Theravance Biopharma, Inc. Reports Record Fourth Quarter and Full Year 2024 Financial Results

February 26, 2025

- *YUPELRI® (revefenacin) US net sales, recognized by Viatris, reached an all-time high of $66.7 million in Q4 2024 and $238.6 million in FY 2024, up 10% and 8%, respectively, compared with 2023*[1]
- *FY 2024 TRELEGY Net Sales, as reported by GSK, of $3.46 billion, up 26% compared with 2023 and triggering a $50 million milestone to Theravance Biopharma*[2,3]
- *CYPRESS study on track to enroll final patient in the open label portion by mid-2025*
- *Ended Q4 2024 with $88 million in cash, excluding the $50 million TRELEGY milestone, with cash receipt in February 2025*

DUBLIN, Feb. 26, 2025 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today announced financial and operational results for the fourth quarter and full-year ended December 31, 2024.

"Theravance Biopharma ended 2024 on a high note, having collaborated closely with Viatris to deliver record fourth quarter YUPELRI net sales and profitability, while achieving $50 million in TRELEGY related sales milestones," said Rick E Winningham, Theravance Biopharma CEO. *"Our hospital-based commercial organization executed particularly well through the end of the year, positioning us to continue driving YUPELRI growth in 2025 and beyond. These achievements, coupled with steady progress towards enrolling the last patient in the open label portion of our pivotal CYPRESS Study by mid-2025 and additional potential YUPELRI and TRELEGY milestones in the coming 12-24 months, highlight the multiple components of value created by our ongoing strategy."*

Portfolio 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):

- Achieved total US net sales of $66.7 million in Q4 2024, increasing 10% year-over-year (Q4 2024 vs Q4 2023), driven by increased customer demand.[1,4]
- Achieved 2024 total US net sales of $238.6 million, up 8% year-over-year; Theravance Biopharma stands to receive a one-time $25 million milestone payment from Viatris for the first calendar year in which YUPELRI achieves at least $250 million in US net sales, which would represent 4% growth from 2024 levels.
- Reached launch-to-date highs in brand profitability during the fourth quarter and full year 2024.
- Grew customer demand 9% for the quarter (Q4 2024 vs Q3 2024) and 11% for the year.[4]
- Grew Q4 2024 doses sold into the hospital channel by 49% year-over-year (Q4 2024 vs Q4 2023), capping off a record year for hospital performance.[5]

TRELEGY

GSK posted Q4 2024 and FY 2024 global TRELEGY net sales of $853 million and $3.46 billion, up 16% and 26%, respectively, compared with prior-year periods.[2]

- FY 2024 global net sales of $3.46 billion sufficient to trigger $50M milestone from Royalty Pharma, with cash received in February 2025.
- FY 2024 global net sales of $3.46 billion would exceed the threshold required to achieve $50 million of milestones in 2025 (based on $3.41 billion of net sales) with only 2% growth required to achieve $100 million of milestones in 2026 (based on $3.51 billion of net sales).
- 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.

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):

- On track to enroll the final patient in the open label portion of the CYPRESS in mid-2025, with top-line data anticipated to be available approximately six months later.
- Continue to prepare for an expedited NDA filing post CYPRESS readout and plan to request a priority review.
- Recent successful interaction with FDA confirming agreement on the content of a complete application, solidifying our path to an NDA.
- Two abstracts accepted for oral presentation at the American Academy of Neurology 2025 Annual Meeting taking place

April 5–9, 2025, in San Diego:
    - *"The Impact of Ampreloxetine on Supine Hypertension: An Ambulatory Blood Pressure Monitoring Study"*
    - *"NET-Inhibition with Ampreloxetine, Blood Pressure, and Catecholamines in Patients with Neurogenic Orthostatic Hypotension"*
- Continued launch readiness activities, including primary provider-focused research. Initial findings confirm strong need for more effective therapies with greater durability in nOH in MSA, as well as existence of many MSA patients with persistent symptoms despite available therapies.

