

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): January 9, 2023

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

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

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

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

**PO Box 309**  
**Ugland House, South Church Street**  
**George Town, Grand Cayman, Cayman Islands KY1-1104**  
**(650) 808-6000**  
(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

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

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

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

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

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

Emerging growth company

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

**Item 2.02. Results of Operations and Financial Condition.**

*The information in this Current Report (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, or otherwise subject to the liabilities of that Section. The information in this Current Report (including Exhibits 99.1 and 99.2) 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.*

On January 9, 2023, Theravance Biopharma, Inc. (the “Company”) issued a press release providing a business update. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Additionally, members of the Company management team will be conducting one-on-one meetings with analysts and investors in San Francisco, CA from January 9-12, 2023, using a slide presentation which includes an update regarding the Company’s anticipated operating expense range for the year ended December 31, 2022 and is being furnished as Exhibit 99.2 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](#) [Press Release dated January 9, 2023](#)

[99.2](#) [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, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**THERAVANCE BIOPHARMA, INC.**

Date: January 9, 2023

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

---



### Theravance Biopharma, Inc. Highlights 2022 Accomplishments and 2023 Key Targets

- Strategic priorities focused on continued Net Sales growth for YUPELRI® (revefenacin) and conduct of the amprelosetine Phase 3 study (CYPRESS) in Multiple System Atrophy (MSA) patients with symptomatic neurogenic orthostatic hypotension (nOH)
- Initiate CYPRESS study in Q1 2023 and submit orphan drug designation in early 2023
- Complete PIFR-2 study for YUPELRI® in 2H 2023
- Execute \$250 million return of capital program, of which ~50% has been completed as of 12/31/2022
- Achieve Non-GAAP<sup>1</sup> profitability by 2H 2023

**DUBLIN, IRELAND – JANUARY 9, 2023** – Theravance Biopharma, Inc. (“Theravance Biopharma” or the “Company”) (NASDAQ: TBPH) today announced its 2022 Accomplishments and 2023 Key Targets.

*“Last year was a transformative year for Theravance Biopharma and demonstrates the power of a team that leans into the Company’s values and core purpose: delivering medicines that make a difference. After restructuring in late 2021, we narrowed our focus, executed on our strategy, and delivered on our key goals. YUPELRI produced all-time high net sales, profitability, and market share in Q2 and Q3, and we expect continued growth in Q4 and beyond. Positive PIFR-2 results in 2023 will enhance the growth trajectory of YUPELRI. Based on successful discussions with the FDA, we will conduct one additional study in MSA patients which is planned to start in Q1 2023. With the new study and a substantial body of preclinical and clinical data in-hand, we have confidence in our ability to file an NDA for amprelosetine as a treatment for MSA patients with symptomatic nOH. The sale of our TRELEGY ELLIPTA royalty interests to Royalty Pharma for over \$1.5 billion in potential value enabled us to eliminate all of our debt and has facilitated the initiation of a return of capital program to shareholders.*

*We are excited about the future of the Company and grateful for the team that has refocused the portfolio and reinvigorated our business model. With an attractive financial profile and several planned near-term milestones, we are well positioned to create shareholder value in 2023 and beyond,”* said Rick E Winningham, Chief Executive Officer.

#### 2022 Accomplishments:

- **YUPELRI®** (revefenacin):
  - o Two consecutive quarters of all-time high Net Sales and Profit in Q2 2022 & Q3 2022, and expect continued growth in Q4 2022
  - o 11 consecutive quarters of market share growth in both hospital and outpatient setting
  - o 56% Y/Y growth in hospital volume, a key driver of overall brand performance<sup>2</sup>
  - o Initiated PIFR-2 study

<sup>1</sup> Non-GAAP profit is expected to consist of GAAP income before taxes less share-based compensation expense and non-cash interest expense. See the section titled “Non-GAAP Financial Measure” for more information.

<sup>2</sup> Year-to-date through Q3 2022.

