#### **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 12, 2023 THERAVANCE BIOPHARMA, INC. (Exact Name of Registrant as Specified in its Charter) Cayman Islands 001-36033 98-1226628 (I.R.S. Employer Identification (State or Other Jurisdiction of (Commission File Number) Incorporation) 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)) П 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: Trading Name of each exchange Title of each class Symbol(s) on which registered Ordinary Share \$0.00001 Par Value 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 Emerging growth company $\ \square$

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.  $\Box$ 

#### 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 be participating in a fireside chat at the H.C. Wainwright 25th Annual Global Investment Conference on September 12, 2023, also 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 Theravance Biopharma Investor Presentation

104 Cover Page Interactive Data File (cover page XBRL tags embedded within the Inline XBRL document)

#### 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 12, 2023

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



Medicines That Make a Difference®

# **Investor Presentation**

## September 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 impact of recent headcount reductions in connection with focusing investments in research, 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, future YUPELRI sales, 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, 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, marketin

Other risks affecting the Company are in the Company's Form 10-Q filed with the SEC on August 9, 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 Measures

Theravance Biopharma provides a non-GAAP profitability target and a non-GAAP metric in this presentation. Theravance Biopharma believes that the non-GAAP profitability target and non-GAAP net 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 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.



# Strategic Objectives to Drive Value Creation



- Continue YUPELRI Net Sales growth by executing on targeted strategies to capture sizeable niche market
- Capitalize on PIFR-2 study results, if successful

#### **Ampreloxetine**

- Drive Phase 3 CYPRESS trial to completion in MSA patients with symptomatic nOH
- ► Position ampreloxetine for regulatory and commercial success

#### **Financial**

- ► Complete expanded \$325M Capital Return by end of 2023
- ► Achieve non-GAAP¹ profitability through continued YUPELRI growth and expense management

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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 Measures" on Slide 2 for more information.

MSA, multiple system atrophy; nOH, neurogenic orthostatic hypotension; PIFR, peak inspiratory flow rate.



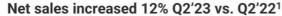
FDA-approved for maintenance treatment of COPD

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

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

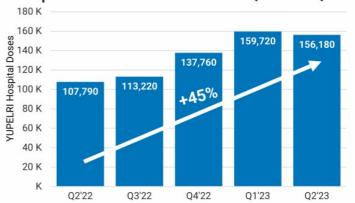


# YUPELRI® | Growing Net Sales and Hospital Volume





#### Hospital doses sold increased 45% Q2'23 vs. Q2'222



20% rolling 4-quarter growth through Q2'23

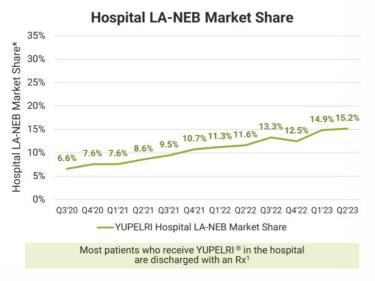
50% rolling 4-quarter growth through Q2'23

Theravance Biopharma Medicines That Make a Difference

1. In the US, Viatris is leading the commercialization of YUPELRI, and Theravance Biopharma co-promotes the product under a profit and loss sharing arrangement (65% to Viatris; 35% to Theravance Biopharma).

Viatris, 35% to Theravance Biophiama).
2. Source: IQVIA DDD, HDS, VA and Non-Reporting Hospital through 6/30/2023. Preliminary data subject to revision upon receipt of final data

# YUPELRI® Hospital and Community Share Trends





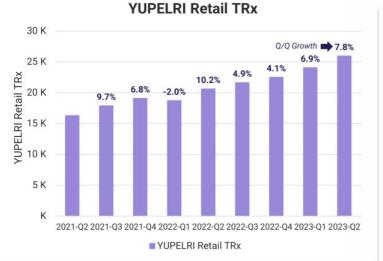
LA-NEB Market: YUPELRI, BROVANA, LONHALA, PERFOROMIST, arformoterol, formoterol

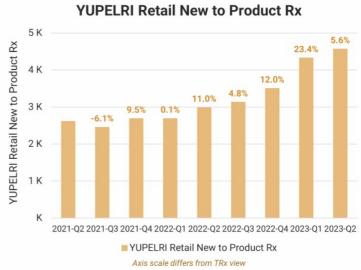
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Joint VTRS/TBPH Market Research.
 \* Hospital LA-NEB Market Share - IQVIA DDD through 6/30/2023.
 †Community LA-NEB Market Share includes Retail + DME / Med B FFS through May'23.

