Theravance Biopharma, Inc. Reports First Quarter 2023 Financial Results and Provides Business Update

May 8, 2023

- *Q1 2023 YUPELRI® (revefenacin) net sales of $47.0 million, recognized by Viatris, up 8% from Q1 2022[1]*
- *Q1 2023 YUPELRI retail new patient starts and total prescriptions up 61% and 29%, respectively, year-over-year, reaching all-time highs[2]*
- *CYPRESS Phase 3 study of ampreloxetine recruiting; anticipate completing enrollment during H2 2024*
- *On track to complete $325 million capital return program by year-end; completed $215 million of share repurchases from inception through 4/30/23*
- *Jim Kelly, Managing Director at Weiss Asset Management, joins Board of Directors*

DUBLIN, May 8, 2023 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today announced financial and operational results for the first quarter of 2023.

"Through the beginning of 2023, we sharpened our commercial and development focus at Theravance, with YUPELRI retail new patient starts growing 61% and achieving a sixth consecutive quarter of record highs. We also delivered an important clinical milestone, having initiated enrollment for CYPRESS, our Phase 3 study for ampreloxetine, since our last update", said Rick E Winningham, Chief Executive Officer. "With the transformation we began nearly two years ago largely completed, we are well positioned to drive an acceleration in YUPELRI performance made possible by its unique value proposition to COPD patients in both the hospital and community settings. We are determined to deliver on this opportunity, while returning substantial capital to shareholders and driving our ampreloxetine study to completion."

"For MSA patients suffering with symptomatic neurogenic orthostatic hypotension (nOH), ampreloxetine has the potential to improve symptoms which impact their quality of life", said Richard Graham, SVP and Head of R&D. "CYPRESS is a focused Phase 3 study designed to confirm the clinical improvements ampreloxetine has demonstrated in MSA patients with symptomatic nOH in Study 0170. We plan to complete enrollment in CYPRESS during the second half of 2024 and provide guidance on timing for top-line results as enrollment progresses."

Quarterly 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 $47.0 million Q1 2023 sales, increasing 8% year-over-year (Q1 2023 vs Q1 2022)[1] and increased its share of the long-acting nebulized COPD market to 27.7% through January 2023, up from 27.1% in Q4 2022. The PIFR-2 study remains on track for completion during the second half of 2023.

- **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 included an increase in norepinephrine levels, a favorable impact on blood pressure, clinically meaningful and durable symptom improvements, and no signal for supine hypertension. The Company presented findings at three scientific sessions at the 2022 American Autonomic Society meeting.[3] Theravance has aligned with the FDA on a new Phase 3 study (CYPRESS) to support a full approval, which was initiated in Q1 2023 and is actively recruiting.

- **$325 Million Return of Capital Program:**
  - **Through 3/31/23:** $55 million of share buybacks in Q1 2023 and $183 million since inception in September 2022 through March 2023. As of 3/31/23, we had $142 million remaining.
  - **Through 4/30/23:** $215 million since inception in September 2022 through April 2023. As of 4/30/23, we had $110 million remaining.
  - Expect to complete the program by the end of 2023.

- **TRELEGY ELLIPTA** (first once-daily single inhaler triple therapy for COPD and asthma)
  GSK posted first quarter 2023 global net sales of $567 million (up from $454 million, or 25%, from first quarter of 2022).[4] 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[5] in 2023, the first of $250 million of potential milestones that can be achieved between 2023 and 2026.

First Quarter Financial Results

- **Revenue:** Total revenue for the first quarter of 2023 was $10.4 million, consisting almost entirely of Viatris collaboration revenue. The Viatris collaboration revenue represents amounts receivable from Viatris and comprises 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 first quarter of 2023 was $16.4 million which represents an 8% increase compared to the same period in 2022. Viatris collaboration revenue decreased by $0.3 million in the first quarter compared to the same period in 2022 due primarily to timing of higher Viatris costs incurred.

  Total revenue for the first quarter represents a $2.8 million decrease compared to the same period in 2022, primarily due to a $2.5 million non-recurring milestone payment received in the first quarter of 2022 related to the Company's licensing arrangement with Pfizer.

