

REFINITIV

# DELTA REPORT

## 10-Q

TBPH - THERAVANCE BIOPHARMA, INC

10-Q - MARCH 31, 2024 COMPARED TO 10-Q - SEPTEMBER 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	2711
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 CHANGES	125
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 DELETIONS	820
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 ADDITIONS	1766
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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
**Form 10-Q**

(Mark One)

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

For the quarterly period ended **September 30, 2023** **March 31, 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.)

**PO Box 309 C/O Theravance Biopharma US, Inc.**  
**Ugland House, South Church Street 901 Gateway Boulevard**  
**George Town, Grand Cayman South San Francisco, Cayman**  
**Islands CA**  
(Address of Principal Executive Offices)

**KY1-1104 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 ☐ Smaller Reporting Company ☒  
Accelerated Filer ☐ Emerging Growth Company ☐  
Non-accelerated Filer ☒

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

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

As of November 1, 2023 May 3, 2024, the number of the registrant's outstanding ordinary shares was 49,797,866 48,633,224.

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**PART I. FINANCIAL INFORMATION**  
**ITEM 1. FINANCIAL STATEMENTS**

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

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
<b>Assets</b>				
Current assets:				
Cash and cash equivalents	\$ 71,685	\$ 298,172	\$ 53,835	\$ 39,545
Short-term marketable securities	62,318	29,312	46,140	62,881
Receivables from collaborative arrangements	17,057	16,785	14,664	17,474
Prepaid clinical and development services	1,634	1,513	2,086	2,038
Other prepaid and current assets	8,996	7,682	7,569	11,603
Total current assets	161,690	353,464	124,294	133,541
Property and equipment, net	9,288	11,875	8,717	9,068
Operating lease assets	37,576	40,126	35,364	36,287
Future contingent milestone and royalty assets	194,200	194,200	194,200	194,200
Restricted cash	836	836	836	836
Other assets	10,000	6,899	7,896	8,067
Total assets	\$ 413,590	\$ 607,400	\$ 371,307	\$ 381,999
<b>Liabilities and Shareholders' Equity</b>				
Current liabilities:				
Accounts payable	\$ 2,368	\$ 1,554	\$ 1,686	\$ 1,524

Accrued personnel-related expenses	6,578	10,314	4,475	6,443
Accrued clinical and development expenses	3,272	4,932	1,399	2,246
Accrued general and administrative expenses	1,903	4,020	2,476	2,900
Operating lease liabilities	9,713	6,753	4,063	3,923
Deferred revenue	24	24		
Tenant improvement payable to sublessee			6,490	6,490
Other accrued liabilities	1,510	1,118	1,073	1,241
<b>Total current liabilities</b>	<b>25,368</b>	<b>28,715</b>	<b>21,662</b>	<b>24,767</b>
Long-term operating lease liabilities	41,118	45,407	43,840	45,236
Future royalty payment contingency	27,165	25,438	28,417	27,788
Long-term deferred revenue	175	192		
Unrecognized tax benefits	65,955	64,191	67,075	65,294
Other long-term liabilities	7,679	1,657	5,445	5,919
<b>Commitments and contingencies</b>				
<b>Commitments and contingencies (Note 10)</b>				
<b>Shareholders' Equity</b>				
Preferred shares, \$0.00001 par value: 230 shares authorized, no shares issued or outstanding	—	—		
Ordinary shares, \$0.00001 par value: 200,000 shares authorized; 50,819 and 65,227 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	1	1		
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; 48,566 and 48,091 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively			—	—
Additional paid-in capital	1,146,948	1,295,725	1,125,677	1,122,164
Accumulated other comprehensive loss	(225)	(15)	(41)	(65)
Accumulated deficit	(900,594)	(853,911)	(920,768)	(909,104)
<b>Total shareholders' equity</b>	<b>246,130</b>	<b>441,800</b>	<b>204,868</b>	<b>212,995</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 413,590</b>	<b>\$ 607,400</b>	<b>\$ 371,307</b>	<b>\$ 381,999</b>

See accompanying notes to condensed consolidated financial statements.

(In thousands, except per share data)

	Three Months Ended		Nine Months Ended		Three Months Ended	
	September 30,		September 30,		March 31,	
	2023	2022	2023	2022	2024	2023
<b>Revenue:</b>						
Viartis collaboration agreement	\$ 15,687	\$ 12,445	\$ 39,841	\$ 34,010	\$ 14,503	\$ 10,411
Collaboration revenue	6	6	18	187	—	6
Licensing revenue	—	—	—	2,500		
Total revenue	15,693	12,451	39,859	36,697	14,503	10,417
<b>Expenses:</b>						
Research and development (1)	8,311	9,867	32,308	48,044	8,968	14,572
Selling, general and administrative (1)	16,142	16,277	54,603	50,341	16,742	19,183
Restructuring and related expenses (1)	—	509	2,743	12,838	—	1,574
Total expenses	24,453	26,653	89,654	111,223	25,710	35,329
<b>Loss from operations</b>	(8,760)	(14,202)	(49,795)	(74,526)	(11,207)	(24,912)
Interest expense (2)	(609)	(1,545)	(1,727)	(5,819)		
Loss on extinguishment of debt	—	(3,034)	—	(3,034)		
Interest expense (non-cash)					(629)	(550)
Interest income and other income (expense), net	1,786	2,758	7,269	4,823	1,434	2,979
Loss from continuing operations before income taxes	(7,583)	(16,023)	(44,253)	(78,556)		
Provision for income tax expense	(1,367)	—	(2,430)	(12)		
<b>Net loss from continuing operations</b>	(8,950)	(16,023)	(46,683)	(78,568)		
Loss before income taxes					(10,402)	(22,483)
Provision for income tax expense (benefit)					1,262	(395)
<b>Net loss</b>					<u>\$(11,664)</u>	<u>\$(22,088)</u>
Income from discontinued operations before income taxes	—	1,115,016	—	1,143,930		
Provision for income tax expense	—	(182,362)	—	(182,868)		
<b>Net income from discontinued operations</b>	—	932,654	—	961,062		
Net unrealized gain on available-for-sale investments					24	66
Total comprehensive loss					<u>\$(11,640)</u>	<u>\$(22,022)</u>
<b>Net income (loss)</b>	<u>\$ (8,950)</u>	<u>\$ 916,631</u>	<u>\$ (46,683)</u>	<u>\$ 882,494</u>		
<b>Net loss per share:</b>						
Basic and diluted net loss per share					<u>\$ (0.24)</u>	<u>\$ (0.35)</u>
Net unrealized gain (loss) on available-for-sale investments	61	(76)	(210)	(121)		
Total comprehensive income (loss)	<u>\$ (8,889)</u>	<u>\$ 916,555</u>	<u>\$ (46,893)</u>	<u>\$ 882,373</u>		
<b>Net income (loss) per share:</b>						
Continuing operations - basic and diluted	<u>\$ (0.17)</u>	<u>\$ (0.21)</u>	<u>\$ (0.81)</u>	<u>\$ (1.04)</u>		
Discontinued operations - basic and diluted	<u>\$ —</u>	<u>\$ 12.35</u>	<u>\$ —</u>	<u>\$ 12.70</u>		

Net income (loss) - basic and diluted	\$ (0.17)	\$ 12.14	\$ (0.81)	\$ 11.66		
Shares used to compute basic and diluted net income (loss) per share	52,361	75,515	57,287	75,678		
Shares used to compute basic and diluted net loss per share					48,283	62,934

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

(In thousands)	Three Months Ended		Nine Months Ended		Three Months Ended March 31,	
	September 30,		September 30,		2024	
	2023	2022	2023	2022	2024	2023
Research and development	\$ 2,004	\$ 2,623	\$ 6,301	\$ 10,062	\$1,465	\$2,441
Selling, general and administrative	4,258	5,196	12,890	15,724	3,764	4,223
Restructuring and related expenses	—	711	356	6,998	—	357
Total share-based compensation expense	\$ 6,262	\$ 8,530	\$ 19,547	\$ 32,784	\$5,229	\$7,021

(2) Interest expense for the three and nine months ended September 30, 2023 was comprised of non-cash interest expense only.

See accompanying notes to condensed consolidated financial statements.

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

	Accumulated							Accumulated				
	Ordinary Shares		Additional	Other	Accumulated	Total	Ordinary Shares		Additional	Other	Accumulated	Total
	Shares	Amount	Capital	Gain (Loss)	Deficit	Equity	Shares	Amount	Capital	Gain (Loss)	Deficit	Equity
Balances at												
June 30, 2023	53,694	\$ 1	\$1,172,090	\$ (286)	\$ (891,644)	\$ 280,161						
Balances at												
December 31, 2023							48,091	\$ —	\$1,122,164	\$ (65)	\$ (909,104)	\$ 212

Repurchase of ordinary shares, net of transaction costs	(3,178)	—	(30,891)	—	—	(30,891)	(38)	—	(445)	—	—	
Proceeds from ESPP purchases	—	—	(1)	—	—	(1)						
Employee share-based compensation expense	—	—	6,262	—	—	6,262	—	—	5,229	—	—	5
Issuance of restricted shares	356	—	—	—	—	—	658	—	—	—	—	
Option exercises	—	—	—	—	—	—						
Repurchase of shares to satisfy tax withholding	(53)	—	(512)	—	—	(512)	(145)	—	(1,271)	—	—	(1)
Net unrealized gain on marketable securities	—	—	—	61	—	61	—	—	—	24	—	
Net loss	—	—	—	—	(8,950)	(8,950)	—	—	—	—	(11,664)	(11)
<b>Balances at September 30, 2023</b>	<b>50,819</b>	<b>\$ 1</b>	<b>\$1,146,948</b>	<b>\$ (225)</b>	<b>\$ (900,594)</b>	<b>\$ 246,130</b>						
<b>Balances at March 31, 2024</b>							<b>48,566</b>	<b>\$ —</b>	<b>\$1,125,677</b>	<b>\$ (41)</b>	<b>\$ (920,768)</b>	<b>\$ 204</b>
	<b>Accumulated</b>						<b>Accumulated</b>					
	<b>Ordinary Shares</b>		<b>Additional</b>	<b>Other</b>	<b>Total</b>		<b>Ordinary Shares</b>		<b>Additional</b>	<b>Other</b>	<b>Total</b>	
	<b>Shares</b>	<b>Amount</b>	<b>Paid-In Capital</b>	<b>Comprehensive Loss</b>	<b>Accumulated Deficit</b>	<b>Shareholders' Equity</b>	<b>Shares</b>	<b>Amount</b>	<b>Paid-In Capital</b>	<b>Gain (Loss)</b>	<b>Accumulated Deficit</b>	<b>Shareholders' Equity</b>
<b>Balances at December 31, 2022</b>	<b>65,227</b>	<b>\$ 1</b>	<b>\$1,295,725</b>	<b>\$ (15)</b>	<b>\$ (853,911)</b>	<b>\$ 441,800</b>	<b>65,227</b>	<b>\$ 1</b>	<b>\$1,295,725</b>	<b>\$ (15)</b>	<b>\$ (853,911)</b>	<b>\$ 441</b>
Repurchase of ordinary shares, net of transaction costs	(15,619)	—	(166,787)	—	—	(166,787)	(5,158)	—	(55,353)	—	—	(55)



Proceeds from ESPP purchases	63	—	445	—	—	445					
Employee share-based compensation expense	—	—	19,547	—	—	19,547					
Issuance of restricted shares	1,337	—	—	—	—	—					
Option exercises	—	—	—	—	—	—					
Repurchase of shares to satisfy tax withholding	(189)	—	(1,982)	—	—	(1,982)					
Net unrealized loss on marketable securities	—	—	—	(210)	—	(210)					
Net loss	—	—	—	—	(46,683)	(46,683)					
Balances at September 30, 2023	50,819	\$ 1	\$1,146,948	\$ (225)	\$ (900,594)	\$ 246,130					
	</										

Net unrealized loss on marketable securities	—	—	—	(76)	—	(76)
Net income	—	—	—	—	916,631	916,631
<b>Balances at September 30, 2022</b>	<b>67,366</b>	<b>\$ 1</b>	<b>\$1,324,247</b>	<b>\$ (121)</b>	<b>\$ (843,549)</b>	<b>\$ 480,578</b>
Net unrealized gain on marketable securities	—	—	—	—	66	—
Net loss	—	—	—	—	—	(22,088)
<b>Balances at March 31, 2023</b>	<b>60,542</b>	<b>\$ 1</b>	<b>\$1,246,506</b>	<b>\$ 51</b>	<b>\$ (875,999)</b>	<b>\$ 370</b>

  

	Accumulated					
	Ordinary Shares		Additional Paid-In	Other Comprehensive	Accumulated	Total
	Shares	Amount	Capital	Loss	Deficit	Shareholders' Equity
<b>Balances at December 31, 2021</b>	<b>74,435</b>	<b>\$ 1</b>	<b>\$1,387,469</b>	<b>\$ —</b>	<b>\$ (1,726,043)</b>	<b>\$ (338,573)</b>
Repurchase of ordinary shares	(9,645)	—	(94,037)	—	—	(94,037)
Proceeds from ESPP purchases	72	—	488	—	—	488
Employee share-based compensation expense	—	—	32,784	—	—	32,784
Issuance of restricted shares	2,764	—	—	—	—	—
Repurchase of shares to satisfy tax withholding	(260)	—	(2,457)	—	—	(2,457)
Net unrealized loss on marketable securities	—	—	—	(121)	—	(121)
Net income	—	—	—	—	882,494	882,494

Balances	at										
September	30,										
2022		67,366	\$	1	\$1,324,247	\$	(121)	\$	(843,549)	\$	480,578

See accompanying notes to condensed consolidated financial statements.

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

	Nine Months Ended September 30,		Three Months Ended March 31,	
	2023	2022	2024	2023
<b>Operating activities</b>				
Net (loss) income	\$ (46,683)	\$ 882,494		
Less: Net income from discontinued operations	—	(961,062)		
Net loss from continuing operations	(46,683)	(78,568)		
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:				
Net loss			\$ (11,664)	\$ (22,088)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:				
Depreciation and amortization	1,609	3,057	432	625
Amortization and accretion income, net	(1,494)	(342)	(354)	(678)
Future royalty payment contingency interest accretion	1,727	424	629	550
Share-based compensation	19,547	32,784	5,229	7,021
Gain on sale of Velusetrag	—	(2,709)		
(Gain) loss on disposal of property and equipment	1,353	(96)	—	29
Amortization of right-of-use assets	2,724	2,284	1,101	1,031
Loss on extinguishment of debt	—	3,034		
Deferred income taxes			(513)	—
Changes in operating assets and liabilities:				
Receivables from collaborative and licensing arrangements	(272)	(49)	2,810	4,515
Prepaid clinical and development services	(121)	7,600	(48)	(13)
Other prepaid and current assets	(1,315)	(1,148)	4,034	1,401
Right-of-use lease assets	(173)	(2,587)	(178)	(109)
Other assets	3,309	(1,743)	148	1,270
Accounts payable	354	2,150	184	1,002
Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued liabilities	(6,657)	(18,465)	(3,396)	(4,337)

Accrued interest payable	—	(1,246)		
Deferred revenue	(17)	(186)	—	(6)
Operating lease liabilities	(1,329)	(1,111)	(1,256)	(966)
Unrecognized tax benefits			1,781	—
Other long-term liabilities	1,295	(421)	39	(468)
Net cash used in operating activities - continuing operations	(26,143)	(57,338)		
Net cash used in operating activities - discontinued operations	—	(5,598)		
Net cash used in operating activities	(26,143)	(62,936)	(1,022)	(11,221)
<b>Investing activities</b>				
Purchases of property and equipment	(1,811)	(306)	(91)	(938)
Purchases of marketable securities	(134,534)	(93,260)	(26,902)	(134,533)
Maturities of marketable securities	31,435	108,700	44,021	29,500
Sale of short-term investments and marketable securities	71,377	5	—	62,715
Proceeds from the sale of Velusetrag	—	2,709		
Proceeds from the sale of property and equipment	1,513	1,866	—	210
Net cash (used in) provided by investing activities - continuing operations	(32,020)	19,714		
Net cash provided by investing activities - discontinued operations	—	1,095,134		
Net cash (used in) provided by investing activities	(32,020)	1,114,848		
Net cash provided by (used in) investing activities			17,028	(43,046)
<b>Financing activities</b>				
Ordinary share repurchases	(166,787)	(94,037)	(445)	(55,353)
Proceeds from amprelosetine funding, net	—	24,464		
Principal payment on 2035 notes	—	(399,998)		
Principal payment on 2023 notes	—	(231,605)		
Proceeds from ESPP purchases	445	488		
Repurchase of shares to satisfy tax withholding	(1,982)	(2,457)	(1,271)	(887)
Net cash used in financing activities - continuing operations	(168,324)	(703,145)		
Net cash used in financing activities - discontinued operations	—	(20,189)		
Net cash used in financing activities	(168,324)	(723,334)	(1,716)	(56,240)
Net (decrease) increase in cash, cash equivalents, and restricted cash	(226,487)	328,578		
Net increase (decrease) in cash, cash equivalents, and restricted cash			14,290	(110,507)
Cash, cash equivalents, and restricted cash at beginning of period	299,008	90,796	40,381	299,008
Cash, cash equivalents, and restricted cash at end of period	\$ 72,521	\$ 419,374	\$ 54,671	\$ 188,501
<b>Supplemental disclosure of cash flow information</b>				
Cash paid for interest	\$ —	\$ 22,244		
Cash paid for income taxes, net	\$ 14	\$ 26		
Cash paid (received) for income taxes, net			\$ (9)	\$ 7
<b>Supplemental disclosure of non-cash investing and financing activities</b>				
<b>Supplemental disclosure of non-cash activities</b>				
Recognition of tenant improvement allowance assigned to sublease	\$ 6,490	\$ —	\$ —	\$ 6,490

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

**1. Organization and Summary of Significant Accounting Policies**

Theravance Biopharma, Inc. ("Theravance Biopharma" 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®* in people's lives.

***Basis of Presentation***

The Company's condensed consolidated financial information statements as of September 30, 2023 March 31, 2024 and for the three and nine months ended September 30, 2023 March 31, 2024 and 2022 2023 is unaudited but includes all adjustments (consisting only of normal recurring adjustments), which are considered necessary for a fair presentation of the financial position at such date and of the operating results and cash flows for those periods, and have been prepared in accordance with United States ("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, 2022 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, 2022 December 31, 2023, filed with the Securities and Exchange Commission ("SEC") on March 1, 2023 March 1, 2024.

The results for the three and nine months ended September 30, 2023 March 31, 2024 are not necessarily indicative of the results to be expected for the year ending December 31, 2023 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.

On July 20, 2022, the Company completed a monetization of its ownership interests in a significant equity method investment which had a major effect on the Company's financial results for the year ended December 31, 2022 (see "Note 7. Discontinued Operations"). In accordance with GAAP, the transaction was accounted for as a sale of a financial asset. For all periods presented, the results of the sale have been included as discontinued operations on these condensed consolidated financial statements. Certain prior year comparable operating expenses within the condensed consolidated statements of operations and comprehensive income (loss) have been reclassified as restructuring and related expenses. The reclassification had no effect on reported losses, total assets, or shareholders' equity.

***Use of Estimates***

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

The Company expects its cash, cash equivalents and marketable securities will be sufficient to fund **its capital return program and** 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, 2022** December 31, 2023.

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### ***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 **condensed** consolidated financial statements and related disclosures.

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

Basic net income (loss) loss per share is computed by dividing the net income (loss) attributable to ordinary shareholders loss by the weighted-average number of ordinary shares outstanding for during the period, excluding shares subject to repurchase and without consideration of potentially dilutive securities. period. Diluted net income (loss) loss per share is computed by giving effect to all potentially dilutive ordinary increasing the weighted-average number of shares outstanding for the period, which primarily consist dilutive effect of instruments potential ordinary shares determined using the treasury stock method. Potential ordinary shares include outstanding share options, ordinary shares expected to be issued and outstanding under the Company's equity incentive and employee share purchase plans. Ordinary plan ("ESPP"), restricted share equivalents units ("RSUs"), and performance-contingent RSUs for which the performance or market vesting conditions have been deemed probable. Performance-contingent RSUs with performance or market vesting conditions that have been deemed not probable as of the end of the period are excluded from not included in the computation in periods in which they have an anti-dilutive effect unless the consideration of any one of them gives a dilutive effect. diluted net loss per share computation.