# YUPELRI® Retail Trends

# TRx and New Patient Starts Continue to Reach New Quarterly Highs





Biopharma Medicines That Make a Difference

ource: Symphony Health METYS Prescription Dashboard through 6/30/2023

# Substantial Opportunity for Further YUPELRI® Growth

# **Current COPD Patients** on Nebulized Therapy

**Long-Acting Nebulized Maintenance Patients** 

~200K Current Long-Acting Neb Patients

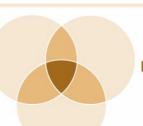
Patients Using Short-Acting Nebulized Therapy

~200K Patients Inappropriately Using Short-Acting Nebulized Treatments for Maintenance Therapy

# COPD Patients Who Could Benefit from Nebulized Therapy

~1.5M Patients on Handheld-Only Maintenance Regimens who Remain Symptomatic

Dexterity Challenges



Cognitive Impairment

Suboptimal PIFR

Addressable Patient Population (U.S.)1

#### ~2M Patients for Whom YUPELRI May Be Appropriate

~60K patients estimated to be on YUPELRI currently

Theravance Biopharma Medicines That Make a Difference

1. 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. COPD, chronic obstructive pulmonary disease; PIFR, peak inspiratory flow rate.

# **Development**

YUPELRI PIFR-2 Last patient enrolled; top-line disclosure anticipated Jan '24 CYPRESS (ampreloxetine) Last patient enrolled anticipated H2 '24



# YUPELRI®:

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



#### Sample size

- N = Up to 488 GOLD 3 and 4 patients
- Top-line disclosure anticipated Jan '24

#### **Endpoints**

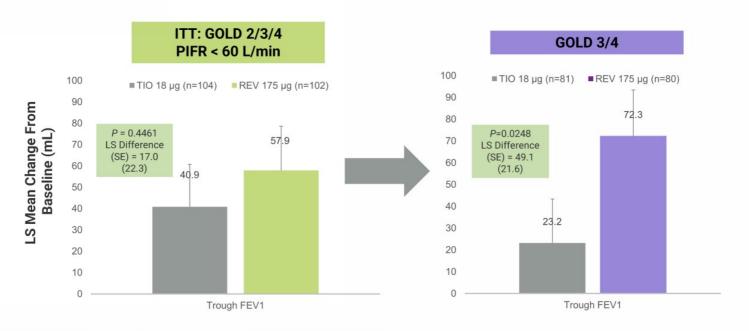
- Primary: Change from baseline in trough FEV<sub>1</sub> (Day 85)
- Key secondary: Trough overall treatment effect on FEV<sub>1</sub>

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Phase 4, Randomized, Double-Blind, Parallel-Group Study in Adults With Severe-to-Very-Severe COPD and Suboptimal Inspiratory Flow Rate. \*Dry powder inhaler (Spiriva® HandiHaler®).

COPD, chronic obstructive pulmonary disease; FEV<sub>1</sub>, forced expiratory volume in 1 second; PIFR, peak inspiratory flow rate.

# PIFR-1 Experience Informed PIFR-2 Design



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Chronic Obstr Pulm Dis. 2019; 6(4): 321–331.

Note: The ns shown are the numbers in the analysis set or subset. Evaluable ns are 90 (Tio) and 89 (Rev) for the ITT analysis and 70 (Tio) and 70 (Rev) for the subset analysis. FEV1, forced expiratory volume in one second; ITT, intent-to-treat; LS, least squares; PIFR, peak inspiratory flow rate; REV, revefenacin; SE, standard error; TIO, tiotropium.

