

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): May 8, 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)

**98-1226628**  
(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 2.02. Results of Operations and Financial Condition.**

On May 8, 2023, Theravance Biopharma, Inc. issued a press release and is holding a conference call regarding its financial results for the quarter ended March 31, 2023 and a business update. A copy of the press release is furnished as Exhibit 99.1 to this Current Report and a copy of materials that will accompany the call is furnished as Exhibit 99.2 to this Current Report.

The information in Item 2.02 and in Item 9.01 of this Current Report on Form 8-K, including Exhibits 99.1 and 99.2, is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Securities Exchange Act of 1934”), or otherwise subject to the liabilities of that Section, nor shall it be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, except as expressly set forth by specific reference in such a filing.

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

(d) Exhibits.

[99.1](#) [Press Release dated May 8, 2023](#)

[99.2](#) [Slide deck entitled First Quarter 2023 Financial Results and Business Update](#)

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: May 8, 2023

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

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### Theravance Biopharma, Inc. Reports First Quarter 2023 Financial Results and Provides Business Update

- Q1 2023 YUPELRI<sup>®</sup> (revefenacin) net sales of \$47.0 million, recognized by Viartis, up 8% from Q1 2022<sup>1</sup>
- Q1 2023 YUPELRI retail new patient starts and total prescriptions up 61% and 29%, respectively, year-over-year, reaching all-time highs<sup>2</sup>
- CYPRESS Phase 3 study of ampreloxetine recruiting; anticipate completing enrollment during H2 2024
- On track to complete \$325 million capital return program by year-end; completed \$215 million of share repurchases from inception through 4/30/23
- Jim Kelly, Managing Director at Weiss Asset Management, joins Board of Directors

**DUBLIN, IRELAND – MAY 8, 2023** – Theravance Biopharma, Inc. (“Theravance Biopharma” or the “Company”) (NASDAQ: TBPH) today announced financial and operational results for the first quarter of 2023.

“Through the beginning of 2023, we sharpened our commercial and development focus at Theravance, with YUPELRI retail new patient starts growing 61% and achieving a sixth consecutive quarter of record highs. We also delivered an important clinical milestone, having initiated enrollment for CYPRESS, our Phase 3 study for ampreloxetine, since our last update”, said Rick E Winningham, Chief Executive Officer. “With the transformation we began nearly two years ago largely completed, we are well positioned to drive an acceleration in YUPELRI performance made possible by its unique value proposition to COPD patients in both the hospital and community settings. We are determined to deliver on this opportunity, while returning substantial capital to shareholders and driving our ampreloxetine study to completion.”

“For MSA patients suffering with symptomatic neurogenic orthostatic hypotension (nOH), ampreloxetine has the potential to improve symptoms which impact their quality of life”, said Richard Graham, SVP and Head of R&D. “CYPRESS is a focused Phase 3 study designed to confirm the clinical improvements ampreloxetine has demonstrated in MSA patients with symptomatic nOH in Study 0170. We plan to complete enrollment in CYPRESS during the second half of 2024 and provide guidance on timing for top-line results as enrollment progresses.”

#### Quarterly Highlights

- **YUPELRI<sup>®</sup>** (revefenacin) inhalation solution, the first and only once-daily, nebulized bronchodilator approved in the US for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), achieved \$47.0 million Q1 2023 sales, increasing 8% year-over-year (Q1 2023 vs Q1 2022)<sup>1</sup> and increased its share of the long-acting nebulized COPD market to 27.7% through January 2023, up from 27.1% in Q4 2022. The PIFR-2 study remains on track for completion during the second half of 2023.
- **Ampreloxetine**, an investigational, once-daily norepinephrine reuptake inhibitor in development for the treatment of symptomatic neurogenic orthostatic hypotension (nOH) in patients with multiple system atrophy (MSA). The unique benefits of ampreloxetine treatment reported from Study 0170 included an increase in norepinephrine levels, a favorable impact on blood pressure, clinically meaningful and durable symptom improvements, and no signal for supine hypertension. The Company presented findings at three scientific sessions at the 2022 American Autonomic Society meeting.<sup>3</sup> Theravance has aligned with the FDA on a new Phase 3 study (CYPRESS) to support a full approval, which was initiated in Q1 2023 and is actively recruiting.

<sup>1</sup> In the US, Viartis is leading the commercialization of YUPELRI, and the Company co-promotes the product under a profit and loss sharing arrangement (65% to Viartis; 35% to the Company).

<sup>2</sup> Symphony Health METYS Prescription Dashboard.

<sup>3</sup> November 2022, 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

**\$325 Million Return of Capital Program:**

- o **Through 3/31/23:** \$55 million of share buybacks in Q1 2023 and \$183 million since inception in September 2022 through March 2023. As of 3/31/23, we had \$142 million remaining.
- o **Through 4/30/23:** \$215 million since inception in September 2022 through April 2023. As of 4/30/23, we had \$110 million remaining.
- o Expect to complete the program by the end of 2023.

**TRELEGY ELLIPTA** (first once-daily single inhaler triple therapy for COPD and asthma) GSK posted first quarter 2023 global net sales of \$567 million (up from \$454 million, or 25%, from first quarter of 2022).<sup>4</sup> Theravance Biopharma is entitled to a milestone payment from Royalty Pharma of \$50 million if TRELEGY global net sales are equal to or exceed \$2.9 billion<sup>5</sup> in 2023, the first of \$250 million of potential milestones that can be achieved between 2023 and 2026.

**First Quarter Financial Results**

**Revenue:** Total revenue for the first quarter of 2023 was \$10.4 million, consisting almost entirely of Viatris collaboration revenue. The Viatris collaboration revenue represents amounts receivable from Viatris and comprises the Company's 35% share of net sales of YUPELRI, as well as its proportionate amount of the total shared costs incurred by the two companies. The non-shared YUPELRI costs incurred by Theravance Biopharma are recorded within operating expenses. While Viatris records the total net sales of YUPELRI within its financial statements, Theravance Biopharma's implied 35% share of net sales of YUPELRI for the first quarter of 2023 was \$16.4 million which represents an 8% increase compared to the same period in 2022. Viatris collaboration revenue decreased by \$0.3 million in the first quarter compared to the same period in 2022 due primarily to timing of higher Viatris costs incurred.

Total revenue for the first quarter represents a \$2.8 million decrease compared to the same period in 2022, primarily due to a \$2.5 million non-recurring milestone payment received in the first quarter of 2022 related to the Company's licensing arrangement with Pfizer.

**Research and Development (R&D) Expenses:** R&D expenses for the first quarter of 2023 were \$14.6 million, compared to \$23.3 million in the same period in 2022. First quarter R&D expenses included total non-cash share-based compensation of \$2.4 million.

<sup>4</sup> Source: GSK-reported Net Sales in USD.

<sup>5</sup> 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. Royalties payable from GSK to Royalty Pharma are upward tiering from 6.5% to 10%.

- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses for the first quarter of 2023 were \$19.2 million, compared to \$17.8 million in the same period in 2022. First quarter SG&A expenses included total non-cash share-based compensation of \$4.2 million.
- **Stock Based Compensation:** Share-based compensation expenses for the first quarter of 2023 were \$7.0 million, compared to \$14.5 million in the same period in 2022. Excluding restructuring-related expenses, share-based compensation expenses were \$6.7 million and \$10.0 million for the first quarter of 2023 and 2022, respectively. Share-based compensation expenses consisted of \$2.5 million for R&D and \$4.2 million for SG&A in the first quarter of 2023, compared to \$4.5 million and \$5.5 million, respectively, in the same period in 2022. The significant reduction in total share-based compensation expenses was primarily driven by our 2021 restructuring, which was substantially completed in early 2022.
- **Restructuring Expenses and Related Expenses:** Restructuring expenses and related expenses for the first quarter of 2023 were \$1.6 million compared to \$9.3 million in the same period in 2022. These expenses primarily comprised severance costs, termination-related benefits, and share-based compensation expense related to the Company's 2023 strategic actions, announced in February 2023, and the Company's 2021 restructuring announced in September 2021. Cash restructuring expenses related to the 2023 strategic actions were \$1.2 million and non-cash restructuring expenses were \$0.4 million in the first quarter of 2023. We do not expect any additional employee-related restructuring expenses, including share-based compensation expenses, after the first quarter of 2023.
- **Net Loss from Operations and Non-GAAP Net Loss** (from continuing operations):<sup>6</sup> Net loss from continuing operations was \$22.1 million in the first quarter of 2023 compared to \$40.3 million in the same period in 2022, and non-GAAP net loss from continuing operations was \$14.9 million in the first quarter of 2023 compared to \$25.2 million in the same period in 2022. Non-GAAP net loss from continuing operations consists of GAAP net income (loss) from operations, excluding share-based compensation expense, non-cash interest expense, and income tax expense (benefit). See the section titled "Non-GAAP Financial Measures" for more information.
- **Cash Position:** Cash, cash equivalents and marketable securities totaled \$260.0 million as of March 31, 2023.

#### 2023 Financial Guidance

- **Operating Expenses** (excluding share-based compensation and one-time restructuring costs): The Company continues to expect full year 2023 R&D expense of \$35 million to \$45 million and SG&A expense of \$45 million to \$55 million.
- The Company reaffirms its expectation that it will generate non-GAAP profit in 2H 2023<sup>6</sup>.

#### Conference Call and Live Webcast Today at 5:00 pm ET

Theravance Biopharma will hold a conference call and live webcast accompanied by slides today at 5:00 pm ET / 2:00 pm PT / 10:00 pm IST. To participate in the live call by telephone, please register [here](#). Those interested in listening to the conference call live via the internet may do so by visiting Theravance Biopharma's website at [www.theravance.com](http://www.theravance.com), under the Investors section, Presentations and Events.

<sup>6</sup> Non-GAAP profit (loss) consists of GAAP net income (loss) before taxes less share-based compensation expense and non-cash interest expense. See the section titled "Non-GAAP Financial Measures" for more information.

A replay of the webcast will be available on Theravance Biopharma's website for 30 days through June 7, 2023.

#### About Theravance Biopharma

Theravance Biopharma, Inc.'s focus is to deliver *Medicines that Make a Difference*<sup>®</sup> in people's lives. In pursuit of its purpose, Theravance Biopharma leverages decades of expertise, which has led to the development of FDA-approved YUPELRI<sup>®</sup> (revefenacin) inhalation solution indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Ampreloxetine, its late-stage investigational norepinephrine reuptake inhibitor in development for symptomatic neurogenic orthostatic hypotension, has the potential to be a first in class therapy effective in treating a constellation of cardinal symptoms in multiple system atrophy patients. The Company is committed to creating/driving shareholder value.

For more information, please visit [www.theravance.com](http://www.theravance.com).

THERAVANCE BIOPHARMA<sup>®</sup>, THERAVANCE<sup>®</sup>, and the Cross/Star logo are registered trademarks of the Theravance Biopharma group of companies (in the U.S. and certain other countries).

YUPELRI<sup>®</sup> is a registered trademark of Mylan Specialty L.P., a Viatrix company. Trademarks, trade names or service marks of other companies appearing on this press release are the property of their respective owners.

#### Forward-Looking Statements

This press release will contain certain "forward-looking" statements as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding, among other things, statements relating to goals, plans, objectives, expectations and future events. Theravance Biopharma intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995. Examples of such statements include statements relating to: the Company's 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 Theravance Biopharma as of the date of this press release 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: 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 Theravance Biopharma 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 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 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.

Contact:  
[investorrelations@theravance.com](mailto:investorrelations@theravance.com)  
650-808-4045



**THERAVANCE BIOPHARMA, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(In thousands)

	March 31, 2023 (Unaudited)	December 31, 2022 (1)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents and short-term marketable securities	\$ 241,263	\$ 327,484
Receivables from collaborative arrangements	12,270	16,785
Prepaid clinical and development services	1,524	1,513
Other prepaid and current assets	6,281	7,682
Total current assets	261,338	353,464
Long-term marketable securities	18,776	-
Property and equipment, net	12,103	11,875
Operating lease assets	39,204	40,126
Future contingent milestone and royalty assets	194,200	194,200
Restricted cash	836	836
Other assets	12,093	6,899
Total assets	\$ 538,550	\$ 607,400
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities		
Long-term operating lease liabilities	\$ 26,184	\$ 28,715
Future royalty payment contingency	43,763	45,407
Unrecognized tax benefits	25,988	25,438
Other long-term liabilities	64,191	64,191
Shareholders' equity	7,865	1,849
Total liabilities and shareholders' equity	370,559	441,800
	\$ 538,550	\$ 607,400

<sup>(1)</sup> The condensed consolidated balance sheet as of December 31, 2022 has been derived from the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

**THERAVANCE BIOPHARMA, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(In thousands, except per share data)

	Three Months Ended March 31,	
	2023	2022
(Unaudited)		
<b>Revenue:</b>		
Viatriis collaboration agreement (1)	\$ 10,411	\$ 10,687
Collaboration revenue	6	9
Licensing revenue	-	2,500
Total revenue	10,417	13,196
<b>Costs and expenses:</b>		
Research and development (2)	14,572	23,253
Selling, general and administrative (2)	19,183	17,842
Restructuring and related expenses (2)	1,574	9,324
Total costs and expenses	35,329	50,419
<b>Loss from operations</b>		
Interest expense	(24,912)	(37,223)
Interest income and other income (expense), net	(550)	(2,137)
Loss from continuing operations before income taxes	2,979	(375)
Provision for income tax benefit (expense)	(22,483)	(39,735)
Provision for income tax benefit (expense)	395	(524)
<b>Net loss from continuing operations</b>	<b>(22,088)</b>	<b>(40,259)</b>
Income from discontinued operations before income taxes	-	14,313
Provision for income tax benefit (expense)	-	-
<b>Net income from discontinued operations</b>	<b>-</b>	<b>14,313</b>
<b>Net loss</b>	<b>\$ (22,088)</b>	<b>\$ (25,946)</b>
<b>Net income (loss) per share:</b>		
Continuing operations - basic and diluted	\$ (0.35)	\$ (0.53)
Discontinued operations - basic and diluted	\$ -	\$ 0.19
Net income (loss) - basic and diluted	\$ (0.35)	\$ (0.34)
Shares used to compute per share calculations - basic and diluted	62,934	75,247
<b>Non-GAAP net loss from continuing operations</b>	<b>(14,912)</b>	<b>(25,190)</b>

(1) While Viatriis, Inc. records the total YUPELRI net sales, the Company is entitled to a 35% share of the net profit (loss) pursuant to a co-promotion agreement with Viatriis as presented below:

(In thousands)	Three Months Ended March 31,	
	2023	2022
YUPELRI net sales (100% recorded by Viatriis)	\$ 46,955	\$ 43,666
YUPELRI net sales (Theravance Biopharma implied 35%)	16,434	15,283

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

(In thousands)	Three Months Ended March 31,	
	2023	2022
Research and development	\$ 2,441	\$ 4,530
Selling, general and administrative	4,223	5,498
Restructuring and related expenses	357	4,517
Total share-based compensation expense	\$ 7,021	\$ 14,545

