

Theravance Biopharma, Inc. Announces Strategic Actions and Reports Fourth Quarter / Full Year 2022 Financial Results and Business Update

February 27, 2023

- Increases capital return program to \$325 million from \$250 million; as of 2/27/23, approximately \$170 million remains in the program
- Discontinuing investments in research, reducing headcount by approximately 17%
- Reports highest quarter of YUPELRI® (revefenacin) net sales and profitability to date; \$19.5 million Q4 2022 sales up 27% from Q4 2021 (TBPH implied 35% share)¹
- On track to begin enrollment in ampreloxetine Phase 3 study in Q1 2023
- Appoints Susannah Gray to Board as new Independent Director
- Commits to declassify the Board of Directors

DUBLIN, Feb. 27, 2023 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today announced financial results for the fourth quarter and full year ended December 31, 2022. The Company also announced three additional strategic actions to sharpen the Company's focus and deliver on its commitment to create shareholder value:

- **Increased Capital Return Program to \$325 million:** Authorized a \$75 million increase to the existing \$250 million capital return program initiated in September 2022, bringing the total capital return program to \$325 million.
 - Company has repurchased \$155 million of stock to date, including \$27 million in 2023.
 - \$170 million remaining and expected to be complete by the end of 2023.
- **Discontinuing investments in research:**
 - Prioritizing resource allocation toward ampreloxetine Phase 3 study and completion of the YUPELRI PIFR-2 study.
 - Discontinuing research activities including the inhaled Janus kinase (JAK) inhibitor program. As a result of halting further research investment, Theravance Biopharma's headcount is being reduced by approximately 17%; reductions planned for completion by end of March 2023. The Company will seek a partnership to continue progression of its inhaled JAK inhibitor program.
- **Appointed Independent Director to the Board and commits to governance change:** Susannah Gray appointed to the Board of Directors as part of ongoing commitment to board refreshment, process aided by an independent search firm and appointed following shareholder consultation.
 - Ms. Gray brings extensive transactional, operational, and value creation expertise within the healthcare and biopharmaceutical industry. She most recently served as the Executive Vice President and Chief Financial Officer of Royalty Pharma, the largest aggregator of pharmaceutical royalty interests worldwide.
 - Lead Independent Director William D. Young has decided to not stand for re-election at the Company's 2023 Annual General Meeting of Shareholders.
 - Following the appointment of Ms. Gray and the departure of Mr. Young, the Board will continue to be comprised of eight directors, seven of whom are independent, who are committed to maximizing value for all shareholders.
 - Company will put forth a proposal to declassify the Board of Directors over time at the May 2, 2023, Annual General Meeting of Shareholders, and will be providing more details in its proxy statement.

"With the successful evolution of Theravance over the past 18 months, we continue to strengthen our position via these strategic actions that build on our focus, execution and measured spending," said Rick E Winningham, Chief Executive Officer. "We remain laser focused on enhancing near- and long-term shareholder value and delivering medicines that make a difference to patients. We are well positioned to drive YUPELRI's growth by building on the 25% annual growth the team achieved last year and generating data from the PIFR-2 study in the second half of 2023. We are advancing our pipeline with the initiation of the Phase 3 study for ampreloxetine and are pursuing orphan drug designation to help bring this potential first-in-class therapy to multiple systems atrophy patients in need of symptomatic nOH relief. We are upsizing our capital return program to \$325 million and expect to complete the program by the end of the year. And, importantly, we remain committed to achieving non-GAAP profitability by the second half of this year and confident in our plan to enhance shareholder value."

"On behalf of the Board and management team, we would like to thank Bill for his many contributions and guidance during his tenure with the Company," added Mr. Winningham. "As a director, Bill has been an instrumental contributor of industry and corporate governance expertise and a strong steward of shareholder interests during his tenure. We wish him the very best in his future endeavors."

Mr. Young commented, "I am grateful for the opportunity to have served Theravance shareholders as a director. In that time, the Company has experienced significant transformation and I'm confident that the appointment of Susannah will further strengthen the Board's ability to guide and oversee the Company as it capitalizes on its next era of growth."