# **Ampreloxetine**

Investigational once-daily norepinephrine reuptake inhibitor

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



# The Ampreloxetine Opportunity: Symptomatic nOH in MSA



Multiple system atrophy (MSA) is a rare, progressive neurologic disorder characterized by misfolded  $\alpha$ -synuclein in regions of the brain. It impacts autonomic processes, including blood pressure regulation and motor control and symptoms can include slow movement, rigid muscles and poor balance<sup>1</sup>.

**Neurogenic orthostatic hypotension (nOH)** is a common symptom of MSA, involving impaired regulation of standing blood pressure, due to autonomic dysfunction. Symptoms include dizziness, feeling faint, vision problems and weakness.

Approximately 50,000 persons in the U.S. suffer from MSA, and 70-90% of MSA patients (35K to 45K) experience symptoms of nOH<sup>2,3</sup>.

Current therapies addressing nOH symptoms suffer from significant safety, dosing and durability limitations.

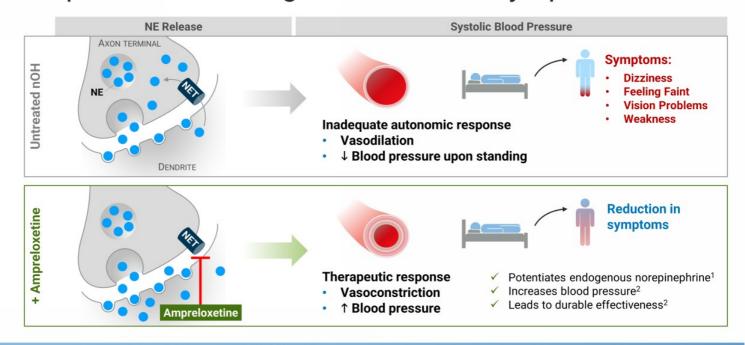
Theravance Biopharma Medicines That Make a Difference

. Wan, L., Zhu, S., Chen, Z. et al., Transl Neurodegener 12, 38 (2023).

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

. Delveinsight MSA Market Forecast (2023); Symptoms associated with orthostatic hypotension in pure autonomic failure and multiple systems atrophy, CJ Mathias (1999).

# Ampreloxetine: Designed to Reduce Symptoms in MSA



Theravance Biopharma Medicines That Make a Difference

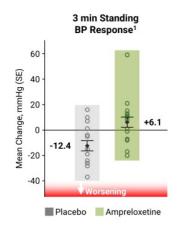
alma JA, Kaufmann H. Mov Disord Clin Pract 2017;4:298-308

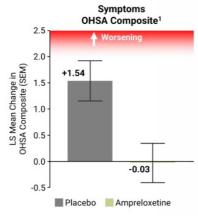
1. Data from MSA patients reported after 4 weeks of ampreloxetine administration in study 0169

Data from MSA patients at week 6 of the randomized withdrawal period of study 0170.

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

# Study 0170: Ampreloxetine Prevented Blood Pressure Drop and Symptoms Worsening in MSA<sup>1</sup>





- In Study 0170, Ampreloxetine demonstrated a standing blood pressure improvement of 18.5mm Hg compared to placebo
- In a prespecified analysis of 38 MSA patients in Study 0170, Ampreloxetine demonstrated a clinically meaningful and statistically significant improvement in the OHSA Composite score<sup>2</sup> compared to placebo
- The OHSA Composite Score has been chosen as the primary endpoint in Theravance's ongoing CYPRESS Phase 3 study

Theravance Biopharma Medicines That Make a Difference

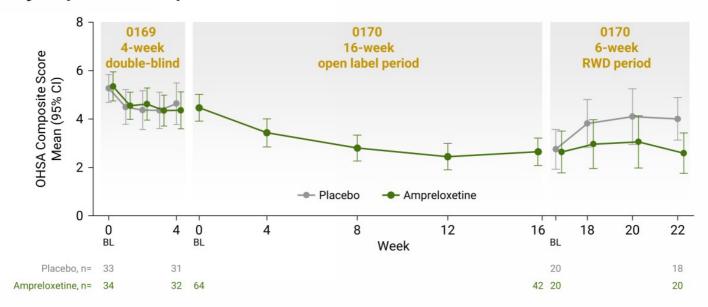
1. Data from MSA patients at week 6 of the randomized withdrawal period of study 0170 (n=33 for BP response, n=38 for OHSA Composite).