**THERAVANCE BIOPHARMA, INC.**  
**Reconciliation of GAAP to Non-GAAP Net Income from Continuing Operations**  
(In thousands, except per share data)

	<u>Three Months Ended March 31,</u>	
	<u>2023</u>	<u>2022</u>
	(Unaudited)	
<b>GAAP Net Loss from Continuing Operations</b>	\$ (22,088)	\$ (40,259)
<u>Adjustments:</u>		
Share-based compensation expense	7,021	14,545
Non-cash interest expense	550	-
Income tax expense (benefit)	(395)	524
<b>Non-GAAP Net Loss from Continuing Operations</b>	<u>\$ (14,912)</u>	<u>\$ (25,190)</u>
<b>Non-GAAP Net Loss per Share from Continuing Operations</b>		
Net loss - basic and diluted	<u>\$ (0.24)</u>	<u>\$ (0.33)</u>
Shares used to compute per share calculations - basic and diluted	<u>62,934</u>	<u>75,247</u>



# First Quarter 2023 Financial Results and Business

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May 8, 2023

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# Forward-Looking Statements

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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, headcount reductions in connection with focusing investments in research, the Company's governance policies and plans, the Company's expectations regarding its 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 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 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 such forward-looking statements include, among others, risks related to: whether the milestone thresholds can be achieved, delays or difficulties in commencing, enrolling and 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 from other products, decisions from regulatory authorities that are unfavorable to the Company, dependence on third parties to conduct clinical studies, delays or failure to achieve and receive 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 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, 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 those risks set forth 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 statement 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.

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# Agenda

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## Introduction and Overview

**Rick E Winningham**  
Chief Executive Officer

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## Commercial and Development Update

**Rhonda F. Farnum**  
Senior Vice President, Chief Business Offi  
**Richard A. Graham**  
Senior Vice President, Research and Deve

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## Financial Update

**Aziz Sawaf**  
Senior Vice President, Chief Financial Offi

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## Closing Remarks

**Rick E Winningham**  
Chief Executive Officer

# 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

## Amprexetine

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

## Financial

- ▶ **Expanded Capital Program to \$325M** to complete by end of 2023
- ▶ **Generate Non-GAAP Profit** in 2H'23
- ▶ **\$50M potential milestone** on TRELEGEY Net Sales

# Progress Against 2023 YUPELRI<sup>®</sup> Targets

## Strong Demand Growth in Both Hospital and Community Settings

### Target

- ▶ **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



### Progress

- ▶ **Total YUPELRI reported net sales reach \$47.0M up 8%**
- ▶ **Retail new patient starts are prescriptions up 61% and 2 accelerating from Q4**
- ▶ **YUPELRI market shares are new highs**
- ▶ On track to complete **PIFR-** and provide top-line results

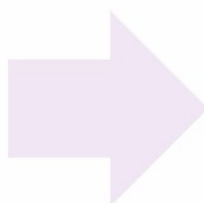


# Progress Against 2023 Ampreloxetine Targets

## Milestones Achieved with CYPRESS Study

### Target

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



### Progress

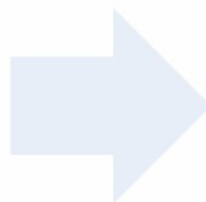
- ▶ **Initiated Phase 3 CYPRESS** in MSA patients with symptomatic nOH in Q1'23
- ▶ Submitted **orphan drug designation** request in early
- ▶ Anticipate **completing CYPRESS enrollment** in 2H'24

# Progress Against 2023 Financial Targets

## Substantial Progress Made on Buyback Program

### Target

- ▶ **Expanded Capital Return Program to \$325M**, and expect to complete by end of 2023
- ▶ **Generate Non-GAAP<sup>1</sup> Profit** in 2H'23
- ▶ **\$50M potential milestone** for TRELEGY Net Sales of ~\$2.86B<sup>2</sup>



### Progress

- ▶ **On track for 2023 completion** - \$87M completed YTD through 4/30/23, with \$110M remaining
- ▶ **Remain on track to generate GAAP<sup>1</sup> Profit** in 2H'23
- ▶ **\$567M TRELEGY Net Sales** Q1'23



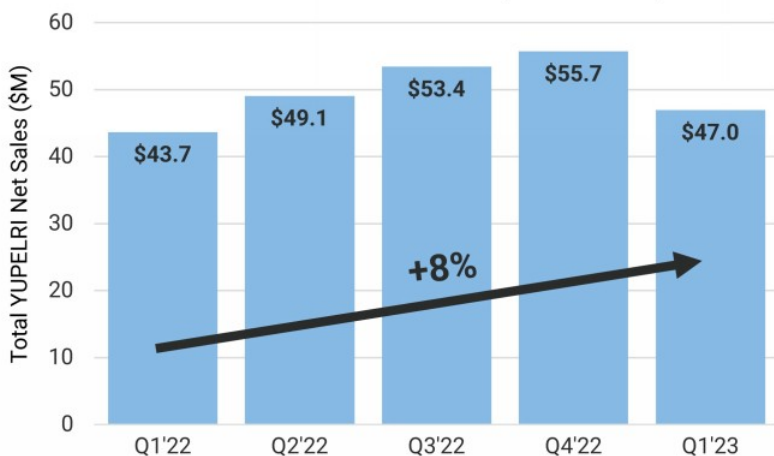
FDA-approved for maintenance treatment of COPD

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

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

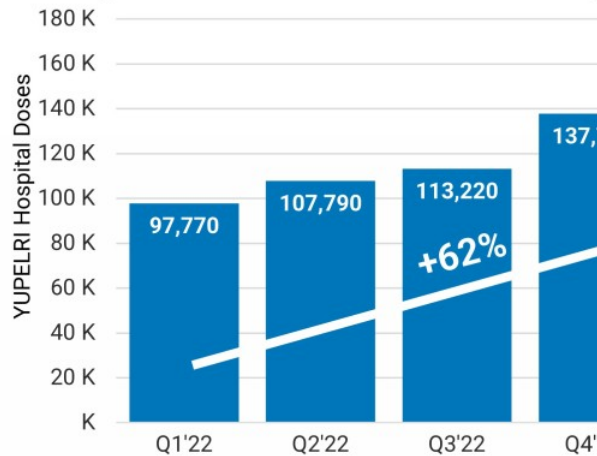
# YUPELRI® | Growing Net Sales and Hospital Volume

Net sales increased 8% Q1'23 vs. Q1'22<sup>1</sup>



22% rolling 4-quarter growth through Q1'23

Hospital doses sold increased 62% Q1'23 vs. Q1'22



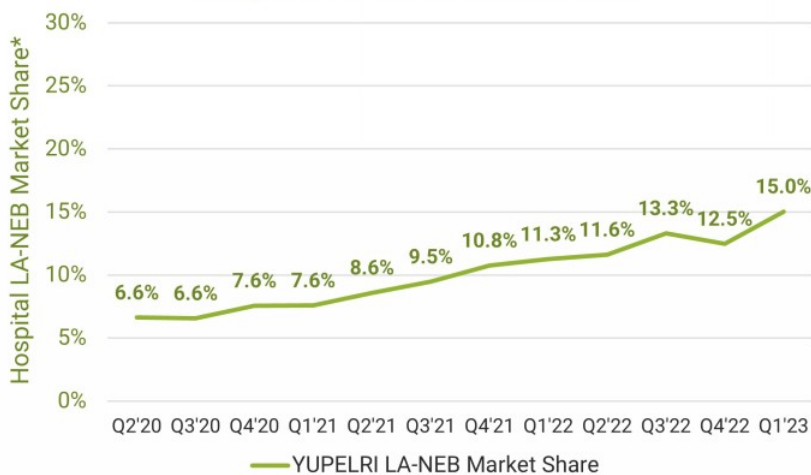
52% rolling 4-quarter growth through Q1'23



1. In the US, Viatrix is leading the commercialization of YUPELRI, and Theravance Biopharma co-promotes the product under a profit and loss sharing arrangement (35% to Viatrix; 35% to Theravance Biopharma).  
Source: IQVIA DDD, HDS, VA and Non-Reporting Hospital through 3/31/2023.