- **Ampreloxetine:**
  - In Study 0170, prevented blood pressure drop and symptoms worsening in MSA<sup>3</sup>
  - Aligned with FDA on new Phase 3 study for NDA filing with Orthostatic Hypotension Symptom Assessment (OHSA) composite score as primary endpoint
  - Three scientific platform presentations at American Autonomic Society meeting<sup>4</sup>
  - Received \$25 million investment from Royalty Pharma to fund majority of new Phase 3 study
- **Financial:**
  - Sold TRELEGY ELLIPTA royalty interests for \$1.1 billion upfront, while retaining value through milestones and certain outer-year royalties for TRELEGY
  - Eliminated all debt
  - Completed financial restructuring
  - Initiated \$250 million capital return program, of which ~50% was completed as of 12/31/2022:
    - § Repurchased ~\$95 million from GSK
    - § Initiated open market share repurchase program in Q4 2022, of which ~\$33 million was completed as of 12/31/22

**2023 Targets:**

- **YUPELRI®:**
  - Continue YUPELRI Net Sales growth by executing on targeted strategies to continue to capture sizeable niche market
  - Complete PIFR-2 study and provide top-line results in 2H 2023
- **Ampreloxetine:**
  - Initiate Phase 3 CYPRESS trial in MSA patients with symptomatic nOH in Q1 2023, targeting ~60 patients to complete the randomized withdrawal period
  - Submit orphan drug designation request in early 2023
- **Financial:**
  - Execute return of capital program
  - Generate Non-GAAP<sup>1</sup> Profit in 2H 2023
  - \$50 million potential milestone for TRELEGY Net Sales of ~\$2.86 billion<sup>5</sup>

<sup>3</sup> Data from MSA patients at week 6 of the randomized withdrawal period of Study 0170.

<sup>4</sup> 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.

<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.



## 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> (revelfenacin) inhalation solution indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Its pipeline of internally discovered programs is targeted to address significant unmet patient needs.

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 Viatris 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: contingent payments due to the Company from the sale of the Company's TRELEGY ELLIPTA royalty interests to Royalty Pharma, the Company's goals, designs, strategies, plans and objectives, the ability to provide value to shareholders, the Company's regulatory strategies and timing of clinical studies (including the data therefrom), the potential characteristics, benefits and mechanisms of action of the Company's product and product candidates, including potential points of differentiation, the market for products being commercialized and product candidates, product sales or profit share revenue and the Company's expectations for its future financial performance and expectations as to future cash flows, the effectiveness of the Company's intellectual property portfolio, and the Company's repurchase of its ordinary shares by way of an open market share repurchase program. 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-Q filed with the SEC on November 9, 2022, and other periodic reports filed with the SEC. In addition to the risks described above and in Theravance Biopharma's filings with the SEC, other unknown or unpredictable factors also could affect Theravance Biopharma's results. No forward-looking statements can be guaranteed, and actual results may differ materially from such statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Theravance Biopharma assumes no obligation to update its forward-looking statements on account of new information, future events or otherwise, except as required by law.

**Non-GAAP Financial Measure**

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

Contact:

[investorrelations@theravance.com](mailto:investorrelations@theravance.com)

650-808-4045

**Theravance  
Biopharma** 

Medicines That Make a Difference<sup>®</sup>

# Theravance Biopharma Investor Presentation

---

January 2023

THERAVANCE BIOPHARMA<sup>®</sup>, THERAVANCE<sup>®</sup>, the Cross/Star logo and MEDICINES THAT MAKE A DIFFERENCE<sup>®</sup> are registered trademarks of the Theravance Biopharma group of companies (in the U.S. and certain other countries). All third party trademarks used herein are the property of their respective owners.  
© 2023 Theravance Biopharma. All rights reserved.



# 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, 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: contingent payments due to the Company from the sale of the Company's TRELEGY ELLIPTA royalty in the United States; the Company's goals, designs, strategies, plans and objectives, the ability to provide value to shareholders, the Company's regulatory strategies and timing of regulatory submissions (including the data therefrom), the potential characteristics, benefits and mechanisms of action of the Company's product and product candidates, including potential for differentiation, the market for products being commercialized and product candidates, product sales or profit share revenue and the Company's expectations for its performance and expectations as to future cash flows, the effectiveness of the Company's intellectual property portfolio and the Company's repurchase of its ordinary shares under an open market share repurchase program. 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 differ 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, 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 agencies that are unfavorable to the Company, dependence on third parties to conduct clinical studies, delays or failure to achieve and maintain regulatory approvals for products, risks of collaborating with or relying on third parties to discover, develop, manufacture and commercialize products, and risks associated with establishing and maintaining manufacturing and distribution capabilities with appropriate technical expertise and supporting infrastructure, ability to retain key personnel, the impact of the Company's recent restructuring, 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 of the Company's shares, and general economic and market conditions.

