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

August 7, 2023

- *Q2 2023 YUPELRI® (revefenacin) net sales of $55.0 million, recognized by Viatris, up 12% from Q2 2022[1]*
- *Q2 2023 YUPELRI total retail TRx and new to product TRx again reached all-time highs, up 26% and 53%, Y/Y, respectively[2]*
- *PIFR-2 enrollment nearing completion; top-line data in late Q4 2023, with disclosure anticipated in January 2024*
- *Company expects to complete $325 million capital return program by year-end, having returned $80.5 million via share repurchases during Q2 2023 and $263.8 million since inception through quarter end*

DUBLIN, Aug. 7, 2023 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today announced financial and operational results for the second quarter of 2023.

"We are very encouraged by our team's performance in Q2, with YUPELRI achieving good growth in both the hospital and community settings over the prior year," said Rick E Winningham, Chief Executive Officer. "We are excited to capitalize on the commercial opportunity for YUPELRI, potentially enhanced near-term by PIFR-2, and realize the significant opportunity for ampreloxetine to dramatically improve the lives of MSA patients with symptomatic nOH."

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). YUPELRI achieved $55.0 million Q2 2023 sales, increasing 12% year-over-year (Q2 2023 vs Q2 2022)[1]. YUPELRI's share of the long-acting nebulized COPD market again reached all-time highs, with hospital share at 15.2% (vs. 11.6% in Q2 '22) and community share at 29.0% (vs. 25.3% in Q2 '22)[3].

  Theravance expects to complete enrollment in the YUPELRI PIFR-2 study shortly, with top-line data to be available late in the fourth quarter of 2023. The Company expects to disclose top line results in January 2024. PIFR-2 evaluates revefenacin delivered via jet nebulizer compared to tiotropium delivered via dry powder inhaler in severe to very severe COPD patients with suboptimal peak inspiratory flow rate.

- **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). During the second quarter, Theravance continued to focus on site activation and recruitment for the CYPRESS Phase 3 study. The team submitted a clinical trial application for multiple EU countries through the region's centralized process, as well as in the UK and other countries around the world; key approvals are expected in the coming months. In addition, Theravance's clinical team submitted abstracts to be presented at medical meetings during the second half of the year.

- **Financial Update:**

  $80.5 million of share buybacks completed in Q2 2023 and $263.8 million from program inception through June 30, 2023. As of June 30, 2023, the Company had $61.2 million remaining in the program, which is expected to be completed by the end of 2023. The Company remains on track to achieve non-GAAP profitability in H2 '23, subject to YUPELRI's increased net sales growth[4].

- **TRELEGY ELLIPTA** (first once-daily single inhaler triple therapy for COPD and asthma) GSK posted second quarter 2023 global net sales of $760 million (up 29% from $591 million reported in the second quarter of 2022).[5] Year to date, through the second quarter, GSK has posted TRELEGY global net sales of $1.3 billion. 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[6] in 2023, the first of $250 million of potential milestones that can be achieved between 2023 and 2026.

Second Quarter Financial Results

- **Revenue:** Total revenue for the second quarter of 2023 was $13.7 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 second quarter of 2023 was $19.3 million which represents a 12% increase compared to the same period in 2022. Viatris collaboration revenue increased by $2.9 million in the second quarter compared to the same period in 2022 due primarily to higher net sales.

Total revenue for the second quarter represents a $2.7 million increase compared to the same period in 2022, primarily due to an increase in YUPELRI net sales.

- **Research and Development (R&D) Expenses:** R&D expenses for the second quarter of 2023 were $9.4 million, compared to $14.9 million in the same period in 2022. Second quarter R&D expenses included total non-cash share-based compensation of $1.9 million.

- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses for the second quarter of 2023 were $19.3 million, compared to $16.2 million in the same period in 2022. Second quarter SG&A expenses included total non-cash share-based compensation of $4.4 million.

- **Stock Based Compensation:** Share-based compensation expenses for the second quarter of 2023 were $6.3 million, compared to $9.7 million in the same period in 2022. Excluding restructuring-related expenses, share-based compensation expenses were $6.3 million and $7.9 million for the second quarter of 2023 and 2022, respectively. Share-based compensation expenses consisted of $1.9 million for R&D and $4.4 million for SG&A in the second quarter of 2023, compared to $2.9 million and $5.0 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 and our 2023 strategic actions, which was substantially completed by the end of March 2023.

- **Restructuring and Related Expenses:** Restructuring and related expenses for the second quarter of 2023 were $1.2 million compared to $3.0 million in the same period in 2022. The restructuring expenses in the second quarter of 2023 were classified as non-cash expenses and was related to the loss from the sale of lab equipment that generated net cash proceeds of $1.5 million. We do not expect any additional employee-related restructuring expenses, including share-based compensation expenses, related to the 2023 strategic actions.

- **Net Loss from Operations and Non-GAAP Net Loss** (from continuing operations)[4] : Net loss from continuing operations was $15.6 million in the second quarter of 2023 compared to $22.8 million in the same period in 2022, and non-GAAP net loss from continuing operations was $7.4 million in the second quarter of 2023 compared to $13.1 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 $167.5 million as of June 30, 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, subject to YUPELRI's increased net sales growth.[4]

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 September 6, 2023.

About the PIFR-2 Study

This study is a randomized, double-blind, parallel-group study, comparing improvements in lung function in adults with severe to very severe COPD and suboptimal inspiratory flow rate following once-daily treatment over 12 weeks with either YUPELRI (revefenacin) inhalation solution delivered via standard jet nebulizer or SPIRIVA® (tiotropium) delivered via a dry powder inhaler (Spiriva® HandiHaler®).

