

Theravance Biopharma, Inc. Reports Third Quarter 2019 Financial Results and Provides Business Update

November 5, 2019

- Late-stage clinical studies of ampreloxetine and gut-selective oral pan-JAK inhibitor TD-1473 progressing
- Lung-selective inhaled pan-JAK inhibitor TD-8236 progressing to allergen challenge study following positive Phase 1 results including biomarker data in asthmatics
- Continued strong customer acceptance of YUPELRI® (revefenacin) inhalation solution, in partnership with Mylan
- Multiple data read-outs from key programs anticipated in 2020
- Company reduces 2019 full-year operating loss guidance to a range of \$200 million to \$210 million, excluding non-cash share-based compensation

DUBLIN, Nov. 5, 2019 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today reported financial results for the third quarter ended September 30, 2019. Revenue for the third quarter of 2019 was \$12.4 million. Third quarter operating loss was \$65.2 million or \$52.2 million excluding share-based compensation expense. Cash, cash equivalents, marketable securities, and restricted cash totaled \$352.9 million as of September 30, 2019.



Rick E Winningham, Chief Executive Officer, commented:

"As we approach the end of 2019, a critical year of progress for Theravance Biopharma, we believe that our organ-selective focus in research, translational science and development has generated a portfolio of product candidates that have the potential to transform the treatment of serious, chronic diseases. We have generated a compelling body of evidence attesting to the potential therapeutic value of organ-selective medicines. These organ-selective medicines are directed at biological targets that cannot be fully leveraged systemically without incurring serious dose-limiting toxicities. We have demonstrated the potential to maximize the value of proven and potent biology to achieve greater efficacy, safety and enhanced outcomes for patients.

"2020 will be an important year for our company in terms of delivering data across all of our key development programs: TD-1473, our gut-selective pan-JAK inhibitor, is moving forward in a Phase 2b/3 study in ulcerative colitis and a Phase 2 study in Crohn's disease, partnered with Janssen; ampreloxetine, our norepinephrine reuptake inhibitor, is advancing in a Phase 3 registrational program in symptomatic neurogenic orthostatic hypotension (nOH); TD-8236, our lung-selective pan-JAK inhibitor for which we reported promising Phase 1 data, is planned to be evaluated in additional asthma trials; and TD-5202, our gut-selective irreversible JAK3 inhibitor for inflammatory intestinal diseases, is advancing in Phase 1.

"Regarding our commercial programs, the YUPELRI® U.S. launch is progressing well in partnership with Mylan and we continue to make headway against key performance metrics. Lastly, we continue to be pleased by the commercial momentum of GSK's TRELEGY ELLIPTA.

"Looking ahead, we expect to achieve important milestones over the next 12 to 18 months as we maintain a strong capital position, advance our promising pipeline, build value through our partnerships and prioritize the commercialization of our innovation."

Program Updates

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
- Data from the Phase 2b portion of the ulcerative colitis and Phase 2 Crohn's disease studies planned late-2020

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

- Supplemental data from a small exploratory Phase 2 study in patients with nOH presented at the International Parkinson and Movement Disorder Society (MDS) in September 2019 suggest mechanistic association between symptom improvement and increases in circulating norepinephrine levels over four weeks of ampreloxetine therapy
- Ongoing registrational program in symptomatic nOH comprised of two studies:
 - Phase 3 four-week treatment study (SEQUOIA) to demonstrate efficacy, with data expected in 2H 2020
 - Phase 3 four-month open label study followed by a six-week randomized withdrawal phase (REDWOOD) to demonstrate durability of response

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

- Positive Phase 1 results in healthy subjects and mild asthmatics reported in September 2018; data demonstrated:
 - Evidence of biological activity in the lung with minimal systemic exposure, favorable overall safety and tolerability; and
 - Preliminary positive FeNO (inhaled nitric oxide) data in patients with mild asthma and elevated FeNO levels at baseline
- Part C extension portion of the Phase 1 trial assessing additional biomarkers in more severe asthmatics underway with results expected in 1H 2020
- Phase 2 lung allergen challenge expected to get underway in 4Q19, with results expected in 2020