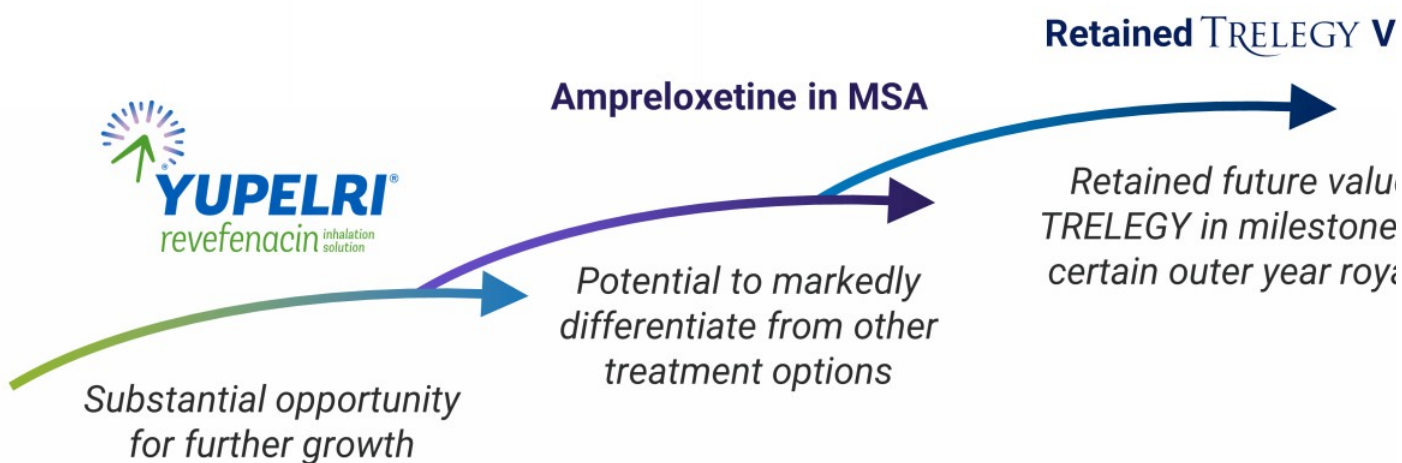
Other risks affecting the Company are in the Company's Form 10-Q filed with the SEC on November 9, 2022, and other periodic reports filed with the SEC. In addition to the risks described above and in Theravance Biopharma's filings with the SEC, other unknown or unpredictable factors also could affect Theravance Biopharma's results. No forward-looking 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.

## Non-GAAP Financial Measure

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

# 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**

# 2022: A Year of Transformation



- ▶ **Two consecutive quarters** of all-time high Net Sales and Profit in Q2'22 & Q3'22, and expect continued growth in Q4'22
- ▶ **11 consecutive quarters of market share growth** in both hospital and outpatient setting
- ▶ **56% 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>
- ▶ Received \$25M investment from Royalty Pharma to **fund majority of new Phase 3 study**

## Financial

- ▶ **Sold TRELEGY ELLIPTA for \$1.1B upfront**, while through milestones and royalties for TRELEGY
- ▶ **Eliminated all debt**
- ▶ **Completed financial res**
- ▶ Initiated \$250 million capex program, of which **~50% as of 12/31/22:**
  - Repurchased ~\$95 mi
  - Initiated open market program in Q4'22, of v**completed as of 12/31/22**

# 2023 Targets



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

## Ampreloxetine

- ▶ **Initiate Phase 3 CYPRESS trial** in MSA patients with symptomatic nOH in Q1'23, targeting ~60 patients to complete the randomized withdrawal period
- ▶ Submit **orphan drug designation request in early 2023**

## Financial

- ▶ **Execute** return of ca
- ▶ **Generate Non-GAAP** 2H'23
- ▶ **\$50M potential mile** TRELEGY Net Sales

