

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

**Form 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
**For the quarterly period ended June 30, 2024**

**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.)

**C/O Theravance Biopharma US, Inc.**

**901 Gateway Boulevard**

**South San Francisco, CA**

(Address of Principal Executive Offices)

**94080**

(Zip Code)

**(650) 808-6000**

(Registrant's Telephone Number, Including Area Code)

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

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
Ordinary Share \$0.00001 Par Value	TBPH	The Nasdaq Global Market

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

Accelerated Filer

Non-accelerated Filer

Smaller Reporting Company

Emerging Growth Company

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

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

As of August 2, 2024, the number of the registrant's outstanding ordinary shares was 48,922,083.

**THERAVANCE BIOPHARMA, INC.**  
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**PART I. FINANCIAL INFORMATION**  
**ITEM 1. FINANCIAL STATEMENTS**

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

	June 30, 2024	December 31, 2023
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 46,345	\$ 39,545
Short-term marketable securities	49,733	62,881
Receivables from collaborative arrangements	14,299	17,474
Prepaid clinical and development services	2,646	2,038
Other prepaid and current assets	6,284	11,603
Total current assets	119,307	133,541
Property and equipment, net	8,142	9,068
Operating lease assets	31,815	36,287
Future contingent milestone and royalty assets	194,200	194,200
Restricted cash	836	836
Other assets	7,729	8,067
Total assets	<u>\$ 362,029</u>	<u>\$ 381,999</u>
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,674	\$ 1,524
Accrued personnel-related expenses	5,774	6,443
Accrued clinical and development expenses	1,966	2,246
Accrued general and administrative expenses	1,959	2,900
Operating lease liabilities	4,219	3,923
Tenant improvement payable to sublessee	6,490	6,490
Other accrued liabilities	864	1,241
Total current liabilities	22,946	24,767
Long-term operating lease liabilities	42,441	45,236
Future royalty payment contingency	29,061	27,788
Unrecognized tax benefits	69,007	65,294
Other long-term liabilities	4,885	5,919
Commitments and contingencies (Note 10)		
<b>Shareholders' Equity</b>		
Preferred shares, \$0.00001 par value per share: 230 shares authorized, no shares issued or outstanding	—	—
Ordinary shares, \$0.00001 par value per share: 200,000 shares authorized; 48,922 and 48,091 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	1,131,008	1,122,164
Accumulated other comprehensive loss	(22)	(65)
Accumulated deficit	(937,297)	(909,104)
Total shareholders' equity	193,689	212,995
Total liabilities and shareholders' equity	<u>\$ 362,029</u>	<u>\$ 381,999</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)**

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2024</b>	<b>2023</b>	<b>2024</b>	<b>2023</b>
<b>Revenue:</b>				
Viatris collaboration agreement	\$ 14,256	\$ 13,743	\$ 28,759	\$ 24,154
Collaboration revenue	—	6	—	12
Total revenue	<u>14,256</u>	<u>13,749</u>	<u>28,759</u>	<u>24,166</u>
<b>Expenses:</b>				
Research and development (1)	9,954	9,425	18,922	23,997
Selling, general and administrative (1)	17,056	19,278	33,798	38,461
Impairment of long-lived assets (non-cash)	2,951	—	2,951	—
Restructuring and related expenses (1)	—	1,169	—	2,743
Total expenses	<u>29,961</u>	<u>29,872</u>	<u>55,671</u>	<u>65,201</u>
<b>Loss from operations</b>	<b>(15,705)</b>	<b>(16,123)</b>	<b>(26,912)</b>	<b>(41,035)</b>
Interest expense (non-cash)	(644)	(568)	(1,273)	(1,118)
Interest income and other income (expense), net	1,128	2,504	2,562	5,483
Loss before income taxes	(15,221)	(14,187)	(25,623)	(36,670)
Provision for income tax expense	(1,308)	(1,458)	(2,570)	(1,063)
<b>Net loss</b>	<b><u>(16,529)</u></b>	<b><u>(15,645)</u></b>	<b><u>\$ (28,193)</u></b>	<b><u>\$ (37,733)</u></b>
Net unrealized gain (loss) on available-for-sale investments	19	(337)	43	(271)
Total comprehensive loss	<u>\$ (16,510)</u>	<u>\$ (15,982)</u>	<u>\$ (28,150)</u>	<u>\$ (38,004)</u>
<b>Net loss per share:</b>				
Basic and diluted net loss per share	<u>\$ (0.34)</u>	<u>\$ (0.28)</u>	<u>\$ (0.58)</u>	<u>\$ (0.63)</u>
Shares used to compute basic and diluted net loss per share	<u>\$ 48,747</u>	<u>\$ 56,682</u>	<u>48,515</u>	<u>59,791</u>

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

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2024</b>	<b>2023</b>	<b>2024</b>	<b>2023</b>
<b>(In thousands)</b>				
Research and development	\$ 1,151	\$ 1,855	\$ 2,616	\$ 4,296
Selling, general and administrative	4,225	4,409	7,988	8,632
Restructuring and related expenses	—	—	—	357
Total share-based compensation expense	<u>\$ 5,376</u>	<u>\$ 6,264</u>	<u>\$ 10,604</u>	<u>\$ 13,285</u>

*See accompanying notes to condensed consolidated financial statements.*

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

	Ordinary Shares		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
<b>Balances at March 31, 2024</b>	48,566	\$ —	\$ 1,125,677	\$ (41)	\$ (920,768)	\$ 204,868
Proceeds from the sale of ordinary shares	5	—	44	—	—	44
Proceeds from ESPP purchases	45	—	375	—	—	375
Employee share-based compensation expense	—	—	5,376	—	—	5,376
Issuance of restricted shares	354	—	—	—	—	—
Repurchase of shares to satisfy tax withholding	(48)	—	(464)	—	—	(464)
Net unrealized gain on marketable securities	—	—	—	19	—	19
Net loss	—	—	—	—	(16,529)	(16,529)
<b>Balances at June 30, 2024</b>	<u>48,922</u>	<u>\$ —</u>	<u>\$ 1,131,008</u>	<u>\$ (22)</u>	<u>\$ (937,297)</u>	<u>\$ 193,689</u>

	Ordinary Shares		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
<b>Balances at December 31, 2023</b>	48,091	\$ —	\$ 1,122,164	\$ (65)	\$ (909,104)	\$ 212,995
Repurchase of ordinary shares, net of transaction costs	(38)	—	(445)	—	—	(445)
Proceeds from the sale of ordinary shares	5	—	44	—	—	44
Proceeds from ESPP purchases	45	—	375	—	—	375
Employee share-based compensation expense	—	—	10,604	—	—	10,604
Issuance of restricted shares	1,013	—	—	—	—	—
Repurchase of shares to satisfy tax withholding	(194)	—	(1,734)	—	—	(1,734)
Net unrealized gain on marketable securities	—	—	—	43	—	43
Net loss	—	—	—	—	(28,193)	(28,193)
<b>Balances at June 30, 2024</b>	<u>48,922</u>	<u>\$ —</u>	<u>\$ 1,131,008</u>	<u>\$ (22)</u>	<u>\$ (937,297)</u>	<u>\$ 193,689</u>

	Ordinary Shares		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
<b>Balances at March 31, 2023</b>	60,542	\$ 1	\$ 1,246,506	\$ 51	\$ (875,999)	\$ 370,559
Repurchase of ordinary shares, net of transaction costs	(7,283)	—	(80,543)	—	—	(80,543)
Proceeds from ESPP purchases	63	—	446	—	—	446
Employee share-based compensation expense	—	—	6,264	—	—	6,264
Issuance of restricted shares	424	—	—	—	—	—
Repurchase of shares to satisfy tax withholding	(52)	—	(583)	—	—	(583)
Net unrealized loss on marketable securities	—	—	—	(337)	—	(337)
Net loss	—	—	—	—	(15,645)	(15,645)
<b>Balances at June 30, 2023</b>	<u>53,694</u>	<u>\$ 1</u>	<u>\$ 1,172,090</u>	<u>\$ (286)</u>	<u>\$ (891,644)</u>	<u>\$ 280,161</u>

	Ordinary Shares		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
<b>Balances at December 31, 2022</b>	65,227	\$ 1	\$ 1,295,725	\$ (15)	\$ (853,911)	\$ 441,800
Repurchase of ordinary shares, net of transaction costs	(12,441)	—	(135,896)	—	—	(135,896)
Proceeds from ESPP purchases	63	—	446	—	—	446
Employee share-based compensation expense	—	—	13,285	—	—	13,285
Issuance of restricted shares	981	—	—	—	—	—
Repurchase of shares to satisfy tax withholding	(136)	—	(1,470)	—	—	(1,470)
Net unrealized loss on marketable securities	—	—	—	(271)	—	(271)
Net loss	—	—	—	—	(37,733)	(37,733)
<b>Balances at June 30, 2023</b>	<u>53,694</u>	<u>\$ 1</u>	<u>\$ 1,172,090</u>	<u>\$ (286)</u>	<u>\$ (891,644)</u>	<u>\$ 280,161</u>

*See accompanying notes to condensed consolidated financial statements.*

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

	<b>Six Months Ended June 30,</b>	
	<b>2024</b>	<b>2023</b>
<b>Operating activities</b>		
Net loss	\$ (28,193)	\$ (37,733)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	859	1,177
Amortization and accretion on investment securities, net	(933)	(1,092)
Future royalty payment contingency interest accretion	1,273	1,118
Share-based compensation	10,604	13,285
Loss on disposal of property and equipment	34	1,352
Loss on impairment of long-lived assets	2,951	—
Amortization of right-of-use assets	2,232	1,817
Deferred income taxes	(1,074)	—
Changes in operating assets and liabilities:		
Receivables from collaborative and licensing arrangements	3,175	989
Prepaid clinical and development services	(608)	533
Other prepaid and current assets	5,318	(95)
Right-of-use lease assets	(548)	(144)
Other assets	292	1,751
Accounts payable	182	83
Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued liabilities	(2,256)	(6,534)
Deferred revenue	—	(11)
Operating lease liabilities	(2,498)	(479)
Unrecognized tax benefits	3,714	—
Other long-term liabilities	39	326
Net cash used in operating activities	<u>(5,437)</u>	<u>(23,657)</u>
<b>Investing activities</b>		
Purchases of property and equipment	(127)	(1,790)
Purchases of marketable securities	(58,140)	(134,534)
Maturities of marketable securities	72,264	31,435
Sale of short-term investments and marketable securities	—	71,377
Proceeds from the sale of property and equipment	—	1,513
Net cash provided by (used in) investing activities	<u>13,997</u>	<u>(31,999)</u>
<b>Financing activities</b>		
Ordinary share repurchases	(445)	(135,896)
Proceeds from the sale of ordinary shares	44	—
Proceeds from ESPP purchases	375	446
Repurchase of shares to satisfy tax withholding	(1,734)	(1,470)
Net cash used in financing activities	<u>(1,760)</u>	<u>(136,920)</u>
<b>Net increase (decrease) in cash, cash equivalents, and restricted cash</b>	<b>6,800</b>	<b>(192,576)</b>
<b>Cash, cash equivalents, and restricted cash at beginning of period</b>	<b>40,381</b>	<b>299,008</b>
<b>Cash, cash equivalents, and restricted cash at end of period</b>	<b>\$ 47,181</b>	<b>\$ 106,432</b>
<b>Supplemental disclosure of cash flow information</b>		
Cash paid for income taxes, net	\$ 12	\$ 14
<b>Supplemental disclosure of non-cash activities</b>		
Recognition of tenant improvement allowance assigned to sublease	\$ —	\$ 6,490

*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 biopharmaceutical company primarily focused on the development and commercialization of medicines. The Company’s focus is to deliver *medicines that make a difference*<sup>®</sup> in people’s lives.

***Basis of Presentation***

The Company’s condensed consolidated financial statements as of June 30, 2024 and for the three and six months ended June 30, 2024 and 2023 are unaudited but include 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 (“US”) generally accepted accounting principles (“GAAP”) for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated December 31, 2023 financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2023, filed with the Securities and Exchange Commission (“SEC”) on March 1, 2024.

The results for the three and six months ended June 30, 2024 are not necessarily indicative of the results to be expected for the year ending December 31, 2024, 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. Due to the inherent uncertainty in making estimates, actual results could differ materially from those estimates.

***Liquidity and Capital Resources***

The Company expects its cash, cash equivalents, and marketable securities will be sufficient to fund its operations for at least the next twelve months from the issuance date of these condensed consolidated financial statements based on current operating plans and financial forecasts.

***Significant Accounting Policies***

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, 2023.

***Recently Issued Accounting Pronouncements Not Yet Adopted***

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* (“ASU 2023-09”). ASU 2023-09 requires entities to provide additional information in their tax rate reconciliation and additional disclosures about income taxes paid by jurisdiction. ASU 2023-09 is effective on a prospective basis for annual periods beginning after December 15, 2024. Early adoption is also permitted for annual financial statements that have not yet been issued or made available for issuance. The Company is evaluating the impact of adopting ASU 2023-09 on its consolidated financial statements income tax disclosures.

The Company has evaluated other recently issued accounting pronouncements and does not currently believe that any of these pronouncements will have a material impact on its consolidated financial statements and related disclosures.

## 2. Net Loss per Share and Anti-dilutive Securities

Basic net loss per share is computed by dividing net loss by the weighted-average number of shares outstanding during the period. Diluted net loss per share is computed by increasing the weighted-average number of shares outstanding for the dilutive effect of potential ordinary shares determined using the treasury stock method. Potential ordinary shares include outstanding options to purchase ordinary shares, ordinary shares expected to be issued under the Company's employee share purchase plan ("ESPP"), restricted share units ("RSUs"), and performance-contingent RSUs ("PSUs") for which the performance vesting conditions have been deemed probable. PSUs with performance or market vesting conditions that have been deemed not probable as of the end of the period are not included in the diluted net loss per share computation.

(In thousands, except per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
<b>Numerator:</b>				
Net loss	\$ (16,529)	\$ (15,645)	\$ (28,193)	\$ (37,733)
<b>Denominator:</b>				
Weighted-average ordinary shares outstanding - basic and diluted	48,747	56,682	48,515	59,791
Net loss per share - basic and diluted	<u>\$ (0.34)</u>	<u>\$ (0.28)</u>	<u>\$ (0.58)</u>	<u>\$ (0.63)</u>

In accordance with Accounting Standards Codification ("ASC") 260, *Earnings Per Share*, if a company incurred a net loss, then potential ordinary shares are considered anti-dilutive for the periods in which the net loss was recognized. As a result, the following potential ordinary shares were not included in the computation of diluted net loss per share above because including them would have had an anti-dilutive effect:

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Options	2,336	2,148	2,320	2,401
Restricted share units and performance-contingent RSUs deemed probable	1,444	1,510	829	1,677
Employee share purchase plan	85	35	113	36
Total	<u>3,865</u>	<u>3,693</u>	<u>3,262</u>	<u>4,114</u>

## 3. Revenue

### *Revenue from Collaborative Arrangements*

#### *Viatrix*

In January 2015, the Company and Viatrix Inc. ("Viatrix") established a strategic collaboration (the "Viatrix Agreement") for the development and commercialization of revefenacin, 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. In November 2018, YUPELRI was approved by the US Food and Drug Administration (the "FDA") for the maintenance treatment of patients with chronic obstructive pulmonary disease ("COPD").

