

REFINITIV

## DELTA REPORT

10-Q

TBPH - THERAVANCE BIOPHARMA, INC

10-Q - SEPTEMBER 30, 2023 COMPARED TO 10-Q - JUNE 30, 2023

The following comparison report has been automatically generated

**TOTAL DELTAS 944**

█ CHANGES 256

█ DELETIONS 341

█ ADDITIONS 347

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549  
**Form 10-Q**

(Mark One)

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

For the quarterly period ended **June September 30, 2023**

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)

<b>Cayman Islands</b> (State or Other Jurisdiction of Incorporation or Organization)	<b>98-1226628</b> (I.R.S. Employer Identification No.)
--	--

<b>PO Box 309</b> <b>Ugland House, South Church Street</b> <b>George Town, Grand Cayman, Cayman Islands</b> (Address of Principal Executive Offices)	<b>KY1-1104</b> (Zip Code)
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**(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 **August 1, 2023** **November 1, 2023**, the number of the registrant's outstanding ordinary shares was **52,813,104** **49,797,866**.

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[Table of Contents](#)

**THERAVANCE BIOPHARMA, INC.**

**TABLE OF CONTENTS**

	<u>Page No.</u>
<b>PART I. FINANCIAL INFORMATION</b>	
<a href="#">Item 1. Financial Statements (unaudited)</a>	3
Condensed Consolidated Balance Sheets as of <b>June 30, 2023</b> <b>September 30, 2023</b> and <b>December 31, 2022</b>	3
Condensed Consolidated Statements of Operations and Comprehensive <b>Loss</b> <b>Income (Loss)</b> for the three and <b>six</b> <b>nine</b> months ended <b>June 30, 2023</b> <b>September 30, 2023</b> and <b>2022</b>	4
Condensed Consolidated Statements of Shareholders' Equity <b>(Deficit)</b> for the three and <b>six</b> <b>nine</b> months ended <b>June 30, 2023</b> <b>September 30, 2023</b> and <b>2022</b>	5
Condensed Consolidated Statements of Cash Flows for the <b>six</b> <b>nine</b> months ended <b>June 30, 2023</b> <b>September 30, 2023</b> and <b>2022</b>	6
Notes to Condensed Consolidated Financial Statements	7
<a href="#">Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	18 <b>19</b>
<a href="#">Item 3. Quantitative and Qualitative Disclosures About Market Risk</a>	29 <b>30</b>
<a href="#">Item 4. Controls and Procedures</a>	29 <b>30</b>
<b>PART II. OTHER INFORMATION</b>	
<a href="#">Item 1. Legal Proceedings</a>	29 <b>31</b>
<a href="#">Item 1A. Risk Factors</a>	30 <b>31</b>
<a href="#">Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</a>	61 <b>63</b>
<a href="#">Item 6. Exhibits</a>	62 <b>64</b>
<a href="#">Signatures</a>	63 <b>65</b>

[Table of Contents](#)

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2023	December 31, 2022	September 30, 2023	December 31, 2022
<b>Assets</b>				
Current assets:				
Cash and cash equivalents	\$ 105,596	\$ 298,172	\$ 71,685	\$ 298,172
Short-term marketable securities	61,855	29,312	62,318	29,312
Receivables from collaborative arrangements	15,796	16,785	17,057	16,785
Prepaid clinical and development services	979	1,513	1,634	1,513
Other prepaid and current assets	7,777	7,682	8,996	7,682
Total current assets	192,003	353,464	161,690	353,464
Property and equipment, net	9,553	11,875	9,288	11,875
Operating lease assets	38,453	40,126	37,576	40,126
Future contingent milestone and royalty assets	194,200	194,200	194,200	194,200
Restricted cash	836	836	836	836
Other assets	11,585	6,899	10,000	6,899
Total assets	<u>\$ 446,630</u>	<u>\$ 607,400</u>	<u>\$ 413,590</u>	<u>\$ 607,400</u>
<b>Liabilities and Shareholders' Equity</b>				
Current liabilities:				
Accounts payable	\$ 1,569	\$ 1,554	\$ 2,368	\$ 1,554
Accrued personnel-related expenses	5,371	10,314	6,578	10,314
Accrued clinical and development expenses	4,006	4,932	3,272	4,932
Accrued general and administrative expenses	2,874	4,020	1,903	4,020
Operating lease liabilities	9,160	6,753	9,713	6,753
Deferred revenue	24	24	24	24
Other accrued liabilities	1,542	1,118	1,510	1,118
Total current liabilities	24,546	28,715	25,368	28,715
Long-term operating lease liabilities	42,521	45,407	41,118	45,407
Future royalty payment contingency	26,556	25,438	27,165	25,438
Long-term deferred revenue	181	192	175	192
Unrecognized tax benefits	64,987	64,191	65,955	64,191
Other long-term liabilities	7,678	1,657	7,679	1,657
Commitments and contingencies				
<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; 53,694 and 65,227 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	1	1	1	1
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
Additional paid-in capital	1,172,090	1,295,725	1,146,948	1,295,725
Accumulated other comprehensive loss	(286)	(15)	(225)	(15)

Accumulated deficit	(891,644)	(853,911)	(900,594)	(853,911)
Total shareholders' equity	280,161	441,800	246,130	441,800
Total liabilities and shareholders' equity	\$ 446,630	\$ 607,400	\$ 413,590	\$ 607,400

See accompanying notes to condensed consolidated financial statements.

[Table of Contents](#)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
<b>Revenue:</b>				
Viatris collaboration agreement	\$ 13,743	\$ 10,878	\$ 24,154	\$ 21,565
Collaboration revenue	6	172	12	181
Licensing revenue	—	—	—	2,500
<b>Total revenue</b>	<b>13,749</b>	<b>11,050</b>	<b>24,166</b>	<b>24,246</b>
<b>Expenses:</b>				
Research and development (1)	9,425	14,924	23,997	38,177
Selling, general and administrative (1)	19,278	16,222	38,461	34,064
Restructuring and related expenses (1)	1,169	3,005	2,743	12,329
<b>Total expenses</b>	<b>29,872</b>	<b>34,151</b>	<b>65,201</b>	<b>84,570</b>
<b>Loss from operations</b>	<b>(16,123)</b>	<b>(23,101)</b>	<b>(41,035)</b>	<b>(60,324)</b>
Interest expense	(568)	(2,137)	(1,118)	(4,274)
Interest income and other income (expense), net	2,504	2,440	5,483	2,065
Loss from continuing operations before income taxes	(14,187)	(22,798)	(36,670)	(62,533)
Provision for income tax (expense) benefit	(1,458)	5	(1,063)	(519)
<b>Net loss from continuing operations</b>	<b>(15,645)</b>	<b>(22,793)</b>	<b>(37,733)</b>	<b>(63,052)</b>
Income from discontinued operations before income taxes	—	14,602	—	28,915
Provision for income tax expense	—	—	—	—
<b>Net income from discontinued operations</b>	<b>—</b>	<b>14,602</b>	<b>—</b>	<b>28,915</b>
<b>Net loss</b>	<b>\$ (15,645)</b>	<b>\$ (8,191)</b>	<b>\$ (37,733)</b>	<b>\$ (34,137)</b>
Net unrealized loss on available-for-sale investments	(337)	(17)	(271)	(45)
<b>Total comprehensive loss</b>	<b>\$ (15,982)</b>	<b>\$ (8,208)</b>	<b>\$ (38,004)</b>	<b>\$ (34,182)</b>
<b>Net income (loss) per share:</b>				

Continuing operations - basic and diluted	\$ (0.28)	\$ (0.30)	\$ (0.63)	\$ (0.83)
Discontinued operations - basic and diluted	\$ —	\$ 0.19	\$ —	\$ 0.38
Net loss - basic and diluted	\$ (0.28)	\$ (0.11)	\$ (0.63)	\$ (0.45)
Shares used to compute basic and diluted net income (loss) per share	56,682	76,270	59,791	75,761
	<b>Three Months Ended</b>	<b>Nine Months Ended</b>		
	<b>September 30,</b>	<b>September 30,</b>		
	<b>2023</b>	<b>2022</b>	<b>2023</b>	<b>2022</b>
<b>Revenue:</b>				
Viatris collaboration agreement	\$ 15,687	\$ 12,445	\$ 39,841	\$ 34,010
Collaboration revenue	6	6	18	187
Licensing revenue	—	—	—	2,500
Total revenue	15,693	12,451	39,859	36,697
<b>Expenses:</b>				
Research and development (1)	8,311	9,867	32,308	48,044
Selling, general and administrative (1)	16,142	16,277	54,603	50,341
Restructuring and related expenses (1)	—	509	2,743	12,838
Total expenses	24,453	26,653	89,654	111,223
<b>Loss from operations</b>	(8,760)	(14,202)	(49,795)	(74,526)
Interest expense (2)	(609)	(1,545)	(1,727)	(5,819)
Loss on extinguishment of debt	—	(3,034)	—	(3,034)
Interest income and other income (expense), net	1,786	2,758	7,269	4,823
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)
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
<b>Net income (loss)</b>	<b>\$ (8,950)</b>	<b>\$ 916,631</b>	<b>\$ (46,683)</b>	<b>\$ 882,494</b>
Net unrealized gain (loss) on available-for-sale investments	61	(76)	(210)	(121)
Total comprehensive income (loss)	\$ (8,889)	\$ 916,555	\$ (46,893)	\$ 882,373
<b>Net income (loss) per share:</b>				
Continuing operations - basic and diluted	\$ (0.17)	\$ (0.21)	\$ (0.81)	\$ (1.04)
Discontinued operations - basic and diluted	\$ —	\$ 12.35	\$ —	\$ 12.70
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

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

(In thousands)	Three Months Ended June			
	30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Research and development	\$ 1,855	\$ 2,909	\$ 4,296	\$ 7,439
Selling, general and administrative	4,409	5,030	8,632	10,528

Restructuring and related expenses	—	1,770	357	6,287
Total share-based compensation expense	\$ 6,264	\$ 9,709	\$ 13,285	\$ 24,254
<b>Three Months Ended</b>				
<b>September 30,</b>				
(In thousands)	2023	2022	2023	2022
Research and development	\$ 2,004	\$ 2,623	\$ 6,301	\$ 10,062
Selling, general and administrative	4,258	5,196	12,890	15,724
Restructuring and related expenses	—	711	356	6,998
Total share-based compensation expense	\$ 6,262	\$ 8,530	\$ 19,547	\$ 32,784

(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.*

[Table of Contents](#)

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

	Accumulated					
	Ordinary Shares		Additional		Total	
	Shares	Amount	Capital	Comprehensive Gain (Loss)	Accumulated Deficit	Shareholders' Equity
<b>Balances at March 31, 2023</b>	60,542	\$ 1	\$ 1,246,506	\$ 51	\$ (875,999)	\$ 370,559
Repurchase of ordinary shares, net of transaction costs	(7,283)	—	(80,543)	—	—	(80,543)
Proceeds from ESPP purchases	63	—	446	—	—	446
Employee share-based compensation expense	—	—	6,264	—	—	6,264
Issuance of restricted shares	424	—	—	—	—	—
Option exercises	—	—	—	—	—	—
Repurchase of shares to satisfy tax withholding	(52)	—	(583)	—	—	(583)
Net unrealized loss on marketable securities	—	—	—	(337)	—	(337)
Net loss	—	—	—	—	(15,645)	(15,645)
<b>Balances at June 30, 2023</b>	53,694	\$ 1	\$ 1,172,090	\$ (286)	\$ (891,644)	\$ 280,161
	Accumulated					
	Ordinary Shares		Additional		Total	
	Shares	Amount	Capital	Comprehensive Loss	Accumulated Deficit	Shareholders' Equity
<b>Balances at December 31, 2022</b>	65,227	\$ 1	\$ 1,295,725	\$ (15)	\$ (853,911)	\$ 441,800
Repurchase of ordinary shares, net of transaction costs	(12,441)	—	(135,896)	—	—	(135,896)
Proceeds from ESPP purchases	63	—	446	—	—	446
Employee share-based compensation expense	—	—	13,285	—	—	13,285
Issuance of restricted shares	981	—	—	—	—	—

Option exercises	—	—	—	—	—	—	—
Repurchase of shares to satisfy tax withholding	(136)	—	(1,470)	—	—	—	(1,470)
Net unrealized loss on marketable securities	—	—	—	(271)	—	—	(271)
Net loss	—	—	—	—	(37,733)	—	(37,733)
<b>Balances at June 30, 2023</b>	<b>53,694</b>	<b>\$ 1</b>	<b>\$ 1,172,090</b>	<b>\$ (286)</b>	<b>\$ (891,644)</b>	<b>\$ 280,161</b>	