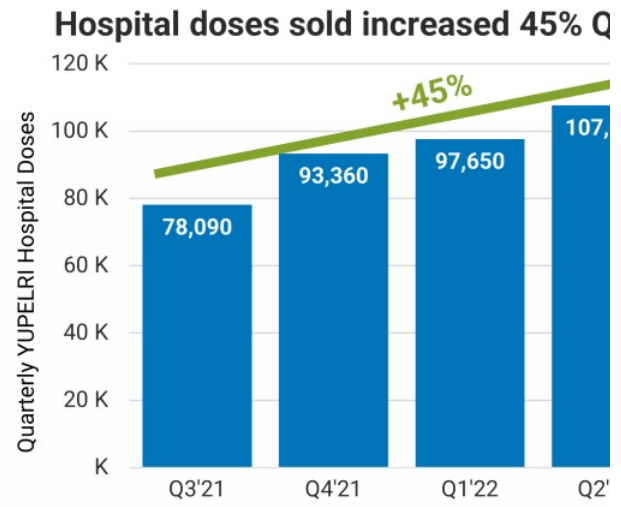
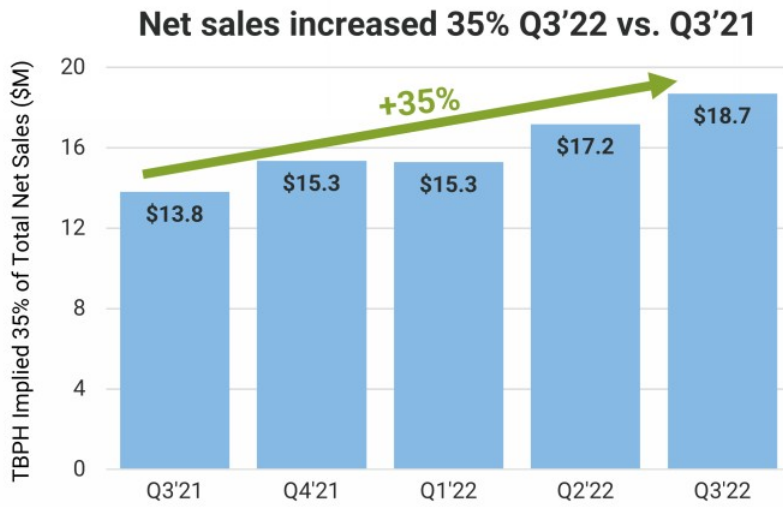


FDA-approved for maintenance treatment of COPD

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

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

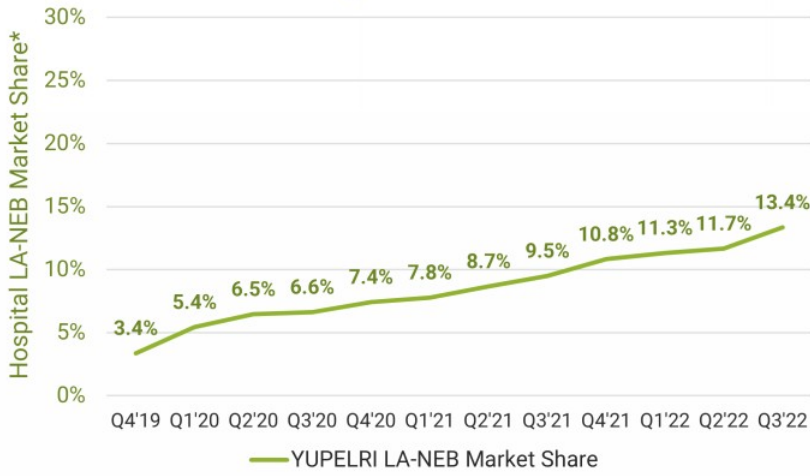
# YUPELRI® | Growing Net Sales and Hospital Volume



