Theravance Biopharma, Inc. Reports Second Quarter 2020 Financial Results and Provides Business Update

August 6, 2020

- Ampreloxetine and TD-1473 programs progressing towards three data readouts in 2021

- YUPELRI® (revefenacin) gained market share despite COVID-19 impact on market demand

- TD-0903 program completed Phase 1, and now enrolling Phase 2

- The Company maintains 2020 financial guidance

DUBLIN, Aug. 6, 2020 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today reported financial results for the second quarter ending June 30, 2020. Revenue for the second quarter 2020 was $15.0 million. Operating loss was $72.2 million, or $55.6 million excluding share-based compensation expense. Cash, cash equivalents and marketable securities totaled $438.3 million as of June 30, 2020.

"This quarter was the first quarter for Theravance Biopharma working completely remotely, with the exception of our essential lab workers, and I could not be more proud and grateful of the work the team has been able to deliver. We will continue to incorporate the key learnings into our processes and will work to ensure that we become an even stronger company post-pandemic," said Rick E Winningham, Chief Executive Officer.

"Our commercial team continued to find ways to sustain market share momentum with YUPELRI, coordinating meaningful interactions with their accounts by leveraging digital and virtual selling tools. Given the challenges in a market which was and continues to be negatively affected by COVID-19, we were able to improve YUPELRI market share. Moving into the third quarter, we are tailoring our sales model to a hybrid model – in-person and remote call options – that can be modified depending on state and local restrictions, as well as customer preference. This allows our field teams to customize their approach based on what's right for them and their customers, always keeping health and safety the priority. We continue to forecast YUPELRI becoming a cash-flow positive brand in the United States (US) by the end of 2020."

"We continue to move our clinical programs forward despite ongoing challenges from the global pandemic. These challenges have resulted in delays in our late stage clinical programs for ampreloxetine, a norepinephrine reuptake inhibitor (NRI) under evaluation for the treatment of symptomatic neurogenic orthostatic hypotension (nOH), and TD-1473, a gut-selective oral JAKi in development for inflammatory intestinal disease in Crohn's and ulcerative colitis. We continue to expect both programs to readout in 2021. Regarding TD-8236, our lung-selective dry powder inhaled pan-JAK inhibitor in development for inflammatory lung disease, we expect to report data from the asthma Phase 2 program in fourth quarter 2020."

"During the second quarter, the team leaned into our organizational expertise in respiratory disease and moved our pre-clinical candidate TD-0903 into the clinic at an accelerated pace in response to the COVID-19 pandemic. We designed TD-0903 to be a lung-selective nebulized JAKi with the intent of addressing lung hyperinflammation in both the acute and chronic setting. In June, we completed Phase 1 and entered a Phase 2 study in the United Kingdom (UK) exploring the potential of TD-0903 to treat hospitalized patients with Acute Lung Injury (ALI) caused by COVID-19 to prevent progression to Acute Respiratory Distress Syndrome (ARDS) and the need for assisted ventilation. We are now opening additional sites in other countries to accelerate TD-0903's progression in the clinic."

Corporate Highlights

YUPELRI® (revefenacin) inhalation solution (lung-selective nebulized long-acting muscarinic antagonist (LAMA)):

- First and only once-daily, nebulized bronchodilator approved in the US for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), reimbursed by Part B Medicare program
- COVID-19 resulted in decreased overall market demand, yet YUPELRI increased market share; trajectory could continue to be affected by COVID-19 in third quarter
- Data as of April 2020 show that YUPELRI achieved a 91.8% share (up from 87% in Q1 2020) of the nebulized LAMA market and a 16% share (up from 13.7% in Q1 2020) of the long-acting nebulized market; market data reflects IQVIA Retail Data and the Durable Medical Equipment (DME) market segment

Key Pipeline Progress

The COVID-19 pandemic continues to be a threat to public health throughout the world, however Theravance Biopharma is encouraged by the ability to initiate the reopening of clinical sites for new patient screenings for ampreloxetine and TD-1473. The health and safety of the community Theravance Biopharma serves is the Company's utmost priority; therefore, the Company is continuing to work closely with investigator sites and vendors to help ensure their safety and that of the study participants as they contribute to our clinical programs. In mid-March, both programs paused new patient screenings for four weeks to allow sites to focus on supporting patients who were already in screening or already randomized and preserve data collection during this period. Screening of new patients resumed in mid-April, and Theravance Biopharma has seen a significant percentage of sites reopen to new patients globally.

