

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

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

Date of Report (Date of earliest event Reported): **September 13, 2022**

THERAVANCE BIOPHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Cayman Islands
(State or Other Jurisdiction of
Incorporation)

001-36033
(Commission File Number)

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

PO Box 309
Ugland House, South Church Street
George Town, Grand Cayman, Cayman Islands KY1-1104
(650) 808-6000

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

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

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

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

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

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

Emerging growth company

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

Item 7.01. Regulation FD Disclosure.

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

Members of the Theravance Biopharma, Inc. management team will be presenting at the Morgan Stanley 20th Annual Global Healthcare Conference on September 13, 2022 and at the H.C. Wainwright 24th Annual Global Investment Conference on September 14, 2022, and from September 13-15, 2022, conducting one-on-one meetings with analysts and investors during the conferences using a slide presentation which is being furnished pursuant to Regulation FD as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

[99.1 Slide deck entitled Transformed and Focused on Medicines that Make a Difference®](#)

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.

By: /s/ Andrew Hindman
Andrew Hindman
Senior Vice President and Chief Financial Officer

Date: September 13, 2022



Transformed and Focused on *Medicines that Make a Difference*[®]

September 13, 2022

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Forward-looking Statements

This presentation contains certain "forward-looking" statements as that term is defined in the Private Securities Litigation Reform Act of 1995 re other things, statements relating to goals, plans, objectives, expectations and future events. Theravance Biopharma, Inc. (the "Company") intend looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Excha 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 TRELEC interests to Royalty Pharma, the Company's goals, designs, strategies, plans and objectives, including the paydown of the Company's debt, the i Company's restructuring plan, ability to provide value to shareholders, the timing of clinical studies, the potential that the Company's research pi progress product candidates into the clinic, the Company's expectations regarding its allocation of resources, potential regulatory actions, prod share revenue and the Company's expectations for its future financial performance and expectations as to future cash flows. These statements current estimates and assumptions of the management of the Company as of the date of this presentation and are subject to risks, uncertainie circumstances, assumptions and other factors that may cause the actual results of the Company to be materially different from those reflected looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking stateme others, risks related to: whether the milestone thresholds can be achieved, delays or difficulties in commencing, enrolling or completing clinical potential that results from clinical or non-clinical studies indicate the Company's product candidates are unsafe, ineffective or not differentiated from regulatory authorities that are unfavorable to the Company, dependence on third parties to conduct clinical studies, delays or failure to ach regulatory approvals for product candidates, risks of collaborating with or relying on third parties to discover, develop, manufacture and comme and risks associated with establishing and maintaining sales, marketing and distribution capabilities with appropriate technical expertise and su infrastructure, ability to retain key personnel, the impact of the Company's restructuring actions on its employees, partners and others. In additic the effects of COVID-19 to continue to adversely impact our business operations and financial results, the extent of the impact on our ability to c from YUPELRI® (revefenacin), and the value of and market for our ordinary shares, will depend on future developments that are highly uncertain predicted with confidence at this time.

Other risks affecting the Company are in the Company's Form 10-Q filed with the SEC on August 8, 2022, and other periodic reports filed with th to the risks described above and in Theravance Biopharma's filings with the SEC, other unknown or unpredictable factors also could affect Ther Biopharma's results. No forward-looking statements can be guaranteed, and actual results may differ materially from such statements. Given th you should not place undue reliance on these forward-looking statements. Theravance Biopharma assumes no obligation to update its forward- statements on account of new information, future events or otherwise, except as required by law.