	Accumulated					
	Ordinary Shares		Additional		Other	
	Shares	Amount	Paid-In Capital	Comprehensive Loss	Accumulated Deficit	Shareholders' Deficit
<b>Balances at March 31, 2022</b>	<b>76,081</b>	<b>\$ 1</b>	<b>\$ 1,400,566</b>	<b>\$ (28)</b>	<b>\$ (1,751,989)</b>	<b>\$ (351,450)</b>
Proceeds from ESPP purchases	72	—	487	—	—	487
Employee share-based compensation expense	—	—	9,709	—	—	9,709
Issuance of restricted shares	313	—	—	—	—	—
Repurchase of shares to satisfy tax withholding	(39)	—	(347)	—	—	(347)
Net unrealized loss on marketable securities	—	—	—	(17)	—	(17)
Net loss	—	—	—	—	(8,191)	(8,191)
<b>Balances at June 30, 2022</b>	<b>76,427</b>	<b>\$ 1</b>	<b>\$ 1,410,415</b>	<b>\$ (45)</b>	<b>\$ (1,760,180)</b>	<b>\$ (349,809)</b>

	Accumulated					
	Ordinary Shares		Additional		Other	
	Shares	Amount	Paid-In Capital	Comprehensive Loss	Accumulated Deficit	Shareholders' Deficit
<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>
Proceeds from ESPP purchases	72	—	487	—	—	487
Employee share-based compensation expense	—	—	24,254	—	—	24,254
Issuance of restricted shares	2,109	—	—	—	—	—
Repurchase of shares to satisfy tax withholding	(189)	—	(1,795)	—	—	(1,795)
Net unrealized loss on marketable securities	—	—	—	(45)	—	(45)
Net loss	—	—	—	—	(34,137)	(34,137)
<b>Balances at June 30, 2022</b>	<b>76,427</b>	<b>\$ 1</b>	<b>\$ 1,410,415</b>	<b>\$ (45)</b>	<b>\$ (1,760,180)</b>	<b>\$ (349,809)</b>

	Accumulated					
	Ordinary Shares		Additional		Other	
	Shares	Amount	Paid-In Capital	Gain (Loss)	Accumulated Deficit	Shareholders' Equity
<b>Balances at June 30, 2023</b>	<b>53,694</b>	<b>\$ 1</b>	<b>\$ 1,172,090</b>	<b>\$ (286)</b>	<b>\$ (891,644)</b>	<b>\$ 280,161</b>
Repurchase of ordinary shares, net of transaction costs	(3,178)	—	(30,891)	—	—	(30,891)
Proceeds from ESPP purchases	—	—	(1)	—	—	(1)
Employee share-based compensation expense	—	—	6,262	—	—	6,262
Issuance of restricted shares	356	—	—	—	—	—
Option exercises	—	—	—	—	—	—
Repurchase of shares to satisfy tax withholding	(53)	—	(512)	—	—	(512)
Net unrealized gain on marketable securities	—	—	—	61	—	61
Net loss	—	—	—	—	(8,950)	(8,950)
<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>

	Accumulated					
	Ordinary Shares		Additional		Other	
	Shares	Amount	Paid-In Capital	Loss	Accumulated Deficit	Shareholders' Equity
<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>
Repurchase of ordinary shares, net of transaction costs	(15,619)	—	(166,787)	—	—	(166,787)

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)
<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>	

	Accumulated					
	Ordinary Shares		Additional		Other	
	Shares	Amount	Capital	Comprehensive	Accumulated	Total
<b>Balances at June 30, 2022</b>	<b>76,427</b>	<b>\$ 1</b>	<b>\$ 1,410,415</b>	<b>\$ (45)</b>	<b>\$ (1,760,180)</b>	<b>\$ (349,809)</b>
Repurchase of ordinary shares	(9,645)	—	(94,037)	—	—	(94,037)
Proceeds from ESPP purchases	—	—	1	—	—	1
Employee share-based compensation expense	—	—	8,530	—	—	8,530
Issuance of restricted shares	655	—	—	—	—	—
Repurchase of shares to satisfy tax withholding	(71)	—	(662)	—	—	(662)
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>

	Accumulated					
	Ordinary Shares		Additional		Other	
	Shares	Amount	Capital	Comprehensive	Accumulated	Total
<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
<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>

See accompanying notes to condensed consolidated financial statements.

[Table of Contents](#)

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

		Six Months Ended June 30,	
		2023	2022

<b>Operating activities</b>		
Net loss	\$ (37,733)	\$ (34,137)
Less: Net income from discontinued operations	—	28,915
Net loss from continuing operations	(37,733)	(63,052)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,177	1,949
Amortization and accretion income, net	(1,092)	(31)
Future royalty payment contingency interest accretion	1,118	—
Share-based compensation	13,285	24,254
Gain on sale of Velusetrag	—	(2,721)
(Gain) loss on disposal of property and equipment	1,352	(96)
Gain from lease modification	—	(47)
Amortization of right-of-use assets	1,817	1,314
Changes in operating assets and liabilities:		
Receivables from collaborative and licensing arrangements	989	1,577
Prepaid clinical and development services	533	7,934
Other prepaid and current assets	(95)	2,619
Right-of-use lease assets	(144)	(2,689)
Other assets	1,751	(145)
Accounts payable	83	(26)
Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued liabilities	(6,534)	(11,135)
Deferred revenue	(11)	(180)
Operating lease liabilities	(479)	82
Other long-term liabilities	326	(17)
Net cash used in operating activities - continuing operations	(23,657)	(40,410)
Net cash used in operating activities - discontinued operations	—	(389)
Net cash used in operating activities	(23,657)	(40,799)
<b>Investing activities</b>		
Purchases of property and equipment	(1,790)	(363)
Purchases of marketable securities	(134,534)	(53,763)
Maturities of marketable securities	31,435	91,699
Sale of short-term investments and marketable securities	71,377	—
Proceeds from the sale of property and equipment	1,513	1,866
Net cash (used in) provided by investing activities - continuing operations	(31,999)	39,439
Net cash provided by (used in) investing activities - discontinued operations	—	—
Net cash (used in) provided by investing activities	(31,999)	39,439
<b>Financing activities</b>		
Ordinary share repurchases	(135,896)	—
Proceeds from ESPP purchases	446	487
Repurchase of shares to satisfy tax withholding	(1,470)	(1,795)
Net cash used in financing activities - continuing operations	(136,920)	(1,308)
Net cash provided by (used in) financing activities - discontinued operations	—	—
Net cash used in financing activities	(136,920)	(1,308)
<b>Net decrease increase in cash, cash equivalents, and restricted cash</b>	(192,576)	(2,668)
<b>Cash, cash equivalents, and restricted cash at beginning of period</b>	299,008	90,796
<b>Cash, cash equivalents, and restricted cash at end of period</b>	\$ 106,432	\$ 88,128
<b>Supplemental disclosure of cash flow information</b>		
Cash paid for interest	\$ —	\$ 15,127
Cash paid for income taxes, net	\$ 14	\$ 25

<b>Supplemental disclosure of non-cash investing and financing activities</b>			
Recognition of tenant improvement allowance assigned to sublease	\$ 6,490	\$ —	—
	<b>Nine Months Ended September 30,</b>		
	<b>2023</b>		<b>2022</b>
<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:			
Depreciation and amortization	1,609	3,057	
Amortization and accretion income, net	(1,494)	(342)	
Future royalty payment contingency interest accretion	1,727	424	
Share-based compensation	19,547	32,784	
Gain on sale of Velusetrag	—	(2,709)	
(Gain) loss on disposal of property and equipment	1,353	(96)	
Amortization of right-of-use assets	2,724	2,284	
Loss on extinguishment of debt	—	3,034	
Changes in operating assets and liabilities:			
Receivables from collaborative and licensing arrangements	(272)	(49)	
Prepaid clinical and development services	(121)	7,600	
Other prepaid and current assets	(1,315)	(1,148)	
Right-of-use lease assets	(173)	(2,587)	
Other assets	3,309	(1,743)	
Accounts payable	354	2,150	
Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued liabilities	(6,657)	(18,465)	
Accrued interest payable	—	(1,246)	
Deferred revenue	(17)	(186)	
Operating lease liabilities	(1,329)	(1,111)	
Other long-term liabilities	1,295	(421)	
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)	
<b>Investing activities</b>			
Purchases of property and equipment	(1,811)	(306)	
Purchases of marketable securities	(134,534)	(93,260)	
Maturities of marketable securities	31,435	108,700	
Sale of short-term investments and marketable securities	71,377	5	
Proceeds from the sale of Velusetrag	—	2,709	
Proceeds from the sale of property and equipment	1,513	1,866	
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	
<b>Financing activities</b>			
Ordinary share repurchases	(166,787)	(94,037)	
Proceeds from amprexetine 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)	

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)
<b>Net (decrease) increase in cash, cash equivalents, and restricted cash</b>	<b>(226,487)</b>	<b>328,578</b>
<b>Cash, cash equivalents, and restricted cash at beginning of period</b>	<b>299,008</b>	<b>90,796</b>
<b>Cash, cash equivalents, and restricted cash at end of period</b>	<b>\$ 72,521</b>	<b>\$ 419,374</b>
<b>Supplemental disclosure of cash flow information</b>		
Cash paid for interest	\$ —	\$ 22,244
Cash paid for income taxes, net	\$ 14	\$ 26
<b>Supplemental disclosure of non-cash investing and financing activities</b>		
Recognition of tenant improvement allowance assigned to sublease	\$ 6,490	\$ —

*See accompanying notes to condensed consolidated financial statements.*

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[Table of Contents](#)

**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 as of **June 30, 2023** **September 30, 2023** and for the three and **six nine** months ended **June 30, 2023** **September 30, 2023** and 2022 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 financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission ("SEC") on March 1, 2023.

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

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#### Table of Contents

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

The Company has evaluated 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.

#### **2. Net Loss Income (Loss) per Share**

Basic net loss income (loss) per share is computed by dividing the net loss income (loss) attributable to ordinary shareholders by the weighted-average number of ordinary shares outstanding for the period, excluding shares subject to repurchase and without consideration of potentially dilutive securities. Diluted net loss income (loss) per share is computed by giving effect to all potentially dilutive ordinary shares outstanding for the period, which primarily consist of instruments issued and outstanding under the Company's equity incentive and employee share purchase plans and shares issuable upon note conversion (for the 2022 periods only). Ordinary share equivalents are excluded from the computation in periods in which they have an anti-dilutive effect unless the consideration of any one of them gives a dilutive effect.

(In thousands, except per share data)	Three Months Ended				Six Months Ended				Three Months Ended		Nine Months Ended	
	June 30,		June 30,		September 30,		September 30,		September 30,		September 30,	
	2023	2022	2023	2022	2023	2022	2023	2022	2023	2022	2023	2022
<b>Numerator:</b>												
Net loss from continuing operations	\$ (15,645)	\$ (22,793)	\$ (37,733)	\$ (63,052)	\$ (8,950)	\$ (16,023)	\$ (46,683)	\$ (78,568)	—	—	—	—
Net income from discontinued operations	—	14,602	—	28,915	—	932,654	—	961,062	—	—	—	—

Net loss	\$ (15,645)	\$ (8,191)	(37,733)	(34,137)				
Net income (loss)					\$ (8,950)	\$ 916,631	(46,683)	882,494
<b>Denominator:</b>								
Weighted-average ordinary shares outstanding	56,682	76,270	59,791	75,761	52,361	75,515	57,287	75,678
Less: weighted-average ordinary shares subject to forfeiture	—	—	—	—	—	—	—	—
Weighted-average ordinary shares outstanding - basic and diluted	56,682	76,270	59,791	75,761	52,361	75,515	57,287	75,678
<b>Net income (loss) per share:</b>								
Continuing operations - basic and diluted	\$ (0.28)	\$ (0.30)	\$ (0.63)	\$ (0.83)	\$ (0.17)	\$ (0.21)	\$ (0.81)	\$ (1.04)
Discontinued operations - basic and diluted	\$ —	\$ 0.19	\$ —	\$ 0.38	\$ —	\$ 12.35	\$ —	\$ 12.70
Net loss per share - basic and diluted	\$ (0.28)	\$ (0.11)	\$ (0.63)	\$ (0.45)				
Net income (loss) per share - basic and diluted					\$ (0.17)	\$ 12.14	\$ (0.81)	\$ 11.66

#### ***Anti-dilutive Securities***

In accordance with Accounting Standards Codification ("ASC") 260, *Earnings Per Share*, if a company incurred a loss related to its continuing operations, then potential ordinary shares are considered anti-dilutive for the periods in which the loss was recognized. For the three and **six** **nine** months ended **June 30, 2023** **September 30, 2023** and 2022, the Company recognized losses from continuing operations. As a result, the following ordinary equivalent shares were not included in the computation of diluted net loss per share for both continuing operations and discontinuing operations:

(In thousands)	Three Months Ended				Nine Months Ended			
	June 30,		Six Months Ended		Three Months Ended		September	
	2023	2022	2023	2022	2023	2022	2023	2022
Share issuances under equity incentive plans and employee share purchase plan	3,693	5,660	4,114	6,239	3,459	5,036	3,972	7,137
Share issuances upon the conversion of convertible senior notes	—	6,676	—	6,676				
<b>Total</b>	<b>3,693</b>	<b>12,336</b>	<b>4,114</b>	<b>12,915</b>				

#### [Table of Contents](#)

### **3. Revenue**

#### ***Revenue from Collaborative Arrangements***

#### ***Viatris***

In January 2015, the Company and Viatris Inc. ("Viatris") established a strategic collaboration (the "Viatris Agreement") for the development and commercialization of revfenecin, including YUPELRI® (revfenecin) inhalation solution. The Company entered into the collaboration to expand the breadth of its revfenecin 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, Viatris is leading the commercialization of YUPELRI, and the Company co-promotes the product under a profit and loss sharing arrangement (65% to Viatris; 35% to the Company). Outside the US (excluding China and adjacent territories), Viatris 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. Viatris also holds exclusive development and commercialization rights to nebulized revefenacin in China and adjacent territories, which include 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. Viatris is responsible for all aspects of development and commercialization in the China and adjacent territories, including pre- and post-launch activities and product registration and all associated costs. Viatris is the principal in the sales transactions, and as a result, the Company does not reflect the product sales in its condensed consolidated financial statements.