# YUPELRI® Hospital Sales and Community TRx T

Continued market share growth across both the hospital and retail channels

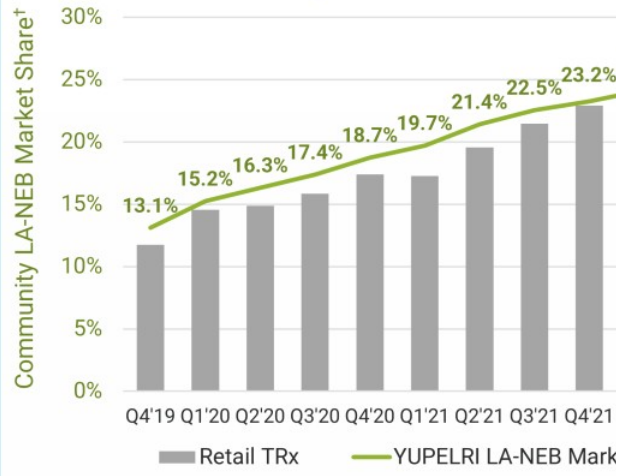
## Hospital Market Share



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

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

## Community Market Share with



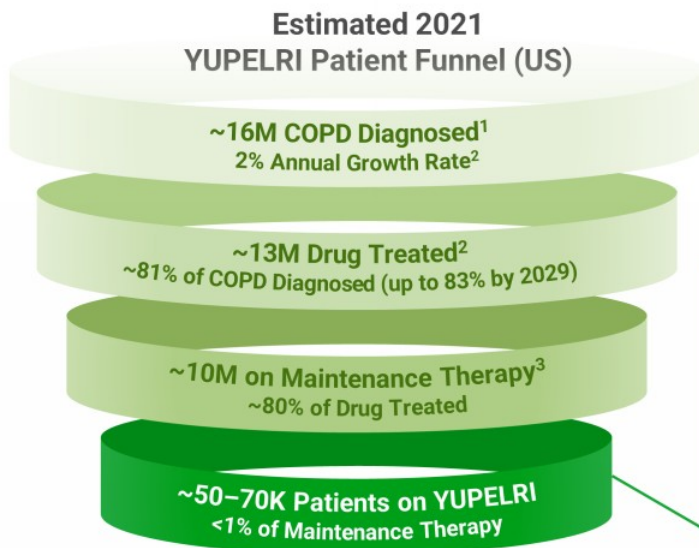
TRx volume represents retail only which is typically 33% Reported DME volume, while lagged, typically follows Re



1. Joint VTRS/TBPH Market Research.  
 \* Hospital LA-NEB Market Share - IQVIA DDD through 9/30/2022.  
 †Community LA-NEB Market Share includes Retail + DME / Med B FFS through Aug'22.  
 ‡Retail TRx Volume - Symphony Health METYS Prescription Dashboard through 9/30/2022.

# Substantial Opportunity for Further YUPELRI® Growth

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



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

- ▶ 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

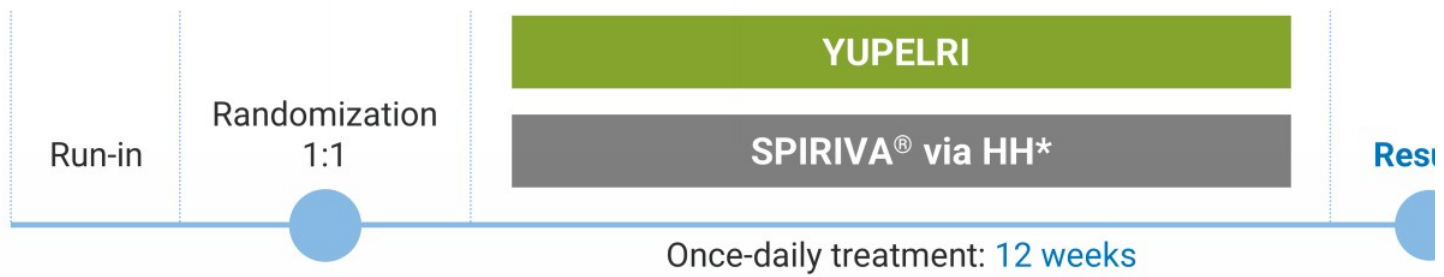
YUPELRI may be appropriate for COPD patients, including but not limited to:

- ▶ **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



# YUPELRI®:

## Phase 4 Randomized, Double-blind, Parallel-group Study (PIFF



### Sample size

- ▶ N= Up to 488
- ▶ Topline 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

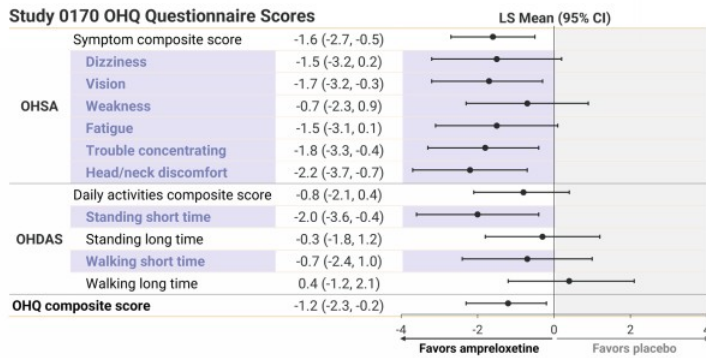
For symptomatic neurogenic orthostatic hypotension (nOH)  
in multiple system atrophy (MSA) patients