In the US, Viatrix is leading the commercialization of YUPELRI, and the Company co-promotes the product under a profit and loss sharing arrangement (65% to Viatrix; 35% to the Company). Outside the US (excluding China and adjacent territories), Viatrix is responsible for development and commercialization and will pay the Company a tiered royalty on net sales at percentage royalty rates ranging from low double-digits to mid-teens. Viatrix also holds exclusive development and commercialization rights to nebulized revefenacin in China and adjacent territories, which include the Hong Kong SAR, the Macau SAR, and Taiwan, and the Company is eligible to receive low double-digit tiered royalties on net sales of nebulized revefenacin in this region, if approved. Viatrix is responsible for all aspects of development and commercialization in the China and adjacent territories, including pre- and post-launch activities and



product registration and all associated costs. Viatris is the principal in the YUPELRI sales transactions, and as a result, the Company does not reflect the product sales in its condensed consolidated financial statements.

As of June 30, 2024, the Company is eligible to receive from Viatris potential global development, regulatory and sales milestone payments (excluding China and adjacent territories) 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 US net sales and \$10.0 million relates to regulatory actions in the European Union (“EU”). The Company is also eligible to receive additional potential development and sales milestones up to \$52.5 million related to Viatris’ development and commercialization of nebulized revefenacin in China and adjacent territories with \$45.0 million associated with YUPELRI monotherapy and \$7.5 million associated with future potential combination products. Of the \$45.0 million associated with monotherapy, \$37.5 million relates to sales milestones based on achieving certain levels of net sales and \$7.5 million relates to regulatory approval in China.

The Viatris Agreement is considered to be within the scope of ASC 808, *Collaborative Arrangements*, as the parties are active participants and exposed to the risks and rewards of the collaborative activity with a unit of account provided to Viatris as a customer. Under the terms of the Viatris Agreement, which included the delivery by the Company of a license to Viatris to develop and commercialize revefenacin, Viatris 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, R&D expenses are shared by both parties according to the profit and loss sharing percentages noted above. Performing R&D services for reimbursement is considered 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, *Revenue Recognition*, and, as such, the reimbursable program costs are excluded from the original transaction price.

The future potential milestone amounts for the Viatris Agreement were not included in the original 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 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.

Following the FDA approval of YUPELRI in November 2018, net amounts payable to or receivable from Viatris each quarter under the profit-sharing structure are disaggregated according to their individual components. In accordance with the applicable accounting guidance, amounts receivable from Viatris in connection with the commercialization of YUPELRI are recorded within the condensed consolidated statements of operations as revenue from “Viatris collaboration agreement” irrespective of whether the overall collaboration is profitable. Amounts payable to Viatris, if any, in connection with the commercialization of YUPELRI are recorded within the condensed consolidated statements of operations as a collaboration loss within selling, general and administrative expenses.

The following YUPELRI-related amounts were recognized within revenue in the Company’s condensed consolidated statements of operations:

(In thousands)	Three Months Ended		Six Months Ended	
	June 30,	2023	June 30,	2023
Viатris collaboration agreement – <i>Amounts receivable from Viатris</i>	\$ 14,256	\$ 13,743	\$ 28,759	\$ 24,154

While Viatris records total YUPELRI net sales within its own consolidated financial statements, Viatris collaboration agreement revenue on the Company’s condensed consolidated statements of operations included the

Company's implied 35% share of total YUPELRI net sales, before deducting shared commercial expenses, as presented below:

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
YUPELRI net sales (Theravance Biopharma implied 35%)	\$ 19,085	\$ 19,263	\$ 38,415	\$ 35,697

#### **Reimbursement of R&D Expenses**

The R&D cost share with Viatris for which the Company contributes 35% is netted within the Company's R&D expenses. The Company does not consider performing research and development services for reimbursement to be a part of its ordinary activities, therefore, the Company does not analogize to ASC 606 or recognize revenue. The Company recorded reimbursements received from Viatris as a reduction to R&D expenses. The Company also owes Viatris its cost share of the R&D activities carried out by Viatris that is also recorded within R&D expenses.

The following table summarizes the reduction to R&D expenses for reimbursements associated with R&D expenses directly incurred by the Company:

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Viatris	\$ 296	\$ 1,947	\$ 485	\$ 3,700

#### **4. Cash, Cash Equivalents, and Restricted Cash**

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

(In thousands)	June 30,	
	2024	2023
Cash and cash equivalents	\$ 46,345	\$ 105,596
Restricted cash	836	836
Total cash, cash equivalents, and restricted cash	\$ 47,181	\$ 106,432

The Company maintains restricted cash for certain lease agreements and letters of credit by which the Company has pledged cash and cash equivalents as collateral. The cash-related amounts reported in the table above exclude the Company's investments in short and long-term marketable securities that are reported separately on the condensed consolidated balance sheets.

The decrease in cash, and cash equivalents, and restricted cash compared to the prior year period, was primarily due to the Company's open market share repurchase program that commenced in December 2022 and was completed in January 2024 (see "Note 7. Completion of Capital Return Program" for more information).

The Company periodically engages in foreign exchange transactions as a part of its operations. These amounts are included in the Company's condensed consolidated statements of operations within "Interest income and other income (expense), net". For the three and six months ended June 30, 2024 and 2023, the Company's net realized and unrealized foreign currency gains (losses) were not material.

#### **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 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:

		June 30, 2024			
(In thousands)		Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
US government securities	Level 1	\$ 22,260	\$ —	\$ (2)	\$ 22,258
Commercial paper	Level 2	39,432	—	(20)	39,412
Marketable securities		61,692	—	(22)	61,670
Money market funds	Level 1	24,842	—	—	24,842
Total		<u>\$ 86,534</u>	<u>\$ —</u>	<u>\$ (22)</u>	<u>\$ 86,512</u>

		December 31, 2023			
(In thousands)		Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
US government securities	Level 1	\$ 29,848	\$ —	\$ (29)	\$ 29,819
US government agency securities	Level 2	4,428	—	(8)	4,420
Corporate notes	Level 2	28,670	4	(32)	28,642
Marketable securities		62,946	4	(69)	62,881
Money market funds	Level 1	26,179	—	—	26,179
Total		<u>\$ 89,125</u>	<u>\$ 4</u>	<u>\$ (69)</u>	<u>\$ 89,060</u>

As of June 30, 2024, all of the Company's available-for-sale securities had contractual maturities within six months, and the weighted-average maturity of marketable securities was approximately two months. There were no transfers between Level 1 and Level 2 during the periods presented, and there have been no material changes to the Company's valuation techniques during the three and six months ended June 30, 2024.

Available-for-sale debt securities with unrealized losses are summarized below:

		June 30, 2024					
		Less than 12 Months		Greater than 12 Months		Total	
(In thousands)		Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses
US government securities		\$ 19,283	\$ (2)	\$ —	\$ —	\$ 19,283	\$ (2)
Commercial paper		39,412	(20)	—	—	39,412	(20)
Total		<u>\$ 58,695</u>	<u>\$ (22)</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 58,695</u>	<u>\$ (22)</u>

		December 31, 2023					
		Less than 12 Months		Greater than 12 Months		Total	
(In thousands)		Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses
US government securities		\$ 29,819	\$ (29)	\$ —	\$ —	\$ 29,819	\$ (29)
US government agency securities		4,420	(8)	—	—	4,420	(8)
Corporate notes		23,641	(32)	—	—	23,641	(32)
Total		<u>\$ 57,880</u>	<u>\$ (69)</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 57,880</u>	<u>\$ (69)</u>

The Company invests primarily in high credit quality and short-term maturity 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 at maturity. The Company reviewed its available-for-sale debt securities and determined that there were no credit-related losses to be recognized as of June 30, 2024, and there were no individual securities that were in a significant unrealized loss position as of June 30, 2024.

For the three and six months ended June 30, 2024, the Company did not sell any marketable securities. For the three and six months ended June 30, 2023, the Company sold marketable securities for total proceeds of \$8.6 million and \$71.5 million, respectively. For the three months ended June 30, 2023, the realized net gain from the sale was immaterial, and for the six months ended June 30, 2023, the realized net loss from the sale was \$0.2 million based on the specific identification method.

### ***Contingent Consideration Asset***

The Company recognizes a contingent consideration asset related to its sale of its equity interests in Theravance Respiratory Company, LLC (“TRC”) to Royalty Pharma Investments 2019 ICAV, an Irish collective asset-management vehicle (“Royalty Pharma”), in July 2022 (the “TRC Transaction”). The contingent consideration asset represents the fair value of potential future milestone payments and royalties (collectively, “Contingent Consideration”) related to worldwide net sales of GSK plc’s (“GSK”) TRELEGY® ELLIPTA (“TRELEGY”). The Contingent Consideration was initially measured at fair value utilizing a Monte Carlo simulation model to calculate the present value of the risk-adjusted cash flows estimated to be received from the Contingent Consideration. The discount rate utilized in the valuation model was 7.83%.

The fair value model involved significant unobservable inputs derived using management’s estimates. Management’s estimates were based in part on external data and reflected management’s judgements and forecasts. The primary significant unobservable input was the estimate of forecasted TRELEGY net sales which is considered a Level 3 fair value input. The Company reassesses the carrying value of the Contingent Consideration when indicators of impairment are identified and will recognize any increases in the carrying value of the asset when such contingent gains are realized. As of June 30, 2024, the Contingent Consideration had a carrying value of \$194.2 million and is presented on the condensed consolidated balance sheets as “Future contingent milestone and royalty assets”. There have been no changes to the carrying value of the Contingent Consideration since its initial measurement date in July 2022.

The Contingent Consideration is subject to counterparty credit risk, and the carrying value of the Contingent Consideration represents the maximum amount of potential loss due to credit risk. To date, the Company has not recorded any credit losses related to the Contingent Consideration.

### ***Amprexetine Funding***

The Company recognizes a contingent liability related to funding received from Royalty Pharma in exchange for certain future royalty rights to amprexetine. The contingent liability consists of an upfront \$25.0 million received in July 2022 and management’s estimate of (i) a risk-adjusted future contingent \$15.0 million milestone; and (ii) the amount and timing of royalties to be paid to Royalty Pharma and then discounted over the life of the arrangement using an imputed rate of interest. The excess of future estimated royalty payments over the amount of cash funding received is recognized as interest expense using the effective interest method. The balance associated with the contingent liability was initially recorded as \$25.0 million, net of allocated transaction costs, in July 2022 and is reported on the condensed consolidated balance sheets as “Future royalty payment contingency”.

The Company periodically reassesses the amount and timing of estimated royalty payments. To the extent such payments are materially greater or less than the Company’s previous estimates, the Company will prospectively adjust the amortization of the contingent liability and the effective interest rate. The imputed effective rate of interest on the unamortized portion of the contingent liability was approximately 8.8% as of June 30, 2024.

There are a number of factors that could materially affect the amount and timing of the contingent \$15.0 million milestone and royalty payments, some of which are not within the Company’s control. Such factors include, but are not limited to, changes in the projected market size, the introduction of competing products, patent protection matters, and

regulatory product approval for amprelosetine. The contingent liability was recognized using significant unobservable inputs. These inputs were derived using internal management estimates and reflect management's judgements and forecasts. The significant unobservable inputs include the forecasted revenues, the probability and timing of the regulatory milestone, and the expected term of the royalty stream, as well as the overall probability of amprelosetine's success. These estimates are considered Level 3 fair value inputs. A significant change in unobservable inputs could result in a material increase or decrease to the effective interest rate of the contingent liability. If amprelosetine regulatory approval is not achieved or if amprelosetine sales are never recognized, the contingent liability recognized would be extinguished as the Company would not be obligated to repay any of the funding amounts received from Royalty Pharma.

Changes to the contingent liability were as follows for the six months ended June 30, 2024:

<b>(In thousands)</b>	
Balance at December 31, 2023	\$ 27,788
Non-cash interest expense accretion	1,273
Balance at June 30, 2024	<u>\$ 29,061</u>

## 6. Subleases

In March 2024, the Company entered into a non-cancelable agreement under which it subleased approximately 8,000 square feet of its South San Francisco office space to an unaffiliated company. The sublease term is for approximately two years expiring in April 2026, and the subtenant has no option to extend the sublease. Under the terms of the sublease, the Company is entitled to receive an initial monthly base rent of \$38,000 with a 3% increase after the first year. The Company will recognize approximately \$0.9 million in total sublease income on a straight-line basis over the two-year sublease term. Sublease income is recognized as a reduction to the Company's facilities expense which is then allocated to selling, general and administrative expenses and R&D expenses in the condensed consolidated statements of operations.

As of June 30, 2024, the Company has subleased approximately 107,000 square feet of a total 162,000 square feet of its South San Francisco office and laboratory space under three separate subleases with unaffiliated companies. The Company's sublease income from all three subleases is summarized below:

<b>(In thousands)</b>	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2024</b>	<b>2023</b>	<b>2024</b>	<b>2023</b>
Sublease income	\$ 2,204	\$ 2,090	\$ 4,294	\$ 4,180

## Impairment of Long-Lived Assets

As of June 30, 2024, the Company had approximately 31,000 square feet of remaining vacant office and laboratory space in South San Francisco on the market for sublease primarily as a result of strategic actions taken in February 2023 (See "Note 8. Restructuring and Related Expenses" for more information). The Company evaluates the carrying value of its long-lived asset groups, which includes operating lease assets and leasehold improvements, for impairment when indicators exist that the carrying amounts of an asset may not be fully recoverable. An impairment loss is recognized when estimated undiscounted future cash flows expected to result from the use of the asset or asset group are less than its carrying amount. Impairment, if any, is measured as the amount by which the carrying amount of a long-lived asset exceeds its fair value.

The Company determined that the ceased occupancy and current sublease marketing of the office and laboratory space were indicators of impairment. The Company operates within a single segment and identified three asset groups for the purposes of its long-lived impairment assessment which were comprised of (i) vivarium laboratory asset group; (ii) general laboratory asset group; and (iii) entity-wide asset group. The vacant office space, which the Company determined it may reoccupy in the future, was considered part of the entity-wide asset group.

