

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

FORM 8-K

Current Report Pursuant  
to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): September 10, 2024

**THERAVANCE BIOPHARMA, INC.**  
(Exact Name of Registrant as Specified in its Charter)

**Cayman Islands**  
(State or Other Jurisdiction of  
Incorporation)

**001-36033**  
(Commission File Number)

**98-1226628**  
(I.R.S. Employer Identification  
Number)

**C/O Theravance Biopharma US, Inc.**  
**901 Gateway Boulevard**  
**South San Francisco, CA 94080**  
**(650) 808-6000**

(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)  
 Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)  
 Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))  
 Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Share \$0.00001 Par Value	TBPH	NASDAQ Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 7.01. Regulation FD Disclosure.**

*The information in this Current Report (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Current Report (including Exhibit 99.1) shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.*

Members of the Theravance Biopharma, Inc. management team will participate in a Fireside Chat at the H.C. Wainwright 26th Annual Global Investment Conference on September 10, 2024, and will be conducting one-on-one meetings with analysts and investors during the conference using a slide presentation which is being furnished pursuant to Regulation FD as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

<a href="#">99.1</a>	<a href="#">Slide deck entitled Investor Presentation September 2024</a>
104	Cover Page Interactive Data File (cover page XBRL tags embedded within the Inline XBRL document)

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**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**THERAVANCE BIOPHARMA, INC.**

Date: September 10, 2024

By: /s/ Aziz Sawaf  
Aziz Sawaf  
Senior Vice President and Chief Financial Officer

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# Theravance Biopharma

## Investor Presentation

September 2024

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# Forward Looking Statements

This presentation contains 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, Inc. (the "Company") 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 the Company 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 continuing 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 presentation for a reconciliation of non-GAAP net profit (loss) from continuing operations to its corresponding measure, net profit (loss) from continuing operations. A reconciliation of non-GAAP net profit (loss) from continuing 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.

# Theravance Biopharma – Medicines That Make a Difference®

## Corporate Profile

Commercial stage company with unique, late-stage asset

Experienced team focusing on **respiratory** and **neurology** indications with high unmet needs

Partnership with Viatris and economic interest in GSK's TRELEGY drive revenue through significant value inflection

Formed as a 2014 R&D spin-off of Theravance, Inc.

## Revenue Generating and Late-Stage Assets

YUPELRI® – First-in-class nebulized long-acting muscarinic antagonist (LAMA) for chronic obstructive pulmonary disease (COPD)







Ampreloxtetine – Potential first-in-class therapy targeting neurogenic orthostatic hypotension (nOH) in Multiple System Atrophy (MSA)

TRELEGY – First FDA approved triple therapy for maintenance treatment of asthma/COPD<sup>1</sup>

3


1. From 2024 through 2026, Theravance stands to receive up to \$200 million in TRELEGY sales milestones paid directly from Royalty Pharma. These payment will be triggered if Royalty Pharma (RP) receives certain minimum royalty payments from GSK based on TRELEGY global net sales. Beginning in 2029, Theravance is eligible to receive royalty payments on global net sales of TRELEGY in the eligible territories. Eligibility generally ends 15 years after first launch on a country-by-country basis—U.S. royalties are expected to end late 2032, while ex-U.S. royalties are expected to end in the mid-2030s on a country-by-country basis. Total royalties owed are 6.5% to 10.0% of global net sales in eligible territories, where Theravance receives 85% of total royalties owed.

## Revenue Generating and Late-Stage Assets

	Indication	Pivotal Development	NDA Filed	Marketed	Partner and Economic Interest
<b>YUPELRI US</b> US launch 2019	COPD				 <b>VIATRIS</b> Co-promote: 35% of profits to Theravance
<b>YUPELRI China</b> NDA filed June 2024	COPD				 <b>VIATRIS</b> Milestones, 14-20% royalties
<b>Amprexetine</b> CYPRESS Pivotal LPI Mid 2025	nOH in MSA				100% Commercial Rights <sup>1</sup>
<b>TRELEGY</b> First launch 2017	Asthma COPD				Milestones, single digit outer-year royalties <sup>2</sup>

1. If commercialized, Royalty Pharma owed 2.5% of global net sales up to \$500M, 4.5% of global net sales > \$500M. 2. From 2024 through 2026, Theravance stands to receive up to \$200 million in TRELEGY sales milestones paid directly from Royalty Pharma. These payment will be triggered if Royalty Pharma receives certain minimum royalty payments from GSK based on TRELEGY global net sales. Beginning in 2029, Theravance is eligible to receive royalty payments on global net sales of TRELEGY in the eligible territories. Eligibility generally ends 15 years after first launch on a country-by-country basis—U.S. royalties are expected to end late 2032, while ex-U.S. royalties are expected to end in the mid-2030s on a country-by-country basis. Total royalties owed are 6.5% to 10.0% of global net sales in eligible territories, where Theravance receives 85% of total royalties owed. COPD, chronic obstructive pulmonary disease; LPI, last patient in; MSA, multiple system atrophy; NDA, New Drug Application; nOH, neurogenic orthostatic hypotension.

## Catalysts and Value Generating Milestones

Product	Catalyst	Value	Date
 <b>YUPELRI</b> revefenacin solution	Milestone for 1 <sup>st</sup> year in which US net sales > \$250M	\$25M	TBD (LTM = \$229M)
	Milestone for NDA approval in China in COPD	\$7.5M	TBD (NDA submitted June 2024)
<b>Amprexetine</b>	Last patient enrolled in Registrational Phase 3 CYPRESS study	–	Mid-2025
	Top-line data readout for Registrational Phase 3 CYPRESS study	–	~6 mo. after last patient enrolled
	Milestone for FDA approval in US for nOH in MSA	\$15M <sup>1</sup>	TBD
<b>TRELEGY</b> <sup>2</sup>	TRELEGY milestone if net sales > either \$2.9B or \$3.2B	\$25M or \$50M	YE 2024
	TRELEGY milestone if net sales > either \$3.1B or \$3.4B	\$25M or \$50M	YE 2025
	TRELEGY milestone if net sales > either \$3.2B or \$3.5B	\$50M or \$100M	YE 2026

1. \$15M milestone due from Royalty Pharma first qualifying regulatory approval (see SEC filings for further information). 2. Theravance stands to receive up to \$200 million in TRELEGY sales milestones paid directly from Royalty Pharma. 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 Royalty Pharma 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.  
 COPD, chronic obstructive pulmonary disease; LTM, last twelve months; MSA, multiple system atrophy; NDA, new drug application; nOH, neurogenic orthostatic hypotension.





## The Only Once-Daily, Nebulized LAMA Maintenance Medicine for COPD

LAMA, long-acting muscarinic antagonist; COPD, chronic obstructive pulmonary disease



# COPD Remains a Serious Respiratory Condition with Unmet Needs

Diagnosed US  
COPD Population:  
14-16M<sup>1</sup>

**Chronic Obstructive Pulmonary Disease (COPD)** is a progressive lung disease and the 6<sup>th</sup> leading cause of death in the US

Most prevalent among people over the age of 65<sup>1</sup>



Symptoms include difficulty breathing, coughing, wheezing, chest tightness and fatigue



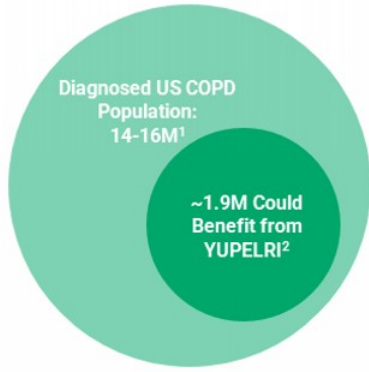
Exacerbations (flare ups) may lead to emergency room visits or hospitalization



Maintenance treatment standard of care includes LABA, LAMA and ICS medications



# Nebulized Maintenance Therapy: An Important Treatment Option in COPD



Nebulized therapy is an important alternative for many COPD patients

Nebulization addresses dexterity, strength and complex hand-breath coordination limitations<sup>3</sup>

28% of Medicare FFS COPD patients have filled a prescription for a nebulizer<sup>4</sup>



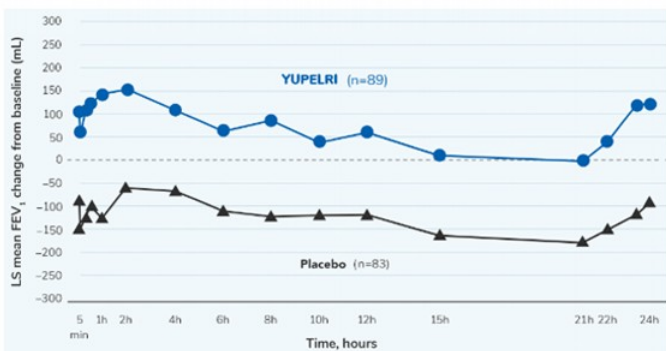
**YUPELRI is the only once-daily nebulized LAMA maintenance medication for COPD approved in the US<sup>5</sup>**

1. CDC, 2023, NIH. 2. Addressable patient population quantifies the number of patients within the intended target profile. Sources: Citeline Pharma Custom Intelligence Primary Research April 2023, Symphony Health METYS Prescription Dashboard, SolutionsRx Med B FFS. 3. Donahue, 2019. 4. Avalere, 2024. YUPELRI is contraindicated in patients with hypersensitivity to revefenacin or any component of this product. 5. YUPELRI should not be initiated in patients during acutely deteriorating or potentially life-threatening episodes of COPD, or for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. Acute symptoms should be treated with an inhaled short-acting beta2-agonist. COPD, chronic obstructive pulmonary disease; FFS, Fee For Service; LAMA, long-acting muscarinic antagonist.