As of **June 30, 2023** **September 30, 2023**, 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 \$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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[Table of Contents](#)

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

[Table of Contents](#)

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 **six** nine months ended **June 30, 2023** **September 30, 2023**, 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				Six Months Ended June				Three Months Ended		Nine Months Ended	
	June 30,		30,		September 30,		September 30,		2023	2022	2023	2022
	2023	2022	2023	2022	2023	2022	2023	2022	2023	2022	2023	2022
Viatris collaboration agreement - <i>Amounts receivable from Viatris</i>	\$ 13,743	\$ 10,878	\$ 24,154	\$ 21,565	\$ 15,687	\$ 12,445	\$ 39,841	\$ 34,010				

While Viatris records the total YUPELRI net sales of YUPELRI within its own condensed consolidated financial statements, Viatris collaboration agreement revenue includes on the Company's condensed consolidated statements of operations included the Company's implied 35% share of total YUPELRI net sales, of YUPELRI for the three and six months ended June 30, 2023 of \$19.3 million and \$35.7 million, respectively, before deducting shared expenses. For the three and six months ended June 30, 2022, the Company's implied 35% share of net sales of YUPELRI were \$17.2 million and \$32.5 million, respectively, before deducting shared expenses, as presented below:

(In thousands)	Three Months Ended				Nine Months Ended			
	September 30,		September 30,		September 30,		September 30,	
	2023	2022	2023	2022	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				Six Months Ended				Nine Months Ended			
	June 30,		June 30,		September 30,		September 30,		September 30,		September 30,	
	2023	2022	2023	2022	2023	2022	2023	2022	2023	2022	2023	2022
Viatris	\$ 6	\$ 6	\$ 12	\$ 12	\$ 6	\$ 6	\$ 18	\$ 18				
Alfasigma	—	166	—	169	—	—	—	169				
Total collaboration revenue	\$ 6	\$ 172	\$ 12	\$ 181	\$ 6	\$ 6	\$ 18	\$ 187				

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.

**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	
	September 30,		September 30,	
	2023	2022	2023	2022
Viatris	\$ 1,340	\$ 1,657	\$ 5,041	\$ 4,736
(In thousands)	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2023	2022	2023	2022
Viatris	\$ 1,947	\$ 1,543	\$ 3,700	\$ 3,079

10

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[Table of Contents](#)

#### **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

10

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[Table of Contents](#)

respiratory applications. The Company received an upfront cash payment of \$10.0 million in 2019, and for the ~~three and six~~ nine months ended ~~June 31, 2022~~ 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 ~~will be~~ 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)	June 30,		September 30,	
	2023	2022	2023	2022

Cash and cash equivalents	\$ 105,596	\$ 87,292	\$71,685	\$418,538
Restricted cash	836	836	836	836
Total cash, cash equivalents, and restricted cash shown on the condensed consolidated statements of cash flows	\$ 106,432	\$ 88,128	\$72,521	\$419,374

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, compared to the prior year period, was primarily due to the Company's capital return program that was initiated in September 2022 (see *Note 10. Strategic Actions* for further information).

The Company periodically engages in foreign exchange transactions as a part of its operations. For the three and ~~six~~ nine months ended ~~June 30, 2023~~ September 30, 2023, the Company's net realized and unrealized foreign currency gains were not material, and for the three and ~~six~~ nine months ended ~~June 30, 2022~~ September 30, 2022, the Company recognized net realized and unrealized foreign currency losses of ~~\$0.7 million~~ \$0.4 million and ~~\$1.1 million~~ \$1.5 million, 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.

Available-for-sale securities are summarized below:

(In thousands)	June 30, 2023			
	Gross		Gross	
	Amortized	Unrealized	Unrealized	Estimated
	Cost	Gains	Losses	Fair Value
US government securities	Level 1	\$ 29,361	\$ —	\$ (139)
US government agency securities	Level 2	4,341	—	(26)
Corporate notes	Level 2	28,439	—	(121)
Marketable securities		62,141	—	(286)
Money market funds	Level 1	96,321	—	96,321
Total		\$ 158,462	\$ —	\$ (286)
		\$ 158,176	\$ —	\$ 96,321

### Table of Contents

Available-for-sale securities are summarized below:

(In thousands)	September 30, 2023				
	Gross		Gross		
	Amortized	Unrealized	Unrealized	Estimated	
	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
<b>Total</b>		<b>\$ 121,118</b>	<b>\$ —</b>	<b>\$ (225)</b>	<b>\$ 120,893</b>

(In thousands)	December 31, 2022				
	Gross		Gross		
	Amortized	Unrealized	Unrealized	Estimated	
	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
<b>Total</b>		<b>\$ 303,557</b>	<b>\$ 12</b>	<b>\$ (27)</b>	<b>\$ 303,542</b>

As of **June 30, 2023** **September 30, 2023**, all of the Company's available-for-sale securities had contractual maturities within **one year, 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 **six nine** months ended **June 30, 2023** **September 30, 2023**.

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

(In thousands)	June 30, 2023						September 30, 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
US government securities	29,222	(138)	—	—	29,222	(138)	29,510	(94)	—	—	29,510	(94)
US government agency securities	4,315	(26)	—	—	4,315	(26)	4,363	(22)	—	—	4,363	(22)
Corporate notes	28,318	(121)	—	—	28,318	(121)	28,445	(109)	—	—	28,445	(109)
<b>Total</b>	<b>\$ 61,855</b>	<b>\$ (286)</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 61,855</b>	<b>\$ (286)</b>	<b>\$ 62,318</b>	<b>\$ (225)</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 62,318</b>	<b>\$ (225)</b>

(In thousands)	December 31, 2022						December 31, 2022					
	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
US government securities	\$ 24,873	\$ 8	\$ —	\$ —	\$ 24,873	\$ 8	\$ 24,881	\$ —	\$ —	\$ —	\$ 24,881	\$ —
US government agency securities	4,315	(26)	—	—	4,315	(26)	4,363	(22)	—	—	4,363	(22)
Corporate notes	28,318	(121)	—	—	28,318	(121)	28,445	(109)	—	—	28,445	(109)
<b>Total</b>	<b>\$ 61,855</b>	<b>\$ (286)</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 61,855</b>	<b>\$ (286)</b>	<b>\$ 62,318</b>	<b>\$ (225)</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 62,318</b>	<b>\$ (225)</b>

Commercial paper	\$ 37,280	\$ (27)	\$ —	\$ —	\$ 37,280	\$ (27)	\$ 37,280	\$ (27)	\$ —	\$ —	\$ 37,280	\$ (27)
Total	\$ 37,280	\$ (27)	\$ —	\$ —	\$ 37,280	\$ (27)	\$ 37,280	\$ (27)	\$ —	\$ —	\$ 37,280	\$ (27)

The Company invests primarily in high credit quality and short-term maturity debt securities with the intent to hold such securities until maturity at par value. The Company does not intend to sell the investments that are currently in an unrealized loss position, and it is unlikely that it will be required to sell the investments before recovery of their amortized cost basis, which may be at maturity. The Company reviewed its available-for-sale debt securities and determined that there were no credit-related losses to be recognized as of **June 30, 2023** **September 30, 2023**.

As of **June 30, 2023** **September 30, 2023**, the Company's accumulated other comprehensive loss on its condensed consolidated balance sheets consisted of net unrealized losses on available-for-sale investments. For the **three and six** **nine** months

12

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## [Table of Contents](#)

ended **June 30, 2023** **September 30, 2023**, the Company sold marketable securities for total proceeds of **\$8.6 million** **\$71.4 million**. The sales were based on the specific identification method, and **\$71.5 million**, respectively. For the three months ended June 30, 2023, the realized net gain from the sale was **immaterial**, **immaterial**. For the three months ended September 30, 2023, and for the **six** **three and nine** months ended June 30, 2023, the realized net loss from the sale was **\$0.2 million** based on the specific identification method. For the three and six months ended June 30, 2022 **September 30, 2022**, the Company did not sell any marketable securities.

### **6. Subleases**

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. **Sublease**

**The Company's sublease income related to the sublease agreements was \$2.1 million and \$4.2 is summarized below:**

12

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

**million** for the three and six months ended June 30, 2023, respectively, and **\$0.3 million** for each of the three and six months ended June 30, 2022. 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 to its sublessees and **will be** **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 the Equity Purchase 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 (collectively with the other transactions contemplated by the Purchase Agreement, the "TRC Transaction").

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 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").

The Contingent Consideration was initially ~~measured fair valued at fair value~~ \$194.2 million 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 which is considered a Level 3 fair value input. The Company reassesses the carrying value of the Contingent Consideration when indicators of impairment are identified and will recognize any increases in the carrying value of the asset when such contingent gains are realized. As of ~~June 30, 2023~~ September 30, 2023, there have been no

13

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## [Table of Contents](#)

indicators of impairment identified, and as a result, there have been no changes to the carrying value of the Contingent Consideration since its initial ~~measurement fair value~~ 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. The Contingent Consideration is presented on the condensed consolidated balance sheets as future contingent milestone and royalty assets.

## ***Discontinued Operations***

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.

13

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## [Table of Contents](#)

The results of discontinued operations consisted of the following:

(In thousands)	Three Months Ended				Six Months Ended				Nine Months Ended			
	June 30,		June 30,		September 30,		September 30,		September 30,		September 30,	
	2023	2022	2023	2022	2023	2022	2023	2022	2023	2022	2023	2022
Income from investments in TRC, LLC	\$ —	\$ 28,127	\$ —	\$ 53,237	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 53,237	\$ —
Transaction-related legal expenses (prior to July 20, 2022)	—	(3,778)	—	(5,057)	—	—	—	—	—	—	(5,057)	—
Interest expense on 9.5% Non-recourse notes due 2035	—	(9,747)	—	(19,265)	—	(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	<u>\$ —</u>	<u>\$ 14,602</u>	<u>\$ —</u>	<u>\$ 28,915</u>	<u>\$ —</u>	<u>\$ 932,654</u>	<u>\$ —</u>	<u>\$ 961,062</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

#### **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 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 of TRC based on the power to direct TRC's activities that most significantly impact TRC's economic performance and its obligation to absorb TRC's losses or the right to receive benefits from TRC that could potentially be significant to TRC. Based on the Company's assessment, the Company determined that it was not the primary beneficiary of TRC, 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 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		Six Months Ended		Three Months Ended		Nine Months Ended	
	June 30,		June 30,		September 30,		September 30,	
	2022	2022	2022	2022	2022	2022	2022	2022
Royalty revenue and gross profit	\$ 42,720	\$ 72,029	\$ —	\$ 72,029	\$ —	\$ —	\$ 72,029	\$ —
Income from continuing operations	42,581	71,693	—	71,693	—	—	71,693	—
Net income	33,091	62,632	—	62,632	—	—	62,632	—

## 8. Share-Based Compensation

### Market and Performance-Contingent Awards

The Company periodically grants market-based performance-contingent share awards to employees. For the three months ended **June 30, 2023** **September 30, 2023**, no such market-based restricted share units ("RSUs") were granted, and for the **six nine** months ended **June 30, 2023** **September 30, 2023**, the Company granted 165,000 of such RSUs. The 165,000 RSUs had a fair value of \$1.4 million, **respectively**, 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 **six nine** months ended **June 30, 2023** **September 30, 2023**, the Company recognized \$0.2 million and **\$0.3 million** **\$0.5 million**, respectively, of share-based compensation expense related to the awards.

For the three months ended **June 30, 2023** **September 30, 2023**, the Company did not grant any performance-contingent RSUs, and for the **six nine** months ended **June 30, 2023** **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. **As of June 30, 2023**, **In September 2023**, the Company concluded that 52,500 of the RSUs were probable of achievement, **of these performance vesting criteria was not probable, and no expense has been recognized related to these awards. However, if it were determined in as a future period that achievement of these performance criteria is probable, result, the Company would recognize a recognized \$0.3 million of cumulative catch-up of expense.** share-based compensation expense for the three and nine months ended September 30, 2023.

### Table of Contents

### 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 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.

## 9. Income Taxes

For the three and **six nine** months ended **June 30, 2023** **September 30, 2023**, the Company recognized an income tax expense of **\$1.5 million** **\$1.4 million** and **\$1.1 million** **\$2.4 million**, respectively. Although the Company incurred net operating losses on a consolidated basis, the income tax expense for the **six nine** months ended **June 30, 2023** **September 30, 2023** was primarily due to 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 **six nine** months ended **June 30, 2023** **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. **The Company determined that as** **As** small changes in estimated ordinary income **would** **may** result in a significant **changes** **change** in the estimated annual effective tax rate, the Company determined that the historical method would not provide a reliable estimate for the **six nine** months ended **June 30, 2023** **September 30, 2023**.

