Theravance Biopharma, Inc. Reports First Quarter 2022 Financial Results and Provides Business Update

May 5, 2022

- *Implied 35% share of YUPELRI® (revefenacin) net sales[1]: $15.3M Q1 2022 up 19% from Q1 2021*
- *TRELEGY Q1 2022 global net sales: $454M, up 33% from Q1 2021[2]*
- *Results from a Phase 3 study of ampreloxetine showed a benefit in study patients with multiple system atrophy (MSA)*
- *Restructuring process completed in Q1 2022*

DUBLIN, May 5, 2022 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today reported financial results for the first quarter of 2022.

"We continue to execute against our business plan, stay disciplined in capital allocation, and 2022 remains on track to become sustainably cash-flow positive by the second half of this year and going forward on an annual basis," said Rick E Winningham, Chief Executive Officer. "Our team's perseverance as demonstrated by YUPELRI's hospital sales performance and continued gain of hospital and community market share creates a strong base for future growth. Considering the benefit that ampreloxetine provided to MSA patients in our Study 0170, we will define a path forward through ongoing discussions with regulators and strategic partners. We plan to continue to unlock value from our pipeline throughout 2022."

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 23.5% through January 2022, up from 23.2% in October 2021, and net sales increased by 19% year-over-year (Q1 2022 vs Q1 2021).

- **Ampreloxetine**, an investigational, Theravance Biopharma-discovered, potent, long-acting, once-daily norepinephrine reuptake inhibitor in development for the treatment of symptomatic neurogenic orthostatic hypotension (nOH). Phase 3 results (Study 0170) showed a benefit to MSA patients in the study that was observed in multiple endpoints including Orthostatic Hypotension Symptom Assessment (OHSA) composite, Orthostatic Hypotension Daily Activities Scale (OHDAS) composite, Orthostatic Hypotension Questionnaire (OHQ) composite and OHSA #1. (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 first quarter 2022 global net sales of $454 million (up from $341 million, 33%, in first quarter of 2021); Theravance Biopharma is entitled to tiered payments equal to approximately 5.5% to 8.5% of TRELEGY global net sales.[3]

First Quarter Financial Results

- **Revenue:** Total revenue for the first quarter of 2022 was $13.2 million, primarily comprised of licensing revenue of $2.5 million related to a development milestone payment from Pfizer for the first patient dosed in a Phase 1 clinical trial of the skin-selective pan-Janus kinase (JAK) inhibitor program and $10.7 million in Viatris collaboration revenue. Total revenue for the first quarter represents a $1.1 million decrease over the same period in 2021 driven by the completion of the recognition of non-cash Janssen collaboration revenue in 2021, resulting from the planned close-out of the izencitinib program.

- **YUPELRI:** The Viatris collaboration revenue of $10.7 million for the first quarter of 2022 represents amounts receivable from Viatris 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 Viatris records the total net sales of YUPELRI within its financial statements, our implied 35% share of net sales of YUPELRI for the first quarter of 2022 was $15.3 million, up 19% from the first quarter of 2021. We achieved 19% year-over-year growth in net sales, however, due to accounting guidelines, our Viatris collaboration revenue increased by only 3% due to lower costs incurred by Theravance Biopharma as a result of the

corporate restructuring, which improves YUPELRI profitability but lowers Viatris collaboration revenue.

- **Research and Development (R&D) Expenses:** R&D expenses for the first quarter of 2022 were $23.3 million, compared to $67.6 million in the same period in 2021. First quarter R&D expenses included total non-cash share-based compensation of $4.5 million.

- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses for the first quarter of 2022 were $19.1 million, compared to $30.6 million in the same period in 2021. First quarter SG&A expenses included total non-cash share-based compensation of $5.5 million.

- **Restructuring and Related Expenses:** Restructuring expenses for the first quarter of 2022 were $9.3 million and primarily comprised of severance costs, termination-related benefits, one-time retention costs, and share-based compensation expense. Cash restructuring expenses were $4.8 million for the first quarter of 2022; and non-cash restructuring expenses were $4.5 million for the first quarter of 2022.