# YUPELRI® Delivers a Full 24 Hours of Efficacy in a Single, Nebulized Daily Dose<sup>1</sup>

## 24-Hour Lung Function at 12 Weeks

Consistent Improvement in FEV<sub>1</sub> vs placebo over 24 hours on days 84/85<sup>1,2</sup>



## Safety Demonstrated in 3 Clinical Studies

Adverse reactions from two 12-week placebo-controlled efficacy trials (n=813)

Adverse reactions ≥ 2% incidence and higher than placebo <sup>1</sup>		
Adverse Reactions	YUPELRI (n=395)	Placebo (n=418)
Cough	17 (4%)	17 (4%)
Nasopharyngitis	15 (4%)	9 (2%)
Upper respiratory tract infection	11 (3%)	9 (2%)
Headache	16 (4%)	11 (3%)
Back pain	9 (2%)	3 (1%)

Fewer patients discontinued treatment with YUPELRI (13%) than with placebo (19%)<sup>1</sup>

Safety results from a 52-week, long-term trial consistent with those observed in previous studies (n=1,055)<sup>1</sup>

1. YUPELRI [package insert], Morgantown, WV: Mylan Specialty LP; 2. YUPELRI was studied in two 12-week, randomized, double-blind, placebo-controlled, parallel-group confirmatory studies (Studies 1 and 2) to evaluate the efficacy of once-daily YUPELRI vs placebo in patients with moderate to very severe COPD. In Studies 1 and 2, serial spirometry was performed on a sub-study population. Pooled results are shown. Primary efficacy endpoint was change from baseline in trough (pre-dose) FEV<sub>1</sub> at day 85 vs placebo. In Studies 1 and 2, a prespecified exploratory analysis was performed. In Study 1, LS mean changes from baseline in FEV<sub>1</sub> ranged from 55.8 mL to 240.4 mL in the YUPELRI group, and from -113.6 mL to 59.6 mL in the placebo group. In Study 2, LS mean changes from baseline in FEV<sub>1</sub> ranged from 19.8 mL to 148.5 mL in the YUPELRI group, and from -176.4 mL to -13.0 mL in the placebo group. Data on file. FEV<sub>1</sub>, forced expiratory volume in one second; LS, least squared.

# YUPELRI® Opportunity: Expand Use of Neb LAMA in ~1.9M COPD Patients<sup>1</sup>

~200K Current Long-Acting Neb Patients

~200K Patients Using Short-Acting (SA) Nebs inappropriately as Maintenance<sup>3</sup>

~1.5M Symptomatic Patients with Reduced Cognition, Dexterity and/or Inspiratory Flow Using Handheld Only as Maintenance



Correct inhaler use is affected by:

- Cognitive ability
- Manual dexterity / coordination
- Inspiratory flow
- Type of inhaler device
- Education on inhaler technique

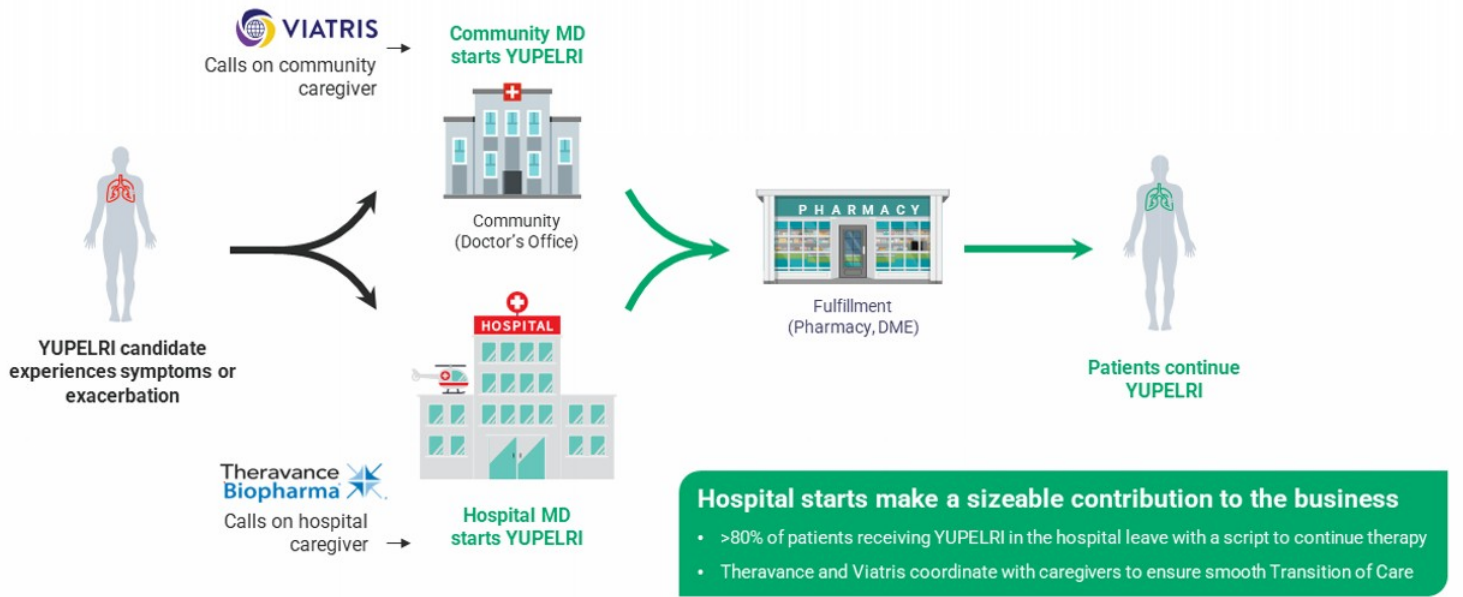
GOLD guidelines now suggest both B and E patients receive LABA/LAMA combination therapy<sup>2</sup>

SA Neb patients switching to YUPELRI cite uncontrolled symptoms and exacerbations as a leading reason for making the switch<sup>1</sup>

Patients switching from handhelds represent the majority of new YUPELRI patients and cite difficulty with dexterity and cognition as reasons for switching<sup>1</sup>

