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

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2022

OR

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

For the transition period from _____ to _____

Commission file number: 001-36033

THERAVANCE BIOPHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Cayman Islands

(State or Other Jurisdiction of
Incorporation or Organization)

98-1226628

(I.R.S. Employer
Identification No.)

PO Box 309

**Ugland House, South Church Street
George Town, Grand Cayman, Cayman Islands**
(Address of Principal Executive Offices)

KY1-1104
(Zip Code)

(650) 808-6000

(Registrant's Telephone Number, Including Area Code)

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

Non-accelerated Filer

Accelerated Filer

Smaller Reporting Company

Emerging Growth Company

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

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

As of October 31, 2022, the number of the registrant's outstanding ordinary shares was 67,365,912.

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

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

| | September 30, 2022 | December 31, 2021 |
|--|-----------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 418,538 | \$ 89,959 |
| Short-term marketable securities | 68,294 | 83,506 |
| Receivables from collaborative arrangements | 14,114 | 14,065 |
| Prepaid clinical and development services | 2,645 | 10,245 |
| Other prepaid and current assets | 8,127 | 8,561 |
| Amounts due from TRC, LLC (Discontinued operations) | — | 43,534 |
| Total current assets | 511,718 | 249,870 |
| Property and equipment, net | 11,884 | 13,657 |
| Operating lease assets | 39,992 | 39,690 |
| Future contingent milestone and royalty assets | 194,200 | — |
| Restricted cash | 836 | 837 |
| Other assets | 4,866 | 3,228 |
| Equity in net assets of TRC, LLC (Discontinued operations) | — | 67,537 |
| Total assets | <u>\$ 763,496</u> | <u>\$ 374,819</u> |
| Liabilities and Shareholders' Equity (Deficit) | | |
| Current liabilities: | | |
| Accounts payable | \$ 5,337 | \$ 3,098 |
| Accrued personnel-related expenses | 7,560 | 12,796 |
| Accrued clinical and development expenses | 4,078 | 17,010 |
| Accrued general and administrative expenses | 3,749 | 2,898 |
| Operating lease liabilities | 692 | 503 |
| Deferred revenue | 24 | 98 |
| Current portion of non-recourse notes due 2035, net | — | 16,940 |
| Accrued interest payable | — | 1,246 |
| Other accrued liabilities | 142 | 1,304 |
| Income tax payable (Discontinued operations) | 120,550 | — |
| Accrued interest payable (Discontinued operations) | — | 2,694 |
| Total current liabilities | 142,132 | 58,587 |
| Long-term operating lease liabilities | 51,381 | 52,681 |
| Future royalty payment contingency | 24,888 | — |
| Long-term deferred revenue | 199 | 310 |
| Unrecognized tax benefits | 62,661 | 240 |
| Other long-term liabilities | 1,657 | 2,180 |
| Non-recourse notes due 2035, net | — | 371,359 |
| Convertible senior notes due 2023, net | — | 228,035 |
| Commitments and contingencies | | |
| Shareholders' Equity (Deficit) | | |
| Preferred shares, \$0.00001 par value: 230 shares authorized, no shares issued or outstanding | — | — |
| Ordinary shares, \$0.00001 par value: 200,000 shares authorized; 67,366 and 74,435 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively | 1 | 1 |
| Additional paid-in capital | 1,324,247 | 1,387,469 |
| Accumulated other comprehensive loss | (121) | — |
| Accumulated deficit | (843,549) | (1,726,043) |
| Total shareholders' equity (deficit) | 480,578 | (338,573) |
| Total liabilities and shareholders' equity (deficit) | <u>\$ 763,496</u> | <u>\$ 374,819</u> |

See accompanying notes to condensed consolidated financial statements.

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|---|--------------------|--|---------------------|
| | 2022 | 2021 | 2022 | 2021 |
| Revenue: | | | | |
| Viartis collaboration agreement | \$ 12,445 | \$ 10,397 | \$ 34,010 | \$ 31,716 |
| Collaboration revenue | 6 | 2,797 | 187 | 8,649 |
| Licensing revenue | — | — | 2,500 | — |
| Total revenue | <u>12,451</u> | <u>13,194</u> | <u>36,697</u> | <u>40,365</u> |
| Expenses: | | | | |
| Research and development (1) | 9,867 | 43,739 | 48,691 | 162,431 |
| Selling, general and administrative (1) | 16,277 | 21,299 | 51,105 | 77,780 |
| Restructuring and related expenses (1) | 509 | 1,771 | 11,427 | 1,771 |
| Total expenses | <u>26,653</u> | <u>66,809</u> | <u>111,223</u> | <u>241,982</u> |
| Loss from operations | (14,202) | (53,615) | (74,526) | (201,617) |
| Interest expense | (1,545) | (2,136) | (5,819) | (6,410) |
| Loss on extinguishment of debt | (3,034) | — | (3,034) | — |
| Interest income and other income (expense), net | 2,758 | (166) | 4,823 | 771 |
| Loss from continuing operations before income taxes | (16,023) | (55,917) | (78,556) | (207,256) |
| Provision for income tax benefit (expense) | — | 7 | (12) | — |
| Net loss from continuing operations | (16,023) | (55,910) | (78,568) | (207,256) |
| Income from discontinued operations before income taxes | 1,115,016 | 20,602 | 1,143,930 | 39,864 |
| Provision for income tax expense | (182,362) | — | (182,868) | — |
| Net income from discontinued operations | <u>932,654</u> | <u>20,602</u> | <u>961,062</u> | <u>39,864</u> |
| Net income (loss) | <u>\$ 916,631</u> | <u>\$ (35,308)</u> | <u>\$ 882,494</u> | <u>\$ (167,392)</u> |
| Net unrealized gain (loss) on available-for-sale investments | (76) | 6 | (121) | (33) |
| Total comprehensive income (loss) | <u>\$ 916,555</u> | <u>\$ (35,302)</u> | <u>\$ 882,373</u> | <u>\$ (167,425)</u> |
| Net income (loss) per share: | | | | |
| Continuing operations - basic and diluted | \$ (0.21) | \$ (0.76) | \$ (1.04) | \$ (3.05) |
| Discontinued operations - basic and diluted | \$ 12.35 | \$ 0.28 | \$ 12.70 | \$ 0.59 |
| Net income (loss) - basis and diluted | <u>\$ 12.14</u> | <u>\$ (0.48)</u> | <u>\$ 11.66</u> | <u>\$ (2.46)</u> |
| Shares used to compute basis and diluted net income (loss) per share | <u>75,515</u> | <u>73,574</u> | <u>75,678</u> | <u>67,945</u> |

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

| (In thousands) | Three Months Ended | | Nine Months Ended | |
|--|---------------------------|------------------|--------------------------|------------------|
| | September 30, | | September 30, | |
| | 2022 | 2021 | 2022 | 2021 |
| Research and development | \$ 2,623 | \$ 6,956 | \$ 10,709 | \$ 22,192 |
| Selling, general and administrative | 5,196 | 7,414 | 16,488 | 22,951 |
| Restructuring and related expenses | 711 | — | 5,587 | — |
| Total share-based compensation expense | <u>\$ 8,530</u> | <u>\$ 14,370</u> | <u>\$ 32,784</u> | <u>\$ 45,143</u> |

See accompanying notes to condensed consolidated financial statements.

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

| | Ordinary Shares | | Additional Paid-In Capital | Accumulated Other | Accumulated Deficit | Total Shareholders' Equity |
|---|-----------------|-------------|----------------------------------|-----------------------|------------------------|----------------------------------|
| | Shares | Amount | | Comprehensive Loss | | |
| Balances at June 30, 2022 | 76,427 | \$ 1 | \$ 1,410,415 | \$ (45) | \$ (1,760,180) | \$ (349,809) |
| 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 |
| Balances at September 30, 2022 | <u>67,366</u> | <u>\$ 1</u> | <u>\$ 1,324,247</u> | <u>\$ (121)</u> | <u>\$ (843,549)</u> | <u>\$ 480,578</u> |

| | Ordinary Shares | | Additional Paid-In Capital | Accumulated Other | Accumulated Deficit | Total Shareholders' Equity |
|---|-----------------|-------------|----------------------------------|-----------------------|------------------------|----------------------------------|
| | Shares | Amount | | Comprehensive Loss | | |
| Balances at December 31, 2021 | 74,435 | \$ 1 | \$ 1,387,469 | \$ — | \$ (1,726,043) | \$ (338,573) |
| Repurchase of ordinary shares | (9,645) | — | (94,037) | — | — | (94,037) |
| Proceeds from ESPP purchases | 72 | — | 488 | — | — | 488 |
| Employee share-based compensation expense | — | — | 32,784 | — | — | 32,784 |
| Issuance of restricted shares | 2,764 | — | — | — | — | — |
| Repurchase of shares to satisfy tax withholding | (260) | — | (2,457) | — | — | (2,457) |
| Net unrealized loss on marketable securities | — | — | — | (121) | — | (121) |
| Net income | — | — | — | — | 882,494 | 882,494 |
| Balances at September 30, 2022 | <u>67,366</u> | <u>\$ 1</u> | <u>\$ 1,324,247</u> | <u>\$ (121)</u> | <u>\$ (843,549)</u> | <u>\$ 480,578</u> |

| | Ordinary Shares | | Additional Paid-In Capital | Accumulated Other | Accumulated Deficit | Total Shareholders' Deficit |
|---|-----------------|-------------|----------------------------------|-------------------------|------------------------|-----------------------------------|
| | Shares | Amount | | Comprehensive Income | | |
| Balances at June 30, 2021 | 73,470 | \$ 1 | \$ 1,358,318 | \$ 8 | \$ (1,658,701) | \$ (300,374) |
| Net proceeds from sale of ordinary shares | — | — | — | — | — | — |
| Proceeds from ESPP purchases | — | — | — | — | — | — |
| Employee share-based compensation expense | — | — | 14,370 | — | — | 14,370 |
| Issuance of restricted shares | 391 | — | — | — | — | — |
| Option exercises | — | — | — | — | — | — |
| Repurchase of shares to satisfy tax withholding | (163) | — | (2,286) | — | — | (2,286) |
| Net unrealized gain on marketable securities | — | — | — | 6 | — | 6 |
| Net loss | — | — | — | — | (35,308) | (35,308) |
| Balances at September 30, 2021 | <u>73,698</u> | <u>\$ 1</u> | <u>\$ 1,370,402</u> | <u>\$ 14</u> | <u>\$ (1,694,009)</u> | <u>\$ (323,592)</u> |

| | Ordinary Shares | | Additional Paid-In Capital | Accumulated Other | Accumulated Deficit | Total Shareholders' Deficit |
|---|-----------------|-------------|----------------------------------|--------------------------------|------------------------|-----------------------------------|
| | Shares | Amount | | Comprehensive Income (Loss) | | |
| Balances at December 31, 2020 | 64,328 | \$ 1 | \$ 1,222,818 | \$ 47 | \$ (1,526,617) | \$ (303,751) |
| Net proceeds from sale of ordinary shares | 7,705 | — | 108,180 | — | — | 108,180 |
| Proceeds from ESPP purchases | 188 | — | 2,862 | — | — | 2,862 |
| Employee share-based compensation expense | — | — | 45,143 | — | — | 45,143 |
| Issuance of restricted shares | 1,978 | — | — | — | — | — |
| Option exercises | — | — | 5 | — | — | 5 |
| Repurchase of shares to satisfy tax withholding | (501) | — | (8,606) | — | — | (8,606) |
| Net unrealized loss on marketable securities | — | — | — | (33) | — | (33) |
| Net loss | — | — | — | — | (167,392) | (167,392) |
| Balances at September 30, 2021 | <u>73,698</u> | <u>\$ 1</u> | <u>\$ 1,370,402</u> | <u>\$ 14</u> | <u>\$ (1,694,009)</u> | <u>\$ (323,592)</u> |

See accompanying notes to condensed consolidated financial statements.

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

| | Nine Months Ended September 30, | |
|--|---------------------------------|-------------------|
| | 2022 | 2021 |
| Operating activities | | |
| Net income (loss) | \$ 882,494 | \$ (167,392) |
| Less: Net income from discontinued operations | (961,062) | (39,864) |
| Net loss from continuing operations | (78,568) | (207,256) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 3,057 | 4,551 |
| Amortization and accretion income, net | (342) | 9 |
| Amprexetine interest accretion | 424 | — |
| Share-based compensation | 32,784 | 45,143 |
| Gain on disposal of property and equipment | (96) | — |
| Gain on sale of Velusetrag | (2,709) | — |
| Amortization of right-of-use assets | 2,284 | 2,758 |
| Gain from lease modification | — | (1,863) |
| Loss on extinguishment of debt | 3,034 | — |
| Other | — | 35 |
| Changes in operating assets and liabilities: | | |
| Receivables from collaborative and licensing arrangements | (49) | 1,867 |
| Prepaid clinical and development services | 7,600 | 7,132 |
| Other prepaid and current assets | (1,148) | (99) |
| Right-of-use lease assets | (2,587) | — |
| Other assets | (1,743) | (1,006) |
| Accounts payable | 2,150 | 2,206 |
| Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued liabilities | (18,465) | (36,573) |
| Accrued interest payable | (1,246) | — |
| Deferred revenue | (186) | (8,648) |
| Operating lease liabilities | (1,111) | 443 |
| Other long-term liabilities | (421) | 776 |
| Net cash used in operating activities - continuing operations | (57,338) | (190,525) |
| Net cash used in operating activities - discontinued operations | (5,598) | 25,101 |
| Net cash used in operating activities | (62,936) | (165,424) |
| Investing activities | | |
| Purchases of property and equipment | (306) | (2,962) |
| Purchases of marketable securities | (93,260) | (104,774) |
| Maturities of marketable securities | 108,700 | 221,400 |
| Sale of short-term investments and marketable securities | 5 | — |
| Proceeds from the sale of Velusetrag | 2,709 | — |
| Proceeds from the sale of property and equipment | 1,866 | 6 |
| Net cash provided by investing activities - continuing operations | 19,714 | 113,670 |
| Net cash provided by investing activities - discontinued operations | 1,095,134 | — |
| Net cash provided by investing activities | 1,114,848 | 113,670 |
| Financing activities | | |
| Proceeds from the sale of ordinary shares, net | — | 108,180 |
| Repurchases of ordinary shares | (94,037) | — |
| Proceeds from amprelosetine funding, net | 24,464 | — |
| Principal payment on 2035 notes | (399,998) | (10,730) |
| Principal payment on 2023 notes | (231,605) | — |
| Proceeds from ESPP purchases | 488 | 2,862 |
| Proceeds from option exercises | — | 5 |
| Repurchase of shares to satisfy tax withholding | (2,457) | (8,606) |
| Net cash (used in) provided by financing activities - continuing operations | (703,145) | 91,711 |
| Net cash used in financing activities - discontinued operations | (20,189) | — |
| Net cash (used in) provided by financing activities | (723,334) | 91,711 |
| Net increase in cash, cash equivalents, and restricted cash | 328,578 | 39,957 |
| Cash, cash equivalents, and restricted cash at beginning of period | 90,796 | 82,300 |
| Cash, cash equivalents, and restricted cash at end of period | \$ 419,374 | \$ 122,257 |
| Supplemental disclosure of cash flow information | | |
| Cash paid for interest | \$ 22,244 | \$ 26,954 |
| Cash paid (received) for income taxes, net | \$ 26 | \$ (3,814) |

See accompanying notes to condensed consolidated financial statements.

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

1. Organization and Summary of Significant Accounting Policies

Theravance Biopharma, Inc. (“Theravance Biopharma” or the “Company”) is a biopharmaceutical company primarily focused on the discovery, development, and commercialization of medicines. The Company’s core purpose is to create *medicines that make a difference*[®] in people's lives.

Basis of Presentation

The Company’s condensed consolidated financial information as of September 30, 2022 and for the three and nine months ended September 30, 2022 and 2021 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, 2021 financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission (“SEC”) on February 28, 2022.

The results for the three and nine months ended September 30, 2022 are not necessarily indicative of the results to be expected for the year ending December 31, 2022, 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 three and nine months ended September 30, 2022 (see Note 8. Sale of Equity Interests in Theravance Respiratory Company, LLC). 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.

Use of Estimates

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

Significant Accounting Policies

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, 2021.

Recently Adopted Accounting Pronouncements

In August 2020, the FASB issued ASU 2020-06, *Debt - Debt with Conversion and other Options (Subtopic 470-20) and Derivatives and Hedging: Contracts in Entity’s Own Equity (Subtopic 815-40)* (“ASU 2020-06”). ASU 2020-06 simplifies the complexity associated with applying GAAP for certain financial instruments with characteristics of liabilities and equity by removing certain accounting models which separate the embedded conversion features from the host contract for convertible instruments. The standard also enhances the consistency of earnings-per-share calculations by requiring that an entity use the if-converted method and that the effect of potential share settlement be included in diluted earnings-per-share calculations. ASU 2020-06 became effective for fiscal years and interim periods

within those fiscal years beginning after December 15, 2021. The Company evaluated ASU 2020-06 and determined that its adoption did not have an impact on the Company's condensed consolidated financial statements and related disclosures.