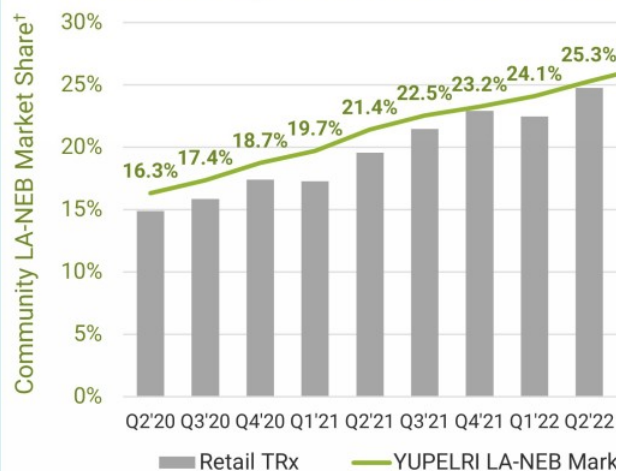
# YUPELRI® Hospital and Community Share Trend

## Hospital LA-NEB Market Share



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

## Community LA-NEB Market Share



TRx volume represents retail only which is typically 33% Reported DME volume, while lagged, typically follows Re

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



1. Joint VTRS/TBPH Market Research.

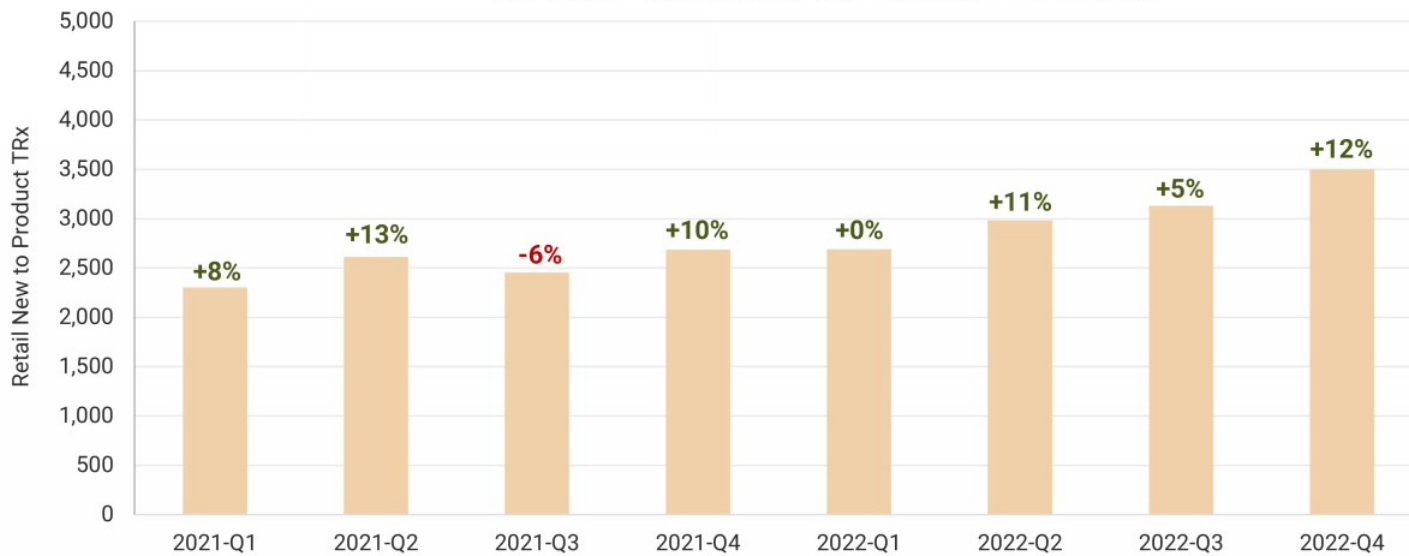
\* Hospital LA-NEB Market Share - IQVIA DDD through 3/31/2023.

†Community LA-NEB Market Share includes Retail + DME / Med B FFS through Jan'23

‡Retail TRx Volume - Symphony Health METYS Prescription Dashboard through 3/31/2023.