# Theravance / Viatris Partnership Drives YUPELRI® Prescription Growth

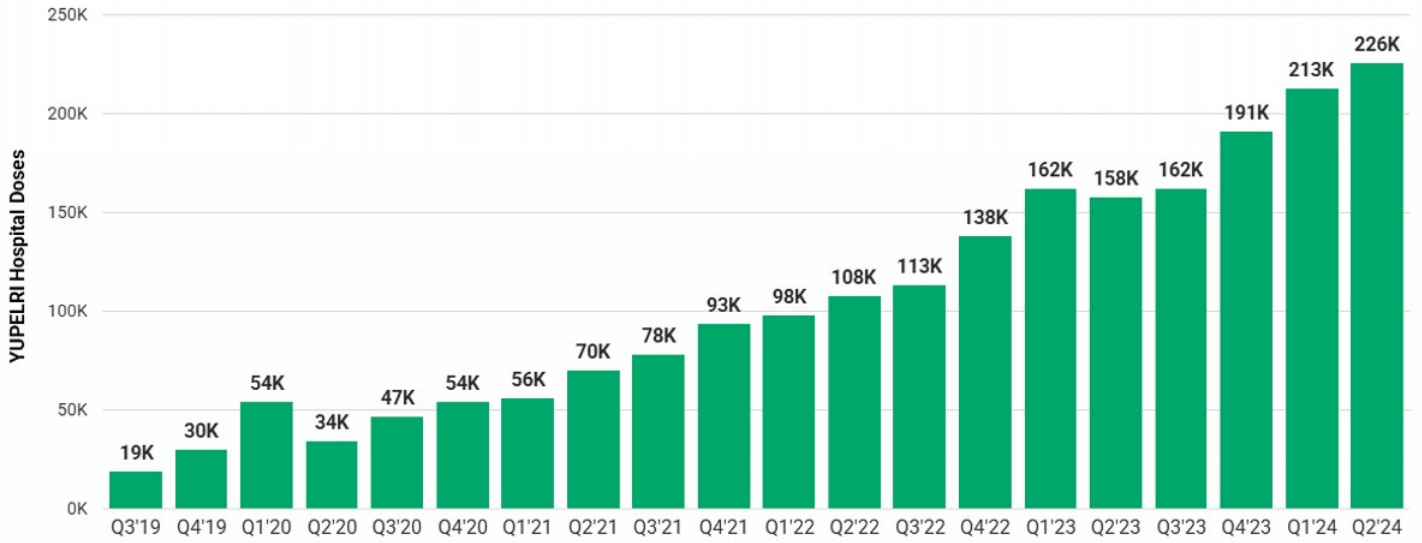
## US Co-Promotion Agreement (35% / 65% Profit Share)



**Hospital starts make a sizeable contribution to the business**

- >80% of patients receiving YUPELRI in the hospital leave with a script to continue therapy
- Theravance and Viatris coordinate with caregivers to ensure smooth Transition of Care

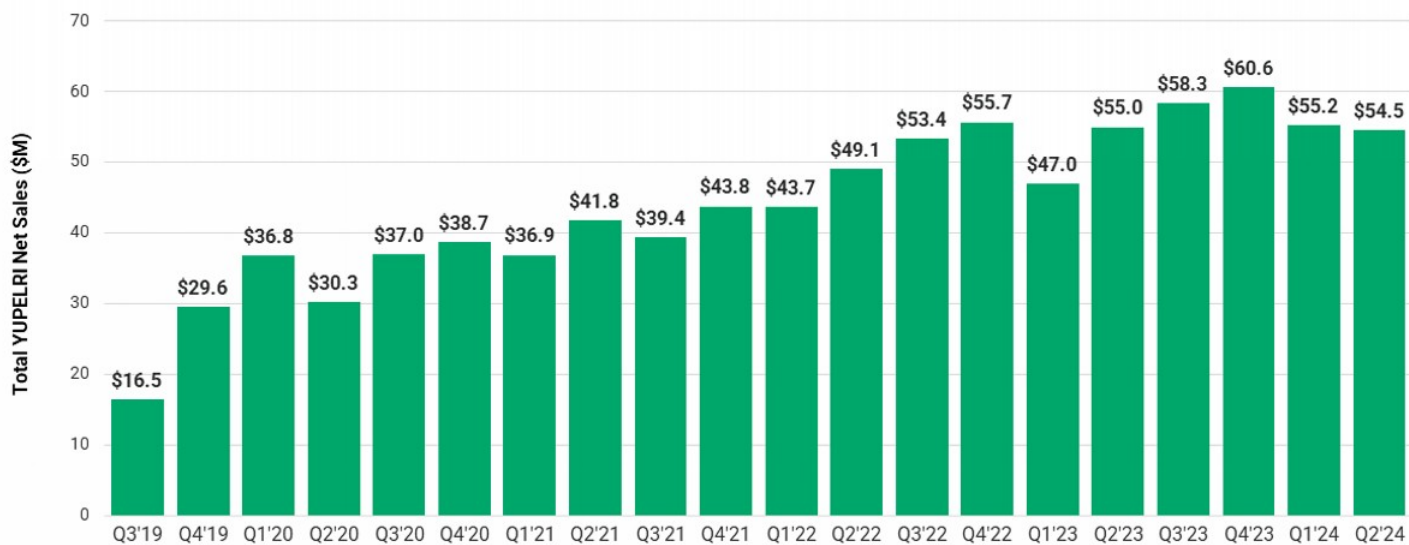
# Strong US Hospital Execution Drives Value Creation



**Hospital doses increased 39% on a trailing 12-month basis<sup>1</sup>**

1. Source: IQVIA DDD, HDS, VA and Non-Reporting Hospital through Mar'24. Preliminary data subject to revision upon receipt of final data.

# YUPELRI® US Net Sales Performance



**Net sales increased 8% on a trailing 12-month basis**



# The YUPELRI® China Opportunity

## Opportunity

**#2**  
pharmaceutical market globally<sup>1</sup>

Nearly **100M** individuals with COPD; **~43%** suffer from moderate to severe disease<sup>2,3</sup>

**15-month**  
median NDA/BLA review time (2023 to present)<sup>4</sup>

Viatis is the **8<sup>th</sup>** largest multinational company in China, with a sales force of **~4,200** covering **>70K** hospitals and **400K** pharmacies in over **300** cities<sup>5</sup>

**NDA Filed  
June 2024**

## Economics<sup>6</sup>

**\$7.5M**  
milestone on approval

**\$37.5M**  
of sales milestones

**14-20%**  
tiered royalties

1. IQVIA Institute Global Use of Medicines 2024. 2. Wang C, Xu J, Yang L, et al., The Lancet, 2018. 3. Yin P, Wang H, Vos T, et al., Chest, 2013. 4. Baipharm Monthly Report: New Drug Approvals, internal analysis (Jan '23 – May '24). 5. Source: Viatis (2021). 6. As of June 30, 2024, Theravance Biopharma is eligible to receive potential development and sales milestones totaling \$52.5 million related to Viatis' development and commercialization of nebulized revefenacin in China and adjacent territories, with \$45.0 million associated with YUPELRI monotherapy and \$7.5 million associated with future potential combination products; refer to our SEC filings for further information. BLA, Biologics License Application; NDA, New Drug Application; COPD, chronic obstructive pulmonary disease.

# YUPELRI® Value Proposition



## Once-Daily Nebulized LAMA COPD Maintenance Medicine

- Last twelve months' US sales up 8% to \$229M; Theravance receives 35% of US profits<sup>1</sup>
- Brand profitable, with expanding profit margins
- Medicare Part B therapy; FFS beneficiaries with supplemental insurance face out-of-pocket costs as low as \$0<sup>2</sup>



## Significant Growth Potential

- Up to 1.9M patients could benefit from YUPELRI in the US
- NDA submitted in China (June 2024)



## Upcoming Milestone and Royalty Potential

- US: Up to \$150M in total monotherapy sales milestones<sup>3</sup>; first \$25M for 1<sup>st</sup> year in which US net sales > \$250M
- China: Up to \$45M in monotherapy development and sales milestones; 14-20% tiered royalties<sup>4</sup>



## IP protection granted to 2039 in the US

1. In the US, Viatriis is leading the commercialization of YUPELRI, and Theravance Biopharma co-promotes the product under a profit and loss sharing arrangement (65% to Viatriis; 35% to Theravance Biopharma). 2. Ochieng, N., et al., "A Snapshot of Sources of Coverage among Medicare Beneficiaries," KFF, 13 Dec. 2023, [www.kff.org/medicare/issue-brief/a-snapshot-of-sources-of-coverage-among-medicare-beneficiaries/](http://www.kff.org/medicare/issue-brief/a-snapshot-of-sources-of-coverage-among-medicare-beneficiaries/). 3. As of June 30, 2024, Theravance Biopharma is eligible to receive from Viatriis potential global development, regulatory and sales milestone payments (excluding China and adjacent territories) totaling up to \$205.0 million in the aggregate; refer to our SEC filings for further information. 4. As of June 30, 2024, Theravance Biopharma is eligible to receive potential development and sales milestones totaling \$52.5 million related to Viatriis' development and commercialization of nebulized revefenacin in China and adjacent territories, with \$45.0 million associated with YUPELRI monotherapy and \$7.5 million associated with future potential combination products; refer to our SEC filings for further information. COPD, chronic obstructive pulmonary disease; FFS, fee-for-service; LAMA, long-acting muscarinic agent.