Recently Issued Accounting Pronouncements Not Yet Adopted

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

2. Net Income (Loss) per Share

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

| (In thousands, except per share data) | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|-------------|------------------------------------|--------------|
| | 2022 | 2021 | 2022 | 2021 |
| Numerator: | | | | |
| Net loss from continuing operations | \$ (16,023) | \$ (55,910) | \$ (78,568) | \$ (207,256) |
| Net income from discontinued operations | 932,654 | 20,602 | 961,062 | 39,864 |
| Net income (loss) | 916,631 | (35,308) | 882,494 | (167,392) |
| Denominator: | | | | |
| Weighted-average ordinary shares outstanding | 75,515 | 73,574 | 75,678 | 68,021 |
| Less: weighted-average ordinary shares subject to forfeiture | — | — | — | (76) |
| Weighted-average ordinary shares outstanding - basic and diluted | 75,515 | 73,574 | 75,678 | 67,945 |
| Net income (loss) per ordinary share: | | | | |
| Continuing operations - basic and diluted | \$ (0.21) | \$ (0.76) | \$ (1.04) | \$ (3.05) |
| Discontinued operations - basic and diluted | \$ 12.35 | \$ 0.28 | \$ 12.70 | \$ 0.59 |
| Net income (loss) - basic and diluted | \$ 12.14 | \$ (0.48) | \$ 11.66 | \$ (2.46) |

Anti-dilutive Securities

In accordance with 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 nine months ended September 30, 2022 and 2021, 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 September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|--------|------------------------------------|--------|
| | 2022 | 2021 | 2022 | 2021 |
| Share issuances under equity incentive plans and purchase plans | 5,036 | 8,900 | 7,137 | 8,307 |
| Share issuances upon the conversion of convertible senior notes | — | 6,676 | — | 6,676 |
| Total | 5,036 | 15,576 | 7,137 | 14,983 |

3. Revenue

Revenue from Collaborative Arrangements

Viatrix

In January 2015, the Company and Viatrix Inc. (“Viatrix”) established a strategic collaboration (the “Viatrix Agreement”) for the development and commercialization of revefenacin, including YUPELRI® (revefenacin) inhalation solution. The Company entered into the collaboration to expand the breadth of its revefenacin development program and extend its commercial reach 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, Viatrix is leading the commercialization of YUPELRI, and the Company co-promotes the product under a profit and loss sharing arrangement (65% to Viatrix; 35% to Theravance Biopharma). Outside the US (including China and adjacent territories), Viatrix is responsible for development and commercialization and will pay the Company a tiered royalty on net sales at percentage royalty rates ranging from low double-digits to mid-teens. Viatrix is the principal in the sales transactions, and as a result, the Company does not reflect the product sales in its condensed consolidated financial statements.

As of September 30, 2022, the Company is eligible to receive from Viatrix potential global development, regulatory and sales milestone payments totaling up to \$257.5 million in the aggregate, with \$205.0 million associated with YUPELRI monotherapy, and \$52.5 million associated with future potential combination products. Of the \$205.0 million associated with monotherapy, \$187.5 million relates to sales milestones based on achieving certain levels of net sales and \$17.5 million relates to global development and regulatory actions. The \$52.5 million associated with future potential combination products relates solely to development and regulatory actions.

The Viatrix Agreement is considered to be within the scope of ASC 808, *Collaborative Arrangements* and partially within the scope of ASC 606, *Revenue from Contracts with Customers*, as the parties are active participants and exposed to the risks and rewards of the collaborative activity with a unit of account provided to Viatrix as a customer. Under the terms of the Viatrix Agreement, which included the delivery by the Company of a license to Viatrix to develop and commercialize revefenacin in exchange for \$15.0 million received in 2015, Viatrix 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 and, as such, the reimbursable program costs are excluded from the transaction price. The Company determined the license to develop and commercialize revefenacin to be a unit of account and a separate performance obligation, for which Viatrix is a customer, with the \$15.0 million for the delivery of the license representing the transaction price.

The future potential milestone amounts for the Viatrix Agreement were not included in the transaction price, as they were all determined to be fully constrained following the concepts of ASC 606. As part of the Company’s evaluation of the development and regulatory milestones constraint, the Company determined that the achievement of such milestones 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 Viatrix each quarter under the profit-sharing structure are disaggregated according to their individual components. In accordance with the applicable accounting guidance, amounts receivable from Viatrix in connection with the commercialization of YUPELRI are recorded within the condensed consolidated statements of operations as revenue from “Viatrix collaboration agreement” irrespective of whether the overall collaboration is profitable. Amounts payable to Viatrix, if any, in connection with the commercialization of YUPELRI are recorded within the condensed consolidated statements of operations as a collaboration loss within selling, general and administrative expenses. Any reimbursement from Viatrix attributed to the 65% cost-sharing of the Company’s R&D expenses is characterized as a reduction of R&D

expense, as the Company does not consider performing research and development services for reimbursement to be a part of its ordinary activities. For the three and nine months ended September 30, 2022, 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 September 30, | | Nine Months Ended September 30, | |
|----------------|--|-----------|------------------------------------|-----------|
| | 2022 | 2021 | 2022 | 2021 |
| | Viatri collaboration agreement - <i>Amounts receivable from Viatri</i> | \$ 12,445 | \$ 10,397 | \$ 34,010 |

While Viatri records the total net sales of YUPELRI within its consolidated financial statements, Viatri collaboration agreement revenue includes the Company’s implied 35% share of net sales of YUPELRI for the three and nine months ended September 30, 2022 of \$18.7 million and \$51.2 million, respectively, before deducting shared expenses. For the three and nine months ended September 30, 2021, the Company’s implied 35% share of net sales of YUPELRI were \$13.8 million and \$41.3 million, respectively, before deducting shared expenses.

Other Collaborative Arrangement Revenues

The Company’s other collaborative arrangement revenues consisted of:

| (In thousands) | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|-----------------------------|-------------------------------------|----------|------------------------------------|----------|
| | 2022 | 2021 | 2022 | 2021 |
| Alfasigma | \$ — | \$ 3 | \$ 169 | \$ 10 |
| Viatri | 6 | 6 | 18 | 18 |
| Janssen | — | 2,788 | — | 8,621 |
| Total collaboration revenue | \$ 6 | \$ 2,797 | \$ 187 | \$ 8,649 |

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.

Janssen Biotech

In February 2018, the Company entered into a global co-development and commercialization agreement with Janssen Biotech, Inc. (“Janssen”) for izencitinib and related back-up compounds for inflammatory intestinal diseases, including ulcerative colitis and Crohn’s disease (the “Janssen Agreement”). The Company received an upfront payment of \$100.0 million related to the Janssen Agreement. Following unfavorable Phase 3 clinical trial results for izencitinib announced in August 2021, Janssen terminated the Janssen Agreement effective January 16, 2022. As a result, the Company did not recognize any collaboration revenue related to the Janssen Agreement for the three and nine months ended September 30, 2022. For the three and nine months ended September 30, 2021, the Company recognized \$2.8 million and \$8.6 million, respectively, in collaboration revenue related to the Janssen Agreement.

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 expense related to the reimbursement payments:

| (In thousands) | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|-------------------------------------|-------------------------------------|----------|------------------------------------|----------|
| | 2022 | 2021 | 2022 | 2021 |
| Viartis | \$ 1,657 | \$ 1,096 | \$ 4,736 | \$ 1,257 |
| Janssen | — | 2,205 | — | 4,730 |
| Total reduction to R&D expense, net | \$ 1,657 | \$ 3,301 | \$ 4,736 | \$ 5,987 |

Revenue from Licensing Arrangements

Pfizer

In December 2019, the Company 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 an exclusive license to develop, manufacture and commercialize certain compounds for all uses other than gastrointestinal, ophthalmic, and respiratory applications. The Company received an upfront cash payment of \$10.0 million in 2019, and in March 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.

As of September 30, 2022, the Company is eligible to receive up to an additional \$237.5 million in development and sales milestone payments from Pfizer. In addition, the Company is eligible to receive a tiered royalty on worldwide net sales of any potential products under the license at percentage royalty rates ranging from middle single-digits to low double-digits.

4. Sale of Velusetrag

Velusetrag is an oral, investigational medicine developed for gastrointestinal motility disorders. It is a highly selective agonist with high intrinsic activity at the human 5-HT₄ receptor.

In 2012, the Company partnered with Alfasigma S.p.A. (“Alfasigma”) in the development of velusetrag and its commercialization in certain countries. In April 2018, Alfasigma exercised its option to continue to develop and commercialize velusetrag, and the Company elected not to pursue further development. Global rights to develop, manufacture and commercialize velusetrag were transferred to Alfasigma under the terms of the collaboration arrangement.

On June 30, 2022, the Company entered into an Asset Purchase Agreement (the “APA”) to sell all of its velusetrag assets to Alfasigma. In connection with the closing of the transaction, Alfasigma acquired, among other things, (i) intellectual property and (ii) books and records related to velusetrag. As consideration for the velusetrag sale, the Company received an upfront payment of \$2.8 million in July 2022, and pursuant to the terms of the APA, the Company is eligible to receive up to \$105.0 million in additional future developmental and sales milestones.

At the time of the sale, the velusetrag assets had no remaining book value on the Company’s records, and all of the velusetrag assets were delivered to Alfasigma. For the nine months ended September 30, 2022, the Company recognized a net gain of \$2.7 million, after transaction costs, related to the sale of velusetrag within “interest income and other income (expense), net” on the consolidated statements of operations.

5. Cash, Cash Equivalents, and Restricted Cash

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

| (In thousands) | September 30, | |
|--|---------------|------------|
| | 2022 | 2021 |
| Cash and cash equivalents | \$ 418,538 | \$ 121,424 |
| Restricted cash | 836 | 833 |
| Total cash, cash equivalents, and restricted cash shown on the condensed consolidated statements of cash flows | \$ 419,374 | \$ 122,257 |

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 any short and long-term marketable securities that are reported separately on the condensed consolidated balance sheets.

The increase in cash and cash equivalents, compared to the prior year period, was primarily due to the sale of the Company's equity interest in Theravance Respiratory Company, LLC (see Note 8 for further information) in July 2022. The Company also proceeded to paydown all of its long-term debt (See Note 10 for further information) by the end of August 2022, and in September 2022, the Company initiated a \$250.0 million capital return program (see Note 14 for further information).

6. 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) | | September 30, 2022 | | | |
|--------------------------|---------|--------------------|------------------------|-------------------------|----------------------|
| | | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
| US government securities | Level 1 | \$ 3,987 | \$ — | \$ (8) | \$ 3,979 |
| Corporate notes | Level 2 | 12,006 | — | (38) | 11,968 |
| Commercial paper | Level 2 | 61,377 | — | (75) | 61,302 |
| Marketable securities | | 77,370 | — | (121) | 77,249 |
| Money market funds | Level 1 | 397,674 | — | — | 397,674 |
| Total | | \$ 475,044 | \$ — | \$ (121) | \$ 474,923 |

| | | December 31, 2021 | | | |
|--------------------------|---------|-------------------|------------------------------|-------------------------------|-------------------------|
| (In thousands) | | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
| US government securities | Level 1 | \$ 29,986 | \$ — | \$ (2) | \$ 29,984 |
| Corporate notes | Level 2 | 5,034 | — | (2) | 5,032 |
| Commercial paper | Level 2 | 48,490 | 1 | (1) | 48,490 |
| Marketable securities | | 83,510 | 1 | (5) | 83,506 |
| Money market funds | Level 1 | 50,228 | — | — | 50,228 |
| Total | | <u>\$ 133,738</u> | <u>\$ 1</u> | <u>\$ (5)</u> | <u>\$ 133,734</u> |

As of September 30, 2022, all of the Company’s available-for-sale securities had contractual maturities within six months, and the weighted-average maturity of marketable securities was less than one month. There were no transfers between Level 1 and Level 2 during the periods presented, and there have been no material changes to the Company’s valuation techniques during the three and nine months ended September 30, 2022.

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

| | | September 30, 2022 | | | | | |
|--------------------------|--|-------------------------|-------------------------------|-------------------------|-------------------------------|-------------------------|-------------------------------|
| | | Less than 12 Months | | Greater than 12 Months | | Total | |
| (In thousands) | | Estimated Fair Value | Gross Unrealized Losses | Estimated Fair Value | Gross Unrealized Losses | Estimated Fair Value | Gross Unrealized Losses |
| US government securities | | \$ 3,979 | \$ (8) | \$ — | \$ — | \$ 3,979 | \$ (8) |
| Corporate notes | | 11,968 | (38) | — | — | 11,968 | (38) |
| Commercial paper | | 61,302 | (75) | — | — | 61,302 | (75) |
| Total | | <u>\$ 77,249</u> | <u>\$ (121)</u> | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 77,249</u> | <u>\$ (121)</u> |

| | | December 31, 2021 | | | | | |
|--------------------------|--|-------------------------|-------------------------------|-------------------------|-------------------------------|-------------------------|-------------------------------|
| | | Less than 12 Months | | Greater than 12 Months | | Total | |
| (In thousands) | | Estimated Fair Value | Gross Unrealized Losses | Estimated Fair Value | Gross Unrealized Losses | Estimated Fair Value | Gross Unrealized Losses |
| US government securities | | \$ 19,991 | \$ (2) | \$ — | \$ — | \$ 19,991 | \$ (2) |
| Corporate notes | | 5,031 | (2) | — | — | 5,031 | (2) |
| Commercial paper | | 9,995 | (1) | — | — | 9,995 | (1) |
| Total | | <u>\$ 35,017</u> | <u>\$ (5)</u> | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 35,017</u> | <u>\$ (5)</u> |

The Company invests primarily in high credit quality and short-term maturity debt securities with the intent to hold such securities until maturity at par value. The Company does not intend to sell the investments that are currently in an unrealized loss position, and it is unlikely that it will be required to sell the investments before recovery of their amortized cost basis, which may be at maturity. The Company reviewed its available-for-sale debt securities and determined that there were no credit-related losses to be recognized as of September 30, 2022.

As of September 30, 2022, the Company’s accumulated other comprehensive income (loss) on its condensed consolidated balance sheets consisted of net unrealized gains (losses) on available-for-sale investments. For the three and nine months ended September 30, 2022 and 2021, the Company did not sell any marketable securities.

7. Leases

Dublin Lease

In April 2017, the Company leased approximately 6,100 square feet of office space in Dublin, Ireland, under a non-cancelable operating lease that expires in April 2027 (“Dublin Lease”). In May 2022, the Company entered into an agreement under which it assigned the Dublin Lease (“Lease Assignment”) to an unaffiliated company. The Company determined that the Lease Assignment would be accounted for as a lease modification under ASC 842, *Leases*.

As a result of the lease modification, the Company reduced the value of its operating lease assets and liabilities in the consolidated balance sheets by \$1.4 million and \$1.5 million, respectively. Under the Lease Assignment, the Company sold furniture and equipment located in the Dublin office to the unaffiliated company and recognized a net loss of \$0.1 million from the sale.

Following the completion of the Lease Assignment, in May 2022, the Company entered into a new operating lease agreement for approximately 700 square feet of office space in Dublin, Ireland, effective June 2022. The lease has a two year term ending in May 2024, and the Company may terminate the lease by providing three months prior written notice. Under the new lease, the Company will incur total base rent expense of approximately \$0.4 million (or \$0.2 million annually) which is recognized on straight-line basis over the two-year lease term. The Company's annual straight-line base rent for its previous Dublin Lease was approximately \$0.4 million annually.

South San Francisco Sublease

In June 2022, the Company entered into a non-cancelable agreement under which it subleased approximately 78,000 square feet of its South San Francisco office and laboratory space to an unaffiliated company. The sublease term continues through May 2030, consistent with the expiration of the Company's head lease, and the subtenant has no option to extend the sublease. Under the terms of the sublease, the Company is entitled to receive an initial monthly base rent of \$0.5 million which will be subject to annual increases of 3%, as well as the subtenant's proportionate share of the property's operating expenses. The Company expects to receive a total of \$51.7 million in base rent over the sublease term which represents a \$13.5 million premium over its proportionate lease payment obligations under the head lease. Under the terms of the head lease, 50% of the sublease premium, equal to \$6.7 million, shall be shared with the landlord and 50% shall be retained by the Company which equates to a base rent savings of approximately \$0.8 million annually. The Company recognizes the sublease income on a straight-line basis over the term of the sublease which is reflected as a reduction of R&D expense and selling, general and administrative expenses in the consolidated statements of operations. No lease modification was deemed to have occurred by entering into the sublease agreement because the Company was not released, either fully or in part, from its obligations under the head lease.

Sublease income related to this sublease agreement, including base rent and certain sublease transaction cost reimbursements from the landlord, was \$1.6 million and \$1.9 million for the three and nine months ended September 30, 2022, respectively. The following table summarizes the future undiscounted cash inflows relating to the sublease agreement as of September 30, 2022:

| <u>(In thousands)</u> | |
|--|------------------|
| <u>Year ending December 31:</u> | |
| 2022 | \$ 3,554 |
| 2023 | 6,495 |
| 2024 | 6,495 |
| 2025 | 6,495 |
| 2026 | 6,495 |
| Thereafter | 22,192 |
| Total operating sublease receipts | <u>\$ 51,726</u> |

8. Sale of Equity Interests in Theravance Respiratory Company, LLC and Discontinued Operations

On July 20, 2022, the Company completed the sale of its 2,125 Class B Units and 6,375 Class C Units (collectively, the "Issuer II Units") of Theravance Respiratory Company, LLC ("TRC") to, and entered into a sale of future royalties from sales of ampreloxetine (see Note 9 below) with, 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"). The Issuer II Units represent the right to receive 85% of the royalty payments on worldwide net sales of Assigned Collaboration Products (as defined in the Purchase Agreement) pursuant to the terms of that certain Collaboration Agreement, dated as of November 14, 2002, by and between Innoviva, Inc. (formerly known as Theravance, Inc.), a Delaware corporation ("Innoviva"), and Glaxo Group Limited, a private company limited by shares registered under the laws of England and Wales ("GSK") (as amended, the "Collaboration Agreement"). Assigned

Collaboration Products is primarily comprised of TRELEGY ELLIPTA (“TRELEGY”). Total consideration payable by Royalty Pharma under the terms of the TRC Transaction included initial consideration of \$1,326.6 million plus additional payments as further described below.

At the closing of the TRC Transaction (the “Closing”), 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 the 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.