2. The OHSA Composite is a neurological assessment tool measuring six clinical symptoms of nOH – dizziness, vision problems, weakness, fatigue, trouble concentrating and head/neck discomfort.

GISCOMIONI

BD blood properties LS languages MSA multiple system attendity OHSA authoritatic hypothesical symmetry accommon SE standard error SEM standard error of man

# Studies 0169/0170: Ampreloxetine Delivered Durable Symptom Improvements in MSA

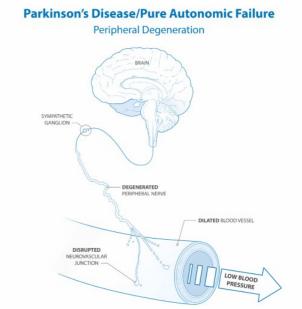


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Cl, confidence interval; MSA, multiple system atrophy; OHSA, Orthostatic Hypotension Symptom Assessment; OL, open-label; RW, randomized withdrawa

# Effective Treatment Requires Intact Peripheral Nerves

# Central Degeneration SYMPATHETIC GANGLION INTACT PERIPHERAL NERVE VASOCONSTRICTED BLOOD VESSEL FUNCTIONING NEUROPASSCULAR JUNCTION NEUROPASSCULAR NEURO



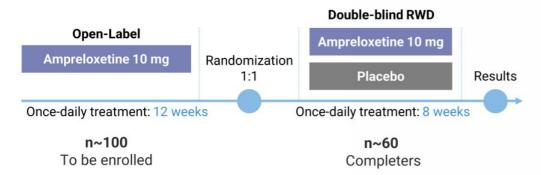
Theravance Biopharma Medicines That Make a Difference

REFERENCES:
Fanciulli A, Wenning GK. Multiple-system atrophy. N Engl J Med. 2015;372(3):249-263.
Jordan J, Shibao C, Biaggioni I. Multiple system atrophy: using clinical pharmacology to reveal pathophysiology. Clin Auton Res. 2015;25(1):53-59.
MSA, multiple system atrophy.

# **CYPRESS:**

## Phase 3 randomized withdrawal (RWD) study in patients with MSA

#### High Probability of Technical Success



#### **CYPRESS KEYS:**

- Primary Endpoint: Change in OHSA Symptoms Composite Score
  - Reduces Variability vs. Individual Symptom Score
  - Informed by Study 0170 Result
- Refined Duration of Open-Label and RWD Periods Based on 0170 Result
- Aligned with FDA

Theravance Biopharma Medicines That Make a Difference

Enrichment Strategies for Clinical Trials to Support Determination of Effectiveness of Human Drugs and Biological Products Guidance for Industry https://www.fda.gov/media/121320/download

# The Unique Benefits of Ampreloxetine Treatment



#### Unique mechanism and durable efficacy

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

Study 01	70 OHQ Questionnaire Scores			LSI	lean (959	% CI)	
	Symptoms composite score	-1.6 (-2.7, -0.5)		-	<b>-</b>		
OHSA	Dizziness	-1.5 (-3.2, 0.2)	-	•			
	Vision	-1.7 (-3.2, -0.3)	-	•	_		
	Weakness	-0.7 (-2.3, 0.9)		-	•		
	Fatigue	-1.5 (-3.1, 0.1)		•	_		
	Trouble concentrating	-1.8 (-3.3, -0.4)	-	-	<b>-</b>		
	Head/neck discomfort	-2.2 (-3.7, -0.7)	-	•	-		
	Daily activities composite score	-0.8 (-2.1, 0.4)		-	•		
	Standing short time	-2.0 (-3.6, -0.4)	-	•	_		
OHDAS	Standing long time	-0.3 (-1.8, 1.2)		_	•	-	
	Walking short time	-0.7 (-2.4, 1.0)			•		
	Walking long time	0.4 (-1.2, 2.1)		-			
OHQ comp	posite score	-1.2 (-2.3, -0.2)		-	_		
			-4	-2	0	2	4
			Equare	amnreloveti	ino Eo	vors nlaceh	