Based on the Company's impairment assessment as of June 30, 2024, the Company determined that the carrying values of two asset groups, consisting of the vacant vivarium laboratory space and vacant general laboratory

space (including related leasehold improvements) and comprising approximately 22,000 square feet, exceeded the estimated undiscounted future cash flows of the two asset groups under the current sublease market conditions. Under ASC 360, *Property, Plant, and Equipment*, the Company then proceeded to estimate the fair value of the two asset groups. The Company applied a discounted cash flow method to estimate the fair values of the two asset groups, which represents Level 3 non-recurring fair value measurements. The estimated fair values of the two asset groups were determined by discounting the estimated sublease net cash flows based on the Company's estimates and assumptions including, but not limited to, expected sublease rental income of \$3.3 million, an annual discount rate of 9.7%, and other variable lease-related expenses to be incurred during the subtenant search period. The Company's estimates and assumptions used to determine the estimated fair values of the two asset groups are subject to risks, uncertainties, and changes in circumstances that may result in adjustments and material changes to the estimated fair values in future periods.

For the three and six months ended June 30, 2024, the Company recognized a non-cash impairment charge of \$3.0 million based on the amount of excess carrying value of the two asset groups over its estimated fair values as described above. The impairment amount is presented in the Company's condensed consolidated statements of operations within "Impairment of long-lived assets". The Company will continue to update its long-lived asset impairment assessment each quarterly period.

#### **7. Completion of Capital Return Program**

In January 2024, the Company repurchased an additional 38,462 of its ordinary shares on the open market at a weighted average cost of \$11.551 per share for an approximate aggregate cost of \$0.4 million, excluding fees and expenses, to complete its capital return program. Since the initiation of the capital return program in September 2022 through January 2024, the Company repurchased a total of 31.412 million of its ordinary shares at a weighted average price of \$10.3544 per share for an approximate aggregate cost of \$325.3 million, excluding fees and expenses.

#### **8. Restructuring and Related Expenses**

In February 2023, the Company announced strategic actions (the "2023 Strategic Actions") that included the discontinuation of its research activities, resulting in a 17% reduction in headcount in March 2023. As a result of the Company's discontinued investment in research activities, the Company incurred restructuring and related expenses of \$1.2 million and \$2.7 million for the three and six months ended June 30, 2023, respectively, which were primarily related to R&D expenses. Of the total \$2.7 million incurred for the six months ended June 30, 2023, cash-related expenses were \$1.2 million and non-cash expenses were \$1.5 million which were primarily related to the modification of equity-based awards for employees affected by the reduction in headcount and a loss on the sale of R&D laboratory equipment.

#### **9. Income Taxes**

For the six months ended June 30, 2024, the Company recognized an income tax expense of \$2.6 million. Although the Company incurred net operating losses on a consolidated basis, the income tax expense for the six months ended June 30, 2024 was primarily due to uncertain tax positions and interest expense on the Company's uncertain tax position liability.

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. In 2022, the Company released its valuation allowance for US federal tax purposes stemming from the effects of the TRC Transaction. As of June 30, 2024, the Company does not believe that a valuation allowance against its deferred tax assets should be re-established to offset its deferred tax assets for US federal tax purposes. As of June 30, 2024, the Company continues to maintain a full valuation allowance in certain states, including California, and other jurisdictions.

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 related to income tax matters in income tax expense.

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.

## **10. Commitments and Contingencies**

### ***Legal Proceedings***

In the ordinary course of business, the Company may be subject to legal claims and regulatory actions that could have a material adverse effect on its business or financial position. The Company assesses its potential liability in such situations by analyzing the possible outcomes of various litigation, regulatory, and settlement strategies. If the Company determines that a material loss is probable and its amount can be reasonably estimated, it will accrue an amount equal to the estimated loss. As of June 30, 2024, the Company did not accrue any estimated losses related to its ongoing legal proceedings.

### ***Litigation – Patent Infringement***

During January 2023, the Company received notice from Accord Healthcare, Inc.; Cipla USA, Inc. and Cipla Limited; Eugia Pharma Specialties Ltd.; Lupin Inc.; Mankind Pharma Ltd.; Orbicular Pharmaceutical Technologies Private Limited; and Teva Pharmaceuticals, Inc. (collectively, the "generic companies"), that they have each filed with FDA an abbreviated new drug application ("ANDA"), for a generic version of YUPELRI. The notices from the generic companies each included a paragraph IV certification with respect to five of the Company's patents listed in FDA's Orange Book for YUPELRI on the date of the Company's receipt of the notice. The asserted patents relate generally to polymorphic forms of and a method of treatment using YUPELRI. In February 2023, the Company filed patent infringement suits against the generic companies in federal district court, including the United States District Court for the District of New Jersey, the U.S. District Court for the District of Delaware, and the U.S. District Court for the Middle District of North Carolina. The suits in Delaware and North Carolina have been dismissed, as all generic companies have agreed to venue in New Jersey. The complaint alleges that by filing the ANDAs, the generic companies have infringed five of the Company's Orange Book listed patents. The Company is seeking a permanent injunction to prevent the generic companies from introducing a generic version of YUPELRI that would infringe its patents. As a result of this lawsuit, a stay of approval through May 2026 has been imposed by the FDA on the generic companies' ANDAs pending any adverse court decision. Additional patents covering YUPELRI granted on July 4, 2023 and January 2, 2024 were subsequently listed in FDA's Orange Book. The Company filed additional patent infringement suits in the U.S. District Court for the District of New Jersey during August 2023 and January 2024. These suits have been consolidated with the above action. Further, the original complaint was amended during December 2023 to include certain patents not listed in the Orange Book.

In May 2024, the Company received notice from Qilu Pharmaceuticals Co., Ltd. ("subsequent ANDA filer"), that it had filed with the FDA an ANDA for a generic version of YUPELRI. The notice from the subsequent ANDA filer included a paragraph IV certification with respect to certain of the Company's patents listed in FDA's Orange Book for YUPELRI. The asserted patents relate generally to polymorphic forms of and a method of treatment using YUPELRI. In June 2024, the Company filed a patent infringement suit against the subsequent ANDA filer in the U.S. District Court for the Eastern District of Pennsylvania. The complaint alleges that by filing the ANDA, the subsequent ANDA filer has infringed certain of the Company's Orange Book listed patents. The Company is seeking a permanent injunction to prevent the subsequent ANDA filer from introducing a generic version of YUPELRI that would infringe its patents. As a result of this lawsuit, the Company expects a 30-month stay of approval through November 2026 to be automatically granted by the FDA on the subsequent filer's ANDA pending any adverse court decision.

As of July 31, 2024, the Company has settled all litigation with Accord Healthcare, Inc.; Lupin Pharmaceuticals, Inc.; Orbicular Pharmaceutical Technologies Private Limited; and Teva Pharmaceuticals, Inc. pursuant to individual agreements in which the Company granted these companies a royalty-free, non-exclusive, non-sublicensable, non-transferable license to manufacture and market their respective generic versions of YUPELRI inhalation solution in the US on or after the licensed launch date of April 23, 2039, subject to certain exceptions as is customary in these type of agreements. As required by law, the settlements are subject to review by the U.S. Department of Justice and the Federal Trade Commission. The patent litigation against the three remaining generic companies, along with certain affiliates, and the subsequent ANDA filer, remains pending.

A further method of treatment patent, with an expiration date of August 2039, was granted on July 30, 2024 and was listed in the Orange Book.

## **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 consolidated 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"). Such forward-looking statements involve risks, uncertainties, and assumptions. 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, designs, expectations, and objectives are forward-looking statements. The words "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "designed," "developed," "drive," "estimate," "expect," "forecast," "goal," "indicate," "intend," "may," "mission," "opportunities," "plan," "possible," "potential," "predict," "project," "pursue," "represent," "seek," "suggest," "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, 2023. 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. When used in this report, all references to "Theravance Biopharma", the "Company", or "we" and other similar pronouns refer to Theravance Biopharma, Inc. collectively with its subsidiaries.*

### **Management Overview**

Theravance Biopharma, Inc. ("we," "our," "Theravance Biopharma" or the "Company") is a biopharmaceutical company primarily focused on the development and commercialization of medicines. Our focus is to deliver *medicines that make a difference*<sup>®</sup> in people's lives.

In pursuit of our purpose, we leverage decades of expertise, which has led to the development of the United States ("US") Food and Drug Administration (the "FDA") approved YUPELRI<sup>®</sup> (revefenacin) inhalation solution indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease ("COPD"). Ampreloxetine, our late-stage investigational once-daily norepinephrine reuptake inhibitor in development for the



treatment of symptomatic neurogenic orthostatic hypotension (“nOH”) in patients with Multiple System Atrophy (“MSA”) has the potential to be a first in class therapy effective in treating a constellation of cardinal symptoms in MSA patients.

## Core Program Updates

### *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 revefenacin in both metered dose inhaler and dry powder inhaler (“MDI/DPI”) formulations suggests that revefenacin could also serve as a foundation for novel handheld combination products.

We co-developed YUPELRI with our collaboration partner, Viatriis Inc. Under the terms of the Viatriis Development and Commercialization Agreement (the “Viatriis Agreement”), we led the US Phase 3 development program for YUPELRI in COPD, and Viatriis was responsible for reimbursement of our costs related to the registration program up until the approval of the first new drug application, after which costs were shared. YUPELRI was approved by the FDA for the maintenance treatment of patients with COPD in November 2018. In the US, Viatriis is leading the commercialization of YUPELRI, and we co-promote the product under a profit and loss sharing arrangement (65% to Viatriis; 35% to us). Outside the US (excluding China and adjacent territories), Viatriis is 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. We retain worldwide rights to revefenacin delivered through other dosage forms, such as a MDI/DPI.

In 2019, we granted Viatriis exclusive development and commercialization rights to nebulized revefenacin in China and adjacent territories, which include the Hong Kong SAR, the Macau SAR, and Taiwan, (collectively, the “China Region”) and we are eligible to receive low double-digit tiered royalties on net sales of nebulized revefenacin, if approved. As noted above, Viatriis is responsible for all aspects of development and commercialization of nebulized revefenacin in the China Region, including pre- and post-launch activities and product registration and all associated costs.

Under the terms of the Viatriis Agreement, as amended, as of June 30, 2024, we were eligible to receive from Viatriis potential global development, regulatory and sales milestone payments (excluding the China Region) of 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, \$10.0 million relates to regulatory actions in the EU and \$150.0 million relates to sales milestones based on achieving certain levels of annual US net sales as follows:

<b>YUPELRI US Net Sales (In a Calendar Year)</b>	<b>Sales Milestones Due from Viatriis</b>
\$250.0 million	\$25.0 million
\$500.0 million	\$50.0 million
\$750.0 million	\$75.0 million

As of June 30, 2024, we were also eligible to receive additional potential development and sales milestones of up to \$52.5 million related to Viatriis’ development and commercialization of nebulized revefenacin in the China Region with \$45.0 million associated with YUPELRI monotherapy and \$7.5 million associated with future potential combination products. Of the \$45.0 million associated with monotherapy, \$7.5 million relates to regulatory approval in the China Region and \$37.5 million relates to sales milestones based on achieving certain levels of cumulative net sales in the China Region as follows:

YUPELRI China Region Net Sales (Cumulative)	Sales Milestones Due from Viatriis
\$100.0 million	\$2.5 million
\$200.0 million	\$5.0 million
\$400.0 million	\$10.0 million
\$800.0 million	\$20.0 million

With respect to the China Region royalties, we are eligible to receive tiered royalties on net sales of nebulized revefenacin as follows:

YUPELRI China Region Net Sales Thresholds (Annual)	Royalty Rate Due from Viatriis
≤ \$75.0 million	14%
> \$75.0 million to ≤ \$150.0 million	17%
> \$150.0 million	20%

In November 2023, we learned that Viatriis’ Phase 3 study of YUPELRI in China was positive, and the data were consistent with previous findings of YUPELRI’s strong efficacy. In June 2024, Viatriis completed a registrational filing for YUPELRI in China which may lead us to receive (i) a \$7.5 million milestone upon regulatory approval in the China Region; and (ii) a 14% - 20% royalty on net sales generated in the China Region, as shown above.

In August 2021, we announced that in collaboration with our partner Viatriis, we were initiating a Phase 4 study comparing improvements in lung function in adults with severe to very severe COPD and suboptimal inspiratory flow rate following once-daily treatment with either revefenacin (YUPELRI) delivered via standard jet nebulizer or tiotropium delivered via a dry powder inhaler (Spiriva® HandiHaler®). This study was aimed at helping to better inform decisions when physicians are designing a personalized COPD treatment plan with patients. In January 2024, we announced that the Phase 4 study did not show a statistically significant difference between YUPELRI and Spiriva HandiHaler on the primary endpoint, change from baseline in trough forced expiratory volume in one second (FEV<sub>1</sub>) at day 85. While the primary endpoint in the Phase 4 study was not met, YUPELRI demonstrated an efficacy and safety profile consistent with its performance in other clinical studies.

While Viatriis records total YUPELRI net sales, we are entitled to a 35% share of the net profit (loss). Our implied 35% share of total YUPELRI net sales is presented below:

(In thousands)	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2024	2023	\$	%	2024	2023	\$	%
YUPELRI net sales (100% recorded by Viatriis)	\$ 54,530	\$ 55,038	\$ (508)	(1)%	\$ 109,756	\$ 101,993	\$ 7,763	8 %
YUPELRI net sales (Theravance Biopharma implied 35%)	19,085	19,263	(178)	(1)	38,415	35,697	2,717	8

The 1% decrease in aggregate net sales during the second quarter of 2024 compared to the prior year period was primarily due to headwinds from an evolved channel mix and a lower realized net price, offset by a 13% increase in customer demand. We are only expecting the lower net price in the second quarter to improve slightly during the second half of the year. For 2025 and beyond, we anticipate a more stable pricing environment and continued YUPELRI demand growth across all patient fulfillment channels. COPD market share growth continued in the second quarter of 2024 with the hospitals surpassing 18% market share and the community setting reaching 32% market share. For the three and six months ended June 30, 2024, YUPELRI continued to be profitable on a brand basis.

### ***Ampreloxetine (TD-9855)***

Ampreloxetine is an investigational, once-daily Norepinephrine Reuptake Inhibitor (“NRI”) that we are developing for the treatment of Multiple System Atrophy (“MSA”) patients with symptomatic neurogenic orthostatic hypotension (“nOH”). nOH is caused by primary autonomic failure conditions and the majority of patients with MSA experience symptoms of nOH. Ampreloxetine has high affinity for binding to the norepinephrine (“NE”) transporter. By blocking the action of the NE transporter, ampreloxetine causes an increase in extracellular concentrations of norepinephrine. Ampreloxetine is wholly owned by Theravance Biopharma.

