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

November 5, 2020

- YUPELRI® (revefenacin) share of the nebulized COPD market increased to 17.4% through July 2020 (up from 16% in April 2020) and achieved brand profitability on a stand-alone basis

- Company updating timelines for ampreloxetine and TD-1473 - top-line results expected in Q3 2021

- TD-8236 reduced FeNO and pSTAT via JAK inhibition in the Phase 1 Part C study in moderate-to-severe asthmatics but did not meet the primary endpoint of the Phase 2a Lung Allergen Challenge study

- TD-0903 data from Phase 1 provided confidence to continue dosing patients in a Phase 2 study; Phase 2 results expected in Q2 2021

- The Company updates 2020 financial guidance

DUBLIN, Nov. 5, 2020 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today reported financial results for the third quarter ending September 30, 2020. Theravance Biopharma's Total Revenue for the third quarter 2020 was $18.3 million. Operating loss was $76.6 million, or $61.1 million excluding share-based compensation expense. Cash, cash equivalents and marketable securities totaled $358.3 million as of September 30, 2020.

In connection with the commercialization of YUPELRI®, the Company is entitled to a share of U.S. profits and losses (65% to Mylan; 35% to the Company) pursuant to its agreement with Mylan. While Mylan records the total Net Sales of YUPELRI within its financial statements, Theravance Biopharma's implied 35% share of net sales for YUPELRI during Q3 2020 was $13.0 million (up from $5.8 million in Q3 2019). Going forward, Theravance Biopharma will report its implied 35% of Net Sales for YUPELRI in public communications and in the Company's quarterly SEC filings on Form 10-Q and Form 10-K.

"YUPELRI gained market share, delivered sales growth versus the second quarter and achieved brand profitability for Theravance Biopharma thanks to the efforts of the Mylan and Theravance Biopharma commercial teams. Based on the constraints posed by the pandemic, the team implemented a hybrid model of virtual selling, utilizing digital resources and in-person meetings when and where permitted," said Rick E Winningham, Chief Executive Officer.

"Despite ongoing challenges and the uncertain environment created by the global pandemic, we have seen a significant uptick in clinical trial enrollment. We therefore have more confidence in guiding to Phase 3 results for ampreloxetine for symptomatic neurogenic orthostatic hypotension (nOH) and for TD-1473 Phase 2b results in ulcerative colitis and Phase 2 results in Crohn's disease in Q3 2021."

"We completed the TD-8236 Phase 1 Part C and Phase 2a Lung Allergen Challenge (LAC) study. The LAC study represented the first time an inhaled JAK inhibitor was studied in such a model. We met our primary objectives with the Phase 1 Part C study in moderate-to-severe asthmatics dosing TD-8236 with an inhaled corticosteroid. Decreases in key inflammatory biomarkers were seen in the TD-8236 plus steroid arm versus the steroid alone arm. Gene expression and cytokine data from the Phase 1 Part C is still under analysis. While we are still reviewing the full data set, TD-8236 as a single agent did not meet the primary objective of the Phase 2a LAC study."

"In regard to TD-0903, we have had a chance to review the Phase 1 data. Results showed favorable safety and tolerability profile across the full range of nebulized doses and low systemic levels of TD-0903 in the systemic circulation, consistent with the lung-selective design. This has given us confidence as we continue to dose patients in the Phase 2 COVID-19 trial, which is being conducted in multiple locations around the world with results expected in Q2 2021."

Corporate Highlights

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

- First and only once-daily, nebulized bronchodilator approved in the U.S. for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), reimbursed by Part B Medicare program
- Overall market challenges remain due to COVID-19, yet YUPELRI increased market share and achieved quarter-over-quarter net sales growth of 22%; achieved stand-alone brand profitability in Q3 2020
- Data as of July 2020 show that YUPELRI achieved 17.4% share (up from 16% in April 2020) of the long-acting nebulized bronchodilator market and 93% share (up from 91.8% in Q2 2020) of the nebulized LAMA market; market data reflects IQVIA Retail Data and the Durable Medical Equipment (DME) market segment

Key Pipeline Progress

The COVID-19 pandemic has made it difficult to operate a business in many ways and none more so than in clinical trials. Despite the challenges, Theravance Biopharma has been encouraged by the response to our ongoing clinical trial recruitment efforts. By design, both ampreloxetine and TD-1473 clinical programs employ geographical diversity, which has allowed the Company to continue to work closely with sites to continue enrollment where possible.