# Continued Record-High Retail New Patient Starts: 61% Y/Y and 23% Q/Q growth; Key Driver of Future Brand Performance

YUPELRI® Retail New to Product TRx Trends<sup>1</sup>

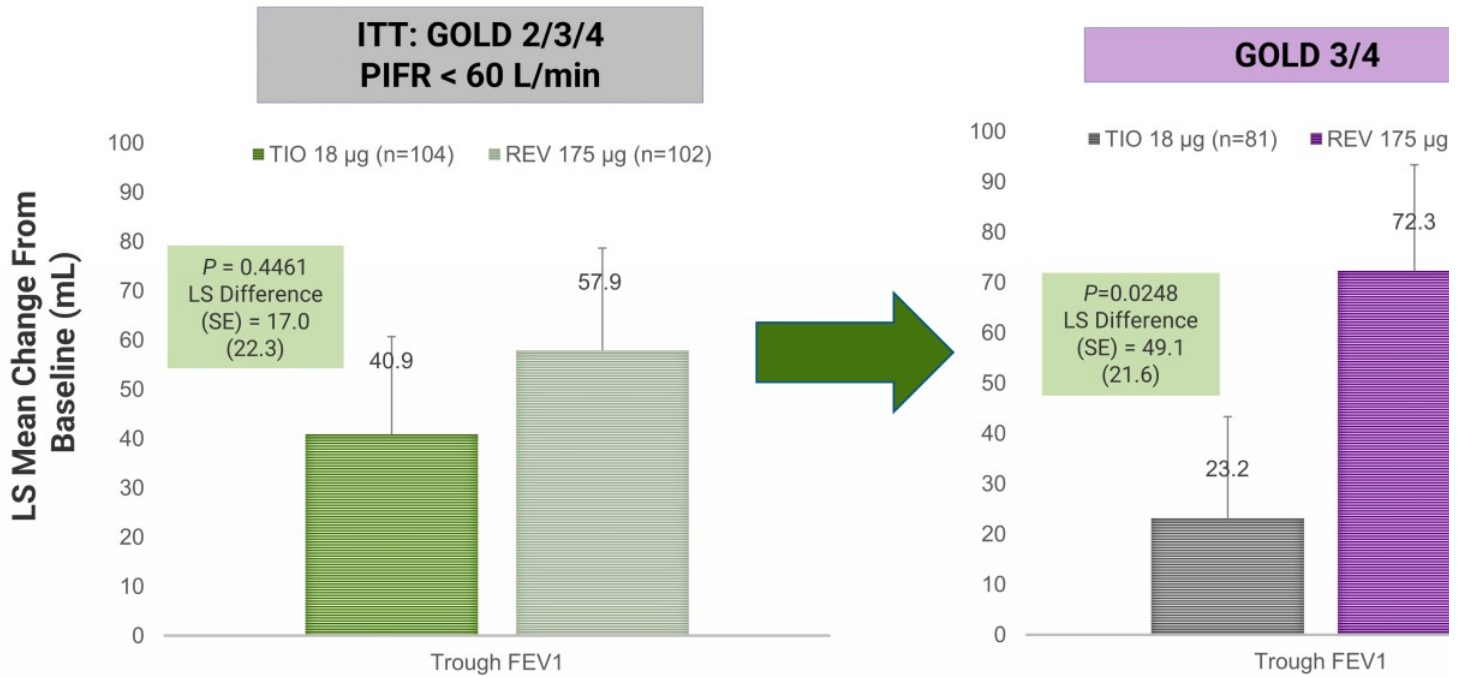


# Development

YUPELRI PIFR-2 Top-line results anticipated H2 '23

CYPRESS (ampreloxetine) Last patient enrolled anticipated H2 '24

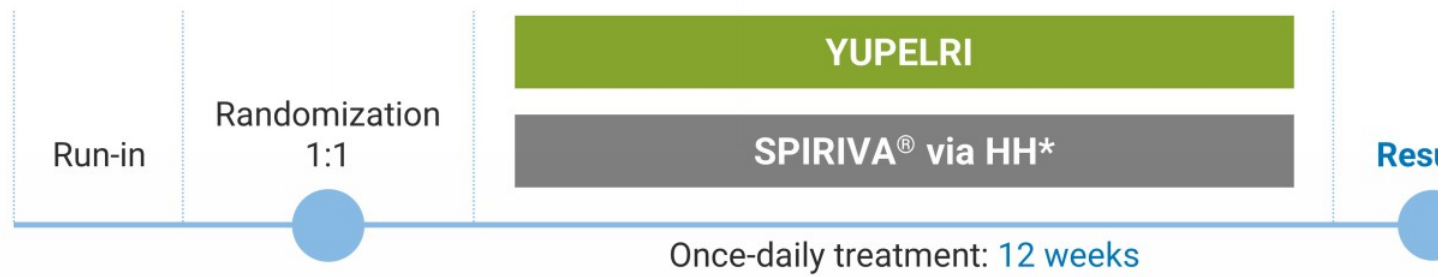
# PIFR-1 Experience Informed PIFR-2 Design





# YUPELRI®:

## Phase 4 Randomized, Double-Blind, Parallel-Group Study (PIFI



### Sample size

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

### Endpoints

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

# Ampreloxetine

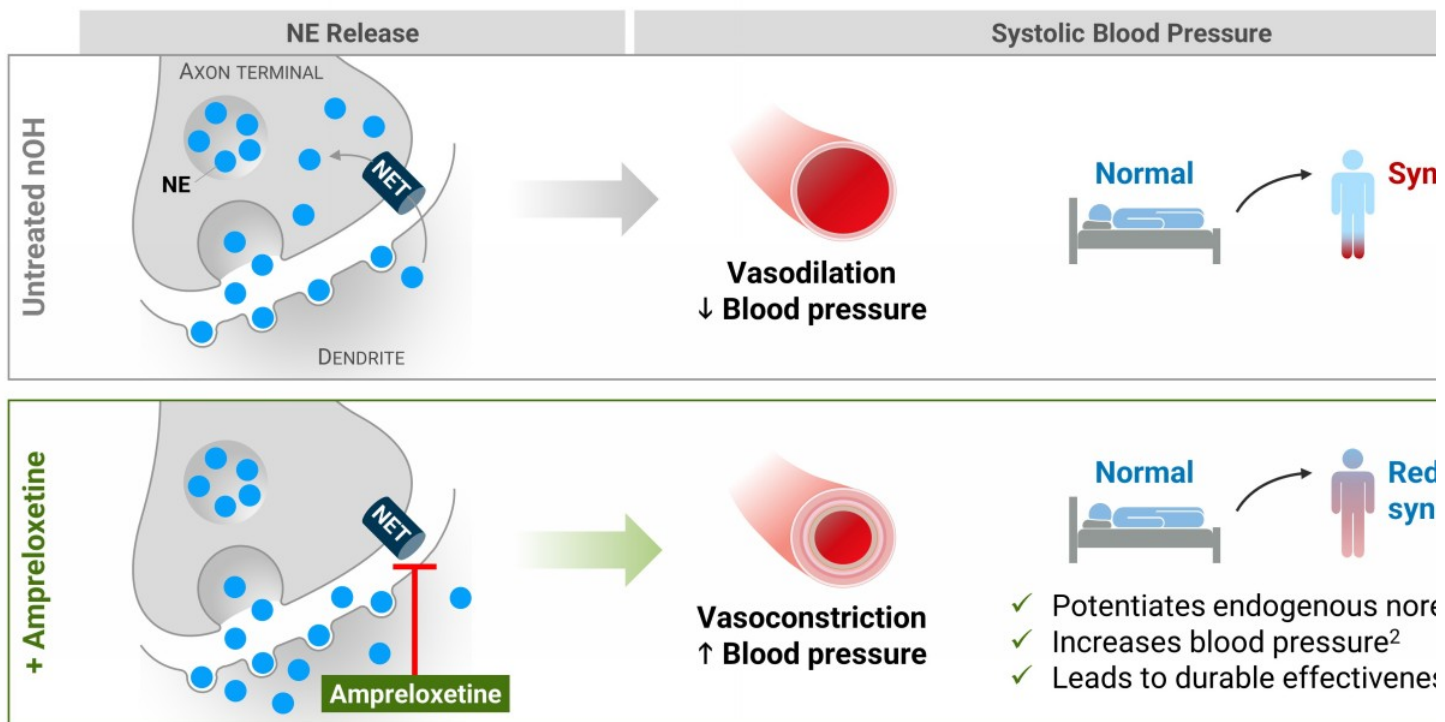
Investigational once-daily norepinephrine reuptake inhibitor