(In thousands, except per share data)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2023	2022	2023	2022
<b>Numerator:</b>				
Net loss from continuing operations	\$ (8,950)	\$ (16,023)	\$ (46,683)	\$ (78,568)
Net income from discontinued operations	—	932,654	—	961,062
Net income (loss)	<u>\$ (8,950)</u>	<u>\$ 916,631</u>	<u>(46,683)</u>	<u>882,494</u>
<b>Denominator:</b>				
Weighted-average ordinary shares outstanding	52,361	75,515	57,287	75,678
Less: weighted-average ordinary shares subject to forfeiture	—	—	—	—
Weighted-average ordinary shares outstanding - basic and diluted	<u>52,361</u>	<u>75,515</u>	<u>57,287</u>	<u>75,678</u>
<b>Net income (loss) per share:</b>				
Continuing operations - basic and diluted	<u>\$ (0.17)</u>	<u>\$ (0.21)</u>	<u>\$ (0.81)</u>	<u>\$ (1.04)</u>
Discontinued operations - basic and diluted	<u>\$ —</u>	<u>\$ 12.35</u>	<u>\$ —</u>	<u>\$ 12.70</u>
Net income (loss) per share - basic and diluted	<u>\$ (0.17)</u>	<u>\$ 12.14</u>	<u>\$ (0.81)</u>	<u>\$ 11.66</u>

### Anti-dilutive Securities

(In thousands, except per share data)	Three Months Ended March 31,	
	2024	2023
<b>Numerator:</b>		
Net loss	\$ (11,664)	\$ (22,088)
<b>Denominator:</b>		
Weighted-average ordinary shares outstanding	48,283	62,934
Less: weighted-average ordinary shares subject to forfeiture	—	—
Weighted-average ordinary shares outstanding - basic and diluted	<u>48,283</u>	<u>62,934</u>
Net loss per share - basic and diluted	<u>\$ (0.24)</u>	<u>\$ (0.35)</u>

In accordance with Accounting Standards Codification ("ASC") 260, *Earnings Per Share*, if a company incurred a net loss, related to its continuing operations, then potential ordinary shares are considered anti-dilutive for the periods in which the net loss was recognized. For the three and nine months ended September 30, 2023 and 2022, the Company recognized

losses from continuing operations. As a result, the following potential ordinary equivalent shares were not included in the computation of diluted net loss per share for both continuing operations and discontinuing operations: because including them would have had an anti-dilutive effect:

(In thousands)	Three Months Ended		Nine Months Ended		Three Months Ended March 31,	
	September 30,		September 30,			
	2023	2022	2023	2022	2024	2023
Share issuances under equity incentive plans and employee share purchase plan	3,459	5,036	3,972	7,137		
Options					2,304	2,467
Restricted share units and performance-contingent RSUs deemed probable					848	1,775
Employee share purchase plan					109	47
Total					3,261	4,289

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### 3. Revenue

#### Revenue from Collaborative Arrangements

##### Viatis

In January 2015, the Company and Viatis Inc. ("Viatis") established a strategic collaboration (the "Viatis 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 beyond the acute care setting. 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, Viatis is leading the commercialization of YUPELRI, and the Company co-promotes the product under a profit and loss sharing arrangement (65% to Viatis; 35% to the Company). Outside the US (excluding China and adjacent territories), Viatis 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. Viatis 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. Viatis is responsible for all aspects of development and commercialization in the China and adjacent territories, including pre- and post-launch activities and



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

As of **September 30, 2023** **March 31, 2024**, the Company is eligible to receive from Viatris potential global development, regulatory and sales milestone payments (excluding China and adjacent territories) **totaling** up to \$205.0 million in the aggregate, with \$160.0 million associated with YUPELRI monotherapy and \$45.0 million associated with future potential combination products. Of the \$160.0 million associated with monotherapy, \$150.0 million relates to sales milestones based on achieving certain levels of 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 **totaling 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. 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

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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. Any reimbursement from Viatris attributed to the 65% cost-sharing of the Company's R&D expenses is characterized as a reduction of R&D expense, as the Company does not consider performing research and development services for reimbursement to be a part of its ordinary activities. For the three and nine months ended **September 30, 2023** **March 31, 2024**, YUPELRI continued to be profitable for the Company.

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

(In thousands)	Three Months Ended		Nine Months Ended		Three Months Ended	
	September 30,		September 30,		March 31,	
	2023	2022	2023	2022	2024	2023
Viatris collaboration agreement - Amounts receivable from Viatris	\$ 15,687	\$ 12,445	\$ 39,841	\$ 34,010		
Viatris collaboration agreement – Amounts receivable from Viatris					\$14,503	\$10,411

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While Viatris records total YUPELRI net sales within its own **condensed** 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 expenses, as presented below:

(In thousands)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2023	2022	2023	2022
YUPELRI net sales (Theravance Biopharma implied 35%)	\$ 20,414	\$ 18,698	\$ 56,111	\$ 51,158

#### **Other Collaborative Arrangement Revenues**

The Company's other collaborative arrangement revenues consisted of:

(In thousands)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2023	2022	2023	2022
Viatis	\$ 6	\$ 6	\$ 18	\$ 18
Alfasigma	—	—	—	169

Total collaboration revenue	\$ 6	\$ 6	\$ 18	\$ 187
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All of the recognized revenues from the Company's other collaborative arrangements presented in the table above were included in deferred revenue at the beginning of the respective periods.

(In thousands)	Three Months Ended March 31,	
	2024	2023
YUPELRI net sales (Theravance Biopharma implied 35%)	\$ 19,329	\$ 16,434

#### Reimbursement of R&D Expenses

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

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

(In thousands)	Three Months Ended		Nine Months Ended		Three Months Ended March 31,	
	September 30,		September 30,		2024	
	2023	2022	2023	2022	2024	2023
Viatis	\$ 1,340	\$ 1,657	\$ 5,041	\$ 4,736	\$189	\$1,753

#### Revenue from Licensing Arrangements

##### Pfizer

In December 2019, the Company entered into a global license agreement with Pfizer Inc. ("Pfizer") for its preclinical skin-selective, locally-acting pan-JAK inhibitor program (the "Pfizer Agreement"). The compounds in this program are designed to target validated pro-inflammatory pathways and are specifically designed to possess skin-selective activity with minimal systemic exposure. Under the Pfizer Agreement, Pfizer had an exclusive license to develop, manufacture and commercialize certain compounds for all uses other than gastrointestinal, ophthalmic, and respiratory applications. The Company received an upfront cash payment of \$10.0 million in 2019, and for the nine months ended September 30, 2022, the Company recognized \$2.5 million in licensing revenue related to a development milestone payment from Pfizer for the dosing of the first patient in the Phase 1 clinical trial. In June 2023, the Company received notice from Pfizer terminating the Pfizer Agreement, effective as of October 7, 2023, at which time the skin-selective pan-JAK inhibitor program was returned to the Company.

#### 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)	September 30,		March 31,	
	2023	2022	2024	2023
Cash and cash equivalents	\$ 71,685	\$ 418,538	\$53,835	\$187,665
Restricted cash	836	836	836	836
Total cash, cash equivalents, and restricted cash shown on the condensed consolidated statements of cash flows	\$ 72,521	\$ 419,374	\$54,671	\$188,501

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 if any, 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 capital return open market share repurchase program that commenced in December 2022 and was initiated completed in September 2022 January 2024 (see "Note 10. Strategic Actions 7. Completion of Capital Return Program" for further more information).

The Company periodically engages in foreign exchange transactions as a part of its operations. For the three and nine months ended September 30, 2023, the Company's net realized and unrealized foreign currency gains were not material, and for the three and nine months ended September 30, 2022, the The Company recognized net realized and unrealized foreign currency losses gains (losses) of \$0.4 million (\$0.1) million and \$1.5 million, \$0.1 million for the three months ended March 31, 2024 and 2023, respectively. These amounts are included in the Company's condensed consolidated statements of operations within "Interest income and other income (expense), net".

## 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.

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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:

		March 31, 2024			
		Amortized	Gross	Gross	Estimated
		Cost	Unrealized Gains	Unrealized Losses	Fair Value
(In thousands)					
US government securities	Level 1	\$ 22,231	\$ —	\$ (3)	\$ 22,228
US government agency securities	Level 2	2,969	—	(3)	2,966
Corporate notes	Level 2	11,211	—	(16)	11,195
Commercial paper	Level 2	24,698	—	(19)	24,679
Marketable securities		61,109	—	(41)	61,068
Money market funds	Level 1	14,271	—	—	14,271
Total		\$ 75,380	\$ —	\$ (41)	\$ 75,339

		December 31, 2023			
		Amortized	Gross	Gross	Estimated
		Cost	Unrealized Gains	Unrealized Losses	Fair Value
(In thousands)					
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		\$ 89,125	\$ 4	\$ (69)	\$ 89,060

As of March 31, 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 months ended March 31, 2024.

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

		March 31, 2024					
		Less than 12 Months		Greater than 12 Months		Total	
		Gross		Gross		Gross	
		Estimated	Unrealized	Estimated	Unrealized	Estimated	Unrealized
		Fair Value	Losses	Fair Value	Losses	Fair Value	Losses
(In thousands)							
US government securities		\$ 10,431	\$ (3)	\$ —	\$ —	\$ 10,431	\$ (3)
US government agency securities		2,965	(3)	—	—	2,965	(3)
Corporate notes		11,195	(16)	—	—	11,195	(16)
Commercial paper		24,680	(19)	—	—	24,680	(19)
Total		\$ 49,271	\$ (41)	\$ —	\$ —	\$ 49,271	\$ (41)

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Available-for-sale securities are summarized below:

		September 30, 2023			
		Gross		Gross	
		Amortized	Unrealized	Unrealized	Estimated
(In thousands)		Cost	Gains	Losses	Fair Value
US government securities	Level 1	\$ 29,604	\$ —	\$ (94)	\$ 29,510
US government agency securities	Level 2	4,385	—	(22)	4,363
Corporate notes	Level 2	28,554	—	(109)	28,445
Marketable securities		62,543	—	(225)	62,318
Money market funds	Level 1	58,575	—	—	58,575
Total		\$ 121,118	\$ —	\$ (225)	\$ 120,893

		December 31, 2022			
		Gross		Gross	
		Amortized	Unrealized	Unrealized	Estimated
(In thousands)		Cost	Gains	Losses	Fair Value
US government securities	Level 1	\$ 24,873	\$ 8	\$ —	\$ 24,881
US government agency securities	Level 2	20,869	4	—	20,873
Commercial paper	Level 2	37,307	—	(27)	37,280
Marketable securities		83,049	12	(27)	83,034
Money market funds	Level 1	220,508	—	—	220,508
Total		\$ 303,557	\$ 12	\$ (27)	\$ 303,542

As of September 30, 2023, all of the Company's available-for-sale securities had contractual maturities within nine months, and the weighted-average maturity of marketable securities was approximately three 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 nine months ended September 30, 2023.

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

		September 30, 2023					
		Less than 12 Months		Greater than 12 Months		Total	
		Gross		Gross		Gross	
		Estimated	Unrealized	Estimated	Unrealized	Estimated	Unrealized
(In thousands)		Fair Value	Losses	Fair Value	Losses	Fair Value	Losses
US government securities		\$ 29,510	\$ (94)	\$ —	\$ —	\$ 29,510	\$ (94)
US government agency securities		4,363	(22)	—	—	4,363	(22)
Corporate notes		28,445	(109)	—	—	28,445	(109)

Total	\$ 62,318	\$ (225)	\$ —	\$ —	\$ 62,318	\$ (225)
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(In thousands)	December 31, 2022						December 31, 2023					
	Less than 12 Months		Greater than 12 Months		Total		Less than 12 Months		Greater than 12 Months		Total	
	Gross		Gross		Gross		Gross		Gross		Gross	
	Estimated	Unrealized	Estimated	Unrealized	Estimated	Unrealized	Estimated	Unrealized	Estimated	Unrealized	Estimated	Unrealized
	Fair Value	Losses	Fair Value	Losses	Fair Value	Losses	Fair Value	Losses	Fair Value	Losses	Fair Value	Losses
Commercial paper	\$ 37,280	\$ (27)	\$ —	\$ —	\$ 37,280	\$ (27)						
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	\$37,280	\$ (27)	\$ —	\$ —	\$37,280	\$ (27)	\$57,880	\$ (69)	\$ —	\$ —	\$57,880	\$ (69)

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 September 30, 2023 March 31, 2024, and there were no individual securities that were in a significant unrealized loss position as of March 31, 2024.

As of September 30, 2023 For the three months ended March 31, 2024, the Company's accumulated other comprehensive loss on its condensed consolidated balance sheets consisted of net unrealized losses on available-for-sale investments. Company did not sell any marketable securities. For the nine three months

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ended September 30, 2023 March 31, 2023, the Company sold marketable securities for total proceeds of \$71.4 million. The sales were \$62.9 million and recognized a net realized gain from the sale of \$0.2 million based on the specific identification method, and the realized net gain from the sale was immaterial. For the three months ended September 30, 2023, and for the three and nine months ended September 30, 2022, the Company did not sell any marketable securities.

## 6. Subleasesmethod.

In July 2021 and June 2022, the Company entered into two non-cancelable agreements under which it subleased a total of approximately 99,000 square feet of its South San Francisco office and laboratory space to two unaffiliated companies. The Company recognizes the sublease income on a straight-line basis over the term of its two subleases which is reflected as a reduction of R&D expense and selling, general and administrative expenses in the condensed consolidated statements of operations. **Contingent Consideration Asset**

The Company's sublease income is summarized below:

(In thousands)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2023	2022	2023	2022
Sublease income	\$ 2,090	\$ 2,090	\$ 6,270	\$ 3,330

During the first quarter of 2023, the Company also recognized increases to other assets and other long-term liabilities of approximately \$6.5 million for lessor tenant improvement allowances that have been assigned recognizes a contingent consideration asset related to its sublessees and are recognized over the term of the related sublease agreements.

## 7. Discontinued Operations

### Background

In July 2022, the Company completed the sale of all of its equity interests in Theravance Respiratory Company, LLC ("TRC") representing its 85% economic interest in the sales-based royalty rights on worldwide net sales of Assigned Collaboration Products, primarily comprised of GSK's TRELEGY ELLIPTA ("TRELEGY") to Royalty Pharma Investments 2019 ICAV, an Irish collective asset-management vehicle ("Royalty Pharma"), pursuant to in July 2022. The contingent consideration asset represents the Equity Purchase fair value of potential future milestone payments and Funding Agreement, dated as of July 13, 2022 (including the schedules and exhibits thereto, the "Purchase Agreement"), by and between the Company and Royalty Pharma royalties (collectively, with the other transactions contemplated by the Purchase Agreement, the "TRC Transaction" "Contingent Consideration").

At the closing of the TRC Transaction, the Company received approximately \$1.1 billion in cash. From and after January 1, 2023, for any calendar year starting with the year ending December 31, 2023 and ending with the year December 31, 2026, upon certain milestone minimum royalty amounts for Assigned Collaboration Products being met, Royalty Pharma is obligated to make certain cash payments to the Company (the "Milestone Payments"), which are not to exceed \$250.0 million in aggregate. Additionally, the Company will receive from Royalty Pharma 85% of the royalty payments on the Assigned Collaboration Products 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 worldwide net sales or other activities occurring on and after July 1, 2029 related to the Assigned Collaboration Products outside of the US (collectively with the Milestone Payments, the "Contingent Consideration" GSK plc's ("GSK") TRELEGY® ELLIPTA ("TRELEGY")).

The Contingent Consideration was initially measured at fair valued at \$194.2 million 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 revenues 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 September 30, 2023 March 31, 2024, there have been no

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[Table the Contingent Consideration had a carrying value of Contents](#)

indicators of impairment identified, \$194.2 million and is presented on the condensed consolidated balance sheets as a result, there future contingent milestone and royalty assets. There have been no changes to the carrying value of the Contingent Consideration since its initial fair value 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 Contingent Consideration Company recognizes a contingent liability related to funding received from Royalty Pharma in exchange for certain future royalty rights to ampreloxetine. 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 presented 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.

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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 March 31, 2024.

There are a number of factors that could materially affect the amount and timing of the contingent \$15.0 million milestone and royalty assets 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 ampreloxetine. 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 three months ended March 31, 2024:

(In thousands)	
Balance at December 31, 2023	\$ 27,788
Non-cash interest expense accretion	629
Balance at March 31, 2024	<u>\$ 28,417</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 \$0.9million 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 March 31, 2024, the Company has subleased approximately 107,000 square feet of a total 162,000 square feet of 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:

(In thousands)	Three Months Ended March	
	31,	
	2024	2023
Sublease income	\$ 2,090	\$ 2,090

As of March 31, 2024, the Company has approximately 31,000 square feet of remaining vacant office and laboratory space in South San Francisco on the market for sublease. The Company evaluates the carrying value of its long-lived asset groups, which includes right-of-use assets, for impairment when indicators exist that the carrying amounts of the 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 TRC Transaction represented a monetization of a significant equity method investment that had a major effect on the Company's financial results. In accordance with ASC 860, *Transfers and Servicing of Financial Assets*, the TRC Transaction was accounted for as a sale of a financial asset. For all periods presented, the balances and the results related to TRC have been classified as discontinued operations on the Company's condensed consolidated financial statements.

The results of discontinued operations consisted of the following:

	Three Months Ended	Nine Months Ended
--	--------------------	-------------------

(In thousands)	September 30,		September 30,	
	2023	2022	2023	2022
Income from investments in TRC, LLC	\$ —	\$ —	\$ —	\$ 53,237
Transaction-related legal expenses (prior to July 20, 2022)	—	—	—	(5,057)
Interest expense on 9.5% Non-recourse notes due 2035	—	(2,046)	—	(21,312)
Loss on extinguishment of debt	—	(24,022)	—	(24,022)
Net gain from sale of equity interests in TRC, LLC	—	1,141,084	—	1,141,084
Provision for income tax expense	—	(182,362)	—	(182,868)
Net income from discontinued operations	\$ —	\$ 932,654	\$ —	\$ 961,062

### TRC Summary Financial Information

Prior to the TRC Transaction, the Company analyzed its ownership, contractual and other interests in TRC to determine if it was a variable-interest entity ("VIE"), whether the Company had a variable interest in TRC and the nature and extent of that interest. The Company determined that TRC's vacant office and laboratory space currently marketed for sublease was a VIE. The party with the controlling financial interest, the primary beneficiary, is required to consolidate the entity determined to be a VIE. Therefore, the Company also assessed whether it was the primary beneficiary an indicator of TRC based on the power to direct TRC's activities that most significantly impact TRC's economic performance and its obligation to absorb TRC's losses or the right to receive benefits from TRC that could potentially be significant to TRC. impairment. Based on the Company's impairment assessment as of March 31, 2024, the Company determined that it was not the primary beneficiary estimated undiscounted future cash flows of TRC, its identified asset groups exceeded the carrying value of such asset groups, and as a result, the Company did not consolidate TRC in its condensed consolidated financial statements. The Company's maximum exposure to loss, as a result of its involvement with TRC, were recognize an impairment charge for the amounts recorded in the condensed consolidated balance sheets within "Equity in net assets of TRC, LLC". TRC was recognized in the Company's condensed consolidated financial statements under the equity method of accounting.

Rule 4-08(g) of Regulation S-X requires that a company include summary financial information for equity method investees when such investees are individually significant for a company. For the prior year comparable period, the income from the Company's investment in TRC was determined to be significant. As a result, TRC's summary financial information, including the portion of equity interest that the Company did not own, was as follows:

(In thousands)	Three Months Ended	Nine Months Ended
	September 30, 2022	September 30, 2022
Royalty revenue and gross profit	\$ —	\$ 72,029
Income from continuing operations	—	71,693
Net income	—	62,632

three months ended

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March 31, 2024. The Company will continue to update its long-lived asset impairment assessment each quarterly period, and the Company may record a non-cash impairment charge in future periods as its estimates change.

## 8. Share-Based Compensation 7. Completion of Capital Return Program

**Market** In January 2024, the Company repurchased an additional 38,462 of its 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 **Performance-Contingent Awards** 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 shares at a weighted average price of \$10.3544 per share for an approximate aggregate cost of \$325.3 million, excluding fees and expenses.