Theravance Biopharma At-a-Glance



- Commercial product poised for significant near-term growth
- YUPELRI PIFR-2 Phase 4

Amprexetine

- Phase 3 potential therapy for MSA patients with opportunity to differentiate from existing treatment options
- \$25 million investment from Royalty Pharma to fund majority of Phase 3 costs

Experienced Board and Management team with the right mix of skills and experience to drive value

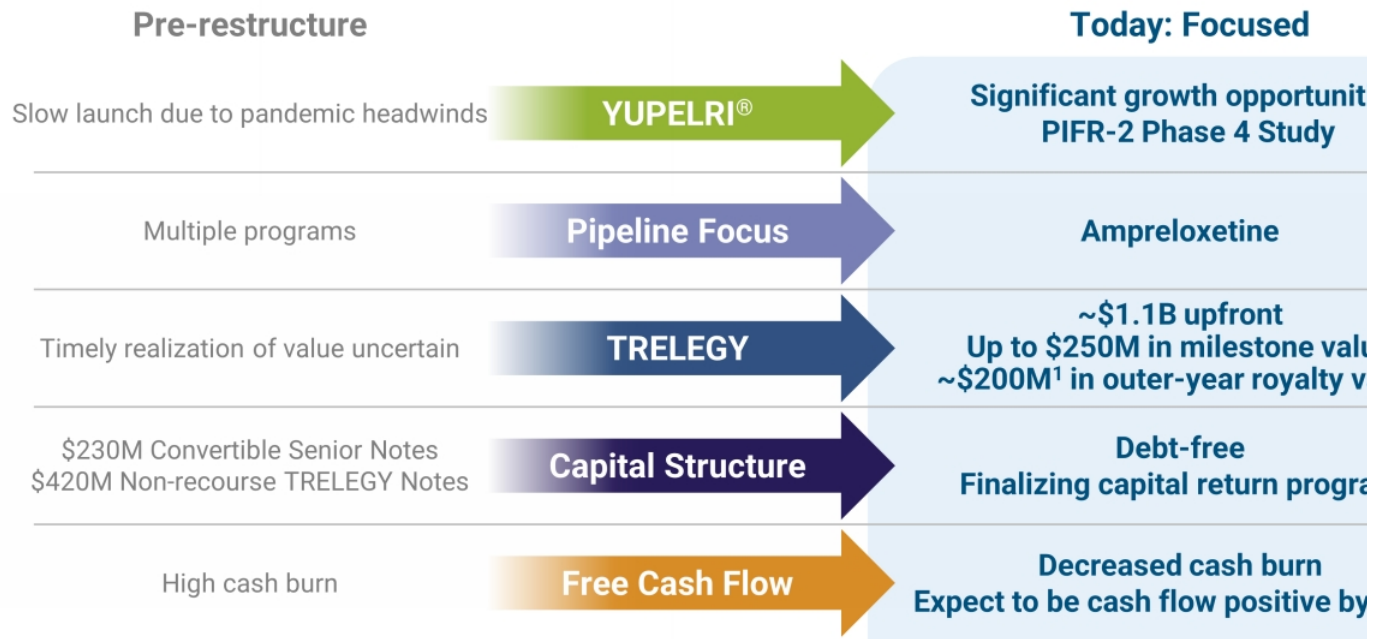
Retained TRELEGY Value

- Mid- to long-term value from milestone and outer-year payments

Financials

- Debt-free balance sheet
- Finalizing capital return program
- On track to be cash flow positive