# Potential Differentiating Features from Other Th



## Differentiated efficacy

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



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

Clinically meaningful and **durable effectiveness** well-beyond 2 weeks<sup>1</sup>



## Differentiated dosing

**Once-a-day dosing** is meaningful in

- Difficulty swallowing
- Less compliance with increased c
- Patients and/or caregiver burden



## Differentiated safety

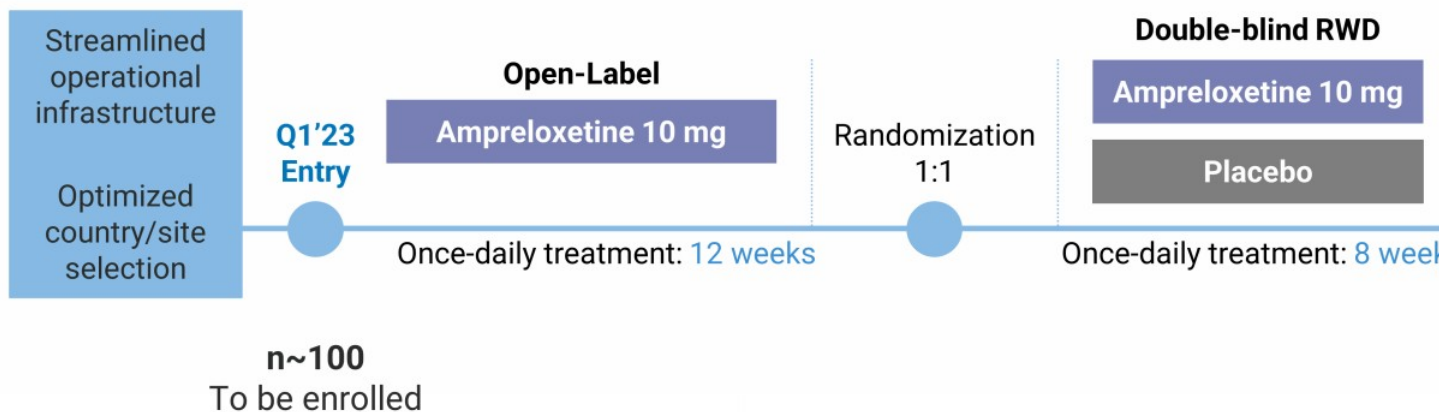
**Supine hypertension** with droxidopa

**Absence** of a signal would be a diffe

- Available to patients with supine l
- Can be taken anytime of day/nigh
- Potential to be combined with oth

# 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



# Financials

# Retained Value of Theravance Biopharma's 85% TRELEGY ELLIPTA

**Over \$1.5 Billion** in potential total value

Upfront:  
**~\$1.1B cash**

- Received in Q3'22

+

Mid-Term:  
**Up to \$250M**

- Sales-based milestones between 2023–2026
- First milestone in 2023 (\$50M) for Global Net Sales of ~\$2.9B<sup>2</sup>
  - Q3'22 actuals of \$552M up 23% from Q3'21
  - YTD Q3'22 actuals of \$1.6B up 34% from 2021

+

Long-Term  
**Outer-Year R**

- Ex-US royalties return
- US royalties return af
- Paid directly from Ro

GSK remains exclusively responsible for commercialization of TRELEGY ELLIPTA



1. All of its units in Theravance Respiratory Company, LLC.
2. The first milestone payment, of \$50.0 million, will be triggered if Royalty Pharma receives \$240.0 million or more in royalty payments from GSK with respect to net sales, which we would expect to occur in the event TRELEGY global net sales reach approximately \$2.863 billion.
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.

