



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

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

May 4, 2021

- Company completed enrollment for Phase 2 nezulcitinib (TD-0903, COVID lung hyperinflammation) and Phase 2b izencitinib (ulcerative colitis) studies, is near completion of enrollment for amprelosetine Phase 3, and reaffirms readout timing for these trials
- Company updates timing for izencitinib (Crohn's disease) readout to late Q4/early Q1 2022
- Company's implied 35% share of YUPELRI<sup>®</sup> (revefenacin) net sales<sup>1</sup>: \$12.9 million
- TRELEGY<sup>®</sup> Q1 2021 global net sales hit a record \$341 million, up 37% from Q1 2020. Company is entitled to tiered royalties of 5.5% to 8.5% on TRELEGY net sales<sup>2</sup>

DUBLIN, May 4, 2021 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today reported financial results for the first quarter of 2021.

"2021 is on track to be a transformational year as we make significant progress towards our business goals," said Rick E Winningham, Chief Executive Officer. "Our commercial assets provide cash flow to invest in our diversified clinical pipeline. GSK's TRELEGY continues an exceptional, unabated growth trajectory. Our YUPELRI team, with our partner Viatris, continues to drive performance despite pandemic-associated headwinds. While we experienced slightly down sequential quarter-over-quarter net sales results, our January 2021 market share was 19%—its highest level since launch—and we ended the quarter on a strong note with March volume demand demonstrating 28% growth over February."

"Additionally, we are focused on advancing development of our innovative and differentiated pipeline. We continue to progress nezulcitinib, our wholly-owned nebulized lung-selective pan-JAK inhibitor, our potentially best-in-class amprelosetine for symptomatic neurogenic orthostatic hypotension and izencitinib, our oral gut-selective pan-JAK inhibitor for inflammatory bowel disease that is partnered with Janssen Pharmaceuticals. Our team is looking forward to four significant clinical readouts between now and Q1 2022: our Phase 2 nezulcitinib trial in Q2, our Phase 3 amprelosetine and Phase 2b izencitinib Ulcerative Colitis trials each in Q3, and the Phase 2 izencitinib Crohn's disease trial in Q4/Q1 2022. We remain committed to delivering each of these clinical data sets with the highest quality as expeditiously as possible."

### Upcoming Clinical Milestones

- **Q2 2021: Nezulcitinib** (nebulized lung-selective pan-Janus kinase (JAK) inhibitor) Phase 2 for acute hyperinflammation of the lung in COVID-19 (study 0188) – enrollment complete and topline results expected in Q2.
- **Q3 2021: Amprelosetine** (norepinephrine reuptake inhibitor) Phase 3 for symptomatic neurogenic orthostatic hypotension (study 0169) – enrollment near complete and topline results expected in Q3.
- **Q3 2021: Izencitinib** (gut-selective oral pan-JAK inhibitor for inflammatory intestinal diseases) Phase 2b in ulcerative colitis (study 0157) – enrollment complete and topline results expected in Q3.
- **Q4 2021/Q1 2022: Izencitinib** (gut-selective oral pan-JAK inhibitor for inflammatory intestinal diseases) due to enrollment challenges, Phase 2 in Crohn's disease (study 0173) – enrollment ongoing and topline results now expected in late Q4 2021/early Q1 2022.

### Quarterly Highlight

- **YUPELRI<sup>®</sup>** (revefenacin) inhalation solution, the first and only once-daily, nebulized bronchodilator approved in the U.S. 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 19.0% in January 2021, up from 18.6% in December 2020.

### 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 2021 global net sales of \$341 million (up from \$249 million, 36.9%, in the first quarter of 2020); Theravance Biopharma is entitled to tiered royalties of 5.5% to 8.5% of TRELEGY global net sales.<sup>3</sup>

### First Quarter Financial Results

- **Revenue:** Total revenue for the first quarter of 2021 was \$14.3 million, comprised of non-cash collaboration revenue of \$3.9 million primarily attributed to our global collaboration with Janssen and \$10.4 million in Viatris collaboration revenue. Total revenue for the first quarter represents a \$5.6 million decrease over the same period in 2020.
- **YUPELRI:** The Viatris collaboration revenue of \$10.4 million for the first quarter of 2021 represents amounts receivable

from Viatriis 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 Viatriis 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 2021 was \$12.9 million.

- **Research and Development (R&D) Expenses:** R&D expenses for the first quarter of 2021 were \$67.6 million, compared to \$66.0 million in the same period in 2020. First quarter R&D expenses included total non-cash share-based compensation of \$7.9 million.
- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses for the first quarter of 2021 were \$30.6 million, compared to \$26.3 million in the same period in 2020. First quarter SG&A expenses included total non-cash share-based compensation of \$7.9 million.
- **Operating Loss:** Operating loss for the first quarter of 2021 was \$83.9 million compared to \$72.5 million in the same period of 2020.
- **Cash Position:** Cash, cash equivalents and marketable securities totaled \$210.0 million as of March 31, 2021.

## 2021 Financial Guidance

- **Operating Expenses** (excluding share-based compensation): The Company expects full year 2021 R&D expense of \$195 million to \$225 million, and SG&A expense of \$80 million to \$90 million.

