mitigate the harm to our business caused by any intellectual property infringement, unauthorized access, use or disclosure of trade secrets. If we fail to effectively enforce our proprietary rights against others, our business will be harmed and the price of our securities could fall.

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

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

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

The risk that we may be sued on product liability claims is inherent in the development and commercialization of pharmaceutical products. Side effects of, or manufacturing defects in, products that we or our partners develop or commercialize could result in the deterioration of a patient's condition, injury or even death. Once a product is approved for

[Table of Contents](#)

sale and commercialized, the likelihood of product liability lawsuits tends to increase. Claims may be brought by individuals seeking relief for themselves or by individuals or groups seeking to represent a class, asserting injuries based both on potential adverse effects described in the label as well as adverse events not yet observed. We also face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials. In addition, changes in laws outside the US are expanding our potential liability for injuries that occur during clinical trials. Product liability claims could harm our reputation, regardless of the merit or ultimate success of the claim, which may adversely affect our and our partners' ability to commercialize our products and cause the price of our securities to fall. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forgo further commercialization of the applicable products.

Although we maintain general liability and product liability insurance, this insurance may not fully cover potential liabilities and we cannot be sure that our insurer will not disclaim coverage as to a future claim. In addition, inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercial production and sale of our products, which could adversely affect our business.

We may also be required to prosecute or defend general commercial, intellectual property, securities and other lawsuits. Litigation typically involves substantial expenses and diverts substantial employee resources from our business. The cost of defending any product liability litigation or engaging in any other legal proceeding, even if resolved in our favor, could be substantial and uncertainties resulting from the initiation and continuation of the litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace and achieve our business goals.

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

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

EU Member States and other jurisdictions where we operate have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the General Data Protection Regulation ("GDPR") which became applicable on May 25, 2018, replacing the EU Data Protection Directive, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting.

[Table of Contents](#)

Switzerland has adopted similar restrictions. These obligations and restrictions concern, in particular, the consent of the individuals to whom the personal data relate, the information provided to the individuals, the transfer of personal data out of the European Economic Area (“EEA”) or Switzerland, security breach notifications, security and confidentiality of the personal data, as well as substantial potential fines for breaches of the data protection obligations. Data protection authorities from the different EU Member States may interpret the GDPR and applicable related national laws differently and impose requirements additional to those provided in the GDPR. In addition, guidance on implementation and compliance practices may be updated or otherwise revised, which adds to the complexity of processing personal data in the EU. When processing personal data of subjects in the EU, we have to comply with the applicable data protection laws. In particular, as we rely on services providers processing personal data of subjects in the EU, we have to enter into suitable contract terms with such providers and receive sufficient guarantees that such providers meet the requirements of the applicable data protection laws, particularly the GDPR which imposes specific and relevant obligations.

Although there are legal mechanisms to allow for the transfer of personal data from the EEA to the US, a decision of the European Court of Justice in the Schrems case (Case C-362/14 Maximillian Schrems v. Data Protection Commissioner) that invalidated the safe harbor framework has increased uncertainty around compliance with EU privacy law requirements. As a result of the decision, it was no longer possible to rely on the safe harbor certification as a legal basis for the transfer of personal data from the EU to entities in the US. On February 29, 2016, however, the European Commission announced an agreement with the US Department of Commerce (“DOC”) to replace the invalidated Safe Harbor framework with a new EU-US “Privacy Shield.” On July 12, 2016, the European Commission adopted a decision on the adequacy of the protection provided by the Privacy Shield. The Privacy Shield is intended to address the requirements set out by the European Court of Justice in its ruling by imposing more stringent obligations on companies, providing stronger monitoring and enforcement by the DOC and Federal Trade Commission, and making commitments on the part of public authorities regarding access to information. US companies have been able to certify to the US Department of Commerce their compliance with the privacy principles of the Privacy Shield since August 1, 2016.