The Company periodically grants market-based performance-contingent share awards to employees. For the three months ended September 30, 2023, no such market-based restricted share units ("RSUs") were granted. **8. Restructuring and for the nine months ended September 30, 2023, Related Expenses**

In February 2023, the Company granted 165,000 announced strategic actions (the "2023 Strategic Actions") that included the discontinuation of such RSUs. The 165,000 RSUs had its research activities, resulting in a fair value 17% reduction in headcount in March 2023. As a result of \$1.4 million that vest upon the Company's ordinary shares meeting certain market-based price targets followed by a service period. The fair value of these market-based RSUs is being recognized through February 2027. For the three and nine months ended September 30, 2023, discontinued investment in research activities, the Company recognized \$0.2 million incurred restructuring and \$0.5 million related expenses of \$1.6 million primarily related to R&D expenses. Of the total \$1.6 million, respectively, of share-based compensation expense cash-related expenses were \$1.2 million and non-cash expenses were \$0.4 million which were primarily related to the awards.

For modification of equity-based awards for employees affected by the three months ended September 30, 2023, the Company did not grant any performance-contingent RSUs, and for the nine months ended September 30, 2023, the Company granted 367,000 of such RSUs. The 367,000 RSUs had a fair value of \$3.7 million with performance vesting dates through February 2026. In September 2023, the Company concluded that 52,500 of the RSUs were probable of achievement, and as a result, the Company recognized \$0.3 million of cumulative catch-up share-based compensation expense for the three and nine months ended September 30, 2023.

## Amendment and Restatement of 2013 Equity Incentive Plan

At the Company's Annual General Meeting of Shareholders on May 2, 2023, the Company's shareholders approved an amendment and restatement of the Company's 2013 Equity Incentive Plan (the "2013 EIP") to effect the following material changes to the existing plan (i) extend the term of the 2013 EIP by an additional ten years; (ii) eliminate the provision that provided for automatic annual increases reduction in the number of shares available for issuance under the 2013 EIP; (iii) reduce the number of shares reserved for issuance by 3,808,287 shares; (iv) eliminate the Company's ability to reprice options and share appreciation rights without first obtaining shareholder approval; and (v) remove certain provisions no longer necessary since the repeal of the exemption from the annual deduction limitation imposed by Section 162(m) of the Internal Revenue Code for performance-based compensation. headcount.

## 9. Income Taxes

For the three and nine months ended September 30, 2023 March 31, 2024, the Company recognized an income tax expense of \$1.4 million and \$2.4 million, respectively. \$1.3 million. Although the Company incurred net operating losses on a consolidated basis, the income tax expense for the nine three months ended September 30, 2023 March 31, 2024 was primarily due to interest expense on uncertain tax positions taken with respect to transfer pricing in 2023.

The Company's provision for income taxes during interim reporting periods has historically been calculated by applying an estimate of the annual effective tax rate for the full fiscal year to ordinary income (loss) (pre-tax income (loss) excluding unusual or infrequently occurring discrete items) for the reporting period. For the nine months ended September 30, 2023, and in accordance with paragraph 82 of FASB interpretation No. 18, "Accounting for Income Taxes in Interim Periods" ("FIN 18"), the Company computed its provision for income taxes based on the actual effective tax rate for the year-to-date period by applying the discrete method. As small changes in estimated ordinary income may result in a significant change in the estimated annual effective tax rate, the Company determined that the historical method would not provide a reliable estimate for the nine months ended September 30, 2023, previous years.

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 federal purposes stemming from the effects of the TRC Transaction. As of September 30, 2023 March 31, 2024, the Company does not believe that a valuation allowance should be re-established to offset it against its deferred tax assets is needed for US federal

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tax purposes, purposes as it is more like than not able to fully utilize such attributes. As of September 30, 2023 March 31, 2024, the Company continues to maintain a full valuation allowance on its California, in other states, and foreign deferred tax assets. jurisdictions, predominantly in Ireland.

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

The Company's future income tax expense may be affected by such factors as changes in tax laws, regulations, 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 and other transactions, 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. Strategic Actions Commitments and Contingencies

**Legal Proceedings** In February 2023, the Company announced and has since largely completed the following strategic actions (the “2023 Strategic Actions”):

#### **Capital Return Program Increase**

The Company's board in the ordinary course of directors authorized a \$75.0 million increase to the existing \$250.0 million capital return program initiated in September 2022, bringing the total capital return program to \$325.0 million. For the three and nine months ended September 30, 2023, business, the Company repurchased 3.18 million shares may be subject to legal claims and 15.62 million shares, respectively, 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 open market at a weighted average cost possible outcomes of \$9.70 per share various litigation, regulatory, and \$10.65 per share, respectively. For the three and nine months ended September 30, 2023, the total aggregate cost of the repurchases, excluding fees and expenses, was \$30.8 million and \$166.4 million, respectively. Since the initiation of the capital return program in September 2022, settlement strategies. If the Company has repurchased \$294.6 million of shares, as of September 30, 2023, determines that a material loss is probable and the Company had approximately \$30.4 million remaining in the capital return program which is expected to its amount can be completed by the end of 2023. In October 2023, the Company repurchased reasonably estimated, it will accrue an additional 1.02 million shares on the open market at a weighted average cost of \$9.09 per share for a total aggregate cost of \$9.3 million, excluding fees and expenses. The Company had approximately \$21.1 million remaining in the capital return program, as of October 31, 2023.

#### **Discontinued Investment in Research Activities**

The Company discontinued its research activities, including the inhaled Janus kinase (JAK) inhibitor program, resulting in a 17% reduction in headcount in March 2023. The Company plans to seek a partnership to continue progression of its inhaled JAK inhibitor program. In order to support the timely progression of the ampreloxetine Phase 3 study (CYPRESS) and the completion of the YUPELRI Peak Inspiratory Flow Rate (PIFR-2) Phase 4 study, the Company has prioritized its R&D resource allocation to these two programs.

As a result of the Company's discontinued investment in research activities, the Company incurred restructuring and related expenses of \$2.7 million for the nine months ended September 30, 2023, primarily related to R&D expenses. Of the total \$2.7 million incurred for the nine months ended September 30, 2023, cash-related expenses were \$1.2 million and non-cash expenses were \$1.5 million which were primarily related to the loss on the sale of R&D laboratory equipment and the modification of equity-based awards for employees affected by the reduction in headcount. The R&D laboratory equipment sold had a carrying value of \$2.7 million, and the sale generated net cash proceeds of \$1.5 million. There were no restructuring and related expenses recognized for the three months ended September 30, 2023, and the Company does not expect to recognize any additional employee-related expenses, including share-based compensation, related to the 2023 Strategic Actions.

As a result of the broader corporate restructuring announcement in September 2021 (the “2021 Restructuring”) for the three and nine months ended September 30, 2022, the Company incurred restructuring and related expenses of

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\$0.5 million and \$12.8 million, respectively. Of the \$0.5 million incurred for the three months ended September 30, 2022, \$0.1 million was related to R&D expenses and \$0.4 million was related to selling, general and administrative expenses. Of the \$12.8

million incurred for the nine months ended September 30, 2022, \$5.9 million was related to R&D expenses and \$6.9 million was related to selling, general and administrative expenses. Of the total \$12.8 million incurred for the nine months ended September 30, 2022, cash-related expenses were \$5.8 million and non-cash expenses were \$7.0 million which were primarily related amount equal to the modification estimated loss. As of equity-based awards for employees affected by the 2021 Restructuring and certain related awards for other employees.

Selected information relating to accrued cash-related restructuring expenses from the recently announced 2023 Strategic Actions was as follows:

(In thousands)

Balance at December 31, 2022	\$	—
Net accruals		1,188
Cash paid		(1,188)
Balance at September 30, 2023	\$	—

All of the restructuring expenses from the 2021 Restructuring were fully recognized and paid in 2022.

The Company also evaluated the impact of the 2023 Strategic Actions on the carrying value of its long-lived assets, such as property and equipment and operating lease assets. This process included evaluating the estimated remaining lives, significant changes in the use, and potential impairment charges related to its long-lived assets.

In March 2023, the Company placed approximately 42,000 square feet of its vacant office and laboratory space in South San Francisco ("Sublease Assets") on the market for sublease. The Company's impairment evaluation process for the Sublease Assets consisted of comparing the estimated undiscounted future sublease income of the Sublease Assets to its carrying value. The Company estimated the sublease income using market participant assumptions, including the length of time to enter into a sublease and sublease payments, which the Company evaluated using recent sublease negotiations and current local subleasing trends. While the Company has not yet completed a new sublease, based on its evaluation, the Company determined that the estimated undiscounted future sublease income exceeds the Sublease Assets' carrying value, and as a result, March 31, 2024, the Company did not recognize an impairment charge as of September 30, 2023. The Company will continue accrue any estimated losses related to update its sublease cash flow estimates based on changes in market conditions, and the Company may record a non-cash impairment charge in future periods as these estimates change.

## 11. Commitments and Contingencies ongoing legal proceedings.

### Legal Proceedings Litigation – Patent Infringement

In 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 courts, 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. An additional patent Additional patents covering YUPELRI

granted on July 4, 2023 **was** and January 2, 2024 **were** subsequently listed in FDA's Orange Book. The Company filed **an** additional patent infringement **suit** against all of the above generic

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**companies** **suits** in the U.S. District Court for the District of New Jersey during August **2023**. This suit has **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.**

**On October 27, 2023** As of May 14, 2024, **subsidiaries of** the Company **has settled all litigation with Accord Healthcare, Inc.; Lupin Pharmaceuticals, Inc.; Orbicular Pharmaceutical Technologies Private Limited; and Mylan Ireland Limited and Mylan Specialty L.P. (together, "Viatis entities"), entered into a Settlement Agreement ("Settlement Agreement") with Teva Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc. (together, "Teva"). The Settlement Agreement resolves ongoing patent litigation described above with respect** pursuant to these parties. Under the Settlement Agreement, **individual agreements in which** the Company **and Viatis entities** granted **Teva these companies** a royalty-free, non-exclusive, non-sublicensable, non-transferable license to manufacture and market **Teva's their respective** generic **version versions** of YUPELRI® (revefenacin) inhalation solution in the **United States US** on or after the licensed launch date of April 23, 2039, subject to certain exceptions as is customary in these **types type** of agreements. As required by law, the **settlement is settlements are** subject to review by the U.S. Department of Justice and the Federal Trade Commission. The patent litigation against the **other three remaining** generic companies, along with certain affiliates, remains pending.

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

### Forward-Looking Statements

*You should read the following discussion in conjunction with our condensed 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, 2022** **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*® 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® (revefenacin) inhalation solution indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease ("COPD"). Amprexetine, 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 **multiple system atrophy MSA** patients. **We are committed to creating and driving shareholder value.**

## 2023 Strategic Actions

On February 27, 2023, we announced additional strategic actions (the "2023 Strategic Actions") to sharpen the Company's focus and further deliver on its commitment to create shareholder value. The following represents an update on the 2023 Strategic Actions:

- Capital Return Program increased to \$325.0 million** – In February 2023, our board of directors authorized a \$75.0 million increase to the existing \$250.0 million capital return program initiated in September 2022, bringing the total capital return program to \$325.0 million. For the nine months ended September 30, 2023, we repurchased 15.62 million shares on the open market at a weighted average cost of \$10.65 per share for an aggregate cost of \$166.4 million, excluding fees and expenses. Since inception of the capital return program in

September 2022 through September 30, 2023, we repurchased \$294.6 million of shares, and as of September 30, 2023, the Company had approximately \$30.4 million remaining in the capital return program which is expected to be completed by the end of 2023.

- *Discontinued investment in research* – In February 2023, we announced that we discontinued our research activities, including the inhaled Janus kinase (JAK) inhibitor program, and prioritized our R&D resources toward the ampreloxetine Phase 3 study and completion of the YUPELRI Peak Inspiratory Flow Rate (PIFR-2) Phase 4 study. As a result of halting further investment in research activities, our headcount was reduced by approximately 17% in March 2023. We also plan to seek a partnership to continue progression of our inhaled JAK inhibitor program.

As a result of our discontinued investment in research activities, for the nine months ended September 30, 2023, we incurred restructuring and related expenses of \$2.7 million primarily related to R&D expenses. Of the total \$2.7 million, 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 sale of R&D laboratory equipment. We do not expect to recognize any additional employee-related expenses, including share-based compensation, related to the 2023 Strategic Actions.

- *Additional independent directors to the board and governance changes*– In February 2023 and April 2023, we appointed two new independent directors as part of our ongoing commitment to board composition refreshment. In addition, we put forth a proposal to declassify the board of the directors over time which was approved at our May 2023 Annual General Meeting of Shareholders.

## 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

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(“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, Viatris Inc. Under the terms of the Viatris Development and Commercialization Agreement (the “Viatris Agreement”), we led the US Phase 3 development program for YUPELRI in COPD, and Viatris was responsible for reimbursement of our costs related to the registrational 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, Viatris is leading the commercialization of YUPELRI, and we co-promote the product under a profit and loss sharing arrangement (65% to Viatris; 35% to us). Outside the US (excluding China and adjacent territories), Viatris 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 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, (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, for ex-US, Viatris is responsible for all aspects of development and commercialization of nebulized revefenacin in the China and adjacent territories, Region, including pre- and post-launch activities and product registration and all associated costs.

Under the terms of the Viatris Agreement, as amended, as of September 30, 2023 March 31, 2024, we are were eligible to receive from Viatris potential global development, regulatory and sales milestone payments (excluding the China and adjacent territories) totaling 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

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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 EU. EU and \$150.0 million relates to sales milestonesWe are based on achieving certain levels of annual US net sales as follows:

YUPELRI US Net Sales (In a Calendar Year)	Sales Milestones Due from Viatris
\$250.0 million	\$25.0 million
\$500.0 million	\$50.0 million
\$750.0 million	\$75.0 million

As of March 31, 2024, we were also eligible to receive additional potential development and sales milestones totaling of up to \$52.5 million related to Viatris' development and commercialization of nebulized revefenacin in the China and adjacent territories 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 Viatris
\$100.0 million	\$2.5 million
\$200.0 million	\$5.0 million
\$400.0 million	\$10.0 million
\$800.0 million	\$20.0 million

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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 Viatris
≤ \$75.0 million	14%
> \$75.0 million to ≤ \$150.0 million	17%
> \$150.0 million	20%

In November 2023, we learned that Viatris' Phase 3 study of YUPELRI in China was positive, and \$7.5 million relates the data were consistent with previous findings of YUPELRI's strong efficacy. Viatris plans to regulatory approval move forward with a registrational filing for YUPELRI in China. China in mid-2024.

In August 2021, we announced that in collaboration with our partner Viatris, 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 is was aimed at helping to better inform decisions when physicians are designing a personalized COPD treatment plan with patients. In the future, this study could also be used to support promotional efforts for YUPELRI, which could aid in the capture of more of YUPELRI's addressable market and further strengthen its competitive advantage. We have agreed to pay 35% of January 2024, we announced that the Phase 4 study costs, did not show a statistically significant difference between YUPELRI and Viatris has agreed to pay 65% of Spiriva HandiHaler on the Phase 4 study costs. The first patient for 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 enrolled not met, YUPELRI demonstrated an efficacy and safety profile consistent with its performance in January 2022, and enrollment was recently completed. We plan to announce top-line results for the Phase 4 study in January 2024, other clinical studies.

While Viatris 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				Nine Months Ended				Three Months Ended			
	September 30,		Change		September 30,		Change		March 31,		Change	
	2023	2022	\$	%	2023	2022	\$	%	2024	2023	\$	%
YUPELRI net sales (100% recorded by Viatris)	\$58,325	\$53,423	\$4,902	9 %	\$160,318	\$146,166	\$14,152	10 %	\$55,226	\$46,955	\$8,271	18 %
YUPELRI net sales (Theravance Biopharma implied 35%)	20,414	18,698	1,716	9	56,111	51,158	4,953	10	19,329	16,434	2,895	18

**Amprexetine (TD-9855)**

Ampreloxetine is an investigational, once-daily **norepinephrine reuptake inhibitor** **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 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

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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.

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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 **an NDA 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 the study is currently open to **recruitment. recruitment with the expectation of enrolling the final patient into the open label period of the study in the second half of 2024.** 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.

#### ***Skin-selective Pan-JAK inhibitor Program***

In December 2019, we entered into a global license agreement with Pfizer Inc. ("Pfizer") for our preclinical skin-selective, locally acting pan-JAK inhibitor program (the "Pfizer Agreement"). The compounds in this program are designed to target validated pro-inflammatory pathways and are specifically designed to possess skin-selective activity with minimal systemic exposure. Under the Pfizer Agreement, Pfizer had an exclusive license to develop, manufacture and commercialize certain compounds for all uses other than gastrointestinal, ophthalmic, and respiratory applications. We received an upfront cash payment of \$10.0 million in 2019, and in March 2022, we received a \$2.5 million development milestone payment from Pfizer for the first patient dosed in a Phase 1 clinical trial of the skin-selective pan-JAK inhibitor program. In June 2023, we received notice from Pfizer terminating the Pfizer Agreement, effective as of October 7, 2023, at which time the skin-selective pan-JAK inhibitor program was returned to us.

#### **Economic Interests and Other Assets**

##### ***Mid- and Long-Term Economic Interest in GSK-Partnered Respiratory Programs 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's GSK plc's ("GSK") TRELEGY ELLIPTA ("TRELEGY")** to Royalty Pharma for approximately **\$1.1 billion \$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 **ending 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 **Payments**" Payment(s)"). **As of March 31, 2024, which may a total \$250.0 million of \$200.0 million in potential Milestone Payments remain available to us. For the aggregate. The first next potential Milestone Payment, of \$50.0 million will be triggered 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 2023 2024 TRELEGY global net sales, which we would expect to occur in the event TRELEGY global net sales reach are approximately \$2.863 billion. Royalties payable \$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 Royalty Pharma are upward-tiering from 6.5% 2024 TRELEGY global net sales, which we would expect to 10% occur in the event TRELEGY global net sales exceed approximately \$3.21 billion.

Additionally, Total 2023 TRELEGY global net sales were \$2.74 billion which represented a 28% year-over-year growth, and TRELEGY's annual growth rate was 28% and 58% in 2022 and 2021, respectively. TRELEGY global net sales for the first quarter of 2024 were \$749 million which represented a 32% year-over-year growth. TRELEGY is expected to generate global peak sales of \$3.80 billion in 2027 according to Bloomberg consensus estimates as of early May 2024.

In addition to potential Milestone Payments, we will receive from Royalty Pharma 85% of the royalty payments on TRELEGY payable due from GSK for (a) for sales or other activities occurring on and after January 1, 2031 related to TRELEGY in the US, and (b) for sales or other

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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:

TRELEGY Global Net Sales Thresholds (Annual)	Royalty Rate Due from GSK to Royalty Pharma
≤ \$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. TRELEGY is currently expected to generate global peak sales of \$3.6 billion annually according to consensus estimates. Over the past three years, TRELEGY has shown substantial growth, with global net sales increasing annually from \$661.4 million in 2019 to \$2.1 billion in 2022.

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 include completion consists of the YUPELRI Peak Inspiratory Flow Rate (PIFR-2) Phase 4 study and conductingexecuting our ampreloxetine registration Phase 3 study (CYPRESS). In February 2023, as part of our 2023 Strategic Actions, we announced the decision to discontinue research activities including our inhaled JAK program, including nezulcitinib, a nebulized, lung-selective JAK inhibitor positioned and preparing for the treatment of acute and chronic lung diseases.

## 2024 Annual General Meeting of Shareholders

The Company will hold its 2024 Annual General Meeting of Shareholders on May 8, 2024 in Dublin, Ireland. Further information regarding the Annual General Meeting will be provided in the Company's proxy materials, which will be filed with the SEC and made available to shareholders prior to the Annual General Meeting. 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. The extent to which COVID-19 may continue to directly or indirectly impact our business, results of operations and financial condition, including these estimates, will depend on future developments that are uncertain and may be impacted by the emergence of new information concerning COVID-19, new variants or sub-variants of the COVID-19 virus, and the actions taken to manage or treat the disease, including vaccine availability, distribution, acceptance and effectiveness. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies and estimates discussed below 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, 2022 December 31, 2023.