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

- Ongoing registrational program in symptomatic nOH comprised of:
  - Phase 3 four-week treatment study (SEQUOIA) to demonstrate efficacy expected to read out in Q3 2021
  - Phase 3 four-month open-label study followed by a six-week randomized withdrawal phase (REDWOOD) to demonstrate durability of response
  - Phase 3 26-week open-label study (OAK), which is a long-term extension study that will be ongoing at the time of registration, to allow subjects completing REDWOOD to have continued access to ampreloxetine for up to 3.5 years and to collect safety and tolerability data over the course of treatment
- Given the ongoing pandemic and the fragility of the patient population, the Company worked with the U.S. Food and Drug Administration (FDA) and other regulatory agencies to update the protocol for these clinical trials to accommodate a decentralized approach in which patients can participate in the majority of the study from home without needing to attend clinic visits; this infrastructure, leveraging a telemedicine platform and in-home healthcare assessments, is now being rolled out globally.

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

- RHEA (this program consists of 3 separate studies in Ulcerative Colitis):
  - Phase 2b eight-week placebo-controlled dose-finding induction study expected to read out in Q3 2021
  - Phase 3 eight-week placebo-controlled dose-confirming induction study to start after dose selection based on Phase 2b Induction Study results (*to be initiated post-Janssen opt-in*)
  - Phase 3 44-week placebo-controlled maintenance study in which subjects roll over from either the Phase 2b or Phase 3 Induction Study
- DIONE:
  - Phase 2 placebo-controlled induction study in Crohn's disease expected to read out in Q3 2021 with patients given the potential to continue to receive ongoing access to TD-1473 as part of a long-term extension study

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

- TD-5202 was generally well-tolerated as a single oral dose up to 2,000 milligrams and as a twice-daily oral dose up to 2,000 milligrams total per day given for 10 consecutive days in healthy subjects

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

- The Part C extension portion of the Phase 1 trial assessing additional biomarkers in moderate-to-severe asthmatics demonstrated biomarkers of JAK target engagement (pSTAT1 and pSTAT6) were reduced in cellular fractions of bronchoalveolar lavage fluid after 7 days of once-daily dosing at a dose level of 1500 µg
- TD-8236 is the first JAK inhibitor to be studied in a Phase 2a Lung Allergen Challenge (LAC) study; TD-8236 had no impact on decrease in lung function (FEV1) following the LAC study after 14 days of once-daily dosing at dose levels of 150 µg and 1500 µg
  - FeNO was reduced at 1500 µg consistent with previous studies; lack of FeNO response at 150 µg and lack of effect on late asthmatic response (LAR) at 150 µg was expected based on previous studies
  - TD-8236 engages the JAK mechanism at a dose of 1500 µg as evidenced by the reductions in FeNO consistent with Phase 1; lack of effect on the LAR at 1500 µg in the LAC study was inconsistent with expectations

The collective data set (pre-clinical, Phase 1, Phase 2a) demonstrates TD-8236 engages the JAK mechanism at a dose of 1500 µg as evidenced by the reduction in FeNO and reductions in pSTAT. The Company will continue to analyze the data set including the forthcoming gene expression and cytokine data from the Phase 1 Part C study.

