



Medicines That Make a Difference®

## Theravance Biopharma, Inc. Reports Third Quarter 2021 Financial Results and Provides Business Update

November 3, 2021

- Implied 35% share of YUPELRI® (revefenacin) US net sales<sup>[1]</sup>: \$13.8 million, up 7% from Q3 2020
- TRELEGY Q3 2021 global net sales: \$449 million, up 77% from Q3 2020<sup>[2]</sup>
- Restructuring proceeding according to plan

DUBLIN, Nov. 3, 2021 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today reported financial results for the third quarter of 2021.

"This last month has been about executing on our strategy to create a new Theravance Biopharma, focused on leveraging expertise in developing and commercializing respiratory therapeutics. We are executing against the strategic plan we announced in mid-September to become cash-flow positive by the second-half of 2022," said Rick E. Winningham, Chief Executive Officer. "We are on track to reduce headcount by approximately 75% with the large majority of staff departing by the end of November and the remainder by the end of February. Our focus is driving growth of YUPELRI, streamlining R&D investment and optimizing our asset portfolio to maximize shareholder value."

### Quarterly Highlights

- **YUPELRI®** (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), continued to increase its share of the long-acting nebulized COPD market, increasing to 22% in July 2021, up from 21% in April 2021, and net sales increased by 7% year-over-year (Q3 2021 vs. Q3 2020).
  - The Company, in collaboration with its partner Viatrix, is also initiating a Phase 4 study comparing improvements in lung function in adults with severe to very severe COPD and suboptimal inspiratory flow rate following once-daily treatment with either YUPELRI® (revefenacin) delivered via standard jet nebulizer or tiotropium delivered via a dry powder inhaler (Spiriva® HandiHaler®). This study is aimed at helping to better inform decisions when physicians are designing a personalized COPD treatment plan with patients. Success in this study would capture more of YUPELRI's addressable market and further strengthen its competitive advantage.
- On September 15, 2021, the Company announced **strategic actions to focus on its respiratory disease portfolio** (read more about the actions [here](#)).
- **Amprelosetine**, an investigational, Theravance Biopharma-discovered, potent, long-acting, once-daily norepinephrine reuptake inhibitor in development for the treatment of symptomatic neurogenic orthostatic hypotension (nOH), reported Phase 3 top-line results (Study 0169 - read more about the data [here](#)).
- **Izencitinib**, an orally administered, once-daily, investigational, internally discovered, high affinity, reversible pan-JAK inhibitor which was designed to be gut-selective, reported Phase 2B top-line results (Study 0157 - read more about the data [here](#)).

### Economic Interest

- **TRELEGY** (first once-daily single inhaler triple therapy for COPD and asthma), in which the Company holds an economic interest, posted third quarter 2021 global net sales of \$449 million (up from \$253 million, 77%, in the third quarter of 2020); Theravance Biopharma is entitled to tiered payments equal to approximately 5.5% to 8.5% of TRELEGY global net sales.<sup>3</sup>

### Upcoming Clinical Milestones

- Izencitinib and amprelosetine study close out activities to be completed by end of Q1 2022.
- **Q1 2022: Izencitinib** (gut-selective oral pan-JAK inhibitor for inflammatory intestinal diseases) Phase 2 in Crohn's disease (Study 0173) – top-line results expected in Q1 2022.
- **Q1 2022: Amprelosetine** (norepinephrine reuptake inhibitor) Phase 3 for symptomatic neurogenic orthostatic hypotension (Study 0170) – top-line results expected in Q1 2022.

### Third Quarter Financial Results

- **Revenue:** Total revenue for the third quarter of 2021 was \$13.2 million, comprised of non-cash collaboration revenue of \$2.8 million primarily attributed to the global collaboration with Janssen and \$10.4 million in Viatrix collaboration revenue. Total revenue for the third quarter represents a \$5.1 million decrease over the same period in 2020 driven by the reduction of non-cash collaboration revenue related to the Janssen collaboration due to the wind down of the izencitinib clinical

program.