By design, both ampreloxetine and TD-1473 clinical programs employ geographical diversity, which has allowed the Company to continue assessing where to reopen sites based on where the pandemic is waning. That said, the pandemic shows no signs of stopping, and Theravance Biopharma expects ongoing challenges as new "hot spots" emerge. We continue to expect both programs to readout in 2021.

Ampreloxetine (TD-9855, norepinephrine reuptake inhibitor (NRI) for symptomatic nOH):

- Ongoing registrational program in symptomatic neurogenic orthostatic hypertension (nOH) comprised of two studies:
  - Phase 3 four-week treatment study (SEQUOIA) to demonstrate efficacy, with data expected in 2021
  - Phase 3 four-month open label study followed by a six-week randomized withdrawal phase (REDWOOD) to demonstrate durability of response
- Given the ongoing pandemic and the fragility of the patient population, the Company, with input from the Food and Drug Administration (FDA) and other regulatory agencies and ethics committees, is working to adjust the protocol for these clinical trials to accommodate a decentralized approach in which patients can participate in the studies from home without needing to attend clinic visits

TD-1473 (gut-selective oral pan-Janus kinase (JAK) inhibitor for inflammatory intestinal diseases):

- Phase 2b/3 induction and maintenance study in ulcerative colitis (RHEA) and Phase 2 induction study in Crohn's disease (DIONE) progressing
- Enrollment continues in both studies, and data from the Phase 2b portion of the ulcerative colitis and Phase 2 Crohn's disease studies is expected in 2021

TD-5202 (gut-selective irreversible JAK3 inhibitor for inflammatory intestinal diseases):

- TD-5202 was generally well tolerated as a single oral dose up to 2000 milligrams and as a twice-daily oral dose up to 2000 milligrams total per day given for 10 consecutive days in healthy subjects

TD-8236 (lung-selective inhaled pan-JAK inhibitor for inflammatory lung diseases):

- Part C extension portion of the Phase 1 trial assessing additional biomarkers in moderate to severe asthmatics underway with results expected in 4Q 2020
- Phase 2 lung allergen challenge study initiated in 4Q 2019; data expected 4Q 2020

TD-0903 (lung-selective nebulized pan-JAK inhibitor for treatment of Acute Lung Injury caused by COVID-19)

- Completed Phase 1 study to assess the safety, tolerability and pharmacokinetics of single-and multiple-ascending doses (SAD/MAD) in healthy volunteers; data expected 4Q 2020
- Phase 2 study was initiated in the UK on June 25, 2020; to expedite enrollment in the study, we are opening additional sites in other regions including Europe and the US, pending approval by the relevant regulatory agencies and ethics committees

Economic Interest

TRELEGY (first once-daily single inhaler triple therapy for COPD)[1]:

- 2Q 2020 net sales of $241 million; Theravance Biopharma is entitled to approximately 5.5% to 8.5% (tiered) of worldwide net sales of the product
- GSK sNDA approval for asthma expected 2H 2020; The European Medicines Agency accepted the regulatory submission for the treatment of asthma in adults supported by the Phase III CAPTAIN study
- GSK sNDA for survival benefit claim over ANORO is under review; FDA postponed the Advisory Committee Meeting originally scheduled to review this sNDA on April 21, 2020; rescheduled Advisory Committee has not been publicly updated by FDA

Notes:
[1] 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 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 Company's investment in TRC is pledged to service outstanding notes, 25% of income from Company's investment in TRC is retained by Company.