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 **June 30, 2023** **September 30, 2023**, the Company does not believe a valuation allowance should be re-established to offset its deferred tax assets for federal

15

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[Table of Contents](#)

tax purposes. As of **June 30, 2023** **September 30, 2023**, the Company continues to maintain a full valuation allowance on its California, other states, and foreign deferred tax assets.

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

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

15

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[Table of Contents](#)

## 10. Strategic Actions

In February 2023, the Company announced and has since **initiated** **largely completed** the following strategic actions (the "2023 Strategic Actions"):

### *Capital Return Program Increase*

The Company's 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 three and **six** **nine** months ended **June 30, 2023** **September 30, 2023**, the Company repurchased **7.28 million** **3.18 million** shares and **12.44 million** **15.62 million** shares, respectively, on the open market at a weighted average cost of **\$11.05** **\$9.70** per share and **\$10.90** **\$10.65** per share, respectively. For the three and **six** **nine** months ended **June 30, 2023** **September 30, 2023**, the total aggregate cost of the repurchases, excluding fees and expenses, was **\$80.5 million** **\$30.8 million** and **\$135.6**

million \$166.4 million, respectively. Since the initiation of the capital return program in September 2022, the Company has repurchased \$263.8 million \$294.6 million of shares, as of June 30, 2023 September 30, 2023, and the Company has had approximately \$61.2 million \$30.4 million remaining in the capital return program which is expected to be completed by the end of 2023. In July October 2023, the Company repurchased an additional 1.04 million 1.02 million shares on the open market at a weighted average cost of \$9.88 \$9.09 per share for a total aggregate cost of \$10.3 million \$9.3 million, excluding fees and expenses. The Company has had approximately \$50.9 million \$21.1 million remaining in the capital return program, as of July 31, 2023, that it is expected to complete by the end of 2023, 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 amprexetine 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, for the three and six months ended June 30, 2023, the Company incurred restructuring and related expenses of \$1.2 million and \$2.7 million for the nine months ended September 30, 2023, respectively, primarily related to R&D expenses. The \$1.2 million of restructuring expenses recognized Of the total \$2.7 million incurred for the three nine months ended June 30, 2023 was classified as September 30, 2023, cash-related expenses were \$1.2 million and non-cash expenses and were \$1.5 million which were primarily related to the loss on the sale of R&D laboratory equipment 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.

Of the total \$2.7 million incurred There were no restructuring and related expenses recognized for the six three months ended June 30, 2023 September 30, 2023, cash-related expenses were \$1.2 million and non-cash expenses were \$1.5 million which were primarily related to the modification of equity-based awards for employees affected by the reduction in headcount and a loss of the sale of R&D laboratory equipment. 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 six nine months ended June 30, 2022 September 30, 2022, the Company incurred restructuring and related expenses of

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#### Table of Contents

\$3.0 million and \$12.3 million \$12.8 million, respectively. Of the \$3.0 \$0.5 million incurred for the three months ended June 30, 2022 September 30, 2022, \$1.0 million \$0.1 million was related to R&D expenses and \$2.0 \$0.4 million was related to selling, general and administrative expenses. Of the \$12.3 million \$12.8 million incurred for the six nine months ended June 30, 2022 September 30, 2022, \$5.7 million \$5.9 million was related to R&D expenses and \$6.6 \$6.9 million was related to selling, general and administrative expenses. Of the total \$12.3 million \$12.8 million incurred for the six nine months ended June 30, 2022 September 30, 2022, cash-related expenses were \$6.0 million \$5.8 million and non-cash expenses were \$6.3 million \$7.0 million which were primarily related to the modification 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	\$ —

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[Table of Contents](#)

Cash paid	(1,174)
Balance at June 30, 2023	<u>\$ 14</u>

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. **Based** While the Company has not yet completed a new sublease, based on its evaluation, the Company determined that **its** the estimated undiscounted future sublease income **exceeded** exceeds the Sublease Assets' carrying value, and as a result, the Company did not recognize an impairment charge as of **June 30, 2023** **September 30, 2023**. The Company will continue 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

### **Legal Proceedings**

In 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, 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 covering YUPELRI granted on July 4, 2023 was 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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[Table of Contents](#)

companies in the U.S. District Court for the District of New Jersey during August 2023. This suit has been consolidated with the above action.

On October 27, 2023, subsidiaries of the Company 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 to these parties. Under the Settlement Agreement, the Company and Viatris entities granted Teva a royalty-free, non-exclusive, non-sublicensable, non-transferable license to manufacture and market Teva's generic version of YUPELRI® (reverfenacin) inhalation solution in the United States on or after the licensed launch date of April 23, 2039, subject to certain exceptions as is customary in these types of agreements. As required by law, the settlement is subject to review by the U.S. Department of Justice and the Federal Trade Commission. The patent litigation against the other generic companies, along with certain affiliates, remains pending.

1718

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## [Table of Contents](#)

### **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. 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. In addition, while the effects of COVID-19, including new variants, may continue to adversely impact our business operations and financial results, the extent of the impact on our ability to generate revenue from YUPELRI® (reverfenacin), our clinical development programs, and the value of and market for our ordinary shares, will depend on future developments that are uncertain and cannot be predicted with confidence at this time. 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® (reverfenacin) inhalation solution indicated for the maintenance treatment of patients

with chronic obstructive pulmonary disease ("COPD"). Ampreloxitine, our late-stage investigational norepinephrine reuptake inhibitor in development for symptomatic neurogenic orthostatic hypotension, has the potential to be a first in class therapy effective in treating a constellation of cardinal symptoms in multiple system atrophy 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

18

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### [Table of Contents](#)

\$75.0 million \$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 six nine months ended June 30, 2023 September 30, 2023, we repurchased 12.44 million 15.62 million shares on the open market at a weighted average cost of \$10.90 \$10.65 per share for an aggregate cost of \$135.6 million \$166.4 million, excluding fees and expenses. Since inception of the capital return program in

19

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### [Table of Contents](#)

September 2022 through June 30, 2023 September 30, 2023, we repurchased \$263.8 million \$294.6 million of shares, and as of June 30, 2023 September 30, 2023, the Company has had approximately \$61.2 million \$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 amprenoxetine 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 six nine months ended June 30, 2023 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 (reverfenacin) Inhalation Solution***

YUPELRI (reverfenacin) 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 reverfenacin in both metered dose inhaler and dry powder inhaler ("MDI/DPI") formulations suggests that reverfenacin 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 reverfenacin delivered through other dosage forms, such as a MDI/DPI.

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. In addition, in 2019, we granted Viatris exclusive development and commercialization rights to nebulized reverfenacin in China and adjacent territories, which include Hong Kong SAR, the Macau SAR, and Taiwan, and we are eligible to receive low double-digit tiered royalties on net sales of nebulized reverfenacin, if approved. In

19

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#### [Table of Contents](#)

March 2020, we earned a \$1.5 million development milestone. As noted above for the acceptance of a clinical trial application associated with the use of reverfenacin monotherapy in China and adjacent territories, ex-US, Viatris is responsible for all aspects of development and commercialization of nebulized reverfenacin in China and adjacent territories, including pre- and post-launch activities and product registration and all associated costs. We retain worldwide rights to reverfenacin delivered through other dosage forms, such as a MDI/DPI.

Under the terms of the Viatris Agreement, as amended, as of June 30, 2023 September 30, 2023, we are 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

20

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#### [Table of Contents](#)

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. We are also eligible to receive additional potential development and sales milestones totaling \$52.5 million related to Viatris' development and commercialization of nebulized reverfenacin in China and adjacent territories, 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.

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 refezenacin (YUPELRI) delivered via standard jet nebulizer or tiotropium delivered via a dry powder inhaler (Spiriva® HandiHaler®). This study is 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 the Phase 4 study costs, and Viatris has agreed to pay 65% of the Phase 4 study costs. **In January 2022, we announced the enrollment of the The first patient in for the Phase 4 study. study was enrolled in January 2022, and enrollment was recently completed. We plan to announce top-line results for the Phase 4 study in January 2024.**

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				Six Months Ended				Three Months Ended				Nine Months Ended			
	June 30,		Change		June 30,		Change		September 30,		Change		September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%	2023	2022	\$	%	2023	2022	\$	%
YUPELRI net sales (100% recorded by Viatris)	\$ 55,038	\$ 49,077	\$ 5,961	12 %	\$ 101,993	\$ 92,743	\$ 9,250	10 %	\$ 58,325	\$ 53,423	\$ 4,902	9 %	\$ 160,318	\$ 146,166	\$ 14,152	10 %
YUPELRI net sales (Theravance Biopharma implied 35%)	19,263	17,177	2,086	12	35,697	32,460	3,237	10	20,414	18,698	1,716	9	56,111	51,158	4,953	10

#### **Ampreloxytine (TD-9855)**

Ampreloxytine is an investigational, once-daily norepinephrine reuptake inhibitor ("NRI") that we are developing for the treatment of Multiple System Atrophy ("MSA") patients with symptomatic neurogenic orthostatic hypotension ("nOH"). nOH is caused by primary autonomic failure conditions and the majority of patients with MSA experience symptoms of nOH. Ampreloxytine has high affinity for binding to the norepinephrine ("NE") transporter. By blocking the action of the NE transporter, amploxytine causes an increase in extracellular concentrations of norepinephrine. Ampreloxytine 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 amploxytine 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 amploxytine 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 amploxytine. The protocol for the pivotal studies stipulated an enrollment threshold of 40% MSA patients based on the hypothesis amploxytine would work the best in patients with MSA because they have more intact nerves on which amploxytine can exert its effect, relative to the other patient types in the study. The third, non-pivotal study (OAK), was a three and half year long-term extension study.

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

21

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## [Table of Contents](#)

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 amprexetine 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 amprexetine 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 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. In May 2023, we announced that the FDA granted Orphan Drug Designation status to amprexetine 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 amprexetine in MSA in exchange for unsecured low single-digit royalties. Royalty Pharma's \$40.0 million investment in amprexetine included a \$25.0 million upfront payment received in July 2022 and an additional \$15.0 million payment upon the first regulatory approval of amprexetine. In exchange, Royalty Pharma will receive future unsecured royalties of 2.5% on annual amprexetine global net sales up to \$500.0 million and 4.5% on annual global net sales over \$500.0 million. If amprexetine regulatory approval is not achieved or if amprexetine sales are never recognized, the amounts invested by Royalty Pharma would not be repaid by us.

## **Out-Licensed Programs**

### ***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 ~~has 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 ~~will be~~ was returned to us.

## **Economic Interests and Other Assets**

### ***Mid- and Long-Term Economic Interest in GSK-Partnered Respiratory Programs***

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 TRELEGY ELLIPTA ("TRELEGY") to Royalty Pharma for approximately \$1.1 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 December 31, 2023 and ending with the year December 31, 2026, upon certain milestone minimum royalty amounts for TRELEGY being met,

21

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[Table of Contents](#)

Royalty Pharma is obligated to make certain cash payments to us (the "Milestone Payments"), which may total \$250.0 million in the aggregate. The first Milestone Payment of \$50.0 million will be triggered if Royalty Pharma receives \$240.0 million or more in royalty payments from GSK with respect to 2023 TRELEGY global net sales, which we would expect to occur in the event TRELEGY global net sales reach approximately \$2.863 billion. Royalties payable from GSK to Royalty Pharma are upward-tiering from 6.5% to 10%.

Additionally, we will receive from Royalty Pharma 85% of the royalty payments on TRELEGY payable (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

22

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[Table of Contents](#)

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 mid-2030s and are country specific.

***TRELEGY (the combination of fluticasone furoate/umeclidinium bromide/vilanterol)***

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 (UMECA, 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 **\$3.7 billion** **\$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 **development projects** are prioritized by those with the highest expected potential value. Our **enhanced** focus remains on near-term value opportunities which include completion of the YUPELRI Peak Inspiratory Flow Rate (PIFR-2) Phase 4 study and conducting our amprexetine 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 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.