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

# Our CYPRESS Study is Now Recruiting

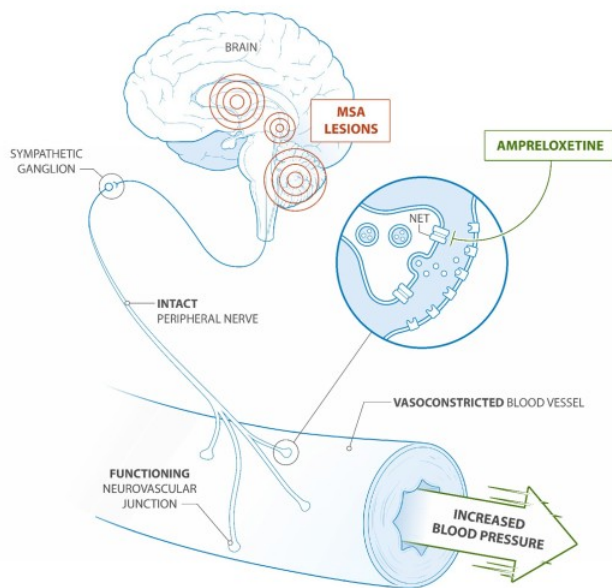


# Amprexetine: Designed to Reduce Symptoms i

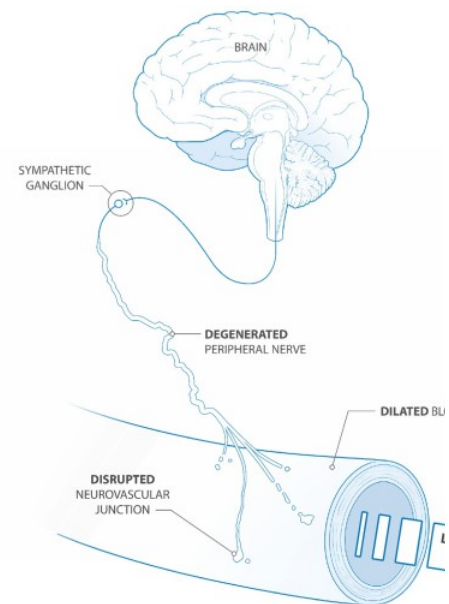


# Effective Treatment Requires Intact Peripheral N

## Multiple System Atrophy Central Degeneration



## Parkinson's Disease/Pure Autonomi Peripheral Degeneration



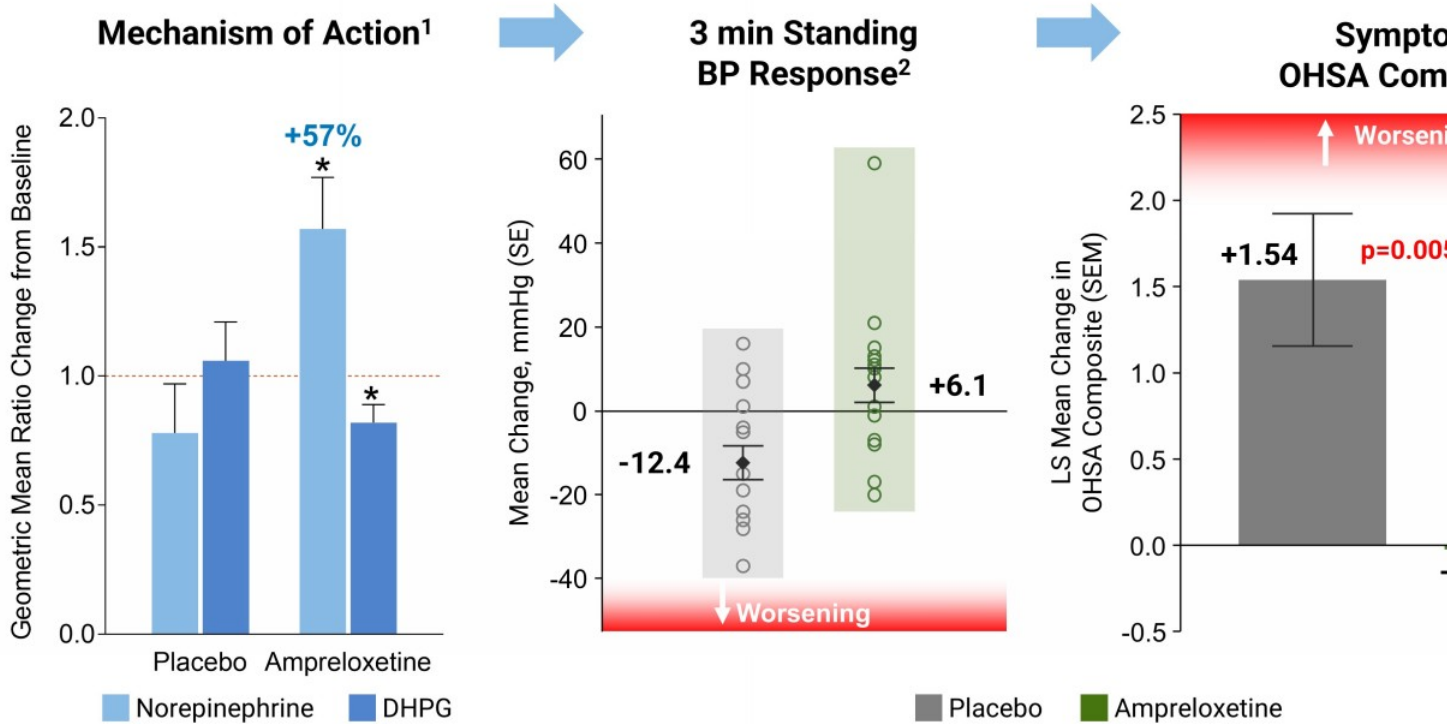
### REFERENCES:

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.

# Increased Norepinephrine, Prevented Blood Pressure Drop Symptoms Worsening in MSA<sup>1, 2</sup>

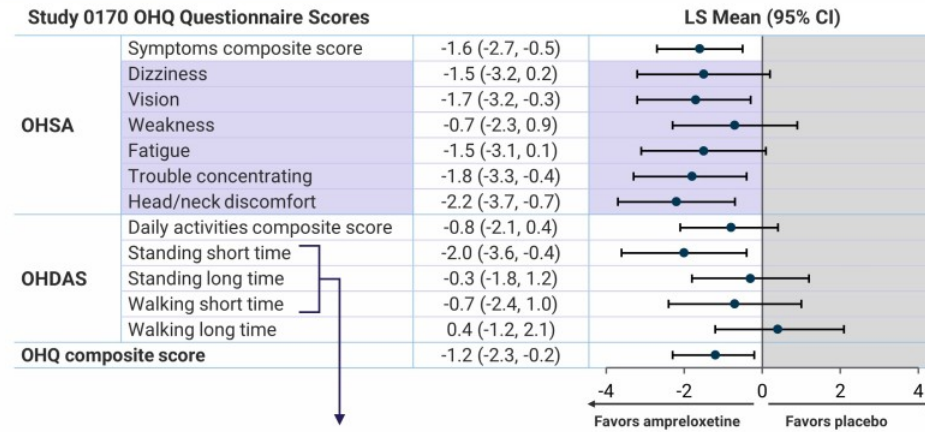


# The Unique Benefits of Ampreloxetine Treatment



## 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 **lasting effectiveness** well beyond 2 weeks



## Patient-friendly dosing

MSA patients may have **difficulty swallowing**

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



## Differentiated safety

**Supine hypertension** with droxidopa  
**Absence** of a signal would be a differentiator

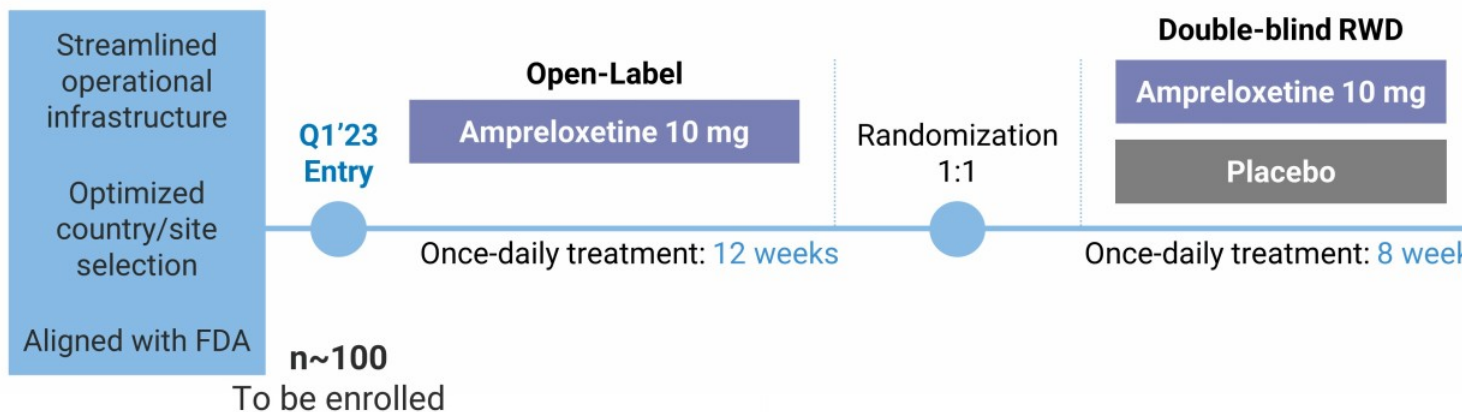
- Available to patients with supine hypertension
- Can be taken anytime of day/night
- Potential to be combined with other therapies



Reflects Theravance Biopharma's expectations for ampreloxetine based on clinical trial data to date. Ampreloxetine is in development and not approved 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: Shire. 2017. CI, confidence interval; MSA, multiple system atrophy; OHDAS, orthostatic hypotension daily activity scale; OHQ, orthostatic hypotension questionnaire; OHSA, Orthostatic Hypotension Symptom Assessment.

