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

August 3, 2021

**- Company reiterates Q3 2021 top-line results timing for ampreloxetine Phase 3 and izencitinib Phase 2b in ulcerative colitis**

**- Company's implied 35% share of YUPELRI® (revefenacin) US net sales[(1)]: $14.6 million, up 38% from Q2 2020**

**- TRELEGY® Q2 2021 global net sales hit $405 million, up 68% from Q2 2020[(2)]**

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

*"We made strong progress in the second quarter. Our field team is energized and has recently been able to increase its face-to-face engagements with customers, driving continued sales volume and market share growth. As we look to the future for YUPELRI, we and our partner Viatris are initiating a controlled clinical study intended to provide data for a possible label update," said Rick E Winningham, Chief Executive Officer. "We continued to execute across our clinical trials and eagerly anticipate study results this quarter and later this year/early next. 2021 is a pivotal year for Theravance Biopharma, and we are looking forward to the second half of the year furthering our mission of medicines that make a difference."*

**Upcoming Clinical Milestones**

- **Q3 2021: Izencitinib** (gut-selective oral pan-Janus kinase (JAK) inhibitor for inflammatory intestinal diseases) Phase 2b in ulcerative colitis (study 0157) – top-line results expected in Q3 2021.
- **Q3 2021: Ampreloxetine** (norepinephrine reuptake inhibitor) Phase 3 for symptomatic neurogenic orthostatic hypotension (study 0169) – enrollment complete and top-line results expected in Q3 2021.
- **Q4 2021/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 late Q4 2021/early Q1 2022.

**Quarterly Highlights**

- **YUPELRI®** (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 21% in April 2021, up from 19% in January 2021, and net sales increased by 38% year-over-year (Q2 2020 vs. Q2 2021).
    - The Company, in collaboration with our partner Viatris, 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.
- **Nezulcitinib,** an investigational, inhaled, lung-selective, pan-JAK inhibitor in development for hospitalized patients with COVID-19, reported Phase 2 top-line results (read more about the data here).
- On June 29, 2021, the Company closed a public offering of ordinary shares at a price to the public of $15.00 per share, with gross proceeds of $115.6 million, before deducting underwriting discounts and commissions and offering expenses.

**Economic Interest**

- **TRELEGY** (first once-daily single inhaler triple therapy for COPD and asthma)**,** in which the Company holds an economic interest, posted second quarter 2021 global net sales of $405 million (up from $241 million, 68%, in the second quarter of 2020); Theravance Biopharma is entitled to tiered payments equal to approximately 5.5% to 8.5% of TRELEGY global net sales.[3]

**Second Quarter Financial Results**

- **Revenue:** Total revenue for the second quarter of 2021 was $12.9 million, comprised of non-cash collaboration revenue of $2.0 million primarily attributed to our global collaboration with Janssen and $10.9 million in Viatris collaboration revenue. Total revenue for the second quarter represents a $2.1 million decrease over the same period in 2020.

- **YUPELRI:** The Viatris collaboration revenue of $10.9 million for the second quarter of 2021 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 second quarter of 2021 was $14.6 million.

- **Research and Development (R&D) Expenses:** R&D expenses for the second quarter of 2021 were $51.1 million, compared to $62.4 million in the same period in 2020. Second quarter R&D expenses included total non-cash share-based compensation of $7.3 million.

- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses for the second quarter of 2021 were $25.9 million, compared to $24.8 million in the same period in 2020. Second quarter SG&A expenses included total non-cash share-based compensation of $7.6 million.

- **Operating Loss:** Operating loss for the second quarter of 2021 was $64.1 million compared to $72.2 million in the same period of 2020.

- **Cash Position:** Cash, cash equivalents and marketable securities totaled $265.0 million as of June 30, 2021.

**2021 Financial Guidance**

- **Operating Expenses** (excluding share-based compensation)**:** The Company reiterates that it 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 2615108. Those interested in listening to the conference call live via the internet may do so by visiting www.theravance.com, under the Investors section, Presentations and Events.

