Theravance Biopharma, Inc. Reports Second Quarter 2024 Financial Results and Provides Business Update

August 5, 2024

- *Q2 2024 YUPELRI® (revefenacin) net sales of $54.5 million, recognized by Viatris, decreased 1% from Q2 2023[1]*
- *Viatris collaboration revenue of $14.3 million, increased 4% versus Q2 2023*
- *Partner Viatris submitted YUPELRI NDA in China; $7.5 million milestone if approved*
- *Now expecting last patient into the open label portion of CYPRESS in mid-2025, top line data anticipated approximately 6 months later*
- *Q2 2024 TRELEGY net sales of $1.065 billion, increasing the likelihood of achieving up to $50 million of milestones in 2024*
- *Q2 2024 ending cash balance of $96.1 million*

DUBLIN, Aug. 5, 2024 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today announced financial and operational results for the second quarter of 2024.

"YUPELRI net sales decreased 1% from the prior quarter, owing to near-term headwinds from an evolved channel mix and a lower realized net price," said Rick Winningham, Theravance Biopharma CEO. "We are disappointed with this quarter's net sales result, but remain confident in our ability to continue to grow YUPELRI in the future, given strong and consistent demand generation." He continued, "In addition, while we have activated over 80% of study sites in CYPRESS and achieved solid enrollment in the quarter, we now anticipate enrolling the last patient into the open-label portion of the study in mid-2025. We continue to prioritize delivering a high-quality study in pursuit of making ampreloxetine available to those MSA patients suffering without viable treatment options for their symptomatic nOH. Finally, we are pleased with another exceptional quarter for TRELEGY, which increases our confidence in achieving milestones in 2024, which would contribute to our existing balance sheet strength."

Second Quarter Highlights

YUPELRI® (revefenacin) inhalation solution, the first and only once-daily, nebulized LAMA (long- acting muscarinic agent) bronchodilator approved in the US for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD):

- Realized total net sales of $54.5 million for the quarter, a decrease of 1% compared with the same period in 2023.[1]
- Generated a robust 13% increase in customer demand (Q2 2024 vs Q2 2023).[2]
- Increased hospital doses sold by 43% (Q2 2024 vs Q2 2023).[3]
- Increased share of the long-acting nebulized segment of the COPD market, with hospital share surpassing 18% and community share reaching 32%, both all-time highs.[4]
- Granted an additional method of use patent for YUPELRI on July 30, 2024, with an expiration date of August 2039. Listed in the FDA Orange Book.

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):

- Achieved steady progress in CYPRESS enrollment, with over 80% of planned sites now activated, including a number of global academic institutions, tertiary care centers and MSA Centers of Excellence.
- Updated anticipated completion of enrollment into the open-label portion of the study to mid-2025. Target completion impacted by lengthier timelines to site activation, and to ensure sufficient patients progress to the randomized withdrawal portion of the study.
- Top line data anticipated to be available approximately 6 months after enrollment is completed in the open label portion of the study.

TRELEGY Update:

- GSK posted second quarter 2024 global net sales of approximately $1.1 billion (up 40% from $760 million reported in the second quarter of 2023), bringing year-to-date TRELEGY global net sales to approximately $1.8 billion (up 37% from the same period in 2023).
- As of June 30, 2024, Theravance Biopharma is eligible to receive a total of $200 million in milestone payments from Royalty Pharma, should TRELEGY achieve certain sales thresholds. The next milestone payment of $25 million will be achieved if TRELEGY global net sales reach approximately $2.9 billion in 2024 (requiring second half 2024 sales of approximately $1.1 billion), and a second $25 million milestone payment (for a total of $50 million) will be achieved if

TRELEGY global net sales exceed approximately $3.2 billion in 2024 (requiring second half 2024 sales of approximately $1.4 billion).

Second Quarter Financial Results

- **Revenue:** Total revenue for the second quarter of 2024 was $14.3 million, consisting entirely of Viatris collaboration revenue. Viatris collaboration revenue increased by $0.5 million, or 4%, in the second quarter compared to the same period in 2023 due primarily to lower costs incurred by Viatris. 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 2024 was $19.1 million which represented a 1% decrease compared to the same period in 2023.