Fourth Quarter Financial Results

- **Revenue:** Total revenue for the fourth quarter of 2024 was $18.8 million, consisting entirely of Viatris collaboration revenue. Viatris collaboration revenue increased by $1.4 million, or 8%, in the fourth quarter compared to the same period in 2023 due primarily to higher net sales. 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 fourth quarter of 2024 was $23.3 million which represents a 10% increase compared to the same period in 2023.

- **Research and Development (R&D) Expenses:** R&D expenses for the fourth quarter of 2024 were $9.5 million, compared to $8.3 million in the same period in 2023. Fourth quarter R&D expenses included total non-cash share-based compensation of $1.4 million. In terms of Financial Guidance, full year 2024 R&D expenses excluding non-cash share-based compensation were $32.5 million which was within our Financial Guidance of $30 million to $36 million.

- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses for the fourth quarter of 2024 were $18.5 million, compared to $15.5 million in the same period in 2023. Fourth quarter SG&A expenses included total non-cash share-based compensation of $4.4 million. In terms of Financial Guidance, full year 2024 SG&A expenses excluding non-cash share-based compensation were $52.9 million which was within our Financial Guidance of $45 million to $55 million.

- **Share-Based Compensation:** Share-based compensation expenses for the fourth quarter of 2024 were $5.8 million, compared to $5.8 million in the same period in 2023. Share-based compensation expenses consisted of $1.4 million for R&D and $4.4 million for SG&A in the fourth quarter of 2024, compared to $1.7 million and $4.1 million, respectively, in the same period in 2023. In terms of Financial Guidance, full year 2024 share-based compensation expenses were $21.4 million which was within our Financial Guidance of $18 million to $22 million.

- **Net Loss and Non-GAAP Net Income (Loss) from Operations[6]**: Net loss was $15.5 million in the fourth quarter of 2024 compared to $8.5 million in the same period in 2023, and non-GAAP net loss was $2.5 million in the fourth quarter 2024 compared to a non-GAAP net income of $1.4 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 $88.4 million as of December 31, 2024.

Strategic Review Committee

Theravance Biopharma announced on November 12th, 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 expects full year 2025 R&D expense of $32 million to $38 million and SG&A expense of $50 million to $60 million, in each case excluding share-based compensation.

- **Share-Based Compensation**: The Company expects full year share-based compensation expense of $18 million to $20 million.

- **Non-GAAP Loss from Operations and Cash Burn[6]:** The Company expects minimal levels of Non-GAAP Losses from Operations and Cash Burn in 2025, 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 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 28, 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).[7] There are approximately 50,000 MSA patients in the US[8] and 70-90% of MSA patients experience nOH symptoms.[9] 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-Q filed with the SEC on November 14, 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 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 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 income (loss) to its corresponding measure, net income (loss). A reconciliation of non-GAAP net income (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 Theravance Biopharma co-promotes the product under a profit and loss sharing arrangement (65% to Viatris; 35% to Theravance Biopharma).

[2] GSK-reported Net Sales in USD.

[3] A first payment of $25 million was triggered when Royalty Pharma (RP) became eligible to receive $240 million or more in royalty payments from GSK based on 2024 TRELEGY global net sales and a second payment of $25 million (for a total of $50 million) was triggered when RP became eligible to receive $275 million or more in royalty payments from GSK. Both royalty thresholds were achieved in the fourth quarter of 2024.

[4] Source: Viatris Customer Demand (Q4'24).

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

[6] Non-GAAP profit (loss) consists of GAAP net 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.