The Purchase Agreement contained customary representations and warranties of the Company and Royalty Pharma, including with respect to organization, authorization, intellectual property matters and tax matters, and certain covenants with respect to confidentiality, taxes and actions and conduct relating to preservation of TRC prior to the Closing. The Company and Royalty Pharma will each indemnify the other against damages arising from breaches of representations, warranties and covenants under the Purchase Agreement.

Effective as of the Closing, the Company consented to certain amendments to the Collaboration Agreement and the Extension Agreement, dated as of March 3, 2014, by and between the Company and GSK, as well as the termination of the Master Agreement, dated as of March 3, 2014, by and between Innoviva, the Company and GSK, and further released Innoviva, Innoviva TRC Holdings LLC, a Delaware limited liability company, Royalty Pharma and TRC for claims relating to TRC or the ownership of TRC by the Company or Innoviva prior to the Closing.

The Company evaluated the TRC Transaction under ASC 860, *Transfers and Servicing of Financial Assets*, (“ASC 860”) and determined that the future potential Milestone Payments and royalty payments are considered a form of continuing involvement between the Company and Royalty Pharma. The Company further evaluated the TRC Transaction under ASC 860 and concluded that (i) the equity interests in TRC have been isolated from the Company (even in the event of bankruptcy or other receivership); (ii) Royalty Pharma has the right to pledge or exchange the TRC assets it received from the Company without constraint; and (iii) the Company had surrendered control over its equity interests in TRC to Royalty Pharma. Based on the Company’s evaluation under ASC 860, the TRC Transaction was treated as a sale, and the Company recognized a gain from the sale of its equity interests in TRC of \$1,141.1 million based on the excess of the total net consideration allocated to the sale of the Company’s equity interests (based on relative fair value) of \$1,301.6 million over the carrying value of the equity interests sold of \$136.7 million, less transaction costs of \$23.8 million. The total net consideration of \$1,301.6 million included upfront cash of \$1,107.4 million, plus an estimated \$194.2 million representing the fair value of the future Milestone Payments and royalties (collectively, “Contingent Consideration”).

The Contingent Consideration was initially measured at fair value utilizing a Monte Carlo simulation model to calculate the present value of the risk-adjusted cash flows estimated to be received from the Contingent Consideration. The discount rate utilized in the valuation model was 7.83%. The fair value model involved significant unobservable inputs derived using management’s estimates. Management’s estimates were based in part on external data, and reflected management’s judgements and forecasts. The significant unobservable inputs included estimates of the forecasted TRELEGY net revenues, the expected volume and term of the royalty stream, and the royalty rate. These estimates are considered Level 3 fair value inputs. The Company will reassess the carrying value of the Contingent Consideration when indicators of impairment are identified and will recognize any increases in the carrying value of the asset when such contingent gains are realized. As of September 30, 2022, there were no changes in the carrying value of the Contingent Consideration since its initial measurement date.

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

On July 20, 2022, the Company completed a monetization of its ownership in a significant equity method investment that had a major effect on the Company’s financial results (see Note 8 for more information). In accordance with GAAP, the sale was accounted for as an asset disposal.

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 GAAP, the TRC Transaction was accounted for as a sale of a financial asset. For all periods presented, balances and the results related to TRC have been classified as discontinued operations on the Company’s condensed consolidated financial statements.

The results of discontinued operations consisted of the following:

| (In thousands) | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|------------------|------------------------------------|------------------|
| | 2022 | 2021 | 2022 | 2021 |
| Income from investments in TRC, LLC | \$ — | \$ 30,208 | \$ 53,237 | \$ 68,681 |
| Transaction-related legal expenses (prior to July 20, 2022) | — | — | (5,057) | — |
| Interest expense on 9.5% Non-recourse notes due 2035 | (2,046) | (9,606) | (21,312) | (28,817) |
| 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>\$ 932,654</u> | <u>\$ 20,602</u> | <u>\$ 961,062</u> | <u>\$ 39,864</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 3-09 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 periods and the current year period through the TRC disposal date, 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 September 30, | | Nine Months Ended September 30, | |
|-----------------------------------|-------------------------------------|-----------|------------------------------------|-----------|
| | 2022 | 2021 | 2022 | 2021 |
| Royalty revenue and gross profit | \$ — | \$ 35,585 | \$ 72,029 | \$ 84,055 |
| Income from continuing operations | — | 35,391 | 71,693 | 80,244 |
| Net income | — | 35,539 | 62,632 | 79,655 |

9. Amprexetine Funding

As part of the Purchase Agreement (see Note 8 above), the Company received \$25.0 million in cash from Royalty Pharma in exchange for certain royalty rights to amprexetine and is entitled to receive an additional \$15.0

million upon the first regulatory approval of any pharmaceutical product that contains amprelosetine as an active pharmaceutical ingredient by either (a) the FDA or (b) the first of (i) the European Medicines Agency or (ii) all four of Germany, France, Italy and Spain. In exchange for the \$25.0 million and potential \$15.0 million in cash (the “Amprelosetine Funding”), the Company will make quarterly royalty payments to Royalty Pharma equal to the amount of Amprelosetine Net Sales (as defined in the Purchase Agreement) recognized during the applicable quarter multiplied by 2.5% for the first \$500.0 million in Amprelosetine Net Sales and 4.5% for Amprelosetine Net Sales in excess of \$500.0 million. These royalty payments from the Company to Royalty Pharma will continue until, on a country by country and product by product basis, the later of (a) the expiration of all valid and enforceable claims of any patent, or pending claim of a good faith patent application during the five (5) years from the initial filing of such application, that cover the applicable amprelosetine product or the manufacture or use thereof in the applicable country and (b) the expiration of regulatory exclusivity granted by the FDA or equivalent organization in the applicable country. As the Amprelosetine Funding and the TRC Transaction were part of the same Purchase Agreement, the Company evaluated the total consideration received from Royalty Pharma and determined that the consideration received for each of the individual transactions approximated their relative fair values.

The Company accounted for the funding received from Royalty Pharma as a liability because the Company has significant continuing involvement in generating the future revenue stream from which the liability would be repaid to Royalty Pharma. If the regulatory approval milestone is achieved, the Company will recognize the \$15.0 million milestone payment as an increase to the accumulated liability. If and when amprelosetine obtains regulatory approval and is commercially launched, the Company will recognize the royalties paid to Royalty Pharma as a decrease to the accumulated liability due to Royalty Pharma and a corresponding reduction in cash. If amprelosetine regulatory approval is not achieved or if amprelosetine sales are never recognized, the liability recognized would be extinguished as the Company would not be obligated to repay any of the funding amounts received from Royalty Pharma.

The carrying amount of the liability for the future royalty payment contingency was based on the upfront \$25.0 million received and management's estimate of (i) the risk-adjusted future contingent \$15.0 million milestone; and (ii) royalties to be paid to Royalty Pharma and then discounted over the life of the arrangement using an imputed rate of interest. The excess of future estimated royalty payments over the amount of cash funding received will be recognized as interest expense using the effective interest method. The balance associated with the liability was initially recorded as \$25.0 million, net of allocated transaction costs, and was reported on the consolidated balance sheets as future royalty payment contingency. The imputed effective rate of interest on the unamortized portion of the liability was 8.5% as of September 30, 2022.

The Company periodically reassesses the amount and timing of estimated royalty payments. To the extent such payments are greater or less than the Company's initial estimates or the timing of such payments is materially different than those estimates, the Company will prospectively adjust the amortization of the liability and the effective interest rate.

There are a number of factors that could materially affect the amount and timing of the contingent \$15.0 million milestone and royalty payments, some of which are not within the Company's control. The liability was recognized using significant unobservable inputs. These inputs were derived using internal management estimates and reflect management's judgements and forecasts. The significant unobservable inputs include the forecasted revenues, the probability and timing of the regulatory milestone, the expected term of the royalty stream, and the royalty rate, as well as the overall probability of amprelosetine's success. These estimates are considered Level 3 fair value inputs. A significant change in unobservable inputs could result in a material increase or decrease to the effective interest rate of the liability.

Changes to the liability for sale of future royalties were as follows for the three and nine months ended September 30, 2022:

| (In thousands) | |
|--|------------------|
| Beginning balance at July 20, 2022 | \$ — |
| Consideration allocated, less transaction costs of \$0.5 million | 24,464 |
| Interest accretion | 424 |
| Balance at September 30, 2022 | <u>\$ 24,888</u> |

10. Extinguishment of Debt

9.5% Non-Recourse Notes Due 2035

On February 21, 2020, Theravance Biopharma R&D, Inc. (“Theravance R&D”), a wholly-owned subsidiary of the Company, and Triple Royalty Sub II LLC (the “Issuer II” or “Triple II”), a wholly-owned subsidiary of Theravance Biopharma R&D, entered into certain note purchase agreements (“Note Purchase Agreements”) with certain note purchasers (“Note Purchasers”), relating to the private placement by Issuer II of \$400.0 million 9.5% Fixed Rate Term Notes due on or before 2035 (the “Non-Recourse 2035 Notes”). Ninety-five percent of the Non-Recourse 2035 Notes were sold to the Note Purchasers pursuant to the Note Purchase Agreements. The remaining 5% of the Non-Recourse 2035 Notes (the “Retained Notes”) were retained by the Company to comply with Regulation RR — Credit Risk Retention (17 C.F.R. Part 246) and eliminated in the Company’s condensed consolidated financial statements.

The Non-Recourse 2035 Notes were secured by all of Issuer II’s right, title and interest as a holder of certain membership interests (the “Issuer II Class C Units”) in TRC. TRC held the right to receive upward-tiering royalties ranging from 6.5% to 10% on worldwide net sales of TRELEGY, and, prior to the closing of the TRC Transaction (see Note 8), the Company held an 85% economic interest in TRC. The Issuer II Class C Units represented 75% of the Company’s 85% economic interest, which equated to 63.75% of the economic interests in TRC.

The Non-Recourse 2035 Notes were not convertible into Company equity and had no security interest in nor rights under any agreement with GSK. The Non-Recourse 2035 Notes were redeemable by Issuer II on and after February 28, 2022, in whole or in part, at specified redemption premiums.

The source of principal and interest payments for the Non-Recourse 2035 Notes were the future royalty payments generated from the TRELEGY program, and as a result, the holders of the Non-Recourse 2035 Notes had no recourse against the Company even if the TRELEGY payments were insufficient to cover the principal and interest payments for the Non-Recourse 2035 Notes. Prior to and including the December 5, 2024 payment date, in the event that the distributions received by the Issuer II from TRC in a quarter were less than the interest accrued for that quarter, the principal amount of the Non-Recourse 2035 Notes increased by the interest shortfall amount for that quarter. While the holders of the Non-Recourse 2035 Notes had no recourse against the Company, the terms of the Non-Recourse 2035 Notes also provided that the Company, at its option, could satisfy the quarterly interest payment obligations by making a capital contribution to the Issuer II.

In connection with the TRC Transaction, the Company redeemed the outstanding Non-Recourse 2035 Notes on July 20, 2022 and paid certain other fees and expenses in conjunction with that redemption. The total repayment was comprised of \$400.0 million of net principal, \$4.7 million of accrued interest, an early redemption premium fee of \$20.0 million, and \$0.2 million of transaction costs. The \$400.0 million of net principal included \$30.7 million of issuance-to-date net interest shortfall. The repayments resulted in a net loss on extinguishment of debt of \$24.0 million, which is included within discontinued operations in the accompanying consolidated statements of operations for the three and nine-months ended September 30, 2022. The loss on extinguishment of debt was calculated as the difference between the carrying amount of the Non-Recourse 2035 Notes and the amounts paid to redeem the Non-Recourse 2035 Notes.

3.25% Convertible Senior Notes Due 2023

On July 26, 2022, subsequent to the closing of the TRC Transaction, the Company launched a tender offer to retire the Company’s \$230.0 million of 3.25% convertible senior notes due in 2023 (“Convertible Senior 2023 Notes”) (the “2023 Notes Tender Offer”). Pursuant to the terms of the 2023 Notes Tender Offer, the Company paid all accrued and unpaid interest on the purchased Convertible Senior 2023 Notes from and including the last interest payment date of May 1, 2022 up to, but not including, the settlement date for the 2023 Notes Tender Offer. The 2023 Notes Tender Offer expired on August 23, 2022 (the “Expiration Time”). As of the Expiration Time, \$230.0 million in aggregate principal amount of the Convertible Senior 2023 Notes, representing 100% of the outstanding Convertible Senior 2023 Notes, were validly tendered and not validly withdrawn pursuant to the 2023 Notes Tender Offer. The Company accepted for purchase all of the Convertible Senior 2023 Notes, and the Company settled the 2023 Notes Tender Offer on August 25, 2022.

Total payments made by the Company under the 2023 Notes Tender Offer included \$230.0 million of principal, \$2.4 million of accrued interest, and \$1.6 million of transaction costs. The repayments resulted in a net loss on extinguishment of debt of \$3.0 million, which is included under the caption loss on extinguishment of debt in the accompanying consolidated statements of operations for the three and nine-months ended September 30, 2022. The loss on extinguishment of debt was calculated as the difference between the carrying amount of the Convertible Senior 2023 Notes and the amounts paid to settle the Convertible Senior 2023 Notes.

11. Share-Based Compensation

Performance-Contingent Awards

The Company periodically grants performance-contingent share-based awards to employees. For the three and nine months ended September 30, 2022, the Company recognized \$0.4 million and \$0.6 million, respectively, of share-based compensation expense related to these types of awards. As of September 30, 2022, there were 305,000 shares of performance-contingent restricted share units (“RSUs”) outstanding that have a maximum remaining share-based compensation expense of \$2.1 million with performance vesting dates through February 2027. For the three and nine months ended September 30, 2021, the Company recognized \$0.1 million and \$0.7 million, respectively, of share-based compensation expense related to performance-contingent share-based awards.

Share-Based Compensation Modification Due to Corporate Restructuring

As a result of the Company’s corporate restructuring announcement in September 2021 (see Note 13), the Board of Directors’ Compensation Committee approved the acceleration of certain equity awards for employees affected by the restructuring. The Company accounted for this acceleration as a Type III modification (improbable to probable) which resulted in a fair value of \$2.5 million, as of the modification date, that was recorded in “Restructuring and related expenses” within the condensed consolidated statements of operations. The total cumulative compensation cost previously recognized for these awards of \$0.8 million within “Research and development” and “Selling, general and administrative” expenses through the modification date, was reversed. The acceleration resulted in net incremental share-based compensation expenses of \$1.7 million for nine months ended September 30, 2022 and impacted approximately 45 terminated employees who met the conditions of the acceleration and departed the Company in the first half of 2022. There were no net incremental share-based compensation expenses related to the acceleration for the three months ended September 30, 2022.

12. Income Taxes

For the three and nine months ended September 30, 2022, the Company recognized income tax expense of \$182.4 million and \$182.9 million, respectively. The income tax expense for the three and nine months ended September 30, 2022 was primarily attributed to the Company’s gain from the TRC Transaction, partially offset by the release of beginning of the year valuation allowance on US federal and state (excluding California) deferred tax assets. Of the \$182.9 million tax expense, \$62.3 million was a deferred tax expense related to the utilization of tax attributes that were previously offset by an unrecognized tax benefit.

The Company’s \$62.7 million liability for unrecognized tax benefits can be relieved only if (i) the contingency becomes legally extinguished through either payment to the taxing authority or expiration of the statute of limitations; (ii) the recognition of the benefits associated with the position meets the more-likely-than-not threshold; or (iii) the liability becomes effectively settled through the examination process. The Company considers matters to be effectively settled once the taxing authority has completed all of its required or expected examination procedures, including all appeals and administrative reviews. The Company also accrues for potential interest and penalties related to unrecognized tax benefits in its income tax expense (benefit) calculation.

As of September 30, 2022, the amount of uncertain tax benefit, that if realized would affect the effective tax rate, was \$62.7 million and was primarily due to the gain from the TRC Transaction.

No provision for income taxes has been recognized on undistributed earnings of the Company’s foreign subsidiaries as the Company considers such earnings to be indefinitely reinvested.

The Company follows the accounting guidance related to accounting for income taxes which requires that a company reduces 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. During the three months ended September 30, 2022, the Company concluded that the valuation allowance related to its US federal and state deferred tax (excluding California) assets was no longer needed primarily due to the current year gain and forecasted future taxable income from the TRC Transaction. Accordingly, the Company has recognized a non-recurring tax benefit of \$61.9 million related to the valuation allowance reversal.

As of September 30, 2022, the Company continued to maintain a full valuation allowance on its foreign and California 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 was recently under Internal Revenue Service ("IRS") examination for the tax year ended December 31, 2018. On July 21, 2022, the IRS informed the Company that the examination was completed and no adjustments to its 2018 tax return were necessary.

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 and other transactions, its international organization, shifts in the amount of income before tax earned in the US as compared with other regions in the world, and changes in overall levels of income before tax.

13. Corporate Restructuring Update

On September 15, 2021, the Company announced a strategic update and corporate restructuring (the "Restructuring") to focus on leveraging its expertise in developing and commercializing respiratory therapeutics. As part of the Restructuring, the Company initiated an approximate 75% reduction in workforce. A majority of the reduction in workforce occurred in November 2021, and the remainder was completed in February 2022.

For the three and nine months ended September 30, 2022, the Company incurred Restructuring and related expenses of \$0.5 million and \$11.4 million, respectively, of which \$0.1 million and \$5.3 million were related to R&D expenses and \$0.4 million and \$6.2 million were related to selling, general and administrative expenses, respectively. Of the total \$0.5 million, net, recognized for the three months ended September 30, 2022, cash-related credits were \$0.2 million and non-cash expenses were \$0.7 million which were primarily related to the modification of equity-based awards for employees affected by the Restructuring and certain related awards for other employees. Of the total \$11.4 million recognized for the nine months ended September 30, 2022, cash-related expenses were \$5.8 million and non-cash expenses were \$5.6 million which were also primarily related to the modification of equity-based awards for employees affected by the Restructuring and certain related awards for other employees.

