Theravance Biopharma, Inc. Reports Fourth Quarter and Full Year 2018 Financial Results and Provides Business Update

February 26, 2019

YUPELRI™ (revefenacin) inhalation solution product launch progressing in partnership with Mylan
Ampreloxetine and TD-1473 late-stage clinical programs advancing

DUBLIN, Feb. 26, 2019 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today reported financial results for the fourth quarter and full year ended December 31, 2018. Revenue for the fourth quarter and full year 2018 was $15.7 million and $60.4 million, respectively. Full year operating loss was $238.8 million or $187.4 million excluding share-based compensation expense, in line with the Company's previously stated financial guidance. Cash, cash equivalents, and marketable securities totaled $517.1 million as of December 31, 2018.

Rick E Winningham, chairman and chief executive officer, commented: "Following a highly productive 2018, we begin the year with great momentum and continue to make meaningful progress towards our goal of designing more effective and safer medicines to address unmet patient needs. Early in 2018, we entered into a global collaboration with Janssen for TD-1473, our gut-selective pan-JAK inhibitor for inflammatory intestinal diseases, for which we are beginning late-stage clinical trials. In the middle of the year, we showed positive four-week results for ampreloxetine in neurogenic orthostatic hypotension, providing us with the confidence to advance into a registrational Phase 3 program which is now underway. In the latter part of 2018, we and our partner Mylan achieved product approval for YUPELRI in COPD, and formal launch efforts are now underway. We closed out the year with R&D Day where we described our innovative research and development strategy of organ-selective medicines designed to expand the therapeutic index beyond that of conventional therapy and introduced several new research programs. Underpinning the progress of our own business, GSK's TRELEGY ELLIPTA for COPD continues its impressive sales trajectory, and we await the results of the Phase 3 CAPTAIN study in asthma in the first half of 2019.

"We anticipate multiple clinical readouts and milestones over the next several months, including supplemental data presentations at upcoming scientific meetings for TD-1473 in ulcerative colitis and ampreloxetine in nOH, as well as Phase 1 data for TD-8236, and initial commercial metrics for YUPELRI. Following our recently completed note financing tied to our economic interest in TRELEGY ELLIPTA, we enter 2019 with a strong cash balance and are well-positioned to execute against our milestones and continue to deliver value to stakeholders."

Program and Corporate Updates

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)
- Formal launch activities underway with partner Mylan; combined sales infrastructures covering the hospital, hospital discharge, and home health settings

TD-1473 (gut-selective pan-Janus kinase (JAK) inhibitor):

- First patients dosed in Phase 2 DIONE induction study in Crohn's disease
- Sites initiated in registrational Phase 2b/3 RHEA induction and maintenance study in ulcerative colitis
- Results from the Phase 1b study of TD-1473 in patients with ulcerative colitis accepted as an oral presentation at Digestive Disease Week (DDW) in May 2019

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

- Recently announced initiation of dosing in registrational Phase 3 program in symptomatic neurogenic orthostatic hypotension (nOH)
- Phase 2 study in patients with nOH complete; 5-month data further support previously-announced clinical observations after four weeks of treatment. Detailed study data to be submitted for presentation at mid-year scientific meeting

TD-8236 (novel, lung-selective inhaled pan-JAK inhibitor for serious respiratory diseases):

- Discovery leverages organizational expertise in respiratory diseases and JAK inhibition
- Phase 1 clinical study underway; designed to evaluate safety and provide biomarker data of TD-8236 in healthy volunteers and asthma patients; completion expected in mid-2019
    - Multiple JAK-dependent pathways clinically validated in asthma and COPD
    - Potentially broad activity with JAK inhibition across a range of respiratory indications and phenotypes
    - TD-8236 shown to potently inhibit targeted mediators of Th2-high and Th2-low asthma in human cells in preclinical studies

R&D Day in December 2018:

- Highlighted our innovative research and development strategy of organ-selective medicines and introduced several new research programs that we plan to advance towards clinical development, each specifically tailored to the organ of interest

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

- GSK reported fourth quarter 2018 net sales of $100 million and $207 million for the full year 2018; Theravance Biopharma entitled to approximately 5.5% to 8.5% (tiered) of worldwide net sales of the product
- Currently available in 26 countries, with additional countries expected over the course of 2019; recent regulatory filings include Japan and China
- Expanded COPD indication in Europe for patients not adequately treated with dual bronchodilation, making it the first single inhaler triple therapy indicated for patients with moderate to severe COPD
- Completion of Phase 3 CAPTAIN study in asthma patients expected in 1H 2019; if positive, submission of supplemental New Drug Application (sNDA) for TRELEGY ELLIPTA in asthma anticipated in 2H 2019
- Completed a non-dilutive private placement of $250.0 million in aggregate principal amount of non-recourse notes secured by a portion of the future payments the Company expects to receive related to royalties due on net sales[1] of TRELEGY ELLIPTA
    - 75% share of the payments will be used to satisfy the debt obligations until notes repaid
    - Remaining 25% of the payments will be directed to benefit the Company on an ongoing basis
    - Proceeds were approximately $229.0 million net of debt issuance costs and a 5% retention of the notes by the Company
- Strategic infusion of cash in late 2018 with retained economics over TRELEGY ELLIPTA's commercial lifespan; proceeds to support key strategic priorities

