

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): April 17, 2023

**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)

**Not Applicable**  
(I.R.S. Employer Identification  
Number)

**PO Box 309**  
**Ugland House, South Church Street**  
**George Town, Grand Cayman, Cayman Islands KY1-1104**  
**(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 Company management team will be presenting at the 22<sup>nd</sup> Annual Needham Virtual Healthcare Conference on April 17, 2023, and 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.

[99.1](#) [Slide deck entitled 22nd Annual Needham Virtual Healthcare Conference](#)

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, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**THERAVANCE BIOPHARMA, INC.**

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

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Date: April 17, 2023

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# 22<sup>nd</sup> Annual Needham Virtual Healthcare Conference

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April 17, 2023

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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 repurchase of its ordinary shares by way of an open market share repurchase program, the Company's governance policies and plans, the Company's expectations regarding its allocation of resources and maintenance of expenditures, the Company's goals, designs, strategies, plans and objectives, the ability to provide value to shareholders, the Company's regulatory strategies and timing of clinical studies, and contingent payments due to the Company from the sale of the Company's TRELEGY ELLIPTA royalty interests to Royalty Pharma. These statements are based on the current estimates and assumptions of the management of the Company as of the date of this presentation and are subject to risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results of the Company 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: 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, ability to retain key personnel, the impact of the Company's recent restructuring actions on its employees, partners and others, 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-K filed with the SEC on March 1, 2023, 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 Measure

Theravance Biopharma provides a non-GAAP profitability target in this presentation. Theravance Biopharma believes that the non-GAAP profitability target provides meaningful information to assist investors in assessing prospects for future performance as it provides a better metric for analyzing the future potential 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, such as non-GAAP profitability, are not standardized, it may not be possible to compare this target with other companies' non-GAAP targets or measures having the same or a similar name. Thus, Theravance Biopharma's non-GAAP target should be considered in addition to, not as a substitute for, in isolation from, the company's actual GAAP results and other targets.

# Strategic Actions Focused on Continued Value Creation

## Authorized \$325M Capital Return Program

**Approved incremental \$75M to existing \$250M program** initiated Sept'22, with goal to complete program by end of 2023

- Repurchased \$155M of stock to date, including \$27M in 2023
- \$170M remains in capital return program; **expected to complete by end of 2023**

## Discontinued Investments in Research

**Prioritize resource allocation** toward ampreloxetine Phase 3 study and YUPELRI® (revedfenacin) PIFR-2 study

- **Discontinued research activities**, including stopping inhaled Janus kinase (JAK) inhibitor program
- **~17% headcount reduction completed** by end of Mar 2023

## Board and Governance Evolution

**Appointed independent directors Susannah Gray and Jim Kelly to Board of Directors**

- Part of ongoing commitment to board refreshment

**Lead Independent Director William D. Young will not stand for re-election** at 2023 AGM

**Company has put forth proposal to declassify the Board of Directors over time** at 2023 AGM

# 2023 Targets



- ▶ **Continue YUPELRI Net Sales growth** by executing on targeted strategies to capture sizeable niche market
- ▶ Complete **PIFR-2 study** and provide top-line results in 2H'23

## Ampreloxetine

- ▶ **Initiated Phase 3 CYPRESS trial** in MSA patients with symptomatic nOH in Q1'23
- ▶ Submitted **orphan drug designation** request in early 2023

## Financial

- ▶ **Expanded Capital Return Program to \$325M**, and expect to complete the remaining \$170M this year
- ▶ **Generate Non-GAAP<sup>1</sup> Profit** in 2H'23
- ▶ **\$50M potential milestone** for TRELEGY Net Sales of ~\$2.86B<sup>2</sup>



1. Non-GAAP profit is expected to consist of GAAP income before taxes less share-based compensation expense and non-cash interest expense. See the section titled "Non-GAAP Financial Measure" for more information. 2. The first milestone payment, of \$50.0 million, will be triggered if Royalty Pharma receives \$240.0 million or more in royalty payments from GSK with respect to 2023 TRELEGY global net sales, which we would expect to occur in the event TRELEGY global net sales reach approximately \$2.863 billion. MSA, multiple system atrophy; nOH, neurogenic orthostatic hypotension; PIFR, peak inspiratory flow rate.