Theravance Biopharma Transformation

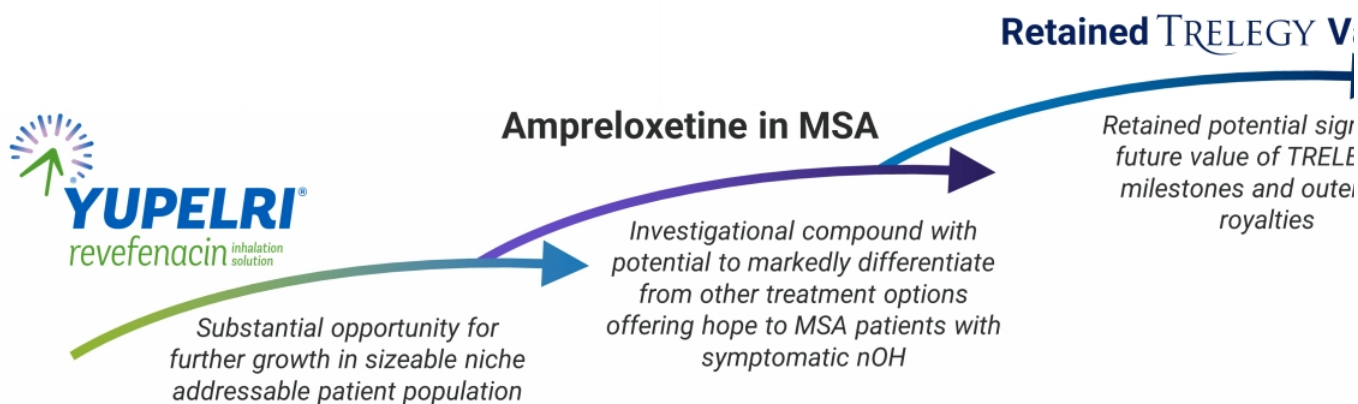


Investment Highlights

- Transformed and focused therapeutics company
- Attractive pipeline and programs with YUPELRI[®], amprelosetine and retained potential significant TRELEGY value
- Strong, debt-free balance sheet
- Finalizing capital return program
- Sustainable, annual cash flow generation 2023
- Experienced Board and Management team with the right mix of skills and experience to drive value

Theravance Biopharma: Key Pillars of Value

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



Theravance is well positioned to maximize the value of its assets from a position of financial strength