## 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. 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.

22 23

## Table of Contents

## Results of Operations

### Revenue

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

(In thousands)	Three Months Ended				Six Months Ended				Three Months Ended				Nine Months Ended			
	June 30,		Change		June 30,		Change		September 30,		Change		September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%	2023	2022	\$	%	2023	2022	\$	%
YUPELRI net sales (100% recorded by Viatris)	\$ 55,038	\$ 49,077	\$ 5,961	12 %	\$ 101,993	\$ 92,743	\$ 9,250	10 %	\$ 58,325	\$ 53,423	\$ 4,902	9 %	\$ 160,318	\$ 146,166	\$ 14,152	10 %
YUPELRI net sales (Theravance Biopharma implied 35%)	19,263	17,177	2,086	12	35,697	32,460	3,237	10	20,414	18,698	1,716	9	56,111	51,158	4,953	10

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

(In thousands)	Three Months Ended				Six Months Ended				Three Months Ended				Nine Months Ended			
	June 30,		Change		June 30,		Change		September 30,		Change		September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%	2023	2022	\$	%	2023	2022	\$	%
YUPELRI net sales (100% recorded by Viatris)	\$ 55,038	\$ 49,077	\$ 5,961	12 %	\$ 101,993	\$ 92,743	\$ 9,250	10 %	\$ 58,325	\$ 53,423	\$ 4,902	9 %	\$ 160,318	\$ 146,166	\$ 14,152	10 %
YUPELRI net sales (Theravance Biopharma implied 35%)	19,263	17,177	2,086	12	35,697	32,460	3,237	10	20,414	18,698	1,716	9	56,111	51,158	4,953	10

Viatris collaboration agreement	\$ 13,743	\$ 10,878	\$ 2,865	26 %	\$ 24,154	\$ 21,565	\$ 2,589	12 %	\$ 15,687	\$ 12,445	\$ 3,242	26 %	\$ 39,841	\$ 34,010	\$ 5,831	17 %
Collaboration revenue	6	172	(166) (97)		12	181	(169) (93)		6	6	—	—	18	187	(169) (90)	
Licensing revenue	—	—	—	—	—	2,500	(2,500)	NM	—	—	—	—	—	2,500	(2,500)	NM
Total revenue	\$ 13,749	\$ 11,050	\$ 2,699	24 %	\$ 24,166	\$ 24,246	\$ (80)	(0)%	\$ 15,693	\$ 12,451	\$ 3,242	26 %	\$ 39,859	\$ 36,697	\$ 3,162	9 %

NM: Not Meaningful

We are entitled to a share of US profits and losses (65% to Viatris; 35% to Theravance Biopharma) received in connection with commercialization of YUPELRI. In accordance with the applicable accounting guidance, amounts receivable from Viatris in connection with the commercialization of YUPELRI are recorded within the condensed consolidated statements of operations as revenue from "Viatris collaboration agreement" irrespective of whether the overall collaboration is profitable. Amounts payable to Viatris 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 Viatris 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 **six** **nine** months ended **June 30, 2023** **September 30, 2023**, we recognized **\$13.7 million** **\$15.7 million** and **\$24.2 million** **\$39.8 million**, respectively, in revenue from the Viatris collaboration agreement which represented **the receivables due from Viatris related to YUPELRI**. Our Viatris collaboration agreement revenue increased by **increases** of 26% and 12% for the three and **six** **nine** months ended **June 30, 2023** **17%**, respectively, compared to the prior year periods. The increases for both periods **were** driven primarily by (i) an increase in net **sales**. In the second quarter of 2023, **sales as YUPELRI** continued to increase its share of the long-acting nebulized COPD market in both the hospital and outpatient **settings**; and (ii) lower costs incurred by Viatris. YUPELRI continued to be profitable for us on a brand **basis**, and total YUPELRI net sales recorded by Viatris reached an all-time high in the third quarter of 2023.

Licensing revenue was \$2.5 million for the **six** **nine** months ended **June 30, 2022** **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 **June 30, 2022** **September 30, 2022** and for the three and **six** **nine** months ended **June 30, 2023** **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 **will be** **was** returned to us.

23 24

## [Table of Contents](#)

### **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, which include such as general and administrative support functions, insurance office rent, and general supplies. insurance.

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

(In thousands)	Three Months Ended						Three Months Ended			Nine Months Ended		
	June 30,		Change		June 30,		Change		September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%	2023	2022	\$	%
Employee-related	\$ 2,758	\$ 3,968	\$ (1,210)	(30)%	\$ 7,135	\$ 10,231	\$ (3,096)	(30)%	\$ 2,859	\$ 3,615	\$ (756)	(21)%
Share-based compensation	1,855	2,909	(1,054)	(36)	4,297	7,439	(3,142)	(42)	2,004	2,623	(619)	(24)
External-related	3,656	4,784	(1,128)	(24)	8,983	12,030	(3,047)	(25)	2,572	739	1,833	248
Facilities, depreciation, and other allocated expenses	1,156	3,263	(2,107)	(65)	3,582	8,477	(4,895)	(58)	876	2,890	(2,014)	(70)
Total research & development	\$ 9,425	\$ 14,924	\$ (5,499)	(37)%	\$ 23,997	\$ 38,177	\$ (14,180)	(37)%	\$ 8,311	\$ 9,867	\$ (1,556)	(16)%
											\$ 32,308	\$ 48,044
												\$ (15,736)
												(33)

R&D expenses decreased by \$5.5 million \$1.6 million and \$14.2 million \$15.7 million for the three and six nine months ended June 30, 2023 September 30, 2023, respectively, compared to the prior year periods. The decreases were across all the majority of our R&D categories and were primarily driven by our (i) 2023 Strategic Actions announced in February 2023 which included the discontinuation of investment in our research activities and (ii) broader corporate restructuring announced in September 2021 (the "2021 Restructuring"), activities. The \$1.1 million and \$3.0 million decreases \$1.8 million increase in external-related expenses for expense in the three and six months ended June 30, 2023, respectively, were third quarter of 2023 was primarily due to the completion of expenses related to the izencitinib program and other discontinued programs which were partially offset by expenses incurred in 2023 associated with the new amprexetine Phase 3 clinical study (CYPRESS) for MSA patients with symptomatic nOH and the continued progression 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 Restructuring and completed during the third quarter of 2022 (the "2021 Restructuring") are included in the *Restructuring and Related Expenses* section below.

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 \$1.9 million \$1.3 million and \$3.7 million \$5.0 million for three and six nine months ended June 30, 2023 September 30, 2023, respectively, and \$1.5 million \$1.7 million and \$3.1 million \$4.7 million for three and six nine months ended June 30, 2022 September 30, 2022, respectively.

#### [Table of Contents](#)

#### **Selling, General and Administrative**

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

(In thousands)	Three Months Ended				Six Months Ended				Three Months Ended				Nine Months Ended			
	June 30,		Change		June 30,		Change		September 30,		Change		September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%	2023	2022	\$	%	2023	2022	\$	%
Selling, general and administrative	\$ 19,278	\$ 16,222	\$ 3,056	19 %	\$ 38,461	\$ 34,064	\$ 4,397	13 %	\$ 16,142	\$ 16,277	(\$135)	(1)%	\$ 54,603	\$ 50,341	\$ 4,262	8 %

25

## Table of Contents

Selling, general and administrative ("SG&A") expenses increased by \$3.1 million and \$4.4 million were relatively unchanged for the three and six months ended June 30, 2023, respectively, September 30, 2023 compared to the prior year periods. Our cost 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 increases were 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 in external-related expenses, of \$2.1 million SG&A allocated overhead expenses, and \$4.4 million for 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 was primarily attributed to professional and financial advisory services and intellectual property protection services (i.e., Hatch Waxman litigation). As discussed above, the three and six months ended June 30, 2023, respectively, compared to increase in SG&A allocated overhead expenses was driven by the prior year periods. reduction in our research activities.

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

Share-based compensation expense related to selling, general and administrative SG&A expenses was \$4.4 \$4.3 million and \$8.6 million \$12.9 million for the three and six nine months ended June 30, 2023 September 30, 2023, respectively, and \$5.0 \$5.2 million and \$10.5 million \$15.7 million for the three and six nine months ended June 30, 2022 September 30, 2022, respectively.

### Restructuring and Related Expenses

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

(In thousands)	Three Months Ended								Six Months Ended								Three Months Ended							
	June 30,		Change		June 30,		Change		September 30,		Change		September 30,		Change		September 30,		Change		September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%	2023	2022	\$	%	2023	2022	\$	%	2023	2022	\$	%	2023	2022	\$	%
Restructuring and related expenses	\$ 1,169	\$ 1,235	\$ (66)	(5)%	\$ 2,743	\$ 6,042	\$ (3,299)	(55)%	\$ —	\$ (202)	\$ 202	NM %	\$ 2,743	\$ 6,042	\$ (3,299)	(55)%	\$ —	\$ (202)	\$ 202	NM %	\$ 2,743	\$ 6,042	\$ (3,299)	(55)%
Share-based compensation expense (non-cash)	—	1,770	(1,770)	NM	—	6,287	(6,287)	NM	—	711	(711)	NM	—	6,287	(6,287)	NM	—	711	(711)	NM	—	6,287	(6,287)	NM
Total restructuring and related expenses	\$ 1,169	\$ 3,005	\$ (1,836)	(61)%	\$ 2,743	\$ 12,329	\$ (9,586)	(78)%	\$ —	\$ 509	\$ (509)	(100)%	\$ 2,743	\$ 12,329	\$ (9,586)	(78)%	\$ —	\$ 509	\$ (509)	(100)%	\$ 2,743	\$ 12,329	\$ (9,586)	(78)%

NM: Not Meaningful

**Restructuring** 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 \$1.8 million and \$9.6 million for the three and six months ended June 30, 2023 \$10.1 million, respectively, compared to the prior year periods. The year-over-year decreases were period, and was primarily attributed to a smaller reduction in workforce related to the 2023 Strategic Actions compared to the much larger broader reduction in workforce related to the 2021 Restructuring. The \$1.2 million in restructuring expenses in the second quarter of 2023 was due to the loss from the sale of lab equipment associated with the 2023 Strategic Actions that also generated net cash proceeds of \$1.5 million.

Restructuring and related expenses were primarily comprised of one-time severance payments, employee-related separation costs, loss on sale of property and equipment, and other restructuring-related expenses. The \$2.7 million in restructuring and related expenses recognized during the six months ended June, 30 2023 was attributed to the 2023 Strategic Actions as the 2021 Restructuring was fully recognized by the third quarter of 2022. The restructuring and related expenses related to the 2023 Strategic Actions were primarily comprised almost entirely of R&D expenses, expenses related to one-time severance payments, employee-related separation costs, and the loss on sale of property and equipment. Cash-related expenses and non-cash related expenses associated with the 2023 Strategic Actions were \$1.2 million and \$1.5 million for the six nine months ended June 30, 2023 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.

25 26

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#### [Table of Contents](#)

#### **Interest Expense**

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

(In thousands)	Three Months Ended				Six Months Ended				Three Months Ended				Nine Months Ended			
	June 30,		Change		June 30,		Change		September 30,		Change		September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%	2023	2022	\$	%	2023	2022	\$	%
Ampreloxytine royalty contingency (non-cash) 3.25%	\$ (568)	\$ —	\$ (568)	NM %	\$ (1,118)	\$ —	\$ (1,118)	NM %	\$ (609)	\$ (424)	\$ (185)	44 %	\$ (1,727)	\$ (424)	\$ (1,303)	307 %
Convertible senior notes due 2023	—	(2,137)	2,137	NM	—	(4,274)	4,274	NM	—	(1,121)	1,121	NM	—	(5,395)	5,395	NM
<b>Total interest expense</b>	<b>\$ (568)</b>	<b>\$ (2,137)</b>	<b>\$1,569</b>	<b>(73)%</b>	<b>\$ (1,118)</b>	<b>\$ (4,274)</b>	<b>\$ 3,156</b>	<b>(74)%</b>	<b>\$ (609)</b>	<b>\$ (1,545)</b>	<b>\$ 936</b>	<b>(61)%</b>	<b>\$ (1,727)</b>	<b>\$ (5,819)</b>	<b>\$ 4,092</b>	<b>(70)%</b>

NM: Not Meaningful

Interest expense related to continuing operations, was \$0.6 million and \$1.1 million \$1.7 million for the three and six nine months ended June 30, 2023 September 30, 2023, respectively, compared to \$2.1 million \$1.5 million and \$4.3 million \$5.8 million for prior year periods. The \$1.6 million \$0.9 million and \$3.2 million \$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 non-cash interest expense associated with the \$25.0 million funding for ampreloxytine received from Royalty Pharma in July 2022. 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, was as follows:

(In thousands)	Three Months Ended				Six Months Ended				Three Months Ended				Nine Months Ended			
	June 30,		Change		Ended June 30,		Change		September 30,		Change		September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%	2023	2022	\$	%	2023	2022	\$	%
Interest income and other income (expense), net	\$ 2,504	\$ 2,440	\$ 64	3 %	\$ 5,483	\$ 2,065	\$ 3,418	166 %	\$ 1,786	\$ 2,758	\$ (972)	(35) %	\$ 7,269	\$ 4,823	\$ 2,446	51 %

Interest income and other income (expense), net, was relatively flat decreased by \$1.0 million for the three months ended June 30, 2023 September 30, 2023. Although higher investment yields generated additional interest income for the three months ended June 30, 2023, the increase September 30, 2023 compared to the prior year period, the increase was offset by a net gain much lower cash and investment balances in the third quarter of \$2.7 million from the sale of velusetrag to Alfasigma S.p.A. 2023 primarily driven by our capital return program that began in June September 2022.

Interest income and other income (expense), net, increased by \$3.4 million \$2.4 million for the six months ended June 30, 2023 September 30, 2023 compared to the prior year period. The \$3.4 million \$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 which were also partially offset by the \$2.7 million net gain sale from the sale of velusetrag to Alfasigma S.p.A. in June 2022.