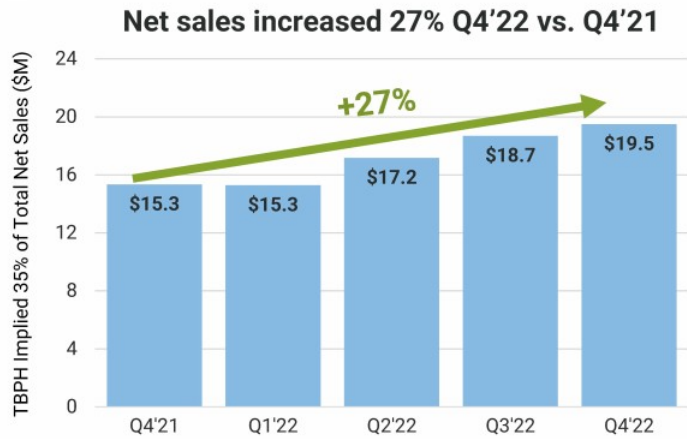
FDA-approved for maintenance treatment of COPD

First and only once-daily, LAMA (long-acting muscarinic agent) nebulized maintenance medicine for COPD

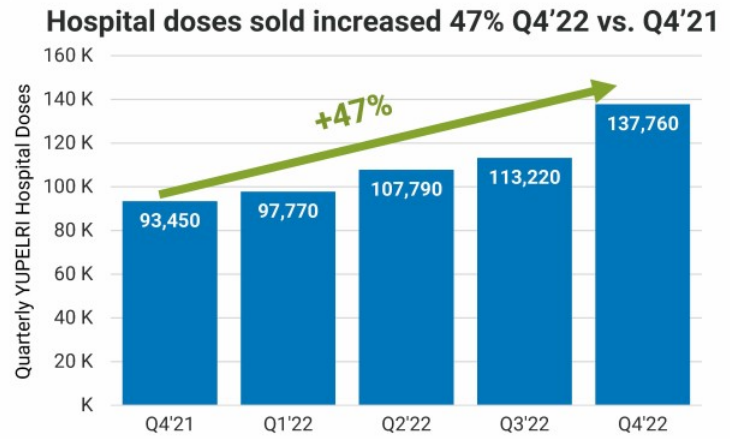
Co-promotion agreement with VIATRIS™ (35% / 65% Profit Share)



# YUPELRI® | Growing Net Sales and Hospital Volume



**25% year-over-year net sales growth in 2022**



**53% year-over-year volume growth in 2022**

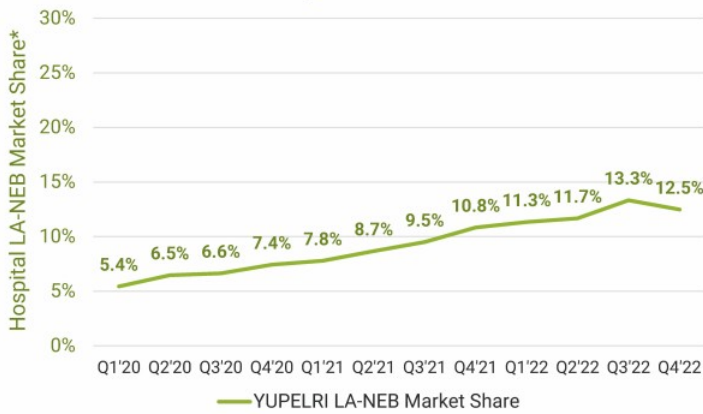


Source: IQVIA DDD, HDS, VA and Non-Reporting Hospital through 12/31/2022. See TBPB 10K filed February 28, 2022 for greater detail re TBPB implied 35%.

# YUPELRI® Hospital Sales and Community TRx Trends

Hospital share dropped slightly due to largest Q/Q growth in market volume since YUPELRI launch

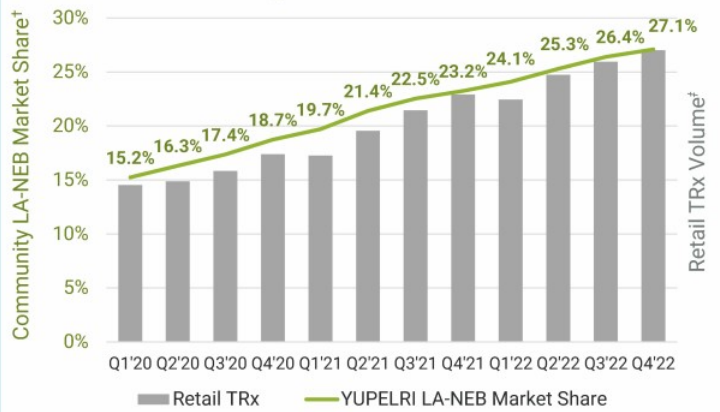
### Hospital Market Share



Most patients who receive YUPELRI® in the hospital are discharged with an Rx<sup>1</sup>