AMPRELOXETINE

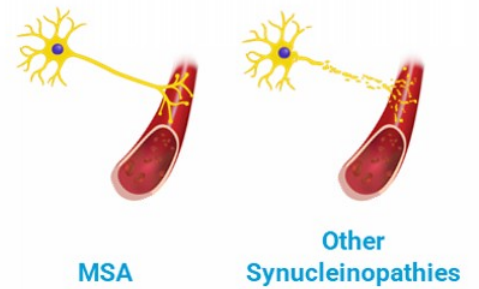
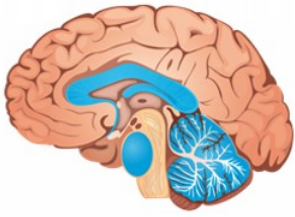
**The first NET inhibitor in development  
exclusively to treat symptoms of nOH in MSA**

NET, norepinephrine transporter; nOH, neurogenic orthostatic hypotension; MSA, multiple system atrophy



## Multiple System Atrophy (MSA):

A progressive neurological disorder leading to autonomic failure and neurogenic orthostatic hypotension (nOH)



In **MSA**, abnormal deposits of misfolded  $\alpha$ -synuclein are associated with **progressive neuro-degeneration**

Neuro-degeneration leads to **autonomic system failure, characterized by nOH**, and significantly reduced quality of life

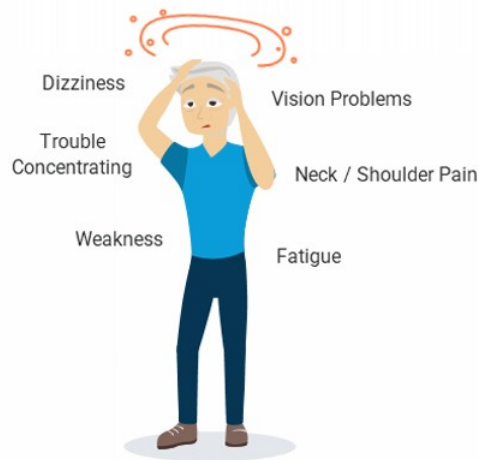
In **MSA, peripheral nerves may be spared**, providing an opportunity to enhance autonomic function and alleviate symptoms of nOH

# Neurogenic Orthostatic Hypotension (nOH):

One of the Most Devastating Consequences of MSA

## nOH patients experience:

- Rapid blood pressure reductions upon standing
- Upper extremity hypoperfusion
- A range of debilitating, unremitting symptoms

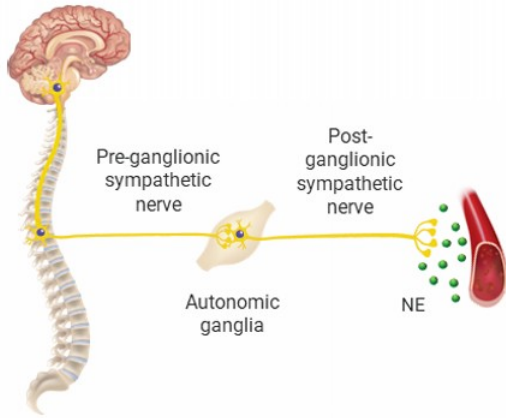


## Orthostatic Hypotension Symptom Assessment (OHSA):

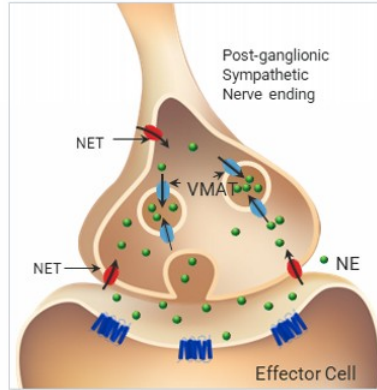
- Patient reported measure of nOH symptom burden, addressing 6 key symptoms
- Questionnaire developed by autonomic system experts
- Accepted by the FDA as an outcome measure for drug approval<sup>1</sup>
- 1-point OHSA change considered clinically meaningful<sup>2</sup>

Symptom intensity can be measured by the OHSA

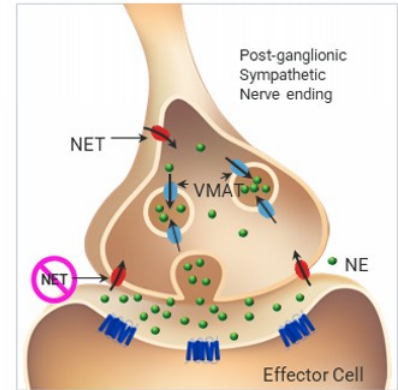
# Amprelosetine Intended to Increase Norepinephrine and Treat nOH



In MSA, postganglionic sympathetic (autonomic) nerves are often intact, with residual sympathetic activity retained

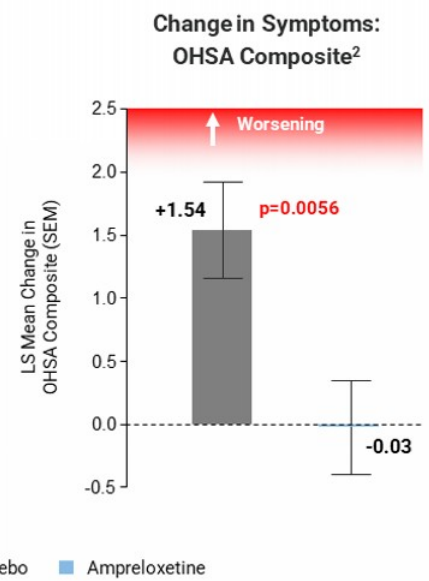
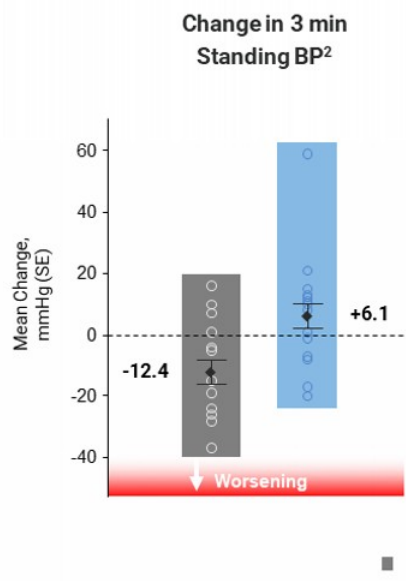
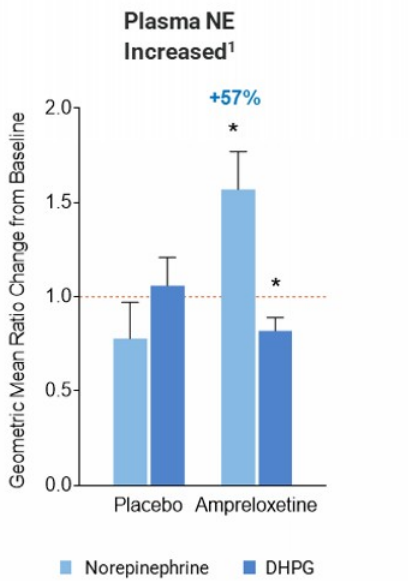


Sympathetic activity (NE released into the synapse) stimulates adrenergic receptors, driving a vascular response



Amprelosetine blocks NE reuptake from the synapse, therein increasing intrasynaptic NE concentrations and actions<sup>1</sup>

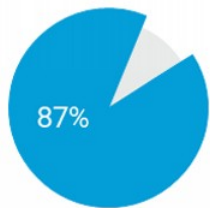
# Amprelosetine MoA Supported by MSA Patient Data<sup>1,2</sup>



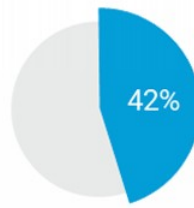
1. Data from MSA patients. Error bars represent SE. \* p < 0.05 comparison to baseline reported after 4 weeks of amprelosetine administration in study 0169. 2. Data from MSA patients at week 6 of the randomized withdrawal period of study 0170. Amprelosetine is in development and not approved for any indication. BP, blood pressure; DHPG, dyhydroxyphenylglycol; LS, least-squares; MSA, multiple system atrophy; NE, norepinephrine; OHSA, orthostatic hypotension symptom assessment; SE, standard error; SEM, standard error of mean.