#### Table of Contents

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

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

	Three Months Ended	Nine Months Ended

(In thousands)	Three Months Ended				Six Months				September 30,				September 30,			
	June 30,		Change		Ended June 30,		Change		2023		Change		2023		Change	
	2023	2022	\$	%	2023	2022	\$	%	2023	2022	\$	%	2023	2022	\$	%
Provision for income tax (expense) benefit - Continuing operations	\$ (1,458)	\$ 5	\$(1,463)	NM %	\$(1,063)	\$ (519)	\$(544)	105 %								
Provision for income tax expense - Continuing operations									\$ (1,367)	\$ —	\$(1,367)	NM %	\$ (2,430)	\$ (12)	\$(2,418)	NM %

NM: Not Meaningful

26

#### Table of Contents

For the **six** **nine** months ended **June 30, 2023** **September 30, 2023**, the provision for income tax expense was **\$1.1 million** **\$2.4 million** compared to **\$0.5 million** **\$12,000** for the **prior year period** **same period in 2022**. Although we incurred net operating losses on a consolidated basis in 2022 and for the **year-to-date 2023 period**, the provision for income taxes was due to uncertain tax positions taken with respect to transfer pricing 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)	Six Months								Three Months Ended				Nine Months Ended			
	Three Months Ended				Ended June				September 30,		Change		September 30,		Change	
	June 30,		Change		30,		Change		2023	2022	\$	%	2023	2022	\$	%
Net income from discontinued operations	\$ —	\$ 14,602	\$(14,602)	NM %	\$ —	\$ 28,915	\$(28,915)	NM %	\$ —	\$ 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 **above** 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 **six** **nine** months ended **June 30, 2023** **September 30, 2023**.

## Liquidity and Capital Resources

As of **June 30, 2023** **September 30, 2023**, we had approximately **\$167.5** **\$134.0** million in cash, cash equivalents, and investments in marketable securities (excluding restricted cash) and a streamlined balance sheet with 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 **six** **nine** months ended **June 30, 2023** **September 30, 2023**, we repurchased **12.44 million** **15.62 million** shares on the open market at a weighted average cost of **\$10.90** **\$10.65** per share for an aggregate cost of **\$135.6 million** **\$166.4 million**, excluding fees and expenses. Since inception of the capital return program in **September 2022** through **June 30, 2023** **September 30, 2023**, we have repurchased **\$263.8 million** **\$294.6 million** of shares. We **have had** approximately **\$61.2 million** **\$30.4 million** remaining in the capital return program, as of **June 30, 2023** **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, whether, when and on what terms we are able to enter into new collaboration

28

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### [Table of Contents](#)

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 condensed consolidated financial statements based on current operating plans and financial forecasts.

27

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### [Table of Contents](#)

## Cash Flows

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

(In thousands)	Six Months Ended June 30,			Nine Months Ended September 30,		
	2023	2022	Change	2023	2022	Change
Net cash used in operating activities	\$ (23,657)	\$ (40,799)	\$ 17,142	\$ (26,143)	\$ (62,936)	\$ 36,793
Net cash (used in) provided by investing activities	(31,999)	39,439	(71,438)	(32,020)	1,114,848	(1,146,868)
Net cash used in financing activities	(136,920)	(1,308)	(135,612)	(168,324)	(723,334)	555,010

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

Net cash used in operating activities was \$23.7 million \$26.1 million for the six nine months ended June 30, 2023 September 30, 2023, consisting of a net loss of \$37.7 million \$46.7 million, a net increase in cash resulting from adjustments for non-cash and other reconciling items of \$17.7 million \$25.5 million and a net decrease in cash resulting from changes in operating assets and liabilities of \$3.6 million \$4.9 million.

Net cash used in operating activities from continuing operations was \$40.4 million \$57.3 million for the six nine months ended June 30, 2022 September 30, 2022, consisting of a net loss of \$63.1 million \$78.6 million, a net increase in cash resulting from adjustments for non-cash and other reconciling items of \$24.6 million \$38.4 million and a net decrease in cash resulting from changes in operating assets and liabilities of \$2.0 million \$17.2 million. Net cash used in operating activities from discontinued operations was \$0.4 million \$5.6 million was related to TRELEGY Royalty Transaction that was completed in July 2022.

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

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

Net cash provided by investing activities from continuing operations was \$39.4 million \$19.7 million for the six nine months ended June 30, 2022 September 30, 2022, consisting primarily of cash inflows from the net purchase and maturities of marketable securities of \$37.9 million \$15.4 million, cash inflow from the sale of Velusetrag in June 2022 of \$2.7 million, and cash inflows from the net purchase and sale property and equipment of \$1.9 million \$1.6 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 \$136.9 million \$168.3 million for the six nine months ended June 30, 2023 September 30, 2023, consisting primarily of \$135.9 million \$166.8 million of cash outflows related to the repurchase of ordinary shares as part of our capital return program, \$1.5 million of cash outflows related to the repurchase of shares to satisfy tax withholding obligations, and \$0.5 million of cash inflows related to the sale of shares through our employee share purchase program ("ESPP") program.

Net cash used in financing activities from continuing operations was \$1.3 million \$703.1 million for the six nine months ended June 30, 2022 September 30, 2022, consisting primarily of \$1.8 million \$94.0 million in cash outflows used for related to the repurchase of ordinary shares as part of our capital return program and \$631.6 million related to satisfy tax withholding obligations and the extinguishment of our debt. These cash outflows was partially offset by \$0.5 million a \$24.5 million cash inflow relate to the funding of an additional Phase 3 study for the ampreloxetine study. Net cash inflows used in financing activities from discontinued operations was \$20.2 million for the nine months ended September 30, 2022 and was related to the sale a debt redemption premium associated with our debt.

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#### [Table of shares through our ESPP](#) [Contents](#)

#### ***Commitments and Contingencies***

We indemnify our officers and directors for certain events or occurrences, subject to certain limits. We maintain insurance policies that may limit our exposure, and therefore, we believe the fair value of these indemnification agreements is minimal. Accordingly, we have not recognized any liabilities relating to these agreements as of June 30, 2023 September 30, 2023. 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 **June 30, 2023** **September 30, 2023**, no such market-based restricted share units ("RSUs") were granted, and for the **six** **nine** months ended **June 30, 2023** **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

[Table of Contents](#)

these market-based RSUs is being recognized through February 2027. For the three and **six** **nine** months ended **June 30, 2023** **September 30, 2023**, we recognized \$0.2 million and **\$0.3 million** **\$0.5 million**, respectively, of share-based compensation expense related to the awards.

For the three months ended **June 30, 2023** **September 30, 2023**, we did not grant any performance-contingent RSUs, and for the **six** **nine** months ended **June 30, 2023** **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. As of June 30, 2023, In September 2023, we concluded that 52,500 of the RSUs were probable of achievement, of these performance vesting criteria was not probable, and no expense has been as a result, we recognized related to these awards. However, if it were determined in a future period that achievement \$0.3 million of these performance criteria is probable, we would recognize a cumulative catch-up of expense. 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 of **June 30, 2023** **September 30, 2023**, have 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.

**ITEM 4. CONTROLS AND PROCEDURES**

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

We conducted an evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act as of **June 20, 2023** **September 30, 2023**, 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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[Table of Contents](#)

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

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

29

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[Table of Contents](#)

companies each included a paragraph IV certification with respect to five of the Company's patents listed in the 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, 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 covering YUPELRI, granted on July 4, 2023, was subsequently listed in FDA's Orange Book. The Company filed an additional patent infringement suit against all of the above generic companies in the U.S. District Court for the District of New Jersey during August 2023. This suit has been consolidated with the above action.**

On October 27, 2023, subsidiaries of the Company 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 to these parties. Under the Settlement Agreement, the Company and Viatris entities granted Teva a royalty-free, non-exclusive, non-sublicensable, non-transferable license to manufacture and market Teva's generic version of YUPELRI® (reverfenacin) inhalation solution in the United States on or after the licensed launch date of April 23, 2039, subject to certain exceptions as is customary in these types of agreements. As required by law, the settlement is subject to review by the U.S. Department of Justice and the Federal Trade Commission. The patent litigation against the other generic companies, along with certain affiliates, remains pending.

Please also see "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 for additional 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.

31

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[Table of Contents](#)

### Summary of Principal Risks Associated with Theravance Biopharma's Business

- We may never achieve or sustain profitability; 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

30

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[Table of Contents](#)

adversely affect our financial condition or our ability to commercialize any approved products; and

- We and/or our collaboration partners and those commercializing products with respect to which we have an economic interest or right to receive royalties may face competition from companies seeking to market generic versions of any approved products in which we have an interest, such as YUPELRI.

## RISKS RELATING TO THE COMPANY

### **We may never achieve or sustain profitability. 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 **six** **nine** months ended **June 30, 2023** **September 30, 2023**, we recognized net losses of **\$15.6 million** **\$9.0 million** and **\$37.7 million** **\$46.7 million**, respectively. Although we recognized \$872.1 million 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. 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 **\$891.6 million** **\$900.6 million** as of **June 30, 2023** **September 30, 2023**. Despite the fact that we are approaching non-GAAP profitability, 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 to 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 pipeline. While our YUPELRI operations have been profitable

32

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### [Table of Contents](#)

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"), including the maintenance of an independent sales and marketing organization with appropriate technical expertise, a medical affairs presence and consultant support, and post-marketing studies. Our commitment of resources to the continued development of amprexetine and YUPELRI will require ongoing funding. 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;
- 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 **new** 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, 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.

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[Table of Contents](#)

***If YUPELRI's acceptance by physicians, patients, third-party payors, or the medical community in general does not continue to grow, we may not receive significant additional revenues from sales of this product.***

The commercial success of YUPELRI depends upon its acceptance by physicians, patients, third-party payors and the medical community in general. YUPELRI's acceptance by these parties may not continue to grow as we have planned. YUPELRI competes predominantly nebulized LAMA Lonhala® Magnair® (glycopyrrrolate) dosed two times per day and with short acting nebulized bronchodilators that are dosed three to four times per day. We have seen increased volatility in sales of YUPELRI coinciding with the suspension of in-person sales calls, having less access to physicians and other healthcare providers and the progression of the COVID-19 pandemic and, if physicians, patients, third-party payors, or the medical community in general believe that nebulized therapy presents a risk of further spreading COVID-19 or that YUPELRI is otherwise 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 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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[Table of Contents](#)

- 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 amprexetine, and product may be delayed and programs may be terminated due to many factors, including, but not limited to:

- lack of effectiveness of product candidates during clinical studies;
- adverse events, safety issues or side effects (or perceived adverse developments or results) relating to the product candidates or their formulation into medicines;

32

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[Table of Contents](#)

- unfavorable study data or unfavorable interpretations of data among the FDA and foreign regulatory authorities;
- insufficient capital to continue our development programs;
- inability to enter into partnering arrangements relating to the development and commercialization of our programs and product candidates or partner decisions not to maintain a partnership with us;
- delays in patient enrollment and variability in the number and types of patients available for clinical studies;
- competitive clinical trials;
- our inability or the inability of our collaborators or licensees to manufacture or obtain from third parties materials sufficient for use in non-clinical and clinical studies;
- governmental or regulatory delays or suspensions of the conduct of the clinical trials and changes in regulatory requirements, policy and guidelines;
- challenges related to the COVID-19 pandemic, including with recruitment and/or progressing patients through studies;
- failure of any partners to advance our product candidates through clinical development;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;

34

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[Table of Contents](#)

- 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 including, without limitation, any delays in development in our programs, any halting of development in our programs, any difficulties or delays encountered with regard to the FDA or other third country regulatory authorities with respect to our programs, or any indication from clinical or non-clinical studies that the compounds in our programs are not safe, 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 amprexetine did not meet its primary endpoint. There can be no assurance that our Phase 3 study for amprexetine will be completed on the timeline we expect or at all.

***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 amprexetine, 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

33

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[Table of Contents](#)

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 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.