LA-NEB Market: YUPELRI, BROVANA, LONHALA, PERFOROMIST, arformoterol, formoterol

### Community Market Share with TRx



TRx volume represents retail only which is typically 33% of Retail + DME Reported DME volume, while lagged, typically follows Retail volume trends



1. Joint VTRS/TBPH Market Research.  
 \* Hospital LA-NEB Market Share - IQVIA DDD through 12/31/2022.  
 †Community LA-NEB Market Share includes Retail + DME / Med B FFS through Nov'22  
 ‡Retail TRx Volume - Symphony Health METYS Prescription Dashboard through 12/31/2022.

# YUPELRI<sup>®</sup>:

## Phase 4 Randomized, Double-Blind, Parallel-Group Study (PIFR-2)



### Sample size

- ▶ N = Up to 488
- ▶ Top-line results 2H'23

### Endpoints

- ▶ **Primary:** Change from baseline in trough FEV<sub>1</sub> (Day 85)
- ▶ **Key secondary:** Trough overall treatment effect on FEV<sub>1</sub>

# Ampreloxetine

Investigational once-daily norepinephrine reuptake inhibitor

For symptomatic neurogenic orthostatic hypotension (nOH)  
in multiple system atrophy (MSA) patients

# New Era in Treating MSA Symptoms: Product Positioning

## MSA Prevalence

~50K MSA patients in U.S.<sup>1</sup>  
(considered orphan disease)

## Prevalence of nOH in MSA Patients

70%-90% of MSA patients  
experience nOH symptoms<sup>2</sup>

## Addressable Patient Population

35K – 45K MSA patients with  
nOH symptoms

## Current Treatment Landscape

	Droxidopa <sup>3</sup>	Midodrine <sup>4</sup>	Amprelosetine
Indication	Symptomatic nOH	OH	Symptomatic nOH associated with MSA
Efficacy / Durability	OHSA#1; clinical effectiveness >2 weeks not established	Increase in systolic blood pressure 1 min after standing	OHSA composite; clinically meaningful and durable response >20 weeks
Dosing	3x daily, titration to effect	3x daily	Once-daily
Safety	Black box warning for supine hypertension		No signal for supine hypertension

## Unique Treatment Profile



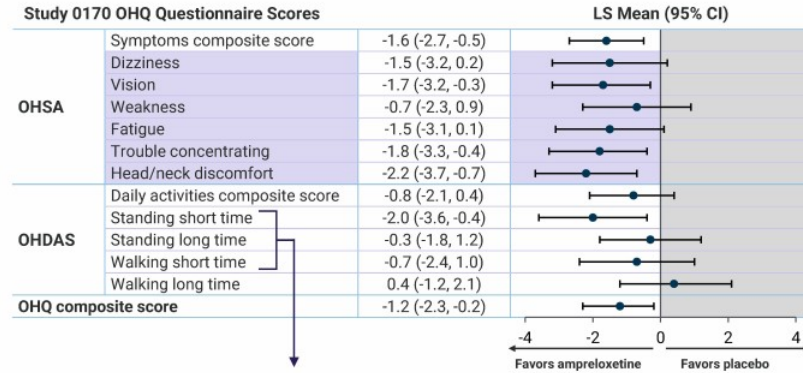
Reflects Theravance Biopharma's expectations for amprelosetine based on clinical trial data to date. Amprelosetine is in development and not approved for any indication. Data on file.  
1. UCSD Neurological Institute (25K-75K, with ~10K new cases per year); NIH National Institute of Neurological Disorders and Stroke (15K-50K). 2. Delveinsight MSA Market Forecast (2023); Symptoms associated with orthostatic hypotension in pure autonomic failure and multiple systems atrophy, CJ Mathias (1999). 3. NORTHERA® (droxidopa) [package insert]. Deerfield, IL: Lundbeck. 2014. 4. ProAmatine® (midodrine hydrochloride) [Warning Ref 4052798]. Lexington, MA: Shire. 2017.  
MSA, multiple system atrophy; nOH, neurogenic orthostatic hypotension; OHSA, Orthostatic Hypotension Symptom Assessment.