# The Unmet Need in MSA Patients with nOH is High

## Burden of nOH on Patients



**87%**  
of nOH patients report a reduced ability to perform activities<sup>1</sup>



**42%**  
claim nOH has robbed them of their independence<sup>1</sup>

## A high unmet need remains, clinically meaningful options are needed

- **Physicians** report an urgency to treat patients with nOH due to the impact on quality of life, deconditioning, high risk of injury from falls, and caregiver burden
- **Advocacy groups, patients and caregivers** are actively engaged and seeking new therapies to better manage nOH



# MSA Patients with nOH are Not Optimally Treated

Clinically meaningful options are needed

01

No approved treatment for orthostatic hypotension has been show to be effective beyond 2 weeks in a well-controlled study

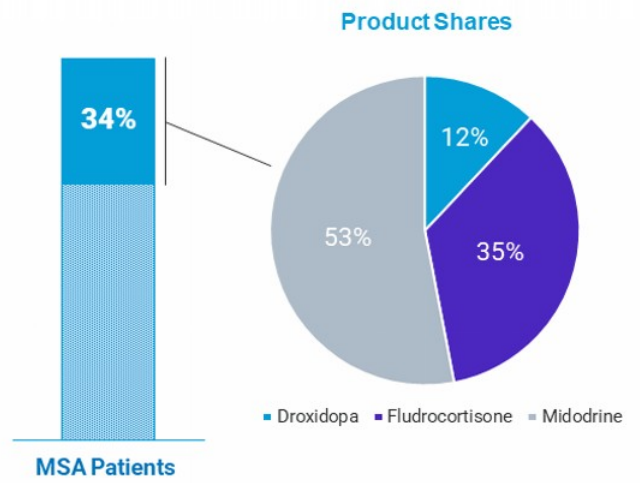
02

All three commonly prescribed orthostatic hypotension treatments carry a risk of worsening high blood pressure while lying down

03

~65% of MSA patients with nOH remain symptomatic despite treatment<sup>1</sup>

Only ~34% of patients are treated; current therapies have not worked in this patient population<sup>2</sup>



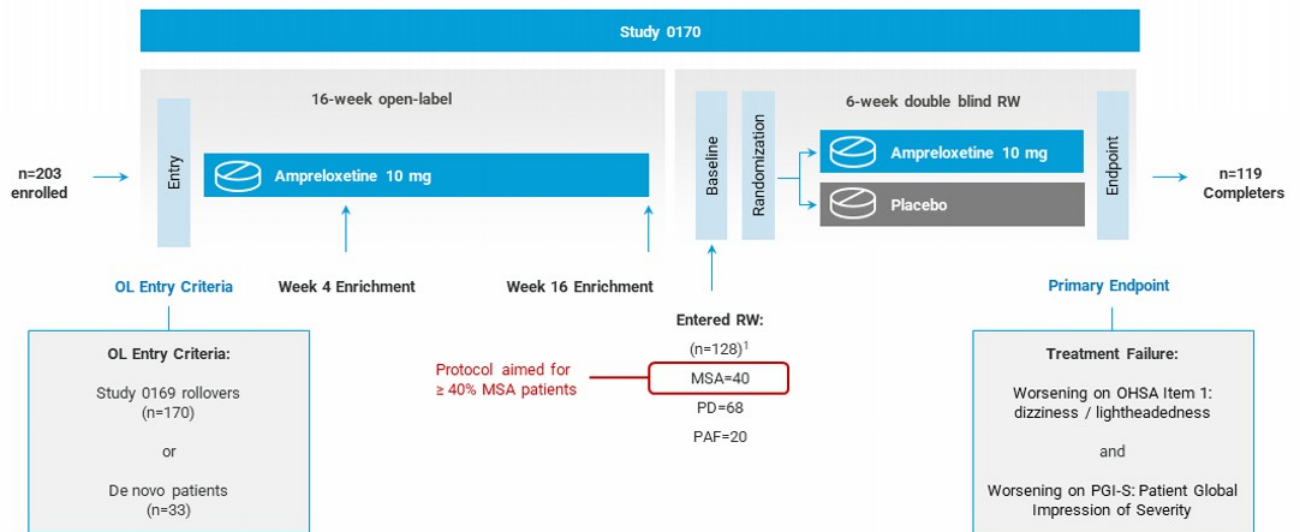
1. MSA Natural History Statistics, NYU September 2019. 2. Veeva Compass patient-level claims data, MSA patients (G90.3) with at least 1 Rx from 2020-2023. Product share defined as total "days supplied" in this patient population. MSA, multiple system atrophy; nOH neurogenic orthostatic hypotension.

AMPRELOXETINE

## Clinical Development

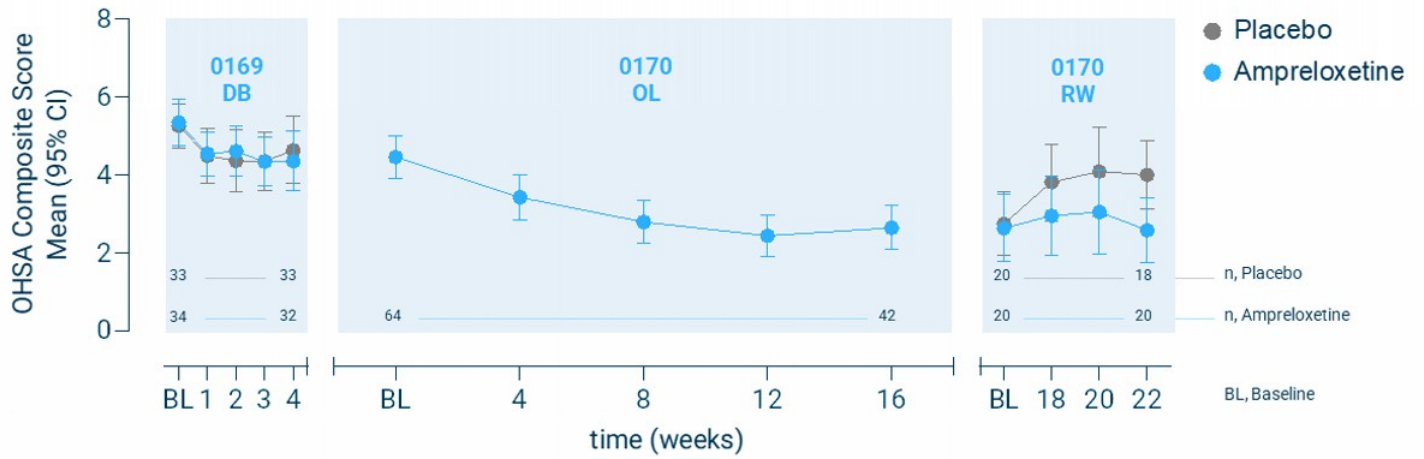


# Study 0170 (REDWOOD) Enrolled MSA, Parkinson's and PAF Patients



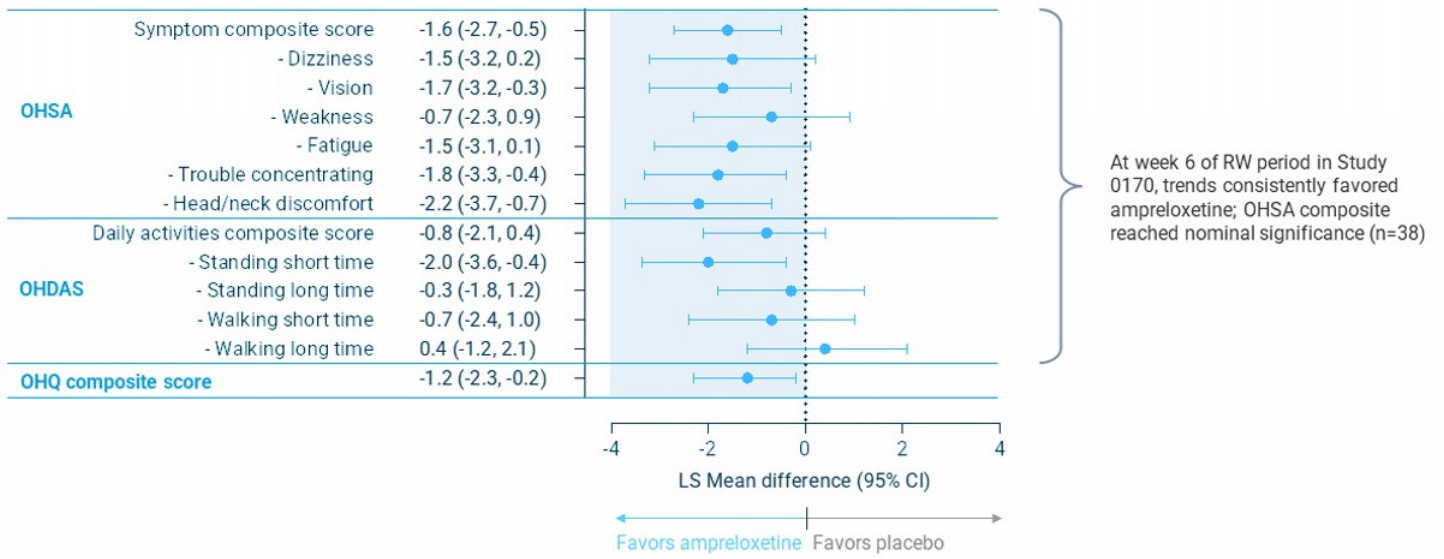
1. Study 0170 was terminated early because of negative results from Study 0169 (n=128 vs. 154 anticipated).  
MSA, multiple system atrophy; OHSa, orthostatic hypotension symptom assessment; OL, open label; PAF, pure autonomic failure; PD, Parkinson's disease; PGI-S, patient global impression of severity; RW, randomized withdrawal.