On September 16, 2016, an Irish privacy advocacy group brought an action for annulment of the European Commission decision on the adequacy of the Privacy Shield before the European Court of Justice (Case T-670/16). In October 2016, a further action for annulment was brought by three French digital rights advocacy groups (Case T-738/16). Case T-670/16 was declared inadmissible and Case T-738/16 is still pending before the European Court of Justice. The US was admitted as an intervenor in the action on September 4, 2018. If the European Court of Justice invalidates the Privacy Shield, it will no longer be possible to rely on the Privacy Shield certification to support transfer of personal data from the EU to entities in the US. Adherence to the Privacy Shield is not, however, mandatory. US-based companies are permitted to rely either on their adherence to the Privacy Shield or on the other authorized means and procedures to transfer personal data provided by the GDPR. If we or our vendors fail to comply with applicable data privacy laws, or if the legal mechanisms we or our vendors rely upon to allow for the transfer of personal data from the EEA or Switzerland to the US (or other countries not considered by the European Commission to provide an adequate level of data protection) are not considered adequate, we could be subject to government enforcement actions and significant penalties against us, and our business could be adversely impacted if our ability to transfer personal data outside of the EEA or Switzerland is restricted, which could adversely impact our operating results.

Changes in healthcare law and implementing regulations, including government restrictions on pricing and reimbursement, as well as healthcare policy and other healthcare payor cost-containment initiatives, may negatively impact us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care may adversely affect us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties in regard to one or more of the following:

- the ability to set and collect a price believed to be reasonable for products;
- the ability to generate revenues and achieve profitability; and
- the availability of capital.

[Table of Contents](#)

The pricing and reimbursement environment for products may change in the future and become more challenging due to, among other reasons, policies advanced by the current or new presidential administrations, federal agencies, new healthcare legislation passed by Congress or fiscal challenges faced by all levels of government health administration authorities. Among policy makers and payors in the US and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access to healthcare. In the US, the pharmaceutical industry has been a particular focus of these efforts and has been and may in the future be significantly affected by major legislative initiatives. For instance, in the fourth quarter of 2018, the Centers for Medicare & Medicaid Services (“CMS”), the federal agency that administers the Medicare and Medicaid programs, released an advance notice of proposed rule-making to solicit feedback on a potential change in the way Medicare Part B pays for certain physician-administered drugs. Under Part B’s current reimbursement policy, Medicare pays providers the average sales price of the drug plus 6% (reduced to 4.3% as a result of sequestration). CMS is considering a proposal that would more closely align payment for these drugs with prices in certain countries (such as Canada, the United Kingdom, Japan, and Germany), allow private-sector vendors to negotiate prices, and pay providers a flat add-on payment not tied to the price of the drug. We expect we, our collaboration partners or those commercializing products with respect to which we have an economic interest or right to receive royalties may experience pricing pressures in connection with the sale of drug products, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative enactments.

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

In particular, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate program under the Healthcare Reform Act. These regulations became effective on April 1, 2016. Congress could enact additional legislation that further increases Medicaid drug rebates or other costs and charges associated with participating in the Medicaid Drug Rebate program. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program has and will continue to increase the costs and the complexity of compliance, has been and will be time-consuming, and could have a material adverse effect on results of operations for us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties.

Some states have elected not to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level, as is permitted under the Healthcare Reform Act. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact the sales, business and financial condition of us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties. Where Medicaid patients receive insurance coverage under any of the new options made available through the Healthcare Reform Act, manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, which could impact manufacturer revenues. In addition, there have been delays in the implementation of key provisions of the Healthcare Reform Act.

Moreover, certain legislative changes to and regulatory changes under the Healthcare Reform Act have occurred in the 115th US Congress and under the Trump Administration. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the individual mandate, effective January 1, 2019. Additional legislative changes to and regulatory changes under the Healthcare Reform Act remain possible, but the nature and extent of such potential additional changes are uncertain at this time. We expect that the Healthcare

[Table of Contents](#)

Reform Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on the ability of us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties to maintain or increase sales of existing products or to successfully commercialize product candidates, if approved.