# The Unique Benefits of Ampreloxetine Treatment



## Unique efficacy and durability

First-in-class therapy effective in treating a **constellation of cardinal symptoms in MSA patients:**



Improvement in **activities of daily living** that require walking and standing for a short time<sup>1</sup> which could favorably impact caregiver burden

Clinically meaningful and **durable effectiveness** well beyond 2 weeks



## Patient-friendly dosing

MSA patients may have **difficulty swallowing:**

- Once-daily dosing, single 10mg tablet
- Low dosing frequency improves compliance
- Decreases caregiver burden



## Differentiated safety profile

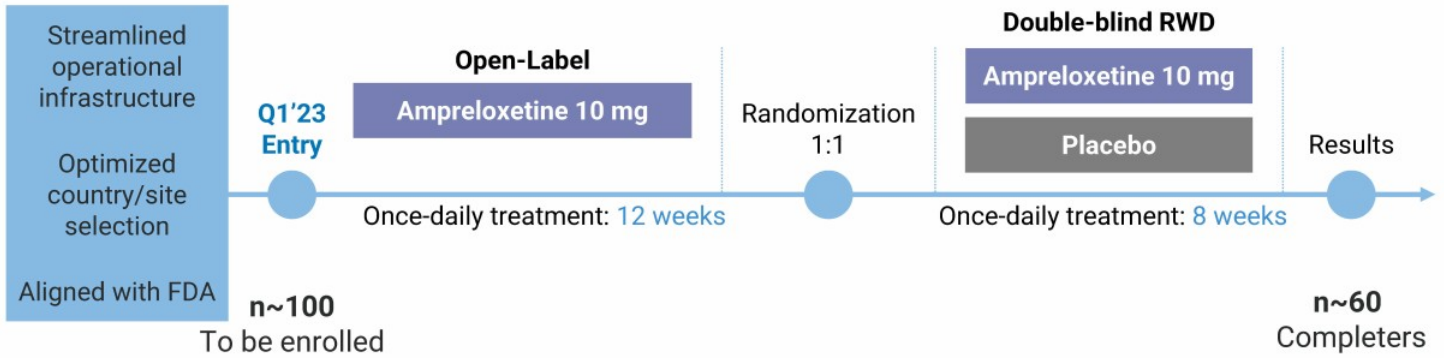
**Supine hypertension** with droxidopa and midodrine<sup>2,3</sup>

**Absence** of a signal would be a differentiator:

- Available to patients with supine hypertension
- Can be taken anytime of day/night
- Potential to be combined with other drugs

# Offering Hope to MSA Patients with Symptomatic nOH

Study 0197 (CYPRESS): Phase 3 randomized withdrawal study in patients with MSA  
Primary endpoint: change in OHSA composite score



# Our CYPRESS Study is Now Recruiting



MSA, multiple system atrophy; nOH, neurogenic orthostatic hypotension.



# Financial Update

# \$325 Million Capital Return Program

## Complete

- ✓ ~\$95M: Purchased GSK's equity stake in Theravance (Sep'22) and completed Dutch auction tender offer (Nov'22)

## Open Market Share Buybacks

- ✓ ~\$33M completed in Dec'22
- ✓ ~\$27M completed in 2023, through 2/27/23

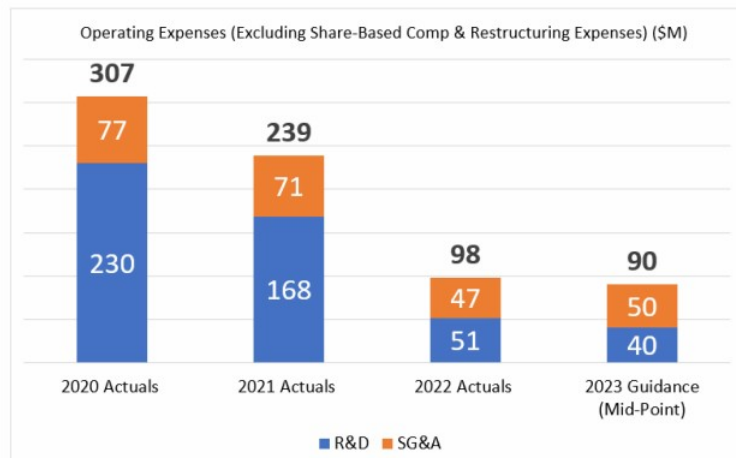
**~50% (or ~\$155M) of \$325M capital return program completed as of 2/27/23**

**\$170M remains in capital return program; expected to complete by end of 2023**

# 2023 Financial Guidance

## Expected to generate non-GAAP<sup>1</sup> Profit in 2H 2023

- 2023 OPEX Guidance Range:
  - R&D: \$35M - \$45M
  - SG&A: \$45M - \$55M
- Guidance Excludes:
  - Non-cash share-based compensation
  - One-time severance and termination costs associated with 2023 headcount reduction:
    - Expected to be \$1M - \$2M in Q1'23
- Share-Based Compensation:
  - Expected to decline materially in 2023 vs. 2022