# Durable, Clinically-Significant Symptom Improvements Seen in MSA Patients



**Study 0170: 1.6 Point Difference on the OHSA Composite Score at Week 6 of the RW Period (n=38)**

# Consistent Symptom Benefits Across Individual OHSA Items in MSA Patients



# Alignment with FDA on CYPRESS Trial Design and Regulatory Approach

June 2022  
Successful Type C Meeting

March 2023  
CYPRESS Initiation

Collaborative CYPRESS Protocol Review

## Aligned with FDA on CYPRESS

Use of randomized withdrawal design including the OHSA composite as primary endpoint

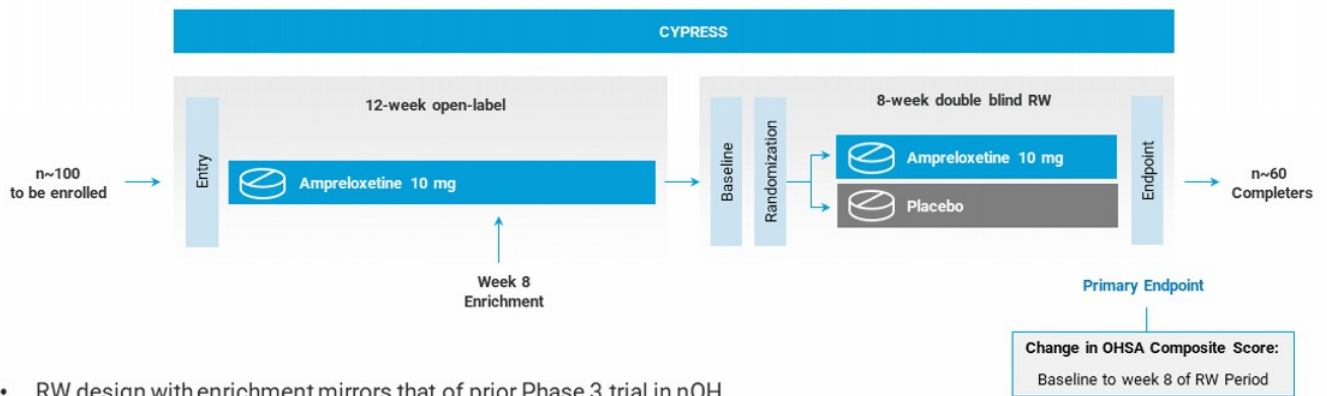
A Positive Study outcome, supported by Study 170 data, expected to be sufficient for regulatory filing

## Use of FDA-supported, Anchor-Based Analysis

Establishes clinically meaningful thresholds for patient-reported outcomes measures

~1 point change in OHSA Composite identified as clinically meaningful<sup>1</sup>

# CYPRESS Designed to Reproduce Study 0170 MSA Patient Results



- RW design with enrichment mirrors that of prior Phase 3 trial in nOH
- FDA aligned with design and use of OHSA composite as primary endpoint
- Last patient into open-label portion in mid-2025; data approximately 6 months later
- **A Positive Study outcome, supported by Study 0170 data, expected to be sufficient for regulatory filing**

AMPRELOXETINE

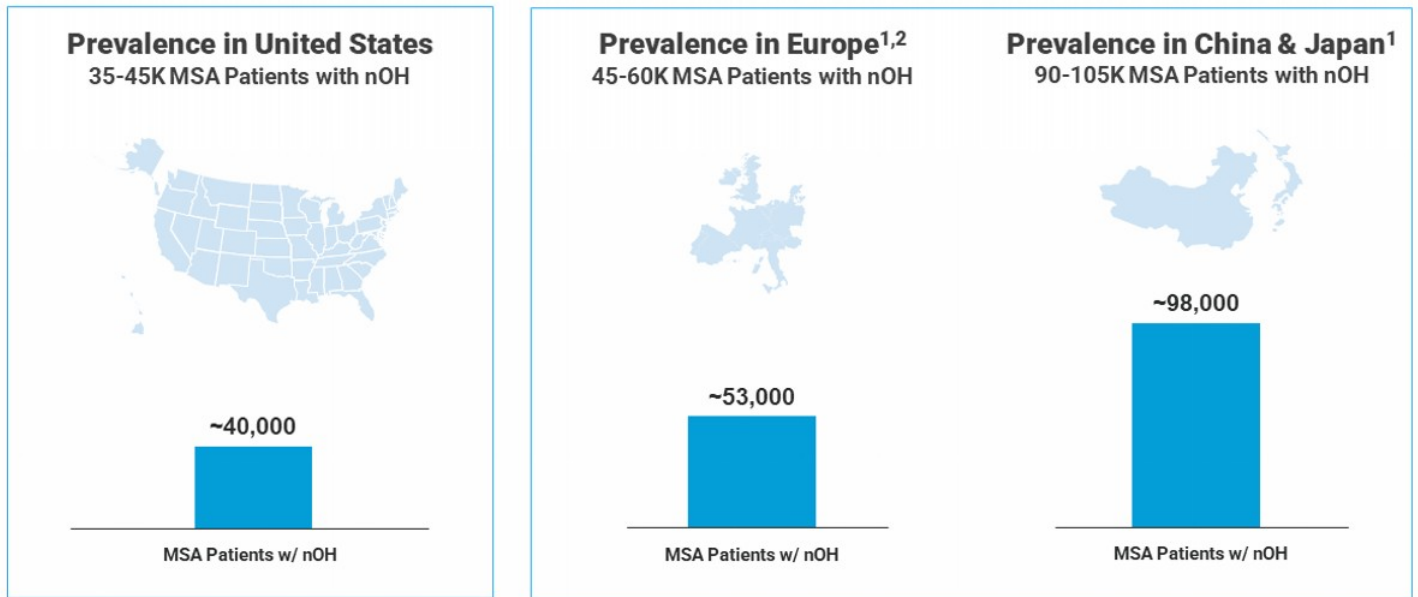
## Market Opportunity





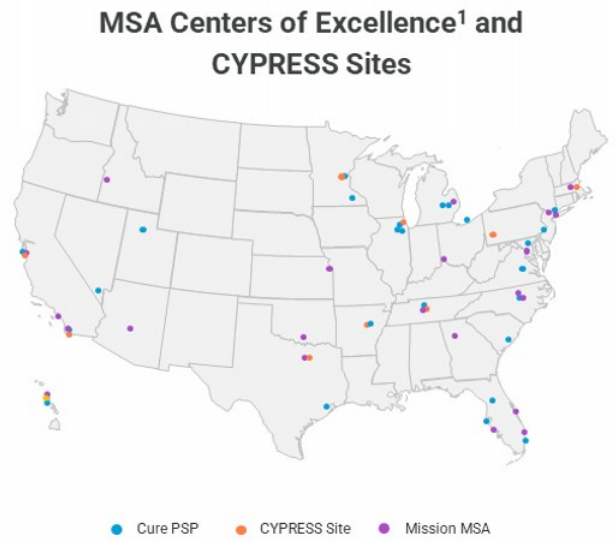
# Amprexetine Global Opportunity

Significant unmet needs in leading therapeutics markets



1. The lansis nOH Market Report 2023; TBPH Internal Analysis. nOH graphics reflect the mid-point of the provided ranges.  
2. Prevalence estimate for Germany, France, UK, Italy and Spain.  
MSA, multiple system atrophy; nOH neurogenic orthostatic hypotension.

# Concentrated Treatment Landscape, Centered on MSA, nOH Specialists



1. Centers of Excellence: <https://missionmsa.org/resource-library/centers-of-excellence-overview/>, <https://www.psp.org/centers-of-care>  
2. Veeva Compass patient-level claims data, MSA patients (G90.3), 1/1/2023-12/31/2023. MSA, multiple system atrophy; nOH neurogenic orthostatic hypotension.