A replay will be available on www.theravance.com for 30 days through September 2, 2021. An audio replay will also be available through 8:00 p.m. ET on August 10, 2021, by dialing (855) 859-2056 from the U.S., or (404) 537-2406 for international callers, and then entering confirmation code 2615108.

**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.



**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 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, 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 or product candidates are unsafe, ineffective or not differentiated, 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® (revefenacin), our clinical development programs (including but not limited to our later stage clinical programs for izencitinib and ampreloxetine), 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 May 6, 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.

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

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*[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 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.*

*[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 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)**

| | June 30, 2021 | December 31, 2020 |
|---|---|---|
| **Assets** | **(Unaudited)** | **(1)** |
| Current assets: | | |
| Cash and cash equivalents and short-term marketable securities | $ 264,953 | $ 292,941 |
| Receivables from collaborative arrangements | 12,220 | 15,868 |
| Amounts due from TRC, LLC | 27,741 | 53,799 |
| Prepaid clinical and development services | 15,913 | 20,374 |
| Other prepaid and current assets | 12,353 | 10,359 |
| Total current assets | 333,180 | 393,341 |
| Property and equipment, net | 16,583 | 16,422 |
| Operating lease assets | 41,508 | 43,260 |
| Equity in net assets of TRC, LLC | 35,822 | 12,750 |
| Restricted cash | 833 | 833 |
| Other assets | 1,325 | 2,451 |
| Total assets | $ 429,251 | $ 469,057 |

**Liabilities and Shareholders' Deficit**

| | | |
|---|---|---|
| Current liabilities | $ 67,127 | $ 123,571 |
| Convertible senior notes due 2023, net | 227,499 | 226,963 |
| Non-recourse notes due 2035, net | 375,069 | 372,873 |
| Long-term operating lease liabilities | 57,768 | 47,220 |
| Other long-term liabilities | 2,162 | 2,181 |
| Shareholders' deficit | (300,374) | (303,751) |
| Total liabilities and shareholders' deficit | $ 429,251 | $ 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| | (Unaudited) | | (Unaudited) | |
| **Revenue:** | | | | |
| Collaboration revenue | $ 1,980 | $ 5,488 | $ 5,852 | $ 12,120 |
| Licensing revenue | - | - | - | 1,500 |
| Viatris collaboration agreement | 10,934 | 9,520 | 21,319 | 21,250 |
| Total revenue | 12,914 | 15,008 | 27,171 | 34,870 |
| **Costs and expenses:** | | | | |
| Research and development (1) | 51,093 | 62,404 | 118,692 | 128,417 |
| Selling, general and administrative (1) | 25,931 | 24,780 | 56,481 | 51,105 |
| Total costs and expenses | 77,024 | 87,184 | 175,173 | 179,522 |
| Loss from operations | (64,110) | (72,176) | (148,002) | (144,652) |
| Income from investment in TRC, LLC | 21,926 | 21,381 | 38,473 | 34,896 |
| Interest expense | (11,612) | (11,391) | (23,485) | (21,332) |
| Loss on extinguishment of debt | - | - | - | (15,464) |
| Interest and other income (expense), net | 1,171 | (662) | 937 | 798 |
| Loss before income taxes | (52,625) | (62,848) | (132,077) | (145,754) |
| Provision for income tax benefit (expense) | 220 | (39) | (7) | (186) |
| **Net loss** | $ (52,405) | $ (62,887) | $ (132,084) | $ (145,940) |
| Net loss per share: | | | | |
| Basic and diluted net loss per share | $ (0.80) | $ (1.00) | $ (2.03) | $ (2.39) |
| Shares used to compute basic and diluted net loss per share | 65,669 | 62,861 | 65,085 | 61,162 |

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| **(In thousands)** | 2021 | 2020 | 2021 | 2020 |
| Research and development | $ 7,315 | $ 8,098 | $ 15,236 | $ 15,963 |
| Selling, general and administrative | 7,626 | 8,487 | 15,537 | 15,898 |
| Total share-based compensation expense | $ 14,941 | $ 16,585 | $ 30,773 | $ 31,861 |

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