Theravance Biopharma, Inc. Reports Third Quarter 2024 Financial Results and Announces Initiatives to Unlock Shareholder Value

November 12, 2024

- *Third quarter results highlight strong operational performance across key value drivers:*
  - *YUPELRI® (revefenacin) net sales of $62.2 million, recognized by Viatris, an all-time high, increased 7% versus Q3 2023 and 14% versus Q2 2024[1]*
  - *CYPRESS enrollment in-line with expectations, with timelines on track*
  - *TRELEGY net sales increased 17%, to $789 million, as reported by GSK:*
    - *Q4 sales of at least ~$260 million needed to earn $25 million milestone[2]*
    - *Q4 sales of at least ~$610 million needed to earn $50 million milestone[2]*
- *Board of Directors announces initiatives to unlock shareholder value and enhance corporate governance*

DUBLIN, Nov. 12, 2024 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today reported financial and operational results for the third quarter of 2024 and announced the formation of a Strategic Review Committee to assess alternatives to unlock shareholder value.

Reflecting on the quarter's operational performance, Rick Winningham, Theravance Biopharma CEO commented, *"Through our collaboration with Viatris, we achieved a strong quarter for YUPELRI demand and made progress on recent mix-related pricing headwinds, therein driving quarterly net sales to an all-time high. We believe we are well positioned to build on recent momentum and achieve continued YUPELRI growth, while continuing to pay careful attention to our cost structure."* He continued, *"In addition, we are pleased with the progress we made in CYPRESS this quarter and reaffirm our development timelines with a goal of making this important therapy available to patients."*

Third Quarter Recent 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):

- Realized total net sales of $62.2 million for the quarter, representing 7% growth compared with Q3 2023 and 14% sequential growth compared with Q2 2024.[1]
- Demand up 14%, (Q3 2024 vs Q3 2023) exceeding expectations and year-to-date trends.[3]
- Hospital doses sold increased by 40% (Q3 2024 vs Q3 2023).[4]
- Continued to achieve all-time market share highs within the long-acting nebulized segment of the COPD market, with hospital share approaching 19% and community share reaching 32%, respectively.[5]
- In October, published YUPELRI FEV_1 AUC[6] analysis of registrational Phase 3 Studies 0126 and 0127, demonstrating a substantial peak response and confirming the significant and sustained improvements in lung function compared with placebo over 24 hours.[7]

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 open-label enrollment still targeted for completion in mid-2025, with data anticipated to be available approximately six months later.
- In September, presented data on the long-term safety of ampreloxetine in nOH at the 2024 International Congress of Parkinson's Disease and Movement Disorders®.
  - Data indicate ampreloxetine was generally well tolerated with a low incidence of treatment-emergent adverse events and study withdrawals over approximately 9 months of exposure to ampreloxetine.
- In November, presented data from Study 0169 at the 2024 American Autonomic Society meeting highlighting the significant burden of symptomatic nOH and the high unmet needs in patients with MSA.
  - MSA patients experienced higher baseline symptom burden, and reduced activities of daily living and quality of life, despite treatment with available pressor agents.

TRELEGY Update:

- GSK posted third quarter 2024 global net sales of approximately $789 million (up 17% from $675 million reported in the third quarter of 2023), bringing year-to-date TRELEGY global net sales to approximately $2.6 billion (up 30% from the

same period in 2023).
- Based on 2024 through 2026 performance, Theravance Biopharma is eligible to receive a total of up to $200 million in milestone payments from Royalty Pharma (RP), should RP receive royalties from GSK exceeding certain thresholds tied to TRELEGY global net sales.
    - Theravance estimates that the first milestone payment of $25 million will be achieved if TRELEGY global net sales exceed approximately $2.9 billion in 2024 (requiring fourth quarter 2024 sales reach at least ~$260 million).[2]
    - Theravance estimates that 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 fourth quarter 2024 sales reach at least ~$610 million).[2]