Based on positive results from a small exploratory Phase 2 study in nOH and discussions with the FDA, we advanced ampreloxetine into a Phase 3 program. We announced the initiation of patient dosing in the study in early 2019. The Phase 3 program consisted of two pivotal studies and one non-pivotal study. The first pivotal study (SEQUOIA), a four-week, randomized double-blind, placebo-controlled study, was designed to evaluate the efficacy and safety of ampreloxetine in Parkinson’s disease (“PD”), pure autonomic failure (“PAF”) and MSA patients with symptomatic nOH. The second pivotal study (REDWOOD), a four-month open label study followed by a six-week randomized withdrawal phase was designed to evaluate the durability of the same patient group’s response to ampreloxetine. The protocol for the pivotal studies stipulated an enrollment threshold of 40% MSA patients based on the hypothesis ampreloxetine would work the best in patients with MSA because they have more intact nerves on which ampreloxetine can exert its effect, relative to the other patient types in the study. The third, non-pivotal study (OAK), was a three and a half year long-term extension study.

In September 2021, we reported that the SEQUOIA Phase 3 clinical study did not meet its primary endpoint. Most treatment-related adverse events were mild or moderate in severity. Serious adverse events occurred in two patients on placebo and four on ampreloxetine, none of which were considered related to the study drug. No deaths were reported, and there was no signal for supine hypertension.

In April 2022, we reported that the REDWOOD Phase 3 clinical study did not meet its primary endpoint as the results were not statistically significant for the overall population of patients which included patients with PD, PAF, and MSA. The pre-specified subgroup analysis by disease type suggested that the average benefit seen in patients receiving ampreloxetine was largely driven by a benefit to MSA patients. The benefit to MSA patients in the study was observed in multiple endpoints including Orthostatic Hypotension Symptom Assessment Scale (“OHSA”) composite, Orthostatic Hypotension Daily Activities Scale (“OHDAS”) composite, Orthostatic Hypotension Questionnaire (“OHQ”) composite and OHSA #1. Throughout the study, there was no indication of worsening of supine hypertension among any of the patient sub-groups. Data suggest that ampreloxetine was well-tolerated and no new safety signals were identified among any of the patient sub-groups.

In June 2022, we held a Type C meeting with the FDA. From this meeting, we aligned on a path to a New Drug Application (“NDA”) filing with one additional Phase 3 clinical study (CYPRESS) in MSA patients with symptomatic nOH, using the OHSA composite score as the primary endpoint. This Phase 3 study was initiated in the first quarter of 2023, and we currently anticipate that the final patient will be enrolled in the open label period of the study in mid-2025 and top-line data will be available approximately 6 months thereafter. In May 2023, we announced that the FDA granted Orphan Drug Designation status to ampreloxetine for the treatment of symptomatic nOH in patients with MSA.

In July 2022, Royalty Pharma Investments 2019 ICAV (“Royalty Pharma”) agreed to invest up to \$40.0 million to advance the development of ampreloxetine in MSA in exchange for unsecured low single-digit royalties. Royalty Pharma’s \$40.0 million investment in ampreloxetine included a \$25.0 million upfront payment received in July 2022 and an additional \$15.0 million payment upon the first regulatory approval of ampreloxetine. In exchange, Royalty Pharma will receive future unsecured royalties of 2.5% on annual ampreloxetine global net sales up to \$500.0 million and 4.5% on annual global net sales over \$500.0 million. If ampreloxetine regulatory approval is not achieved or if ampreloxetine sales are never recognized, the amounts invested by Royalty Pharma would not be repaid by us.

**Economic Interests and Other Assets**

***Mid- and Long-Term Economic Interest in TRELEGY®***

In July 2022, we completed the sale of all of our equity interests in Theravance Respiratory Company, LLC (“TRC”) representing our 85% economic interest in the sales-based royalty rights on worldwide net sales of GSK plc’s (“GSK”) TRELEGY ELLIPTA (“TRELEGY”) to Royalty Pharma for approximately \$1.11 billion in upfront cash while retaining future value through the right to receive contingent milestone payments and certain outer year-royalties (the “TRELEGY Royalty Transaction”).

From and after January 1, 2023, for any calendar year starting with the year ended December 31, 2023 and ending with the year December 31, 2026, upon certain milestone minimum royalty amounts for TRELEGY being met, Royalty Pharma is obligated to make certain cash payments to us (the “Milestone Payment(s)”). As of June 30, 2024, a total of \$200.0 million in potential Milestone Payments remain available to us. For the next potential Milestone Payment, we are eligible to receive either (i) \$25.0 million if Royalty Pharma receives \$240.0 million or more in royalty payments from GSK with respect to 2024 TRELEGY global net sales, which we would expect to occur in the event TRELEGY global net sales are approximately \$2.86 billion; or (ii) \$50.0 million if Royalty Pharma receives \$275.0 million or more in royalty payments from GSK with respect to 2024 TRELEGY global net sales, which we would expect to occur in the event TRELEGY global net sales exceed approximately \$3.21 billion.

TRELEGY global net sales for the three and six months ended June 30, 2024 were \$1.07 billion and \$1.81 billion, respectively, which represented a 40% and 37% year-over-year growth, respectively. TRELEGY is expected to generate global peak sales of \$4.0 billion in 2027 according to Bloomberg consensus estimates as of early August 2024. Total 2023 TRELEGY global net sales were \$2.74 billion which represented a 28% year-over-year growth.

In addition to potential Milestone Payments, we will receive from Royalty Pharma 85% of the royalty payments on TRELEGY due from GSK for (a) sales or other activities occurring on and after January 1, 2031 related to TRELEGY in the US, and (b) sales or other activities occurring on and after July 1, 2029 related to TRELEGY outside of the US. US TRELEGY royalties payable to us by Royalty Pharma are expected to end in late 2032, and ex-US royalties are expected to end in the mid-2030s and are country specific. Royalty rates are upward tiering from 6.5% to 10% and based on total annual global net sales as follows:

<b>TRELEGY Global Net Sales Thresholds (Annual)</b>	<b>Royalty Rate Due from GSK to Royalty Pharma</b>
≤ \$750.0 million	6.5%
> \$750.0 million to ≤ \$1,250.0 million	8.0%
> \$1,250.0 million to ≤ \$2,250.0 million	9.0%
> \$2,250.0 million	10.0%

The following information regarding the TRELEGY program is based solely upon publicly available information and may not reflect the most recent developments under the programs.

TRELEGY provides the activity of an inhaled corticosteroid (FF) plus two bronchodilators (UMEC, a LAMA, and VI, a long-acting beta2 agonist, or LABA) in a single delivery device administered once-daily. TRELEGY is approved for use in the US, European Union (“EU”), and other countries for the long-term, once-daily, maintenance treatment of patients with COPD. Additionally, the FDA approved an sNDA for the use of TRELEGY to treat asthma in adults in September 2020 making TRELEGY the first once-daily single inhaler triple therapy for the treatment of both asthma and COPD in the US. GSK has obtained approval for the asthma indication in ten additional markets.

*See “Risk Factors—We do not control the commercialization of TRELEGY; accordingly, our receipt of Milestone Payments and receipt of the value we currently anticipate from the Outer Years Royalty will depend on, among other factors, GSK’s ability to further commercialize TRELEGY” for additional information.*

## Development Projects

Our focus remains on near-term value opportunities which consists of executing our amprelosetine registration Phase 3 study (CYPRESS) and preparing for the NDA filing process.

## Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our condensed consolidated 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 revenues, expenses, assets, liabilities, and other related disclosures. 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. We believe that the accounting policies and estimates discussed in our Annual Report on Form 10-K for the year ended December 31, 2023 are essential to understanding our operating results and financial condition, as these policies and estimates relate to the more significant areas involving management’s judgments. 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, 2023.

## Results of Operations

### Revenue

While Viatriis records the total net sales of YUPELRI within its own financial statements, our implied 35% YUPELRI revenue, as compared to the prior year comparable periods, was as follows:

(In thousands)	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2024	2023	\$	%	2024	2023	\$	%
YUPELRI net sales (100% recorded by Viatriis)	\$ 54,530	\$ 55,038	\$ (508)	(1)%	\$ 109,756	\$ 101,993	\$ 7,763	8 %
YUPELRI net sales (Theravance Biopharma implied 35%)	19,085	19,263	(178)	(1)	38,415	35,697	2,717	8

Our recognized revenue, as compared to the prior year comparable periods, was as follows:

(In thousands)	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2024	2023	\$	%	2024	2023	\$	%
Viatriis collaboration agreement	\$ 14,256	\$ 13,743	\$ 513	4 %	\$ 28,759	\$ 24,154	\$ 4,605	19 %
Collaboration revenue	—	6	(6)	NM	—	12	(12)	NM
Total revenue	\$ 14,256	\$ 13,749	\$ 507	4 %	\$ 28,759	\$ 24,166	\$ 4,593	19 %

NM: Not Meaningful

We are entitled to a share of US profits and losses (65% to Viatriis; 35% to Theravance Biopharma) received in connection with YUPELRI net sales. In accordance with the applicable accounting guidance, amounts receivable from Viatriis in connection with the commercialization of YUPELRI are recorded within the condensed consolidated statements of operations as revenue from “Viatriis collaboration agreement”. Any reimbursement from Viatriis attributed to the 65% cost-sharing of our research and development (“R&D”) expenses is characterized as a reduction of R&D expense, as we do not consider performing R&D services for reimbursement to be a part of our ordinary operations.

For the three and six months ended June 30, 2024, we recognized \$14.3 million and \$28.8 million, respectively, in revenue from the Viatriis collaboration agreement which represented increases of 4% and 19%, respectively, compared to the prior year periods. The increase for the three months ended June 30, 2024 was primarily due to lower costs

incurred by Viatriis, and the increase for the six months ended June 30, 2024 was primarily due to an increase in net sales during the first three months of the year, as well as lower costs incurred by Viatriis.

**Research and Development**

Our 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 office supplies, depreciation, and other allocated expenses, such as general and administrative support functions, office rent, and insurance.

The following table summarizes our R&D expenses incurred, net of any reimbursements from collaboration partners, as compared to the prior year comparable periods:

(In thousands)	Three Months Ended				Six Months Ended			
	June 30,		Change		June 30,		Change	
	2024	2023	\$	%	2024	2023	\$	%
Employee-related	\$ 3,211	\$ 2,758	\$ 453	16 %	\$ 6,516	\$ 7,135	\$ (619)	(9)%
Share-based compensation	1,151	1,855	(704)	(38)	2,616	4,297	(1,681)	(39)
External-related	4,834	3,656	1,178	32	8,211	8,983	(772)	(9)
Facilities, depreciation, and other allocated expenses	758	1,156	(398)	(34)	1,579	3,582	(2,003)	(56)
<b>Total research &amp; development</b>	<b>\$ 9,954</b>	<b>\$ 9,425</b>	<b>\$ 529</b>	<b>6 %</b>	<b>\$ 18,922</b>	<b>\$ 23,997</b>	<b>\$ (5,075)</b>	<b>(21)%</b>

R&D expenses increased by \$0.5 million for the three months ended June 30, 2024 compared to the prior year period. The \$0.5 million increase was attributed to a \$0.5 million increase in employee-related expenses and a \$1.2 million increase in external-related expense. These increases were primarily driven by the continued progression of the amprelosetine Phase 3 clinical study (CYPRESS) for MSA patients with symptomatic nOH. These clinical development-related increases were partially offset by a \$0.7 million decrease in share-based compensation and a \$0.4 million decrease in allocated expenses primarily driven by our 2023 strategic actions announced in February 2023 (“2023 Strategic Actions”) which included the discontinuation of investment in our research activities.

R&D expenses decreased by \$5.1 million for six months ended June 30, 2024 compared to the prior year period. The \$5.1 million decrease was attributed to all of our R&D categories and was primarily driven by our 2023 Strategic Actions. The \$0.6 million and \$0.8 million decreases in employee-related expenses and external-related expenses, respectively, were partially offset by increases in expenses related to the CYPRESS study as discussed above.

**Selling, General and Administrative**

Selling, general and administrative (“SG&A”) expenses consist primarily of salaries and benefits, facilities and overhead costs, and other costs related to areas such as legal, finance, information technology, sales and marketing, and medical affairs.

SG&A expenses, as compared to the prior year comparable periods, were as follows:

(In thousands)	Three Months Ended				Six Months Ended			
	June 30,		Change		June 30,		Change	
	2024	2023	\$	%	2024	2023	\$	%
Selling, general and administrative	\$ 17,056	\$ 19,278	\$ (2,222)	(12)%	\$ 33,798	\$ 38,461	\$ (4,663)	(12)%

Total SG&A expenses were \$17.1 million for the three months ended June 30, 2024. Excluding share-based compensation expense (“SBC”), total SG&A expenses were \$12.8 million for the second quarter of 2024 and were comprised of \$6.8 million of general and administrative (“G&A”) expenses and \$6.0 million of selling, marketing & medical affairs (“SM&M”) expenses. Total SG&A expenses (excluding SBC) was \$14.9 million for the second quarter of 2023 and were comprised of \$8.8 million of G&A expenses and \$6.1 million of SM&M expenses. The \$2.0 million decrease in G&A expenses (excluding SBC) in the second quarter of 2024 compared to the prior year period represented a 23% reduction and was primarily due to our company-wide cost savings initiative that began in the second half of 2023 and included reductions in various areas such as, finance-related expenses, information & technology, and facility-related expenses. SM&M expenses (excluding SBC) was relatively unchanged in the second quarter of 2024 compared to the prior year period.

Total SG&A expenses were \$33.8 million for the six months ended June 30, 2024. Excluding SBC, total SG&A expenses were \$25.8 million for the current period and were comprised of \$13.7 million of G&A expenses and \$12.1 million of SM&M expenses. Total SG&A expenses (excluding SBC) was \$29.8 million for the prior year period and were comprised of \$18.4 million of G&A expenses and \$11.4 million of SM&M expenses. The \$4.7 million decrease in G&A expenses (excluding SBC) in the current period compared to the prior year period represented a 26% reduction and was primarily due to our company-wide cost savings initiative as discussed above. SM&M expenses (excluding SBC) increased slightly by \$0.7 million in the current period compared to the prior year period and was primarily due to an increase in employee-related expenses.

Total SBC related to SG&A expenses was \$4.2 million and \$8.0 million for the three and six months ended June 30, 2024, respectively. Total SBC related to SG&A expenses was \$4.4 million and \$8.6 million for the three and six months ended June 30, 2023, respectively.

### ***Impairment of Long-Lived Assets***

Impairment of long-lived assets, as compared to the prior year comparable periods, was as follows:

(In thousands)	Three Months Ended				Six Months Ended			
	June 30,		Change		June 30,		Change	
	2024	2023	\$	%	2024	2023	\$	%
Impairment of long-lived assets (non-cash)	\$ 2,951	\$ —	\$ 2,951	NM %	\$ 2,951	\$ —	\$ 2,951	NM %

NM: Not Meaningful

For each of the three and six months ended June 30, 2024, we recognized a non-cash impairment charge of \$3.0 million related to our vacant laboratory spaces and related leasehold improvements in South San Francisco, California, which are currently on the market for sublease. There was no charge for impairment of long-lived assets recognized in the prior year comparable periods.