- **Research and Development (R&D) Expenses:** R&D expenses for the second quarter of 2024 were $10.0 million, compared to $9.4 million in the same period in 2023. Second quarter R&D expenses included total non-cash share-based compensation of $1.2 million.

- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses for the second quarter of 2024 were $17.1 million, compared to $19.3 million in the same period in 2023. Second quarter SG&A expenses included total non-cash share-based compensation of $4.2 million.

- **Non-Cash Impairment of Long-Lived Assets:** As the R&D lab space leasing market in South San Francisco continued to soften in the second quarter, the Company incurred a non-cash impairment charge of $3.0 million on its long-lived assets (consisting primarily of its operating leases) in the second quarter of 2024.

- **Share-Based Compensation:** Share-based compensation expenses for the second quarter of 2024 was $5.4 million, compared to $6.3 million in the same period in 2023. Share-based compensation expenses consisted of $1.2 million for R&D and $4.2 million for SG&A in the second quarter of 2024, compared to $1.9 million and $4.4 million, respectively, in the same period in 2023.

- **Net Loss and Non-GAAP Net Loss from Operations[5]**: Net loss was $16.5 million in the second quarter of 2024 compared to $15.6 million in the same period in 2023. The net loss in the second quarter of 2024 was impacted by the $3.0 million non-cash impairment charge on the Company's long-lived assets. Non-GAAP net loss from operations was $6.3 million in the second quarter 2024 compared to a non-GAAP net loss from operations of $7.4 million in the same period in 2023. See the section titled "Non-GAAP Financial Measures" for more information.

- **Cash Position:** Cash, cash equivalents and marketable securities totaled $96.1 million as of June 30, 2024.

Updated 2024 Financial Guidance

- **Operating Expenses (excluding share-based compensation):** The Company continues to expect full year 2024 R&D expenses of $30 million to $36 million and SG&A expenses of $45 million to $55 million, in each case excluding share-based compensation.

- **Share-Based Compensation**: The Company continues to expect full year share-based compensation expenses of $18 million to $22 million.

- **Non-GAAP Net Profit / Loss:** The Company now expects levels of both non-GAAP losses and cash burn to be similar to first half actuals 2024.

Corporate Initiatives to Maximize Shareholder Value

Pursuant to a recently-completed review of its substantial Irish tax assets, the Company is engaging tax and financial advisors to explore opportunities through which to unlock value, given the gap between our share price and the value of our diverse and unique portfolio, including YUPELRI, ampreloxetine, TRELEGY and the Company's tax assets. We will provide further updates as appropriate.

Intellectual Property Updates

Patent Infringement Suits
Patent litigation is pending against four companies, along with certain affiliates; we previously disclosed litigation involving three of these companies. In June 2024, the Company filed a patent infringement suit in the U.S. District Court for the Eastern District of Pennsylvania against a subsequent filer of an abbreviated new drug application (ANDA) for a generic version of YUPELRI. As a result of this lawsuit, a 30-month stay of approval through November 2026 would be expected to be automatically granted by the FDA on the subsequent filer's ANDA pending any adverse court decision. As of

July 31, 2024, the Company has settled litigation with four companies pursuant to individual agreements in which we granted these companies a royalty-free, non-exclusive, non-sublicensable, non-transferable license to manufacture and market their respective generic versions of YUPELRI inhalation solution in the US on or after the licensed launch date of April 23, 2039, subject to certain exceptions as is customary in these type of agreements. As required by law, the settlements are subject to review by the U.S. Department of Justice and the Federal Trade Commission.

Additional Patent
An additional method of use patent for YUPELRI was granted on July 30, 2024, which expires in August 2039, and is listed in the FDA Orange Book.

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, Events and Presentations.

A replay of the webcast will be available on Theravance Biopharma's website for 30 days through September 4, 2024.