# Ampreloxadne Value Proposition in MSA with nOH



## Potential best-in-class agent with orphan drug disease designation<sup>1</sup>

- Once-daily dosing with durable, clinically meaningful efficacy in target population
- No observed supine hypotension further distinguishes from competitive landscape
- MOA validated by increased NET inhibition with elevated plasma NE levels



## FDA alignment on CYPRESS pivotal study design and path to approval

- CYPRESS to reproduce MSA with nOH results from recent Study 0170 with OSHA composite endpoint
- CYPRESS last patient into open-label mid-2025, with data ~6 months later



## Significant unmet medical need

- Specialist network with easily commercialized concentrated market



## Granted IP through 2037

TRELEGY

**The only once-daily, 3-in-1 treatment for  
COPD or asthma**

COPD, chronic obstructive pulmonary disease



# TRELEGY Milestones and Royalties Represent Added Value

## History

Once-daily, 3-in-1 treatment therapy for COPD and asthma, developed by GSK in collaboration with Theravance, Inc.

Theravance Biopharma entitled to receive TRELEGY sales milestones and royalties as part of 2014 spin-off

Company sold rights to Royalty Pharma in 2022 for \$1.1B, but retained future economics

## Retained Value to Theravance Biopharma

Up to \$200M in sales-based TRELEGY milestones from 2024 – 2026<sup>1</sup>

Royalties on global TRELEGY sales from 2029 through the mid-2030s<sup>2</sup>

Milestones and royalties are paid to Theravance Biopharma by Royalty Pharma<sup>1,2</sup>



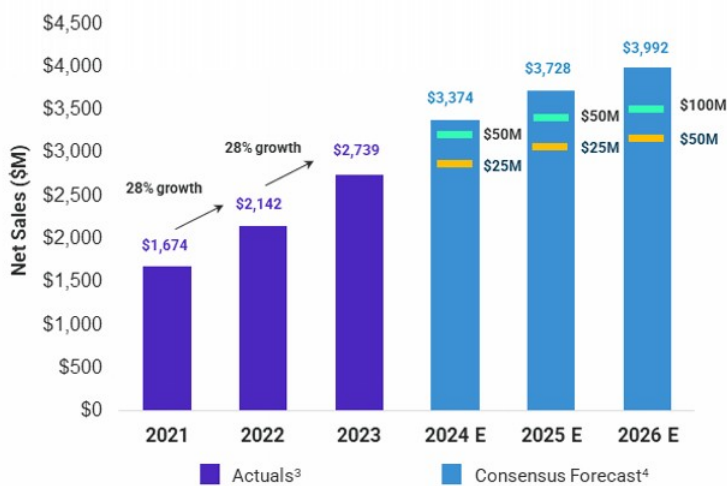
1. As of 06/30/24, Theravance stands to receive up to \$200 million in TRELEGY sales milestones paid directly from Royalty Pharma (RP). In each year from 2024 to 2026, a first payment will be triggered if RP receives a minimum royalty payment from GSK and an additional payment will be triggered if RP receives a higher royalty payment from GSK. In 2024, we expect these respective thresholds to be met, should 2024 TRELEGY global net sales exceed approximately \$2.9 billion and \$3.2 billion. 2. Eligibility generally ends 15 years after first launch in an eligible territory: U.S. royalties are expected to end late 2032, while ex-U.S. royalties are expected to end in the mid-2030s on a country-by-country basis. Total royalties owed are 6.5% to 10.0% of global net sales in eligible territories; Theravance receives 85% of royalties owed COPD, chronic obstructive pulmonary disease.

# \$200M in Potential TRELEGY Sales Milestones if Upper Tier Thresholds are Met

## \$200M in potential sales milestones<sup>1</sup> from '24 to '26

Year	Royalty Threshold <sup>2</sup>	Global Net Sales Equivalent	Milestone to Theravance
2024 <sup>1</sup>	\$240M	\$2,863M	\$25M
	\$275M	\$3,213M	\$50M
2025 <sup>1</sup>	\$260M	\$3,063M	\$25M
	\$295M	\$3,413M	\$50M
2026 <sup>1</sup>	\$270M	\$3,163M	\$50M
	\$305M	\$3,513M	\$100M

## TRELEGY Global Net Sales Trends (\$M)



1. If both milestones are achieved in a given year, Theravance Biopharma will only earn the higher milestone. 2. Based on 100% of TRELEGY ELLIPTA royalties. 3. GSK-reported Net Sales in USD. 4. Bloomberg Consensus as of 08/02/24. As of 06/30/24, Theravance stands to receive up to \$200 million in TRELEGY sales milestones paid directly from Royalty Pharma. In each year from 2024 to 2026, a first payment will be triggered if Royalty Pharma (RP) receives a minimum royalty payment from GSK and an additional payment will be triggered if Royalty Pharma receives a higher royalty payment from GSK. In 2024, we expect these respective thresholds to be met, should 2024 TRELEGY global net sales exceed approximately \$2.9 billion and \$3.2 billion.



# Global TRELEGY Royalties to Return Beginning in 2029

## Royalties Return from 2029 through the mid-2030s<sup>1</sup>

### Royalty Details:

- Royalties returning to Theravance<sup>1</sup>:
  - Ex-US royalties return July 1, 2029
  - US royalties return January 1, 2031
- Calculated on global net sales of eligible territories
- Upwardly tiered effective rate of 5.5 - 8.5%<sup>2</sup>
- Paid directly by Royalty Pharma

## TRELEGY Global Net Sales Trends (\$M)

Annual Global Net Sales <sup>1</sup>	Royalty Rate	85% Share Owed to Theravance
Net Sales up to \$750M	6.5%	<b>5.5%</b>
Additional Sales up to \$1.250B	8.0%	<b>6.8%</b>
Additional Sales up to \$2.250B	9.0%	<b>7.7%</b>
Net Sales Exceeding US \$2.25B	10.0%	<b>8.5%</b>

## Financials & Capital Management





## Q2 2024 Financial Highlights

Metric	Q2 '24 (M)	Q2 '23 (M)	Note
VIATRIS Collaboration Revenue	\$14.3	\$13.7	Representing 4% YoY growth
SG&A and R&D Expense, ex-SBC	\$21.6	\$22.4	
Share-Based Compensation	\$5.4	\$6.3	
GAAP Net Loss from Operations	(\$15.7)	(\$16.1)	Q2'24 impacted by ~\$3.0M non-cash long-lived asset impairment charge
Non-GAAP Net Loss from Operations <sup>1</sup>	(\$6.3)	(\$7.4)	
Cash and Cash Equivalents <sup>2</sup> (as of quarter-end)	\$96.1	\$167.5	Buyback program completed in Jan'24
Debt (as of quarter-end)	\$0.0	\$0.0	
Shares Outstanding (as of quarter-end)	48.9	53.7	

1. Non-GAAP net profit (loss) from continuing operations consists of GAAP net income (loss) before taxes less share-based compensation expense, non-cash interest expense, and non-cash impairment expense; see reconciliation on Slide 46 and the section titled "Non-GAAP Financial Measures" on Slide 2 for more information. 2. Cash, cash equivalents and marketable securities. SBC, Share-Based Compensation.