Since the Restructuring was announced and through its completion in September 2022, the Company has incurred total Restructuring and related expenses of \$31.6 million of which \$15.8 million was each related to R&D expenses and selling, general and administrative expenses. Of the total \$31.6 million, cash-related expenses were \$17.4 million and non-cash expenses were \$14.2 million, which were primarily related to the modification of equity-based awards. As of September 30, 2022, all Restructuring and related expenses have been fully recognized by the Company.

Selected information relating to accrued cash-related Restructuring expenses was as follows:

| (In thousands) | |
|-------------------------------|----------|
| Balance at December 31, 2021 | \$ 9,550 |
| Net accruals | 6,074 |
| Cash paid | (15,624) |
| Balance at September 30, 2022 | \$ — |

The Company also evaluated the impact of the Restructuring 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. Based on its evaluation, the Company determined that its long-lived assets were not impaired as of September 30, 2022, and it has not recognized any impairment charges related to its long-lived assets since the Restructuring announcement.

14. Capital Return Program

In September 2022, the Company's Board of Directors authorized a \$250.0 million capital return program consisting of three elements as described below. The Company expects to fund the capital return program with cash on hand.

GSK Share Repurchase

On September 20, 2022, the Company repurchased 9,644,807 ordinary shares, par value \$0.00001 per share ("Shares"), of the Company from GSK Finance (No.3) plc ("GSK Finance"), representing all of the ordinary shares of the Company owned by GSK Finance or its affiliates. The purchase price under the Share Repurchase Agreement was \$9.75 per share, resulting in a total consideration of \$94.0 million. The repurchased shares were accounted for as authorized shares that are no longer issued and outstanding upon the settlement date of the repurchase transaction.

Modified Dutch Auction Tender Offer

On September 28, 2022, the Company announced a "modified Dutch auction" tender offer (the "Offer") to purchase up to \$95.0 million of its Shares.

Upon the terms and subject to the conditions set forth in the Company's Offer to Purchase, dated September 28, 2022 (the "Offer to Purchase"), and the related Letter of Transmittal, the Company is offering to purchase up to \$95.0 million of its Shares, at a purchase price not greater than \$10.50 nor less than \$9.75 per Share, in cash, less any applicable withholding taxes and without interest. The Offer will expire at midnight, New York City time, at the end of the day on November 17, 2022, or any other date and time to which the Company extends such Offer, unless earlier terminated.

A "modified Dutch auction" tender offer allows shareholders to indicate how many Shares and at what price or within the range described above they wish to tender their Shares. Based on the number of Shares tendered and the prices specified by the tendering shareholders, the Company will determine the lowest per-share price that will enable it to purchase up to \$95.0 million of Shares, or if a lesser value of shares is validly tendered, all Shares that have been validly tendered and not validly withdrawn. All Shares accepted in the Offer will be purchased at the same price even if tendered at a lower price.

As of September 27, 2022, the Company had 67,365,912 Shares outstanding, which reflects the impact of the Company's previous repurchase of 9,644,807 Shares from GSK Finance on September 20, 2022 (see above). If the Offer is fully subscribed, (1) at the maximum purchase price of \$10.50 per share, the Company could purchase 9,047,619 Shares, which would represent approximately 13.4% of Shares outstanding or (2) at the minimum purchase price of \$9.75 per share, the Company could purchase 9,743,589 Shares, which would represent approximately 14.5% of the Shares outstanding.

The Offer is not conditioned on any minimum number of Shares tendered, but is conditioned upon the satisfaction of certain customary conditions, as more fully described in the Offer to Purchase. The Company expressly reserves the right for any reason, subject to applicable law and as set forth in the Offer to Purchase, to extend, abandon, terminate or amend the Offer. Any Shares purchased pursuant to the Offer will be cancelled, and those Shares will cease to be outstanding.

Open Market Share Repurchase Plan

Subsequent to the closing of the Offer, the Company plans to engage in open market share repurchases from time to time of up to approximately \$60.0 million of its Shares in compliance with Rule 10b-18 under the Securities Exchange Act, with a current goal to complete this element of the capital return program by the end of 2023. There were no shares repurchased under the Open Market Stock Repurchase Plan as of September 30, 2022.

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, 2021. 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 we expect the effects of COVID-19, including new variants, to continue to adversely impact our business operations and financial results, the extent of the impact on our ability to generate revenue from YUPELRI® (revefenacin), our clinical development programs, and the value of and market for our ordinary shares, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time. These potential future developments include, but are not limited to, the ultimate duration of the COVID-19 pandemic, travel restrictions, quarantines, vaccination levels, social distancing and business closure requirements in the United States and in other countries, other measures taken by us and those we work with to help protect individuals from contracting COVID-19, and the effectiveness of actions taken globally to contain and treat the disease, including vaccine availability, distribution, acceptance and effectiveness. 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 discovery, development, and commercialization of medicines. Our core purpose is to create *medicines that make a difference*[®] in people's lives.

In pursuit of our purpose, we leverage decades of expertise, which has led to the development of the United States (“US”) Food and Drug Administration (the “FDA”) approved YUPELRI[®] (revefenacin) inhalation solution indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (“COPD”). Our pipeline of internally discovered programs is targeted to address significant unmet patient needs.

Sale of Theravance Respiratory Company, LLC

On July 20, 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 Investments 2019 ICAV (“Royalty Pharma”) for over \$1.5 billion in potential total value (the “TRELEGY Royalty Transaction”). The TRELEGY Royalty Transaction is intended to provide us near-, mid- and long-term value with (i) an upfront cash payment of approximately \$1.1 billion received on July 20, 2022, (ii) up to \$250.0 million in additional milestone payments contingent on the achievement of certain TRELEGY net sales thresholds between 2023 and 2026 and (iii) outer year royalties.

Debt Paydown and Capital Return Program

Immediately after announcing the TRELEGY Royalty Transaction, we initiated a multi-step process to eliminate our outstanding debt and return capital to shareholders. The first step in this process was the repayment of our 9.5% non-recourse TRELEGY notes due 2035 for approximately \$420.0 million, which was completed on July 20, 2022. The second step of the process was a tender offer to retire \$230.0 million in principal amount of our 3.25% convertible senior notes due 2023, at par, which was completed on August 25, 2022. Following the completion of our debt paydown, our Board of Directors authorized a \$250.0 million capital return program consisting of three elements as summarized below:

GSK Share Repurchase

On September 20, 2022, we completed a share repurchase transaction of 9,644,807 ordinary shares, par value \$0.00001 per share (“Shares”), of the Company from GSK Finance (No.3) plc (“GSK Finance”), representing all of the Shares of the Company owned by GSK Finance or its affiliates. The purchase price under the Share Repurchase Agreement was \$9.75 per share, resulting in a total consideration of \$94.0 million.

Modified Dutch Auction Tender Offer

On September 28, 2022, we announced a “modified Dutch auction” tender offer (the “Offer”) to purchase up to \$95.0 million of our Shares, at a purchase price not greater than \$10.50 nor less than \$9.75 per Share, in cash, less any applicable withholding taxes and without interest. The Offer will expire on November 17, 2022, or any other date and time to which we may extend such Offer, unless earlier terminated.

A “modified Dutch auction” tender offer allows shareholders to indicate how many Shares and at what price or within the range described above they wish to tender their Shares. Based on the number of Shares tendered and the prices specified by the tendering shareholders, we will determine the lowest per-share price that will enable us to purchase up to \$95.0 million of Shares, or if a lesser value of shares is validly tendered, all Shares that have been validly tendered and not validly withdrawn. All Shares accepted in the Offer will be purchased at the same price even if tendered at a lower price.

If the Offer is fully subscribed, (1) at the maximum purchase price of \$10.50 per share, we could purchase 9,047,619 Shares, which would represent approximately 13.4% of the Shares outstanding as of October 31, 2022 and (2) at the minimum purchase price of \$9.75 per share, the Company could purchase 9,743,589 Shares, which would represent approximately 14.5% of the Shares outstanding as of October 31, 2022.

Open Market Share Repurchase Plan

Subsequent to the completion of the Offer, we plan to enter into open market repurchases of our shares to facilitate the repurchase of up to approximately \$60.0 million of our Shares, with a current goal to complete this element of the capital return program by the end of 2023.

At the completion of our debt paydown and capital return program, we expect to have a streamlined balance sheet with no long-term debt. We are currently approaching breakeven cash flow from operations, driven by disciplined spending throughout the Company and the growth in sales of YUPELRI.

Corporate Restructuring Update

As previously announced in September 2021, our Board of Directors approved a plan to focus our resources on our most promising programs and reduce the size of the Company in order to maximize shareholder value. The corporate restructuring (the “Restructuring”) resulted in us reducing headcount by approximately 75%. A majority of the total reduction in workforce occurred at the end of November 2021, and the remainder was completed at the end of February 2022. Since the Restructuring was announced and through its completion in the third quarter of 2022, we incurred \$31.6 million in Restructuring and related expenses, which was consistent with our expectations.

As a result of the Restructuring and reduction in workforce, in May 2022, we assigned our Dublin, Ireland, office lease to an unaffiliated company and moved into a smaller office in Dublin, which we estimate will result in approximately \$1.4 million cumulative cash savings through March 2027, or approximately \$0.3 million annually. In addition, in June 2022, we subleased approximately 78,000 square feet of our South San Francisco office and laboratory space to an unaffiliated company. As a result of the sublease, we expect to realize cumulative cash savings of approximately \$52.7 million through May 2030, or approximately \$6.7 million annually.

Ongoing Impact of COVID-19 Pandemic

The effects of the COVID-19 pandemic and the related actions by governmental and health authorities, companies, and individuals around the world in an attempt to reduce the spread of the virus (including new variants of COVID-19) continue to present a substantial public health and economic challenge and are affecting our employees, patients, communities, clinical trial sites, suppliers, business partners and business operations. The full extent to which the COVID-19 pandemic will continue to directly or indirectly impact our business, results of operations and financial condition, including revenue, expenses, clinical trials and research and development costs, will depend on future developments that are highly uncertain and may be impacted by the emergence of new information concerning the COVID-19 pandemic, ongoing spread of the disease across the US and the globe, and the actions taken to contain or treat the disease, including vaccine availability, distribution, acceptance and effectiveness.

As part of our response to the ongoing COVID-19 pandemic, we have taken steps to identify and mitigate the adverse impacts on, and risks to, our business posed by its spread and actions taken by governmental and health authorities, companies, and individuals to address the COVID-19 pandemic. We expect to continue to implement measures as may be required or recommended by governmental authorities or as we determine are in the best interests of our employees, clinical trial sites and participants, the patients we serve, and other stakeholders in light of COVID-19.

Core Program Updates

YUPELRI (revefenacin) Inhalation Solution

YUPELRI (revefenacin) inhalation solution is a once-daily, nebulized long-acting muscarinic antagonist (“LAMA”) approved for the maintenance treatment of COPD in the US. LAMAs are recognized by international COPD treatment guidelines as a cornerstone of maintenance therapy for COPD, regardless of severity of disease. Our market research indicates there is an enduring population of COPD patients in the US that either need or prefer nebulized delivery for maintenance therapy. The stability of revefenacin in both metered dose inhaler and dry powder inhaler (“MDI/DPI”) formulations suggests that revefenacin could also serve as a foundation for novel handheld combination products.

We co-developed YUPELRI with our collaboration partner, Viatris, and 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 Theravance Biopharma). Outside the US (including 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.

Under the terms of the Viatris Development and Commercialization Agreement, as of September 30, 2022, we are eligible to receive from Viatris potential global development, regulatory and sales milestone payments totaling up to \$257.5 million in the aggregate with \$205.0 million associated with YUPELRI monotherapy and \$52.5 million associated with future potential combination products. Of the \$205.0 million associated with monotherapy, \$187.5 million relates to sales milestones based on achieving certain levels of net sales and \$17.5 million relates to global development and regulatory actions. The \$52.5 million associated with future potential combination products relates solely to global development and regulatory actions.

Since March 2020, YUPELRI’s growth trajectory has been impacted by the COVID-19 respiratory pandemic. However, in late 2021, we began to observe a return to growth in YUPELRI sales. We continue to monitor external factors that are associated with the current healthcare market which may be impacting demand for YUPELRI due to the ongoing pandemic, including the return of customer orders to pre-pandemic utilization levels and the duration of use. Although pandemic restrictions have receded in many regions at this time, we are not able to predict with certainty the ultimate enduring disruptive impact of the ongoing pandemic on YUPELRI sales, and it is possible the pandemic may continue to put downward pressure on our sales. As a result, sales volatility may continue throughout 2022. As we have throughout the pandemic, we will continue to track key performance metrics to gauge success in continuing to grow market adoption, including formulary inclusion success and the various aspects of market access. We and Viatris continue to supply YUPELRI to our patients and currently do not anticipate any interruptions in supply.

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 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 and is intended to possibly support promotional efforts for YUPELRI, which would aid the capture of more of YUPELRI’s addressable market and further strengthen its competitive advantage. We pay 35% of the Phase 4 study costs, and Viatris pays 65% of the study costs. In January 2022, we announced the enrollment of the first patient in the Phase 4 study.

While Viatris records the 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 September 30, | | Change | | Nine Months Ended September 30, | | Change | |
|---------------------------------|-------------------------------------|-----------|----------|------|------------------------------------|-----------|----------|------|
| | 2022 | 2021 | \$ | % | 2022 | 2021 | \$ | % |
| YUPELRI net sales (implied 35%) | \$ 18,698 | \$ 13,806 | \$ 4,893 | 35 % | \$ 51,158 | \$ 41,334 | \$ 9,824 | 24 % |
| Viатris collaboration revenue | 12,445 | 10,397 | 2,048 | 20 | 34,010 | 31,716 | 2,294 | 7 |

Ampreloxetine (TD-9855)

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

Based on positive results from a small exploratory Phase 2 study in nOH and discussions with the FDA, we advanced ampreloxetine into a Phase 3 program. We announced the initiation of patient dosing in study in early 2019.

The Phase 3 program consisted of two pivotal studies and one non-pivotal study. The first pivotal study (SEQUOIA), a four-week, randomized double-blind, placebo-controlled study, was designed to evaluate the efficacy and safety of ampreloxetine in 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 patient response of ampreloxetine. The third, non-pivotal study (OAK), was designed to allow patients who completed REDWOOD to have continued access to ampreloxetine for up to three and half years.

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

In April 2022, we reported that the REDWOOD Phase 3 clinical study's primary endpoint was not statistically significant for the overall population of patients which included patients with Parkinson's disease ("PD"), pure autonomic failure ("PAF") and MSA. The pre-specified subgroup analysis by disease type suggests the benefit seen in patients receiving ampreloxetine was largely driven by MSA patients. The benefit to MSA patients in the study was observed in multiple endpoints including Orthostatic Hypotension Symptom Assessment Scale ("OHSAS") composite, Orthostatic Hypotension Daily Activities Scale ("OHDAS") composite, Orthostatic Hypotension Questionnaire ("OHQ") composite and OHSAS #1. Throughout the study, there was no indication of worsening of supine hypertension. Data suggest that ampreloxetine was well-tolerated and no new safety signals were identified.

We recently 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 in MSA patients with symptomatic nOH. We expect this additional Phase 3 study to begin enrolling as early as the first quarter of 2023, and we expect to see efficiencies related to enrollment time and overall R&D expenditures.

On July 13, 2022, in conjunction with the TRELEGY Royalty Transaction, Royalty Pharma agreed to invest up to \$40.0 million to advance the development of ampreloxetine in MSA in exchange for unsecured low single-digit royalties. Royalty Pharma's \$40.0 million investment in ampreloxetine includes a \$25.0 million upfront payment and an additional \$15.0 million payment upon the first regulatory approval of ampreloxetine. We anticipate that the \$25.0 million upfront investment in ampreloxetine will fund the majority of the Phase 3 study costs. In exchange, Royalty Pharma will receive future unsecured royalties of 2.5% on annual global net sales up to \$500.0 million and 4.5% on annual global net sales over \$500.0 million. If ampreloxetine regulatory approval is not achieved or if ampreloxetine sales are never recognized, the amounts invested by Royalty Pharma would not be repaid by us. On July 20, 2022, the TRELEGY Royalty Transaction was completed, and we received \$25.0 million in cash from Royalty Pharma related to ampreloxetine royalty rights.

Lung-selective, Nebulized Pan-Janus Kinase (JAK) Inhibitor (Nezulcitinib)

Nezulcitinib is our nebulized, lung-selective JAK inhibitor in development for the treatment of acute and chronic lung diseases and is our most advanced respiratory clinical candidate. At the start of the COVID-19 pandemic, we quickly progressed nezulcitinib from the research stage to the clinical stage to assess its impact on inflammation of the lung. We released top-line results from a 200 patient Phase 2 COVID-19 study with nezulcitinib in June 2021. Subsequently, we have returned to the research stage to complete preclinical experiments in support of indication selection.

Other Asset Highlights

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

On July 20, 2022, we completed the sale of all of our Issuer II Class C Units in TRC representing our 85% economic interest in the sales-based royalty rights on worldwide net sales of GSK's TRELEGY to Royalty Pharma.

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 the Assigned

Collaboration Products (as defined in the Purchase Agreement) being met, 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 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. US TRELEGY royalties payable to us by GSK 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 (UMEC, a LAMA, and VI, a long-acting beta2 agonist, or LABA) in a single delivery device administered once-daily. TRELEGY is approved for use in the US, European Union (“EU”), and other countries for the long-term, once-daily, maintenance treatment of patients with COPD. Additionally, the FDA approved an sNDA for the use of TRELEGY to treat asthma in adults in September 2020 making TRELEGY the first once-daily single inhaler triple therapy for the treatment of both asthma and COPD in the US. GSK has obtained approval for the asthma indication in ten additional markets. TRELEGY is currently expected to generate global peak sales of \$3.6 billion annually according to consensus estimates. Over the past three years, TRELEGY has shown substantial growth, with global net sales increasing from \$663 million in 2019 to \$1.1 billion in 2020 and to \$1.7 billion in 2021.