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

Theravance
Biopharma 
Medicines That Make a Difference

35%

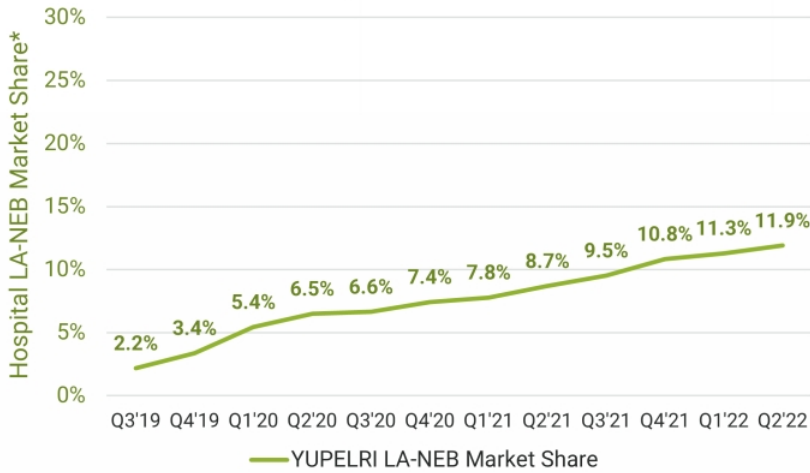


VIATRIS[™] 65%

YUPELRI[®] Hospital Sales and Community TRx T

Continued market share growth across both the hospital and retail channels

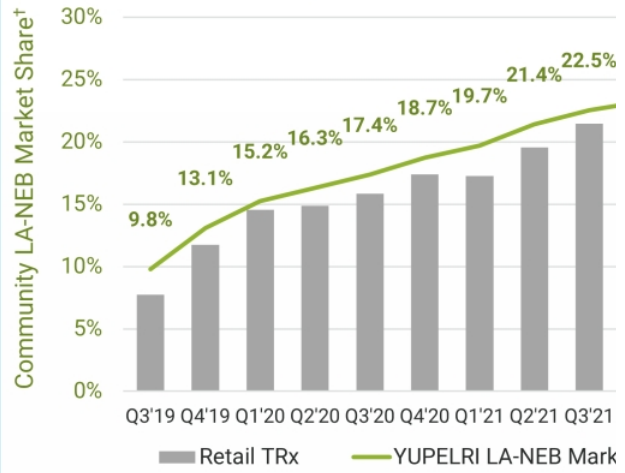
Hospital Market Share



Most patients who receive YUPELRI[®] in the hospital are discharged with an Rx¹

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

Community Market Share with

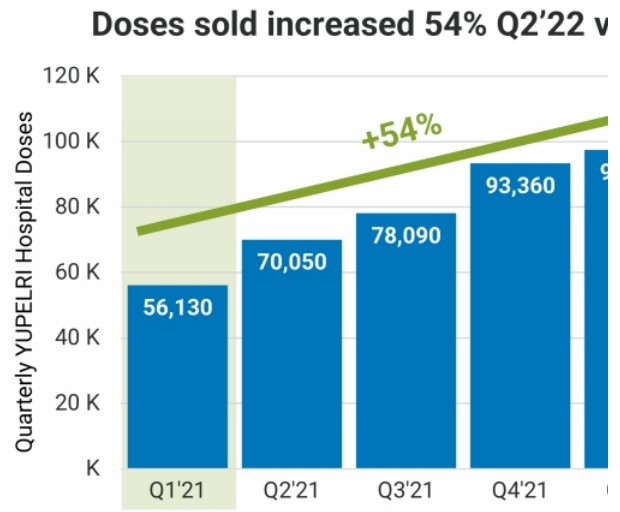
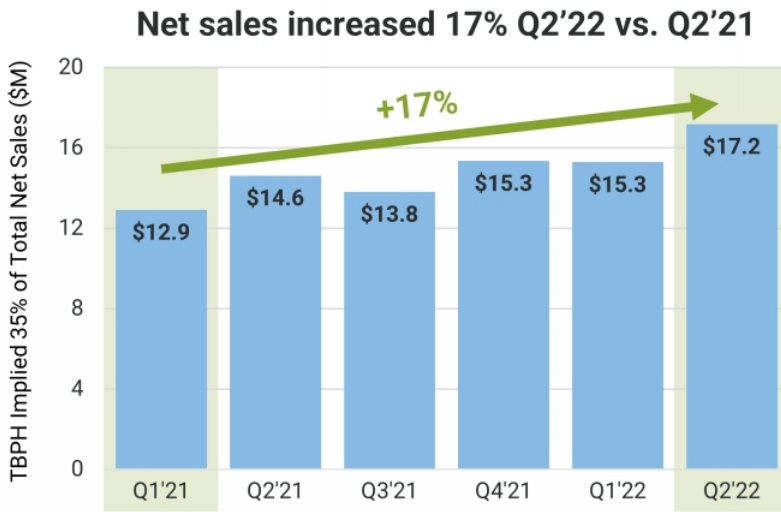


TRx volume represents retail only which is typically 33% Reported DME volume, while lagged, typically follows Re



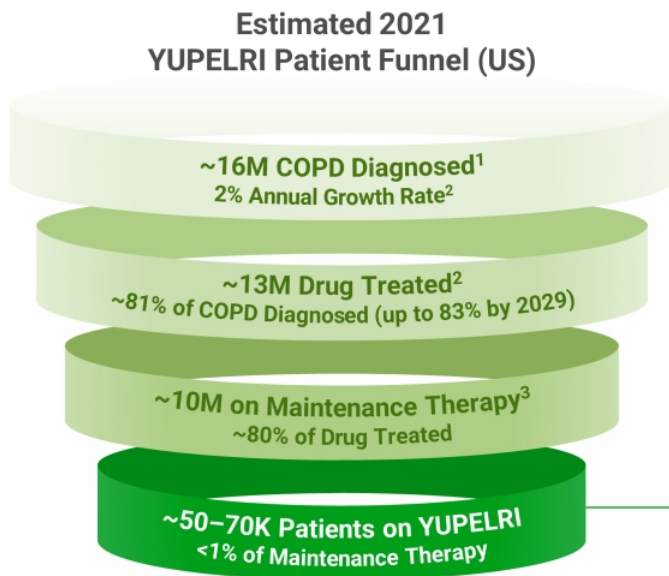
1. Joint VTRS/TBPH Market Research.
 * Hospital LA-NEB Market Share - IQVIA DDD through 6/30/2022.
 †Community LA-NEB Market Share includes Retail + DME / Med B FFS through Apr'22
 ‡Retail TRx Volume - Symphony Health METYS Prescription Dashboard through 6/30/2022.

