Theravance Biopharma, Inc. Reports First Quarter 2025 Financial Results and Provides Corporate Update

May 8, 2025

- *YUPELRI® (revefenacin) net sales of $58.3 million, recognized by Viatris, increased 6% versus Q1 2024[1]*
- *TRELEGY net sales of $854M, as reported by GSK, increased 14% versus Q1 2024[2]*
- *CYPRESS study open label enrollment nearing completion with final patient expected to be enrolled by late summer*
- *Quarter-end cash balance of $131 million, with no debt*
- *Reaffirming all financial guidance metrics*

DUBLIN, May 8, 2025 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today reported financial and operational results for the first quarter of 2025.

"As we begin the year, we remain focused on delivering against our operational priorities for YUPELRI and ampreloxetine," said Rick E Winningham, CEO of Theravance Biopharma. *"Our commercial partnership with Viatris delivered solid YUPELRI sales growth, aided by a strong performance in the hospital setting. TRELEGY delivered another excellent quarter and our clinical team advanced CYPRESS enrollment, which is now nearing completion. Our interactions with the MSA community continue to highlight the urgent need for new treatments for symptomatic nOH and ampreloxetine's potentially significant value to patients, caregivers and providers, underpinning our motivation to complete CYPRESS enrollment and share our results."*

First Quarter Operational Highlights

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

- Achieved total US net sales of $58.3 million in Q1 2025, increasing 6% year-over-year (Q1 2025 vs Q1 2024).[1]
- Grew customer demand 5% for the quarter (Q1 2025 vs Q1 2024).[3]
- Increased doses pulled through the hospital channel by 48% year-over-year (Q1 2025 vs Q1 2024), reflecting another quarter of strong momentum.[4]

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):

- CYPRESS study open label enrollment nearing completion with final patient expected to be enrolled by late summer; top-line data anticipated ~6 months later.
- In April, presented data at American Academy of Neurology 2025 Annual Meeting:
  - Analyses of prior Phase 3 program highlighted expected pharmacodynamic blood pressure effects, with no worsening of supine hypertension.
- Two abstracts accepted for presentation at the International MSA Congress in Boston May 9-11, including a "late breaking" oral presentation of ampreloxetine's benefits in the prespecified MSA subgroup of Study 0170.

TRELEGY Update:

GSK posted first quarter 2025 global net sales of $854 million (up 14% from $749 million reported in the first quarter of 2024):

- FY 2025 global net sales of ~$3.41 billion (representing minus 1% growth vs. 2024) required to trigger $50M milestone from Royalty Pharma.
- FY 2026 global net sales of ~$3.51 billion (representing 2% growth vs. 2024) required to trigger $100M milestone from Royalty Pharma.
- Royalties of up to 8.5% on TRELEGY net sales return to Theravance Biopharma in eligible territories beginning mid-2029, a significant driver of long-term value.[2]

First Quarter Financial Results

- **Revenue:** Total revenue for the first quarter of 2025 was $15.4 million, consisting entirely of Viatris collaboration revenue. Viatris collaboration revenue increased by $0.9 million, or 6%, in the first quarter compared to the same period in 2024. 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 commercial 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 2025 was $20.4 million which represented a 6% increase compared to the same period in 2024.

- **Research and Development (R&D) Expenses:** R&D expenses for the first quarter of 2025 were $11.5 million, compared to $9.0 million in the same period in 2024. First quarter R&D expenses included total non-cash share-based compensation of $1.1 million.

- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses for the first quarter of 2025 were $18.4 million, compared to $16.7 million in the same period in 2024. First quarter SG&A expenses included total non-cash share-based compensation of $3.8 million.

- **Share-Based Compensation:** Share-based compensation expenses for the first quarter of 2025 were $4.9 million, compared to $5.2 million in the same period in 2024. Share-based compensation expenses consisted of $1.1 million for R&D and $3.8 million for SG&A in the first quarter of 2025, compared to $1.5 million and $3.7 million, respectively, in the same period in 2024.

- **Net Loss and Non-GAAP Net Loss from Operations[5]**: Net loss was $13.6 million in the first quarter of 2025 compared to $11.7 million in the same period in 2024. Non-GAAP net loss from operations was $8.6 million in the first quarter 2025 compared to a non-GAAP net loss from operations of $4.5 million in the same period in 2024. See the section titled "Non-GAAP Financial Measures" for more information.

- **Cash Position:** Cash, cash equivalents and marketable securities totaled $130.9 million as of March 31, 2025.