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.

Other Economic Interests

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 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.

As of September 30, 2022, we are eligible to receive up to an additional \$237.5 million in development and sales milestone payments from Pfizer. In addition, we are eligible to receive a tiered royalty on worldwide net sales of any potential products under the license at percentage royalty rates ranging from middle single-digits to low double-digits.

Velusetrag (TD-5108)

Velusetrag is an oral, investigational medicine developed for gastrointestinal motility disorders. It is a highly selective agonist with high intrinsic activity at the human 5-HT4 receptor.

Sale to Alfasigma S.p.A.

In 2012, we partnered with Alfasigma S.p.A. (“Alfasigma”) in the development of velusetrag and its commercialization in certain countries. In April 2018, Alfasigma exercised its option to continue to develop and commercialize velusetrag, and we elected not to pursue further development. Global rights to develop, manufacture and commercialize velusetrag were transferred to Alfasigma under the terms of the collaboration arrangement.

On June 30, 2022, we entered into an Asset Purchase Agreement (“APA”) to sell all of our velusetrag assets to Alfasigma. In connection with the closing of the transaction, Alfasigma acquired, among other things, (i) intellectual property and (ii) books and records, related to velusetrag. As consideration for the velusetrag sale, we received \$2.8 million in cash in July 2022, and pursuant to the terms of the APA, we are eligible to receive future developmental and sales milestones totaling up to \$105.0 million. In the second quarter 2022, we recognized a net gain of approximately \$2.7 million related to the sale of velusetrag.

Selective 5-HT4 Agonist (TD-8954)

TD-8954 is a selective 5-HT4 receptor agonist being developed for potential use in the treatment of gastrointestinal motility disorders. Pursuant to a License and Collaboration Agreement that we executed in June 2016 with Millennium Pharmaceuticals, Inc., an indirect wholly-owned subsidiary of Takeda Pharmaceutical Company Limited (“Takeda”), Takeda is conducting a Phase 2 study of TD-8954 as a potential treatment for post-operative gastrointestinal dysfunction.

Research Projects

We have streamlined and narrowed our R&D focus with disciplined spending on the projects with the highest potential value. Our enhanced focus is on near-term value opportunities which include driving YUPELRI growth and initiating a new FDA-aligned amprelosetine Phase 3 study.

2023 Annual General Meeting of Shareholders

The Company will hold its 2023 Annual General Meeting of Shareholders on Tuesday, May 2, 2023, 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 the COVID-19 pandemic will continue to directly or indirectly impact our business, results of operations and financial condition, including these estimates, will depend on future developments that are highly uncertain and may be impacted by the emergence of new information concerning the COVID-19 pandemic, ongoing spread of the disease across the US and the globe, and the actions taken to contain 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, 2021.

Results of Operations

Revenue

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

| (In thousands) | Three Months Ended September 30, | | Change | | Nine Months Ended September 30, | | Change | |
|----------------------------------|-------------------------------------|-----------|----------|-------|------------------------------------|-----------|------------|------|
| | 2022 | 2021 | \$ | % | 2022 | 2021 | \$ | % |
| Viatriis collaboration agreement | \$ 12,445 | \$ 10,397 | \$ 2,048 | 20 % | \$ 34,010 | \$ 31,716 | \$ 2,294 | 7 % |
| Collaboration revenue | 6 | 2,797 | (2,791) | (100) | 187 | 8,649 | (8,462) | (98) |
| Licensing revenue | — | — | — | — | 2,500 | — | 2,500 | NM |
| Total revenue | \$ 12,451 | \$ 13,194 | \$ (743) | (6)% | \$ 36,697 | \$ 40,365 | \$ (3,668) | (9)% |

NM: Not Meaningful

Revenue from the Viatriis collaboration agreement for YUPELRI was \$12.4 million and \$34.0 million for the three and nine months ended September 30, 2022, respectively, and represented increases of 20% and 7% compared to the respective periods in 2021. These revenue amounts represent the receivables due from Viatriis during the periods. In the third quarter of 2022, YUPELRI continued to increase its share of the long-acting nebulized COPD market and continued to be profitable for us on a brand basis.

While Viatriis records the total net sales of YUPELRI within its own financial statements, Viatriis collaboration agreement revenue in our financial statements includes our implied 35% share of aggregate net sales of YUPELRI of \$18.7 million and \$51.2 million for the three and nine months ended September 30, 2022, respectively, which represented increases of 35% and 24% over the respective prior year periods.

Our other collaboration revenue decreased by \$2.8 million and \$8.5 million for the three and nine months ended September 30, 2022, respectively, compared to the same periods in 2021. The decreases were primarily due to the recognition of the remaining non-cash Janssen collaboration revenue in the fourth quarter of 2021 resulting from the planned close-out of the izencitinib program.

Licensing revenue increased by \$2.5 million for the nine months ended September 30, 2022, compared to the same period in 2021. The \$2.5 million recognized in the first half 2022 was due to a development milestone payment from Pfizer for the first patient dosed in a Phase 1 clinical trial of the skin-selective pan-JAK inhibitor program.

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 general and administrative support functions, insurance and general supplies.

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

| (In thousands) | Three Months Ended September 30, | | Change | | Nine Months Ended September 30, | | Change | |
|---|-------------------------------------|-----------|-------------|-------|------------------------------------|------------|--------------|-------|
| | 2022 | 2021 | \$ | % | 2022 | 2021 | \$ | % |
| Employee-related | \$ 3,615 | \$ 7,506 | \$ (3,891) | (52)% | \$ 13,846 | \$ 39,521 | \$ (25,675) | (65)% |
| Share-based compensation | 2,623 | 6,956 | (4,333) | (62) | 10,710 | 22,192 | (11,482) | (52) |
| External-related | 739 | 23,693 | (22,954) | (97) | 12,768 | 78,551 | (65,783) | (84) |
| Facilities, depreciation and other allocated expenses | 2,890 | 5,584 | (2,694) | (48) | 11,367 | 22,167 | (10,800) | (49) |
| Total research & development | \$ 9,867 | \$ 43,739 | \$ (33,871) | (77)% | \$ 48,691 | \$ 162,431 | \$ (113,739) | (70)% |

R&D expenses decreased by \$33.9 million and \$113.7 million for the three and nine months ended September 30, 2022, respectively, compared to the same periods in 2021, and the decreases were across all R&D categories in both periods. External-related expenses decreased by \$23.0 million and \$65.8 million for the three and nine months ended September 30, 2022, respectively, and were the largest contributor to the total R&D expense decreases. The decreases in external-related expenses were primarily due to the completion, or near completion, of expenses related to the izencitinib program and ampreloxtine studies. The decreases across the remaining R&D categories were primarily related to the Restructuring announced in September 2021 and completed in the third quarter of 2022, which resulted in significant reductions, including (i) employee-related expenses of \$3.9 million and \$25.7 million; and (ii) share-based compensation expenses of \$4.3 million and \$11.5 million, for the three and nine months ended September 30, 2022, respectively. Severance and other costs that were directly attributed to the 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 \$1.7 million and \$4.7 million for three and nine months ended September 30, 2022, respectively, and \$3.3 million and \$6.0 million for the three and nine months ended September 30, 2021, respectively.

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 September 30, | | Change | | Nine Months Ended September 30, | | Change | |
|-------------------------------------|-------------------------------------|-----------|------------|-------|------------------------------------|-----------|-------------|-------|
| | 2022 | 2021 | \$ | % | 2022 | 2021 | \$ | % |
| Selling, general and administrative | \$ 16,277 | \$ 21,299 | \$ (5,022) | (24)% | \$ 51,105 | \$ 77,780 | \$ (26,675) | (34)% |

Selling, general and administrative expenses decreased by \$5.0 million and \$26.7 million for the three and nine months ended September 30, 2022, respectively, compared to the same periods in 2021. The decreases were primarily attributed to (i) a \$1.5 million and \$15.5 million reduction in employee-related expenses, and (ii) a \$1.8 million and \$7.0 million reduction in external-related expenses, for the three and nine months ended September 30, 2022, respectively. These decreases were primarily due to the Restructuring. Severance and other costs that were directly attributed to the Restructuring are included in the *Restructuring and Related Expenses* section below.

Share-based compensation expense related to selling, general and administrative expenses was \$5.2 million and \$16.5 million for the three and nine months ended September 30, 2022, respectively, and \$7.4 million and \$23.0 million for the three and nine months ended September 30, 2021, respectively. These period-over-period reductions in share-based compensation expense were also primarily driven by the Restructuring.

As a result of our Restructuring and reduction in workforce, in May 2022, we assigned our Dublin, Ireland, office lease to an unaffiliated company and moved into a smaller office in Dublin, which we estimate will result in approximately \$1.4 million cumulative cash savings through March 2027, or approximately \$0.3 million annually. In addition, in June 2022, we subleased approximately 78,000 square feet of our South San Francisco office and laboratory space to an unaffiliated company. As a result of the sublease, we expect to realize cumulative cash savings of approximately \$52.7 million through May 2030, or approximately \$6.7 million annually.

Restructuring and Related Expenses

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

| (In thousands) | Three Months Ended | | Change | | Nine Months Ended | | Change | |
|---|--------------------|----------|------------|--------|--------------------|----------|----------|-------|
| | September 30, 2022 | 2021 | \$ | % | September 30, 2022 | 2021 | \$ | % |
| Restructuring and related expenses (credit) | \$ (202) | \$ 1,771 | \$ (1,973) | (111)% | \$ 5,840 | \$ 1,771 | \$ 4,069 | 230 % |
| Share-based compensation expense (non-cash) | 711 | — | 711 | NM | 5,587 | — | 5,587 | NM |
| Total restructuring and related expenses | \$ 509 | \$ 1,771 | \$ (1,262) | NM % | \$ 11,427 | \$ 1,771 | \$ 9,656 | NM % |

NM: Not Meaningful

The Restructuring and related expenses were primarily comprised of one-time severance payments, employee-related separation costs, retention costs, and other Restructuring-related expenses. Of the total \$0.5 million and \$11.4 million in Restructuring and related expenses for the three and nine months ended September 30, 2022, respectively, \$0.1 million and \$5.3 million, respectively, were related to R&D expenses and \$0.4 million and \$6.2 million, respectively, were related to selling, general and administrative expenses. The total Restructuring-related expenses of \$0.5 million and \$11.4 million for the three and nine months ended September 30, 2022, respectively, also included non-cash charges of \$0.7 million and \$5.6 million, respectively, which were primarily related to the modification of equity awards for employees affected by the Restructuring and certain related awards for other employees.

Since the Restructuring was announced and through its completion in the third quarter of 2022, we incurred \$31.6 million in Restructuring and related expenses, which was consistent with our expectations. The \$31.6 million was comprised of \$17.4 million in cash expenses associated with employee termination benefits and related costs and \$14.2 million in non-cash expenses primarily relating to share-based compensation expense.

Interest Expense

Interest expense primarily consisted of interest payments due on our 9.5% non-recourse TRELEGY notes due 2035 (the “Non-Recourse 2035 Notes”) and the 3.25% convertible senior notes due 2023 (the “Convertible Senior 2023 Notes”), as well as the amortization of the associated debt issuance costs. Interest expense, as compared to the prior year comparable periods, was as follows:

| (In thousands) | Three Months Ended | | Change | | Nine Months Ended | | Change | |
|--|--------------------|------------|----------|--------|--------------------|------------|----------|--------|
| | September 30, 2022 | 2021 | \$ | % | September 30, 2022 | 2021 | \$ | % |
| 3.25% Convertible senior notes due 2023 | \$ (1,121) | \$ (2,136) | \$ 1,015 | (48) % | \$ (5,395) | \$ (6,410) | \$ 1,015 | (16) % |
| Amprexetine royalty contingency (non-cash) | (424) | — | (424) | NM | (424) | — | (424) | NM |
| Total interest expense | \$ (1,545) | \$ (2,136) | \$ 591 | (28) % | \$ (5,819) | \$ (6,410) | \$ 591 | (9) % |

NM: Not Meaningful

Interest expense was \$1.5 million and \$5.8 million for the three and nine months ended September 30, 2022. The decreases in interest expense compared to the prior year periods were primarily due to the retirement of all of our remaining long-term debt in the third quarter of 2022. We do not anticipate having material cash interest expense in the near term or foreseeable future.

Loss on Extinguishment of Debt

Loss on extinguishment of debt was as follows:

| (In thousands) | Three Months Ended September 30, | | Change | | Nine Months Ended September 30, | | Change | |
|--------------------------------|-------------------------------------|------|------------|------|------------------------------------|------|------------|------|
| | 2022 | 2021 | \$ | % | 2022 | 2021 | \$ | % |
| Loss on extinguishment of debt | \$ (3,034) | \$ — | \$ (3,034) | NM % | \$ (3,034) | \$ — | \$ (3,034) | NM % |

NM: Not Meaningful

For the three and nine months ended September 30, 2022, 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.

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 September 30, | | Change | | Nine Months Ended September 30, | | Change | |
|---|-------------------------------------|----------|----------|----------|------------------------------------|--------|----------|-------|
| | 2022 | 2021 | \$ | % | 2022 | 2021 | \$ | % |
| Interest income and other income (expense), net | \$ 2,758 | \$ (166) | \$ 2,924 | (1,761)% | \$ 4,823 | \$ 771 | \$ 4,052 | 526 % |

Interest income and other income (expense), net, increased by \$2.9 million and \$4.1 million for the three and nine months ended September 30, 2022, respectively. The increases were primarily due to higher interest income related to an increase in our investment balances in July 2022, as well as the sale of velusetrag to Alfaisigma in June 2022 which resulted in a net gain of approximately \$2.7 million.

Provision for Income Tax Benefit (Expense) – Continuing Operations

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

| (In thousands) | Three Months Ended September 30, | | Change | | Nine Months Ended September 30, | | Change | |
|---|-------------------------------------|------|--------|------|------------------------------------|------|---------|------|
| | 2022 | 2021 | \$ | % | 2022 | 2021 | \$ | % |
| Provision for income tax benefit (expense) - Continuing operations | \$ — | \$ 7 | \$ (7) | NM % | \$ (12) | \$ — | \$ (12) | NM % |

NM: Not Meaningful

We recorded a \$12,000 income tax expense for the nine months ended September 30, 2022 related to our continuing operations.

We were recently under Internal Revenue Service (“IRS”) examination for the tax year ended December 31, 2018. The examination was completed in the third quarter of 2022 with minimal adjustments to the 2018 federal tax return.

Net Income from Discontinued Operations (After tax)

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

| (In thousands) | Three Months Ended | | Change | | Nine Months Ended | | Change | |
|---|--------------------|-----------|------------|-----|-------------------|-----------|------------|------|
| | September 30, | | \$ | % | September 30, | | \$ | % |
| | 2022 | 2021 | | | 2022 | 2021 | | |
| Net income from discontinued operations | \$ 932,654 | \$ 20,602 | \$ 912,052 | NM% | \$ 961,062 | \$ 39,864 | \$ 921,198 | NM % |

NM: Not Meaningful

The sale of our equity interests in TRC, in July 2022, resulted in the income from our investment in TRC, interest expense related to our Non-Recourse 2035 Notes, and the associated net gain from the sale to be reclassified as net income from discontinued operations for both the current and comparable prior year periods.

The \$932.7 million and \$961.1 million in net income from discontinued operations for the three and nine months ended September 30, 2022, respectively, were primarily attributed to the \$1,141.1 million net realized gain from the sale of our equity interests in TRC. This gain was partially offset by a \$24.0 million loss on the extinguishment of our 9.5% non-recourse TRELEGY notes due 2035 in July 2022 and a \$182.4 million provision for income tax expense in the third quarter of 2022. The income tax expense was primarily attributed to the gain from the TRC sale which was partially offset by the release of beginning of the year valuation allowance on the US federal and state (excluding California) deferred tax assets of \$61.9 million.

Liquidity and Capital Resources

As a result of the approximate \$1.1 billion in cash proceeds received from the TRELEGY Royalty Transaction completed in July 2022 (see page 23), our cash position increased significantly during the third quarter of 2022. In connection with TRELEGY Royalty Transaction, we repaid our Non-Recourse 2035 Notes for approximately \$420.0 million and subsequently repaid our convertible senior notes due 2023, at par, for approximately \$230.0 million.

Following the completion of the paydown of all of our long-term debt, our Board of Directors authorized a \$250.0 million capital return program consisting of the three elements listed below:

- (i) Completion of a \$94.0 million repurchase of our shares previously held by GSK Finance and its affiliates in September 2022;
- (ii) Initiation of a modified Dutch auction tender offer to repurchase up to \$95.0 million of our shares that is expected to close in early November 2022;
- (iii) Subsequent to the modified Dutch auction tender offer, the initiation of an Open Market Stock Repurchase Plan to facilitate the repurchase of up to approximately \$60.0 million of our shares in open market purchases with a current goal to complete this element of the capital return program by the end of 2023.

As of September 30, 2022, we had approximately \$486.8 million in cash, cash equivalents, and investments in marketable securities (excluding restricted cash) and a streamlined balance sheet with no long-term debt. As a result of the net gain realized from the TRELEGY Royalty Transaction, we anticipate making an estimated tax liability payment of approximately \$120.6 million to the tax authorities in December 2022.

Corporate Restructuring Update

As previously announced in September 2021, our Board of Directors approved a plan to focus our resources on our most promising respiratory programs and reduce the size of the Company in order to maximize shareholder value. The corporate restructuring (the “Restructuring”) resulted in us reducing headcount by approximately 75%. A majority of the total reduction in workforce occurred at the end of November 2021, and the remainder was completed at the end of February 2022. Since the Restructuring was announced and through its completion in the third quarter of 2022, we incurred \$31.6 million in Restructuring and related expenses, which was consistent with our expectations.