In addition, there have been proposals to impose federal rebates on Medicare Part D drugs, requiring federally-mandated rebates on all drugs dispensed to Medicare Part D enrollees or on only those drugs dispensed to certain groups of lower income beneficiaries. If any of these proposals are adopted and result in additional rebates, this could have a negative impact on revenues for our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties, which could impact our revenues.

Beginning on April 1, 2013, Medicare payments for all items and services under Part A and B, including drugs and biologicals, were reduced by 2% under the sequestration (i.e., automatic spending reductions) as required by federal law, which requires sequestration for most federal programs, excluding Medicaid, Social Security, and certain other programs. The law caps the cuts to Medicare payments for items and services at 2% and this will continue to 2027. As long as these cuts remain in effect, they could adversely impact payment for any products that are reimbursed under Medicare. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for product or additional pricing pressures for our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties, which could impact our revenues.

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

Prior to the sale of VIBATIV to Cumberland, we had certain price reporting obligations to the Medicaid Drug Rebate program and other governmental pricing programs, and we had obligations to report average sales price under the Medicare program. Following the consummation of the transaction with Cumberland, our price reporting obligations related to VIBATIV have been transitioned to Cumberland, and price reporting obligations for YUPELRI reside with Mylan. However, we retain liability related to price reporting for VIBATIV for historic periods.

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

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs to a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. A final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities became effective on January 1, 2019.

Federal law also requires that a company that participates in the Medicaid Drug Rebate program report average sales price information each quarter to CMS for certain categories of drugs that are paid under the Medicare Part B program. Manufacturers calculate the average sales price based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. CMS uses these submissions to determine payment rates for drugs under Medicare Part B.

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

We are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted any false price information to the government, we may be liable for significant civil monetary penalties per item of false information. If we are found to have made a misrepresentation in the reporting of our average sales price, the Medicare statute provides for significant civil monetary penalties for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit the required price data on a timely basis could result in a significant civil monetary penalty per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs.

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

Under Section 703 of the National Defense Authorization Act for FY 2008, the manufacturer is required to pay quarterly rebates to DoD on utilization of its innovator products that are dispensed through DoD’s Tricare network pharmacies to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP for the calendar year that the product was dispensed. A manufacturer that overcharges the government in connection with the FSS contract or Tricare Retail Pharmacy Rebate Program, whether due to a misstated FCP or otherwise, is required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations.

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

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

- The US federal healthcare Anti-Kickback Statute prohibits any person from, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchasing, leasing, ordering or arranging for or recommending of any good or service for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid. The term “remuneration” has been broadly

interpreted to include anything of value. The Anti-Kickback Statute is subject to evolving interpretation and has been applied by government enforcement officials to a number of common business arrangements in the pharmaceutical industry. The government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the statute or specific intent to violate it. There are a number of statutory exemptions and regulatory safe harbors protecting some common activities from prosecution; however, those exceptions and safe harbors are drawn narrowly. Failure to meet all of the requirements of a particular statutory exception or regulatory safe harbor does not make the conduct *per se* illegal under the Anti-Kickback Statute, but the legality of the arrangement will be evaluated on a case-by-case basis based on the totality of the facts and circumstances. We seek to comply with the available statutory exemptions and safe harbors whenever possible, but our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants or patient or product assistance programs.

