# Theravance Biopharma, Inc. Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update

- *Company's implied 35% share of YUPELRI® (revefenacin) net sales[1]: $13.6M Q4 2020, $50.0M FY 2020*
- *TD-0903: Company reports positive top-line results from Part 1 of a two-part Phase 2 study*

**DUBLIN, IRELAND – FEBRUARY 23, 2021** – Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today reported financial results for the fourth quarter and full year ended December 31, 2020.

*"2020 was a critical year of growth for YUPELRI, with our commercial team persevering during a respiratory pandemic and driving increased market share," said Rick E Winningham, Chief Executive Officer. "This same resilience was seen across our organization, laying the foundation for this year's clinical development milestones for ampreloxetine and izencitinib. Our focus in 2021 is to deliver on these milestones in what could be a transformational year."*

*"Importantly, we are also encouraged by the initial clinical data from a TD-0903 study in patients hospitalized with acute lung injury due to COVID-19. The data we are reporting today are from Part 1 of a two-part Phase 2 clinical study. The results show that inhaled administration of nebulized TD-0903, once daily over seven days, was generally well-tolerated and showed a numerical trend towards improved clinical status, reduced hospital stay and fewer deaths compared to placebo during a 28-day observation period. We look forward to reporting data from Part 2 in Q2 2021 and continuing to progress this potential therapy for those hospitalized with COVID-19."*

## 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 market share and achieved year-over-year sales growth of 159%; its share of the nebulized COPD market increased to 18.6% through November 2020 (up from 17.4% in September 2020).

- **TD-0903,** an investigational nebulized lung-selective pan-JAK inhibitor, is in a two-part Phase 2 study (NCT04402866) comparing treatment with TD-0903 versus placebo, on a background of standard of care treatment in hospitalized patients with COVID-19 who required oxygen at the time of enrollment. Part 1 of the study explored three once-daily doses (1 mg, 3 mg, 10 mg) and matched placebo in a double-blind, multiple-ascending dose (MAD) design. Each cohort comprised eight patients (six receiving TD-0903 and two receiving placebo), all treated up to seven days with the majority receiving background standard of care therapy, including oxygen, anticoagulation and dexamethasone.

    - **Part 1 Safety:**
        - TD-0903 was generally well-tolerated across the three dose levels
        - There were no drug-related serious adverse events
        - One patient in the 10 mg dose cohort discontinued therapy after four days because of an isolated increase in liver alanine aminotransferase (ALT) that met pre-defined stopping criteria

[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.*

- **Part 1 Exploratory Clinical Observations:**
  - TD-0903 showed numerical improvements in clinical outcome and duration of hospital stay and fewer deaths compared to placebo (n=25)

| | **Placebo** (n=6) | **1 mg** (n=6) | **3 mg** (n=7*) | **10 mg** (n=6) |
|---|---|---|---|---|
| **All-Cause Mortality by Day 28** | 2 (33%) | 1 (17%) | 0 (0%) | 0 (0%) |
| **Clinical status worsened during 7-day treatment period#** | 3 (50%) | 0 (0%) | 0 (0%) | 0 (0%) |
| **Alive and Respiratory Failure Free on Day 28##** | 4 (67%) | 5 (83%) | 6 (86%) | 6 (100%) |
| **Mean Time to Hospital Discharge (Days)** | 22.5 | 18.8 | 15.3 | 15.2 |

** One patient in the 3 mg group received 2 doses of TD-0903 before repeated polymerase chain reaction (PCR) testing confirmed the patient did not have COVID-19. The patient was replaced per the protocol allowances and their data is included for safety but not for efficacy.*
*# Worsening defined as a score of 8, 7 or 6 on World Health Organization (WHO) COVID-19 Clinical Status Ordinal Scale*
*## Respiratory Failure Free defined as a score of 1, 2, 3 or 4 on WHO COVID-19 Clinical Status Ordinal Scale*

- **Part 1 Biomarkers and Pharmacokinetics (PK):**
  - Evidence of improvement in several relevant inflammatory biomarkers
  - Low systemic exposure at all doses of nebulized TD-0903, in keeping with the lung-selective design features of the molecule

The 3 mg dose is currently being evaluated in Part 2 of the Phase 2 study, which is a randomized, double-blind, parallel-group study evaluating efficacy and safety of a seven-day course of once-daily nebulized TD-0903 compared to placebo in 198 hospitalized COVID-19 patients. The Company expects to announce data from Part 2 in Q2 2021.