Winningham continued, "Susannah is a highly respected industry executive with expertise that will deepen the diverse perspective of the Board. We look forward to benefiting from her insights as we look to deliver transformative medicines and create shareholder value."

Ms. Gray commented, "I am honored to have this opportunity to serve on the Board and leverage my experience to support Theravance's ongoing transformation and development of Medicines that Make a Difference. I look forward to the opportunity to work with the Company as it executes its strategic plan to maximize value for all shareholders."

2023 Financial Guidance

- **Operating Expenses** (excluding share-based compensation and one-time restructuring costs): The Company expects full year 2023 R&D expense of \$35 million to \$45 million and SG&A expense of \$45 million to \$55 million.
- The Company reaffirms its expectation that it will generate non-GAAP profit in 2H 2023.

2022 Year-end Highlights

- **YUPELRI**[®] (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), achieved \$19.5 million Q4 2022 sales (TBPH implied 35% share)¹ increasing 27% year-over-year (Q4 2022 vs Q4 2021) – its strongest quarter to date and increased its share of the long-acting nebulized COPD market by 27.1% through November 2022, up from 26.4% in Q3 2022.
- **Ampreloxetine**, an investigational, once-daily norepinephrine reuptake inhibitor in development for the treatment of symptomatic neurogenic orthostatic hypotension (nOH) in patients with multiple system atrophy (MSA). The unique benefits of ampreloxetine treatment reported from Study 0170 and included an increase in norepinephrine levels, a favorable impact on blood pressure, clinically meaningful and durable symptom improvement, and no signal for supine hypertension. Theravance aligned with FDA on a new Phase 3 study (CYPRESS) for full approval, which is on track to initiate by end of Q1 2023. The Company presented three scientific platform presentations at the 2022 American Autonomic Society meeting.² Theravance secured up to \$40 million from Royalty Pharma for funding development of ampreloxetine in MSA in exchange for low single-digit royalties; \$25 million initial investment from Royalty Pharma to fund majority of new Phase 3 study.
- **TRELEGY ELLIPTA** (first once-daily single inhaler triple therapy for COPD and asthma) GSK posted fourth quarter 2022 global net sales of \$537 million (up from \$475 million, or 13%, from fourth quarter of 2021), and global net sales for the full year 2022 have reached approximately \$2.1 billion (up from \$1.7 billion, or 27% from the full year 2021).³ 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 billion⁴ in 2023, the first of \$250 million of potential milestones that can be achieved between 2023 – 2026.

Fourth Quarter and Full Year Financial Results

- **Revenue:** Total revenue for the fourth quarter of 2022 was \$14.6 million, almost entirely comprised of \$14.6 million in Viatris collaboration revenue. The Viatris collaboration revenue 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 fourth quarter of 2022 was \$19.5 million. In the fourth quarter of 2022, Theravance Biopharma recognized its first revenue associated with non-US YUPELRI royalties. Total revenue for the fourth quarter represents a \$0.3 million decrease over the same period in 2021. Viatris collaboration revenue increased by \$2.5 million in the fourth quarter compared to the same period in 2021. However, this increase was offset by a \$2.8 million decrease related to non-cash Janssen revenue recognized in the fourth quarter of 2021. Full year 2022 revenue was \$51.3 million, primarily comprised of \$48.6 million in Viatris collaboration revenue.
- **Research and Development (R&D) Expenses:** R&D expenses for the fourth quarter of 2022 were \$15.3 million, compared to \$31.2 million in the same period in 2021. Fourth quarter R&D expenses included total non-cash share-based compensation of \$2.8 million. In terms of Financial Guidance, full year 2022 R&D expenses excluding non-cash share-based compensation and one-time restructuring costs were \$50.5 million vs. Guidance of \$45 million to \$55 million.
- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses for the fourth quarter of 2022 were \$16.7 million, compared to \$21.5 million in the same period in 2021. Fourth quarter SG&A expenses included total non-cash share-based compensation of \$4.1 million. In terms of Financial Guidance, full year 2022 SG&A expenses excluding non-cash share-based compensation and one-time restructuring costs were \$47.2 million, which was above Guidance of \$35 million to \$45 million.
- **Stock Based Compensation:** Share-based compensation expenses for the fourth quarter of 2022 were \$2.8 million for R&D and \$4.1 million for SG&A compared to \$3.4 million and \$5.1 million, respectively, in the same period in 2021. The reduction was primarily driven by our restructuring, which was substantially complete in early 2022. Full year 2022 share-based compensation expenses for R&D and SG&A were \$12.9 million and \$19.8 million, respectively, compared to

\$25.6 million and \$28.1 million, respectively, in 2021. Not included in the share-based compensation amounts above were one-time restructuring costs related to share-based compensation of \$8.4 million in the fourth quarter and full year 2021 and \$7.0 million in the full year 2022.