Strategic Review Committee

Theravance Biopharma announced on November 12, 2024, that the Board of Directors had formed a Strategic Review Committee (the "Committee") composed entirely of independent directors to assess all strategic alternatives available to the Company. The Committee is continuing to evaluate a range of alternatives with the objective of unlocking shareholder value. Until this review is complete, we are not in a position to provide additional details on the review process.

2025 Financial Guidance

- **Operating Expenses (excluding share-based compensation):** The Company continues to expect full year 2025 R&D expenses of $32 million to $38 million and SG&A expenses of $50 million to $60 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 $20 million.

- **Non-GAAP Loss from Operations and Cash Burn[5]:** The Company continues to expect 2025 levels of Non-GAAP Losses from Operations and Cash Burn in 2025 to be similar to levels incurred in 2024.

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 dial (800) 715-9871 from the US or (646) 307-1963 for international callers, using the Conference ID 3369474. 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, 2025.

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 worsening of 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, potential, and objectives, future growth of YUPELRI sales, future milestone and royalty payments, the ability to provide value to shareholders, the Company's regulatory strategies and timing of clinical studies, potential or 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-K filed with the SEC on March 7, 2025, 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 income (loss) 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, 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 loss to its corresponding measure, net loss. A reconciliation of non-GAAP net loss 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] GSK-reported Net Sales in USD.

[3] Source: Viatris Customer Demand (Q1'25).

[4] Source: IQVIA DDD, HDS, VA and Non-Reporting Hospital through Mar '25.

[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, if any. 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)

	March 31, 2025	December 31, 2024
Assets	**(Unaudited)**	**(1)**
Current assets:		
Cash and cash equivalents and short-term marketable securities	$ 130,855	$ 88,350
Receivables from collaborative arrangements	15,353	18,440
Receivables from milestone and royalty assets	-	50,000
Other prepaid and current assets	4,056	4,277
Total current assets	150,264	161,067
Property and equipment, net	7,028	7,418
Operating lease assets	27,430	28,354
Future contingent milestone and royalty assets	144,200	144,200
Restricted cash	836	836
Other assets	13,824	12,286
Total assets	$ 343,582	$ 354,161
Liabilities and Shareholders' Equity		
Current liabilities	$ 31,502	$ 32,085
Long-term operating lease liabilities	37,349	39,108
Future royalty payment contingency	30,977	30,334
Unrecognized tax benefits	76,484	75,199
Other long-term liabilities	1,287	1,890
Shareholders' equity	165,983	175,545
Total liabilities and shareholders' equity	$ 343,582	$ 354,161

(1) The condensed consolidated balance sheet as of December 31, 2024 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, 2024.

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

	Three Months Ended March 31,

	2025	2024
	(Unaudited)	
Revenue:		
Viatris collaboration agreement (1)	$ 15,388	$ 14,503
Total revenue	15,388	14,503
Costs and expenses:		
Research and development (2)	11,452	8,968
Selling, general and administrative (2)	18,370	16,742
Total costs and expenses	29,822	25,710
Loss from operations	(14,434)	(11,207)
Interest expense (non-cash)	(643)	(629)
Interest income and other income, net	939	1,434
Loss before income taxes	(14,138)	(10,402)
Provision for income tax benefit (expense)	559	(1,262)
Net loss	**$ (13,579)**	**$ (11,664)**
Net loss per share:		
Basic and diluted net loss per share	$ (0.27)	$ (0.24)
Shares used to compute basic and diluted net loss per share	49,706	48,283
Non-GAAP net loss	**$ (8,618)**	**$ (4,544)**

(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)	**2025**	**2024**
YUPELRI net sales (100% recorded by Viatris)	$ 58,344	$ 55,226
YUPELRI net sales (Theravance Biopharma implied 35%)	20,420	19,329

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

	Three Months Ended March 31,	
(In thousands)	**2025**	**2024**
Research and development	$ 1,070	$ 1,465
Selling, general and administrative	3,807	3,764
Total share-based compensation expense	$ 4,877	$ 5,229

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

	Three Months Ended March 31,	
	2025	**2024**
	(Unaudited)	
GAAP net loss	$ (13,579)	$ (11,664)
Adjustments:		
Share-based compensation expense	4,877	5,229
Non-cash interest expense	643	629
Income tax (benefit) expense	(559)	1,262
Non-GAAP net loss	**$ (8,618)**	**$ (4,544)**

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