**Upcoming Data Milestones**

- **TD-0903 Phase 2 Part 2** expected to report results in Q2 2021
- **Ampreloxetine** (norepinephrine reuptake inhibitor (NRI)) **for symptomatic neurogenic orthostatic hypertension (nOH) Phase 3** study expected to report results in Q3 2021
- **Izencitinib** (gut-selective oral pan-Janus kinase (JAK) inhibitor for inflammatory intestinal diseases) **Phase 2b/3** study in **ulcerative colitis** and **Phase 2** study in **Crohn's disease** expected to report results, separately, in Q3 2021

## Economic Interest

- **TRELEGY** (first once-daily single inhaler triple therapy for COPD and asthma)**,** in which the Company holds an economic interest, posted fourth quarter 2020 net sales of $315 million (up from $224 million in fourth quarter of 2019) and full year 2020 net sales of $1,058 million (up from $663 million in 2019), achieving year-over-year sales growth of 60%; Theravance Biopharma is entitled to approximately 5.5% to 8.5% (tiered) of worldwide net sales of the product.[2,3]

## Fourth Quarter and Full Year Financial Results

- **Revenue:** Total revenue for the fourth quarter of 2020 was $18.7 million, comprised of non-cash collaboration revenue of $7.1 million primarily attributed to our global collaboration with Janssen and $11.6 million in Viatris collaboration revenue. Total revenue for the fourth quarter represents a $10.8 million decrease over the same period in 2019. Full year 2020 revenue was $71.9 million, comprised of non-cash collaboration revenue of $26.5 million primarily attributed to our global collaboration with Janssen, licensing revenue of $1.5 million related to a Viatris clinical trial application milestone and $43.9 million in Viatris collaboration revenue.

- **YUPELRI:** The Viatris collaboration revenue of $11.6 million for the fourth quarter 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 fourth quarter of 2020 was approximately $13.6 million.

- **Research and Development (R&D) Expenses:** R&D expenses for the fourth quarter of 2020 were $65.2 million, compared to $67.0 million in the same period in 2019. Fourth quarter R&D expenses included total non-cash share-based compensation of $7.6 million. Full year 2020 R&D expenses were $261.0 million, or $229.7 million excluding non-cash share-based compensation.

- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses for the fourth quarter of 2020 were $30.1 million, compared to $33.0 million in the same period in 2019. Fourth quarter SG&A expenses included total non-cash share-based compensation of $8.0 million. Full year 2020 SG&A expenses were $108.7 million, or $77.0 million excluding non-cash share-based compensation.

- **Operating Loss:** Operating loss for the fourth quarter of 2020 was $76.5 million compared to $70.6 million in the same period of 2019. Full year 2020 operating loss was $297.8 million, or $234.8 million excluding share-based compensation expense compared to $251.9 million, or $191.5 million excluding share-based compensation expense in 2019.

- **Cash Position:** Cash, cash equivalents and marketable securities totaled $292.9 million as of December 31, 2020.

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[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, 25% of income from the Company's investment in TRC is retained by the Company.*

[3] *On June 10, 2020, the Company disclosed in a Form 8-K that it had formally objected to Theravance Respiratory Company, LLC ("TRC") and Innoviva, as the manager of TRC, regarding their proposed plan to use TRELEGY royalties to invest in certain privately-held companies, funds that would otherwise be available for distribution to the Company under the terms of the TRC LLC Agreement. The Company intends to continue to seek to protect its interests in this matter consistent with the dispute resolution procedures of the TRC LLC Agreement. In this regard, the Company initiated an arbitration proceeding against Innoviva and TRC in October 2020 challenging the authority of Innoviva and TRC to pursue such a business plan rather than distribute such funds to the Company in a manner consistent with the LLC Agreement and the Company's 85% economic interest in TRC. The arbitration hearing was held during the week of February 16, 2021, with post-hearing briefing and arguments to take place over the next few weeks. We currently anticipate a decision in those proceedings near the end of the current quarter or early in the second quarter of 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 GMT**. To participate, please dial (855) 296-9648 from the U.S. or (920) 663-6266 for international callers, using the confirmation code 9469708. Those interested in listening to the conference call live via the internet may do so by visiting Theravance.com, under the Investor Relations section, Events and Presentations.