- **Operating Loss:** Operating loss for the first quarter of 2022 was $38.5 million compared to $83.9 million in the same period of 2021.

- **Cash Position:** Cash, cash equivalents and marketable securities totaled $147.5 million as of March 31, 2022.

2022 Financial Guidance

- **Operating Expenses** (excluding share-based compensation and one-time restructuring costs)**:** The Company expects full year 2022 R&D expense of $45 million to $55 million and SG&A expense of $35 million to $45 million.

- The Company expects to be **sustainably cash-flow positive beginning 2H 2022** and going forward on an annual basis.

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 dial (800) 225-9448 from the US, or (203) 518-9783 for international callers, using the confirmation code TBPH0505. 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, under the Investors section, Presentations and Events.

A replay of the conference call will be available on Theravance Biopharma's website for 30 days through June 4, 2022. An audio replay will also be available through 11:59 pm ET on May 12, 2022, by dialing (800) 839-1337 from the US, or (402) 220-0489 for international callers.

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 make a difference*® in people's lives.

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® (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.

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 or will be partnered successfully, 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® (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-K filed with the SEC on February 28, 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.

Contact: Gail B. Cohen
Corporate Communications / 917-214-6603

1 *While Viatris, Inc. ("Viatris") 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 Viatris.*

2 *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.*

3 *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.*

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

	March 31, 2022	December 31, 2021
Assets	**(Unaudited)**	**(1)**
Current assets:		
Cash and cash equivalents and short-term marketable securities	$ 147,516	$ 173,465
Receivables from collaborative arrangements	12,277	14,065
Amounts due from TRC, LLC	35,559	43,534
Prepaid clinical and development services	4,742	10,245
Other prepaid and current assets	4,542	8,561
Total current assets	204,636	249,870

Property and equipment, net	13,236	13,657
Operating lease assets	39,349	39,690
Equity in net assets of TRC, LLC	94,108	67,537
Restricted cash	836	837
Other assets	3,194	3,228
Total assets	$ 355,359	$ 374,819
Liabilities and Shareholders' Deficit		
Current liabilities	$ 44,201	$ 58,587
Convertible senior notes due 2023, net	228,303	228,035
Non-recourse notes due 2035, net	384,161	371,359
Long-term operating lease liabilities	47,415	52,681
Other long-term liabilities	2,729	2,730
Shareholders' deficit	(351,450)	(338,573)
Total liabilities and shareholders' deficit	$ 355,359	$ 374,819

(1) The condensed consolidated balance sheet as of December 31, 2021 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, 2021.

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

	Three Months Ended March 31,	
	2022	2021
	(Unaudited)	
Revenue:		
Viatris collaboration agreement	$ 10,687	$ 10,385
Collaboration revenue	9	3,872
Licensing revenue	2,500	-
Total revenue	13,196	14,257
Costs and expenses:		
Research and development (1)	23,253	67,599
Selling, general and administrative (1)	19,121	30,550
Restructuring and related expenses (1)	9,324	-
Total costs and expenses	51,698	98,149
Loss from operations	(38,502)	(83,892)
Income from investment in TRC, LLC	25,110	16,547
Interest expense	(11,655)	(11,873)
Interest income and other income (expense), net	(375)	(234)
Loss before income taxes	(25,422)	(79,452)
Provision for income tax expense	(524)	(227)
Net loss	$ (25,946)	$ (79,679)
Net loss per share:		
Basic and diluted net loss per share	$ (0.34)	$ (1.24)
Shares used to compute basic and diluted net loss per share	75,247	64,493

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

	Three Months Ended March 31,	
(In thousands)	**2022**	**2021**
Research and development	$ 4,530	$ 7,921
Selling, general and administrative	5,498	7,911
Restructuring and related expenses	4,517	-
Total share-based compensation expense	$ 14,545	$ 15,832

View original content to download multimedia:https://www.prnewswire.com/news-releases/theravance-biopharma-inc-reports-first-quarter-2022-financial-results-and-provides-business-update-301541217.html

SOURCE Theravance Biopharma, Inc.