YUPELRI® | Gaining Momentum in Sales and Hospital Volume



Substantial opportunity for further YUPELRI® growth

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



- ▶ COPD is **under-diagnosed**¹
- ▶ COPD patients with or without symptoms may be treated with and/or 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%⁴); once-daily LAMAs are the preferred therapy for moderate-to-very severe COPD patients
- ▶ Patients with **suboptimal PIFR** (19–78% of COPD patients⁵)
- ▶ Patients with **cognitive or dexterity challenges**
 - ~36% of COPD patients present episodes of cognitive impairment; ~30% of patients have inadequate hand strength for inhalers⁶
- ▶ Patients inappropriately using **short-acting nebulized treatment** as their primary 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

Potential to increase from n=366 to n=488 resulting from a pre-specified per-protocol blinded sample size re-estimation; top-line results in 2H '23

Endpoints

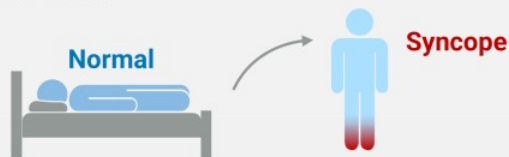
- ▶ **Primary:** Change from baseline in FEV₁ on Day 85
- ▶ **Key secondary:** Trough overall treatment effect on FEV₁

Ampreloxetine (TD-9855)

Investigational once-daily norepinephrine reuptake inhibitor for symptomatic neurogenic orthostatic hypotension in multiple system atrophy patients

Offering Hope to MSA Patients with Symptomati

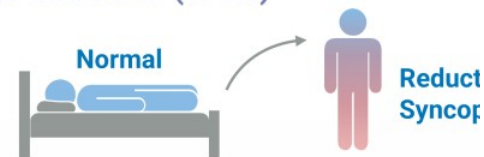
Untreated nOH



nOH Prevalence in MSA Patients

- ~50K MSA patients in US¹ (meets orphan disease criteria)
- 70–90% of MSA patients experience nOH symptoms²
- Despite available therapies, **many** MSA patients **remain symptomatic** with nOH

+ Ampreloxetine (MOA)



Prevents blood pressure drop and symptoms worsening in MSA³

- ✓ Increased standing blood pressure
- ✓ Increased brain perfusion
- ✓ Reduce symptoms of symptomatic nO

Offering Hope to MSA Patients with Symptomatic nOH

Potential for ampreloxadine to differentiate from approved therapies

	Droxidopa	Midodrine	Ampreloxadine
Indication	Symptomatic nOH	OH	Symptomatic nOH associated with orthostatic hypotension
MOA	Norepinephrine prodrug; vasoconstrictor	Desglymidodrine prodrug; alpha ₁ -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	Black box warning for supine hypertension		No signal for supine hypertension in safety databases in patients and healthy subjects

Offering Hope to MSA Patients with Symptom



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

Platform Presentations

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

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

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

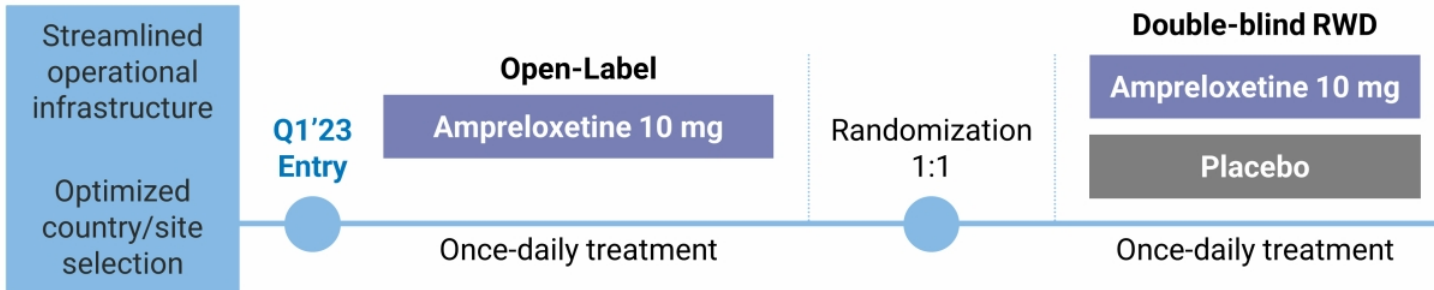
Blood pressure and pharmacodynamic response of ampreloxedine, a norepinephrine reuptake inhibit
in patients with symptomatic nOH