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

- Phase 1 study in healthy subjects underway, with results expected in 1H 2020

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)
- U.S. launch underway with partner Mylan; continued strong customer acceptance across key market metrics; combined sales infrastructures covering the hospital, hospital discharge, and home health settings

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

- 3Q19 net sales of \$172.8 million; Theravance Biopharma entitled to approximately 5.5% to 8.5% (tiered) of worldwide net sales of the product
- Product now launched for COPD in 38 markets; approval in China expected in 4Q19
- GSK filed supplemental NDA for TRELEGY ELLIPTA use in patients with asthma in October 2019

Notes:

¹ As reported by Glaxo Group Limited or one of its affiliates (GSK); reported sales converted to USD; economic interest related to TRELEGY ELLIPTA (the combination of fluticasone furoate, aclidinium, 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 LLC") expenses paid and the amount of cash, if any, expected to be used in TRC over the next four fiscal quarters).

Third Quarter Financial Results

Revenue

Total revenue for the third quarter of 2019 was \$12.4 million compared to \$12.8 million in the same period in 2018. The decrease was primarily due to a decrease in product sales which resulted from the sale of VIBATIV® to Cumberland Pharmaceuticals in late-2018, mostly offset by revenue from the Mylan collaboration agreement for YUPELRI®.

Research and Development (R&D) Expenses

R&D expenses for the third quarter of 2019 were \$52.0 million, compared to \$52.7 million in the same period in 2018. The decrease was primarily due to lower employee-related costs associated with the reduction in force announced in the first quarter of 2019, partially offset by an increase in external expenses related to the progression of our key programs. Third quarter R&D expenses included non-cash share-based compensation of \$6.5 million.

Selling, General and Administrative (SG&A) Expenses

SG&A expenses for the third quarter of 2019 were \$25.6 million, compared to \$21.9 million in the same period in 2018. The increase was primarily due to higher external expenses and share-based compensation, partially offset by lower employee-related costs associated with the reduction in force announced in the first quarter of 2019. Third quarter SG&A expenses included non-cash share-based compensation of \$6.6 million.

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents, marketable securities, and restricted cash, totaled \$352.9 million as of September 30, 2019.

2019 Financial Guidance

The Company has reduced its 2019 full year operating loss guidance to a range of \$200.0 million to \$210.0 million, excluding non-cash share-based compensation. The reduction in operating loss guidance is primarily due to additional licensing revenue recognized in the second quarter of 2019 associated with the upfront payment received from Mylan for YUPELRI development and commercialization rights in China. Operating loss guidance does not include royalty income for TRELEGY ELLIPTA which the Company recognizes as non-operating income. Our future financial guidance could be impacted by factors including, but not limited to our share of U.S. profits and losses related to the commercialization of YUPELRI, potential future business development collaborations as well as the timing and cost of clinical studies associated with its key programs.

Arbitration Against Innoviva

As reported in the Company's filings with the Securities and Exchange Commission, in May 2019, the Company announced that it had initiated an

arbitration against Innoviva, Inc. and Theravance Respiratory Company, LLC. As further reported in a Form 8-K filed by the Company on September 30, 2019, the arbitrator issued a final decision.

Conference Call and Live Webcast Today at 5:00 pm ET

Theravance Biopharma will hold a conference call and live webcast accompanied by slides today at 5:00 pm ET. To participate in the live call by telephone, please dial (855) 296-9648 from the US, or (920) 663-6266 for international callers, and use the confirmation code 6281636. 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. Please go to the website 15 minutes prior to the start of the call to register, download, and install any necessary audio software.

A replay of the conference call will be available on Theravance Biopharma's website for 30 days through December 5, 2019. An audio replay will also be available through 11:00 am ET on November 12, 2019 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 6281636.