# TRELEGY ELLIPTA Milestones and Royalties

GSK's TRELEGY ELLIPTA (FF/UMEC/VI): First and only once-daily single inhaler triple therapy

## Mid-Term Value

Up to \$250M of Sales-based milestones<sup>1,2</sup> between 2023–2026:

Year	Royalties <sub>2</sub>	Global Net Sales Equivalent	Milestone
2023	\$240M	\$2,863M	\$50M
2024 <sub>1</sub>	\$240M	\$2,863M	\$25M
	\$275M	\$3,213M	\$50M
2025 <sub>1</sub>	\$260M	\$3,063M	\$25M
	\$295M	\$3,413M	\$50M
2026 <sub>1</sub>	\$270M	\$3,163M	\$50M
	\$305M	\$3,513M	\$100M

Q4 Net Sales of \$537M | FY 2022 Net Sales of \$2.1B<sup>4</sup>

GSK remains exclusively responsible for commercialization of TRELEGY ELLIPTA

## Long-Term Value

Outer-Year Royalties<sup>3</sup> return in 2029:

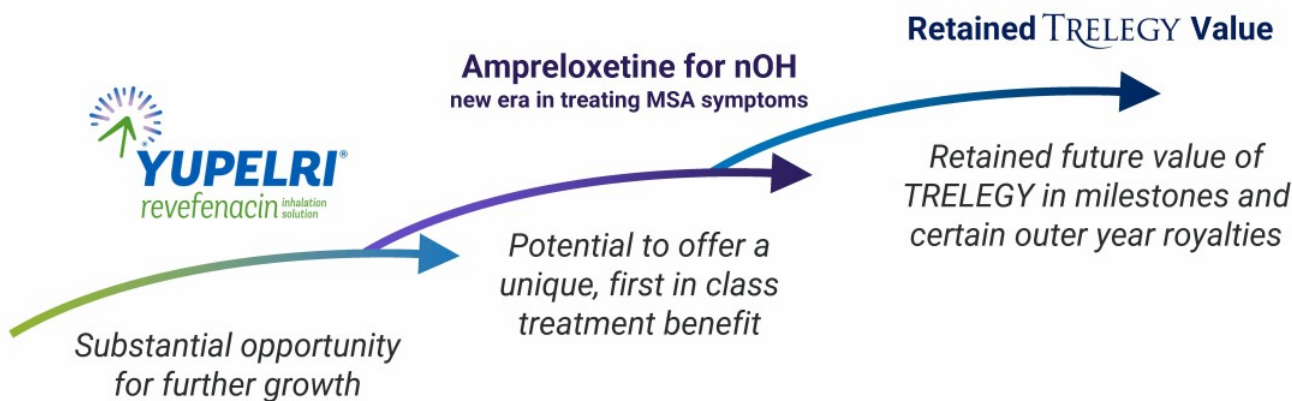
- Ex-US royalties return Jul. 1, 2029
- US royalties return after Jan. 1, 2031
- Paid directly from Royalty Pharma



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. 85% of TRELEGY ELLIPTA royalties return to Theravance Biopharma beginning July 1, 2029 for sales ex-U.S., and January 1, 2031 for sales within the U.S.; U.S. royalties expected to end late 2032; ex-U.S. royalties expected to end mid-2030s and are country specific. 4. Source: Bloomberg FF, Fluticasone Furoate; UMEC, Umeclidinium; VI, Vilanterol.

# Theravance Biopharma: Positioned for Value Creation

Three distinct drivers of value over the near, mid, and long-term



**Positioned to create value from a foundation of financial strength**

# Q&A Session

**Rick E Winningham**  
**Chairman and Chief Executive Officer**

*Former CEO, Theravance, Inc. (now INVA)  
Former President (Oncology/Immunology/Oncology  
Therapeutics Network), Bristol Myers Squibb*



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

*Former Executive Director of Marketing, Amgen  
Former VP (Hematology), Onyx Pharmaceuticals &  
Former Commercial Leadership, Genentech*



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

*Former Theravance Biopharma, Vice President, Finance  
Former Gilead Sciences, Finance*



**Richard A. Graham**  
**Senior Vice President,  
Research and Development**

*Former Senior Director, Head of Translational Medicine,  
Onyx Pharmaceuticals  
Former Clinical Pharmacologist and Project Team Leader,  
Genentech and GlaxoSmithKline*



# YUPELRI<sup>®</sup> (revefenacin) inhalation solution

YUPELRI<sup>®</sup> 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 beta2-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<sup>®</sup> (revefenacin) Inhalation Solution

YUPELRI<sup>®</sup> (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<sup>®</sup> is positioned as the first once-daily single-agent bronchodilator product for COPD patients who require, or prefer, nebulized therapy. YUPELRI<sup>®</sup>'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.





