

# Medicines That Make a Difference\*

# Theravance Biopharma, Inc. Reports Third Quarter 2022 Financial Results, Provides Business Update and Extends Tender Offer

November 7, 2022

- Reported another record quarter of YUPELRI<sup>®</sup> (revefenacin) net sales and profitability: \$18.7 million Q3 2022 sales up 35% from Q3 2021 (TBPH implied 35% share)<sup>1</sup>
- Presented ampreloxetine data in neurogenic orthostatic hypotension (nOH) at the 33rd International Symposium on the Autonomic Nervous System
- Continued to build the Company's intellectual property portfolio with patent covering YUPELRI until 2039
- Closed transaction to sell TRELEGY ELLIPTA royalty interests to Royalty Pharma for approximately \$1.1 billion in upfront cash, up to \$250 million of potential milestones, outer year royalties and an investment in ampreloxetine
- Initiated a \$250 million capital return program; purchased GSK's entire holdings at \$9.75 per share; launched a Dutch auction tender offer for up to \$95 million of its ordinary shares
- Eliminated debt and ended third quarter with \$487 million of cash

DUBLIN, Nov. 7, 2022 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today reported financial results for the third quarter of 2022.

"This quarter is a milestone in the Company's transformation and demonstrates the power of a team of people who are focused and stay true to the Company's purpose, delivering medicines that make a difference. I am proud and grateful for the team that has refocused the portfolio and monetized our interest in TRELEGY to reposition and reinvigorate the Company's business model. Theravance Biopharma today is debt free, and I believe we are well-positioned for value creation," said Rick E Winningham, Chief Executive Officer.

## **Quarterly Highlights**

• YUPELRI<sup>®</sup> (revefenacin) inhalation solution, the first and only once-daily, nebulized bronchodilator approved in the US for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), with net sales increasing by 35% year-over-year (Q3 2022 vs Q3 2021) – its strongest quarter to date and increased its share of the long-acting nebulized COPD market, increasing to 26.3% through August 2022, up from 25.6% in Q2 2022.

Recently issued US Patent No. 11,484,531, covering methods of treating COPD using YUPELRI, is now listed in the U.S. Food and Drug Administration publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the Orange Book. The patent provides for method of use until 2039.

• Ampreloxetine, an investigational, once-daily norepinephrine reuptake inhibitor in development for the treatment of symptomatic nOH in patients with multiple system atrophy (MSA). Phase 3 results (Study 0170) showed a benefit to MSA patients in the study that was observed in multiple endpoints.

The Company held a Type C meeting with the FDA in June 2022 and agreed on a path to NDA filing with one new Phase 3 clinical study in MSA patients with symptomatic nOH which is planned to start in the first quarter of 2023. The registrational Phase 3 Study in MSA patients with nOH (Study 0197, CYPRESS) is expected to be a 12-week open-label; 8-week double-blind, placebo-controlled, randomized withdrawal study with a primary endpoint of change in Orthostatic Hypotension Symptom Assessment (OHSA) composite score. The Company reiterates it expects the \$25 million investment from Royalty Pharma to fund the majority of the Phase 3 costs as a result of study size as well as insights and learnings from earlier studies.

• TRELEGY ELLIPTA (once-daily, single inhaler triple therapy for COPD and asthma)

# Sale of TRELEGY ELLIPTA Royalty Interest

On July 20, 2022, Theravance Biopharma closed the sale of its units in Theravance Respiratory Company, LLC ("TRC, LLC") representing its 85% economic interest in the sales-based royalty rights on worldwide net sales of GSK's TRELEGY ELLIPTA ("TRELEGY") to Royalty Pharma (NASDAQ: RPRX) for over \$1.5 billion in potential total value (the "TRELEGY Royalty Transaction"). The TRELEGY Royalty Transaction is intended to provide near-, mid- and long-term value to the Company with an upfront cash payment of approximately \$1.1 billion, up to \$250 million in additional milestone payments

contingent on the achievement of certain TRELEGY net sales thresholds between 2023 and 2026 and outer year royalties to the Company.

# Global Net Sales and Milestones

GSK posted third quarter 2022 global net sales of \$552 million (up from \$449 million, or 23%, from third quarter of 2021), and global net sales from the first nine months of 2022 have reached approximately \$1.6 billion (up from \$1.2 billion, or 34% from the first nine months of 2021). Theravance Biopharma is entitled to a milestone payment from Royalty Pharma of \$50 million if TRELEGY global net sales are equal to or exceed \$2.9 billion<sup>2</sup> in 2023, the first of \$250 million of potential milestones that can be achieved between 2023 – 2026.