- The federal civil False Claims Act prohibits, among other things, knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent, or knowingly making, or using or causing to be made or used, a false record or statement material to a false or fraudulent claim to avoid, decrease, or conceal an obligation to pay money to the federal government. Private individuals, commonly known as “whistleblowers,” can bring civil False Claims Act *qui tam* actions, on behalf of the government and such individuals and may share in amounts paid by the entity to the government in recovery or settlement. In recent years, several pharmaceutical and other healthcare companies have faced enforcement actions under the federal False Claims Act for, among other things, allegedly submitting false or misleading pricing information to government health care programs and providing free product to customers with the expectation that the customers would bill federal programs for the product. Federal enforcement agencies also have showed increased interest in pharmaceutical companies’ product and patient assistance programs, including reimbursement and co-pay support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. Other companies have faced enforcement actions for causing false claims to be submitted because of the company’s marketing the product for unapproved, and thus non-reimbursable, uses. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties per false claim or statement for violations. Because of the potential for large monetary exposure, healthcare and pharmaceutical companies often resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings. Companies may be required, however, to enter into corporate integrity agreements with the government, which may impose substantial costs on companies to ensure compliance. Criminal penalties, including imprisonment and criminal fines, are also possible for making or presenting a false, fictitious or fraudulent claim to the federal government.
- HIPAA, among other things, imposes criminal and civil liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors, and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HIPAA also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal healthcare Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.
- The federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the US Department of Health and Human Services, Centers for Medicare and Medicaid Services, information related to payments and other transfers of value, directly or indirectly, to physicians (defined to include doctors,

[Table of Contents](#)

dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives. A manufacturer's failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties of up to an aggregate of \$150,000 per year, and up to an aggregate of \$1 million per year for "knowing failures." Manufacturers must submit reports by the 90th day of each calendar year.

- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payors, including private insurers or patients. Several states also require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing-related activities, including the provision of gifts, meals, or other items to certain health care providers, and restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. Some states require the posting of information relating to clinical studies and their outcomes. Some states and cities require identification or licensing of sales representatives. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes.
- Similar restrictions are imposed on the promotion and marketing of medicinal products in the EU Member States and other countries, including restrictions prohibiting the promotion of a compound prior to its approval. Laws (including those governing promotion, marketing and anti-kickback provisions), industry regulations and professional codes of conduct often are strictly enforced. Even in those countries where we may decide not to directly promote or market our products, inappropriate activity by our international distribution partners could have implications for us.

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

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

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical, biological and radioactive materials. In addition, our operations produce hazardous waste products, including hazardous waste. Federal, state and local laws and regulations govern the use, manufacture, management, storage, handling and disposal of hazardous materials and wastes. We may incur significant additional costs or liabilities to comply with, or for violations of, these and other applicable laws in the future. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any such contamination or injury. Further, in the event of a release of or exposure to hazardous materials, including at the sites we currently or formerly operate or at sites such as landfills where we send wastes for disposal, we

could be held liable for cleanup costs or damages or subject to other costs or penalties and such liability could exceed our resources. We do not have any insurance for liabilities arising from hazardous materials or under environmental laws. Compliance with or liability under applicable environmental laws and regulations or with respect to hazardous materials may be expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, which could cause the price of our securities to fall.

RISKS RELATING TO OUR ORDINARY SHARES

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

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

Market prices for securities of biotechnology and biopharmaceutical companies have been highly volatile, and we expect such volatility to continue for the foreseeable future, so that investment in our ordinary shares involves substantial risk. Additionally, the stock market from time to time has experienced significant price and volume fluctuations unrelated to the operating performance of particular companies.

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

- lower than expected sales of YUPELRI;
- any adverse developments or results or perceived adverse developments or results with respect to the GSK Partnered Respiratory Programs including, without limitation, lower than expected sales of TRELEGY ELLIPTA, difficulties or delays encountered with regard to the FDA or other regulatory authorities in these programs or any indication from clinical or non-clinical studies that the compounds in such programs are not safe or efficacious;
- any adverse developments or results or perceived adverse developments or results with respect to our key clinical development programs, for example our JAK inhibitor program or ampreloxetine, including, without limitation, any delays in development in these programs, any halting of development in these programs, any difficulties or delays encountered with regard to the FDA or other regulatory authorities in these programs (including any class-based risks that emerge as a FDA or other regulatory agency focus), or any indication from clinical or non-clinical studies that the compounds in such programs are not safe or efficacious;
- any announcements of developments with, or comments by, the FDA or other regulatory authorities with respect to products we or our partners have under development, are manufacturing or have commercialized;
- any adverse developments or disagreements or perceived adverse developments or disagreements with respect to our relationship with Innoviva, or the relationship of Innoviva or TRC on the one hand and GSK on the other hand, including any such developments or disagreements resulting from or relating to the TRC LLC Agreement or to the Spin-Off. (See Part II, Item 1 “Legal Proceedings” for further information);