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



#### 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 any time of day/night
- · Potential to be combined with other drugs

Theravance Biopharma Medicines That Make a Difference

Reflects Theravance Biopharma's expectations for ampreloxetine based on clinical trial data to date. Ampreloxetine is in development and not approved for any indication. Data on file. 1. Data from MSA patients at week 6 of the randomized withdrawal period of study 0170. 2. NORTHERA® (droxidopa) [package insert]. Deerfield, IL: Lundbeck. 2014. 3. ProAmatine® (midodrine hydrochloride) [Warning Ref 4052798]. Lexington, MA: Shire. 2017. Cl, confidence interval; MSA, multiple system atrophy; OHDAS, orthostatic hypotension daily activity scale; OHQ, orthostatic hypotension questionnaire; OHSA, Orthostatic Hypotension Symptom Assessment.

# Ampreloxetine's Significant Potential

**MSA Prevalence** 

Prevalence of nOH in MSA Patients

**Addressable Patient Population** 

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

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

**35K - 45K** MSA patients with nOH symptoms

#### Competitive Analysis:

- No approved therapy has demonstrated a durable effect on nOH symptoms<sup>1,2</sup>
- In about half of patients with nOH, supine hypertension complicates management<sup>3</sup>
- Many MSA patients remain inadequately managed for nOH symptoms, despite available therapies<sup>4</sup>
- Long-term adherence remains low, despite genericization of approved treatments<sup>4,5</sup>

#### **Ampreloxetine Should:**

- Achieve market leadership as the only treatment proven to deliver durable nOH symptom improvement in MSA patients as measured by OSHA Composite
- Deliver considerable quality of life improvements to patients and caregivers
- Improve rates of compliance and persistence within the treated population
- Significantly expand the percentage of MSA patients treated for nOH symptoms

Theravance Biopharma Medicines That Make a Difference

Reflects Theravance Biopharma's expectations for ampreloxetine based on clinical trial data to date. Ampreloxetine 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.

# **Financial Update**



# Second Quarter 2023 Financials

	Three Months Ended June 30,					Six Months Ended June 30,			
(\$, in thousands)		2023	189	2022	2023		2022		
		(Unau	dited)	ted) (Unaud		udited)			
Revenue:									
Viatris collaboration agreement	\$	13,743	\$	10,878	\$	24,154	\$	21,565	
Collaboration revenue		6		172		12		181	
Licensing revenue	45		(0)	-	100			2,500	
Total revenue		13,749		11,050		24,166		24,246	
Costs and expenses:									
Research and development (1)		9,425		14,924		23,997		38,177	
Selling, general and administrative (1)		19,278		16,222		38,461		34,064	
Restructuring and related expenses (1)		1,169		3,005		2,743		12,329	
Total costs and expenses		29,872		34,151		65,201		84,570	
Loss from continuing operations (before tax and other income & expense)	\$	(16,123)	\$	(23,101)	\$	(41,035)	\$	(60,324)	
Income from discontinued operations (before tax)		-		14,602		=		28,915	
Share-based compensation expense:									
Research and development		1,855		2,909		4,296		7,439	
Selling, general and administrative		4,409		5,030		8,632		10,528	
Restructuring and related expenses	-	-		1,770	23	357		6,287	
Total share-based compensation expense		6,264		9,709		13,285		24,254	
Operating expense excl. share-based compensation and one-time expenses:									
R&D operating expense (excl. share-based comp and restructuring exp.)		7,570		12,015		19,701		30,738	
SG&A operating expense (excl. share-based comp and restructuring exp.)		14,869		11,192		29,829	0	23,536	
Total operating expenses excl. share-based compensation and one-time expenses	\$	22,439	\$	23,207	\$	49,530	\$	54,274	
Non-GAAP net loss from continuing operations (2)	\$	(7,355)	\$	(13,089)	\$	(22,267)	\$	(38,279)	

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<sup>1.</sup> Amounts include share-based compensation.
2. Non-GAAP net loss from continuing operations consists of GAAP net loss before taxes excluding share-based compensation expense and non-cash interest expense; see reconciliation on Slide 20 and the section titled "Non-GAAP Financial Measures" on Slide 2 for more information.