Third Quarter Financial Results

- **Revenue:** Total revenue for the third quarter of 2024 was $16.9 million, consisting entirely of Viatris collaboration revenue. Viatris collaboration revenue increased by $1.2 million, or 8%, in the third quarter compared to the same period in 2023, and by 18% sequentially compared to Q2 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 third quarter of 2024 was $21.8 million which represented a 7% increase compared to the same period in 2023.
- **Research and Development (R&D) Expenses:** R&D expenses for the third quarter of 2024 were $9.3 million, compared to $8.3 million in the same period in 2023. Third 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 third quarter of 2024 were $16.9 million, compared to $16.1 million in the same period in 2023. Third quarter SG&A expenses included total non-cash share-based compensation of $3.9 million.
- **Non-Cash Impairment of Long-Lived Assets:** The Company incurred a non-cash impairment charge of $1.6 million on its long-lived assets (consisting primarily of its operating leases) in the third quarter of 2024. This impairment charge includes a full write-off of its excess R&D lab space operating lease.
- **Share-Based Compensation:** Share-based compensation expenses for the third quarter of 2024 was $5.0 million, compared to $6.3 million in the same period in 2023. Share-based compensation expenses consisted of $1.1 million for R&D and $3.9 million for SG&A in the third quarter of 2024, compared to $2.0 million and $4.3 million, respectively, in the same period in 2023.
- **Net Loss and Non-GAAP Net Loss from Operations[8]**: Net loss was $12.7 million in the third quarter of 2024 compared to $9.0 million in the same period in 2023. The net loss in the third quarter of 2024 was impacted by the $1.6 million non-cash impairment charge on the Company's long-lived assets. Non-GAAP net loss from operations was $2.9 million in the third quarter 2024 compared to a non-GAAP net loss from operations of $0.7 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 $91.4 million as of September 30, 2024.

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 expects levels of both non-GAAP losses and cash burn in the second half to be similar to first half actuals 2024.

Formation of Strategic Review Committee & Enhanced Corporate Governance

The Board of Directors has formed a Strategic Review Committee (the "Committee") composed entirely of independent directors to assess all strategic alternatives available to the Company, including those related to YUPELRI, ampreloxetine and TRELEGY, with the objective of unlocking shareholder value. The Committee is chaired by Susannah Gray and includes Jeremy Grant, Dean Mitchell, Donal O'Connor, and Deepa Pakianathan. Lazard will be acting as financial advisor to assist in this review process.

There can be no assurance that the Company's strategic review process will result in any transaction. Theravance Biopharma has not set a timetable for completion of this process, and it does not intend to disclose further developments unless and until it determines that such disclosure is appropriate or necessary.

Additionally, as part of its ongoing review of its corporate governance policies, the Company announced today that it has separated the roles of Chair of the Board and Chief Executive Officer. The Company believes that the separation of these roles will allow management to sharpen its focus on operational goals, including growing YUPELRI and completing the CYPRESS study. The Board of Directors elected Susannah Gray as Chair of the

Board of the Company, while Rick Winningham will continue as a member of the Board of Directors and Chief Executive Officer.

Settlement Agreement

On September 18, 2024, certain subsidiaries of Theravance Biopharma and Viatris, entered into a settlement agreement (the "Settlement Agreement") with Qilu Pharmaceutical Co., Ltd. and Qilu Pharma Inc. (together Qilu) relating to Theravance Biopharma's and Viatris' YUPELRI® (revefenacin) inhalation solution. The Settlement Agreement resolves ongoing patent litigation brought by Theravance Biopharma and Viatris against Qilu pursuant to the Hatch-Waxman Act based on Qilu's filing of an abbreviated new drug application (ANDA) seeking approval to market a generic version of YUPELRI® (revefenacin) inhalation solution prior to expiration of certain Orange Book listed patents.

Under the Settlement Agreement, Theravance and Viatris granted Qilu a royalty-free, non-exclusive, non-sublicensable, non-transferable license to manufacture and market Qilu's generic version of YUPELRI® (revefenacin) inhalation solution in the United States on or after the Licensed Launch Date of April 23, 2039, subject to certain exceptions as is customary in these types of agreements. As required by law, the settlement is subject to review by the U.S. Department of Justice and the Federal Trade Commission. The patent litigation previously disclosed by the Company remains pending against three other ANDA filers.

Conference Call and Live Webcast Today at 5:00 pm EST

Theravance Biopharma will hold a conference call and live webcast accompanied by slides today at 5:00 pm EST / 2:00 pm PST / 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, Events and Presentations.