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## Results of Operations

### Revenue

While Viatrix 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, period, was as follows:

Three Months Ended		Nine Months Ended		Three Months Ended	
September 30,	Change	September 30,	Change	March 31,	Change



(In thousands)	2023	2022	\$	%	2023	2022	\$	%	2024	2023	\$	%
YUPELRI net sales (100% recorded by Viatriis)	\$58,325	\$53,423	\$4,902	9 %	\$160,318	\$146,166	\$14,152	10 %	\$55,226	\$46,955	\$8,271	18 %
YUPELRI net sales (Theravance Biopharma implied 35%)	20,414	18,698	1,716	9	56,111	51,158	4,953	10	19,329	16,434	2,895	18

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

(In thousands)	Three Months Ended				Nine Months Ended				Three Months Ended			
	September 30,		Change		September 30,		Change		March 31,		Change	
	2023	2022	\$	%	2023	2022	\$	%	2024	2023	\$	%
Viatriis collaboration agreement	\$15,687	\$12,445	\$3,242	26 %	\$39,841	\$34,010	\$ 5,831	17 %	\$14,503	\$10,411	\$4,092	39 %
Collaboration revenue	6	6	—	—	18	187	(169)	(90)	—	6	(6)	NM
Licensing revenue	—	—	—	—	—	2,500	(2,500)	NM				
Total revenue	\$15,693	\$12,451	\$3,242	26 %	\$39,859	\$36,697	\$ 3,162	9 %	\$14,503	\$10,417	\$4,086	39 %

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 commercialization of YUPELRI. 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" irrespective of whether the overall collaboration is profitable. Amounts payable to Viatriis in connection with the commercialization of YUPELRI, if any, are recorded within the condensed consolidated statements of operations as a collaboration loss within selling, general and administrative expenses. Any reimbursement from Viatriis attributed to the 65% cost-sharing of our 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 nine months ended September 30, 2023 March 31, 2024, we recognized \$15.7 million and \$39.8 million, respectively, \$14.5 million in revenue from the Viartis collaboration agreement which represented increases of 26% and 17%, respectively, a 39% increase compared to the prior year periods. comparable period. The increases for both periods were increase was driven primarily by (i) an increase in year-over-year net sales growth as YUPELRI continued to increase its the brand achieved year-over-year market share of the long-acting nebulized COPD market increases in both the hospital and outpatient settings; community segments; and (ii) lower costs incurred by Viartis. YUPELRI continued to be profitable for us on a brand basis, and total YUPELRI We traditionally experience seasonal dips in net sales recorded by Viartis reached an all-time high in for the third year's first quarter as we transition from the fourth quarter to the first quarter of 2023, the following year. We believe this may be partially due to ordering patterns at the end of the fourth quarter of the prior year.

Licensing revenue was \$2.5 million for the nine months ended September 30, 2022 and was related to a non-recurring development milestone payment from Pfizer for the first patient dosed in a Phase 1 clinical trial of the skin-selective pan-JAK inhibitor program. We did not recognize any licensing revenue for the three months ended September 30, 2022 and for the three and nine months ended September 30, 2023. In June 2023, we received notice from Pfizer terminating the Pfizer licensing agreement, effective as of October 7, 2023, at which time the skin-selective pan-JAK inhibitor program was returned to us.

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### 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 laboratory and 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: period:

(In thousands)	Three Months Ended				Nine Months Ended				Three Months Ended			
	September 30,		Change		September 30,		Change		March 31,		Change	
	2023	2022	\$	%	2023	2022	\$	%	2024	2023	\$	%

Employee-related	\$ 2,859	\$ 3,615	\$ (756)	(21)%	\$ 9,995	\$13,846	\$ (3,851)	(28)%	\$3,305	\$ 4,377	\$ (1,072)	(24)%
Share-based compensation	2,004	2,623	(619)	(24)	6,301	10,062	(3,761)	(37)	1,465	2,441	(976)	(40)
External-related	2,572	739	1,833	248	11,555	12,768	(1,213)	(10)	3,377	5,328	(1,951)	(37)
Facilities, depreciation, and other allocated expenses	876	2,890	(2,014)	(70)	4,457	11,368	(6,911)	(61)	821	2,426	(1,605)	(66)
Total research & development	\$ 8,311	\$ 9,867	\$ (1,556)	(16)%	\$32,308	\$48,044	\$ (15,736)	(33)%	\$8,968	\$14,572	\$ (5,604)	(38)%

R&D expenses decreased by \$1.6 million and \$15.7 million \$5.6 million for the three and nine months ended September 30, 2023, respectively, March 31, 2024 compared to the prior year periods. comparable period. The decreases were decrease was across the majority all of our R&D categories and were was primarily driven by our 2023 Strategic Actions

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strategic actions announced in February 2023 ("2023 Strategic Actions") which included the discontinuation of investment in our research activities. The \$1.8 million increase \$2.0 million decrease in external-related expense in the third quarter expenses was net of 2023 was primarily due to expenses an \$0.8 million increase related to the new progression of the amprelosetine Phase 3 clinical study (CYPRESS) for MSA patients with symptomatic nOH and completion of enrollment in the YUPELRI Phase 4 study (PIFR-2).

R&D expenses directly attributed to the 2023 Strategic Actions and the restructuring announced in 2021 and completed during the third quarter of 2022 (the "2021 Restructuring") are included in the *Restructuring and Related Expenses* section below. nOH.

Under certain of our collaborative arrangements, we receive partial reimbursement of employee-related costs and external costs, which have been reflected as a reduction of R&D expenses of \$1.3 million \$0.2 million and \$5.0 million \$1.8 million for three and nine months ended September 30, 2023, respectively, March 31, 2024 and \$1.7 million and \$4.7 million for three and nine months ended September 30, 2022, 2023, respectively.

## **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, period, were as follows:

(In thousands)	Three Months Ended				Nine Months Ended				Three Months Ended			
	September 30,		Change		September 30,		Change		March 31,		Change	
	2023	2022	\$	%	2023	2022	\$	%	2024	2023	\$	%
Selling, general and administrative	\$16,142	\$16,277	\$(135)	(1)%	\$54,603	\$50,341	\$4,262	8 %	\$16,742	\$19,183	\$(2,441)	(13)%

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Selling, general and administrative ("Total SG&A") &A expenses were relatively unchanged \$16.7 million for the three months ended September 30, 2023 March 31, 2024. Total SG&A expenses (excluding share-based compensation expense, or "SBC") were \$13.0 million and were comprised of \$6.9 million of general and administrative ("G&A") expenses and \$6.1 million of selling, marketing & medical affairs ("SM&M") expenses. Total SG&A expenses (excluding SBC) was \$15.0 million for the comparable prior year period and was comprised of \$9.7 million of G&A expenses and \$5.3 million of SM&M expenses.

The \$2.8 million decrease in G&A expenses (excluding SBC) compared to the prior year period. Our cost comparable period represented a 29% reduction efforts led to decreases in employee-related expenses, share-based compensation expenses, and Company-wide overall overhead expenses. However, these decreases were offset by increases in external-related expenses and overhead expenses allocated to SG&A. The increase in overhead expenses allocated to SG&A was a result of our 2023 Strategic Actions to discontinue research activities which led to a corresponding decrease in allocated overhead expenses to R&D.

For the nine months ended September 30, 2023, SG&A expenses increased by \$4.3 million compared to the prior year period and was primarily due to increases our company-wide cost savings initiative that began in external-related the second half of 2023 and included reductions in various areas such as, finance-related expenses, SG&A allocated overhead information & technology, and facility-related expenses. The \$0.8 million increase in SM&M expenses and employee-related expenses. These increases were partially offset by decreases in share-based compensation expenses and Company-wide overhead expenses. External-related expenses increased by \$5.0 million and (excluding SBC) was primarily attributed due to professional and financial advisory services and intellectual property protection services (i.e., Hatch Waxman litigation). As discussed above, the an increase in SG&A allocated overhead expenses was driven by the reduction in our research activities.

SG&A expenses that were directly attributed to the 2023 Strategic Actions and the restructuring announced in 2021 and completed during the third quarter of 2022 (the "2021 Restructuring") are included in the *Restructuring and Related Expenses* section below. employee-related expenses.

Share-based compensation expense Total SBC related to SG&A expenses was \$4.3 \$3.8 million and \$12.9 million \$4.2 million for the three and nine months ended September 30, 2023, respectively, March 31, 2024 and \$5.2 million and \$15.7 million for the three and nine months ended September 30, 2022, 2023, respectively.

### **Restructuring and Related Expenses**

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

(In thousands)	Three Months Ended				Nine Months Ended				Three Months Ended March			
	September 30,		Change		September 30,		Change		31,		Change	
	2023	2022	\$	%	2023	2022	\$	%	2024	2023	\$	%
Restructuring and related expenses	\$ —	\$ (202)	\$ 202	NM %	\$ 2,743	\$ 5,840	\$ (3,097)	(53)%	\$—	\$1,217	\$(1,217)	NM %
Share-based compensation expense (non-cash)	—	711	(711)	NM	—	6,998	(6,998)	NM	—	357	(357)	NM
Total restructuring and related expenses	\$ —	\$ 509	\$(509)	(100)%	\$ 2,743	\$ 12,838	\$(10,095)	(79)%	\$—	\$1,574	\$(1,574)	NM %

NM: Not Meaningful

There were no restructuring and related expenses recognized for the three months ended September 30, 2023 resulting from the 2023 Strategic Actions. For the nine months ended September 30, 2023, restructuring and related expenses decreased by \$10.1 million, compared to the prior year period, and was primarily attributed to a smaller reduction in workforce related to the 2023 Strategic Actions compared to the much broader reduction in workforce related to the 2021 Restructuring.

March 31, 2024. The restructuring and related expenses related to recognized for the prior year comparable period were a result of our 2023 Strategic Actions were primarily comprised of R&D expenses related to one-time severance payments, employee-related separation costs, and the loss on sale of property and equipment as discussed above. Cash-related expenses and non-cash related expenses associated with the 2023 Strategic Actions were \$1.2 million and \$1.5 million for the nine months ended September 30, 2023, respectively. We do not expect to recognize any additional employee-related expenses, including share-based compensation, related to the 2023 Strategic Actions.

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### Interest Expense

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

(In thousands)	Three Months Ended				Nine Months Ended			
	September 30,		Change		September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%

Ampreloxetine royalty contingency (non-cash)	\$ (609)	\$ (424)	\$ (185)	44 %	\$ (1,727)	\$ (424)	\$ (1,303)	307 %
3.25% Convertible senior notes due 2023	—	(1,121)	1,121	NM	—	(5,395)	5,395	NM
Total interest expense	\$ (609)	\$ (1,545)	\$ 936	(61)%	\$ (1,727)	\$ (5,819)	\$ 4,092	(70)%

NM: Not Meaningful

(In thousands)	Three Months Ended March 31,		Change	
	2024	2023	\$	%
Ampreloxetine royalty contingency (non-cash)	\$ (629)	\$ (550)	\$ (79)	14 %

Interest expense was \$0.6 million and \$1.7 million for the three and nine months ended September 30, 2023, respectively, compared to \$1.5 million March 31, 2024 and \$5.8 million for prior year periods. The \$0.9 million and \$4.1 million decreases in interest expense for the respective periods were due to the retirement of our 3.25% convertible senior notes in August 2022 which was partially offset by the represented non-cash interest expense associated with the \$25.0 million funding for ampreloxetine received from Royalty Pharma in July 2022, 2022 to fund the ampreloxetine Phase 3 clinical study (CYPRESS). 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.

### Loss on Extinguishment of Debt

Loss on extinguishment of debt was as follows:

(In thousands)	Three Months Ended				Nine Months Ended			
	September 30,		Change		September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%
Loss on extinguishment of debt	\$ —	\$ (3,034)	\$ 3,034	NM %	\$ —	\$ (3,034)	\$ 3,034	NM %

NM: Not Meaningful

In the prior year period, we incurred a \$3.0 million loss on the extinguishment of our 3.25% convertible senior notes due 2023 that was completed in August 2022. The \$3.0 million loss was comprised of transaction costs related to the extinguishment and the write-off of the remaining debt issuance costs. We no longer have any long-term debt.

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

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

(In thousands)	Three Months Ended				Nine Months Ended				Three Months Ended March 31,			
	September 30,		Change		September 30,		Change		Ended March 31,		Change	
	2023	2022	\$	%	2023	2022	\$	%	2024	2023	\$	%
Interest income and other income (expense), net	\$ 1,786	\$ 2,758	\$ (972)	(35)%	\$ 7,269	\$ 4,823	\$ 2,446	51 %	\$ 1,434	\$ 2,979	\$ (1,545)	(52)%

Interest income and other income (expense), net, decreased by \$1.0 million \$1.5 million for the three months ended September 30, 2023. Although higher investment yields generated additional March 31, 2024 compared to the prior year

period. The decrease was primarily due to a reduction in interest income for 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 three months ended September 30, 2023 March 31, 2024, compared to the prior year period, due to the increase was offset by much lower cash and investment balances in the third quarter completion of 2023 primarily driven by our previously announced capital return program that began in September 2022, 2022 and was completed in early January 2024.

Interest income and other income (expense), net, increased by \$2.4 million for the nine months ended September 30, 2023 compared to the prior year period. The \$2.4 million increase was primarily due to (i) higher interest income related to an increase in investment yields and (ii) higher investment balances resulting from cash proceeds received from the TRELEGY Royalty Transaction in July 2022.

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### **Provision for Income Tax Expense – Continuing Operations (Benefit)**

The provision for income tax expense related to continuing operations, (benefit), as compared to the prior year comparable periods, period, was as follows:

(In thousands)	Three Months Ended				Nine Months Ended			
	September 30,		Change		September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%
Provision for income tax expense -								
Continuing operations	\$ (1,367)	\$ —	\$ (1,367)	NM %	\$ (2,430)	\$ (12)	\$ (2,418)	NM %

NM: Not Meaningful

(In thousands)	Three Months Ended March 31,		Change	
	2024	2023	\$	%
Provision for income tax expense (benefit)	\$ 1,262	\$ (395)	\$ 1,657	(419)%

For the nine three months ended September 30, 2023 March 31, 2024, the provision for income tax expense was \$2.4 million \$1.3 million compared to \$12,000 a \$0.4 million benefit for the same period in 2022. Although we incurred net operating losses on a consolidated basis in 2022 and for prior year period. In 2023, the year-to-date 2023 period, the provision for income taxes benefit was due to R&D tax credits generated and losses in the US which we expect to be realizable. The income tax expense in the first quarter of 2024 was primarily due to interest expense recorded on uncertain tax positions taken with respect which we began to transfer pricing accrue in 2022 and 2023.

In the fourth quarter of 2023, we anticipate recognizing a net tax benefit adjustment of approximately \$2.0 million relating to our 2022 US federal income tax return that was filed in October 2023. However, for the full year 2023, we are anticipating an income tax expense due to uncertain tax positions taken with respect to transfer pricing.

### **Net Income from Discontinued Operations**

Net income from discontinued operations, as compared to the prior year comparable periods, was as follows:

(In thousands)	Three Months Ended				Nine Months Ended			
	September 30,		Change		September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%
Net income from discontinued operations	\$ —	\$ 932,654	\$ (932,654)	NM %	\$ —	\$ 961,062	\$ (961,062)	NM %

NM: Not Meaningful

The TRELEGY Royalty Transaction, completed in July 2022, resulted in (i) income from our investment in TRC; (ii) interest expense related to our non-recourse 2035 notes; and (iii) the net gain from the sale of our equity interests in TRC for the prior year periods to be reclassified as net income from discontinued operations. We did not recognize any net income from activities related to discontinued operations for the three and nine months ended September 30, 2023.

### Liquidity and Capital Resources

As of September 30, 2023 March 31, 2024, we had approximately \$134.0 \$100.0 million in cash, cash equivalents, and investments in marketable securities (excluding restricted cash) and no long-term debt.

### 2023 Strategic Actions

As discussed above, in February 2023, we announced strategic actions to sharpen the Company's focus and further deliver on its commitment to create shareholder value. The strategic actions included a \$75.0 million increase to the existing \$250.0 million capital return program initiated in September 2022, bringing the total capital return program to \$325.0 million. For the nine months ended September 30, 2023, we repurchased 15.62 million shares on the open market at a weighted average cost of \$10.65 per share for an aggregate cost of \$166.4 million, excluding fees and expenses. Since inception of the capital return program in September 2022 through September 30, 2023, we have repurchased \$294.6 million of shares. We had approximately \$30.4 million remaining in the capital return program, as of September 30, 2023, which is expected to be completed by the end of 2023.

Our strategic business plan is subject to significant uncertainties and risks as a result of, among other factors, COVID-19, 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

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arrangements, expenses being higher than anticipated, the sales levels of our approved product, unplanned expenses, 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 capital return program and our operations for at least the next twelve months from the issuance date of these our condensed consolidated financial statements based on current operating plans and financial forecasts.



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## Cash Flows

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

(In thousands)	Nine Months Ended September 30,			Three Months Ended		
	2023	2022	Change	March 31, 2024	2023	Change
Net cash used in operating activities	\$ (26,143)	\$ (62,936)	\$ 36,793	\$ (1,022)	\$ (11,221)	\$ 10,199
Net cash (used in) provided by investing activities	(32,020)	1,114,848	(1,146,868)			
Net cash provided by (used in) investing activities				17,028	(43,046)	60,074
Net cash used in financing activities	(168,324)	(723,334)	555,010	(1,716)	(56,240)	54,524

### Net cash flows used in operating activities

Net cash used in operating activities was \$26.1 million \$1.0 million for the nine three months ended September 30, 2023 March 31, 2024, consisting of a net loss of \$46.7 million \$11.7 million, a net increase in cash resulting from adjustments for non-cash and other reconciling items of \$25.5 million \$6.5 million and a net decrease increase in cash resulting from changes in operating assets and liabilities of \$4.9 million \$4.1 million.

Net cash used in operating activities from continuing operations was \$57.3 million \$11.2 million for the nine three months ended September 30, 2022 March 31, 2023, consisting of a net loss of \$78.6 million \$22.1 million, a net increase in cash resulting from adjustments for non-cash and other reconciling items of \$38.4 million \$8.6 million and a net decrease increase in cash resulting from changes in operating assets and liabilities of \$17.2 million \$2.3 million. Net cash used in operating activities from discontinued operations was \$5.6 million was related to TRELEGY Royalty Transaction that was completed in July 2022.

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

Net cash used in provided by investing activities was \$32.0 million \$17.0 million for the nine three months ended September 30, 2023 March 31, 2024, consisting primarily of cash outflows inflows from the net purchase and maturities of marketable securities of \$31.7 million \$17.1 million and cash outflows from the net purchase and sale of property and equipment of \$0.3 million \$0.1 million.

Net cash provided by used in investing activities from continuing operations was \$19.7 million \$43.0 million for the nine three months ended September 30, 2022 March 31, 2023, consisting primarily of cash inflows outflows from the net purchase and maturities of marketable securities of \$15.4 million, cash inflow from the sale of Velusetrag in June 2022 of \$2.7 million, \$42.3 million and cash inflows outflows from the net purchase and sale of property and equipment of \$1.6 million \$0.7 million. Net cash provided by investing activities from discontinued operations was \$1.1 billion for the nine months ended September 30, 2022, consisting primarily of cash inflows from the TRELEGY Royalty Transaction that was completed in July 2022.

#### *Net cash flows used in financing activities*

Net cash used in financing activities was \$168.3 million \$1.7 million for the nine three months ended September 30, 2023 March 31, 2024, consisting primarily of \$166.8 million \$0.4 million of cash outflows related to the repurchase of ordinary shares as part of completion of our capital return program, program and \$1.3 million of cash outflows related to the repurchase of shares to satisfy tax withholding obligations.

Net cash used in financing activities from continuing operations was \$703.1 million \$56.2 million for the nine three months ended September 30, 2022 March 31, 2023, consisting primarily of \$94.0 million in \$55.3 million of cash outflows related to the repurchase of ordinary shares as part of our capital return program and \$631.6 million \$0.9 million of cash outflows related to the extinguishment repurchase of our debt. These cash outflows was partially offset by a \$24.5 million cash inflow relate shares to the funding of an additional Phase 3 study for the amprelosetine study. Net cash used in financing activities from discontinued operations was \$20.2 million for the nine months ended September 30, 2022 and was related to a debt redemption premium associated with our debt, satisfy tax withholding obligations.

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#### ***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 September 30, 2023 March 31, 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.

#### ***Market and Performance-Contingent Awards***

We periodically grant market-based and performance-contingent share-based awards to our employees. For the three months ended September 30, 2023, no such market-based restricted share units ("RSUs") were granted, and for the nine months ended September 30, 2023, we granted 165,000 of such RSUs. The 165,000 RSUs had a fair value of \$1.4 million that vest upon our ordinary shares meeting certain market-based price targets followed by a service period. The fair value of these market-based RSUs is being recognized through February 2027. For the three and nine months ended September 30, 2023, we recognized \$0.2 million and \$0.5 million, respectively, of share-based compensation expense related to the awards.