- **Cash Position:** Cash, cash equivalents and marketable securities totaled \$327.5 million as of December 31, 2022. Cash burn in fourth quarter of 2022 was \$7 million excluding a \$118 million tax payment and \$34 million of share repurchases.

Biography – Susannah Gray, New Independent Director

Susannah Gray served as the Executive Vice President and Chief Financial Officer of Royalty Pharma, the largest aggregator of pharmaceutical royalty interests worldwide, from January 2005 to December 2018. She was promoted to Executive Vice President of Finance and Strategy in December 2018 and retired from Royalty Pharma in September 2019. Prior to Royalty Pharma, Ms. Gray served as a managing director and senior analyst covering the healthcare sector in CIBC World Markets' high yield group from 2002 to 2004, and also previously served in similar roles at Merrill Lynch and Chase Securities (predecessor of J.P. Morgan Securities). She currently serves on the Boards of Directors of Maravai LifeSciences, 4D Molecular Therapeutics and Morphic Therapeutic. Previously, Ms. Gray served on the Board of Directors of Apria until its sale to Owens & Minor. Ms. Gray received a BA, with honors, from Wesleyan University and an MBA from Columbia University.

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 [here](#). Those interested in listening to the conference call live via the internet may do so by visiting Theravance Biopharma's website at www.theravance.com, under the Investors section, Presentations and Events.

A replay of the webcast will be available on Theravance Biopharma's website for 30 days through March 29, 2023.

About Theravance Biopharma

Theravance Biopharma, Inc.'s focus is to deliver *Medicines that Make a Difference*[®] 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[®] (revefenacin) inhalation solution indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Ampreloxetine, its late-stage investigational norepinephrine reuptake inhibitor in development for symptomatic neurogenic orthostatic hypotension, has the potential to be a first in class therapy effective in treating a constellation of cardinal symptoms in multiple symptom atrophy patients. The Company is committed to creating/driving shareholder value.

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

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YUPELRI[®] is a registered trademark of Mylan Specialty L.P., a Viatrix 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 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: the Company's repurchase of its ordinary shares by way of an open market share repurchase program, headcount reductions in connection with focusing investments in research, the Company's governance policies and plans, the Company's expectations regarding its allocation of resources and maintenance of expenditures, 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, and contingent payments due to the Company from the sale of the Company's TRELEGY ELLIPTA royalty interests to Royalty Pharma. 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 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 recent restructuring actions on its employees, partners and others, the ability of the Company to protect and to enforce its intellectual property rights, volatility and fluctuations in the trading price and volume of the Company's 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 November 9, 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.

Non-GAAP Financial Measure

Theravance Biopharma provides a non-GAAP profitability target in this presentation. Theravance Biopharma believes that the non-GAAP profitability target provides meaningful information to assist investors in assessing prospects for future performance as it provides a better metric for analyzing the