# 2024 Financial Guidance

## H1 2024 Financial Performance:

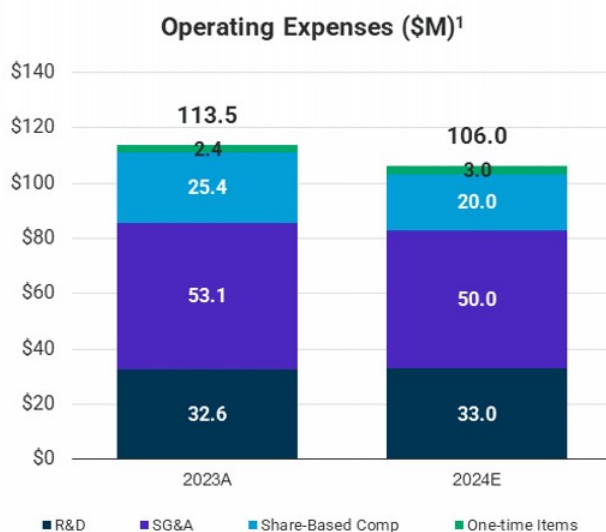
- \$28M GAAP net loss from operations
- \$11M non-GAAP net loss from operations
- \$96M cash, \$0M debt as of 6/30/24

## 2024 Operating Expense Guidance:

- R&D (excluding share-based comp): \$30M - \$36M
- SG&A (excluding share-based comp): \$45M - \$55M
- Share-Based Compensation: \$18M - \$22M

## 2024 Non-GAAP Profitability / Loss Guidance<sup>2</sup>:

- H2 '24 non-GAAP loss and cash burn expected to be similar to H1 '24
- Excludes potential milestones



# Summary: Theravance's Strategic Imperatives

## Grow YUPELRI®

Only once-daily nebulized LAMA: currently <5% penetrated addressable market<sup>1</sup>

Winning strategy aligned with clinical best practices

## Address the Significant Problem of nOH in MSA

Devastating neurological disorder causing unremitting symptoms of autonomic failure in ~80% of patients<sup>2,3</sup>

**Ampreloxetine** as best-in-class agent may be uniquely tailored to mitigate these symptoms and improve quality of life

## Preserve Financial Strength

\$96 million in cash / no debt, limited cash use anticipated in 2024

Up to \$200 million in **TRELEGY** milestones possible through 2026; eligible for additional future royalties<sup>4</sup>

1. Sources: Citeline Pharma Custom Intelligence Primary Research April 2023, Symphony Health METYS Prescription Dashboard, SolutionsRx Med B FFS. 2. Kalra DK, et al. Clin Med Insights: Cardiol. 2020 (70%-90%);14:1179546820953415. 3. Delveinsight MSA Market Forecast (2023); Symptoms associated with orthostatic hypotension in pure autonomic failure and multiple systems atrophy, C J Mathias (1999). 4. From 2024 through 2026, Theravance stands to receive up to \$200 million in TRELEGY sales milestones paid directly from Royalty Pharma. These payment will be triggered if Royalty Pharma receives certain minimum royalty payments from GSK based on TRELEGY global net sales. Beginning in 2029, Theravance is eligible to receive royalty payments on global net sales of TRELEGY in the eligible territories. Eligibility generally ends 15 years after first launch on a country-by-country basis—U.S. royalties are expected to end late 2032, while ex-U.S. royalties are expected to end in the mid-2030s on a country-by-country basis. Total royalties owed are 6.5% to 10.0% of global net sales in eligible territories, where Theravance receives 85% of total royalties owed. LAMA, long-acting muscarinic antagonist; MSA, multiple system atrophy; nOH, neurogenic orthostatic hypotension.

# Senior Leadership

**Rick Winningham**  
Chairman and Chief Executive Officer



**Aziz Sawaf, CFA**  
Senior Vice President,  
Chief Financial Officer



**Rhonda Farnum**  
Senior Vice President,  
Chief Business Officer



**Áine Miller**  
Senior Vice President,  
Development



## Appendix Slides



# YUPELRI® (revefenacin) Inhalation Solution

YUPELRI® inhalation solution is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

## Important Safety Information (US)

YUPELRI is contraindicated in patients with hypersensitivity to revefenacin or any component of this product.

YUPELRI should not be initiated in patients during acutely deteriorating or potentially life-threatening episodes of COPD, or for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. Acute symptoms should be treated with an inhaled short-acting beta<sub>2</sub>-agonist.

As with other inhaled medicines, YUPELRI can produce paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs following dosing with YUPELRI, it should be treated immediately with an inhaled, short-acting bronchodilator. YUPELRI should be discontinued immediately and alternative therapy should be instituted.

YUPELRI should be used with caution in patients with narrow-angle glaucoma. Patients should be instructed to immediately consult their healthcare provider if they develop any signs and symptoms of acute narrow-angle glaucoma, including eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema.

Worsening of urinary retention may occur. Use with caution in patients with prostatic hyperplasia or bladder-neck obstruction and instruct patients to contact a healthcare provider immediately if symptoms occur.

Immediate hypersensitivity reactions may occur after administration of YUPELRI. If a reaction occurs, YUPELRI should be stopped at once and alternative treatments considered.

The most common adverse reactions occurring in clinical trials at an incidence greater than or equal to 2% in the YUPELRI group, and higher than placebo, included cough, nasopharyngitis, upper respiratory infection, headache and back pain.

Coadministration of anticholinergic medicines or OATP1B1 and OATP1B3 inhibitors with YUPELRI is not recommended.

YUPELRI is not recommended in patients with any degree of hepatic impairment.

## About YUPELRI® (revefenacin) Inhalation Solution

YUPELRI® (revefenacin) inhalation solution is a once-daily nebulized LAMA approved for the maintenance treatment of COPD in the US.

Market research by Theravance Biopharma indicates approximately 9% of the treated COPD patients in the US use nebulizers for ongoing maintenance therapy.<sup>1</sup> LAMAs are a cornerstone of maintenance therapy for COPD and YUPELRI® is positioned as the first once-daily single-agent bronchodilator product for COPD patients who require, or prefer, nebulized therapy. YUPELRI®'s stability in both metered dose inhaler and dry powder device formulations suggest that this LAMA could also serve as a foundation for novel handheld combination products.

1. TBPH market research (N=160 physicians); refers to US COPD patients.  
COPD, chronic obstructive pulmonary disease; LAMA, long-acting muscarinic antagonist.

## Second Quarter 2024 Financials (Unaudited)

(\$, in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(Unaudited)		(Unaudited)	
<b>Revenue:</b>				
Viatis collaboration agreement	\$ 14,256	\$ 13,743	\$ 28,759	\$ 24,154
Collaboration revenue	-	6	-	12
Total revenue	14,256	13,749	28,759	24,166
<b>Costs and expenses:</b>				
Research and development (1)	9,954	9,425	18,922	23,997
Selling, general and administrative (1)	17,056	19,278	33,798	38,461
Impairment of long-lived assets (non-cash)	2,951	-	2,951	-
Restructuring and related expenses (1)	-	1,169	-	2,743
Total costs and expenses	29,961	29,872	55,671	65,201
<b>Loss from operations (before tax and other income &amp; expense)</b>	<b>\$ (15,705)</b>	<b>\$ (16,123)</b>	<b>\$ (26,912)</b>	<b>\$ (41,035)</b>
<b>Share-based compensation expense:</b>				
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
<b>Operating expense excl. share-based compensation:</b>				
R&D operating expense (excl. share-based compensation)	8,803	7,570	16,306	19,701
SG&A operating expense (excl. share-based compensation)	12,831	14,869	25,810	29,829
<b>Total operating expenses excl. share-based compensation</b>	<b>\$ 21,634</b>	<b>\$ 22,439</b>	<b>\$ 42,116</b>	<b>\$ 49,530</b>
<b>Non-GAAP net loss (2)</b>	<b>\$ (6,250)</b>	<b>\$ (7,355)</b>	<b>\$ (10,795)</b>	<b>\$ (22,267)</b>

1. Amounts include share-based compensation. 2. Non-GAAP net profit (loss) from continuing operations consists of GAAP net loss before taxes excluding share-based compensation expense, non-cash interest expense and non-cash impairment expense; see reconciliation on Slide 18 and the section titled "Non-GAAP Financial Measures" on Slide 2 for more information.



## Second Quarter 2024 Financials (Unaudited) (Cont'd)

### Reconciliation of GAAP to Non-GAAP Net Loss (In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(Unaudited)		(Unaudited)	
<b>GAAP Net Loss</b>	\$ (16,529)	\$ (15,645)	\$ (28,193)	\$ (37,733)
<u>Adjustments:</u>				
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
<b>Non-GAAP Net Loss</b>	<u>\$ (6,250)</u>	<u>\$ (7,355)</u>	<u>\$ (10,795)</u>	<u>\$ (22,267)</u>
<b>Non-GAAP Net Loss per Share</b>				
Basic and diluted non-GAAP net loss per share	<u>\$ (0.13)</u>	<u>\$ (0.13)</u>	<u>\$ (0.22)</u>	<u>\$ (0.37)</u>
Shares used to compute basic and diluted non-GAAP net loss per share	<u>48,747</u>	<u>56,682</u>	<u>48,515</u>	<u>59,791</u>

## Granted Patent Protection into Late 2030s

Compound	Invention	Estimated Patent Expiry
YUPELRI® / revefenacin	Composition of Matter	2028
	Polymorph	2030-2031
	Method for the maintenance treatment of COPD patients	2039
Amprexetine	Composition of Matter	2030 (plus PTE of up to 5 years)
	Method of Treating nOH	2037