# Offering Hope to MSA Patients with Symptom

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





# New Era in Treating MSA Symptoms: Product Pos

## 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

35K – 45K MSA pa  
nOH sympto

## Current Treatment Landscape

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



Reflects Theravance Biopharma's expectations for amprelosetine based on clinical trial data to date. Amprelosetine is in development and not approved for any indication. 1. National Institute of Neurological Disorders and Stroke (NINDS) Multiple System Atrophy (MSA) Clinical Guidelines (2015). 2. DelveInsight MSA Market Forecast (2020-2027). 3. NORTHERA® (droxidopa) [package insert]. Deerfield, IL: Theravance Biopharma; 2017. 4. ProAmatine® (midodrine hydrochloride) [Warning Ref 4052798]. Lexington, MA: Shire; 2017. MSA, multiple system atrophy; nOH, neurogenic orthostatic hypotension; OHSA, Orthostatic Hypotension Symptom Assessment.

# Financial Update

# First Quarter 2023 Financials

(\$, in thousands)	Three Months Ended March 31,	
	2023	2022
	(Unaudited)	
<b>Revenue:</b>		
Viatris collaboration agreement	\$ 10,411	\$ 10,687
Collaboration revenue	6	9
Licensing revenue	-	2,500
Total revenue	10,417	13,196
<b>Costs and expenses:</b>		
Research and development (1)	14,572	23,253
Selling, general and administrative (1)	19,183	17,842
Restructuring and related expenses (1)	1,574	9,324
Total costs and expenses	35,329	50,419
<b>Loss from continuing operations (before tax and other income &amp; expense)</b>	<b>(24,912)</b>	<b>(37,223)</b>
<b>Income from discontinued operations (before tax)</b>	<b>-</b>	<b>14,313</b>
<b>Share-based compensation expense:</b>		
Research and development	2,441	4,530
Selling, general and administrative	4,223	5,498
Restructuring and related expenses	357	4,517
Total share-based compensation expense	7,021	14,545
<b>Operating expense excl. share-based compensation and one-time expenses:</b>		
R&D operating expense (excl. share-based comp and restructuring exp.)	12,131	18,723
SG&A operating expense (excl. share-based comp and restructuring exp.)	14,960	12,344
<b>Total operating expenses excl. share-based compensation and one-time expenses</b>	<b>27,092</b>	<b>31,067</b>
<b>Non-GAAP net loss from continuing operations (2)</b>	<b>(14,912)</b>	<b>(25,190)</b>



1. 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 in reconciliation on Slide 25 and the section titled "Non-GAAP Financial Measure" on Slide 2 for more information.

# First Quarter 2023 Financials

(Cont'd)

## Reconciliation of GAAP to Non-GAAP Net Income from Continuing Operations (In thousands, except per share data)

	Three Months Ended March 31,	
	2023	2022
	(Unaudited)	
<b>GAAP Net Loss from Continuing Operations</b>	\$ (22,088)	\$ (40,25)
<u>Adjustments:</u>		
Share-based compensation expense	7,021	14,54
Non-cash interest expense	550	-
Income tax expense (benefit)	(395)	52
<b>Non-GAAP Net Loss from Continuing Operations</b>	<b>\$ (14,912)</b>	<b>\$ (25,19)</b>
<b>Non-GAAP Net Loss per Share from Continuing Operations</b>		
Net loss - basic and diluted	\$ (0.24)	\$ (0.3)
Shares used to compute per share calculations - basic and diluted	62,934	75,24

# Q1 2023 Financial Highlights

## Significant Capital Returns from a Position of Strength

Metric	Q1 '23 (M)	Q1 '22 (M)	Note
VIATRIS Collaboration Revenue	\$10.4	\$10.7	
SG&A and R&D Expense, ex-SBC & One-time Items	\$27.1	\$31.1	
Share-Based Compensation	\$6.7	\$10.0	• Excluding restructuring expenses
Non-GAAP Loss from Continuing Operations <sup>1</sup>	(\$14.9)	(\$25.2)	
Cash and Cash Equivalents <sup>2</sup> (as of quarter-end)	\$260.0	\$147.5	• \$55M of share buybacks in Q1'23
Debt (as of quarter-end)	\$0.0	\$621.5	
Shares Outstanding (as of quarter-end)	60.5	76.1	• ~5.2M shares repurchased in Q1'23



1. Non-GAAP loss from continuing operations consists of GAAP loss before taxes excluding share-based compensation expense and non-cash interest expense on Slide 25 and the section titled "Non-GAAP Financial Measure" on Slide 2 for more information.  
 2. Cash, cash equivalents and marketable securities.  
 SBC, Share-Based Compensation.

# \$325 Million Capital Return Program

On Track to Complete Program by Year-End

## Complete (\$95M)

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

## Open Market Share Buybacks Complete (\$120M)

- ✓ ~\$33M completed in Dec'22
- ✓ ~\$55M completed in 2023, through 3/31/23
- ✓ ~\$87M completed in 2023, through 4/30/23

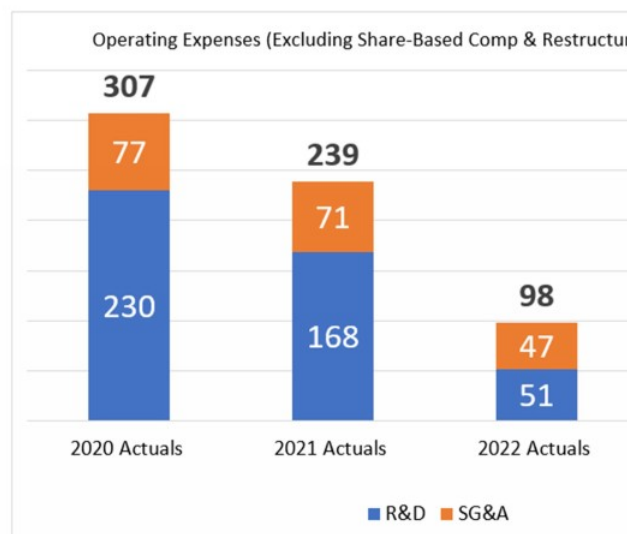
As of 3/31/23: \$183M complete; \$142M remaining