# Second Quarter 2023 Financials (Cont'd)

# Reconciliation of GAAP to Non-GAAP Net Loss from Continuing Operations (In thousands)

	Three Months Ended June 30,		Six Months Ended June 30			ine 30,		
	2023		2022		2023		2022	
	(Unaudited)			(Unaudited)				
GAAP Net Loss from Continuing Operations	\$	(15,645)	\$	(22,793)	\$	(37,733)	\$	(63,052)
Adjustments:						10.500.000.000.000.000		
Share-based compensation expense		6,264		9,709		13,285		24,254
Non-cash interest expense		568		-		1,118		-
Income tax expense (benefit)		1,458		(5)		1,063		519
Non-GAAP Net Loss from Continuing Operations	\$	(7,355)	\$	(13,089)	\$	(22,267)	\$	(38,279)

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See the section titled "Non-GAAP Financial Measures" on Slide 2 for more information.

# Q2 2023 Financial Highlights Significant Capital Returns from a Position of Strength

Metric	Q2 '23 (M)	Q2 '22 (M)	Note
VIATRIS Collaboration Revenue	\$13.7	\$10.9	
SG&A and R&D Expense, ex-SBC & One-time Items	\$22.4	\$23.2	
Share-Based Compensation	\$6.3	\$7.9	Excluding restructuring expenses in Q3'22
Non-GAAP Loss from Continuing Operations <sup>1</sup>	(\$7.4)	(\$13.1)	<ul> <li>~(\$6.2M) in Q2'23, excluding non-cash impairment charge related to sale of lab equipment</li> </ul>
Cash and Cash Equivalents <sup>2</sup> (as of quarter-end)	\$167.5	\$132.9	>\$80M of share buybacks in Q2'23
Debt (as of quarter-end)	\$0.0	\$624.7	
Shares Outstanding (as of quarter-end)	53.7	76.4	<ul> <li>~7.3M shares repurchased in Q2'23</li> </ul>



# 2023 Financial Guidance

# Expect to Generate Non-GAAP<sup>1</sup> Profit in 2H 2023

- · 2023 OPEX Guidance Range:
  - R&D: \$35M \$45MSG&A: \$45M \$55M
- · Guidance Excludes:
  - · Non-cash share-based compensation
  - · Non-recurring costs:
    - Incurred \$1.6M in Q1'23 associated with headcount reduction, \$1.2M in Q2'23 associated with lab equipment sale
    - · No further severance and termination costs expected
- · Share-Based Compensation:
  - · Expected to decline materially in 2023 vs. 2022
  - Q2'23 down 21% Y/Y, excluding restructuring costs, and 35%, including restructuring



Theravance Biopharma Medicines That Make a Difference

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 Measures" on Slide 2 for more information.

# \$325 Million Capital Return Program

On Track to Complete Program by Year-End

Complete (\$95M)

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

Open Market Share Buybacks Complete (\$169M)

✓ >\$80M completed in Q2 2023

At 6/30/23: ~\$264M completed overall; ~\$61M remaining in capital return program



# 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	\$240M	\$2,863M	\$25M
20241	\$275M	\$3,213M	\$50M
2025	\$260M	\$3,063M	\$25M
20251	\$295M	\$3,413M	\$50M
2026	\$270M	\$3,163M	\$50M
20261	\$305M	\$3,513M	\$100M

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

Q2'23 Net Sales of \$760M JYTD Net Sales of \$1.33B4

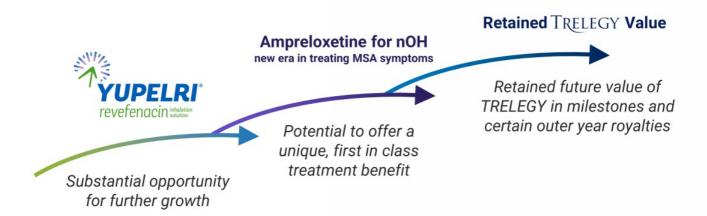
GSK remains exclusively responsible for commercialization of TRELEGY ELLIPTA



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 mild-2030s and are country specific. 4. Source: GSK-reported Net Sales in USD.