A replay of the webcast will be available on Theravance Biopharma's website for 30 days through December 12, 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).[9] There are approximately 50,000 MSA patients in the US[10] and 70-90% of MSA patients experience nOH symptoms.[11] 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 August 8, 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 The first payment of $25 million will be triggered if Royalty Pharma (RP) receives $240 million or more in royalty payments from GSK based on 2024 TRELEGY global net sales, which we expect would occur should TRELEGY global net sales reach approximately $2.9 billion. A second payment of $25 million (for a total of $50 million) will be triggered if RP receives $275 million or more in royalty payments from GSK, which we expect would occur should 2024 TRELEGY global net sales exceed approximately $3.2 billion.
3 Source: Viatris Customer Demand (Q3'24).
4 Source: IQVIA DDD, HDS, VA and Non-Reporting Hospital through Sep '24.
5 Hospital LA-NEB Market Share - IQVIA DDD through Sep '24. Community LA-NEB Market Share includes Retail + DME / Med B FFS through Jul '24.
6 Area under the forced expiratory volume in 1 second vs time curve.
7 LeMaster, W. B., Witenko, C. J., Lacy, M. K., Olmsted, A. W., Moran, E. J., & Mahler, D. A. (2024). Revefenacin Area Under the Curve Spirometry in Patients with Moderate to Very Severe COPD. *International Journal of Chronic Obstructive Pulmonary Disease*, 19, 2299–2308. https://doi.org/10.2147/COPD.S483176
8 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.
9 https://medlineplus.gov/genetics/condition/multiple-system-atrophy/
10 UCSD Neurological Institute (25K-75K, with ~10K new cases per year); NIH National Institute of Neurological Disorders and Stroke (15K-50K).
11 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)

	September 30, 2024	December 31, 2023
Assets	**(Unaudited)**	**(1)**
Current assets:		
Cash and cash equivalents and short-term marketable securities	$ 91,361	$ 102,426
Receivables from collaborative arrangements	16,845	17,474
Prepaid clinical and development services	597	2,038
Other prepaid and current assets	7,677	11,603
Total current assets	116,480	133,541
Property and equipment, net	7,788	9,068
Operating lease assets	29,334	36,287
Future contingent milestone and royalty assets	194,200	194,200
Restricted cash	836	836
Other assets	7,467	8,067
Total assets	$ 356,105	$ 381,999
Liabilities and Shareholders' Equity		
Current liabilities	$ 23,435	$ 24,767
Long-term operating lease liabilities	40,785	45,236
Future royalty payment contingency	29,691	27,788
Unrecognized tax benefits	71,563	65,294
Other long-term liabilities	4,977	5,919
Shareholders' equity	185,654	212,995
Total liabilities and shareholders' equity	$ 356,105	$ 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(Unaudited)		(Unaudited)	
Revenue:				
Viatris collaboration agreement (1)	$ 16,868	$ 15,687	$ 45,627	$ 39,841
Collaboration revenue	-	6	-	18
Total revenue	16,868	15,693	45,627	39,859
Costs and expenses:				
Research and development (2)	9,268	8,311	28,190	32,308
Selling, general and administrative (2)	16,875	16,142	50,673	54,603
Impairment of long-lived assets (non-cash)	1,562	-	4,513	-
Restructuring and related expenses (2)	-	-	-	2,743
Total costs and expenses	27,705	24,453	83,376	89,654
Loss from operations	(10,837)	(8,760)	(37,749)	(49,795)
Interest expense (non-cash)	(630)	(609)	(1,903)	(1,727)
Interest income and other income (expense), net	1,415	1,786	3,977	7,269
Loss before income taxes	(10,052)	(7,583)	(35,675)	(44,253)
Provision for income tax expense	(2,646)	(1,367)	(5,216)	(2,430)
Net loss	**$ (12,698)**	**$ (8,950)**	**$ (40,891)**	**$ (46,683)**
Net loss per share:				
Basic and diluted net loss per share	$ (0.26)	$ (0.17)	$ (0.84)	$ (0.81)
Shares used to compute basic and diluted net loss per share	49,038	52,361	48,690	57,287

Non-GAAP net loss	**$ (2,897)**	**$ (712)**	**$ (13,692)**	**$ (22,979)**

(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 September 30,		Nine Months Ended September 30,	
(In thousands)	**2024**	**2023**	**2024**	**2023**
YUPELRI net sales (100% recorded by Viatris)	$ 62,189	$ 58,325	$ 171,945	$ 160,318
YUPELRI net sales (Theravance Biopharma implied 35%)	21,766	20,414	60,181	56,111

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	**2024**	**2023**	**2024**	**2023**
Research and development	$ 1,111	$ 2,004	$ 3,727	$ 6,301
Selling, general and administrative	3,852	4,258	11,840	12,890
Restructuring and related expenses	-	-	-	356
Total share-based compensation expense	$ 4,963	$ 6,262	$ 15,567	$ 19,547

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
	(Unaudited)		**(Unaudited)**	
GAAP net loss	$ (12,698)	$ (8,950)	$ (40,891)	$ (46,683)
Adjustments:				
Share-based compensation expense	4,963	6,262	15,567	19,547
Non-cash impairment of long-lived assets	1,562	-	4,513	-
Non-cash interest expense	630	609	1,903	1,727
Income tax expense	2,646	1,367	5,216	2,430
Non-GAAP net loss	**$ (2,897)**	**$ (712)**	**$ (13,692)**	**$ (22,979)**

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