About Ampreloxetine

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 in MSA patients from Study 0170 included an increase in norepinephrine levels, a favorable impact on blood pressure, clinically meaningful and durable symptom improvement, and no signal for supine hypertension. In the US, the Company has been granted an Orphan Drug Designation for ampreloxetine for the treatment of symptomatic nOH in patients with MSA and, if results from the ongoing Phase 3 CYPRESS study are supportive, plans to file an NDA for full approval in this indication.

About CYPRESS (Study 0197), a Phase 3 Study

Study 0197 (NCT05696717) is currently enrolling. This is a registrational Phase 3, multi-center, randomized withdrawal study to evaluate the efficacy and durability of ampreloxetine in participants with MSA and symptomatic nOH after 20 weeks of treatment; the primary endpoint of the study is change in the Orthostatic Hypotension Symptom Assessment (OHSA) composite score. The Study includes four periods: screening, open label (12-week period, participants will receive a single daily 10 mg dose of ampreloxetine), randomized withdrawal (eight-week period, double-blind, placebo-controlled, participants will receive a single daily 10 mg dose of placebo or ampreloxetine), and a long-term treatment extension. Secondary outcome measures include change from baseline in Orthostatic Hypotension Daily Activity Scale (OHDAS) item 1 (activities that require standing for a short time) and item 3 (activities that require walking for a short time).

About Multiple System Atrophy (MSA) and Symptomatic Neurogenic Orthostatic Hypotension (nOH)

MSA is a progressive brain disorder that affects movement and balance and disrupts the function of the autonomic nervous system. The autonomic nervous system controls body functions that are mostly involuntary. One of the most frequent autonomic symptoms associated with MSA is a sudden drop in blood pressure upon standing (nOH).[6] There are approximately 50,000 MSA patients in the US[7] and 70-90% of MSA patients experience nOH symptoms.[8] Despite available therapies, many MSA patients remain symptomatic with nOH.

Neurogenic orthostatic hypotension (nOH) is a rare disorder defined as a fall in systolic blood pressure of ⩾20 mm Hg or diastolic blood pressure of ⩾10 mm Hg, within 3 minutes of standing. Severely affected patients are unable to stand for more than a few seconds because of their decrease in blood pressure, leading to cerebral hypoperfusion and syncope. A debilitating condition, nOH results in a range of symptoms including dizziness, lightheadedness, fainting, fatigue, blurry vision, weakness, trouble concentrating, and head and neck pain.

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 once-daily norepinephrine reuptake inhibitor in development for symptomatic neurogenic orthostatic hypotension (nOH) in patients with Multiple System Atrophy (MSA), has the potential to be a first in class therapy effective in treating a constellation of cardinal symptoms in MSA patients. The Company is committed to creating/driving shareholder value.

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

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 expectations regarding its future profitability, expenses and uses of cash, the Company's goals, designs, strategies, plans and objectives, future growth of YUPELRI sales, future royalty payments, 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, the status of patent infringement litigation initiated by the Company and its partner against certain generic companies in federal district courts; contingent payments due to the Company from the sale of the Company's TRELEGY ELLIPTA royalty interests to Royalty Pharma, and expectations around the use of OHSA

scores as endpoints for clinical trials. 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: factors that could increase the Company's cash requirements or expenses beyond its expectations and any factors that could adversely affect its profitability, 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, 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 15, 2024, 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 profit (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 continuing 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.

Please see the appendix attached to this press release for a reconciliation of non-GAAP net profit (loss) from operations to its corresponding measure, net profit (loss) from operations. A reconciliation of non-GAAP net profit (loss) from operations to its corresponding GAAP measure is not available on a forward-looking basis without unreasonable effort due to the uncertainty regarding, and the potential variability of, expenses and other factors in the future.

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[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] Source: Viatris Customer Demand (Q2'24).

[3] Source: IQVIA DDD, HDS, VA and Non-Reporting Hospital through Jun '24.

[4] Hospital LA-NEB Market Share - IQVIA DDD through Jun '24. Community LA-NEB Market Share includes Retail + DME / Med B FFS through May '24.

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

[6] https://medlineplus.gov/genetics/condition/multiple-system-atrophy/

[7] UCSD Neurological Institute (25K-75K, with ~10K new cases per year); NIH National Institute of Neurological Disorders and Stroke (15K-50K).