future potential performance of its business by excluding items that may not be indicative of core operating results and the Company's cash position. Because non-GAAP financial targets, such as non-GAAP profitability, are not standardized, it may not be possible to compare this target with other companies' non-GAAP targets or measures having the same or a similar name. Thus, Theravance Biopharma's non-GAAP target should be considered in addition to, not as a substitute for, in isolation from, the company's actual GAAP results and other targets.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
	(Unaudited)		(Unaudited)	
Revenue:				
Viatrix collaboration agreement (2)	\$ 14,613	\$ 12,132	\$ 48,624	\$ 43,848
Viatrix royalties (Non-US)	30	-	30	-
Collaboration revenue	6	2,813	192	11,463
Licensing revenue	-	-	2,500	-
Total revenue	14,649	14,945	51,346	55,311
Costs and expenses:				
Research and development (3)	15,347	31,225	63,392	193,657
Selling, general and administrative (3)	16,734	21,516	67,073	99,296
Restructuring and related expenses (3)	-	18,371	12,838	20,142
Total costs and expenses	32,081	71,112	143,303	313,095
Loss from operations	(17,432)	(56,167)	(91,957)	(257,784)
Interest expense	(551)	(2,137)	(6,369)	(8,547)
Loss on extinguishment of debt	-	-	(3,034)	-
Interest income and other income (expense), net	3,722	338	8,545	1,109
Loss from continuing operations before income taxes	(14,261)	(57,966)	(92,815)	(265,222)
Provision for income tax benefit (expense)	3	151	(9)	151
Net loss from continuing operations	(14,258)	(57,815)	(92,823)	(265,071)
Income from discontinued operations before income taxes	-	25,780	1,143,930	65,645
Provision for income tax benefit (expense)	3,894	-	(178,974)	-
Net income from discontinued operations	3,894	25,780	964,956	65,645
Net income (loss)	\$ (10,364)	\$ (32,035)	\$ 872,132	\$ (199,426)
Net income (loss) per share:				
Continuing operations - basic and diluted	\$ (0.21)	\$ (0.78)	\$ (1.26)	\$ (3.82)
Discontinued operations - basic and diluted	\$ 0.06	\$ 0.35	\$ 13.11	\$ 0.95
Net income (loss) - basic and diluted	\$ (0.15)	\$ (0.43)	\$ 11.85	\$ (2.87)
Shares used in compute per share calculations - basic and diluted	67,395	73,960	73,591	69,461

(1) The condensed consolidated statement of operations for the year ended 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.

(2) While Viatrix, 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 Viatrix. The Company's implied 35% share of total YUPELRI net sales is presented below:

(In thousands)	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
YUPELRI net sales (implied 35%)	\$ 19,495	\$ 15,344	\$ 70,653	\$ 56,678

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

(In thousands)	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Research and development	\$ 2,825	\$ 3,442	\$ 12,888	\$ 25,634
Selling, general and administrative	4,123	5,113	19,848	28,065

Restructuring and related expenses	-	8,362	6,998	8,362
Total share-based compensation expense	\$ 6,948	\$ 16,917	\$ 39,734	\$ 62,061

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

	December 31, 2022 (Unaudited)	December 31, 2021 (1)
Assets		
Current assets:		
Cash and cash equivalents and short-term marketable securities	\$ 327,484	\$ 173,465
Receivables from collaborative arrangements	16,785	14,065
Prepaid clinical and development services	1,513	10,245
Other prepaid and current assets	7,682	8,561
Current assets - Discontinued operations	-	43,534
Total current assets	353,464	249,870
Property and equipment, net	11,875	13,657
Operating lease assets	40,126	39,690
Future contingent milestone and royalty assets	194,200	-
Restricted cash	836	837
Other assets	6,899	3,228
Non-current assets - Discontinued operations	-	67,537
Total assets	\$ 607,400	\$ 374,819
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities - Continuing operations	\$ 28,715	\$ 55,893
<u>Current liabilities - Discontinued operations:</u>		
Accrued interest payable on Non-recourse notes due 2035, net	-	2,694
<u>Non-Current liabilities - Continuing operations:</u>		
Long-term operating lease liabilities	45,407	52,681
Future royalty payment contingency	25,438	-
Unrecognized tax benefits	64,191	240
Other long-term liabilities	1,849	2,490
Non-recourse notes due 2035, net	-	371,359
Convertible senior notes due 2023, net	-	228,035
Shareholders' equity (deficit)	441,800	(338,573)
Total liabilities and shareholders' equity (deficit)	\$ 607,400	\$ 374,819

(1) 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.

¹ While Viatris, Inc. ("Viatri") 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 Viatri.

² November 2022, Biaggioni I, et al. Abstract 34 / Virtual Poster 106; Kaufmann H, et al. Abstract 33 / Virtual Poster 117; Freeman R, et al. Abstract 30 / Virtual Poster 4

³ Source: Bloomberg

⁴ 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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