## Appendix

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# Appoints Susannah Gray to Board as new Independent Director



**Susannah Gray** served as the Executive Vice President and Chief Financial Officer of Royalty Pharma, the largest aggregator of pharmaceutical royalty interests worldwide, from January 2005 to December 2018. She was promoted to Executive Vice President of Finance and Strategy in December 2018 and retired from Royalty Pharma in September 2019. Prior to Royalty Pharma, Ms. Gray served as a managing director and senior analyst covering the healthcare sector in CIBC World Markets' high yield group from 2002 to 2004, and also previously served in similar roles at Merrill Lynch and Chase Securities (predecessor of J.P. Morgan Securities). She currently serves on the Boards of Directors of Maravai LifeSciences, 4D Molecular Therapeutics and Morpich Therapeutic. Previously, Ms. Gray served on the Board of Directors of Apria until its sale to Owens & Minor. Ms. Gray received a BA, with honors, from Wesleyan University and an MBA from Columbia University.

# Appoints Jim Kelly to Board as new Independent Director



**Jim Kelly** joined Weiss Asset Management in November 2010, where he is currently a Managing Director and a member of the Investment Committee. Prior to joining Weiss Asset Management, Mr. Kelly worked at Farallon Capital Management, Madison Dearborn Partners and Lehman Brothers. Mr. Kelly graduated cum laude from Duke University in 2002 with a BS in Economics and with minors in Math and Political Science.

# 2022: A Year of Transformation



- ▶ **Three consecutive quarters** of all-time high Net Sales and Profit in Q2-Q4
- ▶ **Continued community market share growth** every quarter since launch
- ▶ **53% Y/Y growth in hospital volume**, a key driver of overall brand performance<sup>1</sup>
- ▶ **Initiated** PIFR-2 study

## Ampreloxetine

- ▶ In study 0170, **prevented blood pressure drop and symptoms worsening in MSA**<sup>2</sup>
- ▶ **Aligned with FDA on new Phase 3 study for NDA filing** with OHSA composite score as primary endpoint
- ▶ **Three scientific platform presentations** at American Autonomic Society meeting<sup>3</sup>
- ▶ **Secured up to \$40 million** from Royalty Pharma for funding ampreloxetine development; \$25M to fund majority of new P3 study

## Financial

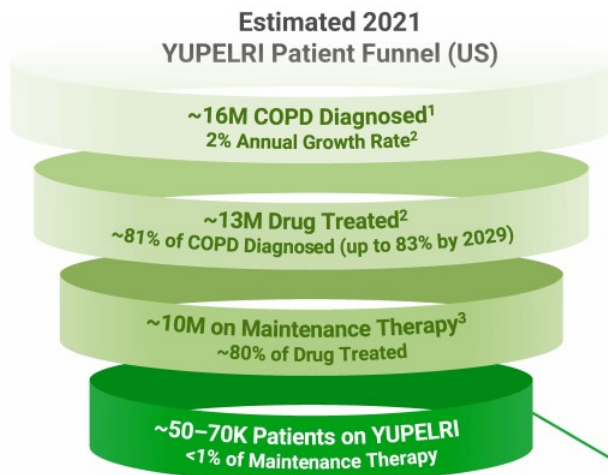
- ▶ **Sold TRELEGY ELLIPTA royalty interests for \$1.1B upfront**, while retaining value through milestones and certain outer-year royalties
- ▶ **Eliminated all debt, ~\$650 million**
- ▶ **Completed financial restructuring**
- ▶ **Initiated \$250 million capital return program**, of which ~62% was completed as of February 27, 2023

# Patent Protection Into Late 2030s

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

# Substantial Opportunity for Further YUPELRI® Growth

Once-Daily Nebulized LAMA COPD treatment represents a sizeable niche market



- ▶ COPD is **under-diagnosed**<sup>1</sup>
- ▶ COPD patients with or without symptoms may be treated with rescue and/or maintenance therapies
- ▶ Estimated patient counts from volume using average 'days of therapy' assumptions vary considerably across DME and retail channels