As of 4/30/23: \$215M complete; \$110M remaining

# 2023 Financial Guidance

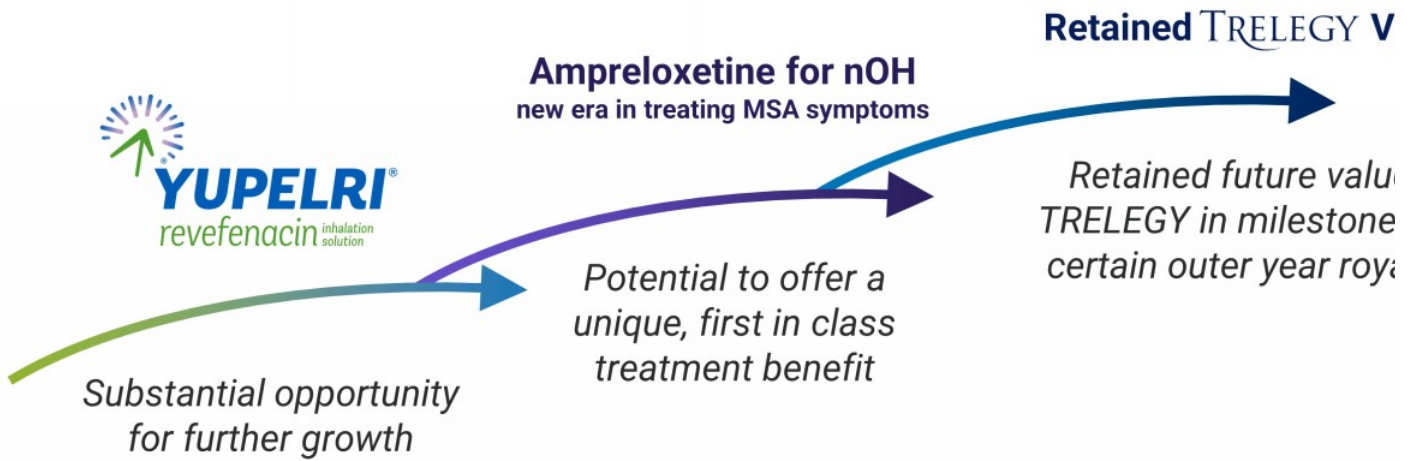
Expected to Generate Non-GAAP<sup>1</sup> Profit in 2H 2023

- 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:
    - Incurred \$1.6M in Q1'23
    - No further severance and termination costs expected
- Share-Based Compensation:
  - Expected to decline materially in 2023 vs. 2022
  - Q1'23 down 34% year-over-year, excluding restructuring costs, and 52%, including restructuring



# Theravance Biopharma: Positioned for Value Creat

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



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



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



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



# 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 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 during dosing with YUPELRI, it should be treated immediately with an inhaled, short-acting bronchodilator. YUPELRI should be discontinued immediately and 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 arcs, or 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 consult their healthcare provider immediately if symptoms occur.

Immediate hypersensitivity reactions may occur after administration of YUPELRI. If a reaction occurs, YUPELRI should be stopped and appropriate 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 which were not included in the placebo group, 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 nebulized maintenance therapy.<sup>1</sup> LAMAs are a cornerstone of maintenance therapy for COPD and YUPELRI® is positioned as the single-agent bronchodilator product for COPD patients who require, or prefer, nebulized therapy. YUPELRI®'s stability in dose inhaler and dry powder device formulations suggest that this LAMA could also serve as a foundation for combination products.



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



# Appendix

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# Patent Protection Into Late 2030s

Compound	Invention	Granted / Pending Application	Estimated Patent Expiration
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

# Viатris Collaboration Agreement Revenue

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

35% of YUPELRI® Net Sales



Reimbursement of shared Theravance expenses (65%)



Payment of shared Viатris expenses (35%)



Viатris Collaboration Agreement Revenue

*Cash amount receivable from Viатris<sup>1,2</sup>*

Collaboration Revenue given period can fluctuate absolute and relative expenses incurred by Viатris Theravance, in addition to Sales generated in the

# TRELEGY ELLIPTA Milestones and Royalties

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

## 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

Q1'23 Net Sales of \$567M | 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

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



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. 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 return in late 2032; ex-U.S. royalties expected to end mid-2030s and are country specific. 4. Source: GSK-reported Net Sales in USD for FF, Fluticasone Furoate; UMEC, Umeclidinium; VI, Vilanterol.

# Theravance Biopharma and Royalty Pharma Deal S

## 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>

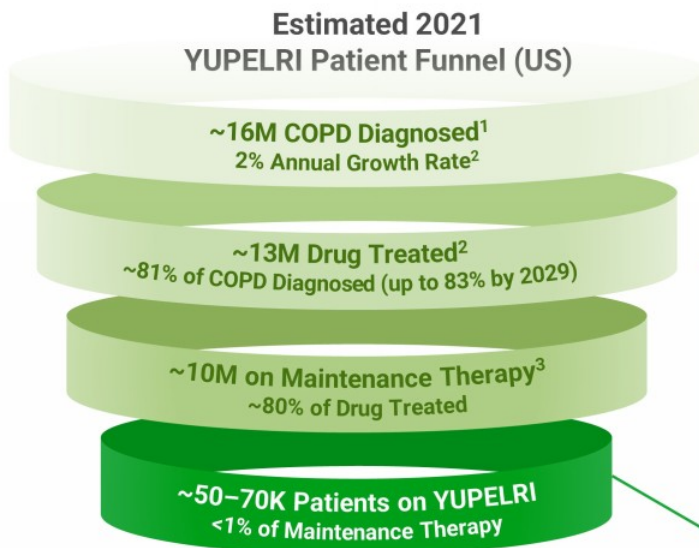
## Amprexetine (Unsecured Royalty)

- Upfront payment: \$25M (Received)
- 1st Regulatory approval milestone: \$15M
  - Approval by either FDA or first of the EMA, 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



# 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 maintenance therapies
- ▶ Estimated patient counts from volume using average 'days of 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 the preferred 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
- ▶ 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*

# Offering Hope to MSA Patients with Symptom



33rd International Symposium on the Autonomic Nervous Sys  
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 symptom

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

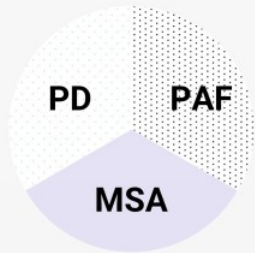
Blood pressure and pharmacodynamic response of amprelosetine, a norepinephrine reuptake inhibit  
in patients with symptomatic nOH

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

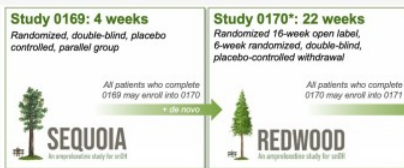
Longitudinal analysis of amprelosetine for the treatment of symptomatic nOH in subset of patients w

# Shift Toward Broad Symptomatic Improvement for MSA

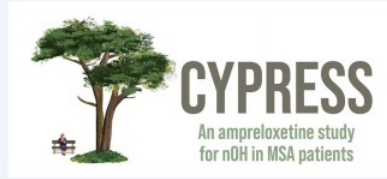
## "Old" Amprelosetine Program



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



## "New" MSA-focused Amprelosetine Program

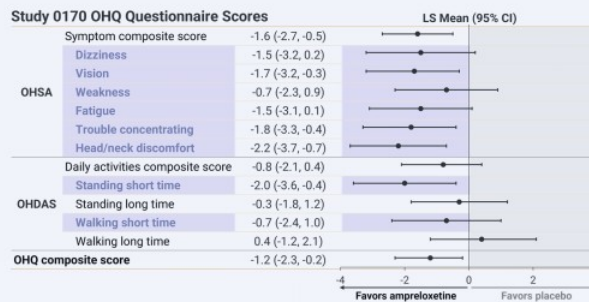


In study 0170, amprelosetine pressure drop and symptom

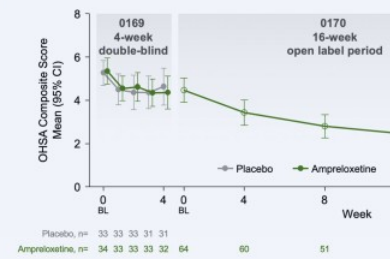
Support from the scientific with 3 scientific presentation American Autonomic Societ

Aligned with FDA on new Ph approval with OHSA compo:

## 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; OHSA, Orthostatic Hypotension Symptom Assessment; PAF, Pure Autonomic Failure; PD, Parkinson's Disease.

# 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 interests for \$1.1B** up retaining value through certain outer-year royalties
- ▶ **Eliminated all debt**, ~\$
- ▶ **Completed financial re**
- ▶ **Initiated \$250 million program**, of which ~6% completed as of Febru