- **Research and Development (R&D) Expenses:** R&D expenses for the first quarter of 2023 were $14.6 million, compared to $23.3 million in the same period in 2022. First quarter R&D expenses included total non-cash share-based compensation of $2.4 million.

- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses for the first quarter of 2023 were $19.2 million, compared to $17.8 million in the same period in 2022. First quarter SG&A expenses included total non-cash share-based compensation of $4.2 million.

- **Stock Based Compensation:** Share-based compensation expenses for the first quarter of 2023 were $7.0 million, compared to $14.5 million in the same period in 2022. Excluding restructuring-related expenses, share-based compensation expenses were $6.7 million and $10.0 million for the first quarter of 2023 and 2022, respectively. Share-based compensation expenses consisted of $2.4 million for R&D and $4.2 million for SG&A in the first quarter of 2023, compared to $4.5 million and $5.5 million, respectively, in the same period in 2022. The significant reduction in total share-based compensation expenses was primarily driven by our 2021 restructuring, which was substantially completed in early 2022.

- **Restructuring Expenses and Related Expenses:** Restructuring expenses and related expenses for the first quarter of 2023 were $1.6 million compared to $9.3 million in the same period in 2022. These expenses primarily comprised severance costs, termination-related benefits, and share-based compensation expense related to the Company's 2023 strategic actions, announced in February 2023, and the Company's 2021 restructuring announced in September 2021. Cash restructuring expenses related to the 2023 strategic actions were $1.2 million and non-cash restructuring expenses were $0.4 million in the first quarter of 2023. We do not expect any additional employee-related restructuring expenses, including share-based compensation expenses, after the first quarter of 2023.

- **Net Loss from Operations and Non-GAAP Net Loss** (from continuing operations)[6]: Net loss from continuing operations was $22.1 million in the first quarter of 2023 compared to $40.3 million in the same period in 2022, and non-GAAP net loss from continuing operations was $14.9 million in the first quarter of 2023 compared to $25.2 million in the same period in 2022. Non-GAAP net loss from continuing operations consists of GAAP net income (loss) from operations, excluding share-based compensation expense, non-cash interest expense, and income tax expense (benefit). See the section titled "Non-GAAP Financial Measures" for more information.

- **Cash Position:** Cash, cash equivalents and marketable securities totaled $260.0 million as of March 31, 2023.

2023 Financial Guidance

- **Operating Expenses** (excluding share-based compensation and one-time restructuring costs)**:** The Company continues to expect 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.[6]

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 IST. 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 June 7, 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 system atrophy patients. The Company is committed to creating/driving shareholder value.

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

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, the impact of recent 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, future YUPELRI sales, the ability to provide value to shareholders, the Company's regulatory strategies and timing of clinical studies, possible safety, efficacy or differentiation of our investigational therapy, 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-K filed with the SEC on March 1, 2023, 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 Measures

Theravance Biopharma provides a non-GAAP profitability target and a non-GAAP metric in this press release. Theravance Biopharma believes that the non-GAAP profitability target and non-GAAP net loss from operations provide meaningful information to assist investors in assessing prospects for future performance and actual performance as they provide better metrics for analyzing the 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 and metrics, such as non-GAAP profitability and non-GAAP net loss from operations, are not standardized, it may not be possible to compare these measures with other companies' non-GAAP targets or measures having the same or a similar name. Thus, Theravance Biopharma's non-GAAP measures should be considered in addition to, not as a substitute for, or in isolation from, the Company's actual GAAP results and other targets.