About Theravance Biopharma

Theravance Biopharma, Inc. ("Theravance Biopharma") 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 or one of its affiliates (GSK) pursuant to its agreements with Innoviva, Inc. relating to certain programs, including TRELEGY ELLIPTA.

For more information, please visit www.theravance.com.

THERAVANCE[®] and the Cross/Star logo are registered trademarks of the Theravance Biopharma group of companies. YUPELRI[®] is a United States registered trademark of Mylan Specialty L.P. Trademarks, 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 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 2019 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: 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. Other risks affecting Theravance Biopharma are described under the heading "Risk Factors" contained in Theravance Biopharma's Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 5, 2019 and Theravance Biopharma's other filings 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 Information:

Jessica Stitt
650-808-4045
investor.relations@theravance.com

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(Unaudited)		(Unaudited)	
Revenue:				
Product sales	\$ -	\$ 3,849	\$ -	\$ 12,889
Collaboration revenue	8,836	8,989	21,666	31,744
Licensing revenue	-	-	18,500	-
Mylan collaboration agreement	3,591	-	3,749	-
Total revenue	12,427	12,838	43,915	44,633
Costs and expenses:				
Cost of goods sold	-	705	-	83
Research and development ⁽¹⁾	52,006	52,693	152,223	149,079
Selling, general and administrative ⁽¹⁾	25,622	21,890	73,035	71,601
Total costs and expenses				
	77,628	75,288	225,258	220,763
Loss from operations	(65,201)	(62,450)	(181,343)	(176,130)
Income from investment in TRC, LLC	7,197	3,119	21,792	5,754
Interest expense	(8,068)	(2,137)	(23,827)	(6,411)
Interest and other income, net	2,089	1,376	7,258	4,144
Loss before income taxes	(63,983)	(60,092)	(176,120)	(172,643)
Provision for income tax benefit	5,552	659	5,271	7,305
Net loss	\$ (58,431)	\$ (59,433)	\$ (170,849)	\$ (165,338)
Net loss per share:				
Basic and diluted net loss per share	\$ (1.05)	\$ (1.10)	\$ (3.08)	\$ (3.07)
Shares used to compute basic and diluted net loss per share	55,858	54,248	55,445	53,771

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2019	2018	2019	2018
Research and development	\$ 6,458	\$ 6,294	\$ 18,338	\$ 19,757
Selling, general and administrative	6,561	5,452	18,200	19,842
Total share-based compensation expense	\$ 13,019	\$ 11,746	\$ 36,538	\$ 39,599

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

	September 30, 2019	December 31, 2018
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents and short-term marketable securities	\$ 319,681	\$ 505,276
Receivables from collaborative arrangements	4,595	10,053
Amounts due from TRC, LLC	16,661	5,422
Short-term restricted cash	7,496	-
Other prepaid and current assets	7,219	12,072
Total current assets	355,652	532,823
Property and equipment, net	12,189	13,176
Long-term marketable securities	24,939	11,869
Operating lease assets	46,755	-
Restricted cash	833	833
Other assets	4,969	1,534
Total assets	<u>\$ 445,337</u>	<u>\$ 560,235</u>
Liabilities and Shareholders' Deficit		
Current liabilities	\$ 108,823	\$ 98,554
Convertible senior notes due 2023, net	225,622	224,818
Non-recourse notes due 2033, net	222,008	229,535

Long-term operating lease liabilities	48,620	-
Other long-term liabilities	23,069	58,917
Shareholders' deficit	(182,805)	(51,589)
Total liabilities and shareholders' deficit	<u>\$ 445,337</u>	<u>\$ 560,235</u>

-
- (1) The condensed consolidated balance sheet as of December 31, 2018 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, 2018.

 View original content to download multimedia: <http://www.prnewswire.com/news-releases/theravance-biopharma-inc-reports-third-quarter-2019-financial-results-and-provides-business-update-300952230.html>

SOURCE Theravance Biopharma, Inc.