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.

THERAVANCE BIOPHARMA®, THERAVANCE®, and the Cross/Star logo are registered trademarks of the Theravance Biopharma group of companies (in the U.S. and certain other countries).

YUPELRI® 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: 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 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 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 May 10, 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

[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. Retail data serves as a proxy for the total community (Retail + DME).

[3] Hospital LA-NEB Market Share - IQVIA DDD through 6/30/2023. Community LA-NEB Market Share includes Retail + DME / Med B FFS through May '23.

[4] 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.

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

[6] 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%.

THERAVANCE BIOPHARMA, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	June 30, 2023	December 31, 2022
Assets	**(Unaudited)**	**(1)**
Current assets:		
Cash and cash equivalents and short-term marketable securities	$ 167,451	$ 327,484
Receivables from collaborative arrangements	15,796	16,785
Prepaid clinical and development services	979	1,513
Other prepaid and current assets	7,777	7,682
Total current assets	192,003	353,464
Long-term marketable securities	-	-
Property and equipment, net	9,553	11,875
Operating lease assets	38,453	40,126
Future contingent milestone and royalty assets	194,200	194,200
Restricted cash	836	836
Other assets	11,585	6,899
Total assets	$ 446,630	$ 607,400
Liabilities and Shareholders' Equity		
Current liabilities	$ 24,546	$ 28,715
Long-term operating lease liabilities	42,521	45,407
Future royalty payment contingency	26,556	25,438
Unrecognized tax benefits	64,987	64,191
Other long-term liabilities	7,859	1,849
Shareholders' equity	280,161	441,800
Total liabilities and shareholders' equity	$ 446,630	$ 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(Unaudited)		(Unaudited)	
Revenue:				
Viatris collaboration agreement (1)	$ 13,743	$ 10,878	$ 24,154	$ 21,565
Collaboration revenue	6	172	12	181
Licensing revenue	-	-	-	2,500
Total revenue	13,749	11,050	24,166	24,246
Costs and expenses:				
Research and development (2)	9,425	14,924	23,997	38,177
Selling, general and administrative (2)	19,278	16,222	38,461	34,064
Restructuring and related expenses (2)	1,169	3,005	2,743	12,329
Total costs and expenses	29,872	34,151	65,201	84,570
Loss from operations	(16,123)	(23,101)	(41,035)	(60,324)
Interest expense	(568)	(2,137)	(1,118)	(4,274)
Interest income and other income (expense), net	2,504	2,440	5,483	2,065
Loss from continuing operations before income taxes	(14,187)	(22,798)	(36,670)	(62,533)
Provision for income tax (expense) benefit	(1,458)	5	(1,063)	(519)
Net loss from continuing operations	**(15,645)**	**(22,793)**	**(37,733)**	**(63,052)**

Income from discontinued operations before income taxes	-	14,602	-	28,915
Provision for income tax expense	-	-	-	-
Net income from discontinued operations	**-**	**14,602**	**-**	**28,915**
Net loss	**$ (15,645)**	**$ (8,191)**	**$ (37,733)**	**$ (34,137)**
Net income (loss) per share:				
Continuing operations - basic and diluted	$ (0.28)	$ (0.30)	$ (0.63)	$ (0.83)
Discontinued operations - basic and diluted	$ -	$ 0.19	$ -	$ 0.38
Net income (loss) - basic and diluted	$ (0.28)	$ (0.11)	$ (0.63)	$ (0.45)
Shares used to compute per share calculations - basic and diluted	56,682	76,270	59,791	75,761
Non-GAAP net loss from continuing operations	**$ (7,355)**	**$ (13,089)**	**$ (22,267)**	**$ (38,279)**

(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 June 30,		Six Months Ended June 30,	
(In thousands)	**2023**	**2022**	**2023**	**2022**
YUPELRI net sales (100% recorded by Viatris)	$ 55,038	$ 49,077	$ 101,993	$ 92,743
YUPELRI net sales (Theravance Biopharma implied 35%)	19,263	17,177	35,697	32,460

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	**2023**	**2022**	**2023**	**2022**
Research and development	$ 1,855	$ 2,909	$ 4,296	$ 7,439
Selling, general and administrative	4,409	5,030	8,632	10,528
Restructuring and related expenses	-	1,770	357	6,287
Total share-based compensation expense	$ 6,264	$ 9,709	$ 13,285	$ 24,254

THERAVANCE BIOPHARMA, INC.
Reconciliation of GAAP to Non-GAAP Net Loss from Continuing Operations
(In thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
	(Unaudited)		**(Unaudited)**	
GAAP Net Loss from Continuing Operations	$ (15,645)	$ (22,793)	$ (37,733)	$ (63,052)
Adjustments:				
Share-based compensation expense	6,264	9,709	13,285	24,254
Non-cash interest expense	568	-	1,118	-
Income tax expense (benefit)	1,458	(5)	1,063	519
Non-GAAP Net Loss from Continuing Operations	**$ (7,355)**	**$ (13,089)**	**$ (22,267)**	**$ (38,279)**

View original content to download multimedia:https://www.prnewswire.com/news-releases/theravance-biopharma-inc-reports-second-quarter-2023-financial-results-and-provides-business-update-301894966.html

SOURCE Theravance Biopharma, Inc.