For the three months ended September 30, 2023, we did not grant any performance-contingent RSUs, and for the nine months ended September 30, 2023, we granted 367,000 performance-contingent RSUs, with a fair value of \$3.7 million with performance vesting dates through February 2026. In September 2023, we concluded that 52,500 of the RSUs were probable of achievement, and as a result, we recognized \$0.3 million of cumulative catch-up share-based compensation expense for the three and nine months ended September 30, 2023.

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

Our market risks, As a "smaller reporting company," as defined by Item 10 of September 30, 2023, have Regulation S-K, we are not changed materially from those discussed in "Item 7A. Quantitative and Qualitative Disclosures About Market Risk" of our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 1, 2023, required to provide this information.

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#### ITEM 4. CONTROLS AND PROCEDURES

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

We conducted an evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act as of September 30, 2023 March 31, 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.

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## Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act, which occurred during the **third first** quarter of the year ending **December 31, 2023** **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

**In** **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 **the Company's our** patents listed in the FDA's Orange Book for YUPELRI on the date of **the Company's our** 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 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 **the Company's our** Orange Book listed patents. **The Company is 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. **An additional patent Additional patents** covering YUPELRI, granted on July 4, 2023 **and January 2, 2024, was were** subsequently listed in FDA's Orange Book. **The Company We** filed **an** additional patent infringement **suit against all of the above generic companies suits** in the U.S. District Court for the District of New Jersey during August **2023. This suit has 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.**

**On October 27, 2023 25**

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**As of May 14, 2024, subsidiaries of the Company we have settled all litigation with Accord Healthcare, Inc.; Lupin Pharmaceuticals, Inc.; Orbicular Pharmaceutical Technologies Private Limited; and Mylan Ireland Limited and Mylan Specialty L.P. (together, “Viatris entities”), entered into a Settlement Agreement (“Settlement Agreement”) with** Teva Pharmaceuticals, Inc. **and Teva Pharmaceuticals USA, Inc. (together, “Teva”). The Settlement Agreement resolves ongoing patent litigation described above with respect pursuant to individual agreements in which we granted these parties. Under the Settlement Agreement, the Company and Viatris entities granted Teva companies a royalty-free, non-exclusive, non-sublicensable, non-transferable license to manufacture and market Teva's their respective generic version versions of YUPELRI® (revefenacin) inhalation solution in the United States US on or after the licensed launch date of April 23, 2039, subject to certain exceptions as is customary in these types type of agreements. As required by law, the settlement is settlements are** subject to review by

the U.S. Department of Justice and the Federal Trade Commission. The patent litigation against the other three remaining generic companies, along with certain affiliates, remains pending.

Please also see "Business"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, 2022 December 31, 2023 for additional 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.

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### 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 Viatris, 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

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- 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 are currently approaching non-GAAP profitability; however, we may never generate sufficient cash or revenue to achieve sustainable cash flow or profitability from our operations. For the three and nine months ended September 30, 2023 March 31, 2024, we recognized a net losses loss of \$9.0 million \$11.7 million, and \$46.7 million for the year ended December 31, 2023, respectively. Although we recognized \$872.1 million a net loss of net income for year ended December 31, 2022, which results were largely driven by net income from discontinued operations following the one-time TRELEGY Royalty Transaction, we recognized \$92.8 million in net losses from continuing operations during the same period, \$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 \$900.6 million \$920.8 million as of September 30, 2023 March 31, 2024. Despite the fact that we are approaching non-GAAP profitability, we 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 into and through later stage clinical studies without a partner and which we may prepare are preparing to potentially commercialize. In addition, although we have no current plans to do so, we may in the future invest strategically in our research efforts to continue to support our development and commercial pipeline. While our YUPELRI operations have been profitable

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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 United States ("US"), US, including the maintenance of an independent sales and marketing organization with appropriate technical expertise, and a medical affairs presence and consultant support, and post-marketing studies, support. Our commitment of resources to the continued development of amprelosetine 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 amprelosetine. Our operating expenses also will increase if, among other things:

any earlier stage potential products move into and through later-stage clinical development, which is generally more expensive than early stage development;

- 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, our economic and royalty interests, and payments under collaboration agreements, 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, 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 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 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 predominantly nebulized LAMA Lonhala® Magnair® (glycopyrrolate) dosed two times per day and 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 third party payors, or the medical community in general believe that YUPELRI is not

a preferred treatment option for those with COPD, we may see declines, or fail to grow. If YUPELRI's acceptance does not continue to 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 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;

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- 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. In addition, we have voluntarily undertaken post-marketing studies with respect to YUPELRI. The commencement and completion of clinical studies for our product candidates, including ampreloxetine, and product candidate may be delayed and programs may be terminated due to many factors, including, but not limited to:

- lack of effectiveness efficacy of product candidates candidate during clinical studies;
- adverse events, safety issues or side effects (or perceived adverse developments or results) relating to the product candidates candidate or their 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 **programs; program;**
- inability to enter into partnering arrangements relating to the development and commercialization of our **programs program** and product **candidates candidate** or partner decisions not to maintain a partnership with us;

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- 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 **our** product candidates through clinical development;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;

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- 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 **programs program** including, without limitation, any delays in development in our **programs, program**, any halting of

development in our **programs, program**, any difficulties or delays encountered with regard to the FDA or other third country regulatory authorities with respect to our **programs, program**, or any indication from clinical or non-clinical studies that the compounds in our **programs 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 izencitinib 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 study for amprelosetine will be completed on the timeline we expect or at **all, all, that the CYPRESS 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. **The shifting environment surrounding the collective response to the COVID-19 pandemic has led to and may lead to additional guidance from US and foreign regulatory agencies with respect to numerous matters regarding the conduct of clinical trials in general and the development of COVID-19 related therapies, which is subject to the risk of further change, misinterpretation or non-compliance due to the changing regulatory landscape.** In addition, the FDA has additional standards for approval of new drugs, including recommended

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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.

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***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. 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 effective as of October 7, 2023. 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 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 **current** 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 and are currently winding down our development programs for** 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

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- 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 candidates 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 candidates 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 predominantly with the nebulized LAMA Lonhala® Magnair® (glycopyrrolate) dosed two times per day and 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, is expected to launch in the US in the second half of 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.

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***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 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 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 healthy 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 third party** manufacturers;
- the availability of specialized materials needed to manufacture our APIs and drug products or YUPELRI;

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- because some of the **third-party 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

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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.

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***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. **In fact, 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. **We As of May 14, 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 **the ongoing litigation,** 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."*

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***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 Viartis 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 third party** collaborators, we may fail to meet our business objectives and our financial

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condition may be adversely affected. We face significant competition in seeking **third-party 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, Viartis' 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, Viartis 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, Viartis 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 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. **Furthermore, to the extent the operations of these third parties are disrupted as result of the COVID-19 pandemic or otherwise, our development programs could be delayed.**

The FDA, and equivalent authorities in **third other** countries, **enforces enforce** GxPs and other regulations through periodic inspections of trial sponsors, clinical research organizations ("CROs"), principal investigators and trial sites. If we or any

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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

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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 adverse effects resulting from the COVID-19 pandemic;
- 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** **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.

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***If we lose key management, sales 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 **Restructuring 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 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

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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 Viatris 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, Viatris 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

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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 security measures cybersecurity risk management program and processes, including our policies, controls, or procedures, will prevent service interruptions be fully implemented, complied with or security breaches that could adversely affect effective in protecting our business, 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 and 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.

***We face risks related to widespread illnesses, including the recent COVID-19 pandemic, which could have a material adverse effect on our business and results of operations.***

Our business has been and may continue to be adversely affected by the outbreak of respiratory illness caused by a novel strain of coronavirus, SARS-CoV-2, causing the Coronavirus Disease 2019, also known as COVID-19 (the “COVID-19 pandemic”).

Sales momentum was affected by COVID-19 and may continue to be in the future. We market YUPELRI in the hospital setting and to pulmonologists, whose practices were, and may be in the future, impacted by the pandemic or future respiratory pandemics. Customer orders or new patient use of YUPELRI may decline or fail to grow as a result of, among other things, a shift in our marketing efforts, increased workload of healthcare providers, staffing challenges at hospitals, and the impact of any concerns regarding nebulization in COVID-19 positive patients.

Challenges to the conduct of clinical trials may continue to arise due to the COVID-19 pandemic from site closures, site staffing shortages, potential interruptions to the supply chain for investigational products, or other considerations if site personnel or trial participants become infected with COVID-19. These challenges may lead to difficulties in meeting protocol-specified procedures.

If significant portions of our workforce, and particularly our field-based teams, are unable to work effectively, including due to illness, quarantines, social distancing, government actions or other restrictions in connection with the COVID-19 pandemic or other health emergencies, our operations will be impacted. The COVID-19 pandemic or other health emergencies could limit the ability of our customers, suppliers and business partners to perform under their contracts with us, including third-party payers’ ability to make timely payments to us during and following the pandemic. Even now that the COVID-19 pandemic has largely subsided, we may continue to experience an adverse impact to our business as a result of its global economic impacts.

***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

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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

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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, even

assuming that we draw on such resources to repurchase the remaining approximately \$30.4 million (as of September 30, 2023) of our ordinary shares authorized under our share repurchase program. 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 September 30, 2023 March 31, 2024, we had cash, cash equivalents and marketable securities of \$134.0 million approximately \$100.0 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;

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- the scope, duration, expenditures, and technical obstacles associated with our amprelosetine program, including preparing for potential product approvals of amprelosetine; amprelosetine 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.

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

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

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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.

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***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 the Company's 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

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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.

***We were a passive foreign investment company, or "PFIC," for 2014, but we were not a PFIC from 2015 through 2022, 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 2022, 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

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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.

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## RISKS RELATED TO LEGAL AND REGULATORY UNCERTAINTY

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

We rely upon a combination of patents, patent applications, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any involuntary disclosure to or misappropriation by third parties of this proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. The status of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and is very uncertain. As of September 30, 2023 March 31, 2024, we owned a total of 232 177 issued US patents and 1,234 975 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

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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 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 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 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

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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. 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. 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 2030 2026 to 2039. Our collaboration partner, Viartis, 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

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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

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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

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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, and 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 obligations and restrictions under the GDPR and Switzerland's data protection laws concern, in particular, 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, relate), providing detailed information about the processing details disclosed activities to the individuals, the dealing with restrictions on sharing of personal data with third parties the transfer of and transferring personal data out of the European Economic Area ("EEA") or Switzerland, having contracting requirements arrangements in place where required (such as with clinical trial sites and vendors), and security breach notifications, as well as substantial potential fines, notifying in some cases up certain instances personal data breaches to 4% of annual global



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turnover, for breaches of the data protection obligations, 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.

**Legal mechanisms** With regard to allow for the transfer of personal data, from the EEA or UK to GDPR restricts the US may impact our ability of companies to transfer personal data or otherwise may cause us to incur significant costs to do so legally. On July 16, 2020, the European Court of Justice ruled that the Privacy Shield is an invalid data transfer mechanism and confirmed that the Standard Contractual Clauses remain valid. If companies are relying on the Standard Contractual Clauses as their transfer mechanism to transfer personal information from the EEA to the US (or to other jurisdictions not recognized as adequate by the EU), they must be incorporated into new and existing agreements within prescribed timeframes. The UK adopted versions of their own SCCs. Updating agreements to incorporate these new SCCs for the EEA and UK may require significant time and resources to implement, including through adjusting our operations, conducting requisite data transfer assessments, and revising our contracts. Companies that have not taken steps to demonstrate that their SCCs and personal data recipients in the US or other non-adequate jurisdictions are suitable to receive the personal data may be subject to enforcement actions by competent authorities in the EU for failure to comply with related data privacy rules.

Additionally, the European Commission adopted a draft adequacy decision for the EU-US Data Privacy Framework, which reflects the assessment by the European Commission of the US legal framework. The draft decision concludes that the United States ensures an adequate level of protection for personal data transferred from the EU to US companies. After an approval process, the European Commission is expected to adopt the final adequacy decision, which will allow data to flow freely from the EU to the US, U.S. 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 as approved by the European Commission in June 2021. 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 cost-containment initiatives, may negatively impact us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties.***

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

- the ability to set and collect a price believed to be reasonable for products;

- the ability to generate revenues and achieve profitability; and
- the availability of capital.

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 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 ~~has been~~ will be eliminated effective 2025 under the Inflation Reduction Act) ~~Act 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.

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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 ~~six months~~ 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.

On August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 (the "IRA"). 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

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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 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.

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***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 **uses 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

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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

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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. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. 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 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 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 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

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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

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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** **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. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives. A manufacturer's failure to submit

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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** **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.

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***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.

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## 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, 2022** **December 31, 2023**, the last reported sales price of our ordinary shares on Nasdaq fluctuated between a low of **\$8.33** **\$8.38** per share and a high of **\$12.96** **\$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

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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;

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- 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 **Woodford Investment Management Limited**, 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;

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- 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.

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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 **September 30, 2023** **March 31, 2024**, our three largest shareholders collectively owned **43.1%****45.1%** 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. **The beneficial ownership percentage**

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[Table of any of our shareholders would increase if they do not participate in our ongoing open market purchase program. Contents](#)

***Certain provisions in our constitutional and other documents may discourage our acquisition by a **third-party, 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;

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- 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, the Company will be the proper plaintiff in any claim based on a breach of duty owed to it, and a claim against (for example) our officers or directors usually may not be brought by a shareholder. However, based on English authorities, which would in all likelihood be of persuasive authority and be applied by a court in the Cayman Islands, exceptions to the foregoing principle apply in circumstances in which:

- a company is acting, or proposing to act, illegally or beyond the scope of its authority;

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- 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.

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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.

***We are in the process of implementing a strategy to return capital to our shareholders. But there is no guarantee that it will be fully implemented; as a result, 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. In Starting in September 2022, however, our board of directors authorized we undertook a \$250.0 million capital return program. On February 27, 2023, we announced that our board of directors had authorized an increase of \$75.0 million to the existing \$250.0 million capital return program initiated of \$325.3 million which was completed in September 2022, bringing the total capital return program to \$325.0 million. As of September 30, 2023, we had repurchased \$294.6 million of shares, and we had approximately \$30.4 million remaining in the capital return program which is expected to be completed by the end of 2023. January 2024. There is no guarantee that any of the remaining approximately \$30.4 million of our ongoing \$325.0 million we will implement another capital return program will be spent or that this overall capital return program will be fully implemented on a timely basis or at all or that shareholders will participate at in the rates they expect. 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, 2023, 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

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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 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

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common stock and greater stock price volatility. For so long as we are 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.

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

## Issuer Purchases of Equity Securities

On September 19, 2022, we announced that our board of directors had approved a \$250.0 million capital return program. Furthermore, on February 27, 2023, we announced that our board of directors had authorized a \$75.0 million increase to the existing \$250.0 million capital return program initiated in September 2022, bringing the total capital return program to \$325.0 million. As of September 30, 2023 January 31, 2024, we had repurchased \$294.6 million \$325.3 million of shares in aggregate and as of September 30, 2023, we had approximately \$30.4 million remaining in completed the capital return program which is expected to be completed by the end program. We did not repurchase any of 2023. our ordinary shares in February or March 2024.

The table below summarizes information about the Company's purchases of its equity securities registered pursuant to Section 12 of the Exchange Act during the three months ended September 30, 2023 March 31, 2024. All shares purchased to date under the capital return program were cancelled and ceased to be outstanding.

Period	Maximum Dollar				Maximum Dollar			
	Total Number of		Value of Shares		Total Number of		Value of Shares	
	Total Number	Weighted	as Part of Publicly	Purchased Under the	Total Number	Weighted	as Part of Publicly	Purchased Under the
	of Shares	Average Price	Announced Plans	Plans or Programs	of Shares	Average Price	Announced Plans	Plans or Programs
	Purchased	Per Share (1)	or Programs	(in thousands)	Purchased	Per Share (1)	or Programs	(in thousands)
July 1, 2023 to July 31, 2023	1,039,000	\$ 9.88	1,039,000	\$ 50,928 (2)				
August 1, 2023 to August 31, 2023	960,900	9.82	960,900	41,493 (2)				
September 1, 2023 to September 30, 2023	1,178,000	9.43	1,178,000	30,381 (2)				
January 1, 2024 to January 31, 2024					38,462	\$ 11.551	38,462	\$ —
Total	3,177,900	\$ 9.70	3,177,900		38,462	\$ 11.551	38,462	

(1) The weighted average price paid per ordinary share does not include the cost of commissions.

## ITEM 5. OTHER INFORMATION

### Trading Plans

During the three months ended March 31, 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:

Rule 10b5-1		
Duration of Trading	Trading Arrangement?	Number of Ordinary

Name and Title	Action	Date	Arrangement	(Y / N) (1)	Shares to be Sold
Rhonda F. Farnum, Chief Business Officer and Senior Vice President, Commercial & Medical Affairs	Adoption	March 14, 2024	June 24, 2024 - July 30, 2025	Y	Up to 90,000

(1) Denotes whether the \$75.0 million increase in trading plan is intended to satisfy the size affirmative defense Rule 10b5-1(c) of our capital return program announced on February 27, 2023 the Exchange Act.

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## ITEM 6. EXHIBITS

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference	
			Form	Filing Date/Period End Date
10.1	<a href="#">Form of Restricted Share Purchase Agreement under the Amended and Restated 2013 Equity Incentive Plan</a>	X		
10.2	<a href="#">Separation and Release of Claims by and between Richard Graham and Theravance Biopharma US, Inc.</a>	X		
10.3	<a href="#">Employment Contract with Aine Miller</a>	X		
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 September 30, 2023 March 31, 2024, formatted in iXBRL: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Income (Loss), 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.

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## SIGNATURES

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

Theravance Biopharma, Inc.

Date: November 9, 2023 May 15, 2024

/s/ RICK E WINNINGHAM

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

Date: November 9, 2023 May 15, 2024

/s/ AZIZ SAWAF

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

**THERAVANCE BIOPHARMA INC.**  
**AMENDED AND RESTATED 2013 EQUITY INCENTIVE PLAN**  
**RESTRICTED SHARE PURCHASE AGREEMENT**

THIS RESTRICTED SHARE PURCHASE AGREEMENT (the “Agreement”) is entered into as of [·], by THERAVANCE BIOPHARMA, INC., a Cayman Islands exempted limited liability company (the “Company”), and [·] (the “Purchaser”).

**SECTION 1. ACQUISITION OF SHARES.**

(a) **Purchase of Ordinary Shares.** On [(i) [·] (Date 1), (ii) after close of market on the second full trading day after the Company reports its [·] financial results (Date 2), (iii) after close of market on the second full trading day after the Company reports its [·] financial results (Date 3), (iv) after close of market on the second full trading day after the Company reports its [·] financial results (Date 4) and (v) after close of market on the second full trading day after the Company reports its [·] financial results (Date 5)] (each, a “Purchase Date”), the Purchaser agrees to purchase, and the Company agrees to transfer to the Purchaser, a number of the Company's Ordinary Shares determined as follows:

(i) on Date 1: a number of Ordinary Shares equal to \$[·] (i.e., [·]% of Purchaser's gross pay from base salary less taxes withheld on same for the period from January 1 – [·]) divided by the closing price of an Ordinary Share on Date 1, rounded down to the nearest whole share; and

(ii) On each Purchase Date after Date 1: a number of Ordinary Shares (rounded down to the nearest whole share) equal to (A) that number of base salary paychecks for the [·] fiscal year since the immediately prior Purchase Date multiplied by \$[·], divided by (B) the closing price of an Ordinary Share on the applicable Purchase Date.

Notwithstanding the foregoing, in the event that a Purchase Date occurs on a date that is during a blackout period under the Company's insider trading policy, the Purchase Date shall instead occur on the first business day occurring after the expiration of such blackout period. The Ordinary Shares purchased on each Purchase Date shall be referred to in this Agreement as the “Purchased Shares”. The purchase price for each Purchased Share shall be the closing price of an Ordinary Share on the relevant Purchase Date (the “Purchase Price”).

(b) **No Purchase Above [·] Per Share.** Notwithstanding anything in this Agreement to the contrary, if the Purchase Price on a Purchase Date is greater than \$[·] (as proportionately adjusted in the event of a share split or other event set forth in Section 11.1 of the Plan), no purchase or sale of Ordinary Shares shall occur on such Purchase Date.

(c) **Transfer.** On the terms and conditions set forth in this Agreement and the Plan, the Company agrees to transfer to the Purchaser the Purchased Shares. The transfer shall occur at the offices of the Company on the applicable Purchase Date or at such other place and time as the parties may agree.