**Restructuring and Related Expenses**

Restructuring and related expenses, as compared to the prior year comparable periods, were as follows:

(In thousands)	Three Months Ended June 30,				Six Months Ended June 30,			
	2024	2023	Change		2024	2023	Change	
			\$	%			\$	%
Restructuring and related expenses	\$ —	\$ 1,169	\$ (1,169)	NM %	\$ —	\$ 2,386	\$ (2,386)	NM %
Share-based compensation expense (non-cash)	—	—	—	NM	—	357	(357)	NM
Total restructuring and related expenses	\$ —	\$ 1,169	\$ (1,169)	NM %	\$ —	\$ 2,743	\$ (2,743)	NM %

NM: Not Meaningful

There were no restructuring and related expenses recognized for the three and six months ended June 30, 2024. The restructuring and related expenses recognized for the prior year comparable periods were a result of our 2023 Strategic Actions as discussed above.

**Interest Expense**

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

(In thousands)	Three Months Ended June 30,				Six Months Ended June 30,			
	2024	2023	Change		2024	2023	Change	
			\$	%			\$	%
Amprexetine royalty contingency (non-cash)	\$ (644)	\$ (568)	\$ (76)	13 %	\$ (1,273)	\$ (1,118)	\$ (155)	14 %

Interest expense was \$0.6 million and \$1.3 million for the three and six months ended June 30, 2024, respectively, and represented non-cash interest expense associated with \$25.0 million received from Royalty Pharma in July 2022 to fund the CYPRESS study. The increase in interest expense was primarily due to the compounding of non-cash interest due to Royalty Pharma. We do not anticipate having any cash interest expense in the foreseeable future.

**Interest Income and Other Income (Expense), net**

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

(In thousands)	Three Months Ended June 30,				Six Months Ended June 30,			
	2024	2023	Change		2024	2023	Change	
			\$	%			\$	%
Interest income and other income (expense), net	\$ 1,128	\$ 2,504	\$ (1,376)	(55)%	\$ 2,562	\$ 5,483	\$ (2,921)	(53)%

Interest income and other income (expense), net, decreased by \$1.4 million and \$2.9 million for the three and six months ended June 30, 2024, respectively, compared to the prior year periods. The decreases were primarily due to a reduction in interest income earned on our cash, cash equivalents, and marketable securities driven by a significant reduction in such balances over the past year. Our cash, cash equivalents, and marketable securities balances were lower in the current year, compared to the prior year, due to the completion of our previously announced capital return program that began in September 2022 and was completed in early January 2024.



**Provision for Income Tax Expense**

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

(In thousands)	Three Months Ended		Change		Six Months Ended		Change	
	June 30,		\$	%	June 30,		\$	%
	2024	2023			2024	2023		
Provision for income tax expense	\$ (1,308)	\$ (1,458)	\$ 150	(10)%	\$ (2,570)	\$ (1,063)	\$ (1,507)	142 %

For the six months ended June 30, 2024, we recognized an income tax expense of \$2.6 million compared to \$1.1 million for the same period in 2023. For the six months ended June 30, 2024, our income tax expense was related to the uncertain tax positions, as well as interest expense on our uncertain tax position liability which we began to accrue in the fourth quarter of 2023. For the 2023 comparable period, the income tax expense was primarily due to uncertain tax positions related to our transfer pricing position.

**Liquidity and Capital Resources**

As of June 30, 2024, we had approximately \$96.1 million in cash, cash equivalents, and investments in marketable securities (excluding restricted cash) and no long-term debt.

Our strategic business plan is subject to significant uncertainties and risks as a result of, among other factors, clinical program outcomes, expenses being higher than anticipated, the sales levels of YUPERLI, whether, when and on what terms we are able to enter into new collaboration arrangements, and the need to satisfy contingent liabilities, including tax, litigation matters and indemnification obligations.

*Adequacy of cash resources to meet future needs*

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

**Cash Flows**

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

(In thousands)	Six Months Ended June 30,		Change
	2024	2023	
Net cash used in operating activities	\$ (5,437)	\$ (23,657)	\$ 18,220
Net cash provided by (used in) investing activities	13,997	(31,999)	45,996
Net cash used in financing activities	(1,760)	(136,920)	135,160

*Net cash flows used in operating activities*

Net cash used in operating activities was \$5.4 million for the six months ended June 30, 2024, consisting of a net loss of \$28.2 million, a net increase in cash resulting from adjustments for non-cash and other reconciling items of \$15.9 million and a net increase in cash resulting from changes in operating assets and liabilities of \$6.8 million.

Net cash used in operating activities was \$23.7 million for the six months ended June 30, 2023, consisting of a net loss of \$37.7 million, a net increase in cash resulting from adjustments for non-cash and other reconciling items of \$17.7 million and a net decrease in cash resulting from changes in operating assets and liabilities of \$3.6 million.

*Net cash flows provided by (used in) investing activities*

Net cash provided by investing activities was \$14.0 million for the six months ended June 30, 2024, consisting of cash inflows from the net purchase and maturities of marketable securities of \$14.1 million and cash outflows from the purchase of property and equipment of \$0.1 million.

Net cash used in investing activities was \$32.0 million for the six months ended June 30, 2023, consisting primarily of cash outflows from the net purchase and maturities of marketable securities of \$31.7 million and cash outflows from the net purchase and sale of property and equipment of \$0.3 million.

*Net cash flows used in financing activities*

Net cash used in financing activities was \$1.8 million for the six months ended June 30, 2024, consisting primarily of \$0.4 million of cash outflows related to the repurchase of ordinary shares as part of completion of our capital return program, \$0.4 million of cash inflows related to the sale of shares through our employee share purchase program (“ESPP”) and \$1.7 million of cash outflows related to the repurchase of shares to satisfy tax withholding obligations.

Net cash used in financing activities was \$136.9 million for the six months ended June 30, 2023, consisting of \$135.9 million of cash outflows related to the repurchase of ordinary shares as part of our capital return program, \$1.5 million of cash outflows related to the repurchase of shares to satisfy tax withholding obligations, and \$0.5 million of cash inflows related to the sale of shares through our ESPP.

***Commitments and Contingencies***

We indemnify our officers and directors for certain events or occurrences, subject to certain limits. We maintain insurance policies that may limit our exposure, and therefore, we believe the fair value of these indemnification agreements is minimal. Accordingly, we have not recognized any liabilities relating to these agreements as of June 30, 2024. However, no assurances can be given regarding the amounts that may ultimately be covered by the insurers, and we may incur substantial liabilities because of these indemnification obligations.

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

As a “smaller reporting company,” as defined by Item 10 of Regulation S-K, we are not required to provide this information.

**ITEM 4. CONTROLS AND PROCEDURES**

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

We conducted an evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act as of June 30, 2024, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined under Rule 13a-15(e) of the Exchange Act), which are controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Exchange Act is recorded, processed, summarized and reported within required time periods. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

***Limitations on the Effectiveness of Controls***

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

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

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act, which occurred during the second quarter of the year ending December 31, 2024, 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**

During January 2023, we received notice from Accord Healthcare, Inc.; Cipla USA, Inc. and Cipla Limited; Eugia Pharma Specialties Ltd.; Lupin Inc.; Mankind Pharma Ltd.; Orbicular Pharmaceutical Technologies Private Limited; and Teva Pharmaceuticals, Inc. (collectively, the “generic companies”), that they have each filed with the FDA an abbreviated new drug application (“ANDA”), for a generic version of YUPELRI. The notices from the generic companies each included a paragraph IV certification with respect to five of our patents listed in the FDA’s Orange Book for YUPELRI on the date of our receipt of the notice. The asserted patents relate generally to polymorphic forms of and a method of treatment using YUPELRI. In February 2023, we filed patent infringement suits against the generic companies in federal district courts, including the United States District Court for the District of New Jersey, the U.S. District Court for the District of Delaware, and the U.S. District Court for the Middle District of North Carolina. The suits in Delaware and North Carolina have been dismissed, as all generic companies have agreed to venue in New Jersey. The complaint alleges that by filing the ANDAs, the generic companies have infringed five of our Orange Book listed patents. We are seeking a permanent injunction to prevent the generic companies from introducing a generic version of YUPELRI that would infringe its patents. As a result of this lawsuit, a stay of approval through May 2026 has been imposed by the FDA on the generic companies’ ANDAs pending any adverse court decision. Additional patents covering YUPELRI, granted on July 4, 2023 and January 2, 2024, were subsequently listed in FDA’s Orange Book. We filed additional patent infringement suits in the U.S. District Court for the District of New Jersey during August 2023 and January 2024. These suits have been consolidated with the above action. Further, the original complaint was amended during December 2023 to include certain patents not listed in the Orange Book.

In May 2024, we received notice from Qilu Pharmaceuticals Co., Ltd. (“subsequent ANDA filer”), that it had filed with the FDA an ANDA for a generic version of YUPELRI. The notice from the subsequent ANDA filer included a paragraph IV certification with respect to certain of our patents listed in FDA’s Orange Book for YUPELRI. The asserted patents relate generally to polymorphic forms of and a method of treatment using YUPELRI. In June 2024, we filed a patent infringement suit against the subsequent ANDA filer in the U.S. District Court for the Eastern District of Pennsylvania. The complaint alleges that by filing the ANDA, the subsequent ANDA filer has infringed certain of our Orange Book listed patents. We are seeking a permanent injunction to prevent the subsequent ANDA filer from introducing a generic version of YUPELRI that would infringe our patents. As a result of this lawsuit, we expect a 30-month stay of approval through November 2026 to be automatically granted by the FDA on the subsequent filer’s ANDA pending any adverse court decision.

As of July 31, 2024, we have settled all litigation with Accord Healthcare, Inc.; Lupin Pharmaceuticals, Inc.; Orbicular Pharmaceutical Technologies Private Limited; and Teva Pharmaceuticals, Inc. pursuant to individual agreements in which we granted these companies a royalty-free, non-exclusive, non-sublicensable, non-transferable license to manufacture and market their respective generic versions of YUPELRI inhalation solution in the US on or after the licensed launch date of April 23, 2039, subject to certain exceptions as is customary in these type of agreements. As required by law, the settlements are subject to review by the U.S. Department of Justice and the Federal Trade Commission. The patent litigation against the three remaining generic companies, and the subsequent ANDA filer, remains pending.

A further method of treatment patent, with an expiration date of August 2039, was granted on July 30, 2024 and was listed in the Orange Book.

Please also see “*Item 1, Business – Patents and Proprietary Rights -- Patent Term Restoration, Regulatory Exclusivities, and Hatch-Waxman Litigation*” in our Annual Report on Form 10-K for the year ended December 31, 2023 for more information. In addition, this litigation and the related risks are described in greater detail under the risk factor “*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*” of this Quarterly Report on Form 10-Q.

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

The risks described below and elsewhere in this Quarterly Report on Form 10-Q and in our other public filings with the SEC are not the only risks facing us. 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.

### **Summary of Principal Risks Associated with Theravance Biopharma’s Business**

- We may never achieve or sustain profitability from our operations;
- If YUPELRI’s acceptance by physicians, patients, third party payors, or the medical community in general does not continue to grow, we may not receive significant additional revenues from sales of this product;
- In collaboration with Viartis, we are responsible for marketing and sales of YUPELRI in the US, which subjects us to certain risks;
- Any delay in commencing or completing clinical studies for product candidates or product and any adverse results from clinical or non-clinical studies or regulatory obstacles product candidates or product may face, would harm our business and the price of our securities could fall;
- If our product candidates are not approved by regulatory authorities, including the FDA, we will be unable to commercialize them;
- 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;
- Our ongoing drug development efforts might not generate additional approvable drugs;
- 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;
- 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; and
- 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 YUPELRI.

## RISKS RELATING TO THE COMPANY

### ***We may never achieve or sustain profitability from our operations.***

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 1997. We may never generate sufficient cash or revenue to achieve sustainable cash flow or profitability from our operations. For the three and six months ended June 30, 2024, we recognized net losses of \$16.5 million and \$28.2 million, respectively, and for the year ended December 31, 2023, we recognized a net loss of \$55.2 million. We reflect the 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 condensed consolidated balance sheets, which was \$937.3 million as of June 30, 2024. We may continue to incur net losses over the next several years due to expenditures relating to the development of our current product candidate, which we are advancing through later stage clinical studies without a partner and which we are preparing to potentially commercialize. In addition, we may invest strategically in efforts to continue to support our development and commercial pipeline. While our YUPELRI operations have been profitable on a brand basis since the third quarter of 2020, we will continue to incur costs and expenses associated with the commercialization of YUPELRI in the US, including the maintenance of an independent sales and marketing organization with appropriate technical expertise, and a medical affairs presence and consultant support. Our commitment of resources to the continued development of ampreloxetine and YUPELRI will require ongoing funding, and we expect our sales and marketing expenditures to increase in 2024 as we prepare for the potential commercial launch of ampreloxetine. Our operating expenses also will increase if, among other things:

- we pursue clinical development of our potential or current products in new indications;
- our clinical trials become more complicated or need to be extended due to other external factors;
- we increase the number of patents we are prosecuting or maintaining or otherwise expend additional resources on patent prosecution or defense or patent litigation; or
- we acquire or in-license additional technologies, product candidates, products or businesses.

While we are generating revenues and income from sales of YUPELRI and our economic and royalty interests, we may not generate significant profit from our operations in the near future. We could fail to meet our revenue expectations. If we or our collaborators or licensees are not able to 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, and do so with desired margins, our expenses will continue to exceed any revenues we may receive in the future.

Our strategic business plan is subject to significant uncertainties and risks as a result of, among other factors, the sales levels of our approved product, unplanned expenses, clinical program outcomes, expenses being higher than anticipated, revenue and cash receipts being lower than anticipated, whether, when and on what terms we are able to enter into new collaboration arrangements, and the need to satisfy contingent liabilities. Our ability to reach, and the time required to reach, and then to sustain, profitability from operations is uncertain. As a result, we may incur substantial losses in the future. Failure to become and remain profitable from operations would adversely affect the price of our securities and our ability to continue operations as planned.

### ***If YUPELRI’s acceptance by physicians, patients, third party payors, or the medical community in general does not continue to grow, we may not receive significant additional 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’s acceptance by these parties may not continue to grow as we have planned. YUPELRI competes predominately with short acting nebulized bronchodilators that are dosed three to four times per day. See the Risk Factor entitled “*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*” for additional information regarding the competitive landscape in which we operate. If physicians, patients, third party payors, or the medical community in general believe that YUPELRI is not a preferred treatment option for those with COPD, do not continue to prescribe, fill prescriptions for, cover, or

reimburse for YUPELRI, we may see declines, or fail to grow. In addition, we have recently experienced headwinds from an evolved channel mix and a lower realized net price. While we anticipate a more stable pricing environment and continued YUPELRI demand growth in 2025 and beyond, there can be no assurance that our and our partner VIATRIS' efforts to improve our current pricing dynamics will be successful. See the Risk Factor entitled "*Changes in healthcare law and implementing regulations, including government restrictions on pricing and reimbursement, as well as healthcare policy and other healthcare payor and distributor 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*" for additional information regarding certain elements of the pricing landscape in which we operate. If YUPELRI's acceptance and net price does not grow, or declines from previous levels, our business and financial results could be materially harmed.