[Table of Contents](#)

- any adverse developments or perceived adverse developments with respect to our relationship with any of our research, development or commercialization partners, including, without limitation, disagreements that may arise between us and any of those partners;
- any adverse developments or perceived adverse developments in our programs with respect to partnering efforts or otherwise;
- announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors;
- publicity regarding actual or potential study results or the outcome of regulatory review relating to products under development by us, our partners or our competitors;
- regulatory developments in the US and foreign countries;
- announcements with respect to governmental or private insurer reimbursement policies;
- announcements of equity or debt financings;
- possible impairment charges on non-marketable equity securities;
- economic and other external factors beyond our control, such as fluctuations in interest rates;
- loss of key personnel;
- likelihood of our ordinary shares to be more sensitive to changes in sales volume, market fluctuations and events or perceived events with respect to our business due to our small public float;
- low public market trading volumes for our ordinary shares related in part to the concentration of ownership of our shares;
- the sale of large concentrations of our shares;
- developments or disputes as to patent or other proprietary rights;
- approval or introduction of competing products and technologies;
- results of clinical trials;
- failures or unexpected delays in timelines for our potential products in development, including the obtaining of regulatory approvals;
- delays in manufacturing adversely affecting clinical or commercial operations;
- fluctuations in our operating results;
- market reaction to announcements by other biotechnology or pharmaceutical companies;
- initiation, termination or modification of agreements with our collaborators or disputes or disagreements with collaborators;
- litigation or the threat of litigation;

[Table of Contents](#)

- public concern as to the safety of product candidates or medicines developed by us; and
- comments and expectations of results made by securities analysts or investors.

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

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

Based on our review of publicly available filings, as of September 30, 2019 our three largest shareholders collectively owned approximately 54.8% of our outstanding ordinary shares. These shareholders could control the outcome of actions taken by us that require shareholder approval, including a transaction in which shareholders might receive a premium over the prevailing market price for their shares.

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

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

- require supermajority shareholder voting to effect certain amendments to our amended and restated memorandum and articles of association;
- establish a classified board of directors;
- restrict our shareholders from calling meetings or acting by written consent in lieu of a meeting;
- limit the ability of our shareholders to propose actions at duly convened meetings; and
- authorize our board of directors, without action by our shareholders, to issue preferred shares and additional ordinary shares.

In addition, in May 2018, our shareholders approved a resolution authorizing our board of directors to adopt a shareholder rights plan in the future intended to deter any person from acquiring more than 19.9% of our outstanding ordinary shares without the approval of our board of directors.

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

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

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

Shareholders of Cayman Islands exempted companies such as our Company have no general rights under Cayman Islands law to inspect corporate records and accounts or to obtain copies of lists of shareholders. Our directors have

[Table of Contents](#)

discretion under our amended and restated memorandum and articles of association to determine whether or not, and under what conditions, our corporate records may be inspected by our shareholders, but are not obliged to make them available to our shareholders. This may make it more difficult for you to obtain the information needed to establish any facts necessary for a shareholder motion or to solicit proxies from other shareholders in connection with a proxy contest.