# \$250 Million Capital Return Program

Complete

~\$95M: Purchased GSK's equity stake in Theravance B (Sep'22) and completed Dutch auction tender offer (No

Initiated in Q4'22

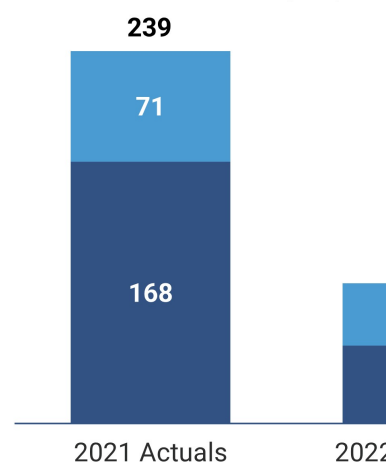
- Initiated open market share repurchase program in Q4'22
- ~\$33M completed as of 12/31/22

**~50% (or ~\$128M) of \$250M capital return program completed as of 12/31/22**

# Financial Guidance

- 2022 OPEX Range:
  - Total OPEX: narrowing range to \$90-100M<sup>1,2</sup>
- 2022 guidance includes **~\$10M in non-recurring spend**:
  - Majority in Q1 to support completion of late-stage programs
- Guidance **excludes**:
  - Non-cash share-based compensation (SBC)
  - One-time restructuring, severance & termination costs
    - ~ \$11.4M in 2022 (\$9.3M<sup>3</sup> Q1 / \$1.6M<sup>4</sup> Q2 / \$0.5M<sup>5</sup> Q3 / \$0M Q4)
    - No restructuring costs expected post Q3'22
- 2023 Financial Guidance to be provided in Feb'23 during Q4 earnings call

2021 Actuals vs. 2022 Original Guidance  
OPEX (\$M)<sup>2</sup>



## Expect to generate Non-GAAP<sup>6</sup> Profit in 2H'23



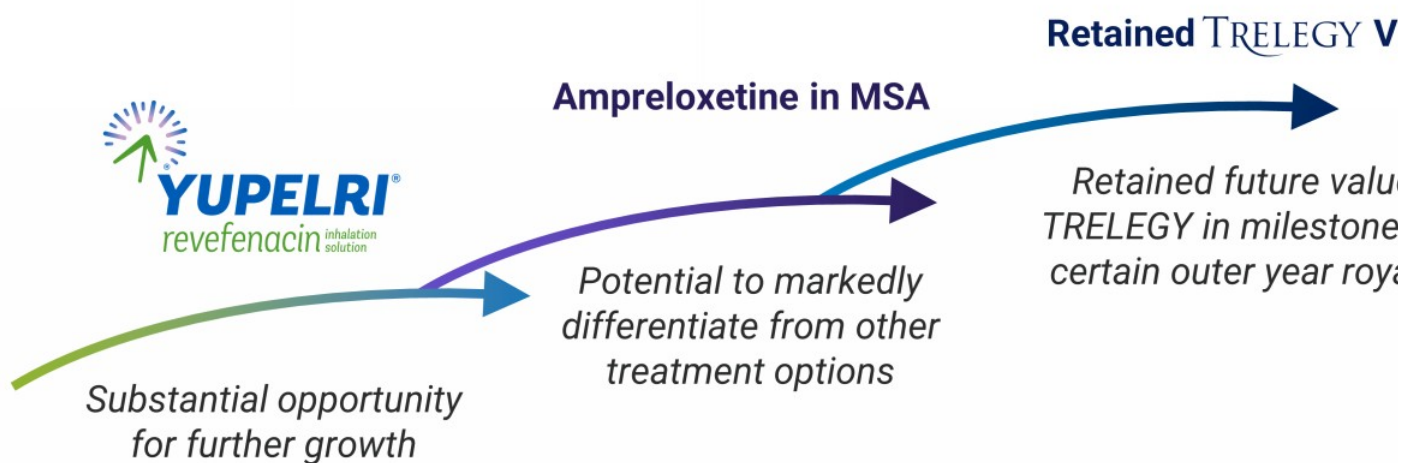
1. Based on preliminary actuals and subject to change.  
 2. Excludes non-cash share-based compensation (SBC) and one-time restructuring, severance and termination costs.  
 3. \$4.8M of cash related expenses and \$4.5M of non-cash expenses.  
 4. \$1.2M of cash related expenses and \$0.4M of non-cash expenses.  
 5. (\$0.2M) of cash related expenses and \$0.7M of non-cash expenses.

6. Non-GAAP profit is expected to consist of GAAP income, non-cash share-based compensation expense and non-cash interest expense. See "Financial Measures" for more information.