***In collaboration with Viatris, 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 to support our co-promotion obligations for YUPELRI under our agreement with Viatris. The risks of fulfilling our US co-promotion obligations to Viatris include:

- costs and expenses associated with 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;
- 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 prescribers 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 a 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 maintaining effective commercialization of YUPELRI in the hospital setting, which would adversely affect our business and financial results, and the condition and the price of our securities could fall.

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

Product candidates must undergo extensive non-clinical and clinical studies as a condition to regulatory approval. 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 completion of clinical studies for our product candidate may be delayed and programs may be terminated due to many factors, including, but not limited to:

- lack of efficacy of product candidate during clinical studies;
- adverse events, safety issues or side effects (or perceived adverse developments or results) relating to the product candidate or its formulation into medicines;
- unfavorable study data or unfavorable interpretations of data among the FDA and foreign regulatory authorities;
- insufficient capital to continue our development program;

- inability to enter into partnering arrangements relating to the development and commercialization of our program and product candidate or partner decisions not to maintain a partnership with us;
- delays in patient enrollment and variability in the number and types of patients available for clinical studies;
- competitive clinical trials;
- 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;
- challenges related to the COVID-19 pandemic, including with recruitment and/or progressing patients through studies;
- failure of any partners to advance 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;
- new clinical trial regulations in the European Union; and
- a 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 program including, without limitation, any delays in development in our program, any halting of development in our program, any difficulties or delays encountered with regard to the FDA or other third country regulatory authorities with respect to our program, or any indication from clinical or non-clinical studies that the compounds in our program are not safe, efficacious or sufficiently differentiated from those of our competitors, could have a material adverse effect on our business and cause the price of our securities to fall. For example, in August 2021 we announced that our Phase 2b study of izecintinib in ulcerative colitis did not meet its primary endpoint, and in September 2021, we announced that our four-week SEQUOIA Phase 3 study for amprelosetine did not meet its primary endpoint. There can be no assurance that our Phase 3 CYPRESS study for amprelosetine will be completed on the timeline we expect or at all, that data from the Phase 3 study for amprelosetine will be read out on the timeline we expect or at all, that the study will meet its endpoints, or that amprelosetine will ultimately be found to be safe and effective.

***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, such as amprelosetine, 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 non-clinical 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 or product and any adverse results from clinical or non-clinical studies or regulatory obstacles product candidates or product 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.

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 partners’ product candidates, which would materially harm our business and financial condition and could cause the price of our securities to fall.

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

In January 2015, we entered into a collaboration agreement with Viatris for the development and commercialization of a nebulized formulation of our LAMA revefenacin, including YUPELRI. Under the terms of the agreement, we and Viatris will co-develop nebulized revefenacin, including YUPELRI, for COPD and other respiratory diseases. VIATRIS is the New Drug Application (“NDA”) holder and is responsible for as manufacturing, pricing and compliance matters as well as sales and marketing in the community setting. We are responsible for sales and marketing in the hospital setting. In 2019, we granted Viatris exclusive development and commercialization rights to nebulized revefenacin in China and adjacent territories, which include the Hong Kong SAR, the Macau SAR, and Taiwan, and we are eligible to receive low double-digit tiered royalties on net sales of nebulized revefenacin, if approved. Viatris is responsible for all aspects of development and commercialization of nebulized revefenacin in China and adjacent territories, including pre- and post-launch activities and product registration and all associated costs. In connection with these agreements, Viatris has certain rights regarding the use of patents and technology with respect to the compounds in our development programs, including development and marketing rights.

Our partner may not fulfill their obligations under our agreements, and, in certain circumstances, they or we may terminate our partnership with them. For example, in June 2023, we received notice from Pfizer terminating the License Agreement (the “Pfizer Agreement”) with Pfizer Inc. (“Pfizer”) regarding our preclinical program for skin targeted, locally acting pan Janus kinase (JAK) inhibitors that can be rapidly metabolized as of October 2023. We are assessing our choices with respect to the program covered by the Pfizer Agreement. 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 or product candidates or is otherwise unsuccessful in its efforts with respect to our products or product candidates, the development and commercialization of products and 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 products and 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 products and 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.

***Our ongoing drug development efforts might not generate additional approvable drugs.***

Our compounds in clinical trials 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. For example, despite promising early stage studies, we previously announced that two late stage clinical programs failed to meet their primary endpoints. There can be no assurance that our Phase 3 study for amprelosetine will meet its primary endpoint, and developments and results from that study may be adverse or may be perceived to be adverse.

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. As our clinical studies for one of our prior product candidates suggested that our product candidate was not efficacious in the indications we were investigating, we choose to cease development of this product candidate. In addition, our product candidates may have undesirable side effects or other unexpected characteristics that could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restricted label or the delay or denial of regulatory approval by regulatory authorities.

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

Our ability to succeed in the future depends on our ability to demonstrate and maintain a competitive advantage with respect to our approach to the discovery, development and commercialization of medicines. Our objective is to develop and commercialize new small molecule medicines with superior efficacy, convenience, tolerability and/or safety. 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 development and commercialization to:

- 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 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 or product candidate obsolete. Accordingly, other companies may succeed in obtaining patent protection, conducting clinical trials, 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 candidate that we are developing or our existing product.

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 predominately with short acting nebulized bronchodilators that are dosed three to four times per day. Verona Pharma plc's ensifentrine, a selective inhaled dual inhibitor of PDE3 and PDE4, was launched in the US in June 2024 and Sanofi and Regeneron Pharmaceutical, Inc.'s IL-4/IL-13 monoclonal antibody (mAb) Dupixent® (dupilumab) is expected to receive US approval for COPD in the second half of 2024 for maintenance treatment for patients with moderate-to-severe COPD, who are uncontrolled with current SOC triple therapy (LAMA + LABA + ICS) and have evidence of Type 2 inflammation and frequent exacerbation history. If successfully developed and approved, amprelosetine would be expected to serve as the only safe, convenient, and durably effective treatment option for MSA patients with symptomatic nOH, entering a market where generic droxidopa is currently the sole product approved for nOH patients and midodrine is approved for OH. 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.

***There is a single source of supply for our product candidates and for YUPELRI, 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 depend on a number of third party Active Pharmaceutical Ingredient ("API") and drug product manufacturers for clinical study purposes and we depend on third party suppliers for warehousing and storage of our existing API and drug product. 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. In addition, there is a single supplier of YUPELRI API, a single supplier of YUPELRI drug product and YUPELRI is warehoused in a single facility. If, for any reason, any of these third party manufacturers are unable or unwilling to perform, or if their performance does not meet regulatory requirements, alternative manufacturers may not be available or may not be available on acceptable terms. For example, while we have not been directly or indirectly materially impacted, manufacturers and warehousing suppliers are periodically impacted by natural disasters, accidents, labor disputes, labor shortages, regulatory actions, public health emergencies and geopolitical factors. Any inability to acquire sufficient quantities of API and drug product in a timely manner from these third parties could delay clinical studies or prevent us from developing our product candidates in a cost-effective manner or on a timely basis or adversely impact YUPELRI sales. In addition, manufacturers of our API and drug product are subject to the FDA's current Good Manufacturing Practice ("cGMP") regulations and similar foreign standards and we do not have control over compliance with these regulations by our manufacturers.

Our manufacturing strategy presents the following additional risks:

- because of the complex nature of many of our compounds, our manufacturers may not be able to successfully manufacture our APIs and/or drug products in a cost-effective and/or timely manner and changing manufacturers for our APIs or drug products could involve lengthy technology transfer, validation and regulatory qualification activities for the new manufacturer;

- the processes required to manufacture certain of our APIs and drug products are specialized and available only from a limited number of third party manufacturers;
- the availability of specialized materials needed to manufacture our APIs and drug products or YUPELRI;
- because some of the third party manufacturers are located in numerous locations outside of the US, and we are conducting global clinical trials there may be difficulties in shipping and importing and exporting our APIs and drug products or their components globally.

***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 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 YUPELRI.***

Under the Drug Price Competition and Patent Term Restoration Act of 1984, a company may submit an abbreviated new drug application (“ANDA”) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to market a generic version of an approved drug. Because a generic applicant does not conduct its own clinical studies, but instead relies on the FDA’s finding of safety and effectiveness for the approved drug, it is able to introduce a competing product into the market at a cost significantly below that of the original drug. Although we have multiple patents protecting YUPELRI with expiration dates ranging from 2025 to 2039 that are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, generic applicants have submitted, and could potentially submit additional, “paragraph IV certifications” to FDA stating that such patents are invalid or will not be infringed by the applicant’s product. For example, on January 10, 2023, the FDA included seven ANDAs that referred to YUPELRI (revefenacin) inhalation solution and contained a paragraph IV certification on its Paragraph IV Certifications List and, in May 2024, we received notice from a subsequent filer that it had filed with the FDA an ANDA for a generic version of YUPELRI and included a paragraph IV certification with respect to certain of our patents listed in FDA’s Orange Book for YUPELRI. As of July 31, 2024, we have settled litigation with some of the generic applicants, and pursuant to individual agreements, we granted these companies a royalty-free, non-exclusive, non-sublicensable, non-transferable license to manufacture and market their respective generic versions of YUPELRI inhalation solution in the US on or after the licensed launch date of April 23, 2039, subject to certain exceptions as is customary in these type of agreements. Based on publicly-available information, we are not aware of any other paragraph IV notifications with respect to other products in which we have an economic interest or right to receive royalties. Our collaboration partner, Viatris, is responsible for enforcing our Orange Book patents relating to YUPELRI, in consultation with us, and our views may differ from theirs with respect to process or strategy, and we have a reduced ability to control the outcome of the litigation. If any competitors successfully challenge the patents related to these products, including YUPELRI, 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 risk factor below entitled “*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*” and “*Litigation to protect or defend our intellectual property or third party claims of intellectual property infringement will require us to divert resources and may prevent or delay our drug discovery and development efforts.*”

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

We have a collaboration with Viatris for the development and commercialization of a nebulized formulation of revefenacin, which is a LAMA compound (including YUPELRI). In addition, we plan to seek a partnership to continue progression of our inhaled JAK inhibitor program. Additional collaborations, if any, may be needed to progress additional programs and to commercialize the product candidates in our programs if approved by the necessary regulatory authorities. We evaluate commercial strategy on a product by product basis either to engage pharmaceutical or other healthcare companies with an existing sales and marketing organization and distribution system to market, sell and distribute our products or to commercialize a product ourselves. However, we may not be able to establish these sales and distribution relationships on acceptable terms, or at all, or may encounter difficulties in commercializing a product ourselves. For any of our product candidates that receive regulatory approval in the future and are not covered by our current collaboration agreements, we will need a partner in order to commercialize such products unless we establish independent sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure.

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

unable to reach agreements with third party collaborators, we may fail to meet our business objectives and our financial condition may be adversely affected. We face significant competition in seeking third party collaborators. We may be unable to find third parties to pursue product collaborations on a timely basis or on acceptable terms.

Furthermore, once we enter into a collaboration, our collaboration partners are frequently important for the success of the product or product candidate. For example, Viatris' role in the commercialization of YUPELRI is important to the overall success of product. In addition, since we do not currently intend to progress our skin-selective pan-JAK inhibitor program internally, Pfizer was important to such program's development. However, for any collaboration, we may not be able to control the amount of time and resources that our partners devote to our products or 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, Viatris has a substantial existing product portfolio largely comprising generic products, other considerations and incentives that influence its resource allocation, and background, experiences, priorities, and internal organizational processes that differ from our own. As a result of these differing backgrounds, interests, and processes, Viatris 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 non-clinical and 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, enforce 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.

***If there are any adverse developments or perceived adverse developments with respect to TRELEGY, we may not receive Milestone Payments or the revenue we expect from the Outer Years Royalty, which would harm our business and could cause the price of our securities to fall.***

Through the milestone payments we may receive from Royalty Pharma if certain TRELEGY global net sales thresholds are met following our sale of our economic interest in TRELEGY (the "Milestone Payments") and pursuant to our right to receive from Royalty Pharma 85% of the royalty payments on the Assigned Collaboration Products (as defined in the Purchase Agreement) payable (a) for sales or other activities occurring on and after January 1, 2031 related to the Assigned Collaboration Products in the US, and (b) for sales or other activities occurring on and after July 1, 2029 related to the Assigned Collaboration Products outside of the US (the "Outer Years Royalty" and, together with the Milestone Payments, the "Ongoing Economic Interest"), we may participate in the mid- and long-term economically in royalty payments from GSK with respect to the TRELEGY. However, we cannot assure you as to the amount, if any, we might receive. We have no access to non-public information regarding the development progress of, or plans for TRELEGY, and we have no current authority to enforce rights under the GSK Agreements assigned to TRC. However,

if there are any adverse developments or perceived adverse developments with respect to TRELEGY, we may not realize the value we currently anticipate from the Ongoing Economic Interest, which would harm our business and may cause the price of our securities to fall. Examples of such adverse developments include, but are not limited to:

- disappointing or lower than expected sales of TRELEGY;
- the emergence of new closed triple or other alternative therapies or any developments regarding competitive therapies, including comparative price or efficacy of competitive therapies;
- disputes between any of Royalty Pharma, GSK, Innoviva and us;
- GSK deciding to modify, delay or halt the TRELEGY program;
- any safety, efficacy or other concerns regarding the TRELEGY program; or
- any particular FDA requirements or changes in FDA policy or guidance regarding the TRELEGY program or any particular regulatory requirements in other jurisdictions or changes in the policies or guidance adopted by foreign regulatory authorities.

***We do not control the commercialization of TRELEGY; accordingly, our receipt of Milestone Payments and receipt of the value we currently anticipate from the Outer Years Royalty will depend on, among other factors, GSK's ability to further commercialize TRELEGY.***

Our Ongoing Economic Interest in TRELEGY consists of the potential Milestone Payments and our right to receive from Royalty Pharma the Outer Years Royalty, both of which are ultimately based on the amount of sales of this product by GSK. Any benefit we may receive from the Ongoing Economic Interest will depend on GSK's ability to commercialize the product, and the future payments, if any, made by GSK to Royalty Pharma.

Accordingly, our Ongoing Economic Interest involves a number of risks and uncertainties, including:

- GSK's ability to have an adequate supply of TRELEGY 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;
- any future disruptions in GSK's business which would affect its ability to commercialize TRELEGY, including, disruptions due to the COVID-19 pandemic;
- the ability of TRELEGY to achieve wider acceptance among physicians, patients, third party payors, or the medical community in general;
- global economic conditions; and
- any of the other risks relating to commercialization of TRELEGY.