- **YUPELRI:** The Viatri collaboration revenue of \$10.4 million for the third quarter of 2021 represents amounts receivable from Viatri and is comprised of 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 Viatri records the total net sales of YUPELRI within its financial statements, the implied 35% share of net sales of YUPELRI for the third quarter of 2021 was \$13.8 million, up 7% from Q3 2020.
- **Research and Development (R&D) Expenses:** R&D expenses for the third quarter of 2021 were \$43.7 million, compared to \$67.4 million in the same period in 2020. Third quarter R&D expenses included total non-cash share-based compensation of \$7.0 million.
- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses for the third quarter of 2021 were \$21.3 million, compared to \$27.5 million in the same period in 2020. Third quarter SG&A expenses included total non-cash share-based compensation of \$7.4 million.
- **Restructuring and Related Expenses:** Restructuring expenses for the third quarter of 2021 were \$1.8 million and primarily comprised of severance costs, termination-related benefits, and one-time retention costs.
- **Operating Loss:** Operating loss for the third quarter of 2021 was \$53.6 million compared to \$76.6 million in the same period of 2020.
- **Cash Position:** Cash, cash equivalents and marketable securities totaled \$216.2 million as of September 30, 2021.

## 2021 Financial Guidance

- **Operating Expenses** (excluding share-based compensation): The Company reiterates that it expects full year 2021 R&D expense of \$180 million to \$190 million, and SG&A expense of \$70 million to \$80 million.

## 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 / 9:00 pm GMT.** To participate, please dial (855) 296-9648 from the US, or (920) 663-6266 for international callers, using the confirmation code 9772385. Those interested in listening to the conference call live via the internet may do so by visiting [www.theravance.com](http://www.theravance.com), under the Investors section, Presentations and Events.

A replay will be available on [www.theravance.com](http://www.theravance.com) for 30 days through December 3, 2021. An audio replay will also be available through 7:00 pm ET on November 10, 2021, by dialing (855) 859-2056 from the US, or (404) 537-2406 for international callers, and then entering confirmation code 9772385.

## About Theravance Biopharma

Theravance Biopharma, Inc. is a biopharmaceutical company primarily focused on the discovery, development and commercialization of respiratory medicines. Its core purpose is to create medicines that help improve the lives of patients suffering from respiratory illness.

In pursuit of its purpose, Theravance Biopharma leverages decades of respiratory expertise to discover and develop transformational medicines that make a difference. These efforts have 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). Its respiratory pipeline of internally discovered programs is targeted to address significant patient respiratory needs.

Theravance Biopharma has an economic interest in potential future payments from Glaxo Group Limited or one of its affiliates (GSK) pursuant to its agreements with Innoviva, Inc. relating to certain programs, including TRELEGY.

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 US and certain other countries).

YUPELRI<sup>®</sup> is a registered trademark of Mylan Specialty L.P., a Viatri 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 contains and the conference call 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 and the Private Securities Litigation Reform Act of 1995. Examples of such statements include statements relating to: the Company's goals, designs, strategies, plans and objectives, the impact of the Company's restructuring plan, 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, the potential that the Company's research programs will progress product candidates into the clinic, the Company's expectations for product candidates through development and the market for products being commercialized, the Company's expectations regarding its allocation of resources, potential regulatory actions and commercialization (including differentiation from other products or potential products and addressable market), product sales or profit share revenue and the Company's expectations for its expenses, excluding share-based compensation and other financial results. These statements are based on the current estimates and assumptions of the management of Theravance Biopharma as of the date of the press release and the conference call 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: disagreements with Innoviva, Inc. and TRC LLC, the uncertainty of arbitration and litigation and the possibility that the results of these proceedings could be adverse to the Company, additional future analysis of the data resulting from our clinical trial(s), delays or difficulties in commencing, enrolling or completing clinical studies, the potential that results from clinical or non-clinical studies indicate the Company's compounds, products or product candidates are unsafe, ineffective or not differentiated, risks of decisions from regulatory authorities that are unfavorable to the Company, the feasibility of undertaking future clinical trials based on policies and feedback from regulatory authorities, 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 restructuring actions on its employees, partners and others. In addition, while we expect 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 generate revenue from YUPELRI<sup>®</sup> (revefenacin), our clinical development programs, and the value of and market for our ordinary shares, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time. These potential future developments include, but are not limited to, the ultimate duration of the COVID-19 pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States and in other countries, other measures taken by us and those we work with to help protect individuals from contracting COVID-19, and the effectiveness of actions taken globally to contain and treat the disease, including vaccine availability, distribution, acceptance and effectiveness. Other risks affecting Theravance Biopharma are in the Company's Form 10-Q filed with the SEC on August 5, 2021 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.