# Theravance Biopharma: Positioned for Value Creation

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



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

# Q&A Session

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

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



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

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



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

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



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

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



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

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

## Important Safety Information (US)

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

YUPELRI should not be initiated in patients during acutely deteriorating or potentially life-threatening episodes of COPD, or for the relief of acute 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

---

# Offering Hope to MSA Patients with Symptomatic Orthostatic Hypotension

## Potential for amprelosetine to differentiate from approved therapies

	Droxidopa	Midodrine	Amprelosetine
Indication	Symptomatic nOH	OH	Symptomatic orthostatic hypotension associated with MSA
MOA	Norepinephrine prodrug; vasoconstrictor	Desglymidodrine prodrug; alpha <sub>1</sub> -receptor agonist; vasoconstrictor	Norepinephrine transporter reuptake inhibitor
Dosing	3x daily, titration to effect	3x daily	Once-daily
Clinical Efficacy/Durability	OHSA#1, clinical effectiveness >2 weeks not established	Increase in systolic blood pressure 1 min after standing	OHSA composite meaningful and durable over 22 weeks
Clinical Safety	<b>Black box warning for supine hypertension</b>		No signal for supine hypertension in safety databases for MSA patients and healthy controls

# Offering Hope to MSA Patients with Symptomati



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**

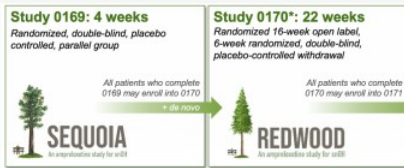
Longitudinal analysis of amprelosetine for the treatment of symptomatic nOH in subset of patients w

# Shift Toward Broad Symptomatic Improvement for MSA

## "Old" Amprelosetine Program



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



## "New" MSA-focused Amprelosetine Program

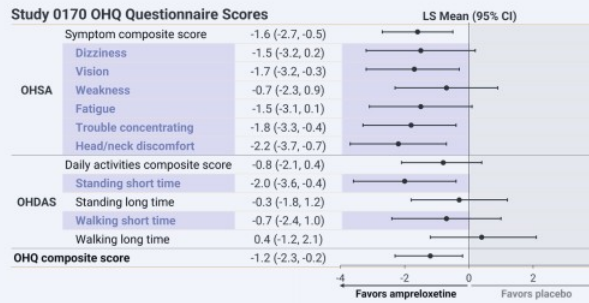


In study 0170, amprelosetine pressure drop and symptom

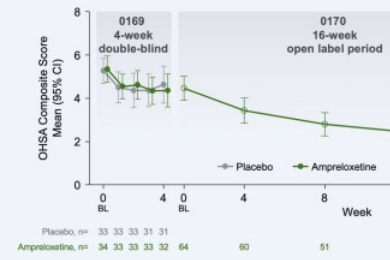
Support from the scientific with 3 scientific presentation American Autonomic Societ

Aligned with FDA on new Ph approval with OHSA compo:

## Constellation of symptoms-based indication



## Durable effectiveness





# 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 EMU (UK, 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

# Third Quarter 2022 Financial Highlights

\$487 million cash<sup>1</sup> as of September 30, 2022

(\$, in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(Unaudited)		(Unaudited)	
<b>Revenue:</b>				
Viatrix collaboration agreement	\$ 12,445	\$ 10,397	\$ 34,010	\$ 31,817
Collaboration revenue	6	2,797	187	8,211
Licensing revenue	-	-	2,500	-
Total revenue	12,451	13,194	36,697	40,028
<b>Costs and expenses:</b>				
Research and development (2)	9,867	43,739	48,691	162,311
Selling, general and administrative (2)	16,277	21,299	51,105	77,111
Restructuring and related expenses (2)	509	1,771	11,427	1,111
Total costs and expenses	26,653	66,809	111,223	240,533
Loss from continuing operations (before tax and other income/expense)	(14,202)	(53,615)	(74,526)	(200,505)
Income from discontinued operations (before tax)	1,115,016	20,602	1,143,930	39,111
<b>Share-based compensation expense:</b>				
Research and development	2,623	6,956	10,709	22,111
Selling, general and administrative	5,196	7,414	16,488	22,111
Restructuring and related expenses	711	-	5,587	-
Total share-based compensation expense	8,530	14,370	32,784	44,222
<b>Operating expense excl. share-based compensation and one-time expenses:</b>				
R&D operating expense (excl. share-based comp and restructuring exp.)	7,244	36,783	37,982	140,200
SG&A operating expense (excl. share-based comp and restructuring exp.)	11,081	13,885	34,617	54,111



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