These risks and uncertainties could materially impact the amount and timing of future Milestone Payments and Outer Years Royalty, 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.

***If we lose key management, sales, clinical development 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 will be impaired.***

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

If we fail to retain our qualified personnel or replace them when they leave, we may be unable to continue our development and commercialization activities, which may cause the price of our securities to fall. The corporate restructuring announced in September 2021 and completed in the third quarter of 2022, and the additional headcount reductions announced in February 2023, may make retention of our current personnel both more important and more challenging.

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.

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

We, our vendors, and third parties that are important to how we operate and monitor our business 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, other third parties that are important to how we operate and monitor our business, and other service providers, including cloud-based and hosted applications, data and services, may be 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, including but not limited to those involving malware and ransomware, which can disrupt operations significantly, 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. For example, in February 2024, UnitedHealth's Change Healthcare Unit, a large US insurance claim and co-pay card processing clearinghouse, experienced a ransomware attack that caused significant disruptions to healthcare provider and pharmacy operations. Change Healthcare does not provide services to us, however, disruptions to co-pay card support, insurance billing and Medicaid rebate processing potentially led to lost sales and, in response to disruptions from this breach, we and our partner Viatrix took steps to help patients access their medications. Although services have been rerouted, and in some cases restored, similar disruptions may occur in the future stemming from the interconnectedness of the US healthcare ecosystem and industry reliance on centralized claims processing systems and networks, and such future disruptions may have a material adverse effect on our business or results of operations. In addition, Viatrix distributes YUPELRI in the US through durable medical equipment suppliers, specialty pharmacies and pharmaceutical wholesalers, and a security breach that impairs the distribution operations or retail pharmacies could materially and adversely impair our ability to deliver YUPELRI to healthcare providers and patients and therefore result in reduced revenue.

If a disruption of information technology systems or security breach results in a loss of or damage to our data or regulatory applications, unauthorized access, use, or disclosure of, or the prevention of access to, confidential information, or other harm to our business, we could incur liability and reputational harm, we could be required to comply with federal and/or state breach notification laws and foreign law equivalents, we may incur legal expenses to

protect our confidential information, the further development of our product candidates could be delayed and the price of our securities could fall. For example, the loss of clinical trial data from completed or ongoing clinical trials of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. 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. In addition, we may suffer damages as a result of civil claims, including potential class action claims, in response to security breaches. 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 our cybersecurity risk management program and processes, including our policies, controls, or procedures, will be fully implemented, complied with or effective in protecting our information technology systems and sensitive data. These same risks also apply to our partners and vendors, who similarly hold sensitive and critical information related to our business in computer systems as well as any other third parties in our industry whose operations may indirectly affect our business. Such third parties are similarly potentially vulnerable to service interruptions and security breaches.

***Global 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 current global economic challenges, war and hostilities in Ukraine and the Middle East, the COVID-19 pandemic and other health emergencies, the United Kingdom's ("UK") withdrawal from the EU (often referred to as "Brexit"), inflation, instability in the US banking sector and other disruptions to global and regional economies and markets.

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, including as a result of the US failing to raise the debt ceiling, 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, including China, 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.

Brexit created significant uncertainty about the future relationship between the UK and the EU, including with respect to the laws and regulations that will apply as the UK determines which EU laws to replace or replicate after withdrawal. From a regulatory perspective, the UK's withdrawal bears significant complexity and risks.

External factors, such as potential terrorist attacks, acts of war, geopolitical and social turmoil, including the ongoing hostilities between Russia and Ukraine and those between Israel and Hamas or Iran, similar events in many parts of the world or the worsening of such factors, could also prevent or hinder our ability to do business, increase our costs and negatively affect our stock price. These geopolitical, social, and economic conditions could harm our business.

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

Our US operating subsidiary's facility is located in the San Francisco Bay Area near known earthquake fault zones and therefore will be vulnerable to damage from earthquakes. In October 1989, a major earthquake struck this area and caused significant property damage and a number of fatalities. We are also vulnerable to damage from other types of disasters, including power loss, attacks from extremist organizations, fire, floods, communications failures, and similar events. If any disaster were to occur, our ability to operate our business could be seriously impaired. In addition, the unique nature of our drug development 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 sufficient capital is not available, we may have to further curtail 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 existing 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 of izencitinib in our JAK inhibitor program. In addition, following unfavorable results from our late-stage development programs, in September 2021, we announced a strategic update and corporate restructuring (the “2021 Restructuring”), including a reduction in headcount by approximately 75% through a reduction in our workforce of regular and contingent workers. The 2021 Restructuring was completed during the third quarter of 2022, and we announced additional headcount reductions in February 2023. If our current operating plans or financial forecasts change, we may require or seek additional funding in the form of public or private equity or equity-linked offerings, debt financings or additional collaborations and licensing arrangements. In addition, as of June 30, 2024, we had cash, cash equivalents and marketable securities of approximately \$96.1 million.

Our future capital needs depend on many factors, including:

- support and investments in YUPELRI, including funding our commercialization strategies and post marketing clinical studies;
- the scope, duration, expenditures, and technical obstacles associated with our ampreloxtine program, including preparing for potential product approvals of ampreloxtine and its potential commercialization;
- the occurrence of events triggering Royalty Pharma’s obligations to make Milestone Payments to us;
- the outcome of potential licensing or partnering transactions, if any;
- responding to competitive pressures and competing technological developments;
- the extent of our proprietary patent position in any approved products and our product candidates;
- our facilities expenses, which will vary depending on the time and terms of any facility lease or sublease we may enter into, and other operating expenses;
- the scope and extent of the sales and marketing efforts, including our independent sales and marketing organization and medical affairs team;
- litigation, potential litigation and other contingencies; and
- the regulatory approval process for our product candidates.

If we require additional funding, 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 also have to sequence studies as opposed to conducting them concomitantly in order to conserve resources, or, as we announced in September 2021 and in February 2023, we may need to delay, reduce, or eliminate one or more of our programs and reduce overall overhead expenses. In addition, we may have to make additional reductions in our workforce and may be prevented from continuing our 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.***

We may in the future need to raise additional funds to continue to progress 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. We do not have any outstanding long-term debt, but if additional debt is issued or we otherwise borrow additional funds in the future, there is a possibility that once all senior claims are settled, there may be no assets remaining to pay out to the holders of ordinary shares. In addition, if we raise funds through the issuance of additional equity, whether through private placements or public offerings, such an issuance would dilute ownership of our current shareholders that do not participate in the issuance. 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 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 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.

***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.

***Future tax reform, including changes in tax rates and imposition of new taxes, could impact our results of operations and financial condition.***

We are incorporated in the Cayman Islands, maintain subsidiaries in the Cayman Islands (until December 2020), the US, the UK and Ireland, and effective July 1, 2015, we migrated our tax residency from the Cayman Islands to Ireland. We are subject to new, evolving, or revised tax laws and regulations in such jurisdictions, and the enactment of or increases in taxes, or other changes in the application of existing taxes, in such jurisdictions may have an adverse effect on our business or on our results of operations. Due to economic and political conditions, tax rates in various jurisdictions may be subject to significant change. Our future effective tax rate could be affected by changes in our mix of earnings in countries with differing statutory tax rates, changes in valuation of our deferred tax assets and liabilities, or changes in tax laws or their interpretation, including possible US tax reform and contemplated changes in other countries of long-standing tax principles. These and other similar changes, if finalized and adopted, could have a material impact on our income tax expense and deferred tax balances.

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

We are incorporated in the Cayman Islands, maintain subsidiaries in the Cayman Islands (until December 2020), the US, the UK 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. Ireland has implemented further tax law changes through the Finance Act 2021 to comply with the European Union Anti-Tax Avoidance Directives. Changes to date, including reverse-hybrid mismatch and interest limitation rules, are not expected to have a material impact on our tax position.

In April 2020, we became aware of a withholding tax regulation that could be interpreted to apply to certain of our previous intra-group transactions. Additional draft guidance on this withholding tax regime was released in late 2020 and early 2021, and based on our analysis of this guidance, we do not believe the exposure to be material. We continue to monitor the evolving legislation relating to this matter and will consider its impact on our condensed consolidated financial statements.

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.

Moreover, pursuant to a recently-completed review of our Irish tax assets, we are engaging tax and financial advisors to explore opportunities to create additional shareholder value from our assets, including our tax assets. There can be no assurance that we will implement any steps or that any such steps will result in greater shareholder value, and the tax-related effects of any such steps could be uncertain or could be challenged by taxing authorities.

***We were a passive foreign investment company, or "PFIC," for 2014, but we were not a PFIC from 2015 through 2023, 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 2023, we do not believe that our company is a PFIC since 2015. Based on existing tax law, 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.

***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. These reporting and other obligations place significant demands on our management and administrative and operational resources, including accounting resources.

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

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

We rely upon a combination of patents, patent applications, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any involuntary disclosure to or misappropriation by third parties of this proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. The status of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and is very uncertain. As of June 30, 2024, we owned a total of 179 issued US patents and 987 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, including the patents that relate to YUPELRI. 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 effective patent lives of the related product candidates could 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 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 will 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 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 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, we have initiated, and in the future we could again 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. For example, in February 2023, we filed patent infringement lawsuits against seven companies and certain of their affiliates seeking to market a generic version of YUPELRI, and in December 2023, we amended the lawsuit to include several non-Orange Book listed patents. Additional lawsuits were filed later in 2023 and into 2024 based on newly-issued patents. A further lawsuit was filed during 2024 in response to a subsequent company seeking to market a generic version of YUPELRI. If these companies are found not to infringe one or more of our patents or the litigation results in one or more of our patents being invalidated, the generic companies may be able to launch their products prior to the expiration of the patents, which range from 2026 to 2039. Another Orange Book listed patent expiring in October 2028 remains unchallenged. Our collaboration partner, Viatris, is responsible for enforcing our Orange Book patents relating to YUPELRI, in consultation with us, and their views on the ongoing litigation, process or strategy may differ from ours, and we have a reduced ability to control the outcome of the litigation. For additional discussion of risks related to partnering programs, please see the risk factor entitled “*If we are unable to enter into future collaboration arrangements or if any such collaborations with third parties are unsuccessful, we may be unable to fully develop and commercialize certain product candidates and our business will be adversely affected.*” 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 negatively impacted, 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 TRELEGY in which we maintain the Ongoing Economic Interest. To the extent the intellectual property protection of any partnered assets is successfully challenged or encounters problems with the US Patent and Trademark Office or other comparable agencies throughout the world, the future commercialization of these potential medicines could no longer be economically feasible. Any challenge to the intellectual property protection of a late-stage development or commercial-stage asset, particularly those of TRELEGY, 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 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 and/or genetic 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. In California, the California Consumer Privacy Act (“CCPA”) establishes certain requirements for data use and sharing transparency, and provides California residents certain rights concerning the use, disclosure, and retention of their personal data. The California Privacy Rights Act (“CPRA”) currently in effect, significantly amends the CCPA. Virginia, Colorado, Utah, Indiana, Iowa, Tennessee, Montana, Texas, and Connecticut have enacted privacy laws similar to the CCPA that impose new obligations or limitations in areas affecting our business. These laws and regulations are evolving and subject to interpretation and may impose limitations on our activities or otherwise adversely affect our business. The obligations to comply with the CCPA and evolving legislation involve, among other things, updates to our notices and the development of new processes internally and with our partners. We may be subject to fines, penalties, or private actions in the event of non-compliance with such laws.

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, the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, (collectively, “HIPAA”). HIPAA imposes privacy and security obligations on covered entity health care providers, health plans, and health care clearinghouses, as well as their “business associates”—certain persons or entities that create, receive, maintain, or transmit protected health information in connection with providing a specified service or performing a function on behalf of a covered entity. Although we are not directly subject to HIPAA, we could be subject to criminal penalties if we knowingly receive individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA.

Further at the federal level, the Federal Trade Commission (“FTC”) also sets expectations for failing to take appropriate steps to keep consumers’ personal information secure, or failing to provide a level of security commensurate to promises made to individual about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of Section 5(a) of the Federal Trade Commission Act (“FTC Act”). The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets expectations that companies honor the privacy promises made to individuals about how the company handles consumers’ personal information; any failure to honor promises, such as the statements made in a privacy policy or on a website, may also constitute unfair or deceptive acts or practices in violation of the FTC Act. While we do not intend to engage in unfair or deceptive acts or practices, the FTC has the power to enforce promises as it interprets them, and events that we cannot fully control, such as data breaches, may be result in FTC enforcement. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions.

EU Member States and other jurisdictions where we operate, such as Switzerland and the UK, have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the General Data Protection Regulation (“GDPR”), imposes strict obligations and restrictions on the ability to collect, analyze, use, store,

disclose, transfer or otherwise process personal data, including health data from clinical trials subjects and adverse event reporting. Switzerland has adopted laws that impose restrictions and obligations similar to the GDPR. The GDPR and Switzerland's data protection laws impose a broad range of requirements and obligations relating to the processing and protection of personal data, including obligations to having legal bases for processing personal data (which may result in some instances in obtaining the consent of the individuals to whom the personal data relate), providing detailed information about the processing activities to the individuals, dealing with restrictions on sharing of personal data with third parties and transferring personal data out of the European Economic Area ("EEA") or Switzerland, having contracting arrangements in place where required (such as with clinical trial sites and vendors), notifying in certain instances personal data breaches to data protection authorities and/or affected individuals, appointing data protection officers, conducting data protection impact assessments, responding to privacy rights requests and keeping records of processing activities. Data protection authorities from the different EU Member States and the EEA may interpret the GDPR and applicable related national laws differently which could effectively result in requirements additional to those currently understood to apply under 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 applicable data protection and electronic communications laws. In particular, as we rely on service providers processing personal data of data 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. Enforcement by EU and UK regulators is active, and failure to comply with the GDPR or applicable Member State law may result in substantial fines. The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover for more serious offenses. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with data protection authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR.

With regard to transfer of personal data, the GDPR restricts the ability of companies to transfer personal data from the EU to the US and other countries, which may incur compliance costs for implementing lawful transfer mechanisms, conducting data transfer impact assessments, and implementing additional measures where necessary to ensure that personal data transferred are adequately protected in a manner essentially equivalent to the EU. The GDPR provides different transfer mechanisms we can use to lawfully transfer personal data from the EU to countries outside the EU. An example is relying on the EU Standard Contractual Clauses and the EU - US Data Privacy Framework. The suitability of Standard Contractual Clauses for data transfer in some scenarios has recently been the subject of legal challenge, and while the US and the EU reached agreement on the EU - US Data Privacy Framework, there are legal challenges to that data transfer mechanism as well. Compliance with EU data transfer obligations can be costly and time-consuming. Data importers must also expend resources in analyzing their ability to comply with transfer obligations, including implementing new safeguards and controls to further protect personal data. If we or our vendors fail to comply with applicable data privacy laws concerning, or if the legal mechanisms we or our vendors rely upon to allow, 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, including an order to stop transferring the personal data outside of the EEA and significant penalties against us. Moreover, our business could be adversely impacted if our ability to transfer personal data out of the EEA, the UK or Switzerland to the US is restricted, which could adversely impact our operating results.