TD-0903 (nebulized lung-selective pan-JAK inhibitor for acute hyperinflammation of the lung in COVID-19 and chronic inflammation for the prevention of lung transplant rejection):

For treatment of Acute Lung Injury caused by COVID-19

- Completed Phase 1 study to assess the safety, tolerability and pharmacokinetics (PK) of single- and multiple-ascending doses (SAD/MAD) in healthy volunteers; data provided confidence to continue dosing patients in a Phase 2 study
  - Favorable safety and tolerability profile across the full range of nebulized doses from 1 to 10 mg after once-daily dosing for 7 days
  - Low systemic levels of TD-0903 in the blood, consistent with lung-selective design
  - PK profile supports long duration of exposure in the lung, consistent with pre-clinical models and supporting

once-daily dosing

- Initiated Phase 2 study in June 2020; Part 1 was a multiple dose-ascending study (from 1 to 10 mg doses) conducted in 24 hospitalized COVID-19 patients that has now completed dosing. Part 2 is a randomized, double-blind, parallel-group study evaluating efficacy and safety of one dose of TD-0903 compared with placebo in approximately 200 hospitalized COVID-19 patients; the Company expects to report results of the Phase 2 study in Q2 2021

The ongoing effects of the COVID-19 pandemic present a substantial public health and economic challenge, affecting our employees, patients, communities, clinical trial sites, suppliers, business partners and business operations. The full extent to which the COVID-19 pandemic will continue to directly or indirectly impact our business will depend on future developments that are highly uncertain, including the ongoing spread of the virus globally, and the actions taken to contain or treat it.

Economic Interest

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

- 3Q 2020 net sales of $251.9 million (up from $172.8 million in Q3 2019); Theravance Biopharma is entitled to approximately 5.5% to 8.5% (tiered) of worldwide net sales of the product
- GSK received FDA approval to expand the label to include asthma on September 9, 2020; the European Medicines Agency accepted the regulatory submission for the treatment of asthma in adults supported by the Phase III CAPTAIN study
- GSK received a Complete Response Letter for the addition of the mortality indication

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 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.

Innoviva and Theravance Respiratory Company

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. An arbitration hearing is scheduled for the first quarter of 2021.

Third Quarter Financial Results

- **Revenue:** Total revenue for the third quarter of 2020 was $18.3 million, comprised of non-cash collaboration revenue of $7.3 million primarily attributed to the Janssen collaboration agreement for TD-1473 and $11.0 million in Mylan collaboration revenue related to net sales of YUPELRI. Total revenue for the third quarter represents a $5.8 million increase over the same period in 2019. The increase was primarily due to a $7.4 million increase in Mylan collaboration revenue which was partially offset by a $1.6 million decrease in Janssen collaboration revenue. The decrease in Janssen collaboration revenue was due to a smaller portion of revenue recognized in the third quarter 2020 related to the $100.0 million upfront payment from the Janssen collaboration agreement that was entered into in February 2018.

- **YUPELRI:** The Mylan collaboration revenue of $11.0 million represents amounts receivable from Mylan and is comprised of the Company's implied 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 us are recorded within operating expenses. While Mylan records the total net sales of YUPELRI within its financial statements, our implied 35% share of net sales of YUPELRI for the third quarter of 2020 was approximately $13.0 million. Going forward, we will report our implied 35% share of net sales for YUPELRI in future communications.

- **Research and Development (R&D) Expenses:** R&D expenses for the third quarter of 2020 were $67.4 million, compared to $52.0 million in the same period in 2019. The $15.4 million increase was primarily due to (i) a $10.2 million increase in external-related expenses related to the advancement of our priority programs, notably the continued progression of TD-1473, ampreloxetine, TD-8236, and the initiation of TD-0903 in COVID-19; (ii) a $3.5 million increase in employee-related expenses primarily due to increases in compensation-related expenses; and (iii) a $1.3 million increase in share-based compensation expense primarily due to an increase in annual grants of share-based awards to employees. Third quarter R&D expenses included total non-cash share-based compensation of $7.8 million.

- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses for the third quarter of 2020 were $27.5 million, compared to $25.6 million in the same period in 2019. The $1.9 million increase was primarily attributed to (i) a

$1.2 million increase in employee-related expenses primarily due to increases in compensation-related expenses; (ii) a $1.2 million increase in share-based compensation expense primarily due to an increase in annual grants of share-based awards to employees; and (iii) a $0.6 million increase in facilities and other expenses. These increases were partially offset by a $1.2 million decrease in external-related expenses primarily related to legal and consulting services. Third quarter SG&A expenses included total non-cash share-based compensation of $7.8 million.