A replay will be available on Theravance.com for 30 days through March 25, 2021. An audio replay will also be available through 8:00 pm ET on March 2, 2021 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 9469708.

**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 utilize 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.



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 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: current and potential future disagreements with Innoviva, Inc. and TRC LLC, the uncertainty of arbitration and litigation and the possibility that an arbitration award or litigation result 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® (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 November 9, 2020 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 STATEMENTS OF OPERATIONS**
**(In thousands, except per share data)**

| | Three Months Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| | (Unaudited) | | (Unaudited) | (1) |
| **Revenue:** | | | | |
| Collaboration revenue | $ 7,083 | $ 9,584 | $ 26,464 | $ 31,250 |
| Licensing revenue | - | 10,000 | 1,500 | 28,500 |
| Viatris collaboration agreement | 11,647 | 9,915 | 43,893 | 13,664 |
| Total revenue | 18,730 | 29,499 | 71,857 | 73,414 |
| **Costs and expenses:** | | | | |
| Research and development [2] | 65,165 | 67,025 | 260,953 | 219,248 |
| Selling, general and administrative [2] | 30,055 | 33,046 | 108,661 | 106,081 |
| Total costs and expenses | 95,220 | 100,071 | 369,614 | 325,329 |
| Loss from operations | (76,490) | (70,572) | (297,757) | (251,915) |
| Income from investment in TRC, LLC | 20,139 | 11,913 | 68,438 | 33,705 |
| Interest expense | (11,680) | (8,035) | (44,585) | (31,862) |
| Loss on extinguishment of debt | - | - | (15,464) | - |
| Interest and other income, net | 798 | 1,137 | 2,831 | 8,395 |
| Loss before income taxes | (67,233) | (65,557) | (286,537) | (241,677) |
| Provision for income tax benefit (expense) | 8,799 | (49) | 8,520 | 5,222 |
| **Net loss** | $ (58,434) | $ (65,606) | $ (278,017) | $ (236,455) |
| Net loss per share: | | | | |
| Basic and diluted net loss per share | $ (0.92) | $ (1.17) | $ (4.46) | $ (4.25) |
| Shares used to compute basic and diluted net loss per share | 63,725 | 56,102 | 62,345 | 55,610 |

[1] The condensed consolidated statement of operations for the year ended December 31, 2019 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, 2019.

[2] Amounts include share-based compensation expense as follows:

| | Three Months Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| (In thousands) | 2020 | 2019 | 2020 | 2019 |
| Research and development | $ 7,570 | $ 10,615 | $ 31,294 | $ 28,953 |
| Selling, general and administrative | 7,981 | 13,297 | 31,682 | 31,497 |
| Total share-based compensation expense | $ 15,551 | $ 23,912 | $ 62,976 | $ 60,450 |

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

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| **Assets** | **(Unaudited)** | **(1)** |
| Current assets: | | |
| Cash and cash equivalents and short-term marketable securities | $ 292,941 | $ 280,831 |
| Receivables from collaborative arrangements | 15,868 | 11,996 |
| Receivables from licensing arrangements | - | 10,000 |
| Amounts due from TRC, LLC | 53,799 | 28,574 |
| Prepaid clinical and development services | 20,374 | 2,736 |
| Other prepaid and current assets | 10,359 | 4,351 |
| Total current assets | 393,341 | 338,488 |
| Property and equipment, net | 16,422 | 12,644 |
| Long-term marketable securities | - | 4,985 |
| Operating lease assets | 43,260 | 46,604 |
| Equity in net assets of TRC, LLC | 12,750 | - |
| Restricted cash | 833 | 833 |
| Other assets | 2,451 | 5,272 |
| Total assets | $ 469,057 | $ 408,826 |
| | | |
| **Liabilities and Shareholders' Deficit** | | |
| Current liabilities | $ 123,571 | $ 111,703 |
| Convertible senior notes due 2023, net | 226,963 | 225,890 |
| Non-recourse notes due 2035, net | 372,873 | - |
| Non-recourse notes due 2033, net | - | 219,300 |
| Long-term operating lease liabilities | 47,220 | 47,725 |
| Other long-term liabilities | 2,181 | 28,048 |
| Shareholders' deficit | (303,751) | (223,840) |
| Total liabilities and shareholders' deficit | $ 469,057 | $ 408,826 |

(1) The condensed consolidated balance sheet as of December 31, 2019 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, 2019.