## Growth opportunities within numerous patient segments

YUPELRI may be appropriate for COPD patients, including but not limited to:

- ▶ **Moderate-to-very-severe COPD** (73-92%<sup>4</sup>); once-daily LAMAs are first-line therapy for moderate-to-very severe COPD patients
- ▶ Patients with **suboptimal PIFR** (19-78% of COPD patients<sup>5</sup>)
- ▶ Patients with **cognitive or dexterity challenges**
  - ~36% of COPD patients present episodes of cognitive impairment;
  - ~33% of elderly patients have inadequate hand strength for inhalers<sup>6</sup>
- ▶ Patients inappropriately using **short-acting nebulized treatment as maintenance therapy**
- ▶ Patients **transitioning from hospital to home care** after being stabilized on nebulized treatment during hospitalization

Patent No 11,484,531, methods of treating COPD, expiring in 2039, is now listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations*

1. American Lung Association.

2. Clarivate COPD Disease Landscape & Forecast US 2021.

3. Revefenacin COPD Joint Venture Research 2016.

4. Safka KA, et al. Chronic Obstr Pulm Dis 2017.

5. Mahler DA, et al. Chronic Obstr Pulm Dis 2019.

6. Armitage JM, Williams SJ. Inhaler technique in the elderly. Age Ageing 1988 17:275-278.

COPD, chronic obstructive pulmonary disease; DME, durable medical equipment; LAMA, long-acting muscarinic antagonist; PIFR, peak inspiratory flow rate.

# Offering Hope to MSA Patients with Symptomatic nOH



33rd International Symposium on the Autonomic Nervous System  
November 2–5, 2022: Sheraton Maui, Hawaii

## Platform Presentations, Session 1, November 2, 2022

### **Biaggioni I, et al. Abstract 34 / Virtual Poster 106**

A phase 3, 22-week, multi-center, randomized withdrawal study of amprelosetine in treating symptomatic nOH

### **Kaufmann H, et al. Abstract 33 / Virtual Poster 117**

Blood pressure and pharmacodynamic response of amprelosetine, a norepinephrine reuptake inhibitor, in patients with symptomatic nOH

### **Freeman R, et al. Abstract 30 / Virtual Poster 4**

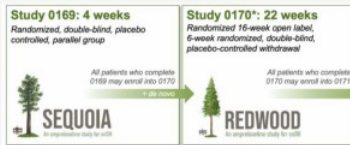
Longitudinal analysis of amprelosetine for the treatment of symptomatic nOH in subset of patients with MSA

# Shift Toward Broad Symptomatic Improvement for MSA Patients

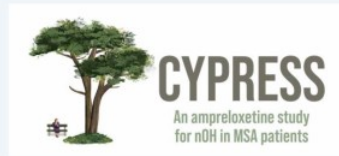
## "Old" Amprelosetine Program



### "Dizziness" based indication for short-term effectiveness



## "New" MSA-focused Amprelosetine Program

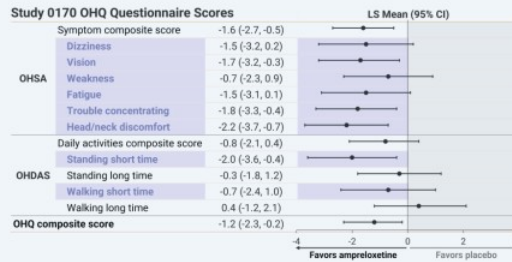


In study 0170, amprelosetine prevented blood pressure drop and symptoms worsening in MSA<sub>1</sub>

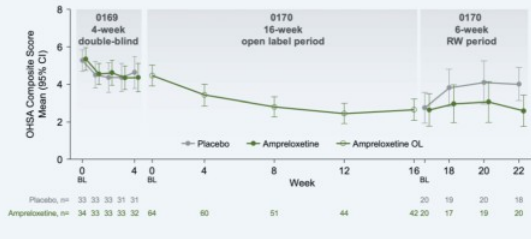
Support from the scientific and medical community with 3 scientific presentations presented at the American Autonomic Society meeting<sub>2</sub>

Aligned with FDA on new Phase 3 study for approval with OHSA composite as primary endpoint

### Constellation of symptoms-based indication



### Durable effectiveness



1. Data from MSA patients at week 6 of the randomized withdrawal period of study 0170.
  2. Biaggioni I, et al. Abstract 34 / Virtual Poster 106; Kaufmann H, et al. Abstract 33 / Virtual Poster 117; Freeman R, et al. Abstract 30 / Virtual Poster 4.
- MSA, Multiple System Atrophy; nOH, neurogenic orthostatic hypotension; OHDAS, orthostatic hypotension daily activity scale; OHQ, orthostatic hypotension questionnaire; OHSA, Orthostatic Hypotension Symptom Assessment; PAF, Pure Autonomic Failure; PD, Parkinson's Disease.