[8] Delveinsight MSA Market Forecast (2023); Symptoms associated with orthostatic hypotension in pure autonomic failure and multiple systems atrophy, CJ Mathias (1999).

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

	June 30, 2024	December 31, 2023
Assets	**(Unaudited)**	**(1)**
Current assets:		
Cash and cash equivalents and short-term marketable securities	$ 96,078	$ 102,426
Receivables from collaborative arrangements	14,299	17,474
Prepaid clinical and development services	2,646	2,038
Other prepaid and current assets	6,284	11,603
Total current assets	119,307	133,541
Property and equipment, net	8,142	9,068
Operating lease assets	31,815	36,287
Future contingent milestone and royalty assets	194,200	194,200

Restricted cash	836	836
Other assets	7,729	8,067
Total assets	$ 362,029	$ 381,999
Liabilities and Shareholders' Equity		
Current liabilities	$ 22,946	$ 24,767
Long-term operating lease liabilities	42,441	45,236
Future royalty payment contingency	29,061	27,788
Unrecognized tax benefits	69,007	65,294
Other long-term liabilities	4,885	5,919
Shareholders' equity	193,689	212,995
Total liabilities and shareholders' equity	$ 362,029	$ 381,999

(1) The condensed consolidated balance sheet as of December 31, 2023 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, 2023.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
	(Unaudited)		**(Unaudited)**	
Revenue:				
Viatris collaboration agreement (1)	$ 14,256	$ 13,743	$ 28,759	$ 24,154
Collaboration revenue	-	6	-	12
Total revenue	14,256	13,749	28,759	24,166
Costs and expenses:				
Research and development (2)	9,954	9,425	18,922	23,997
Selling, general and administrative (2)	17,056	19,278	33,798	38,461
Impairment of long-lived assets (non-cash)	2,951	-	2,951	-
Restructuring and related expenses (2)	-	1,169	-	2,743
Total costs and expenses	29,961	29,872	55,671	65,201
Loss from operations	(15,705)	(16,123)	(26,912)	(41,035)
Interest expense (non-cash)	(644)	(568)	(1,273)	(1,118)
Interest income and other income (expense), net	1,128	2,504	2,562	5,483
Loss before income taxes	(15,221)	(14,187)	(25,623)	(36,670)
Provision for income tax expense	(1,308)	(1,458)	(2,570)	(1,063)
Net loss	**$ (16,529)**	**$ (15,645)**	**$ (28,193)**	**$ (37,733)**
Net loss per share:				
Basic and diluted net loss per share	$ (0.34)	$ (0.28)	$ (0.58)	$ (0.63)
Shares used to compute basic and diluted net loss per share	48,747	56,682	48,515	59,791
Non-GAAP net loss	**$ (6,250)**	**$ (7,355)**	**$ (10,795)**	**$ (22,267)**

(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)	**2024**	**2023**	**2024**	**2023**
YUPELRI net sales (100% recorded by Viatris)	$ 54,530	$ 55,038	$ 109,756	$ 101,993
YUPELRI net sales (Theravance Biopharma implied 35%)	19,085	19,263	38,415	35,697

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	**2024**	**2023**	**2024**	**2023**
Research and development	$ 1,151	$ 1,855	$ 2,616	$ 4,296
Selling, general and administrative	4,225	4,409	7,988	8,632
Restructuring and related expenses	-	-	-	357
Total share-based compensation expense	$ 5,376	$ 6,264	$ 10,604	$ 13,285

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
	(Unaudited)		**(Unaudited)**	
GAAP net loss	$ (16,529)	$ (15,645)	$ (28,193)	$ (37,733)
Adjustments:				
Share-based compensation expense	5,376	6,264	10,604	13,285
Non-cash impairment of long-lived assets	2,951	-	2,951	-
Non-cash interest expense	644	568	1,273	1,118
Income tax expense	1,308	1,458	2,570	1,063
Non-GAAP net loss	**$ (6,250)**	**$ (7,355)**	**$ (10,795)**	**$ (22,267)**

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