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

A phase 3, 22-week, multi-center, randomized withdrawal study of ampreloxedine in treating symptom

Offering Hope to MSA Patients with Symptom

Phase 3 randomized withdrawal study in patients with MSA
Primary endpoint: change in OHSA composite score



Sale of Economic Interest

GSK's TRELEGY ELLIPTA (FF/UMEC/VI):
Once-daily single inhaler triple therapy

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

Over \$1.5 Billion in potential total value to Company shareholders

Upfront:
~\$1.1B cash

+

Mid-Term:
Up to \$250M

+

Long-Term:
~\$200M



- TRELEGY ELLIPTA sales-based milestones between 2023–2026
- First milestone in 2023 (\$50M) for Global Net Sales of \$2.863B²
 - Q2'22 actuals of \$591M up 46% from Q2'21

- Will be paid to TBF from Royalty Pharma
- Estimated NPV

**Unlocks and accelerates capture of
TRELEGY ELLIPTA value**

**Additional value from continued
TRELEGY ELLIPTA performance**

**Retain long-term
TRELEGY ELLIPTA value**

GSK remains exclusively responsible for commercialization of TRELEGY ELLIPTA

Theravance Biopharma and Royalty Pharma Deal Summary

TRELEGY ELLIPTA

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

Year	Royalties ₂	Global Net Sales Equivalent	Milestone
2023	\$240M	\$2,863M	\$50M
2024 ₁	\$240M	\$2,863M	\$25M
	\$275M	\$3,213M	\$50M
2025 ₁	\$260M	\$3,063M	\$25M
	\$295M	\$3,413M	\$50M
2026 ₁	\$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. sales³
 - On and after July 1, 2029 for ex-U.S. sales³
 - NPV estimated at ~\$200M⁴

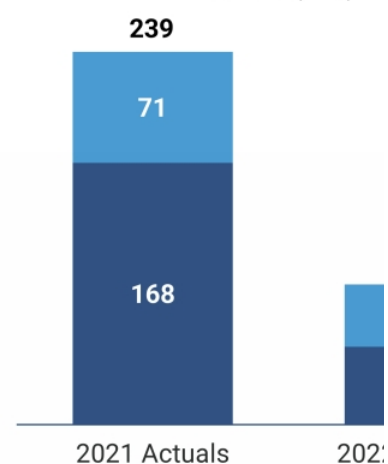
Amprexetine (Unsecured Royalty)

- Upfront payment: \$25M
- 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

Financial Guidance

- **Reiterating** 2022 OPEX guidance:
 - R&D: range of \$45–55M
 - SG&A: range of \$35–45M
- 2022 guidance includes **~\$10M in non-recurring spend**:
 - Majority in Q1 to support completion of late-stage programs
 - OPEX Q3 and onward will reflect recurring spend only
- Guidance **excludes**:
 - Non-cash share-based compensation (SBC)
 - One-time restructuring, severance & termination costs
 - ~\$11.7M in 2022 (\$9.3M₂ Q1 / \$1.6M₃ Q2 / \$0.8M₄ Q3 / \$0M₄ Q4)
 - One-time transaction related costs of \$5.1M YTD

2021 Actuals vs. 2022 Guidance
OPEX (\$M)¹



Theravance Biopharma expects to approach breakeven cash flow from operations in 2H and become sustainably cash flow positive going forward on an annual basis



1.) Excludes non-cash share-based compensation (SBC), one-time restructuring, severance and termination costs, and one-time transaction related legal expenses.
 2.) \$4.8M of cash related expenses and \$4.5M of non-cash expenses.
 3.) \$1.2M of cash related expenses and \$0.4M of non-cash expenses.
 4.) Q3 / Q4 are estimates and subject to change; primarily comprised of non-cash expenses.