# • \$250 Million Capital Return Program

The Company purchased all of GSK's equity stake in Theravance Biopharma, consisting of approximately 9.6 million shares at \$9.75 per share on September 20, 2022.

The Company announced a Dutch auction tender offer (the "Offer") for up to \$95 million of its ordinary shares on September 28, 2022.

The Company plans to enter into an Open Market Share Repurchase Plan to facilitate the repurchase of approximately \$60 million of its ordinary shares in open market purchases subsequent to the completion of the Offer, with a goal to complete this program by the end of 2023.

## Extension of the Offer

The Company is extending the length of the Offer such that the Offer will expire at midnight, New York City time, at the end of the day on November 17, 2022, unless the Company extends the Offer for an additional period of time. Based on information provided by Computershare Trust Company, N.A., the depositary for the Offer, to date, approximately 95,487 shares have been validly tendered for purchase in the Offer. Shareholders who have validly tendered and not withdrawn their shares do not need to re-tender their shares or take any other action in response to the extension of the Offer.

#### **Third Quarter Financial Results**

- **Revenue:** Total revenue for the third quarter of 2022 was \$12.5 million, primarily comprised of \$12.4 million in Viatris collaboration revenue. Total revenue for the third quarter represents a \$0.7 million decrease over the same period in 2021 primarily driven by the completion of the recognition of non-cash Janssen collaboration revenue in 2021, resulting from the planned close-out of the izencitinib program.
- YUPELRI: The Viatris collaboration revenue of \$12.4 million for the third quarter of 2022 represents amounts receivable from Viatris and is comprised of the Company's 35% share of net sales of YUPELRI as well as its proportionate amount of the total shared costs incurred by the two companies. The non-shared YUPELRI costs incurred by Theravance Biopharma are recorded within operating expenses. While Viatris records the total net sales of YUPELRI within its financial statements, Theravance Biopharma's implied 35% share of net sales of YUPELRI for the third quarter of 2022 was \$18.7 million, up 9% from the second quarter of 2022. There was a 35% increase in year-over-year implied net sales for the third quarter, however, due to accounting guidelines, Viatris collaboration revenue increased by 20% due to lower costs incurred by Theravance Biopharma as a result of the corporate restructuring, which improves YUPELRI profitability but lowers Viatris collaboration revenue. Additionally, during the period there were higher costs incurred by Viatris, which also reduced our Viatris collaboration revenue.
- Research and Development (R&D) Expenses: R&D expenses for the third quarter of 2022 were \$9.9 million, compared to \$43.7 million in the same period in 2021. Third quarter R&D expenses included total non-cash share-based compensation of \$2.6 million.
- Selling, General and Administrative (SG&A) Expenses: SG&A expenses for the third quarter of 2022 were \$16.3 million, compared to \$21.3 million in the same period in 2021. Third quarter SG&A expenses included total non-cash share-based compensation of \$5.2 million.
- Loss on Extinguishment of Debt: Loss on extinguishment of debt of \$3.0 million for the third quarter of 2022 was related to the paydown of our 2023 convertible senior notes.

- Income from Discontinued Operations (before income taxes): Income from discontinued operations (before income tax) of \$1,115.0 million for the third quarter of 2022 was primarily related to the \$1,141.1 million gain from the sale of our equity interests in TRC, LLC and was partially offset by a \$24.0 million loss on the extinguishment of our non-recourse 2035 notes.
- Provision for Income Tax Expense (Discontinued Operations): Income tax expense from discontinued operations of \$182.4 million for the third quarter of 2022 was primarily related to the tax liability arising from the gain from the sale of our equity interests in TRC, LLC. The Company estimates a current tax liability of approximately \$120.6 million.
- Cash Position: Cash, cash equivalents and marketable securities totaled \$486.8 million as of September 30, 2022.

#### 2022 Financial Guidance

- Operating Expenses: The Company reiterates that it expects full year 2022 R&D expense of \$45 million to \$55 million and SG&A expense of \$35 million to \$45 million (in each case, excluding share-based compensation, one-time restructuring costs and one-time transaction related legal expenses).
- The Company continues to expect to approach breakeven cash flow from operations.