Innoviva and Theravance Respiratory Company

On June 10, 2020, we disclosed in a Form 8-K our objections to Theravance Respiratory Company, LLC ("TRC") and Innoviva, as the manager of TRC, regarding TRC's proposed use of funds to invest in certain privately-held companies. On July 16, Innoviva and TRC filed a complaint in Delaware Chancery Court seeking an order establishing that the arbitration award from the parties' 2019 dispute conclusively established that (a) Innoviva possesses the authority as Manager of TRC to cause TRC to make such investments and (b) Innoviva possesses the authority as Manager of TRC to cause TRC to reserve cash to make such investments. The Court directed the parties to refer certain relevant questions raised by the complaint to the arbitrator in the 2019 dispute, who in turn determined that the 2019 proceedings did not resolve the issues currently in dispute. On

August 5, Innoviva and TRC voluntarily dismissed the complaint, without prejudice. We are pursuing and intend to continue to pursue the protection of the interests of the Company in this matter consistent with the dispute resolution procedures of the TRC LLC Agreement, including, if necessary, the initiation of a new arbitration proceeding.

Second Quarter Financial Results

- **Revenue:** Total revenue for the second quarter of 2020 was $15.0 million, comprised of collaboration revenue of $5.5 million primarily attributed to the Janssen collaboration agreement for TD-1473 and $9.5 million in Mylan collaboration revenue related to net sales of YUPELRI. Total revenue for the second quarter represents a $11.1 million decrease over the same period in 2019. The decrease was primarily due to a $2.0 million decrease in Janssen collaboration revenue and a $18.5 million decrease in licensing revenue. The decrease in Janssen collaboration revenue was due to a smaller portion of revenue recognized in the second quarter 2020 related to the $100.0 million upfront payment from the Janssen collaboration agreement that was entered into in February 2018. The decrease in licensing revenue was due to an $18.5 million upfront payment received from Mylan associated with an amendment signed in June 2019 for the commercialization and development rights to nebulized revefenacin in China and adjacent territories. The overall decrease in revenue was partially offset by a $9.4 million increase in the Mylan collaboration revenue related to YUPELRI.
- **Research and Development (R&D) Expenses:** R&D expenses for the second quarter of 2020 were $62.4 million, compared to $46.4 million in the same period in 2019. The $16.0 million increase was primarily due to a $12.8 million increase in external-related expenses related to the advancement of our priority programs, notably the continued progression of ampreloxetine and TD-8236, and the initiation of TD-0903 for COVID-19 and a $2.4 million increase in share-based compensation expense. Second quarter R&D expenses included non-cash share-based compensation of $8.1 million.
- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses for the second quarter of 2020 were $24.8 million, compared to $22.2 million in the same period in 2019. The $2.6 million increase was primarily attributed to a $2.9 million increase in share-based compensation expense, a $0.3 million increase in employee-related expenses, and a $0.3 million increase in facilities and other expenses. These increases were partially offset by a $0.8 million decrease in external-related expenses related to consulting services. Second quarter SG&A expenses included non-cash share-based compensation of $8.5 million.
- **Cash, Cash Equivalents and Marketable Securities** Cash, cash equivalents and marketable securities totaled $438.3 million as of June 30, 2020.

2020 Financial Guidance

- **Operating Loss** (excluding share-based compensation)**:** The Company is not changing financial guidance and expects full-year 2020 operating loss, excluding share-based compensation, of $205 million to $225 million. Operating loss guidance does not include:
  - Royalty income for TRELEGY which the Company recognizes in its statement of operations as "income from investment in TRC, LLC;" or
  - Potential future business development collaborations

On June 22, 2020, GlaxoSmithKline plc (GSK) completed an offering of $300 million of exchangeable senior notes due 2023; $280.3 million of which are exchangeable into existing ordinary shares of Theravance Biopharma held by GSK. The notes are guaranteed by GSK and will be exchangeable at the option of noteholders on any business day on or after September 1, 2020, under certain terms and conditions outlined in the offering documents. The Company will not be issuing any new shares in connection with this offering, and the Company did not receive any proceeds from the GSK offering.

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 2 pm PT / 9 pm GMT. To participate in the live call by telephone, please dial (855) 296-9648 from the US or (920) 663-6266 for international callers, using the confirmation code 8098314. 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 Investor Relations section, Presentations and Events.

A replay of the conference call will be available on Theravance Biopharma's website for 30 days through September 5, 2020. An audio replay will also be available through 8:00 pm ET on August 13, 2020 by dialing (855) 859-2056 from the US, or (404) 537-3406 for international callers, and then entering confirmation code 8098314.