35

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[Table of Contents](#)

**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 refevenacin, including YUPELRI. Under the terms of the agreement, we and Viatris will co-develop nebulized refevenacin, including YUPELRI, for COPD and other respiratory diseases. In December 2019, we entered into a License Agreement with Pfizer Inc. ("Pfizer"). Under the agreement, Viatris granted exclusive development and commercialization rights to nebulized refevenacin in China and adjacent territories, which include Hong Kong SAR, the license agreement, Macau SAR, and Taiwan, and we provided Pfizer with an exclusive global license. The license is eligible to develop, manufacture, and receive low double-digit tiered royalties on net sales of nebulized refevenacin, if approved. Viatris is responsible for all aspects of development and commercialization of the compounds from our preclinical program for skin-targeted, locally-acting pan-Janus kinase (JAK) inhibitors that can be rapidly metabolized. The commercialization of nebulized refevenacin in China and adjacent territories, including pre- and post-launch activities and product registration and all associated costs. In connection with these agreements, these parties have 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 partners may not fulfill their obligations under these 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 Agreement, 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. We are assessing our choices with respect to the program covered by the Pfizer Agreement. We may be unable to assume the development and commercialization responsibilities covered by the agreements or enter into alternative arrangements with a third-party to develop and commercialize such product candidates. If a partner elected to promote alternative products and product candidates such as its own products and product candidates in preference to those licensed from us, does not devote an adequate amount of time and resources to our product or product candidates or is otherwise unsuccessful in its efforts with respect to our products or product candidates, the development and commercialization of products and product candidates covered by the agreements could be delayed or terminated, and future payments to us could be delayed, reduced or eliminated and our business and financial condition could be materially and adversely affected. Accordingly, our ability to receive any revenue from the products and product candidates covered by these agreements is dependent on the efforts of our partners. If a partner terminates or breaches its agreements with us, otherwise fails to complete its obligations in a timely manner or alleges that we have breached our contractual obligations under these agreements, the chances of successfully developing or commercializing products and product candidates under the collaboration could be materially and adversely affected. In addition, effective collaboration with a partner requires coordination to achieve complex and detail-intensive goals between entities that potentially have different priorities, capabilities and processes and successful navigation of the challenges such coordination entails. We could also become involved in disputes with a partner, which

34

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[Table of Contents](#)

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 ampreloxetine 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

[Table of Contents](#)

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;

[Table of Contents](#)

- conduct effective clinical trials and obtain required regulatory approvals;
- develop and effectively implement commercialization strategies, with or without collaborative partners; and
- successfully collaborate with pharmaceutical companies in the development and commercialization of new medicines.

Pharmaceutical companies, including companies with which we collaborate, may invest heavily to quickly discover and develop or in-license novel compounds that could make our product candidates 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 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® (glycopyrrrolate) dosed two times per day and with short acting nebulized bronchodilators that are dosed three to four times per day. If we are not able to compete effectively against our current and future competitors, our business will not grow, our financial condition and operations will suffer and the price of our securities could fall.

37

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[Table of Contents](#)

***There is a single source of supply for our product candidates and for YUPELRI, and our business will be harmed if any of these single-source manufacturers are not able to satisfy demand and alternative sources are not available.***

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

Our manufacturing strategy presents the following additional risks:

- because of the complex nature of many of our compounds, our manufacturers may not be able to successfully manufacture our APIs and/or drug products in a cost-effective and/or timely manner and changing manufacturers for our APIs or drug products could involve lengthy technology transfer, validation and regulatory qualification activities for the new manufacturer;
- the processes required to manufacture certain of our APIs and drug products are specialized and available only from a limited number of third-party manufacturers;
- the availability of specialized materials needed to manufacture our APIs and drug products or YUPELRI;
- because some of the third-party manufacturers are located in numerous locations outside of the US, and we are conducting global clinical trials there may be difficulties in shipping and importing and exporting our APIs and drug products or their components globally.

36

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[Table of Contents](#)

***We are subject to extensive and ongoing regulation, oversight and other requirements by the FDA and failure to comply with these regulations and requirements may subject us to penalties that may adversely affect our financial condition or our ability to commercialize any approved products.***

Prescription drug advertising and promotion are closely scrutinized by the FDA, including substantiation of promotional claims, disclosure of risks and safety information, and the use of themes and imagery in advertising and promotional materials. As with all companies selling and marketing products regulated by the FDA in the US, we are prohibited from promoting any uses of an approved product, such as YUPELRI, that are outside the scope of those uses that have been expressly approved by the FDA as safe and effective on the product's label.

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

We are also subject to regulation by regional, national, state and local agencies, including the Department of Justice, the Federal Trade Commission, the Office of Inspector General of the US Department of Health and Human Services ("OIG") and other regulatory bodies with respect to any approved product, such as YUPELRI, as well as governmental authorities in those foreign countries in which any product is approved for commercialization. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern

38

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#### [Table of Contents](#)

to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including non-clinical and clinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information and promotion. If we or any third parties that provide these services for us are unable to comply, we may be subject to regulatory or civil actions or penalties that could significantly and adversely affect our business.

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

Failure to satisfy required post-approval requirements and/or commitments may have implications for a product's approval and may carry civil monetary penalties. Any failure to maintain regulatory approval will materially limit the ability to commercialize a product or any future product candidates and if we fail to comply with FDA regulations and requirements, the FDA could potentially take a number of enforcement actions against us, including the issuance of untitled letters, warning letters, preventing the introduction or delivery of the product into interstate commerce in the US, misbranding charges, product seizures, injunctions, and civil monetary penalties, which would materially and adversely affect our business and financial condition and may cause the price of our securities to fall.

The risks identified in this risk factor relating to regulatory actions and oversight by agencies in the US and throughout the world also apply to the commercialization of any partnered products by our collaboration partners and those commercializing products with respect to which we have an economic interest or right to receive royalties, including GSK, and such regulatory actions and oversight may limit those parties' ability to commercialize such products, which could materially and adversely affect our business and financial condition, and which may cause the price of our securities to fall.

***We and/or our collaboration partners and those commercializing products with respect to which we have an economic interest or right to receive royalties may face competition from companies seeking to market generic versions of any approved products in which we have an interest, such as YUPELRI.***

Under the Drug Price Competition and Patent Term Restoration Act of 1984, a company may submit an abbreviated new drug application ("ANDA") under section 505(j) of the Federal Food, Drug, and Cosmetic Act to market a generic version of an approved drug. Because a generic applicant does not conduct its own clinical studies, but instead relies on the FDA's finding of safety and effectiveness for the

approved drug, it is able to introduce a competing product into the market at a cost significantly below that of the original drug. Although we have multiple patents

37

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[Table of Contents](#)

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, on January 10, 2023, the FDA included seven ANDAs that referred to YUPELRI (reverfenacin) inhalation solution and contained a paragraph IV certification on its Paragraph IV Certifications List. We are not aware of any other paragraph IV notifications with respect to 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.*"

39

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[Table of Contents](#)

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

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

Collaborations with third parties regarding our programs may require us to relinquish material rights, including revenue from commercialization of our medicines, or to assume material ongoing development obligations that we would have to fund. These collaboration arrangements are complex and time-consuming to negotiate, and if we are unable to reach agreements with third-party collaborators, we may fail to meet our business objectives and our financial condition may be adversely affected. We face significant competition in seeking third-party collaborators. We may be unable to find third parties to pursue product collaborations on a timely basis or on acceptable terms.

Furthermore, once we enter into a collaboration, our collaboration partners are frequently important for the success of the product or product candidate. For example, Viatris' role in the commercialization of YUPELRI is important to the overall success of product. In addition, since we do not currently intend to progress our skin-selective pan-JAK inhibitor program internally, Pfizer was important to such program's development. However, for any collaboration, we may not be able to control the amount of time and resources that our partners devote to our products or product candidates and our partners may choose to prioritize alternative programs or otherwise be unsuccessful in their efforts with respect to our products or product candidates. In addition, effective collaboration with a partner requires coordination to achieve complex and detail-intensive goals between entities that potentially have different priorities, capabilities and processes and successful navigation of the challenges such coordination entails. For example, Viatris has a substantial existing product portfolio largely comprising generic products, other considerations and incentives that influence its resource allocation, and background, experiences, priorities and internal organizational processes that differ from our own. As a result of these differing backgrounds, interests and processes, Viatris may take actions that it believes are in its best interest, but which

38

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[Table of Contents](#)

might not be in the best interests of either us or our other shareholders. Our inability to successfully collaborate with third parties would increase our development costs and may cause us to choose not to continue development of certain product candidates, would limit the likelihood of successful commercialization of some of our product candidates, may cause us not to continue commercialization of our authorized products and could cause the price of our securities to fall.

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

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

40

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[Table of Contents](#)

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 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 TRELEGY, and we have no current authority to enforce rights under the GSK Agreements assigned to TRC. However, if there are any adverse developments or perceived adverse developments with respect to TRELEGY, we may not realize the value we currently anticipate from the Ongoing Economic Interest, which would harm our business and may cause the price of our securities to fall. Examples of such adverse developments include, but are not limited to:

- disappointing or lower than expected sales of TRELEGY;
- the emergence of new closed triple or other alternative therapies or any developments regarding competitive therapies, including comparative price or efficacy of competitive therapies;
- disputes between any of Royalty Pharma, GSK, Innoviva and us;
- GSK deciding to modify, delay or halt the TRELEGY program;
- any adverse effects resulting from the COVID-19 pandemic;
- any safety, efficacy or other concerns regarding the TRELEGY program; or

39

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[Table of Contents](#)

- 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;

41

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[Table of Contents](#)

- compliance with other applicable FDA and other regulatory requirements in the US or other foreign jurisdictions, including those described elsewhere in this report;
- competition, whether from current competitors or new products developed by others in the future;
- claims relating to intellectual property;
- any future disruptions in GSK's business which would affect its ability to commercialize TRELEGY, including, disruptions due to the COVID-19 pandemic;
- the ability of TRELEGY to achieve wider acceptance among physicians, patients, third-party payors, or the medical community in general;
- global economic conditions; and
- any of the other risks relating to commercialization of TRELEGY.

These risks and uncertainties could materially impact the amount and timing of future Milestone Payments and Outer Years Royalty, which could have a material adverse effect on our future revenues, other financial results and our financial position and cause the price of our securities to fall.

***If we lose key management, sales 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 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

40

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[Table of Contents](#)

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 rely extensively on computer systems to maintain information and manage our finances and business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including but not limited to trade secrets or other intellectual property, proprietary business information and personal information) and it is critical that we maintain the confidentiality and integrity of such confidential information. Although we have security measures in place, our internal information technology systems and those of our CROs and other service providers, including cloud based and hosted applications, data and services, 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

[Table of Contents](#)

and/or significant disruption to our business. If a disruption of information technology systems or security breach results in a loss of or damage to our data or regulatory applications, unauthorized access, use, or disclosure of, or the prevention of access to, confidential information, or other harm to our business, we could incur liability and reputational harm, we could be required to comply with federal and/or state breach notification laws and foreign law equivalents, we may incur legal expenses to protect our confidential information, the further development of our product candidates could be delayed and the price of our securities could fall. For example, the loss of clinical trial data from completed or ongoing clinical trials of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. As another example, we may incur penalties imposed by the competent authorities in the EU Member States in case of breach of the EU rules governing the collection and processing of personal data, including unauthorized access to or disclosure of personal data. Although we have security and fraud prevention measures in place, we have been subject to immaterial payment fraud activity. In 2017, we filed a lawsuit (which has since been resolved) against a former employee for misappropriation of our confidential, proprietary and trade secret information. Moreover, there can be no assurance that our security measures will prevent service interruptions or security breaches that could adversely affect our business. 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 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.

[Table of Contents](#)

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, hostilities in Ukraine, 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

43

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[Table of Contents](#)

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, 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 **research** drug development activities and of much of our equipment could make it difficult and costly for us to recover from this type of disaster. We may not have adequate insurance to cover our losses resulting from disasters or other similar significant business interruptions and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business and financial condition, which could cause the price of our securities to fall.

42

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## [Table of Contents](#)

**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 **\$61.2 million** **\$30.4 million** (as of **June 30, 2023** **September 30, 2023**) of our ordinary shares authorized under our share repurchase program. 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 **"Restructuring"** **"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 **and** announced additional headcount reductions in February 2023. If our current operating plans or financial forecasts change, we may require or seek additional funding in the form of public or private equity or equity-linked offerings, debt financings or additional collaborations and licensing arrangements. In addition, as of **June 30, 2023** **September 30, 2023**, we had cash, cash equivalents and marketable securities of **\$167.5 million** **\$134.0 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;

44

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## [Table of Contents](#)

- the scope, duration, expenditures and technical obstacles associated with our amprexetine program, including preparing for potential product approvals of amprexetine;
- 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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[Table of Contents](#)

***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 research, development and commercialization activities or to license to third parties the rights to develop and/or commercialize products or technologies that we would otherwise seek to develop and/or commercialize ourselves or on terms that are less attractive than they might otherwise be, any of which could materially harm our business.

Furthermore, the terms of any 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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[Table of Contents](#)

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.

44

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[Table of Contents](#)

***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

46

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[Table of Contents](#)

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 2021, 2022, 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, 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

45

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[Table of Contents](#)

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.

47

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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 **June 30, 2023** **September 30, 2023**, we owned a total of **235** **232** issued US patents and **1,385** **1,234** granted foreign patents, as well as additional pending US and foreign patent applications. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be invalidated or be too narrow to prevent third parties from developing or designing around these patents, including the patents that relate to YUPELRI. If the sufficiency of the breadth or strength of protection provided by our patents with respect to a product candidate is threatened, it could dissuade companies from collaborating with us to develop product candidates and threaten our ability to commercialize products. Further, if we encounter delays in our clinical trials or in obtaining regulatory approval of our product candidates, the effective patent lives of the related product candidates could be reduced.

In addition, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, for processes for which patents are difficult to enforce and for any other elements of our drug discovery and development processes that involve proprietary know-how, information and technology that is not covered by patent applications. Although we require our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be misappropriated, disclosed or used for unauthorized purposes or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the US. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the US and abroad. If we are unable to prevent material disclosure of the intellectual

property related to our technologies to third parties, we will not be able to establish or, if established, maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition and results of operations, which could cause the price of our securities to fall.