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

**Theravance Biopharma will hold a conference call and live webcast accompanied by slides today at 5 pm ET / 2 pm PT / 10 pm IST.** To participate, please dial (855) 296-9648 from the U.S. or (920) 663-6266 for international callers, using the confirmation code 1092615. Those interested in listening to the conference call live via the internet may do so by visiting [Theravance.com](https://www.theravance.com), under the Investors section, Presentations and Events.

A replay will be available on [Theravance.com](https://www.theravance.com) for 30 days through June 3, 2021. An audio replay will also be available through 8:00 pm ET on May 11, 2021, by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 1092615.

## About Theravance Biopharma

Theravance Biopharma, Inc. is a diversified biopharmaceutical company primarily focused on the discovery, development and commercialization of organ-selective medicines. Its purpose is to pioneer a new generation of small molecule drugs designed to better meet patient needs. Its research is focused in the areas of inflammation and immunology.

In pursuit of its purpose, Theravance Biopharma applies insights and innovation at each stage of its business and utilizes its internal capabilities and those of partners around the world. The Company applies organ-selective expertise to target disease biologically, to discover and develop medicines that may expand the therapeutic index with the goal of maximizing efficacy and limiting systemic side effects. These efforts leverage years of experience in developing lung-selective medicines to treat respiratory disease, including FDA-approved YUPELRI® (revefenacin) 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 patient 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](https://www.theravance.com).

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YUPELRI® is a registered trademark of Mylan Specialty L.P., a Viatriis company. Trade names or service marks of other companies appearing on this press release are the property of their respective owners

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 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, the Company's expectations regarding its allocation of resources, potential regulatory approval and commercialization (including their differentiation from other products or potential products), 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, 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 or product candidates are unsafe or ineffective, risks that product candidates do not obtain approval from regulatory authorities, the feasibility of undertaking future clinical trials for our product candidates 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. 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® (revelenacin), our clinical development programs (including but not limited to our later stage clinical programs for izencitinib and amprelosetine), 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 26, 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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<sup>1</sup> While Viatrix Inc. ("Viatrix") 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 Viatrix.

<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 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.

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

	March 31, 2021	December 31, 2020
	(Unaudited)	(1)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents and short-term marketable securities	\$ 209,968	\$ 292,941
Receivables from collaborative arrangements	11,915	15,868
Receivables from licensing arrangements	-	-
Amounts due from TRC, LLC	42,359	53,799
Prepaid clinical and development services	18,792	20,374
Other prepaid and current assets	10,037	10,359
Total current assets	<u>293,071</u>	<u>393,341</u>
Property and equipment, net	16,944	16,422
Operating lease assets	42,517	43,260
Equity in net assets of TRC, LLC	19,439	12,750
Restricted cash	833	833
Other assets	2,304	2,451
Total assets	<u>\$ 375,108</u>	<u>\$ 469,057</u>
<b>Liabilities and Shareholders' Deficit</b>		
Current liabilities	\$ 86,492	\$ 123,571
Convertible senior notes due 2023, net	227,230	226,963
Non-recourse notes due 2035, net	375,181	372,873
Long-term operating lease liabilities	57,026	47,220
Other long-term liabilities	2,397	2,181
Shareholders' deficit	<u>(373,218)</u>	<u>(303,751)</u>
Total liabilities and shareholders' deficit	<u>\$ 375,108</u>	<u>\$ 469,057</u>

(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)

	<b>Three Months Ended March 31,</b>	
	<b>2021</b>	<b>2020</b>
	<b>(Unaudited)</b>	
<b>Revenue:</b>		
Collaboration revenue	\$ 3,872	\$ 6,632
Licensing revenue	-	1,500
Viatrix collaboration agreement	10,385	11,730
Total revenue	<u>14,257</u>	<u>19,862</u>
<b>Costs and expenses:</b>		
Research and development (1)	67,599	66,013
Selling, general and administrative (1)	30,550	26,325
Total costs and expenses	<u>98,149</u>	<u>92,338</u>
Loss from operations	(83,892)	(72,476)
Income from investment in TRC, LLC	16,547	13,515
Interest expense	(11,873)	(9,941)
Loss on extinguishment of debt	-	(15,464)
Interest and other income, net	(234)	1,460
Loss before income taxes	(79,452)	(82,906)
Provision for income tax expense	(227)	(147)
<b>Net loss</b>	<u>\$ (79,679)</u>	<u>\$ (83,053)</u>
Net loss per share:		
Basic and diluted net loss per share	<u>\$ (1.24)</u>	<u>\$ (1.40)</u>
Shares used to compute basic and diluted net loss per share	<u>64,493</u>	<u>59,463</u>

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

	<b>Three Months Ended March 31,</b>	
<b>(In thousands)</b>	<b>2021</b>	<b>2020</b>
Research and development	\$ 7,921	\$ 7,865
Selling, general and administrative	7,911	7,411
Total share-based compensation expense	<u>\$ 15,832</u>	<u>\$ 15,276</u>

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