About Theravance Biopharma

Theravance Biopharma, Inc. is a diversified biopharmaceutical company primarily focused on the discovery, development and commercialization of organ-selective medicines. Our purpose is to create transformational medicines to improve the lives of patients suffering from serious illnesses. Our research is focused in the areas of inflammation and immunology.

In pursuit of our purpose, we apply insights and innovation at each stage of our business and utilize our internal capabilities and those of partners around the world. We apply organ-selective expertise to biologically compelling targets to discover and develop medicines designed to treat underserved localized diseases and to limit systemic exposure, in order to maximize patient benefit and minimize risk. 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). Our pipeline of internally discovered programs is targeted to address significant patient needs.

We have 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.

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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, 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 2020 operating loss, excluding share-based compensation. 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 COVID-19 pandemic to continue to adversely impact our business operations and financial results, the extent of the impact on our ability to generate revenue from YUPELRI, our clinical development programs (in particular our later stage clinical programs for TD-1473 and Ampreloxetine) and the value of and market for our common 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 pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the U.S. and in other countries, and the effectiveness of actions taken globally to contain and treat the disease. Other risks affecting Theravance Biopharma are in the company's Form 10-Q filed with the SEC on May 8, 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 BALANCE SHEETS
(In thousands)

	June 30, 2020	December 31, 2019
Assets	**(Unaudited)**	**(1)**
Current assets:		
Cash and cash equivalents and short-term marketable securities	$ 438,340	$ 280,831
Receivables from collaborative arrangements	11,413	11,996
Receivables from licensing arrangements	-	10,000
Amounts due from TRC, LLC	35,509	28,574
Other prepaid and current assets	13,124	7,087
Total current assets	498,386	338,488
Property and equipment, net	14,433	12,644
Long-term marketable securities	-	4,985
Operating lease assets	45,184	46,604
Restricted cash	833	833
Other assets	5,494	5,272
Total assets	$ 564,330	$ 408,826

Liabilities and Shareholders' Deficit

Current liabilities	$ 106,574	$ 111,703
Convertible senior notes due 2023, net	226,427	225,890
Non-recourse notes due 2035, net	375,266	-
Non-recourse notes due 2033, net	-	219,300
Long-term operating lease liabilities	47,631	47,725
Other long-term liabilities	10,768	28,048
Shareholders' deficit	(202,336)	(223,840)
Total liabilities and shareholders' deficit	$ 564,330	$ 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(Unaudited)		(Unaudited)	
Revenue:				
Collaboration revenue	$ 5,488	$ 7,493	$ 12,120	$ 12,831
Licensing revenue	-	18,500	1,500	18,500
Mylan collaboration agreement	9,520	157	21,250	157
Total revenue	15,008	26,150	34,870	31,488
Costs and expenses:				
Research and development (1)	62,404	46,399	128,417	100,217
Selling, general and administrative (1)	24,780	22,227	51,105	47,413
Total costs and expenses	87,184	68,626	179,522	147,630
Loss from operations	(72,176)	(42,476)	(144,652)	(116,142)
Income from investment in TRC, LLC	21,381	8,366	34,896	14,595
Interest expense	(11,391)	(7,901)	(21,332)	(15,759)
Loss on extinguishment of debt	-	-	(15,464)	-
Interest and other income (expense), net	(662)	2,374	798	5,169
Loss before income taxes	(62,848)	(39,637)	(145,754)	(112,137)
Provision for income tax expense	(39)	(201)	(186)	(281)
Net loss	$ (62,887)	$ (39,838)	$ (145,940)	$ (112,418)
Net loss per share:				
Basic and diluted net loss per share	$ (1.00)	$ (0.72)	$ (2.39)	$ (2.04)
Shares used to compute basic and diluted net loss per share	62,861	55,529	61,162	55,235

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	2020	2019	2020	2019
Research and development	$ 8,098	$ 5,720	$ 15,963	$ 11,880
Selling, general and administrative	8,487	5,578	15,898	11,639
Total share-based compensation expense	$ 16,585	$ 11,298	$ 31,861	$ 23,519

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