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

	<b>September 30, 2021</b>	<b>December 31, 2020</b>
	<b>(Unaudited)</b>	<b>(1)</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents and short-term marketable securities	\$ 216,213	\$ 292,941
Receivables from collaborative arrangements	14,001	15,868
Amounts due from TRC, LLC	43,773	53,799
Prepaid clinical and development services	13,242	20,374
Other prepaid and current assets	9,943	10,359
Total current assets	297,172	393,341
Property and equipment, net	16,003	16,422
Operating lease assets	40,718	43,260
Equity in net assets of TRC, LLC	45,086	12,750
Restricted cash	833	833
Other assets	3,297	2,451
Total assets	\$ 403,109	\$ 469,057
<b>Liabilities and Shareholders' Deficit</b>		
Current liabilities	\$ 66,082	\$ 123,571
Convertible senior notes due 2023, net	227,767	226,963
Non-recourse notes due 2035, net	375,570	372,873
Long-term operating lease liabilities	54,353	47,220
Other long-term liabilities	2,929	2,181
Shareholders' deficit	(323,592)	(303,751)
Total liabilities and shareholders' deficit	\$ 403,109	\$ 469,057

(1) The condensed consolidated balance sheet as of December 31, 2020 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, 2020.

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

**Three Months Ended September 30, Nine Months Ended September 30,**

	2021	2020	2021	2020
	(Unaudited)		(Unaudited)	
<b>Revenue:</b>				
Collaboration revenue	\$ 2,797	\$ 7,261	\$ 8,649	\$ 19,381
Licensing revenue	-	-	-	1,500
Viatriis collaboration agreement	10,397	10,996	31,716	32,246
Total revenue	13,194	18,257	40,365	53,127
<b>Costs and expenses:</b>				
Research and development (1)	43,739	67,371	162,431	195,788
Selling, general and administrative (1)	21,299	27,501	77,780	78,606
Restructuring and related expenses	1,771	-	1,771	-
Total costs and expenses	66,809	94,872	241,982	274,394
Loss from operations	(53,615)	(76,615)	(201,617)	(221,267)
Income from investment in TRC, LLC	30,208	13,403	68,681	48,299
Interest expense	(11,742)	(11,573)	(35,227)	(32,905)
Loss on extinguishment of debt	-	-	-	(15,464)
Interest and other income (expense), net	(166)	1,235	771	2,033
Loss before income taxes	(35,315)	(73,550)	(167,392)	(219,304)
Provision for income tax benefit (expense)	7	(93)	-	(279)
<b>Net loss</b>	<b>\$ (35,308)</b>	<b>\$ (73,643)</b>	<b>\$ (167,392)</b>	<b>\$ (219,583)</b>
Net loss per share:				
Basic and diluted net loss per share	\$ (0.48)	\$ (1.16)	\$ (2.46)	\$ (3.55)
Shares used to compute basic and diluted net loss per share	73,574	63,303	67,945	61,881

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

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	\$ 6,956	\$ 7,761	\$ 22,192	\$ 23,724
Selling, general and administrative	7,414	7,803	22,951	23,701
Total share-based compensation expense	\$ 14,370	\$ 15,564	\$ 45,143	\$ 47,425

<sup>1</sup> While Viatriis Inc. ("Viatriis") records the total YUPELRI net sales, the Company is entitled to a 35% share of the profits and losses pursuant to a co-promotion agreement with Viatriis.

<sup>2</sup> As reported by Glaxo Group Limited or one of its affiliates (GSK); reported sales converted to USD; economic interest related to TRELEGY (the combination of fluticasone furoate, umeclidinium, and vilanterol (FF/UMEC/VI), jointly developed by GSK and Innoviva, Inc.) entitles the Company to upward tiering payments equal to approximately 5.5% to 8.5% on worldwide net sales of the product (net of Theravance Respiratory Company, LLC (TRC) expenses paid and the amount of cash, if any, expected to be used in TRC over the next four fiscal quarters). 75% of the income from the Company's investment in TRC is pledged to service outstanding notes and 25% of income from the Company's investment in TRC is retained by the Company.

<sup>3</sup> As reported by Glaxo Group Limited or one of its affiliates (GSK); reported sales converted to USD; economic interest related to TRELEGY (the combination of fluticasone furoate, umeclidinium, and vilanterol (FF/UMEC/VI), jointly developed by GSK and Innoviva, Inc.) entitles the Company to upward tiering payments equal to approximately 5.5% to 8.5% on worldwide net sales of the product (net of Theravance Respiratory Company, LLC (TRC) expenses paid and the amount of cash, if any, expected to be used by TRC over the next four fiscal quarters). 75% of the income from the Company's investment in TRC is pledged to service outstanding notes and 25% of income from the Company's investment in TRC is retained by the Company.

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