# 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

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

# Senior Leadership

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



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



Rhonda F. Farnum Senior Vice President, Chief Business Officer



Richard A. Graham Senior Vice President, Research and Development





# 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 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.

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OATP, organic anion transporting polypeptide

# 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.¹ 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.



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



# **Appendix**

# 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
Ampreloxetine	Composition of Matter	Granted US	2030 (plus PTE of up to 5 years)
	Method of Treating nOH	Granted US	2037

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OPD, Chronic obstructive pulmonary disease; nOH, neurogenic orthostatic hypotension; PTE, patent term extensions

# Viatris Collaboration Agreement Revenue

Theravance Entitled to Share of US profits (65% to Viatris; 35% to Theravance)

35% of YUPELRI® Net Sales



Reimbursement of shared Theravance expenses (65%)



Payment of shared Viatris expenses (35%)



Viatris Collaboration Agreement Revenue Cash amount receivable from Viatris<sup>1,2</sup> Collaboration Revenue, in any given period can fluctuate by the absolute and relative expenses incurred by Viatris and Theravance, in addition to the Net Sales generated in the period

Theravance Biopharma Medicines That Make a Difference

1. Any reimbursement from Viatris attributed to the 65% cost-sharing of our R&D expenses is characterized as a reduction of R&D expense.

2. Amount included as a receivable on the balance sheet as "Receivables from collaborative arrangements."

# 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
	\$240M	\$2,863M	\$25M
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	\$270M	\$3,163M	\$50M
20261	\$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

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If both milestones are achieved in a given year, Theravance Biopharma will only earn the higher milestone.
 Based on 100% of TRELEGY ELLIPTA royalties.
 U.S. royalties expected to end late 2032; ex-U.S. royalties expected to end mid-2030s and are country specific.

# Droxidopa RESTORE Study Results<sup>1</sup>

RESTORE: A post-marketing requirement under accelerated approval to evaluate the durability of droxidopa

**Basic Study Schema:** 



#### Primary Endpoint: Time to Intervention\*\*

	requiring ention	Time to In	tervention		
Placebo	Droxidopa	CP Hazard Ratio	1.04		
40 (31.7%)	41 (32.5%)	P-value	0.803		

#### RESTORE Key Items<sup>1</sup>

- RESTORE failed its primary endpoint with no significant difference between droxidopa and placebo over the 12week double-blind period
- No observed trend in favor of droxidopa across secondary endpoints which included OHSA#1 and OHQ composite

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!RESTORE results: https://classic.clinicaltrials.gov/ct2/show/results/NCT02586623
\*Number of participants treated
\*\* "intervention" can be described as a worsening of at least 2 points on the OHSA1 scale and/or discontinuation of treatment due to lack of efficacy.
CP= Cox proportional

# 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 ampreloxetine in treating symptomatic nOH

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

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

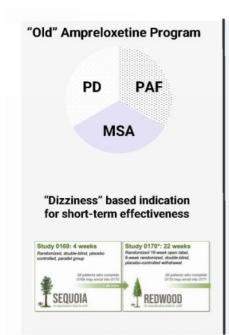
#### Freeman R, et al. Abstract 30 / Virtual Poster 4

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

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MSA, multiple system atrophy; nOH, neurogenic orthostatic hypotension

# Shift Toward Broad Symptomatic Improvement for MSA Patients



#### "New" MSA-focused Ampreloxetine Program



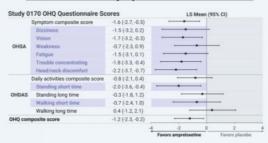


In study 0170, ampreloxetine **prevented blood pressure drop and symptoms worsening in MSA**<sub>1</sub>

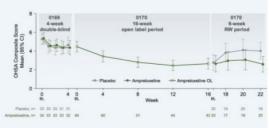
Support from the scientific and medical community with 3 scientific presentations presented at the American Autonomic Society meeting<sub>2</sub>

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

#### Constellation of symptoms-based indication



#### **Durable effectiveness**



Theravance Biopharma McMedicines That Make a Difference

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.