- **Cash, Cash Equivalents and Marketable Securities:** Cash, cash equivalents and marketable securities totaled $358.3 million as of September 30, 2020.

2020 Financial Guidance

- **Operating Loss** (excluding share-based compensation)**:** The Company is changing financial guidance and expects full-year 2020 operating loss, excluding share-based compensation, of $225 million to $235 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

Annual Meeting

The Company will hold its 2021 Annual General Meeting on April 27, 2021.

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 in the live call by telephone, please dial (855) 296-9648 from the U.S. or (920) 663-6266 for international callers, using the confirmation code 1269525. 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 December 5, 2020. An audio replay will also be available through 8:00 pm ET on November 12, 2020 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 1269525.

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.

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 August 10, 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.

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

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

	September 30, 2020	December 31, 2019
Assets	**(Unaudited)**	**(1)**
Current assets:		
Cash and cash equivalents and short-term marketable securities	$ 358,347	$ 280,831
Receivables from collaborative arrangements	12,399	11,996
Receivables from licensing arrangements	-	10,000
Amounts due from TRC, LLC	48,909	28,574
Prepaid clinical and development services	20,761	2,736
Other prepaid and current assets	10,308	4,351
Total current assets	450,724	338,488
Property and equipment, net	15,430	12,644
Long-term marketable securities	-	4,985
Operating lease assets	44,391	46,604
Restricted cash	833	833
Other assets	810	5,272
Total assets	$ 512,188	$ 408,826
Liabilities and Shareholders' Deficit		
Current liabilities	$ 104,270	$ 111,703
Convertible senior notes due 2023, net	226,695	225,890
Non-recourse notes due 2035, net	384,482	-
Non-recourse notes due 2033, net	-	219,300
Long-term operating lease liabilities	47,823	47,725
Other long-term liabilities	10,454	28,048
Shareholders' deficit	(261,536)	(223,840)
Total liabilities and shareholders' deficit	$ 512,188	$ 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(Unaudited)		(Unaudited)	
Revenue:				
Collaboration revenue	$ 7,261	$ 8,836	$ 19,381	$ 21,666
Licensing revenue	-	-	1,500	18,500
Mylan collaboration agreement	10,996	3,591	32,246	3,749
Total revenue	18,257	12,427	53,127	43,915
Costs and expenses:				
Research and development (1)	67,371	52,006	195,788	152,223
Selling, general and administrative (1)	27,501	25,622	78,606	73,035
Total costs and expenses	94,872	77,628	274,394	225,258
Loss from operations	(76,615)	(65,201)	(221,267)	(181,343)
Income from investment in TRC, LLC	13,403	7,197	48,299	21,792
Interest expense	(11,573)	(8,068)	(32,905)	(23,827)
Loss on extinguishment of debt	-	-	(15,464)	-
Interest and other income, net	1,235	2,089	2,033	7,258
Loss before income taxes	(73,550)	(63,983)	(219,304)	(176,120)
Provision for income tax (expense) benefit	(93)	5,552	(279)	5,271
Net loss	$ (73,643)	$ (58,431)	$ (219,583)	$ (170,849)
Net loss per share:				
Basic and diluted net loss per share	$ (1.16)	$ (1.05)	$ (3.55)	$ (3.08)
Shares used to compute basic and diluted net loss per share	63,303	55,858	61,881	55,445

---

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2020	2019	2020	2019
Research and development	$ 7,761	$ 6,458	$ 23,724	$ 18,338
Selling, general and administrative	7,803	6,561	23,701	18,200
Total share-based compensation expense	$ 15,564	$ 13,019	$ 47,425	$ 36,538

View original content to download multimedia:http://www.prnewswire.com/news-releases/theravance-biopharma-inc-reports-third-quarter-2020-financial-results-and-provides-business-update-301167304.html

SOURCE Theravance Biopharma, Inc.