As a result of the Restructuring and reduction in workforce, in May 2022, we assigned our Dublin, Ireland, office lease to an unaffiliated company and moved into a smaller office in Dublin, which we estimate will result in

approximately \$1.4 million cumulative cash savings through March 2027, or approximately \$0.3 million annually. In addition, in June 2022, we subleased approximately 78,000 square feet of our South San Francisco office and laboratory space to an unaffiliated company. As a result of the sublease, we expect to realize cumulative cash savings of approximately \$52.7 million through May 2030, or approximately \$6.7 million annually.

Despite the expected expense savings from the Restructuring, we may incur net losses over the next several years due to several factors, including but not limited to, the loss of future income as a result of the TRELEGY Royalty Transaction and expenditures relating to our drug discovery and commercialization efforts. In the past, we have received a number of significant payments from collaboration agreements and other significant transactions. In the future, we may continue to receive potential substantial payments from future collaboration transactions if the drug candidates in our pipeline achieve positive clinical or regulatory outcomes or if our product candidates are approved and meet certain milestones.

Our strategic business plan is subject to significant uncertainties and risks as a result of, among other factors, the COVID-19 pandemic, clinical program outcomes, whether, when and on what terms we are able to enter into new collaboration arrangements, expenses being higher than anticipated, the sales levels of our approved product, unplanned expenses, cash receipts being lower than anticipated, and the need to satisfy contingent liabilities, including litigation matters and indemnification obligations.

Adequacy of cash resources to meet future needs

We are currently approaching breakeven cash flow from operations, driven by disciplined spending throughout the Company and the growth of YUPELRI. 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.

Cash Flows

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

| (In thousands) | Nine Months Ended September 30, | | Change |
|---|--|--------------|---------------|
| | 2022 | 2021 | |
| Net cash used in operating activities | \$ (62,936) | \$ (165,424) | \$ 102,488 |
| Net cash provided by investing activities | 1,114,848 | 113,670 | 1,001,178 |
| Net cash (used in) provided by financing activities | (723,334) | 91,711 | (815,045) |

Net cash flows used in operating activities

Net cash used in operating activities was \$62.9 million for the nine months ended September 30, 2022, of which \$57.3 million was used in continuing operations and \$5.6 million was used in discontinued operations, consisting of net income of \$882.5 million, adjustments for non-cash expenses and other reconciling items of (\$1,108.4) million, primarily related to the net gain from the sale of our equity interests in TRC, and a net increase in cash resulting from changes in operating assets and liabilities of \$163.0 million.

Net cash used in operating activities was \$165.4 million for the nine months ended September 30, 2021, of which \$190.5 million was used in continuing operations and \$25.1 million was provided by discontinuing operations, consisting of a net loss of \$167.4 million, adjustments for non-cash expenses and other reconciling items of \$34.0 million and a net decrease in cash resulting from changes in operating assets and liabilities of \$32.1 million.

Net cash flows provided by investing activities

Net cash provided by investing activities was \$1,114.8 million for the nine months ended September 30, 2022, of which \$19.7 million was from continuing operations and \$1,095.1 million was from discontinued operations, consisting primarily of \$15.4 million in net cash inflow from the purchase and maturities of marketable securities and \$1,095.1 million in net proceeds related to the sale of our equity interests in TRC.

Net cash provided by investing activities from continuing operations was \$113.7 million for the nine months ended September 30, 2021, consisting primarily of cash inflows from the net purchase and maturities of marketable securities of \$116.6 million and partially offset by \$3.0 million used for the purchase of property and equipment.

Net cash flows (used in) provided by financing activities

Net cash used in financing activities was \$723.3 million for the nine months ended September 30, 2022, of which \$703.1 million was used in continuing operations and \$20.2 million was used in discontinued operations, consisting primarily of a \$94.0 million cash outflow related to the repurchase of ordinary shares, a \$631.6 million cash outflow related to the extinguishment of debt, and a \$20.2 million cash outflow related to a debt redemption premium. These cash outflows were partially offset by a \$24.5 million cash inflow related to the funding of an additional Phase 3 study for the amprelosetine program.

Net cash provided by financing activities from continuing operations was \$91.7 million for the nine months ended September 30, 2021, consisting of the sale of 7,705,000 ordinary shares for total net proceeds of \$108.2 million and \$2.9 million in proceeds from ESPP and share option purchases. These proceeds were partially offset by \$10.7 million in principal payments on our Non-Recourse 2035 Notes and \$8.6 million related to the repurchase of shares to satisfy tax withholding obligations.

Commitments and Contingencies

We indemnify our officers and directors for certain events or occurrences, subject to certain limits. We maintain insurance policies that may limit our exposure, and therefore, we believe the fair value of these indemnification agreements is minimal. Accordingly, we have not recognized any liabilities relating to these agreements as of September 30, 2022. 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.

Performance-Contingent Awards

We periodically grant share-based and cash-based performance-contingent awards to our employees. For the three and nine months ended September 30, 2022, we recognized \$0.4 million and \$0.6 million, respectively, of aggregate share-based compensation expense related to performance-contingent awards. There were no cash-based performance-contingent expenses recognized for the three and nine months ended September 30, 2022. As of September 30, 2022, the maximum remaining expense related to outstanding share-based performance-contingent awards was \$2.1 million which had performance vesting dates through February 2027.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks, as of September 30, 2022, 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, 2021, filed with the SEC on February 28, 2022.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We conducted an evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act as of September 30, 2022, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined under Rule 13a-15(e) of the Exchange Act), which are controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Exchange Act is recorded, processed, summarized and reported within required time periods. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Limitations on the Effectiveness of Controls

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

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act, which occurred during the third quarter of the year ending December 31, 2022, 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

Not applicable.

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 the Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

Summary of Principal Risks Associated with Theravance Biopharma's Business

- We may never achieve or sustain profitability from our operations over the long term;
- If YUPELRI does not continue to be accepted by physicians, patients, third-party payors, or the medical community in general, we may not receive significant additional revenues from sales of this product;
- We face risks related to health epidemics, including the recent COVID-19 pandemic, which could have a material adverse effect on our business and results of operations;
- Any delay in commencing or completing clinical studies for product candidates and any adverse results from clinical or non-clinical studies or regulatory obstacles product candidates may face, would harm our business and the price of our securities could fall;
- 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 discovery and development efforts might not generate additional successful product

candidates or approvable drugs;

- Our capital return program and our restructuring activities may not provide the benefits we anticipate;
- 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; and
- 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.

RISKS RELATING TO THE COMPANY

We may never achieve or sustain profitability.

First as part of Innoviva, Inc., and since June 2, 2014 as Theravance Biopharma, we have been engaged in discovery and development of compounds and product candidates since mid-1997. We are currently approaching breakeven cash flow from operations; however, we may never generate sufficient revenue to achieve sustainable profitability from our operations. Although we recognized \$916.6 million and \$882.5 million of net income for the three months and nine months ended September, 30, 2022, respectively, which results were largely driven by net income from discontinued operations following the one-time TRC Transaction, we recognized \$16.0 million and \$78.6 million in net losses from continuing operations during the corresponding periods. Despite the fact that we are approaching breakeven cash flow from operations, we may continue to incur net losses over the next several years due to expenditures relating to our continuing drug discovery efforts and preclinical and clinical development of our current product candidates. During the years ended December 31, 2021 and 2020, we recognized net losses of \$199.4 million and \$278.0 million, respectively, which are reflected in the shareholders' equity (deficit) on our condensed consolidated balance sheets. 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 \$843.5 million as of September 30, 2022. To the extent we advance our product candidates into and through later stage clinical studies without a partner, we may incur substantial expenses. In addition, we may invest strategically in our research efforts to continue to grow our development pipeline. While our YUPELRI operations have been profitable on a brand basis since the third quarter of 2020, we will continue to incur costs and expenses associated with the commercialization of YUPELRI in the 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 our existing product candidates, our discovery programs, and YUPELRI will require ongoing funding. Our operating expenses also will increase if, among other things:

- our earlier stage potential products move into later-stage clinical development, which is generally more expensive than early stage development;
- additional preclinical product candidates are selected for clinical development;
- we pursue clinical development of our potential or current products in new indications;
- our clinical trials become more complicated or need to be extended due to the COVID-19 pandemic or 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
- 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 do not expect to generate significant revenues in the near future. As a

result of the COVID-19 pandemic (defined below), we could experience declines in revenues from these sources or 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 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 COVID-19 pandemic, the sales levels of our approved products, unplanned expenses, cash receipts being lower than anticipated, 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 are uncertain. As a result, we may incur substantial losses in the future. Failure to become and remain profitable would adversely affect the price of our securities and our ability to continue operations as planned.

We face risks related to health epidemics, 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 will 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”). Global health concerns relating to the COVID-19 pandemic have weighed on the macroeconomic environment, and the pandemic has significantly increased economic volatility and uncertainty.

The pandemic resulted in government authorities implementing numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns. These measures have adversely impacted and may further impact our employees and operations and the operations of our customers, suppliers and business partners, and may negatively impact spending patterns, payment cycles and insurance coverage levels. In addition, certain aspects of our business, such as laboratory-based research, cannot be conducted remotely and other aspects of our business, like our hospital-based sales team, our field-based medical affairs team, and our support of sites in our clinical trials, cannot be accomplished as effectively or efficiently remotely. These measures by government authorities, as well as the precautions we and others will take in order to operate our business responsibly in light of the COVID-19 pandemic, may continue to remain in place for a significant period of time, and they are likely to continue to adversely affect our business and results of operations.

In addition, we expect sales cycles, particularly for new customers, to continue to be impacted as a result of the COVID-19 pandemic, and we have observed continued volatility in YUPELRI sales. Sales momentum has been affected by COVID-19 and may continue to be in the future. We market YUPELRI in the hospital setting and to pulmonologists, whose practices have been impacted by the pandemic. In mid-March 2020, we suspended in-person sales calls to accounts in response to the COVID-19 pandemic. In August 2020, we began reengaging with these customers in-person when certain criteria are met and remotely via telephone calls, electronic mail, digital outreach or video conferencing as we seek to continue to support healthcare professionals and patient care. We are now able to more frequently conduct in-person customer engagements, however there is still high variability of access regionally. 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, and the impact of any concerns regarding nebulization in COVID-19 positive patients. We are preparing for continued volatility as disruptions of day-to-day operations of hospitals and clinics may continue. In addition, while we do not currently anticipate any supply issues, the COVID-19 pandemic could impact our supply of YUPELRI in the future. At this stage, we are unable to predict with certainty the ultimate disruptive impact of the COVID-19 pandemic on both YUPELRI and the rest of our business.

In addition, the COVID-19 pandemic makes the conduct of clinical trials more challenging given the paramount importance of adequate safety monitoring, collection of data and distribution of study drug, all of which are traditionally achieved by in-person visits to our study sites. Challenges may continue to arise from quarantines, shelter-in-place or stay-at-home orders, site closures, travel limitations, potential interruptions to the supply chain for investigational products, other measures to help prevent the spread of COVID-19 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. The Company implemented mitigation plans to help ensure patients in the clinical trials have continued access to drug supply and regular visits with their physicians for study visits per trial protocols, but there is a risk that

our trial data could be impacted if our efforts are insufficient. It is also possible that demand for products that we may pursue could be materially and adversely affected as a result of COVID-19 and any related economic impact. Furthermore, we cannot assure you that our publicly-announced initiatives addressing COVID-19 will result in commercially-viable products.

The spread of COVID-19 has caused us to modify our business practices and we may take further actions as may be required by government authorities or that we determine are in the best interests of our employees, customers and business partners. There is no certainty that such actions will be sufficient to mitigate the risks posed by the virus or otherwise be satisfactory to government authorities. If significant portions of our workforce, and particularly our field-based teams and laboratory staff, 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 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. We may also experience a shortage of supplies and materials or a suspension of services from third parties. Even after the COVID-19 pandemic subsides, we may continue to experience an adverse impact to our business as a result of its global economic impact.

The extent to which the COVID-19 pandemic impacts our business, results of operations and financial condition will depend on future developments, which are highly uncertain and difficult to predict, including, but not limited to, the duration and spread of the pandemic, its severity, the actions to contain the virus or address its impact, vaccine rollout, distribution and acceptance, and how quickly and to what extent normal economic and operating activities can permanently resume. There are no comparable recent events which may provide guidance as to the effect of the spread of the COVID-19 pandemic, and, as a result, the ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of COVID-19's impact on our business, our operations, or the global economy as a whole. However, the effects are likely to continue to have a material adverse impact on our future results of 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.

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 with the nebulized LAMA Lonhala[®] Magnair[®] (glycopyrrolate) 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;
- 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.

Each of our product candidates must undergo extensive non-clinical and clinical studies as a condition to regulatory approval. Non-clinical and clinical studies are expensive, take many years to complete and study results may lead to delays in further studies, new requirements for conducting future studies or decisions to terminate programs. In addition, we have voluntarily undertaken post-marketing studies with respect to YUPELRI. The commencement and completion of clinical studies for our product candidates 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;
- 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;
- the need to sequence clinical studies as opposed to conducting them concomitantly in order to conserve resources;
- our inability or the inability of our collaborators or licensees to manufacture or obtain from third parties materials sufficient for use in non-clinical and clinical studies;
- governmental or regulatory delays or suspensions of the conduct of the clinical trials and changes in regulatory requirements, policy and guidelines;
- challenges related to the COVID-19 pandemic, including with recruitment and/or progressing patients through studies;
- failure of our partners to advance our product candidates through clinical development;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- varying regulatory requirements or interpretations of data among the FDA and foreign regulatory authorities; and

- a 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 ampreloxtine did not meet its primary endpoint.

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

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

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

The FDA must approve any new medicine before it can be marketed and sold in the US. We will not obtain this approval for a product candidate unless and until the FDA approves an NDA. We, or our collaborative partners, must provide the FDA and similar foreign regulatory authorities with data from preclinical and clinical studies that demonstrate that our product candidates comply with the regulatory requirements for the quality of medicinal products and are safe and effective for a defined indication before they can be approved for commercial distribution. FDA or foreign regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. The processes by which regulatory approvals are obtained from the FDA and foreign regulatory authorities to market and sell a new product are complex, require a number of years, depend upon the type, complexity and novelty of the product candidate and involve the expenditure of substantial resources for research, development and testing. The FDA has substantial discretion in the drug approval process and may require us to conduct additional 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.

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

In January 2015, we entered into a collaboration agreement with Viatris for the development and commercialization of a nebulized formulation of our LAMA revefenacin, including YUPELRI. Under the terms of the agreement, we and Viatris will co-develop nebulized revefenacin, including YUPELRI, for COPD and other respiratory diseases. In June 2016, we entered into a License and Collaboration Agreement with Millennium Pharmaceuticals, Inc., an indirect wholly-owned subsidiary of Takeda Pharmaceutical Company Limited (collectively with Millennium, "Takeda") in order to establish a collaboration for the development and commercialization of TD-8954, a selective 5-HT₄ receptor agonist in development for gastrointestinal motility disorders. In December 2019, we entered into a License Agreement with Pfizer Inc. ("Pfizer"). Under the license agreement, we provide Pfizer with an exclusive global license to develop, manufacture and commercialize compounds from our preclinical program for skin-targeted, locally-acting pan-Janus kinase (JAK) inhibitors that can be rapidly metabolized. In connection with these agreements, these parties have certain rights regarding the use of patents and technology with respect to the compounds in our development programs, including development and marketing rights.

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

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

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

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

Clinical studies involving our product candidates may reveal that those candidates are ineffective, inferior to existing approved medicines, unacceptably toxic, or that they have other unacceptable side effects. In addition, the results of preclinical studies do not necessarily predict clinical success, and larger and later-stage clinical studies may not produce the same results as earlier-stage clinical studies. For example, despite promising early stage studies, we recently announced that two late stage clinical programs failed to meet their primary endpoints.

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

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

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

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

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

Pharmaceutical companies, including companies with which we collaborate, may invest heavily to quickly discover and develop or in-license novel compounds that could make our product candidates obsolete. Accordingly, our

competitors may succeed in obtaining patent protection, receiving FDA or equivalent regulatory approval outside the US or discovering, developing and commercializing medicines before we do. Other companies are engaged in the discovery of medicines that would compete with the product candidates that we are developing or our existing product.

Any new medicine that competes with a generic or proprietary market leading medicine must demonstrate compelling advantages in efficacy, convenience, tolerability and/or safety in order to overcome severe price competition and be commercially successful. For example, YUPELRI competes predominantly with the nebulized LAMA Lonhala[®] Magnair[®] (glycopyrrolate) dosed two times per day and 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.

There is a single source of supply for a number of 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 have limited in-house production capabilities for preclinical and clinical study purposes and depend primarily on a number of third-party Active Pharmaceutical Ingredient (“API”) and drug product manufacturers. We may not have long-term agreements with these third parties and our agreements with these parties may be terminable at will by either party at any time. In addition, there is a single supplier of YUPELRI API and a single supplier of YUPELRI drug product. 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. Any inability to acquire sufficient quantities of API and drug product in a timely manner from these third parties could delay preclinical and clinical studies, prevent us from developing our product candidates in a cost-effective manner or on a timely basis or adversely impact the commercialization of YUPELRI. In addition, manufacturers of our API and drug product are subject to the FDA’s current Good Manufacturing Practice (“cGMP”) regulations and similar foreign standards and we do not have control over compliance with these regulations by our manufacturers.