(d) **Consideration.** The Purchaser agrees to pay the Purchase Price for each Purchased Share. The Purchase Price is agreed to be not less than 100% of the Fair Market Value of each Purchased Share. Payment shall be made in cash or cash equivalents on

the applicable Purchase Date.

(e) **Vesting.** The Purchased Shares shall be fully vested.

(f) **Plan and Defined Terms.** Purchaser and the Company agree that the Purchased Shares are being sold under, and are governed by the terms and conditions of, the Theravance Biopharma, Inc. Amended and Restated 2013 Equity Incentive Plan (the “Plan”). The provisions of the Plan are incorporated into this Agreement by this reference. Capitalized terms not defined herein shall have the meaning ascribed to such terms in the Plan.

(g) **For Own Account.** The Purchased Shares are being acquired for investment for the Purchaser's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and that the Purchaser has no present intention of selling, granting any participation in, or otherwise distributing the same.

## SECTION 2. TERMINATION OF SERVICE

No Ordinary Shares will be purchased or sold pursuant to this Agreement on a Purchase Date unless Purchaser remains an Employee on such Purchase Date.

## SECTION 3. CHANGE IN CONTROL

This Agreement will terminate immediately prior to a Change in Control (as defined in the Plan). No Ordinary Shares shall be purchased or sold pursuant to this Agreement on or after the effective date of such Change in Control.

## SECTION 4. SHARE CERTIFICATES

(a) **Share Certificates.** The Purchased Shares will be issued in book-entry form, registered in the Purchaser's name in the register of members of the Company or in the name of Purchaser's legal representatives, beneficiaries or heirs, as the case may be.

(b) **Legend.** The Purchaser acknowledges that any certificates or book-entry records representing the Purchased Shares shall contain a legend to the effect that the Purchased Shares are held by “affiliate” of the Company within the meaning of the Securities Act of 1933, as amended.

## SECTION 5. MISCELLANEOUS PROVISIONS

(a) **Withholding Taxes.** The Purchaser agrees to make arrangements satisfactory to the Company (or the Parent, Subsidiary or Affiliate employing the Purchaser) to pay any withholding taxes that may be due as a result of this award.

(b) **The Plan.** The text of the Plan is incorporated into this Agreement by reference. A copy of the Plan is available on the Company's intranet or by request to the Finance

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Department. Capitalized terms not otherwise defined herein shall have the meanings ascribed to such terms in the Plan.

(c) **Restrictions on Resale.** The Purchaser agrees not to sell any shares at a time when applicable laws, regulations, Company trading policies (including the Company's Insider Trading Policy, a copy of which can be found on the Company's intranet) or an agreement between the Company and its underwriters prohibit a sale. This restriction will apply as long the Purchaser's service with the Company continues and for such period of time after termination of the Purchaser's service as the Company may specify.

(d) **No Retention Rights.** This award and this Agreement do not give Purchaser the right to be employed by or retained by the Company, a Parent, Subsidiary or Affiliate in any capacity. The Company and its Parent, Subsidiaries and Affiliates reserve the right to terminate the Purchaser's service at any time, with or without cause.

(e) **Recoupment Policy.** The shares issued pursuant to this Agreement shall be subject to any Company recoupment policy in effect from time to time.

(f) **Electronic Delivery.** The Purchaser agrees that the Company may deliver by email all documents relating to the Plan or this award (including, without limitation, prospectuses required by the Securities and Exchange Commission) and all other documents that the Company is required to deliver to its security holders (including, without limitation, annual reports and proxy statements). The Purchaser also agrees that the Company may deliver these documents by posting them on a web site maintained by the Company or by a third party under contract with the Company. If the Company posts these documents on a website, it will notify the Purchaser by email.

(g) **Entire Agreement.** This Agreement and the Plan constitute the entire understanding between the Purchaser and the Company regarding the Purchased Shares. Any prior agreements, commitments or negotiations concerning this award are superseded. This Agreement may be amended only by another written agreement between the parties.

(h) **Choice of Law.** This Agreement shall be governed by, and construed in accordance with, the laws of the Cayman Islands (without regard to their choice-of-law provisions).

(i) **Severability.** Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement shall be held to be prohibited by or invalid under applicable law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement.

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IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the day and year first above written.

**PURCHASER:**

**THERAVANCE BIOPHARMA, INC.**

By: \_\_\_\_\_

[.]

Name: [.]

Title: [.]

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## SEPARATION AGREEMENT AND RELEASE OF CLAIMS

This Separation Agreement and Release of Claims ("Agreement") is made and entered into by and between Richard Graham ("Employee") and Theravance Biopharma US, Inc. ("Theravance" or "Company"). Employee and Theravance shall be referred to herein as the "Parties."

Employee's employment with Theravance terminated on February 29, 2024 (the "Termination Date"). When this Agreement becomes effective as set forth in paragraph K it will constitute the agreement to provide severance benefits to Employee in exchange for Employee entering this Agreement which among other things includes a release of claims.

Employee and Theravance agree as follows:

**A. Severance Benefits**

After this Agreement becomes effective pursuant to paragraph K Theravance shall provide Employee with the following severance benefits:

1. **Severance Payment:** Following the Termination Date and provided Employee has complied with the terms of this Agreement, Theravance will pay Employee a lump sum equivalent to thirteen (13) weeks of Employee's full time base salary December 31, 2023 which equals the gross amount of \$130,000 and which will be subject to all applicable taxes, deductions, and other withholdings.
2. **Health Insurance Continuation:** Provided Employee completes the required documentation to continue Employee's health insurance coverage under COBRA Theravance will pay the cost of continuing Employee's health insurance coverage under COBRA for up to nine months at the level of coverage applicable to the employee on the Termination Date. COBRA coverage payment by Theravance will cease if Employee obtains other health insurance coverage during the period Employee is eligible for Theravance paid coverage under the terms of this Agreement. Employee agrees to notify Theravance in the event Employee obtains other health insurance coverage. Employee will be responsible for making payments to continue health insurance under COBRA after the period for which Theravance is paying the cost under the terms of this Agreement.
3. **Acceleration of Vesting:** The treatment of Employee's outstanding equity awards to acquire ordinary shares of Theravance Biopharma, Inc. shall be governed by the applicable award agreement and plan rules, including but not limited to the Theravance Biopharma, Inc. Amended and Restated 2013 Equity Incentive Plan or other applicable equity incentive plan. To the extent permissible under the rules of any applicable plans, and subject to strict compliance by Employee with Employee's obligations hereunder, the Company will vest 7,500 of Employee's outstanding unvested restricted share units ("RSUs") as of the effective date of this Agreement (the "Vesting Acceleration"). The Vesting Acceleration will apply to the

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7,500 unvested RSUs subject to Employee's 2023 performance RSU award for which the performance conditions have been achieved and which remain subject to service- based vesting. To the extent any RSUs vest pursuant to this paragraph A.3, the RSUs will be settled within ten (10) business days after the effective date of this Agreement, with the exact date or dates to be selected by the Company in its sole discretion. Upon settlement of any RSUs that vest pursuant to this paragraph A.3, the Employee's tax withholding obligations will be satisfied by having the Company withhold a number of ordinary shares that would otherwise be issued to Employee when the RSUs are settled with a fair market value equal to such tax withholding obligations. For this purpose only, the Employee's tax withholding obligations will be calculated using the federal income tax



rate of 37% previously elected by Employee or if applicable using the federal supplemental rate. Employee acknowledges and agrees that except as set forth in this paragraph, vesting of Employee's outstanding equity awards will cease on the Termination Date and that no further vesting will occur other than pursuant to the Theravance Biopharma, Inc. Change in Control Severance Plan ("Severance Plan") and the applicable award agreement.

4. **Change in Control Severance Benefits:** To the extent Theravance Biopharma, Inc. is subject to a "Change in Control" (as defined in the Severance Plan) within three months after the Termination Date, Employee will be eligible for the severance benefits described in the Severance Plan on the terms and conditions set forth therein; provided, however, that such severance benefits shall be reduced by any amounts paid to or on account of Employee pursuant to paragraphs A.1. and A.2. hereof.

## **B. Release of Claims by Employee**

### **1. General Release and Releasees:**

Except as set forth below, in consideration of the severance benefits provided herein, Employee on Employee's behalf, and on behalf of Employee's agents, heirs, beneficiaries and assigns, hereby fully and forever releases, waives, discharges and promises not to sue or otherwise maintain, institute or cause to be instituted any legal proceedings against Theravance, or its related entities and subsidiaries, or any of its or its related entities' and subsidiaries' current or former officers, directors, shareholders, predecessors, successors, agents, employees, contractors, insurers, representatives, joint employers, or any person or entity to which Theravance has provided services (collectively, "Releasees"), with respect to any and all liabilities, claims, demands, contracts, debts, monetary damages or other form of personal relief, of any nature, kind and description, whether at law, in equity or otherwise, whether or not now known or ascertained, which currently do or may exist, including without limitation any matter, cause or claim arising out of or related to any and all acts, events or omissions, occurring prior to the date this Agreement is executed (collectively "Released Claims").

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### **2. Claims Covered by General Release:**

Except as set forth herein, the Released Claims include, but are not limited to, those that have been or could be asserted against any Releasee arising out of, in connection with, or in any way related to (a) Employee's employment with, or separation from, Theravance; (b) any term or condition of Employee's employment with Theravance, including but not limited to any and all disputed wages, compensation, salaries, commissions, pay, allowances, monies, expenses/reimbursements, employee benefits, sick/vacation pay, paid leave benefits, any other disputed wage and hour related claims, and any other benefits, penalties, interest, damages, and promises related to the same; and (c) any claims to any equity interest in Theravance, including without limitation stock options, shadow stock, restricted stock, membership units, distribution rights, partnership, stock, and all other forms of equity.

Without limiting the foregoing, by way of example only and except as set forth herein, the Released Claims also include any and all claims for severance benefits, attorneys' fees, indemnification, injunctive relief, breach of contract, promissory estoppel, quantum meruit, breach of the covenant of good faith and fair dealing, violation of public policy, intentional or negligent infliction of emotional distress, intentional or negligent misrepresentation, fraud, defamation, negligent hiring/supervision, assault/battery, constructive discharge, wrongful discharge, retaliation, claims under Title VII of the Civil Rights Act of 1964, the Civil Rights Act of 1964, the Private Attorneys General Act of 2004 ("PAGA"), the Civil Rights Act of 1866, the Americans with Disabilities Act, the Unruh Act, the Family and Medical Leave Act, the Worker Adjustment and Retraining Notification Act, the Older Workers Benefit Protection Act, the Age Discrimination in Employment Act, the California Fair Employment and Housing Act, the California Labor Code, California Wage Orders, the California Business and Professions Code, the California Family Rights Act, the Pregnancy Disability Leave law, the California Constitution, and any other statutory, regulatory or common law claims relating to employment.

Except as set forth herein, all Released Claims are forever waived and barred by this Agreement regardless of the forum in which they may be brought. The Parties intend for this release to be as broad as legally permissible.

**C. Waiver of Unknown Claims – Civil Code Section 1542**

In furtherance of the intent to waive, release and discharge Theravance from any and all Released Claims, whether known or unknown, Employee understands and agrees that except as set forth herein the Release stated in paragraph B applies to claims known and presently unknown by Employee; and that this means that if, hereafter, Employee discovers facts different from or in addition to those which Employee now knows or believes to be true, that the release and waiver in paragraph B shall be and remain effective in all respects notwithstanding such different or additional facts or the discovery of such facts.

Accordingly, Employee hereby expressly and knowingly waives, fully and forever, any and all rights and benefits conferred upon Employee by the provisions of Section 1542 of the Civil Code of the State of California and any statutes or legal principles of like effect of any other jurisdiction. Civil Code Section 1542 states:

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**A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.**

**D. Matters Excluded From Released Claims**

Notwithstanding the terms of paragraphs B and C, nothing contained in this Agreement shall be deemed to be a release or waiver by Employee of any claim which cannot be waived or released by private agreement. In addition, the Released Claims in Paragraph B hereof shall not include: (a) any benefit entitlements vested as of the date Employee's employment ended, including pursuant to written terms of any applicable employee benefit plan governed by the Employment Income Security Act of 1974 ("ERISA"); (b) rights under Workers' Compensation or Unemployment Insurance law; (c) rights if any under any equity or stock option grant previously made to employee; and (d) rights arising under this Agreement.

This Agreement shall not prohibit Employee from filing a claim with a government agency that is responsible for enforcing a law such as the Securities and Exchange Commission ("SEC"), the National Labor Relations Board ("NLRB"), the Equal Employment Opportunity Commission ("EEOC"), the Department of Fair Employment and Housing ("DFEH"), the Office of Federal Contract Compliance Programs ("OFCCP") or the Occupational Safety and Health Administration ("OSHA"). However, unless subject to legal requirements to the contrary, if any, Employee understands that by entering this Agreement, Employee will not be entitled to recover any monetary damages or any other form of personal relief in connection with such a claim, investigation or proceeding.

This Agreement shall not be construed to prohibit Employee from providing information regarding Employee's former employment relationship with Theravance as may be required by law or legal process, or from cooperating, participating or assisting in any government or regulatory entity investigation or proceeding.

**E. Proprietary Information**

Employee acknowledges that Employee signed the Theravance Biopharma US, Inc. Proprietary Information and Inventions Agreement ("PIIA") in connection with Employee's employment with Theravance. Employee represents that Employee has not breached the PIIA, including but not limited to by retaining possession or control of any Proprietary Information, Company Documents and/or other Theravance materials, or causing another person or persons to retain possession or control of Proprietary Information, Company documents and/or other Theravance materials, in violation of the PIIA. Employee understands that the terms of the PIIA

survive the termination of Employee's employment and shall remain binding and enforceable against Employee. Notwithstanding anything herein to the contrary, an individual shall not be held criminally

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or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order. Nothing herein is intended, or should be construed, to affect the immunities created by the Federal Defend Trade Secrets Act of 2016 or any similar state law.

If Employee does not possess a copy of the PIIA that Employee signed, a copy may be obtained by contacting Charissa Shaughnessy, [cshaughnessy@theravance.com](mailto:cshaughnessy@theravance.com), (650) 465-4546.

**F. Governing Law**

The Parties hereby agree that California law shall govern the construction, interpretation and enforcement of this Agreement.

**G. Severability**

The Parties agree that if any provision, or portion thereof, of this Agreement shall for any reason be determined to be invalid, unenforceable or contrary to public policy or any law, it shall if possible be interpreted, modified or reformed as necessary to be enforceable. If it cannot be interpreted, modified or reformed to be enforceable, such provision or portion thereof that is determined to be invalid, unenforceable, contrary to public policy or law shall be severed and deemed null and void, leaving the remainder of this Agreement in force and effect as a separation agreement and release of claims.

**H. Consideration Period**

Employee will have twenty-one (21) days from February 29, 2024 within which to consider this Agreement and to decide whether to enter it; however, Employee is free to execute it at any time before the expiration of the consideration period. Employee is hereby is advised to consult with an attorney regarding this Agreement; however, Employee is not required to do so.

**I. Signing Agreement**

If Employee decides to enter this Agreement, it must be signed electronically by completing the DocuSign process linked on the signature line on page 6. Agreements signed and accepted by the DocuSign process will be automatically forwarded to Theravance. Employee will not be eligible to sign this Agreement until on or after the Termination Date.

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**J. Revocation**

Employee will have seven (7) days following Employee's signing of this Agreement to revoke Employee's acceptance of it. To revoke, Employee must deliver a written statement of revocation to Charissa Shaughnessy, cshaughnessy@theravance.com by e-mail or mail or delivery of a physical document addressed to Charissa Shaughnessy, 901 Gateway Boulevard, South San Francisco, CA 94080, no later than midnight on the seventh (7th) day after Employee signed this Agreement. If Employee revokes within seven (7) days, Employee will receive no benefits under this Agreement.

**K. Effective Date**

If Employee signs and does not exercise Employee's right to revoke this Agreement, it shall become effective on the eighth day after Employee signs it. The severance payment provided for herein shall be paid to Employee on or by the normal Theravance payday following the next payday after the Agreement becomes effective. COBRA payment and coverage will become effective retroactive to March 1, 2024 if Employee completes the required COBRA documentation. Receipt of severance benefits is expressly conditioned on Employee's compliance with the terms of this Agreement, and return of all Theravance property, except for Theravance property Employee receives written permission to retain.

**L. Effect of Agreement**

This Agreement, once it has been executed by Employee and has become effective and fully enforceable, will be a full and complete defense to any action or proceeding initiated or prosecuted by Employee concerning rights released and waived herein. If Employee does not sign this Agreement or revokes Employee's acceptance after signing Employee will not receive the severance benefits set forth in paragraph A.

**M. Entire Agreement**

This Agreement constitutes the entire agreement between the Parties regarding the matters set forth herein, and no amendment or modification will be effective unless in writing and signed by the party against whom enforcement is sought. This Agreement supersedes and replaces all agreements currently in effect between Employee and Theravance regarding the subjects addressed herein, except for those agreements expressly identified herein as continuing in effect.

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I knowingly and voluntarily agree to the terms of this Agreement.

Dated: 2/29/2024

By: /s/ Richard Graham

Signature

Richard Graham

Print Name

Dated: February 29, 2024

**Theravance Biopharma US, Inc.**

[Theravance Biopharma Ireland Letterhead]

13 December 2019

**STRICTLY PRIVATE & CONFIDENTIAL**

Aine Miller, PhD

**Re: Offer of Employment**

Dear Dr. Miller:

On behalf of Theravance Biopharma Ireland Limited (the “**Company**”) I am pleased to offer you employment in the position of Vice President, Regulatory Affairs with the anticipated start date of 10 February 2020.

It is a condition of this offer that:

- (a) your references are satisfactory to the Company;
- (b) you supply certification to prove that your qualifications and prior work experience are accurately stated in your application;
- (c) you supply proof of your car insurance coverage and your driver's licence; and
- (d) you are free from any obligations owed to a third party which might prevent you from starting work on the date mentioned above or from properly performing the duties of your position.

If you are in any doubt about any of the foregoing, you may wish to talk to Human Resources in order to clarify the matter.

Please note that if you accept this offer of employment, you will be employed by the Company under the terms and conditions outlined in the enclosed contract of employment.

If you wish to accept this offer, please sign and return the attached employment contract to me by hand or email by Thursday, 19 December 2019.

Yours sincerely,

/s/ Ann Brady

Dr. Ann Brady

President, Theravance Biopharma Ireland Limited

[Theravance Biopharma Ireland Footer]

**EMPLOYMENT CONTRACT OF INDEFINITE DURATION****Employee Name:**

Dr. Aine Miller

**Employer Name:** Theravance Biopharma Ireland Limited

**Employment Start Date:** 10 February 2020

[continued]

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## TERMS AND CONDITIONS OF EMPLOYMENT

### 1. Commencement of Employment

1.1 Your employer is Theravance Biopharma Ireland Limited (the “Company”) having its registered office at Connaught House, 1 Burlington Road, Dublin 4, D04 C5Y6

1.2 Your employment with the Company will begin on 10 February 2020 (the “Commencement Date”).

### 2. Probationary Period

2.1 The first six months of your employment will be probationary. Your performance and suitability for continued employment will be reviewed during your probationary period.

2.2 Should the Company be dissatisfied or consider you unsuitable for any reason, your employment may be terminated by the Company on one months' notice at any time during or at the end of the probationary period. Alternatively, the Company may choose to extend the probationary period for a further period of up to six months on the same terms.

2.3 The Company's Disciplinary Procedure will not apply to your employment during the probationary period or any extension thereof.

### 3. Appointment, Duties and Reporting

3.1 You are employed as Vice President, Regulatory Affairs. A job description for your role is attached at Appendix 1. You may be required to undertake other duties and carry out other such reasonable instructions from time to time as the Company may reasonably require. The Company reserves the right to change your area of work, specific responsibilities and/or reporting line, as the needs of the business require.

3.2 You will report directly to Gary Barrera or such other direct supervisor as the Company may designate from time to time. Your reporting line may change to reflect changes in the Company's business organisation in which event you will report to such other officer in the Company as may be notified to you from time to time.