An Experienced Leadership Team

Rick E Winningham
Chairman and Chief Executive Officer

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



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*

Andrew A. Hindman
**Senior Vice President,
Chief Financial Officer**

*Former Chief Business Officer, Acorda Therapeutics
Former President & CEO, Tobira Therapeutics*



Brett A. Grimaud
**Senior Vice President,
General Counsel and Secretary**

*Former Senior Director, Theravance, Inc. (now INVA)
Former Senior Attorney, Gunderson Dettmer*

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

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



Stacy Pryce
**Senior Vice President,
Chief Strategy Officer**

*Former VP Business Development, Aerogen
Former Senior Director, Alliance Management &
Business Development Vertex Pharmaceuticals*

The Board of Directors

Experienced leaders from a diverse range of relevant backgro



Rick Winningham
Chairman & CEO,
Theravance Biopharma

- Demonstrated leadership and senior management experience in the biopharmaceutical industry
- Former Chairman & CEO at Theravance, Inc. (now INVA) and former President of Oncology / Immunology / Oncology Therapeutics Network and President of Global Marketing at Bristol Myers Squibb



William Young
Senior Advisor,
Blackstone Life Sciences

- Extensive leadership experience at numerous pharmaceutical and biotechnology organizations as well as financial / investing expertise gained as a venture capitalist
- Former Chairman & CEO at Monogram Biosciences and Venture Partner at Claris Ventures



Laurie Smaldone Alsup, M.D.
Chief Medical &
Chief Scientific Officer, NDA Group

- Extensive leadership experience with regulatory and clinical expertise in the life sciences industry
- Former President and Chief Scientific Officer at PharmApprove and CEO at Phytomedics



- Demonstrated leadership in healthcare in addition to industry
- Former Partner and Healthcare Practice Group and CEO at



Burton Malkiel, Ph.D.
CIO & Chair of the Investment Committee,
Wealthfront

- Demonstrated leadership and knowledge of financial and financing matters
- Former Appointee to the President's Council of Economic Advisors



Dean Mitchell
Former President & CEO,
Lux Biosciences

- Extensive management experience in the pharmaceutical and biotherapeutics industries with expertise in later stage drug development and commercialization
- Former President & CEO at Alharma and Guilford Pharmaceuticals



Donal O'Connor
Former Senior Partner,
PwC Ireland

- Extensive experience across the financial and pharmaceutical industries, including with Irish entities, in addition to accounting and financial expertise
- Former Chairman of Anglo Irish Bank and Board member at the Irish Auditing and Accountancy Supervisory Authority



- Knowledge and expertise in business development in healthcare comparable to a biotechnology and research scientist
- Managing Member

Investment Highlights

- Transformed and focused therapeutics company
- Attractive pipeline and programs with YUPELRI[®], ampreloxetine and retained potential significant TRELEGY value
- Strong, debt-free balance sheet
- Finalizing capital return program
- Sustainable, annual cash flow generation 2023
- Experienced Board and Management team with the right mix of skills and experience to drive value

YUPELRI[®] (revefenacin) inhalation solution

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

Important Safety Information (US)

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

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

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

YUPELRI should be used with caution in patients with narrow-angle glaucoma. Patients should be instructed to immediately consult their healthcare provider if they develop any signs and symptoms of acute narrow-angle glaucoma, including eye pain or discomfort, blurred vision, visual halos or 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 other 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 high incidence 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 ongoing maintenance therapy.¹ LAMAs are a cornerstone of maintenance therapy for COPD and YUPELRI® is positioned as a once-daily single-agent bronchodilator product for COPD patients who require, or prefer, nebulized therapy. YUPELRI®'s metered 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.