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

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

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

In addition, 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

48

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[Table of Contents](#)

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. 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 to 2039. Our collaboration partner, Viatris, is responsible for enforcing our Orange Book patents relating to YUPELRI, in consultation with us, and their views on the ongoing litigation, process or strategy may differ from ours, and we have a reduced ability to control the outcome of the litigation. For additional discussion of risks related to partnering programs, please see the risk factor entitled *"If we are unable to enter into future collaboration arrangements or if any such collaborations with third parties are unsuccessful, we may be unable to fully develop and commercialize certain product candidates and our business will be adversely affected."* If we fail to effectively enforce our proprietary rights against others, our business will be harmed and the price of our securities could fall.

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

The risks identified in the two preceding risk factors may also apply to the intellectual property protection efforts of our partners or future partners and to GSK with respect to TRELEGY in which we maintain the Ongoing Economic Interest. To the extent the intellectual property protection of any partnered assets is successfully challenged or encounters problems with the US Patent and Trademark Office or other comparable agencies throughout the world, the future commercialization of these potential medicines could no longer be economically feasible. Any challenge to the intellectual property protection of a late-stage development or commercial-stage asset, particularly those of TRELEGY, could harm our business and cause the price of our securities to fall.

47

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[Table of Contents](#)

***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

49

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#### [Table of Contents](#)

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, and Connecticut have enacted privacy laws similar to the CCPA that impose new obligations or limitations in areas affecting our business. These laws and regulations are evolving and subject to interpretation and may impose limitations on our activities or otherwise adversely affect our business. The obligations to comply with the CCPA and evolving legislation involve, among other things, updates to our notices and the development of new processes internally and with our partners. We may be subject to fines, penalties, or private actions in the event of non-compliance with such laws.

In addition, we may obtain health information from third parties (e.g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, (collectively, "HIPAA"). HIPAA imposes privacy and security obligations on covered entity health care providers, health plans, and health care clearinghouses, as well as their "business associates"—certain persons or entities that create, receive, maintain, or transmit protected health information in connection with providing a specified service or performing a function on behalf of a covered entity. Although we are not directly subject to HIPAA, we could be

48

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[Table of Contents](#)

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 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 transfer personal data, including health data from clinical trials 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 laws concern, in particular, in some instances the consent of the individuals to whom the personal data relate, the processing details disclosed to the individuals, the sharing of personal data with third parties, the transfer of personal data out of the European Economic Area ("EEA") or Switzerland, contracting requirements (such as with clinical trial sites and vendors), and security breach notifications, as well as substantial potential fines, in some cases up to 4% of annual global

[Table of Contents](#)

turnover, for breaches of the data protection obligations. 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 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.

Legal mechanisms to allow for the transfer of personal data from the EEA or UK to the US may impact our ability 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

49

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[Table of Contents](#)

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.

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 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;

51

---

[Table of Contents](#)

- 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 eliminated effective 2025 under the Inflation Reduction **Act (IRA) Act**), 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.

50

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#### [Table of Contents](#)

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 **IRA 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 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

52

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#### [Table of Contents](#)

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. Ampreloxytine received an orphan drug designation 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.

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.

51

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#### [Table of Contents](#)

***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 Viatris. 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 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

53

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[\*\*Table of Contents\*\*](#)

liability for past quarters. Price recalculations also may affect the 340B ceiling price and the average sales price. Manufacturers may need to make additional restatements beyond the three-year period.

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

In order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by the Department of Veterans Affairs ("VA"), Department of Defense ("DoD"), Public Health Service, and Coast Guard (the "Big Four agencies") and certain federal grantees, a manufacturer is required to list its innovator products on a VA Federal Supply Schedule ("FSS") contract and charge a price to the Big Four agencies that is no higher than the Federal Ceiling Price ("FCP"), which is a price calculated pursuant to a statutory formula. In addition, manufacturers must submit to the VA quarterly and annual "non-federal average manufacturer price" ("Non-FAMP") calculations for each NDC-11 of their innovator drugs. Under Section 703 of the National Defense Authorization Act for FY 2008, the manufacturer is required to pay quarterly rebates to DoD on utilization of its innovator products that are dispensed through DoD's Tricare network pharmacies to Tricare beneficiaries.

52

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[\*\*Table of Contents\*\*](#)

Individual states in the US, as noted, have also passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including 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.

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

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

- The US federal healthcare Anti-Kickback Statute prohibits any person from, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchasing, leasing, ordering or arranging for or recommending of any good or service for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute is subject to evolving interpretation and has been applied by government enforcement officials to a number of common business arrangements in the pharmaceutical industry. The government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the statute or specific intent to violate it. There are a number of statutory exemptions and regulatory safe harbors protecting some common activities from prosecution; however, those exceptions and safe harbors are drawn narrowly. Failure to meet all of the requirements of a particular statutory exception or regulatory

54

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[Table of Contents](#)

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

53

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[Table of Contents](#)

significant mandatory penalties per false claim or statement for violations. Because of the potential for large monetary exposure, healthcare and pharmaceutical companies often resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings. As part of these resolutions, Companies may enter into corporate integrity agreements with the government, which may impose substantial costs on companies to ensure compliance. Criminal penalties, including imprisonment and criminal fines, are also possible for making or presenting a false, fictitious or fraudulent claim to the federal government.

- HIPAA, among other things, imposes criminal and civil liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors, and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HIPAA also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal healthcare Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.
- The federal Physician Payment Sunshine Act, implemented as the Open Payments Program, requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the US Department of Health and Human Services, Centers for Medicare and Medicaid Services, information related to payments and other transfers of value, directly or indirectly, to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. 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

55

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[Table of Contents](#)

timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties.

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

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that we or our partners may fail to comply fully with one or more of these requirements. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply

54

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[Table of Contents](#)

with applicable fraud and abuse or other healthcare laws and regulations or guidance. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid in the US and similar programs outside the US, contractual damages, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. If any of the physicians or other providers or entities with whom we do or expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert resources and the attention of our management from operating our business.

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

Our research and 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 research, development and production efforts, which could harm our business, which could cause the price of our securities to fall.

[Table of Contents](#)

**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, the last reported sales price of our ordinary shares on Nasdaq fluctuated between a low of \$8.33 per share and a high of \$12.96 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.

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[\*\*Table of Contents\*\*](#)

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

- any adverse developments or results or perceived adverse developments or results with respect to YUPELRI, including without limitation, lower than expected sales of YUPELRI, difficulties or delays encountered with regard to the FDA or other regulatory authorities in this program or any indication from clinical or non-clinical studies that YUPELRI is not safe or efficacious;
- any adverse developments or results or perceived adverse developments or results with respect to TRELEGY;
- any adverse developments or results or perceived adverse developments or results with respect to our clinical development programs, including, without limitation, any delays in development in these programs, any halting of development in these programs, any difficulties or delays encountered with regard to the FDA or other regulatory authorities in these programs, or any indication from clinical or non-clinical studies that the compounds in such programs are not safe or efficacious;
- any announcements of developments with, or comments by, the FDA or other regulatory authorities with respect to products we or our partners have under development, are manufacturing or have commercialized;
- any adverse developments or disagreements or perceived adverse developments or disagreements with respect to our relationship with Royalty Pharma, or the relationship of Royalty Pharma and GSK;
- any adverse developments or perceived adverse developments with respect to our relationship with any of our research, development or commercialization partners, including, without limitation, disagreements that may arise between us and any of those partners;
- any adverse developments or perceived adverse developments in our programs with respect to partnering efforts or otherwise;

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[\*\*Table of Contents\*\*](#)

- 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;

56

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[Table of Contents](#)

- 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 ~~largest~~ 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;
- 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.

58

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[Table of Contents](#)

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. 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

[Table of Contents](#)

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 the Company, us, and the market price of our ordinary shares could also experience periods of increased volatility as a result.

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

Based solely on our review of publicly available filings, as of **June 30, 2023** **September 30, 2023**, our three largest shareholders collectively owned **40.8%** **43.1%** 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 of any of our shareholders would increase if they do not participate in our ongoing open market purchase program.

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

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

- require supermajority shareholder voting to effect certain amendments to our amended and restated memorandum and articles of association;
- maintain a classified board of directors until our annual general meeting in 2026;
- restrict our shareholders from calling meetings or acting by written consent in lieu of a meeting;

[Table of Contents](#)

- 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

58

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[Table of Contents](#)

any facts necessary for a shareholder motion or to solicit proxies from other shareholders in connection with a proxy contest.

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

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

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

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

We are incorporated as an exempted company limited by shares with limited liability under the laws of the Cayman Islands. A material portion of our assets are located outside of the US. As a result, it may be difficult for our shareholders to enforce judgments against us or

judgments obtained in US courts predicated upon the civil liability provisions of the federal securities laws of the US or any state of the US.

[Table of Contents](#)

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.

[Table of Contents](#)

***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 September 2022, however, our board of directors authorized 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 in September 2022, bringing the total capital return program to \$325.0 million. As of ~~June 30, 2023~~ September 30, 2023, we had repurchased ~~\$263.8 million~~ \$294.6 million of shares, and we had approximately ~~\$61.2 million~~ \$30.4 million remaining in the capital return program which is expected to be completed by the end of 2023. There is no guarantee that any of the remaining approximately ~~\$61.2 million~~ \$30.4 million of our ongoing \$325.0 million 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 the rates they expect. 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 and only being required to provide two years of audited financial statements in annual reports.

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

61

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[Table of Contents](#)

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.

60 62

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[Table of Contents](#)

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF 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 **June 30, 2023** **September 30, 2023**, we had repurchased **\$263.8 million** **\$294.6 million** of shares, and, as of **September 30, 2023**, we **have** had approximately **\$61.2 million** **\$30.4 million** remaining in the capital return program which is expected to be completed by the end of 2023.

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 **June 30, 2023** **September 30, 2023**. All shares purchased to date under the capital return program were cancelled and ceased to be outstanding.

	Maximum Dollar			Maximum Dollar	
	Total Number of	Value of Shares		Total Number of	Value of Shares

Period	Shares Purchased that May Yet Be as Part of Publicly Announced Plans or Programs (in thousands)				Shares Purchased that May Yet Be as Part of Publicly Announced Plans or Programs (in thousands)			
	Total Number of Shares Purchased	Weighted Per Share (1)	Announced Plans or Programs	Plans or Programs (in thousands)	Total Number of Shares Purchased	Weighted Per Share (1)	Announced Plans or Programs	Plans or Programs (in thousands)
April 1, 2023 to April 30, 2023	2,834,088	\$ 11.26	2,834,088	\$ 109,747 (2)				
May 1, 2023 to May 31, 2023	2,860,878	11.06	2,860,878	78,093 (2)				
June 1, 2023 to June 30, 2023	1,588,500	10.64	1,588,500	61,193 (2)				
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)
<b>Total</b>	<b>7,283,466</b>	<b>\$ 11.05</b>	<b>7,283,466</b>	<b>\$ 61,193 (2)</b>	<b>3,177,900</b>	<b>\$ 9.70</b>	<b>3,177,900</b>	

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

(2) Gives effect to the \$75.0 million increase in the size of our capital return program announced on February 27, 2023.

6163

## Table of Contents

### ITEM 6. EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference		
		Filed Herewith	Form	Date/Period End Date
3.1	<a href="#">Amended Memorandum and Articles of Association of Theravance Biopharma, Inc.</a>		8-K	May 3, 2023
10.1+	<a href="#">Amended and Restated 2013 Equity Incentive Plan of Theravance Biopharma, Inc.</a>		8-K	May 3, 2023

31.1	<a href="#"><u>Certification of Chief Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended</u></a>	X
31.2	<a href="#"><u>Certification of Chief Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended</u></a>	X
32(1)	<a href="#"><u>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</u></a>	X
101	Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended <b>June 30, 2023</b> <b>September 30, 2023</b> , formatted in iXBRL: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations and Comprehensive <b>Loss, Income (Loss)</b> , (iii) Condensed Consolidated Statements of Shareholders' Equity, <b>(Deficit)</b> , (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.

+ Management contract or compensatory plan or arrangement.

6264

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[Table of Contents](#)

**SIGNATURES**

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

Theravance Biopharma, Inc.

Date: **August 9, 2023** **November 9, 2023**

/s/ Rick E WINNINGHAM

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

Date: **August 9, 2023** **November 9, 2023**

/s/ Aziz SAWAF

Aziz Sawaf  
Senior Vice President and Chief Financial Officer

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**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.

Date: August 9, 2023 November 9, 2023

/S/ Rick E WINNINGHAM

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

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**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: **August 9, 2023** November 9, 2023

**/s/ Aziz SAWAF**

Aziz Sawaf

Senior Vice President and Chief Financial Officer

(Principal Financial Officer)

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**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 **six** **nine** months ended **June 30, 2023** **September 30, 2023** 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: **August 9, 2023** November 9, 2023

By:

**/s/ Rick E WINNINGHAM**

Rick E Winningham

Chairman of the Board and Chief Executive Officer

(Principal Executive Officer)

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

I, 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 **six** **nine** months ended **June 30, 2023** **September 30, 2023** 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: **August 9, 2023** November 9, 2023

By:

**/s/ Aziz SAWAF**

Aziz Sawaf

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

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