3.3 The initial priorities and objectives of the role have been discussed with you. In this role, you shall:

- (a) faithfully and diligently perform such job duties and exercise such powers in relation to the Company and its business, not being inconsistent with the position, as the Company shall from time to time assign to you;

- (b) in the discharge of such duties and in the exercise of such powers, observe and comply with all lawful directions, resolutions, policies, procedures and regulations from time to time made or given by the Company or an Associated Company;
- (c) devote the whole of your time and attention during business hours to the discharge of the duties hereunder and use your best endeavours to promote the interests, welfare and reputation of the Company;
- (d) observe and adhere to all health and safety regulations in force from time to time;

- (e) except to the extent, if any, permitted by the Company's or an Associated Company's code of business conduct, not directly or indirectly give or receive gifts, incentives or inducements to or from any person or company in the carrying out of any activity in connection with the Company and/or any Associated Company; and
- (f) not in any way pledge the credit of the Company or expose the Company to any pecuniary liability except so far as you may be authorised from time to time to do so by the Company whether generally or in any particular case.

3.4 Without prejudice to the generality of the foregoing, you acknowledge that you will be expected to perform and carry out all job duties, acts and obligations and to comply with such directions as may be designated by the Company to be reasonably consistent with your position. You acknowledge that during the course of your employment with the Company, it may be necessary to expand or alter your duties within the general scope of your position. Without prejudice to the generality of the provisions of this clause, your key duties and responsibilities shall include those reasonably notified by the Company to you from time to time.

3.5 You warrant that by virtue of entering into this Employment Contract, you will not be in breach of any express or implied terms of any contract with or of any other obligation to any third party binding upon you.

3.6 You shall at all times during the continuance of this Employment Contract operate to a high degree of integrity and performance and shall comply with the Company's and any Associated Company's code of business conduct and with any other policies or regulations as may apply to the Company from time to time.

3.7 You shall not engage in any activities or do or fail to do anything which would undermine the Company's trust and confidence in you.

3.8 You shall (without further remuneration) if and for so long as the Company requires:

- (a) carry out the duties of your appointment on behalf of any Associated Company;
- (b) hold any other appointment or office as nominee or representative of Company or any Associated Company; and
- (c) carry out such duties on any such appointment as if they were duties to be performed by you on behalf of the Company.

- 3.9 You may not during your employment, without the prior written consent of the Company, be in any way, directly or indirectly, actively engaged or concerned in any other business where this is likely to be in conflict with the interests of the Company.

If you are in any doubt as to the application of this clause, you should consult the Company signatory above.

#### 4. Place of Work

- 4.1 You will be based at the Company's business premises currently located at Connaught House, 1 Burlington Road, Dublin 4, D04 C5Y6 or such other place as the Company may reasonably determine.
- 4.2 The Company reserves the right to relocate and/or establish further operations in Ireland, and you may be required to transfer to another department, subsidiary

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and/or place of work, without additional compensation.

- 4.3 You acknowledge and agree to travel within Ireland or abroad as may be required in carrying out your duties.

#### 5. Hours of Work

- 5.1 Normal office hours are between 9am and 5.30pm Monday to Friday, which includes a daily rest break of one hour. The Company reserves the right to change your working hours and start/finish times on reasonable notice.
- 5.2 You may be required to work such additional hours from time to time as may be necessary for the proper performance of your duties as reasonably required by the Company up to an average of 48 hours per week.
- 5.3 You are not eligible to receive any overtime pay or time off in lieu in respect of any work carried out by you outside of your normal working hours up to 48 hours per week.

#### 6. Remuneration

- 6.1 Your base salary will be €290,000 gross per annum (and pro-rata for any lesser period) and will be paid monthly in arrears in equal instalments less statutory and any other agreed deductions. Your monthly net base salary will be deposited electronically to such bank account as you may designate in writing.
- 6.2 The Company may at its absolute discretion pay you a bonus of up to 30% (thirty percent) in each calendar year subject to such conditions as the Company may in its absolute discretion determine taking into account specific performance targets to be notified to you and a review of your individual performance. In order to be eligible for a bonus entitlement, you must have remained in continuous service through the date that annual bonuses are paid and your bonus will not exceed 100%. You must be an active employee in good standing at the time the bonus is paid in order to receive the bonus.



- 6.3 Any bonus payment shall be purely discretionary and shall not form part of your contractual remuneration under this Employment Contract. If the Company makes a bonus payment to you in respect of a particular financial year of the Company, it shall not be obliged to make subsequent bonus payments in respect of subsequent financial years of the Company. The Company may alter the terms of any bonus targets or withdraw them altogether at any time without prior notice. In any event, you shall have no right to a bonus or a time apportioned bonus if your employment terminates for any reason or you are under notice of termination (whether given by you or the Company) at or prior to the date when a bonus might otherwise have been payable.
- 6.4 Your salary shall be reviewed annually at the Company's discretion without affecting the other terms of your employment. There is no obligation to award an increase. Your salary will not be reviewed after notice has been given by either party to terminate your employment.
- 6.5 The Company shall be entitled at any time during your employment, or on termination, to deduct from your remuneration any monies due from you to the Company including but not limited to any outstanding loans, advances, training costs, the cost of repairing any damage or loss to Company property caused by you (and of

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recovering the same), any sums due under this contract and any other monies owed to the Company for any reason. By signing this contract, you hereby consent to any such deductions being made.

- 6.6 As the details of your salary and terms and conditions of employment with the Company are personal and confidential to you, it is the Company's policy that employees are not permitted to discuss the details of the terms and conditions of their employment with other employees excluding your direct manager, members of the Company's management team and HR.

## 7. Access to a Personal Retirement Savings Account

- 7.1 Employees are provided with access to a Pension Scheme.

## 8. Employee Benefits

- 8.1 You may be eligible for participation in the benefit plans as may be specified in this Employment Contract and such other benefit plans as may be approved in writing by the Company and specifically notified to you from time to time. Participation in such benefit plans shall be subject always to the rules and conditions applicable to each such plan. The Company reserves the right at all times to vary or discontinue any benefit plans in which you may be entitled to participate. The Company shall also have the right to substitute new benefit plans for any plan in which the Company may be eligible to participate. The Company shall be under no obligation to replace any terminated or discontinued benefit plan(s) and/or to provide the same or similar benefits in lieu thereof.
- 8.2 Any Company benefit plan which is insured will be subject to and conditional upon the terms and conditions of the relevant policy of insurance and the decisions of the insurer.

- 8.3 All benefits payable or otherwise made available to you under any Company benefit plan(s) in which you may be entitled to participate from time to time shall automatically cease, as shall your eligibility to participate in such plan(s), upon the termination of your employment for any reason whatsoever. In the event of the termination of your employment, the Company shall be under no obligation to replace the terminated or discontinued benefit plan(s) and/or provide the same or similar benefits in lieu thereof.
- 8.4 The Company will provide the following benefits to you:
- (a) The Company provides VHI Theravance Biopharma Healthcare Plan in respect of yourself, your spouse and dependent children up to 25 years if full time education or otherwise up to 18 years (subject to any statutory tax deductions).
  - (b) You shall be entitled to participate in the Theravance Biopharma, Inc. Employee Stock Purchase Plan, subject to the terms and conditions of that plan and the Irish Addendum thereto.
  - (c) A Car Allowance amount of €1,000 gross per month. This will be paid monthly as an additional payment in your monthly salary and is subject to statutory deductions. Insurance, maintenance, taxes and registration costs will be borne by you.
- 8.5 Subject to the approval by the appropriate committee of the Theravance Biopharma, Inc. Board of Directors, you will be granted an option to purchase 37,500 ordinary shares of Theravance Biopharma, Inc., at a share purchase price equal to the fair

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market value of one Theravance Biopharma, Inc. ordinary share on the date of grant, which we anticipate will be on or around the first business day of the month following your commencement date. The number of shares subject to the option and the vesting and exercise details of your option grant will be set forth in your option paperwork, but in general your option will vest monthly over the first four years of your employment with a one year "cliff provision" that prevents it from being exercised before the first anniversary of the grant date. The option granted to you will be contingent on your execution of Theravance Biopharma, Inc.'s standard form of option agreement and will be subject to all of the terms and conditions contained in the Theravance Biopharma, Inc. Employee Equity Plan (or other applicable equity incentive plan as directed by the Board of Theravance Biopharma, Inc., in its sole discretion).

- 8.6 Subject to the approval by the appropriate committee of the Theravance Biopharma, Inc. Board of Directors, you will also be granted a restricted share unit (RSU) award for 18,750 ordinary shares of Theravance Biopharma, Inc. The RSU award will be subject to the terms and conditions applicable to restricted share units awarded under the Company's applicable Equity Incentive Plan and shall be evidenced by the applicable form of RSU agreement as approved by the committee. The RSU award will vest as follows: 25% of the RSUs will vest on the first Company Vesting Date after the first anniversary of the grant date; 25% of the shares will vest on the first Company Vesting Date after the second anniversary of the grant date; 25% of the shares will vest on the first Company Vesting Date after the third anniversary of your grant date; and 25% of the shares will vest on the first Company Vesting Date after the fourth anniversary of the grant date, provided you remain in continuous service through each such vesting date, and as described in the applicable RSU agreement. A "Company Vesting Date" means February 20, May 20, August 20 or November 20.

- 8.7 You will be liable for any benefit-in-kind tax that may arise in connection with the provision of employee benefits provided for by the Company.

## 9. Expenses

- 9.1 All properly vouched and authorised expenses incurred by you on Company business that are directly related to your job functions or to the business of the Company will be reimbursed by the Company in accordance with the Company's business expense policy in effect from time to time.

## 10. Holidays

- 10.1 The Company's holiday year runs from 1 January to 31 December each year.
- 10.2 You will be entitled to 25 days of paid holidays, which includes two bank holidays, Christmas Eve and Good Friday in Ireland (in addition to statutory public holidays) and pro rata for any lesser period. You shall give at least two weeks' notice in writing of any proposed holiday dates and these must be approved by your manager.
- 10.3 Unused holidays may not be carried forward from one year to the next unless otherwise approved by your manager in writing and, if granted, must be taken within 3 months of the ending of the leave year.
- 10.4 Upon termination of your employment you will be entitled to salary in lieu of any outstanding holiday entitlement or be required to repay to the Company any salary received in respect of holiday taken in excess of your holiday entitlement and the amount so due will be deducted from your final salary or other termination payment.

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- 10.5 The Company may require you to take any accrued but unused holiday entitlement during the notice period or, if applicable, any such holiday shall be deemed to be taken during the Garden Leave Period (as defined below).

## 11. Sickness Absence

- 11.1 If you are absent from work due to illness, injury accident or any other circumstances, you must notify your manager of the reason for your absence as soon as possible but no later than 10.00 am on the first day of absence. Notification or text message is not acceptable.
- 11.2 If you are absent from work due to sickness, illness or other medical incapacity, the rules of the Company Sick Leave policy, as amended from time to time and which can be obtained from HR, will apply.
- 11.3 For any period of absence due to sickness or injury which lasts for three consecutive days or more, a doctor's certificate stating the reason for absence must be obtained at your own cost and supplied to your manager. Further certificates must be obtained if the absence continues for longer than the period of the original certificate.
- 11.4 You will be eligible to be paid for up to 90 days of sick leave (less any illness benefits received from the State) in any 12 month period in accordance with the Company's Sick Leave policy. It is at the discretion of the Company whether any payment is made to employees under its Sick Leave Policy.

- 11.5 You agree to consent to and attend at a medical examination (at the Company's expense) by a doctor and/or medical practitioner nominated by the Company should the Company so require. You agree that any report produced in connection with any such examination may be disclosed to the Company and the Company may discuss the contents of the report with the relevant doctor and/or medical practitioner and its advisers.

## 12. Termination with Notice

- 12.1 You shall be entitled to terminate your employment at any time by giving the Company three months prior notice in writing. The Company may also terminate your employment at any time by also giving three months prior notice in writing.
- 12.2 Where notice of termination of your employment is given, whether by you or the Company, the Company will have the right to:
- (a) pay you in lieu of notice the amount of your entitlement to basic salary in respect of such notice period; or
  - (b) require you to cease performing or exercising during some or all of the remainder of any notice period some or all of the powers, authorities and discretions delegated to you in your employment and/or to cease attending your place of work and/or to cease contact with the Company's employees and customers in relation to business matters, during such period, any such period to be referred to hereinafter as a "Garden Leave Period". During a Garden Leave Period, you will remain subject to the provisions of this Employment Contract and to your obligation of fidelity to the Company and you will continue to receive your normal remuneration and benefits.

## 13. Termination without Notice

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- 13.1 The Company reserves the right to terminate your employment without prior notice, or with payment in lieu thereof, if at any time you:
- (a) are guilty of any gross misconduct, gross negligence or wilful neglect in the discharge of your duties of your employment or in connection with or affecting the business of the Company and/or any Associated Company;
  - (b) are guilty of any material breach or material non-observance or persistent breaches or non-observances of the provisions contained in this Employment Contract;
  - (c) commit any serious act of fraud, dishonesty or repeated acts of dishonesty;
  - (d) are convicted of any offence other than minor traffic offences for which the non-custodial sentence is imposed or any other offence which in the opinion of the Company does not affect your position with the Company;
  - (e) are guilty of any material or repeated breach of any Company policy or procedure; and/or
  - (f) any other reason that is sufficient in law to terminate your employment without prior notice.

#### 14. **Grievance and Disciplinary Procedures**

- 14.1 Your attention is drawn to the disciplinary and grievance procedures applicable to your employment, copies of which are available from HR and posted on the intranet.
- 14.2 Whilst it is Company policy to observe its disciplinary procedure, strict observance of the procedure is not appropriate in all cases. Circumstances may warrant that the procedure is abridged or varied and the Company reserves the right to do so at any time. The disciplinary and grievance procedures do not form part of your contract of employment.
- 14.3 The Company reserves the right to suspend you at any time with pay pending an investigation or pending the outcome of any disciplinary process (including any disciplinary appeals process).
- 14.4 The Company reserves the right in case of your infringement of its rules, policies, procedures or terms and conditions to demote, re-deploy and/or suspend you with or without pay. If you are suspended without pay as a disciplinary sanction, the period of suspension will vary in length at the Company's discretion according to the gravity of the misconduct.
- 14.5 If you have any grievance relating to your employment you should ideally raise it in the first instance with your manager. All grievances must be dealt with in accordance with the Company Grievance Procedure, a copy of which will be made available to you upon request.

#### 15. **Health and Safety**

- 15.1 You must comply with the health and safety policies of the Company that apply to the Company's employees and other persons working at the Company's premises and should familiarise yourself with same on the commencement of

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your employment.

- 15.2 You are bound to comply with the duties imposed upon employees by the Safety, Health and Welfare at Work Act 2005 or any substitution thereof or amendment or alteration thereto and the Regulations made or to be made thereunder and in particular with the duty of the Act which requires you to:
- (a) take reasonable care for the health and safety of yourself and of others who may be affected by your acts or omissions at work; and
  - (b) with regard any duty imposed on the Company or any other person, to cooperate with it/them insofar as is necessary to enable that duty to be performed or complied with.

#### 16. **Confidential Information**

- 16.1 You must not, without appropriate authority either disclose to any third party or use any trade secrets or confidential information about the Company's business and/or the Group or that of customers, suppliers or employees, nor may you without appropriate authority make or possess copies of documents or other media on which such information is recorded. You shall continue to honour this obligation after the termination of your employment.

16.2 A non-exhaustive list of examples of information which is confidential information, whether or not the information is marked or treated as confidential, for the purposes of this clause is as follows:

- (a) business methods and confidential financial information (including but not limited to prices charged, discounts given to customers or obtained from suppliers, product development, marketing and advertising programmes, costings, budgets, turnover, sales targets, rebates or other financial information) of the Company and/or the Group;
- (b) lists and particulars of customers, suppliers and employees and their arrangements with the Company and/or the Group and the individual contacts at such suppliers and customers;
- (c) details and terms of the Company's and any Group Company's agreements with suppliers and customers;
- (d) confidential details as to the design of the Company's and any Group Company's and its and/or their suppliers' products and inventions or developments relating to future products;
- (e) confidential details of trade and production processes, know how, research and development projects, inventions, formulae and formulations, quality control, product design, technical design or specifications and materials used including the development, creation and/or production of software applications or the Company and/or any Group Company;
- (f) current business activities and future plans of the Company and any Group Company relating to all or any development, production, marketing strategies, publicity or sales including the timing of all such matters;

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- (g) information about third parties which the Company and any Group Company is required to keep confidential including but not limited to information about suppliers and customers and their production and delivery capabilities.

16.3 Nothing in this clause prevents you from disclosing information:

- (a) you are authorised by the Company to disclose; or
- (b) has entered the public domain unless it enters the public domain as a result of an unauthorised disclosure by you or an authorised disclosure for an unauthorised purpose by you or anyone else employed or engaged by the Company or any Group Company; or
- (c) you are required to disclose by law.

## 17. Intellectual Property

17.1 You acknowledge and agree that any Intellectual Property arising from your employment with the Company shall belong to and be the absolute property of the Company and you undertake not to dispute the Company's ownership of such Intellectual Property.

- 17.2 You shall provide to the Company full details of all Intellectual Property arising from your employment with the Company. To the extent that the Intellectual Property Rights have not automatically vested in the Company through operation of law (and in accordance with clause 17.1 above), you hereby agree to assign and do hereby expressly assign to the Company all Intellectual Property Rights for their full term throughout the world including without limitation the right to sue for any infringement or threatened infringement of any such Intellectual Property Rights, title or interest whether such infringement or threatened infringement occurs prior to or after the execution of this contract and you waive all moral rights you may have in respect of such Intellectual Property.
- 17.3 You agree if and whenever required to do so (whether during or after the termination of this contract) at the expense of the Company to do all things necessary, execute such deeds and documents and provide all such assistance as the Company may reasonably require to enable the Company to obtain and maintain the benefit of all Intellectual Property Rights in any part of the world and you acknowledge that you will not be entitled to any further compensation or fees in respect of the performance of your obligations under this clause save as may be provided for by law.
- 17.4 You irrevocably appoint the Company (or any nominee of the Company) to be your attorney or agent in your name and on your behalf to do all such acts and things and to sign all such deeds and documents as may be necessary in order to give the Company the full benefit of the provisions of this clause and you agree that a certificate in writing in favour of any third party signed by any duly authorised officer of the Company that any act or thing or deed, document or instrument falls within the authority hereby conferred shall be conclusive evidence that this is the case.
- 17.5 The obligations of the parties under this clause 17 shall survive the expiry or the termination of this contract for whatever reason.
- 17.6 In this clause 17 the following expressions have the following meanings:
- (a) **"Intellectual Property"** means without limitation, patents, inventions, know how, trade secrets and other confidential information, rights in design (registered and unregistered), copyright including copyright works, data,

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database rights and sui generis rights, rights affording equivalent protection to copyright, semiconductor topography rights, trade marks, service marks, logos, domain names, business names, trade names, brand names, certification marks, assumed names and other indicators or origin, and all other industrial or intellectual property developed, discovered, acquired, conceived or made by you in connection with your employment with the Company;

- (b) **"Intellectual Property Rights"** means present or future rights title and interest and applications for rights title and interest or forms of protection of similar nature or having similar effect in one part of the world, or relating to Intellectual Property and copyright works including (without prejudice to the generality of the foregoing) author certificates, inventor certificates, improvement patents, utility certificates, moral rights, models and certificates of addition and including any divisions, renewals, continuation, extensions or reissues thereof and rights in the nature of unfair competition rights and rights for passing off.

## 18. Data Protection

- 18.1 The Company holds personal information about you which is subject to the General Data Protection Regulation (GDPR) and the associated ancillary local laws. By signing this contract you acknowledge and accept the Company's processing, both manually and by electronic means, your personal and sensitive personal data for the purposes of the administration and management of your employment and/or the Company's business (which may include investments in the Company or the sale of the Company or any part thereof).
- 18.2 In addition, the Company may from time to time require that the personal information is transferred within the Group, outside of the European Economic Area (including to the U.S.) and also to third party service providers as necessary for the purpose of administering your employment entitlements (e.g. Revenue Commissioners, occupational health advisors, payroll providers, benefit providers).
- 18.3 Your data will be retained for the duration of your employment plus an additional period (typically 7 years but possibly longer where required by law) to address the relevant retention and limitation periods determined by law. The Company will treat all personal/sensitive personal data as confidential and will not use or process it other than for legitimate purposes. The Company will ensure that the information is accurate, kept up to date and not kept for longer than is necessary. You have the right to access your personal data stored by the Company pursuant to the Acts. Measures will also be taken to safeguard against unauthorised or unlawful processing and accidental loss or destruction or damage to the data. You must let the Company know of any material change in your personal data (e.g. address, contact details, next of kin for emergency contact purposes, etc.).
- 18.4 The Company will process your personal information in accordance with data protection laws and you can consult the Company's Data Protection Policy for details about how to exercise your rights in respect of your data. The Company relies on you as an employee to comply with all applicable workplace policies and procedures governing the use of Company facilities and the use and disclosure of data, with which you must comply.