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

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

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

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

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

We have been advised by our Cayman Islands legal counsel, Maples and Calder, that the courts of the Cayman Islands are unlikely (i) to recognize or enforce against Theravance Biopharma judgments of courts of the US predicated upon the civil liability provisions of the securities laws of the US or any State; and (ii) in original actions brought in the Cayman Islands, to impose liabilities against Theravance Biopharma predicated upon the civil liability provisions of the securities laws of the US or any State, on the grounds that such provisions are penal in nature. However, in the case of laws that are not penal in nature, although there is no statutory enforcement in the Cayman Islands of judgments obtained in the US, the courts of the Cayman Islands will recognize and enforce a foreign money judgment of a foreign court of competent jurisdiction without retrial on the merits based on the principle that a judgment of a competent foreign court imposes upon the judgment debtor an obligation to pay the sum for which judgment has been given provided certain conditions are met. For a foreign judgment to be enforced in the Cayman Islands, such judgment must be final and conclusive and for a liquidated sum, and must not be in respect of taxes or a fine or penalty, inconsistent with a Cayman Islands' judgment in respect of the same matter, impeachable on the grounds of fraud or obtained in a manner, and or be of a kind the enforcement of which is, contrary to natural justice or the public policy of the Cayman Islands (awards of punitive or multiple damages may well be held to be contrary to public policy). A Cayman Islands court, including the Grand Court of the Cayman Islands, may stay proceedings if concurrent proceedings are being brought elsewhere, which would delay proceedings and make it more difficult for our shareholders to bring action against us.

If securities or industry analysts cease coverage of us or do not publish research, or publish inaccurate or unfavorable research, about our business, the price of our ordinary shares and trading volume could decline.

The trading market for our ordinary shares depends in part on the research and reports that securities or industry analysts publish about us or our business. If few securities analysts commence coverage of us, or if industry analysts cease coverage of us, the trading price for our ordinary shares could be negatively affected. If one or more of the analysts who cover us downgrade our ordinary shares or publish inaccurate or unfavorable research about our business, the price of our ordinary shares would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our ordinary shares could decrease, which might cause our share price and trading volume to decline.

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

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

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

None.

ITEM 6. EXHIBITS

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference	
			Form	Filing Date/Period End Date
31.1	<u>Certification of Chief Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended</u>		X	
31.2	<u>Certification of Chief Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended</u>		X	
32(1)	<u>Certifications Pursuant to 18 U.S.C. Section 1350</u>		X	
101	Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended September 30, 2019, formatted in iXBRL: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss, (iii) Condensed Consolidated Statement of Shareholders' Equity (Deficit), (iv) the Condensed Consolidated Statements of Cash Flows, and (v) the Notes to the Condensed Consolidated Financial Statements		X	

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

SIGNATURES

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

Theravance Biopharma, Inc.

Date: November 8, 2019

/s/ RICK E WINNINGHAM

Rick E Winningham

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

Date: November 8, 2019

/s/ ANDREW HINDMAN

Andrew Hindman

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

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

I, Rick E Winningham, certify that:

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

Date: November 8, 2019

/s/ Rick E Winningham

Rick E Winningham
Chairman of the Board and Chief Executive Officer
(Principal Executive Officer)

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

I, Andrew Hindman, certify that:

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

Date: November 8, 2019

/s/ Andrew Hindman

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

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Rick E Winningham, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Theravance Biopharma, Inc. on Form 10-Q for the three and nine months ended September 30, 2019 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition of Theravance Biopharma, Inc. at the end of the periods covered by such Quarterly Report on Form 10-Q and results of operations of Theravance Biopharma, Inc. for the periods covered by such Quarterly Report on Form 10-Q.

Date: November 8, 2019

By: _____ /s/ Rick E Winningham
Rick E Winningham
Chairman of the Board and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Andrew Hindman, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Theravance Biopharma, Inc. on Form 10-Q for the three and nine months ended September 30, 2019 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition of Theravance Biopharma, Inc. at the end of the periods covered by such Quarterly Report on Form 10-Q and results of operations of Theravance Biopharma, Inc. for the periods covered by such Quarterly Report on Form 10-Q.

Date: November 8, 2019

By: _____ /s/ Andrew Hindman
Andrew Hindman
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)