Contact:
investor.relations@theravance.com
650-808-4045

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

	March 31, 2023	December 31, 2022
Assets	**(Unaudited)**	**(1)**
Current assets:		
Cash and cash equivalents and short-term marketable securities	$ 241,263	$ 327,484

Receivables from collaborative arrangements	12,270	16,785
Prepaid clinical and development services	1,524	1,513
Other prepaid and current assets	6,281	7,682
Total current assets	261,338	353,464
Long-term marketable securities	18,776	-
Property and equipment, net	12,103	11,875
Operating lease assets	39,204	40,126
Future contingent milestone and royalty assets	194,200	194,200
Restricted cash	836	836
Other assets	12,093	6,899
Total assets	$ 538,550	$ 607,400
Liabilities and Shareholders' Equity		
Current liabilities	$ 26,184	$ 28,715
Long-term operating lease liabilities	43,763	45,407
Future royalty payment contingency	25,988	25,438
Unrecognized tax benefits	64,191	64,191
Other long-term liabilities	7,865	1,849
Shareholders' equity	370,559	441,800
Total liabilities and shareholders' equity	$ 538,550	$ 607,400

(1) The condensed consolidated balance sheet as of December 31, 2022 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, 2022.

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

	Three Months Ended March 31,	
	2023	**2022**
	(Unaudited)	
Revenue:		
Viatris collaboration agreement (1)	$ 10,411	$ 10,687
Collaboration revenue	6	9
Licensing revenue	-	2,500
Total revenue	10,417	13,196
Costs and expenses:		
Research and development (2)	14,572	23,253
Selling, general and administrative (2)	19,183	17,842
Restructuring and related expenses (2)	1,574	9,324
Total costs and expenses	35,329	50,419
Loss from operations	(24,912)	(37,223)
Interest expense	(550)	(2,137)
Interest income and other income (expense), net	2,979	(375)
Loss from continuing operations before income taxes	(22,483)	(39,735)
Provision for income tax benefit (expense)	395	(524)
Net loss from continuing operations	**(22,088)**	**(40,259)**
Income from discontinued operations before income taxes	-	14,313
Provision for income tax benefit (expense)	-	-
Net income from discontinued operations	**-**	**14,313**
Net loss	**$ (22,088)**	**$ (25,946)**

Net income (loss) per share:

Continuing operations - basic and diluted	$	(0.35)	$	(0.53)
Discontinued operations - basic and diluted	$	-	$	0.19
Net income (loss) - basic and diluted	$	(0.35)	$	(0.34)
Shares used to compute per share calculations - basic and diluted		62,934		75,247
Non-GAAP net loss from continuing operations		**(14,912)**		**(25,190)**

(1) 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 as presented below:

	Three Months Ended March 31,			
(In thousands)		**2023**		**2022**
YUPELRI net sales (100% recorded by Viatris)	$	46,955	$	43,666
YUPELRI net sales (Theravance Biopharma implied 35%)		16,434		15,283

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

	Three Months Ended March 31,			
(In thousands)		**2023**		**2022**
Research and development	$	2,441	$	4,530
Selling, general and administrative		4,223		5,498
Restructuring and related expenses		357		4,517
Total share-based compensation expense	$	7,021	$	14,545

THERAVANCE BIOPHARMA, INC.
Reconciliation of GAAP to Non-GAAP Net Income from Continuing Operations
(In thousands, except per share data)

	Three Months Ended March 31,			
		2023		**2022**
		(Unaudited)		
GAAP Net Loss from Continuing Operations	$	(22,088)	$	(40,259)
Adjustments:				
Share-based compensation expense		7,021		14,545
Non-cash interest expense		550		-
Income tax expense (benefit)		(395)		524
Non-GAAP Net Loss from Continuing Operations	**$**	**(14,912)**	**$**	**(25,190)**
Non-GAAP Net Loss per Share from Continuing Operations				
Net loss - basic and diluted	$	(0.24)	$	(0.33)
Shares used to compute per share calculations - basic and diluted		62,934		75,247

[1] In the US, Viatris is leading the commercialization of YUPELRI, and the Company co-promotes the product under a profit and loss sharing arrangement (65% to Viatris; 35% to the Company).

[2] Symphony Health METYS Prescription Dashboard.

[3] 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

[4] Source: GSK-reported Net Sales in USD.

[5] 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%.

[6] Non-GAAP profit (loss) consists of GAAP net income (loss) before taxes less share-based compensation expense and non-cash interest expense. See the section titled "Non-GAAP Financial Measures" for more information.

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