## 19. Computer Usage, Access to Internet and Email

- 19.1 It is necessary for the Company to protect its interests by monitoring computer usage and all communications on its private networks (including office telephone

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networks and email systems). You understand and accept that the Company may legitimately monitor any communications sent or received by you either in the performance of your duties or by way of the Company's networks and consent to such monitoring for the purposes of:

- (a) Ensuring proper working order of the IT systems;
- (b) Ensuring that employees comply with the Company's practices and procedures;
- (c) Investigating misconduct;
- (d) Preventing or detecting crime; and
- (e) Investigation or detecting the unauthorized use of the Company's IT systems.



19.2 For the purpose of this clause:

- (a) **“monitoring”** means the checking, recording, and reviewing of telephone calls, computer files, records and emails and the undertaking of any other compliance, security or risk analysis checks the Company reasonably considers necessary; and
- (b) **“networks”** includes the Company's telephone, voicemail system and the Company's email, intranet and intranet networks.

19.3 You undertake at all times, to comply with all conditions of use which may from time to time be imposed by the Company with regard to the use of the equipment networks and systems provided by the Company including without limitation the Company's internet, intranet, social media and email policy. A breach of these policies or any unauthorized use of a Company computer may result in disciplinary action up to and including dismissal. You are advised that where appropriate and available, evidence such as CCTV footage, web-logs, etc. will be used by the Company in the context of internal investigations and/or disciplinary proceedings.

## 20. Searches

The Company reserves the right to search employees on entering or leaving the Company's premises, as well as any package, handbag, motor vehicle or other items which are brought by employees on to the Company's premises. Should a need for this arise, the reason for the search will be explained to you by your manager or a representative from HR, who will undertake the search in the presence of another member of staff.

## 21. Lay-Off and Short Time

21.1 The Company reserves the right to lay you off without pay and/or place you on short time and effect a proportionate reduction in pay, where this is deemed by the Company to be necessary for business reasons.

## 22. Changes to your Terms of Employment

22.1 The Company reserves the right to make reasonable changes to the terms and

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conditions of your employment as the requirements of the business dictates. You will be notified in writing of any change as soon as possible and any material changes will be subject to your prior consent.

## 23. Previous Contracts

23.1 This Employment Contract over-rides and supersedes all (if any) previous offers, understandings, representations and/or agreements with the Company concerning the terms and conditions applicable to your employment. You confirm that you are not entering into employment with the Company in reliance upon any representations or warranties not expressly set out in this letter.

## 24. Restrictive Covenants

24.1 In this clause 24:

**Associated Company:** is as defined in clause 27.7.

**Board:** means the board of directors of the Company (including any committee of the board duly appointed by it).

**Capacity:** means as agent, consultant, director, employee, owner, partner, shareholder or in any other capacity.

**Confidential Information:** means information (whether or not recorded in documentary form, or stored on any magnetic or optical disk or memory) which is not in the public domain relating to the business, products, affairs and finances of the Company and/or Associated Company for the time being confidential to the Company and/or Associated Company and trade secrets including, without limitation, technical data and know-how relating to the business of the Company and/or Associated Company and/or their customer, business partner and client contacts.

**Employment:** means your employment by the Company on the terms of this Contract.

**Garden Leave:** means any period during which the Company has exercised its rights under clause 12.2(b).

**Prospective Customer:** means any person with whom the Company or any Associated Company is in negotiations or is tendering in relation to the sale/supply of its goods, products, services.

**Prospective Supplier:** means any person with whom the Company or any Associated Company is in negotiations or is tendering in relation to the sale/supply of its goods, products, services.

**Restricted Business:** means a biopharmaceutical company involved in the discovery, development and commercialization of products and product candidates in antibiotics and infectious disease, respiratory disease, gastrointestinal disease and/or cardiovascular and renal diseases.

**Restricted Customer:** means any firm, company or person who, during the 12 months before the Termination Date, was a customer or Prospective Customer of the Company or any Associated Company with whom you had contact in the course of your employment.

**Restricted Person:** means anyone employed or engaged by the Company or any Associated Company as an executive director, senior manager or in a key technical or

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commercial role at any time during the 12 month period before the Termination Date who, by means of such employment, is or is likely to be in possession of Confidential Information relating to the Company or any Associated Company and with whom you had dealt, in the 12 months before the Termination Date, in the course of your employment.

**Restricted Supplier:** means any firm, company or person who, during the 12 months before the Termination Date, was a supplier or Prospective Supplier to the Company or any Associated Company with whom you had contact in the course of your employment.

**Termination Date:** means the date of termination of your employment with the Company howsoever caused.

**Territory:** means the island of Ireland, the United Kingdom and the rest of Europe and the USA.

- 24.2 In order to protect the Confidential Information and business connections of the Company and each Associated Company to which you have had access as a result of the Employment, you covenant with the Company (for itself and as trustee and agent for each Associated Company) that you shall not:
- (a) for 6 months after the Termination Date, solicit or endeavour to entice away from the Company or any Associated Company the business or custom of a Restricted Customer with a view to providing goods or services to that Restricted Customer in competition with any Restricted Business;
  - (b) for 6 months after the Termination Date, accept any business from a Restricted Customer with a view to providing goods or services to that Restricted Customer in competition with any Restricted Business;
  - (c) for 6 months after the Termination Date, solicit or endeavour to entice away from the Company or any Associated Company any Restricted Supplier to the Company or any Associated Company with a view to providing goods or services to a Restricted Customer in competition with any Restricted Business;
  - (d) for 6 months after the Termination Date, have any dealings with a Restricted Supplier to the Company or an Associated Company with a view to providing goods or services to a Restricted Customer in competition with any Restricted Business;
  - (e) for 6 months after the Termination Date, offer to employ or engage or otherwise endeavour to entice away from the Company or any Associated Company any Restricted Person;
  - (f) for 6 months after the Termination Date, employ or engage or otherwise facilitate the employment or engagement of any Restricted Person, whether or not such person would be in breach of contract as a result of such employment or engagement;
  - (g) for 6 months after the Termination Date, be involved within the Territory in any Capacity with any business concern whose business is, intends to be or is any way related to, a Restricted Business;
  - (h) for 6 months after the Termination Date, be involved with the provision of goods or services to (or otherwise have any business dealings with) any

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Restricted Customer in the course of any business concern which is in competition with any Restricted Business; or

- (i) at any time after the Termination Date, represent yourself as connected with the Company or any Associated Company in any Capacity, other than as a former employee, or use any registered names or trading names associated with the Company or any Associated Company.

24.3 None of the restrictions in clause 24.2 shall prevent you from holding an investment by way of shares or other securities of not more than 5% of the total issued share capital of any company, whether or not it is listed or dealt in on a recognised stock exchange.

24.4 The restrictions imposed on you by this clause 24 shall apply to you acting:

- (a) directly or indirectly; and
- (b) on your own behalf or on behalf of, or in conjunction with, any firm, company or person.

- 24.5 The periods for which the restrictions in clause 24.2 apply shall be reduced by any period that you spend on Garden Leave immediately before the Termination Date.
- 24.6 If you receive an offer to be involved in a business concern in any Capacity during the Employment, or before the expiry of the last of the covenants in this clause 24 you shall give the person making the offer a copy of this clause 24 and shall inform the Company of the identity of that person as soon as possible after receiving the offer.
- 24.7 Each of the restrictions in this clause 24 is intended to be separate and severable. If any of the restrictions shall be held to be void but would be valid if part of their wording were deleted, modified or reduced in scope, such restriction shall apply with such deletion, modifications or reductions in scope as may be necessary to make it valid or effective.
- 24.8 If your employment is transferred to any firm, company, person or entity other than an Associated Company (the “**New Employer**”) pursuant to the European Communities (Protection of Employees on Transfer of Undertakings) Regulations 2003, you will, if required, enter into an agreement with the New Employer containing post-termination restrictions corresponding to those restrictions in this clause 24 protecting the Confidential Information, trade secrets and business connections of the New Employer.

## 25. **Reconstruction or Amalgamation**

- 25.1 If your employment under this Employment Contract is terminated by reason of the liquidation of the Company for the purpose of reorganisation, reconstruction or amalgamation and you are offered a contract of employment with any concern or undertaking resulting from the reconstruction or amalgamation on terms and conditions not less favourable than the terms of this Employment Contract, then you shall have no claim against the Company in respect of the termination of this contract.

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## 26. **Miscellaneous**

- 26.1 You will comply with all such employee policies, procedures, rules and practices as are applicable to your employment with the Company from time to time including those contained in the Company Handbook which will be made available to you.
- 26.2 Waiver by the Company of any breach of any term of this Employment Contract shall not prevent the subsequent enforcement of that term and shall not be deemed a waiver of any subsequent breach.
- 26.3 No material or substantial variation or amendment of this Employment Contract or oral promise or commitment relating to it shall be varied unless committed to writing and signed by and on behalf of both parties.

- 26.4 Any notice required to be given under this Employment Contract shall be given in writing and shall be delivered by hand or sent by recorded delivery post to the address of the addressee contained in this Employment Contract or as notified in writing to the other party as its address for the service of notices.
- 26.5 The parties acknowledge that this Contract contains the particulars of the Employee's employment for the purposes of the Terms of Employment (Information) Act, 1994.
- 26.6 No collective bargaining agreement applies to or covers your employment with the Company.
- 26.7 The expiration or determination of this Employment Contract howsoever arising shall not affect such of the provisions hereof as are expressed to operate or have effect thereafter and shall be without prejudice to any right of action already accrued to either party in respect of any breach of this Employment Contract by the other party.
- 26.8 This Employment Contract may be executed by the parties hereto on separate counterparts each of which when executed and delivered shall constitute an original, it being the intent that all such counterparts together shall constitute but one and the same instrument.
- 26.9 This Contract shall in all respects be governed by the laws of Ireland.

## 27. Definitions And Interpretations

- 27.1 The headings and marginal headings to the clauses are for convenience only and have no legal effect.
- 27.2 The expression the "Company" shall, unless the context otherwise requires, include any person acting on behalf of the Company within her or her proper authority.
- 27.3 Any reference to any statutory provision, or to any order or regulation shall be construed as a reference to that provision, order or regulation as extended, modified, replaced or re-enacted from time to time (whether before or after the date of this Contract) and all statutory instruments, regulations and orders from time to time made thereunder or deriving validity therefrom (whether before or after the date of this Contract).
- 27.4 Words denoting any gender include all genders and words denoting the singular include the plural and vice versa.
- 27.5 Words such as "hereunder", "hereto", "hereof" and "herein" and other words

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commencing with "here" shall, unless the context clearly indicates to the contrary, refer to the whole of this Contract and not to any particular clause, paragraph or sub paragraph thereof.

- 27.6 The expression "person" shall, unless the context otherwise requires, include partnerships, companies and other bodies corporate.
- 27.7 In this Contract:

**“Associated Company”** means any undertaking which for the time being is a subsidiary undertaking or joint venture of the Company, a holding undertaking of which the Company is a subsidiary undertaking, or a subsidiary undertaking or joint venture of such holding undertaking, or an undertaking in which any of the foregoing has a participating interest

(the terms “undertaking”, “subsidiary undertaking” and “holding undertaking” each having the meaning given to it in section 275 of the Companies Act 2014, and the terms “joint venture” and “participating interest” each having the meaning given to it in Schedule 4 to that Act).

**“Group”** means the Company and all companies which are from time to time Associated Companies;

**“Group Company”** means any company within the Group;

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Please confirm your acceptance of these terms by signing and returning to me the attached copy of this letter.

Yours sincerely,

/s/ Ann Brady

Dr. Ann Brady  
President, Theravance Biopharma Ireland Limited

ACCEPTANCE AND ACKNOWLEDGMENT

I, the undersigned Dr. Aine Miller, acknowledge receipt of the letter of offer of employment and the Employment Contract of Indefinite Duration, which I have read and understood and which correctly sets out my terms and conditions of employment. I hereby accept the Company's offer of employment and also the Employment Contract of Indefinite Duration and agree to the terms and conditions set out in those documents.

Signed: /s/ Aine Miller

Date: December 16, 2019

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**Appendix 1**

**Job Description**

**Position, Location and Scope**

Theravance is actively recruiting an accomplished Vice President, Regulatory Affairs to serve as a member of the management team reporting to the Company's Head of Quality, Regulatory and Pharmacovigilance (QRP). The successful candidate will work closely with the Head of QRP and other members of the leadership group to develop and advance Theravance's regulatory strategy and execute the regulatory vision and roadmap for the Company. This person will have over-arching responsibility for driving the successful regulatory strategy that helps advance both the clinical development of Theravance's pipeline programs as well as their commercial products. They will be an important external "face" representing the Company with regulatory agencies around the world.

The VP Regulatory Affairs will oversee the development of regulatory strategies for the Company's compounds consistent with the goals for each development project. Primary responsibilities will include developing a regulatory roadmap for pipeline development compounds. The VP RA will work closely with the Head of QRP to ensure that Theravance Biopharma maintains compliance with internal, Federal, State, International and other regulations governing drug development and marketing. They (and the Regulatory Affairs staff) will serve as the primary contact for the FDA and other regulatory agencies for all company interactions related to clinical trial and marketing applications.

The candidate filling this role will be a proven regulatory leader who has demonstrated success advancing products through the drug development process. The position will ideally be based in Theravance's South San Francisco or Dublin, Ireland headquarters.

### Specific Responsibilities

- Oversee the Regulatory Affairs function to ensure Theravance compliance with applicable internal standards, FDA and other regulations, and associated requirements for pharmaceutical development
- Pro-actively drive communications with all regulatory bodies to obtain all necessary IND's/CTA's and other regulatory pre-approvals for clinical research, as well as NDA/MAA approvals for Company products on a timely basis
- Serve as the subject matter expert to US and international regulatory authorities for site inspections, presentations, submissions, and compliance matters
- Lead the development of regulatory submissions for FDA, EMA and other international agencies
- Guide the establishment of procedures and processes that ensure document compliance with Regulatory Company guidance/template specifications and data standards
- Oversee Regulatory Affairs product files to support compliance with all regulatory requirements
- Lead, train, develop, build and guide the Regulatory Affairs department into a highly functioning team that exemplifies Theravance core values
- In conjunction with the senior leadership team, ensure that key regulatory and legislative issues are addressed by Theravance that protect the development of the company's medicines while improving patient access to care.

### Position Requirements & Experience

- BS degree in one of the physical and life sciences such as Chemistry, Biology and Microbiology required; advanced degree and/or professional certification strongly preferred
- 15+ years in the pharmaceutical industry with direct regulatory experience in submissions and FDA interactions for new drugs applications including successful NDA approvals.
- Experience developing regulatory strategies that involved Prime, Orphan, Priority, Accelerated, Breakthrough, or other abbreviated approaches to application.
- 7+ years of direct RA leadership responsibility
- Previous success managing partnership relationships
- Previous small molecule experience that includes strong working knowledge of full CMC, non-clinical

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and clinical development activities

- Strong domestic US and European experience successfully interacting with regulatory authorities
- Expert knowledge of current FDA and EMA laws, rules and relevant guidance documents
- Demonstrated leader in Regulatory Affairs writing and submission compilation
- Extensive knowledge and experience with eCTD regulatory filings/ FDA electronic submissions
- Extensive knowledge of U.S. and International regulations including cGMP, GCP, GLP, ICH guidance documents
- Strong understanding of Drug Development R&D, manufacturing, laboratory, and Quality Systems
- Specialized knowledge including:
  - o Labelling and promotional material review with OPDP (formerly DDMAC)
  - o Experience managing post-marketing CMC changes
  - o Experience with US and European pediatric drug development requirements and regulations
  - o Experience executing REMS or another extended post approval repotting or commitment program a plus
  - o Experience managing core labeling development and review
  - o Orphan Drug experience
  - o Good understanding of key functional areas including toxicology, pharmacology, chemistry / manufacturing, clinical research and biometrics

#### Personal Characteristics & Cultural Fit

- The candidate should be a highly responsible, self-motivated individual
- Professional who consistently demonstrates strong moral character and operates with integrity
- Strong leadership qualities that include defining a clear vision and mission for the Regulatory Affairs team consistent with that of the Company
- Proven ability to lead, guide, mentor, train and develop a highly functioning Regulatory Affairs team
- Exceptional leadership qualities that are identifiable and extend across the entire company
- Strong leadership skills that include a desire for accountability
- Highly collaborative working style with the ability to influence others
- Superior work ethic that includes working with an appropriate sense of urgency
- Entrepreneurial orientation with the ability to effectively operate in a dynamic environment
- Excellent organizational skills that enable the successful execution of multiple simultaneous projects
- High energy, enthusiasm and passion around the work that you do each day



STRICTLY PRIVATE & CONFIDENTIAL

Aine Miller, PHD

Re: Your employment contract dated 10 February 2020

Dear Dr. Miller:

I refer to your contract of employment dated 10 February 2020 with Theravance Biopharma Ireland Limited.

The purpose of this letter is to amend this contract to reflect the following:

- 1.1 You have now been promoted to the role of Senior Vice President, Development and Head of Ireland Office effective from 7 November 2023;
- 1.2 Your salary has increased from €290,000 gross per annum to €390,000 effective from 1 October 2023 (and to €401,700 gross per annum from 1 February 2024); and
- 1.3 You were granted a restricted share unit award for 37,500 ordinary shares of Theravance Biopharma, Inc. with a grant date of 7 November 2023 by the compensation committee of Theravance Biopharma, Inc. The RSU award is subject to the terms and conditions applicable to restricted share units awarded under the Company's applicable Equity Incentive Plan and shall be evidenced by the applicable form of RSU agreement as approved by the committee. The RSU award vests as follows: 25% on November 20, 2024; 6.25% on February 20, 2025; and an additional 6.25% on the final day of each 3-month period thereafter through November 20, 2027, provided that the recipient remains in continuous service through each such date and as described in the applicable RSU agreement. A "Company Vesting Date" means February 20, May 20, August 20 or November 20.
- 1.4 The Company may at its absolute discretion pay you a bonus of up to 50% (fifty percent) in each calendar year subject to such conditions as the Company may in its absolute discretion determine taking into account specific performance targets to be notified to you and a review of your individual performance. In order to be eligible for a bonus entitlement, you must have remained in continuous service through the date that annual bonuses are paid. You must be an active employee in good standing at the time the bonus is paid in order to receive the bonus.

Clauses 3.1, 6.1, 6.2 and 8.6 of your contract are hereby amended accordingly.

Please note this letter is supplemental to your existing terms and conditions of employment contained in your contract of employment and is not intended to replace or substitute same (with the exception of the variations to the above clauses). In all other respects the terms and conditions of your contract of employment are un-amended and continue in full force and effect.

Please acknowledge this change by signing and returning a copy of this letter.

Yours sincerely

Rick E Winningham

Director, Theravance Biopharma Ireland Limited

ACCEPTANCE

I hereby acknowledge and agree to the change to my contract of employment dated 10 February 2020.

Aine Miller

[Theravance Biopharma Ireland Footer]

Exhibit 31.1

**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.

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

**Exhibit 31.2**

**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: November 9, 2023 May 15, 2024

/s/ AZIZ SAWAF

Aziz Sawaf

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

Exhibit 32

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

I, Rick E Winningham, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Theravance Biopharma, Inc. on Form 10-Q for the three and nine months ended September 30, 2023 March 31, 2024 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition of Theravance Biopharma, Inc. at the end of the periods covered by such Quarterly Report on Form 10-Q and results of operations of Theravance Biopharma, Inc. for the periods covered by such Quarterly Report on Form 10-Q.

Date: November 9, 2023 May 15, 2024

By: /s/ RICK E WINNINGHAM

Rick E Winningham

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

**CERTIFICATION OF CHIEF FINANCIAL OFFICER  
PURSUANT TO  
18 U.S.C. SECTION 1350,**

I, Aziz Sawaf, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Theravance Biopharma, Inc. on Form 10-Q for the three and nine months ended September 30, 2023 March 31, 2024 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition of Theravance Biopharma, Inc. at the end of the periods covered by such Quarterly Report on Form 10-Q and results of operations of Theravance Biopharma, Inc. for the periods covered by such Quarterly Report on Form 10-Q.

By: /s/ AZIZ SAWAF  
Aziz Sawaf  
Senior Vice President and Chief Financial Officer  
(Principal Financial Officer)

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