#### Conference Call and Live Webcast Today at 5:00 pm ET

Theravance Biopharma will hold a conference call and live webcast accompanied by slides today at 5:00 pm ET / 2:00 pm PT / 10:00 pm GMT. To participate in the live call by telephone, please register <u>here</u>. Those interested in listening to the conference call live via the internet may do so by visiting Theravance Biopharma's website at <u>www.theravance.com</u>, under the Investors section, Presentations and Events.

A replay of the webcast will be available on Theravance Biopharma's website for 30 days through December 7, 2022.

#### **About Theravance Biopharma**

Theravance Biopharma, Inc.'s focus is to deliver *Medicines that Make a Difference*<sup>®</sup> in people's lives. In pursuit of its purpose, Theravance Biopharma leverages decades of expertise, which has led to the development of FDA-approved YUPELRI<sup>®</sup> (revefenacin) inhalation solution indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Its pipeline of internally discovered programs is targeted to address significant unmet patient needs.

For more information, please visit www.theravance.com.

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YUPELRI<sup>®</sup> is a registered trademark of Mylan Specialty L.P., a Viatris Company. Trademarks, trade names or service marks of other companies appearing on this press release are the property of their respective owners.

#### **Forward-Looking Statements**

This press release and the conference call will contain certain "forward-looking" statements as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding, among other things, statements relating to goals, plans, objectives, expectations and future events. Theravance Biopharma intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995. Examples of such statements include statements relating to: contingent payments due to the Company from the sale of the Company's TRELEGY ELLIPTA royalty interests to Royalty Pharma, the Company's goals, designs, strategies, plans and objectives, the ability to provide value to shareholders, the Company's regulatory strategies and timing of clinical studies (including the data therefrom), the potential characteristics, benefits and mechanisms of action of the Company's product and product candidates, including potential points of differentiation, the market for products being commercialized and product candidates, product sales or profit share revenue and the Company's expectations for its future financial performance and expectations as to future cash flows, the effectiveness of the Company's intellectual property portfolio, the timing of the Offer, including the settlement thereof and the satisfaction of conditions to the Offer, and the Company's repurchase of its ordinary shares by way of an open market share repurchase plan. These statements are based on the current estimates and assumptions of the management of Theravance Biopharma as of the date of this press release and the conference call and are subject to risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results of Theravance Biopharma to be materially different from those reflected in the forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, among others, risks related to: whether the milestone thresholds can be achieved, delays or difficulties in commencing, enrolling or completing clinical studies, the potential that results from clinical or non-clinical studies indicate the Company's product candidates or product are unsafe, ineffective or not differentiated, risks of decisions from regulatory authorities that are unfavorable to the Company, dependence on third parties to conduct clinical studies, delays or failure to achieve and maintain regulatory approvals for product candidates, risks of collaborating with or relying on third parties to discover, develop, manufacture and commercialize products, and risks associated with establishing and maintaining sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure, ability to retain key personnel, the impact of the Company's restructuring actions on its employees, partners and others, the ability of the Company to protect and to enforce its intellectual property rights, the satisfaction of the conditions to the Offer, volatility and fluctuations in the trading price and volume of the Shares, and general economic and market conditions. Other risks affecting Theravance Biopharma are in the Company's Form 10-Q filed with the SEC on August 8, 2022, and other periodic reports filed with the SEC. In addition to the risks described above and in Theravance Biopharma's filings with the SEC, other unknown or unpredictable factors also could affect Theravance Biopharma's results. No forward-looking statements can be guaranteed, and actual results may differ materially from such statements. Given these

uncertainties, you should not place undue reliance on these forward-looking statements. Theravance Biopharma assumes no obligation to update its forward-looking statements on account of new information, future events or otherwise, except as required by law.

# Important Information Regarding the Tender Offer

This press release is for informational purposes only and is neither an offer to buy nor the solicitation of an offer to sell any of the Company's ordinary shares, par value \$0.00001 per share (the "Shares"). A Dutch auction tender offer (the "Offer") to purchase up to \$95 million of the Shares is being made solely by the Company's Offer to Purchase, dated September 28, 2022, the related Letter of Transmittal and other related materials, as they may be amended or supplemented. Holders of Shares should read the Company's offer statement on Schedule TO filed with the SEC in connection with the Offer, which includes as exhibits the Offer to Purchase, the Letter of Transmittal and related materials, as well as any amendments or supplements to the Schedule TO when they become available, because they will contain important information. Each of these documents has been, or will be, filed with the SEC, and, when available, holders may obtain them for free from the SEC at its website (<u>www.sec.gov</u>) or from the information agent in connection with the Offer.