# Theravance Biopharma and Royalty Pharma Deal Summary

## TRELEGY ELLIPTA

- Upfront: \$1.1B (Received)
- Milestones: Up to \$250M

Year	Royalties <sub>2</sub>	Global Net Sales Equivalent	Milestone
2023	\$240M	\$2,863M	\$50M
2024 <sub>1</sub>	\$240M	\$2,863M	\$25M
	\$275M	\$3,213M	\$50M
2025 <sub>1</sub>	\$260M	\$3,063M	\$25M
	\$295M	\$3,413M	\$50M
2026 <sub>1</sub>	\$270M	\$3,163M	\$50M
	\$305M	\$3,513M	\$100M

- Outer Year Royalty ("OYR"): 85% of royalties for TRELEGY ELLIPTA return to Theravance Biopharma:
  - On and after January 1, 2031 for U.S. sales<sup>3</sup>
  - On and after July 1, 2029 for ex-U.S. sales<sup>3</sup>

## Ampreloxetine (Unsecured Royalty)

- Upfront payment: \$25M (Received)
- 1st Regulatory approval milestone: \$15M
  - Approval by either FDA or first of the EMA or all four Germany, France, Italy and Spain
- Future royalties paid to Royalty Pharma:
  - 2.5% on annual global net sales up to \$500M
  - 4.5% on annual global net sales > \$500M

# Q4 2022 Financial Highlights

## Beginning 2023 from a position of strength

Metric	Amount (M)	Note
Cash and Cash Equivalents <sup>1</sup> <small>(as of December 31, 2022)</small>	\$327.5	<ul style="list-style-type: none"> <li>• \$118M taxes paid in Q4'22 for sale of TRELEGY royalty interests</li> <li>• \$34M of share buybacks in Q4'22</li> <li>• \$7M of cash burn in Q4'22</li> </ul>
Shares Outstanding <small>(as of December 31, 2022)</small>	65.2	~13M shares repurchased in 2022
VIATRIS Collaboration Revenue <small>(quarter ended December 31, 2022)</small>	\$14.6	
Operating Expenses (excluding SBC) <small>(quarter ended December 31, 2022)</small>	\$25.1	
Share-Based Compensation <small>(quarter ended December 31, 2022)</small>	\$6.9	

# Fourth Quarter 2022 Financials

\$327.5 million cash<sup>1</sup> as of December 31, 2022

(\$, in thousands)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
	(Unaudited)		(Unaudited)	
<b>Revenue:</b>				
Viatrix collaboration agreement	\$ 14,613	\$ 12,132	\$ 48,624	\$ 43,848
Viatrix royalties (Non-US)	30	-	30	-
Collaboration revenue	6	2,813	192	11,463
Licensing revenue	-	-	2,500	-
Total revenue	14,649	14,945	51,346	55,311
<b>Costs and expenses:</b>				
Research and development (2)	15,347	31,225	63,392	193,657
Selling, general and administrative (2)	16,734	21,516	67,073	99,296
Restructuring and related expenses (2)	-	18,371	12,838	20,142
Total costs and expenses	32,081	71,112	143,303	313,095
<b>Loss from continuing operations (before tax and other income/expense)</b>	<b>(17,432)</b>	<b>(56,167)</b>	<b>(91,957)</b>	<b>(257,784)</b>
<b>Income from discontinued operations (before tax)</b>	<b>-</b>	<b>25,780</b>	<b>1,143,930</b>	<b>65,645</b>
<b>Share-based compensation expense:</b>				
Research and development	2,825	3,442	12,888	25,634
Selling, general and administrative	4,123	5,113	19,848	28,065
Restructuring and related expenses	-	8,362	6,998	8,362
Total share-based compensation expense	6,948	16,917	39,734	62,061
<b>Operating expense excl. share-based compensation and one-time expenses:</b>				
R&D operating expense (excl. share-based comp and restructuring exp.)	12,522	27,783	50,504	168,023
SG&A operating expense (excl. share-based comp and restructuring exp.)	12,611	16,403	47,225	71,231



1. Cash, cash equivalents and marketable securities.
2. Amounts include share-based compensation.