Failure to comply with data protection laws and regulations could result in unfavorable outcomes, including increased compliance costs, delays or impediments in the development of new products, increased operating costs, diversion of management time and attention, government enforcement actions and create liability for us (which could include civil, administrative, and/or criminal penalties), private litigation and/or adverse publicity that could negatively affect our operating results and business.



***Changes in healthcare law and implementing regulations, including government restrictions on pricing and reimbursement, as well as healthcare policy and other healthcare payor and distributor 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, and distributors to contain or reduce costs that they or patients are charged 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.

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 presidential administration, federal agencies, new healthcare legislation passed by Congress or fiscal challenges faced by all levels of government health administration authorities. Among policy makers and payors in the 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 regulatory or legislative initiatives, including those related to pricing of or reimbursement for prescription drugs. 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, distributors and additional legislative enactments and administrative policies.

The Patient Protection and Affordable Care Act, as amended (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”; the coverage gap will be eliminated effective 2025 under the Inflation Reduction Act of 2022 (the “IRA”) and will be replaced with a new manufacturer discount program), rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicare Drug Rebate program, expansion of the Public Health Service Act’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.

Certain provisions of the Healthcare Reform Act have been subject to judicial challenges as well as efforts to modify them or to alter their interpretation or implementation and 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 Reform Act, its implementation, efforts to modify, or invalidate the Healthcare Reform Act, or portions thereof, or its implementation, and other healthcare reform measures including those 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.

The Bipartisan Budget Act of 2018, among other things, amended the Healthcare Reform Act to increase the point-of-sale discounts that manufacturers must agree to offer under the Medicare Part D coverage discount program from 50% to 70% off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D. Civil monetary penalties can be applied if a manufacturer fails to provide these discounts in the amount of 125 percent of the discount that was due (the coverage gap has been eliminated effective 2025 under the Inflation Reduction Act).

The Budget Control Act of 2011, among other things, and in concert with subsequent legislation, has resulted in aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2031. Sequestration is currently set at 2% and will increase to 2.25% for the first half of fiscal year 2030, to 3% for the second half of fiscal year 2030, and to 4% for the remainder of the sequestration period that lasts through the first half of fiscal year 2031. As long as these cuts remain in effect, they could adversely impact payment for any products that are reimbursed under Medicare.

The IRA sunsets the coverage gap discount program starting in 2025 and replaces it with a new manufacturer discount program and establishes Part B and Part D inflation rebates. The IRA also creates a Drug Price Negotiation Program under which the prices for Medicare units of certain high Medicare spend drugs and biologics without generic or biosimilar competition will be capped by reference to, among other things, a specified non-federal average manufacturer price, with negotiated prices set to take effect starting in 2026. Failure to comply with requirements under the drug price negotiation program is subject to an excise tax and/or a civil monetary penalty. Whether any of our products are selected for negotiation for a given year will depend on whether they are at least 7 years post-approval/licensure; whether they meet any of the exclusions from eligibility for selection for negotiation, such as the exclusion of certain orphan drugs; their expenditures under Medicare Part B or Part D during a statutorily specified period; and whether a generic of the product has been determined to have come to market. Amprexetine received an Orphan Drug Designation status from the FDA, which should mean it will not be selected for negotiation; however, our understanding of whether and when our products are likely to be subject to selection for negotiation could evolve as the Drug Price Negotiation Program is implemented. These or any other legislative change could impact the market conditions for our products. We further expect continued scrutiny on pricing from Congress, agencies, and other bodies with respect to drug pricing.

Individual states in the US have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement limitations, marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. For example, California has enacted a prescription drug price transparency law requiring prescription drug manufacturers to provide advance notice and explanation for price increases of certain drugs with prices that exceed a specified threshold, and to report new prescription drugs introduced to the market at a wholesale acquisition cost exceeding the Medicare Part D specialty drug threshold. Additionally, some individual states have begun establishing Prescription Drug Affordability Boards (or similar entities) to review high-cost drugs and, in some cases, set upper payment limits.

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 Pharmaceuticals Inc. (“Cumberland”) in November 2018, 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 Viatriis. We retain certain obligations with respect to record retention for these programs. These programs included the following:

- The Medicaid Drug Rebate program, under which a manufacturer is required to pay a rebate based on reported pricing data 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 made available to the states for the manufacturer’s drugs under Medicaid and Medicare Part B.

- The 340B Program, in which manufacturers must participate 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 certain entities, and that price is calculated based on the information reported under the Medicaid Drug Rebate program.
- Reporting of average sales price, which manufacturers report for certain categories of drugs that are paid under the Medicare Part B program to CMS on a quarterly basis and which CMS may use in determining payment rates for drugs under Medicare Part B.

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 and the average sales price. Manufacturers may need to make additional restatements beyond the three-year period.

We may be liable for errors associated with our submission of pricing data for VIBATIV for historic periods, and we may retain some liability for price reporting by Cumberland for VIBATIV sold under our labeler code. 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. If we are found to have charged 340B covered entities more than the statutorily mandated ceiling price, we could be subject to significant civil monetary penalties and/or such failure also could be grounds for HRSA to terminate a manufacturer's agreement to participate in the 340B program, in which case covered outpatient drugs under our labeler code may no longer be eligible for federal payment under the Medicaid or Medicare Part B program. If we are found to have not submitted required price data on a timely basis, that could result in a significant civil monetary penalty per day for each day the information is late beyond the due date.

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 list its innovator products on a VA Federal Supply Schedule ("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. In addition, manufacturers must submit to the VA quarterly and annual "non-federal average manufacturer price" ("Non-FAMP") calculations for each NDC-11 of their innovator drugs. 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.

Individual states in the US, as noted, have also passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including establishing Prescription Drug Affordability Boards (or similar entities) to review high-cost drugs and, in some cases, set upper payment limits and implementing marketing cost disclosure and transparency measures. Some states require the submission of reports related to pricing information, including based on the introduction of new prescription drugs, certain increases in wholesale acquisition cost of prescription drugs, marketing of prescription drugs within the state, and sales of prescription drugs in or into the state. Some states may pursue available enforcement measures, including imposition of civil monetary penalties, for a manufacturer's failure to report such information.

***The coverage and reimbursement status of new or current products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.***

Market acceptance and sales of any one or more of our product candidates will depend on reimbursement policies and may be affected by future healthcare reform measures in the US. Government authorities and third party payers, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. We cannot be certain that reimbursement will be available for any commercialized products. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, our products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any product candidates that we develop.

The pricing, coverage and reimbursement of our product candidates, if commercialized, must be adequate to support our commercial infrastructure. Our per-patient prices must be sufficient to recover our development and manufacturing costs and potentially achieve profitability. However, sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. One third party payor's decision to cover a product does not ensure that other payors will also provide coverage for the product. As a result, we do not have assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

In addition, third party payors are increasingly reducing reimbursements for pharmaceutical products and services. The US government and state legislatures have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement, and requirements for substitution of generic products. Third party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost effectiveness of pharmaceutical products, in addition to questioning their safety and efficacy. Increasingly, third party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit or delay sales of any of our future products. A decision by a third party payor not to cover a product could reduce physician ordering and patient demand for any of our future products.

***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 companies’ 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. As part of these resolutions, Companies may 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, 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, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Applicable manufacturers are also 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.

- 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 drug 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 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 fluctuated and may continue to fluctuate and may result in substantial losses for purchasers of our ordinary shares. For example, in the year ended December 31, 2023, the last reported sales price of our ordinary shares on Nasdaq fluctuated between a low of \$8.38 per share and a high of \$11.92 per share. 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 to third parties 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:

- any adverse developments or results or perceived adverse developments or results with respect to YUPELRI, including without limitation, lower than expected sales of YUPELRI, difficulties or delays encountered with regard to the FDA or other regulatory authorities in this program or any indication from clinical or non-clinical studies that YUPELRI is not safe or efficacious;
- any adverse developments or results or perceived adverse developments or results with respect to TRELEGY;
- any adverse developments or results or perceived adverse developments or results with respect to our clinical development programs, including, without limitation, any delays in development in these programs, any halting of development in these programs, any difficulties or delays encountered with regard to the FDA or other regulatory authorities in these programs, or any indication from clinical or non-clinical studies that the compounds in such programs are not safe or efficacious;
- any 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 Royalty Pharma, or the relationship of Royalty Pharma and GSK;
- 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 the COVID-19 pandemic and 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;
- the sale of large concentrations of our shares to third parties, which may be more likely to occur due to the concentration of ownership of our shares, such as what we experienced when our then-largest shareholder divested its holdings in 2019;
- developments or disputes as to patent or other proprietary rights;
- approval or introduction of competing products and technologies;
- results of clinical trials;
- failures or unexpected delays in timelines for our potential products in development, including the obtaining of regulatory approvals;
- delays in manufacturing adversely affecting clinical or commercial operations;
- fluctuations in our operating results;
- market reaction to announcements by other biotechnology or pharmaceutical companies;
- initiation, termination, or modification of agreements with our collaborators or disputes or disagreements with collaborators;
- litigation or the threat of litigation;
- public concern as to the safety of 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. For example, our stock price dropped significantly when we announced that izencitinib did not meet its primary endpoint in our Phase 2b/3 induction and maintenance study of izencitinib in ulcerative colitis. In addition, though none has been filed to our knowledge, 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.

***Activist shareholders could negatively impact our business and cause disruptions.***

We value constructive input from investors and regularly engage in dialogue with our shareholders regarding strategy and performance. While our board of directors and management team welcome their views and opinions with the goal of enhancing value for all shareholders, we may be subject to actions or proposals from activist shareholders that may not align with our business strategies or the best interests of all of our shareholders.

For example, in February 2023, Irenic Capital Management LP ("Irenic") released a public letter communicating its opinions regarding actions that it believes we should take and made public statements critical of our board of directors and management. In December 2023, we entered into a cooperation agreement with Irenic pursuant to which Irenic designated a member of our board of directors. Nevertheless, Irenic may continue to make and/or other activist shareholders may make such public communications in the future.

In the event of such shareholder activism – particularly with respect to matters which our board of directors, in exercising their fiduciary duties, disagree with or have determined not to pursue – our business could be adversely affected because responding to such actions by activist shareholders can be costly and time-consuming, disruptive to our operations and divert the attention of management, our board of directors and our employees, and our ability to execute our strategic plan could also be impaired as a result. Such an activist campaign could require us to incur substantial legal, public relations and other advisory fees and proxy solicitation expenses. Further, we may become subject to, or we may initiate, litigation as a result of proposals by activist shareholders or matters relating thereto, which could be a further distraction to our board of directors and management and could require us to incur significant additional costs. In addition, perceived uncertainties as to our future direction, strategy, or leadership created as a consequence of activist shareholders may result in the loss of potential business opportunities, harm our ability to attract new or retain existing investors, customers, directors, employees, collaborators or other partners, harm or impair our ability to accrue patients to clinical trials because of concerns the study may be disrupted, disrupt relationships with us, and the market price of our ordinary shares could also experience periods of increased volatility as a result.

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

Based solely on our review of publicly available filings, as of June 30, 2024, our three largest shareholders collectively owned 46.1% 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;
- maintain a classified board of directors until our annual general meeting in 2026;
- 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 (2020 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 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, we 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 understand 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 or if our results fail to meet the expectations of these analysts, 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.

***Capital appreciation, if any, of our ordinary shares may be your sole source of gain for the foreseeable future.***

We have never declared or paid cash dividends on our capital shares. Starting in September 2022, we undertook a capital return program of \$325.3 million which was completed in January 2024. There is no guarantee that we will implement another capital return program in the future. As a result, capital appreciation, if any, of our ordinary shares may be your sole source of gain for the foreseeable future.

***We are a smaller reporting company, and any decision on our part to comply only with reduced reporting and disclosure requirements applicable to such companies could make our ordinary shares less attractive to investors.***

As of June 30, 2024, we qualified as a “smaller reporting company,” as defined in the Exchange Act. For as long as we continue to be a smaller reporting company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies that are not smaller reporting companies, including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and only being required to provide two years of audited financial statements in annual reports. In addition, for so long as we remain a smaller reporting company and not classified as an “accelerated filer” or “large accelerated filer” pursuant to SEC rules, we will be exempt from the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act.

We will remain a smaller reporting company so long as, as of June 30 of the preceding year, (i) the market value of our ordinary shares held by non-affiliates, or our public float, is less than \$250.0 million; or (ii) we have annual revenues less than \$100.0 million and either we have no public float or our public float is less than \$700.0 million.

If we continue to take advantage of some or all of the reduced disclosure requirements available to smaller reporting companies, investors may find our ordinary shares less attractive, which may result in a less active trading market for our common stock and greater stock price volatility.

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

None.

**ITEM 5. OTHER INFORMATION**

*Trading Plans*

During the three months ended June 30, 2024, none of our Section 16 officers or directors adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as those terms are defined in Item 408 of Regulation S-K, except as described in the table below:

<u>Name and Title</u>	<u>Action</u>	<u>Date</u>	<u>Duration of Trading Arrangement</u>	<u>Rule 10b5-1 Trading Arrangement? (Y/N) (1)</u>	<u>Number of Ordinary Shares to be Sold</u>
Eran Broshy, <i>Director</i>	Adoption	June 14, 2024	September 13, 2024 - December 31, 2025	Y	Up to 74,501

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(1) Denotes whether the trading plan is intended to satisfy the affirmative defense Rule 10b5-1(c) of the Exchange Act.

**ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Filed Herewith</b>	<b>Incorporated by Reference</b>	
			<b>Form</b>	<b>Filing Date/Period End Date</b>
31.1	<a href="#">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</a>	X		
31.2	<a href="#">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</a>	X		
32(1)	<a href="#">Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>	X		
101	Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended June 30, 2024, formatted in iXBRL: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss, (iii) Condensed Consolidated Statements of Shareholders' Equity, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) the Notes to the Condensed Consolidated Financial Statements	X		
104	Cover Page Interactive Data File (Formatted in iXBRL and contained in Exhibit 101)	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: August 8, 2024

/s/ RICK E WINNINGHAM

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

Date: August 8, 2024

/s/ AZIZ SAWAF

Aziz Sawaf  
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 periods 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: August 8, 2024

/s/ RICK E WINNINGHAM

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

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

I, Aziz Sawaf, 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 periods 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: August 8, 2024

/s/ AZIZ SAWAF

Aziz Sawaf

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

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