This press release does not set forth all of the terms and conditions of the Offer. Shareholders should carefully read the Offer to Purchase, the Letter of Transmittal and related materials, for a complete description of all terms and conditions before making any decision with respect to the Offer. None of the Company, its management, its board of directors, its officers, the dealer manager, the depositary, or the information agent, or any of their respective affiliates, makes any recommendation that holders tender or refrain from tendering all or any portion of their Shares, and no one has been authorized by any of them to make such a recommendation. Holders must make their own decision as to whether to tender their Shares and, if so, the amount of Shares to tender and the purchase price or prices at which to tender.

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#### THERAVANCE BIOPHARMA, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (In thousands)

		tember 30, 2022	December 31, 2021			
Assets	(Unaudited)			(1)		
Current assets:						
Cash and cash equivalents and short-term marketable securities	\$	486,832	\$	173,465		
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		
Current assets - 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		
Non-current assets - Discontinued operations		-		67,537		
Total assets	\$	763,496	\$	374,819		
Liabilities and Shareholders' Equity (Deficit)						
Current liabilities - Continuing operations	\$	21,582	\$	55,893		
Current liabilities - Discontinued operations:						
Income tax payable		120,550		-		
Accrued interest payable on Non-recourse notes due 2035, net		-		2,694		
Non-Current liabilities - Continuing operations:						
Long-term operating lease liabilities		51,381		52,681		
Future royalty payment contingency		24,888		-		
Unrecognized tax benefits		62,661		240		
Other long-term liabilities		1,856		2,490		
Non-recourse notes due 2035, net		-		371,359		
Convertible senior notes due 2023, net		-		228,035		
Shareholders' equity (deficit)		480,578		(338,573)		
Total liabilities and shareholders' equity (deficit)	\$	763,496	\$	374,819		

<sup>&</sup>lt;sup>(1)</sup> The condensed consolidated balance sheet as of December 31, 2021 has been derived from the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

#### THERAVANCE BIOPHARMA, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,					
		2022		2021		2022		2021
	(Unaudited)						dited)	)
Revenue:								
Viatris collaboration agreement (1)	\$	12,445	\$	10,397	\$	34,010	\$	31,716
Collaboration revenue		6		2,797		187		8,649
Licensing revenue		-		-		2,500		-
Total revenue		12,451		13,194		36,697		40,365
Costs and expenses:								
Research and development (2)		9,867		43,739		48,691		162,431
Selling, general and administrative (2)		16,277		21,299		51,105		77,780
Restructuring and related expenses (2)		509		1,771		11,427		1,771
Total costs and expenses		26,653		66,809		111,223		241,982
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		932,654		20,602		961,062		39,864
Net income (loss)	\$	916,631	\$	(35,308)	\$	882,494	\$	(167,392)
Net income (loss) per share:								
Continuing operations - basic and diluted	\$	(0.21)	\$	(0.76)	\$	(1.04)	\$	(3.05)
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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)
Shares used in compute per share calculations - basic and diluted		75,515		73,574		75,678		67,945

<sup>(1)</sup> While Viatris, Inc. records the total YUPELRI net sales, the Company is entitled to a 35% share of the net profit (loss) pursuant to a co-promotion agreement with Viatris. The Company's implied 35% share of total YUPELRI net sales is presented below:

	Three	Months Ended	September 30,	Nine Months E	eptember 30,	
(In thousands)		2022	2021	2022		2021
YUPELRI net sales (implied 35%)	\$	18,698 \$	13,806	\$ 51,1	58 \$	41,334

<sup>(2)</sup> Amounts include share-based compensation expense as follows:

	Three	Months Ende	eptember 30,	Nine Months Ended September 30,				
(In thousands)		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	\$	8,530	\$	14,370	\$	32,784	\$	45,143

<sup>1</sup> While Viatris, Inc. ("Viatris") records the total YUPELRI net sales, the Company is entitled to a 35% share of the profits and losses pursuant to a co-promotion agreement with Viatris.

<sup>2</sup> 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%.

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