Our manufacturing strategy presents the following additional risks:

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

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

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

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

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

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

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

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

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

Under the Drug Price Competition and Patent Term Restoration Act of 1984, a company may submit an abbreviated new drug application ("ANDA") under section 505(j) of the Federal Food, Drug, and Cosmetic Act to market a generic version of an approved drug. Because a generic applicant does not conduct its own clinical studies, but instead relies on the FDA's finding of safety and effectiveness for the approved drug, it is able to introduce a competing product into the market at a cost significantly below that of the original drug. Although we have multiple patents protecting YUPELRI with expiration dates ranging from 2025 to 2039 that are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book (and those commercializing products with respect to which we have an economic interest or right to receive royalties have patents protecting their products) generic applicants could potentially submit "paragraph IV certifications" to FDA stating that such patents are invalid or will not be infringed by the applicant's product. We have not received any such paragraph IV notifications nor are we aware of any with respect to products in which we have an economic interest or right to receive royalties, but if any competitors successfully challenge the patents related to these products, we and/or our collaboration partners and those commercializing products with respect to which we have an economic interest or right to receive royalties would face substantial competition. If we are not able to compete effectively against such future competition, our business will not grow, our financial condition and operations will suffer and the price of our securities could fall.

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

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 collaborations with a number of third parties including Viatris for the development and commercialization of a nebulized formulation of revefenacin, which is a LAMA compound (including YUPELRI). Also, 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 U.S., and (b) for sales or other activities occurring on and after July 1, 2029 related to the Assigned Collaboration Products outside of the U.S. (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. Additional collaborations, if any, may be needed to fund development of certain programs that have not been licensed to a collaborator and to commercialize the product candidates in our programs if approved by the necessary regulatory authorities. We evaluate commercial strategy on a product by product basis either to engage pharmaceutical or other healthcare companies with an existing sales and marketing organization and distribution system to market, sell and distribute our products or to commercialize a product ourselves. However, we may not be able to establish these sales and distribution relationships on acceptable terms, or at all, or may encounter difficulties in commercializing a product ourselves. For any of our product candidates that receive regulatory approval in the future and are not covered by our current collaboration agreements, we will need a partner in order to commercialize such products unless we establish independent sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure.

Collaborations with third parties regarding our programs may require us to relinquish material rights, including revenue from commercialization of our medicines, or to assume material ongoing development obligations that we would have to fund. These collaboration arrangements are complex and time-consuming to negotiate, and if we are unable to reach agreements with third-party collaborators, we may fail to meet our business objectives and our financial condition may be adversely affected. We face significant competition in seeking third-party collaborators. We may be unable to find third parties to pursue product collaborations on a timely basis or on acceptable terms. Furthermore, for any collaboration, we may not be able to control the amount of time and resources that our partners devote to our product candidates and our partners may choose to prioritize alternative programs or otherwise be unsuccessful in their efforts with respect to our products or product candidates. 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 and other considerations that influence its resource allocation, and other priorities and internal organizational processes that differ from our own. As a result of these differing interests and processes, Viatris may take actions that it believes are in its best interest but which might not be in the best interests of either us or our other shareholders. Our inability to successfully collaborate with third parties would increase our development costs and may cause us to choose not to continue development of certain product candidates, would limit the likelihood of successful commercialization of some of our product candidates, may cause us not to continue commercialization of our authorized products and could cause the price of our securities to fall.

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

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

non-approval of our product candidates by regulatory authorities. 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 GXP's and other regulations through periodic inspections of trial sponsors, clinical research organizations ("CROs"), principal investigators and trial sites. If we or any of the third parties on which we have relied to conduct our clinical studies are determined to have failed to comply with GXP's (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.

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
- any particular FDA requirements or changes in FDA policy or guidance regarding the TRELEGY program or any particular regulatory requirements in other jurisdictions or changes in the policies or guidance adopted by foreign regulatory authorities.

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

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

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

- GSK's ability to have an adequate supply of TRELEGY product;
- ongoing compliance by GSK or its suppliers with the FDA's current Good Manufacturing Practice;
- compliance with other applicable FDA and other regulatory requirements in the US or other foreign jurisdictions, including those described elsewhere in this report;

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

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

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

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

If we fail to retain our qualified personnel or replace them when they leave, we may be unable to continue our discovery, development and commercialization activities, which may cause the price of our securities to fall. The Restructuring announced in September 2021 may make retention of our current personnel both more important and more challenging.

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

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

We 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 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.

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 purchase \$95.0 million of our ordinary shares pursuant to our ongoing tender offer and that we purchase \$60.0 million of our ordinary shares pursuant to an open-market share repurchase program by the end of 2023. 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”), including a reduction in headcount by approximately 75% through a reduction in our workforce of regular and contingent workers. The Restructuring was completed during the third quarter of 2022. If our current operating plans or financial forecasts change, we may require or seek additional funding sooner in the form of public or private equity or equity-linked offerings, debt financings or additional collaborations and licensing arrangements. In addition, as of September 30, 2022, we had cash, cash equivalents and short-term marketable securities of \$486.8 million.

We may need to raise additional capital in the future to, among other things:

- fund our discovery efforts and research and development programs;
- fund our commercialization strategies for any approved products and to prepare for potential product approvals;
- support our independent sales and marketing organization and medical affairs team;
- support our additional investments in YUPELRI, including post-marketing clinical studies;
- progress any additional product candidates into later-stage development without funding from a collaboration partner;
- progress mid-to-late stage product candidates into later-stage development, if warranted;
- respond to competitive pressures; and
- acquire complementary businesses or technologies.

Our future capital needs depend on many factors, including:

- the scope, duration and expenditures associated with our discovery efforts and research and development programs;
- continued scientific progress in these programs;
- the extent to which we encounter technical obstacles in our research and development programs;
- the outcome of potential licensing or partnering transactions, if any;
- competing technological developments;
- the extent of our proprietary patent position in any approved products and our product candidates;
- our facilities expenses, which will vary depending on the time and terms of any facility lease or sublease we may enter into, and other operating expenses;
- the scope and extent of the expansion of our sales and marketing efforts;
- potential litigation and other contingencies; and
- the regulatory approval process for our product candidates.

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 preclinical and clinical studies as opposed to conducting them concomitantly in order to conserve resources, or, as we announced in September 2021, we may need to delay, reduce, or eliminate one or more of our research or development programs and reduce overall overhead expenses. In addition, we may have to make additional reductions in our workforce and may be prevented from continuing our discovery, development and commercialization efforts and exploiting other corporate opportunities. This would likely harm our business, prospects and financial condition, and cause the price of our securities to fall.

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

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 fail to achieve the expected cost savings and related benefits from our Restructuring.

In September 2021, our Board approved a plan to restructure our business operations to drive long term sustainable revenue growth, better align resources, improve operational efficiencies and to increase profitability. Following the completion of this Restructuring in the third quarter of 2022, our management and employees are primarily focused on managing our most promising programs. As part of the Restructuring, we reduced employee headcount by approximately 75%. We incurred total Restructuring and related expenses of \$31.6 million comprised of \$17.4 million in cash expenses and \$14.2 million in non-cash expenses. The Restructuring and related expenses were primarily comprised of severance, retention, and other costs relating to the Restructuring and were incurred from the third quarter of 2021 through the third quarter of 2022. Affected employees received notification and were eligible to receive severance payments based on their responsibilities within the organization and years of service, contingent upon effectiveness of an affected employee's a separation agreement, which includes a general release of claims against us.

The Restructuring was completed in the third quarter of 2022. Our plans may change as we continue to optimize our asset portfolio to maximize shareholder value, and there can be no guarantee that the Restructuring will result in long term sustainable revenue growth, the better alignment of resources, improvement in operational efficiencies and increased profitability, and such results may fall short of the benefits we expected from the Restructuring or may not occur on the timeline that we expect. The foregoing factors could cause us not to achieve the expected benefits of these actions, and adversely affect our financial condition.

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 the United Kingdom's ("UK") withdrawal from the EU (often referred to as "Brexit"), current global economic challenges, the COVID-19 pandemic, and other disruptions to global and regional economies and markets.

Brexit has 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.

In light of the fact that a significant portion of the regulatory framework in the UK is derived from EU laws, Brexit could materially impact the regulatory regime governing development, manufacture, importation, approval and commercialization of our product candidates in the UK or the EU. For example, a marketing authorization for a medicinal product granted by the European Commission or by the competent authorities of EU member states will no longer encompass the UK. A separate authorization granted by the UK competent authorities will be required to place medicinal products on the UK market. In addition, the UK's withdrawal from the EU affects manufacturing sites that hold an EU manufacturing authorization issued by the UK competent authorities which could impact our ability to rely on UK manufacturing sites to supply medicinal products intended for the EU market will depend on. All of these changes could increase our costs and otherwise adversely affect our business. In addition, currency exchange rates for the British Pound and the Euro with respect to each other and to the US dollar have already been, and may continue to be, negatively affected by Brexit, which could cause volatility in our quarterly financial results.

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

Our operations also depend upon favorable trade relations between the US and those foreign countries in which our materials suppliers have operations. A protectionist trade environment in either the US or those foreign countries in

which we do business, such as a change in the current tariff structures, export compliance or other trade policies, may materially and adversely affect our operations.

External factors, such as potential terrorist attacks, acts of war, geopolitical and social turmoil, 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 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.

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

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

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

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

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

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

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

Taxing authorities may challenge our structure and transfer pricing arrangements.

We are incorporated in the Cayman Islands, maintain subsidiaries in the Cayman Islands (until December 2020), the US, the UK and Ireland, and effective July 1, 2015, we migrated our tax residency from the Cayman Islands to Ireland. Due to economic and political conditions, various countries are actively considering changes to existing tax laws. We cannot predict the form or timing of potential legislative changes that could have a material adverse impact on our results of operations. Ireland has implemented further tax law changes through the Finance Act 2021 to comply with the European Union Anti-Tax Avoidance Directives. Changes to date, including reverse-hybrid mismatch and interest limitation rules, are not expected to have a material impact on 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 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, 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 2021, we do not believe that our Company is a PFIC since 2015. Based on existing tax law, we do not expect to be a PFIC for the foreseeable future based on our current business plans and current business model. For any taxable year (or portion thereof) in which our Company is a PFIC that is included in the holding period

of a US holder, the US holder is generally subject to additional US federal income taxes plus an interest charge with respect to certain distributions from Theravance Biopharma or gain recognized on a sale of Theravance Biopharma shares. Similar rules would apply with respect to distributions from or gain recognized on an indirect sale of Theravance Biopharma Ireland Limited. US holders of our ordinary shares may have filed an election with respect to Company shares held at any time during 2014 to be treated as owning an interest in a “qualified electing fund” (“QEF”) or to “mark to market” their ordinary shares to avoid the otherwise applicable interest charge consequences of PFIC treatment with respect to our ordinary shares. A foreign corporation will not be treated as a QEF for any taxable year in which such foreign corporation is not treated as a PFIC. QEF and mark to market elections generally apply to the taxable year for which the election is made and all subsequent taxable years unless the election is revoked with consent of the Secretary of Treasury. US holders of our ordinary shares should consult their tax advisers regarding the tax reporting implications with respect to any QEF and mark to market elections made with respect to our Company and with respect to their indirect interests in Theravance Biopharma R&D, Inc.

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

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

RISKS RELATED TO LEGAL AND REGULATORY UNCERTAINTY

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

We rely upon a combination of patents, patent applications, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any involuntary disclosure to or misappropriation by third parties of this proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. The status of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and is very uncertain. As of September 30, 2022, we owned 252 issued US patents and 1,631 granted foreign patents, as well as additional pending US and foreign patent applications. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be invalidated or be too narrow to prevent third parties from developing or designing around these patents. If the sufficiency of the breadth or strength of protection provided by our patents with respect to a product candidate is threatened, it could dissuade companies from collaborating with us to develop product candidates and threaten our ability to commercialize products. Further, if we encounter delays in our clinical trials or in obtaining regulatory approval of our product candidates, the 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 would require us to divert resources and may prevent or delay our drug discovery and development efforts.

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

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

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

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

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

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

The risk that we may be sued on product liability claims is inherent in the development and commercialization of pharmaceutical products. Side effects of, or manufacturing defects in, products that we or our partners develop or

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

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

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

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

We are subject to data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the US, numerous federal and state laws and regulations, including state data breach notification laws, state health information and/or genetic privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the FTC Act), govern the collection, use, disclosure, and protection of health related and other personal information. In California, the California Consumer Privacy Act ("CCPA") took effect on January 1, 2020. The 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. In addition, in November 2020, California voters approved the California Privacy Rights Act ("CPRA") ballot initiative which introduced significant amendments to the CCPA and established and funded a dedicated California privacy regulator, the California Privacy Protection Agency ("CPPA"). The amendments introduced by the CPRA go into effect on January 1, 2023, and new implementing regulations are expected to be introduced by the CPPA. And in 2021, Virginia and Colorado adopted laws, effective January 1, 2023, and July 1, 2023, respectively, introducing new privacy obligations for which we may need to take additional steps to comply. Similarly, there are a number of legislative proposals and enactments in the United States, at both the federal and state level, that could 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"). Although we are not directly subject to HIPAA, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA. HIPAA generally requires that healthcare providers and other covered entities obtain written authorizations from patients prior to disclosing protected health information of the patient (unless an exception to the authorization requirement applies). If authorization is required and

the patient fails to execute an authorization or the authorization fails to contain all required provisions, then we may not be allowed access to and use of the patient's information and our research efforts could be impaired or delayed. Furthermore, use and disclosure of protected health information that is provided to us pursuant to a valid patient authorization is subject to the limits set forth in the authorization (e.g., for use in research and in submissions to regulatory authorities for product approvals). Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may have contractual rights that limit our ability to use and disclose the information. In addition, HIPAA does not replace federal, state, international or other laws that may grant individuals even greater privacy protections.

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

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 information provided to the individuals, the transfer of personal data out of the European Economic Area ("EEA") or Switzerland, security breach notifications, security and confidentiality of the personal data, as well as substantial potential fines, in some cases up to 4% of global revenues, 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.

Legal mechanisms to allow for the transfer of personal data from the EEA to the US have been challenged in the European Court of Justice, which generally increases uncertainty around compliance with EU privacy law requirements as these relate to transfer of data from the EU to the US. In 2016, the European Commission and the US Department of Commerce ("DOC") put in place the EU US "Privacy Shield," which has been relied on by some US companies since that time to transfer data to the US. However, on July 16, 2020, the European Court of Justice ruled that the Privacy Shield is invalid. As a result, from July 16, 2020 companies could no longer rely on the Privacy Shield as a basis on which to transfer personal data from the EU to the US. Data exporters and US-based companies are permitted to rely on other authorized means and procedures to transfer personal data subject to the GDPR to the US. Recent changes have been made to another commonly used authorized procedure to transfer personal data out of the EU, the European Commission's Standard Contractual Clauses (SCCs). In June 2021, the European Commission published updated versions of the SCCs, which, if companies are relying on them as the mechanism to transfer personal information from the EEA to the US (or to other jurisdictions not recognized as adequate by the EU), must be incorporated into new and existing agreements within prescribed timeframes. The UK is expected to publish final versions of their own SCCs during 2022. 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.

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;
- 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.

On August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 (the “IRA”), which, among other changes, requires the Department of Health and Human Services to negotiate, with respect to Medicare units and subject to a specified cap, the price of a set number of certain high Medicare spend drugs and biologicals per year starting in 2026, penalizes manufacturers of certain Medicare Parts B and D drugs for price increases above inflation, and makes several changes to the Medicare Part D benefit, including a limit on annual out-of-pocket costs, and a change in manufacturer liability under the program. Although we are monitoring developments relating to the IRA, it is currently unclear to us how the IRA will be implemented or whether it will be amended or subject to legal challenge, and the impact of the IRA on our business and our industry cannot yet be fully determined.

In addition, the Patient Protection and Affordable Care Act, as amended (the “Healthcare Reform Act”), is a sweeping measure intended to expand healthcare coverage within the US, primarily through the imposition of health insurance mandates on employers and individuals (the latter of which since made non-enforceable), the provision of subsidies to eligible individuals enrolled in plans offered on the health insurance exchanges, and expansion of the Medicaid program. This law has substantially changed the way healthcare is financed by both governmental and private insurers and has significantly impacted the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions that impact our business and operations, including those governing enrollment in federal healthcare programs, reimbursement changes, benefits for patients within a coverage gap in the Medicare Part D prescription drug program (commonly known as the “donut hole”), rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicare Drug Rebate program, expansion of the Public Health Service 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.

On December 21, 2020, CMS issued a final regulation that modified prior Medicaid Drug Rebate program regulations to permit reporting multiple best price figures with regard to value based purchasing arrangements; and to provide definitions for “line extension,” “new formulation,” and related terms, with the practical effect of expanding the scope of drugs considered to be line extensions that are subject to an alternative rebate formula. While the regulatory provisions that purported to affect the applicability of the best price and average manufacturer price exclusions of manufacturer-sponsored patient benefit programs were invalidated by a court, such programs may continue to negatively affect us in other ways. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program have increased and will continue to increase the costs and the complexity of compliance, and could have a material adverse effect on results of operations for us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties, particularly if CMS challenges the approach taken to comply with the regulations and other law.

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. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017 (the “Tax Act”), eliminated the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the individual mandate, effective January 1, 2019. Additional legislative changes to and regulatory changes under the Healthcare Reform Act remain possible, but the nature and extent of such potential additional changes are uncertain at this time. We expect that the Healthcare Reform Act, its implementation, efforts to modify, or invalidate the Healthcare Reform Act, or portions thereof, or its implementation, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on the ability of us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties to maintain or increase sales of existing products or to successfully commercialize product candidates, if approved.

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 IRA sunsets the coverage gap discount program starting in 2025 and replaces it with a new manufacturer discount program, which may increase our Part D liability. In addition, starting October 2022, the IRA establishes a Medicare Part D inflation rebate scheme, under which, generally speaking, manufacturers will owe additional rebates if the average manufacturer price of a Part D drug increases faster than the pace of inflation. Failure to timely pay a Part D inflation rebate is subject to a civil monetary penalty.