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

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

[9] 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)

	December 31, 2024	December 31, 2023
Assets	**(Unaudited)**	**(1)**
Current assets:		
Cash and cash equivalents and short-term marketable securities	$ 88,350	$ 102,426
Receivables from collaborative arrangements	18,440	17,474
Receivables from milestone and royalty assets	50,000	-
Prepaid clinical and development services	73	2,038
Other prepaid and current assets	4,204	11,603
Total current assets	161,067	133,541
Property and equipment, net	7,418	9,068
Operating lease assets	28,354	36,287
Future contingent milestone and royalty assets	144,200	194,200
Restricted cash	836	836
Other assets	12,286	8,067
Total assets	$ 354,161	$ 381,999

Liabilities and Shareholders' Equity

Current liabilities	$ 32,085	$ 24,767
Long-term operating lease liabilities	39,108	45,236
Future royalty payment contingency	30,334	27,788
Unrecognized tax benefits	75,199	65,294
Other long-term liabilities	1,890	5,919
Shareholders' equity	175,545	212,995
Total liabilities and shareholders' equity	$ 354,161	$ 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 December 31,		Year Ended December 31,	
	2024	**2023**	**2024**	**2023**
	(Unaudited)		**(Unaudited)**	
Revenue:				
Viatris collaboration agreement (1)	$ 18,754	$ 17,360	$ 64,381	$ 57,201
Viatris royalties (Non-US)	-	7	-	7
Collaboration revenue	-	198	-	216
Total revenue	18,754	17,565	64,381	57,424
Costs and expenses:				
Research and development (2)	9,452	8,314	37,643	40,621
Selling, general and administrative (2)	18,502	15,492	69,174	70,095
Impairment of long-lived assets (non-cash)	-	-	4,513	-
Restructuring and related expenses (2)	-	-	-	2,743
Total costs and expenses	27,954	23,806	111,330	113,459
Loss from operations	(9,200)	(6,241)	(46,949)	(56,035)
Interest expense (non-cash)	(643)	(623)	(2,546)	(2,350)
Interest income and other income, net	902	1,847	4,881	9,116
Loss before income taxes	(8,941)	(5,017)	(44,614)	(49,269)
Provision for income tax expense	(6,587)	(3,494)	(11,804)	(5,924)
Net loss	**$ (15,528)**	**$ (8,511)**	**$ (56,418)**	**$ (55,193)**
Net loss per share:				
Basic and diluted net loss per share	$ (0.31)	$ (0.17)	$ (1.15)	$ (1.00)
Shares used to compute basic and diluted net loss per share	49,306	49,415	48,847	55,303
Non-GAAP net income (loss)	**$ (2,472)**	**$ 1,431**	**$ (16,162)**	**$ (21,548)**

(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 December 31,		Year Ended December 31,	
(In thousands)	**2024**	**2023**	**2024**	**2023**
YUPELRI net sales (100% recorded by Viatris)	$ 66,680	$ 60,644	$ 238,626	$ 220,962
YUPELRI net sales (Theravance Biopharma implied 35%)	23,338	21,225	83,519	77,337

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

	Three Months Ended December 31,		Year Ended December 31,	
(In thousands)	**2024**	**2023**	**2024**	**2023**

Research and development	$ 1,377	$ 1,747	$ 5,104	$ 8,048
Selling, general and administrative	4,449	4,078	16,289	16,966
Restructuring and related expenses	-	-	-	357
Total share-based compensation expense	$ 5,826	$ 5,825	$ 21,393	$ 25,371

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

	Three Months Ended December 31,		Year Ended December 31,	
	2024	2023	2024	2023
	(Unaudited)		(Unaudited)	
GAAP net loss	$ (15,528)	$ (8,511)	$ (56,418)	$ (55,193)
Adjustments:				
Share-based compensation expense	5,826	5,825	21,393	25,371
Non-cash impairment of long-lived assets	-	-	4,513	-
Non-cash interest expense	643	623	2,546	2,350
Income tax expense	6,587	3,494	11,804	5,924
Non-GAAP net income (loss)	**$ (2,472)**	**$ 1,431**	**$ (16,162)**	**$ (21,548)**

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