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, 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. Further, starting January 2023, the IRA establishes a Medicare Part B inflation rebate scheme, under which, generally speaking, manufacturers will owe rebates if the average sales price of a Part B drug increases faster than the pace of inflation. Failure to timely pay a Part B inflation rebate is subject to a civil monetary penalty. 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.

Additionally, in November 2020, the Department of Health and Human Services finalized a previously abandoned proposal to amend the discount safe harbor regulation of the federal anti-kickback statute in a purported effort to create incentives to manufacturers to lower their list prices, and to lower federal program beneficiary out-of-pocket costs. The rule, for which the effective date was delayed to 2032 in the IRA, revises the discount safe harbor to exclude manufacturer rebates to Medicare Part D plans, either directly or through pharmacy benefit managers (“PBMs”), creates a new safe harbor for point-of-sale price reductions that are set in advance and are available to the beneficiary at

the point-of-sale, and creates a new safe harbor for service fees paid by manufacturers to PBMs for services rendered to the manufacturer. It is unclear whether the rule will be further delayed, rewritten, or allowed to go into effect, and if so, what the effect of the rule will be on negotiations of coverage for our products with Medicare Part D plans, or whether the rule will affect our coverage arrangements with commercial insurers. It is also unclear whether the rule will have the intended effect of reducing net prices and beneficiary out-of-pocket costs without also increasing Medicare Part D premiums, which may impact the willingness of Part D plans to cover our products and the price concessions or other terms the plans or their PBMs may seek from us.

On August 2, 2011, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction, which triggered the legislation's automatic reductions. In concert with subsequent legislation, this has resulted in aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2030 (with the exception of a temporary suspension from May 1, 2020 through May 31, 2022, due to the COVID-19 pandemic). The law provides for 1% Medicare sequestration in the second quarter of 2022 and allows the full 2% sequestration thereafter until 2030. To offset the temporary suspension during the COVID-19 pandemic, in 2030, the sequestration will be 2.25% for the first half of the year, and 3% in the second half of the year. As long as these cuts remain in effect, they could adversely impact payment for any products that are reimbursed under Medicare.

Individual states in the United States 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.

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

Prior to the sale of VIBATIV to Cumberland Pharmaceuticals Inc. ("Cumberland") in November 2018, we had certain price reporting obligations to the Medicaid Drug Rebate program and other governmental pricing programs, and we had obligations to report average sales price under the Medicare program. Following the consummation of the transaction with Cumberland, our price reporting obligations related to VIBATIV have been transitioned to Cumberland, and price reporting obligations for YUPELRI reside with Viatriis. We retain certain obligations with respect to record retention for these programs.

Under the Medicaid Drug Rebate program, a manufacturer is required to pay a rebate to each state Medicaid program for its covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by the manufacturer on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the US in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions. The amount of the rebate is adjusted upward if the average manufacturer price increases at a pace faster than inflation (measured by reference to the Consumer Price Index - Urban). Currently, the rebate is capped at 100 percent of the average manufacturer price, but, effective January 1, 2024, this cap on the rebate will be removed, and our rebate liability could increase accordingly.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs to a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. Manufacturers also are required to report their 340B ceiling prices to HRSA on a quarterly basis, and HRSA then publishes them to 340B covered entities. A final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities became effective on January 1, 2019. Moreover, under a final regulation effective January 13, 2021, HRSA newly established an administrative dispute resolution ("ADR") process for claims by covered entities that a manufacturer has engaged in overcharging, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed only in federal court. An ADR proceeding could subject us to onerous procedural requirements and could result in additional liability.

Federal law also requires that manufacturers report average sales price information for certain categories of drugs that are paid under the Medicare Part B program to CMS on a quarterly basis. Manufacturers calculate the average sales price based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. CMS uses these submissions to determine payment rates for drugs under Medicare Part B. Effective January 1, 2023, manufacturers will be obligated to pay refunds to Medicare for single source drugs or biologicals, or biosimilar biological products, reimbursed under Medicare Part B and packaged in single-dose containers or single-use packages, for units of discarded drug reimbursed by Medicare Part B in excess of 10 percent of total allowed charges under Medicare Part B for that drug. Manufacturers that fail to pay refunds could be subject to civil monetary penalties of 125 percent of the refund amount.

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

We 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. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid or Medicare Part B for covered outpatient drugs under our labeler code.

In order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by the Department of Veterans Affairs ("VA"), Department of Defense ("DoD"), Public Health Service, and Coast Guard (the "Big Four agencies") and certain federal grantees, a manufacturer is required to participate in the VA Federal Supply Schedule ("FSS") pricing program, established under Section 603 of the Veterans Health Care Act of 1992. Under this program, the manufacturer is obligated to make its covered drugs available for procurement on an FSS contract and charge a price to the Big Four agencies that is no higher than the Federal Ceiling

Price (“FCP”), which is a price calculated pursuant to a statutory formula. The FCP is derived from a calculated price point called the “non-federal average manufacturer price” (“Non-FAMP”), which the manufacturer calculates and reports to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to significant penalties for each item of false information. The FSS contract also contains extensive disclosure and certification requirements.

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

Individual states in the United States, 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 safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute, but the legality of the arrangement will be evaluated on a case-by-case basis based on the totality of the facts and circumstances. We seek to comply with the available statutory exemptions and safe harbors whenever possible, but our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants or patient or product assistance programs.
- The federal civil False Claims Act prohibits, among other things, knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent, or knowingly making, or using or causing to be made or used, a false record or statement material to a false or fraudulent claim to

avoid, decrease, or conceal an obligation to pay money to the federal government. Private individuals, commonly known as “whistleblowers,” can bring civil False Claims Act *qui tam* actions, on behalf of the government and such individuals and may share in amounts paid by the entity to the government in recovery or settlement. In recent years, several pharmaceutical and other healthcare companies have faced enforcement actions under the federal False Claims Act for, among other things, allegedly submitting false or misleading pricing information to government health care programs and providing free product to customers with the expectation that the customers would bill federal programs for the product. Federal enforcement agencies also have showed increased interest in pharmaceutical companies’ product and patient assistance programs, including reimbursement and co-pay support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. Other companies have faced enforcement actions for causing false claims to be submitted because of the companies’ marketing the product for unapproved, and thus non-reimbursable, uses. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties per false claim or statement for violations. Because of the potential for large monetary exposure, healthcare and pharmaceutical companies often resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings. As part of these resolutions, Companies may enter into corporate integrity agreements with the government, which may impose substantial costs on companies to ensure compliance. Criminal penalties, including imprisonment and criminal fines, are also possible for making or presenting a false, fictitious or fraudulent claim to the federal government.

- HIPAA, among other things, imposes criminal and civil liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors, and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HIPAA also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal healthcare Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.
- The federal Physician Payment Sunshine Act, implemented as the Open Payments Program, requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the US Department of Health and Human Services, Centers for Medicare and Medicaid Services, information related to payments and other transfers of value, directly or indirectly, to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives. A manufacturer’s failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties.
- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payors, including private insurers or patients. Several states also require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing-related activities, including the provision of gifts, meals, or other items to certain health care providers, and restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. Some states require the posting of information relating to clinical studies and their

outcomes. Some states and cities require identification or licensing of sales representatives. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes.

- Similar restrictions are imposed on the promotion and marketing of medicinal products in the EU Member States and other countries, including restrictions prohibiting the promotion of a compound prior to its approval. Laws (including those governing promotion, marketing and anti-kickback provisions), industry regulations and professional codes of conduct often are strictly enforced. Even in those countries where we may decide not to directly promote or market our products, inappropriate activity by our international distribution partners could have implications for us.

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

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

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical, biological and radioactive materials. In addition, our operations produce hazardous waste products, including hazardous waste. Federal, state and local laws and regulations govern the use, manufacture, management, storage, handling and disposal of hazardous materials and wastes. We may incur significant additional costs or liabilities to comply with, or for violations of, these and other applicable laws in the future. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any such contamination or injury. Further, in the event of a release of or exposure to hazardous materials, including at the sites we currently or formerly operate or at sites such as landfills where we send wastes for disposal, we could be held liable for cleanup costs or damages or subject to other costs or penalties and such liability could exceed our resources. We do not have any insurance for liabilities arising from hazardous materials or under environmental laws. Compliance with or liability under applicable environmental laws and regulations or with respect to hazardous materials may be expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, which could cause the price of our securities to fall.

RISKS RELATING TO OUR ORDINARY SHARES

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

The market price for our shares has fluctuated, and may continue to fluctuate widely and may result in substantial losses for purchasers of our ordinary shares. To the extent that low trading volumes for our ordinary shares continues, our stock price may fluctuate significantly more than the stock market as a whole or the stock prices of similar companies. Without a larger public float of actively traded shares, our ordinary shares are likely to be more sensitive to changes in sales volumes, market fluctuations and events or perceived events with respect to our business, than the shares of common stock of companies with broader public ownership, and as a result, the trading prices for our ordinary

shares may be more volatile. Among other things, trading of a relatively small volume of ordinary shares may have a greater effect on the trading price than would be the case if our public float of actively traded shares were larger. In addition, as further described below under the risk factor entitled “—*Concentration of ownership will limit your ability to influence corporate matters,*” a number of shareholders hold large concentrations of our shares which, if sold to third parties within a relatively short timeframe, could cause the price of our shares to drop significantly.

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

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

- any adverse developments or results or perceived adverse developments or results with respect to YUPELRI, including without limitation, lower than expected sales of YUPELRI, difficulties or delays encountered with regard to the FDA or other regulatory authorities in this program or any indication from clinical or non-clinical studies that YUPELRI is not safe or efficacious;
- any adverse developments or results or perceived adverse developments or results with respect to TRELEGY;
- any adverse developments or results or perceived adverse developments or results with respect to our clinical development programs, including, without limitation, any delays in development in these programs, any halting of development in these programs, any difficulties or delays encountered with regard to the FDA or other regulatory authorities in these programs (including any class-based risks that emerge as a FDA or other regulatory agency focus), or any indication from clinical or non-clinical studies that the compounds in such programs are not safe or efficacious;
- any announcements of developments with, or comments by, the FDA or other regulatory authorities with respect to products we or our partners have under development, are manufacturing or have commercialized;
- any adverse developments or disagreements or perceived adverse developments or disagreements with respect to our relationship with Royalty Pharma, or the relationship of Royalty Pharma and GSK;
- any adverse developments or perceived adverse developments with respect to our relationship with any of our research, development or commercialization partners, including, without limitation, disagreements that may arise between us and any of those partners;
- any adverse developments or perceived adverse developments in our programs with respect to partnering efforts or otherwise;
- announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors;
- publicity regarding actual or potential study results or the outcome of regulatory review relating to products under development by us, our partners or our competitors;
- regulatory developments in the US and foreign countries;
- announcements with respect to governmental or private insurer reimbursement policies;
- announcements of equity or debt financings;

- possible impairment charges on non-marketable equity securities;
- economic and other external factors beyond our control, such as the COVID-19 pandemic and fluctuations in interest rates;
- loss of key personnel;
- likelihood of our ordinary shares to be more sensitive to changes in sales volume, market fluctuations and events or perceived events with respect to our business due to our small public float;
- low public market trading volumes for our ordinary shares;
- the sale of large concentrations of our shares to third parties, which may be more likely to occur due to the concentration of ownership of our shares, such as what we experienced when our 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.

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.

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

Based solely on our review of publicly available filings, as of September 30, 2022, our three largest shareholders collectively owned 40.4% 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 issuer tender offer and do not otherwise sell their shares, assuming that our ongoing tender offer is consummated and we repurchase shares pursuant to our authorized 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;
- establish a classified board of directors;
- restrict our shareholders from calling meetings or acting by written consent in lieu of a meeting;
- limit the ability of our shareholders to propose actions at duly convened meetings; and
- authorize our board of directors, without action by our shareholders, to issue preferred shares and additional ordinary shares.

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

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

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

Our corporate affairs are governed by our amended and restated memorandum and articles of association, by the Companies Law (2020 Revision) of the Cayman Islands and by the common law of the Cayman Islands. The rights of our shareholders and the fiduciary responsibilities of our directors under the laws of the Cayman Islands are different from those under statutes or judicial precedent in existence in jurisdictions in the US. Therefore, you may have more difficulty in protecting your interests than would shareholders of a corporation incorporated in a jurisdiction in the US, due to the different nature of Cayman Islands law in this area.

Shareholders of Cayman Islands exempted companies such as our company have no general rights under Cayman Islands law to inspect corporate records and accounts or to obtain copies of lists of shareholders. Our directors have discretion under our amended and restated memorandum and articles of association to determine whether or not, and under what conditions, our corporate records may be inspected by our shareholders, but are not obliged to make them available to our shareholders. This may make it more difficult for you to obtain the information needed to establish any facts necessary for a shareholder motion or to solicit proxies from other shareholders in connection with a proxy contest.

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

authority and be applied by a court in the Cayman Islands, exceptions to the foregoing principle apply in circumstances in which:

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

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

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

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

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

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

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

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, consisting of the following three elements: the repurchase of GSK’s ordinary shares, which was completed on September 20, 2022, a Dutch auction tender offer for up to \$95.0 million of our ordinary shares, and an Open Market Share Repurchase Program for approximately \$60.0 million dollars with the goal of completing it by the end of 2023. The tender offer has not yet been completed, its consummation

is subject to conditions, and if it is oversubscribed, we may not repurchase all the shares tendered by participating shareholders. Moreover, no purchases have been made pursuant to the authorized open market share repurchase program. There is therefore no guarantee that 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.

ITEM 6. EXHIBITS

| Exhibit Number | Exhibit Description | Filed Herewith | Incorporated by Reference | |
|---------------------|---|----------------|---------------------------|-----------------------------|
| | | | Form | Filing Date/Period End Date |
| 2.1 ⁽¹⁾ | Equity Purchase and Funding Agreement, dated as of July 13, 2022, by and between Theravance Biopharma, Inc. and Royalty Pharma Investments 2019 ICAV | | 8-K | July 14, 2022 |
| 10.1 | Master Consent, dated as of July 13, 2022, by and among Glaxo Group Limited, Theravance Biopharma, Inc. and Royalty Pharma Investments 2019 ICAV | | 8-K | July 14, 2022 |
| 10.2 ⁽¹⁾ | Release Agreement, dated as of July 13, 2022, by and among Innoviva, Inc., Innoviva TRC Holdings LLC, Royalty Pharma Investments 2019 ICAV, Theravance Respiratory Company, LLC, Theravance Biopharma, Inc., Theravance Biopharma US Holdings, Inc. and Triple Royalty Sub II LLC | | 8-K | July 14, 2022 |
| 10.3 ⁽¹⁾ | Share Repurchase Agreement dated September 16, 2022, by and between Theravance Biopharma, Inc. and GSK Finance (No.3) plc | | SC TO | September 28, 2022 |
| 10.4 | First Amendment to the Theravance Biopharma, Inc. Change in Control Severance Plan | X | | |
| 31.1 | 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 | X | | |
| 31.2 | 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 | X | | |
| 32 ⁽²⁾ | 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 | X | | |
| 101 | Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended September 30, 2022, formatted in iXBRL: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Income (Loss), (iii) Condensed | X | | |

Consolidated Statements of Shareholders' Equity
(Deficit), (iv) the Condensed Consolidated Statements of
Cash Flows, and (v) the Notes to the Condensed
Consolidated Financial Statements

104 Cover Page Interactive Data File (Formatted in iXBRL and contained in Exhibit 101) X

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- (1) Certain schedules and exhibits to this Exhibit have been omitted pursuant to Item 601(a)(5) or Item 601(b)(2)(ii), as applicable, of Regulation S-K. The registrant agrees to furnish supplemental copies of all omitted exhibits and schedules to the Securities and Exchange Commission upon its request.
 - (2) The certifications provided as Exhibit 32 are being furnished to accompany the Report pursuant to 18 U.S.C. Section 1350 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

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

Theravance Biopharma, Inc.

Date: November 9, 2022

/s/ RICK E WINNINGHAM

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

Date: November 9, 2022

/s/ ANDREW HINDMAN

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

**FIRST AMENDMENT
TO THE THERAVANCE BIOPHARMA, INC.
CHANGE IN CONTROL SEVERANCE PLAN**

The following amendment (the “First Amendment”) to the Theravance Biopharma, Inc. (the “Company”) Change in Control Severance Plan (the “Plan”) was adopted by the Board of Directors of the Company (the “Board”) on July 12, 2022. Capitalized terms used and not otherwise defined herein shall have the meanings ascribed to such terms in the Plan.

1. Amendment to Definition of Change in Control. The definition of “Change in Control” in the Plan is amended to add the following to the last paragraph thereof:

Notwithstanding anything herein to the contrary, a sale by Theravance Biopharma US Holdings, Inc. and Triple Royalty Sub II LLC, each a wholly-owned subsidiary of the Company, of the Class B Units and Class C Units held by each of them in Theravance Respiratory Company, LLC , shall not constitute a Change in Control.

2. Effect on the Plan. Except as specifically amended by this First Amendment, the Plan shall remain in full force and effect.
3. Governing Law. This First Amendment shall be governed by the Employee Retirement Income Security Act of 1974, as amended and, to the extent applicable, the laws of the State of California.

[Signature Page Follows]

IN WITNESS WHEREOF, the Company has caused this First Amendment to be executed as of the date first above written.

THERAVANCE BIOPHARMA, INC.

By: /s/ Rick E Winningham

Name: Rick E Winningham

Title: Chief Executive Officer

[Signature Page to First Amendment to the Theravance Biopharma, Inc. Change in Control Severance Plan]

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

I, Rick E Winningham, certify that:

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

Date: November 9, 2022

/s/ RICK E WINNINGHAM

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

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

I, Andrew Hindman, certify that:

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

Date: November 9, 2022

/s/ ANDREW HINDMAN

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