VIBATIV® (telavancin): Sale of VIBATIV to Cumberland Pharmaceuticals Inc. completed in November 2018

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, 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 TRC LLC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters)

Fourth Quarter and Full Year Financial Results

Revenue

Revenue for the fourth quarter of 2018 was $15.7 million, comprised of collaboration revenue primarily related to our global collaboration with Janssen for TD-1473 of $10.0 million, profit sharing revenue related to YUPELRI of $3.3 million, and product sales of VIBATIV® (telavancin) of $2.4 million. Revenue in the fourth quarter represents an increase of approximately $11.2 million over the same period in 2017. The increase was primarily related to revenue recognized from the upfront payment associated with the global collaboration agreement with Janssen for TD-1473. The increase was partially offset as a full quarter of Product Sales was not recognized due to the sale of VIBATIV to Cumberland Pharmaceuticals in November 2018. Full year 2018 revenue was $60.4 million, comprised of collaboration revenue of $41.8 million primarily associated with the upfront payment from Janssen for TD-1473, product sales of VIBATIV® of $15.3 million and profit sharing revenue related to YUPELRI of $3.3 million.

Research and Development (R&D) Expenses

R&D expenses for the fourth quarter of 2018 were $52.3 million, compared to $51.1 million in the same period in 2017. The increase was primarily due to higher external expenses to support our key programs and was partially offset by lower employee-related and share-based compensation expenses. Full year 2018 R&D expenses were $201.3 million, or $175.8 million excluding non-cash share-based compensation.

Selling, General and Administrative (SG&A) Expenses

SG&A expenses for the fourth quarter of 2018 were $25.5 million, compared to $29.5 million in the same period in 2017. The decrease was primarily due to lower expenses related to share-based compensation. Full year 2018 SG&A expenses were $97.1 million, or $71.3 million excluding non-cash share-based compensation.

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities totaled $517.1 million as of December 31, 2018, which includes net proceeds of $229.4 million resulting from the private placement of notes secured by a portion of the future payments related to royalties due on net sales of TRELEGY ELLIPTA.

2019 Financial Guidance

The Company expects full-year 2019 operating loss, excluding share-based compensation, of $210 million to $230 million. Operating loss guidance does not include royalty income for TRELEGY ELLIPTA which we recognize in our statement of operations as "income from investment in TRC, LLC." Our share of US 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 our key programs, among other factors, could impact our financial guidance.

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 8086288. 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 March 28, 2019. An audio replay will also be available through 8:00 pm ET on March 5, 2019 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 8086288.

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.

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: 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 November 8, 2018 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:

Alexander Dobbin
650-808-4045
investor.relations@theravance.com

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

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
	(Unaudited)		(Unaudited)	(1)
Revenue:				
Product sales	$ 2,415	$ 4,124	$ 15,304	$ 14,788
Collaboration revenue	10,047	391	41,791	598

Profit sharing revenue	3,275	-	3,275	-
Total revenue	15,737	4,515	60,370	15,386
Costs and expenses:				
Cost of goods sold	632	3,116	715	6,030
Research and development (2)	52,269	51,051	201,348	173,887
Selling, general and administrative (2)	25,457	29,524	97,058	95,592
Total costs and expenses	78,358	83,691	299,121	275,509
Loss from operations	(62,621)	(79,176)	(238,751)	(260,123)
Income from investment in TRC, LLC	5,428	170	11,182	170
Interest expense	(4,071)	(2,137)	(10,482)	(8,547)
Other-than-temporary impairment loss	-	-	-	(8,000)
Interest and other income, net	7,822	1,209	11,966	4,789
Loss before income taxes	(53,442)	(79,934)	(226,085)	(271,711)
Provision for income tax benefit (expense)	3,256	(6,988)	10,561	(13,694)
Net loss	$ (50,186)	$ (86,922)	$ (215,524)	$ (285,405)
Net loss per share:				
Basic and diluted net loss per share	$ (0.92)	$ (1.64)	$ (3.99)	$ (5.45)
Shares used to compute basic and diluted net loss per share	54,555	52,908	53,969	52,352

(1) The condensed consolidated statement of operations for the year ended December 31, 2017 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, 2017.

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

	Three Months Ended December 31,		Year Ended December 31,	
(In thousands)	**2018**	**2017**	**2018**	**2017**
Research and development	$ 5,806	$ 7,668	$ 25,563	$ 22,691
Selling, general and administrative	5,908	10,125	25,750	26,454
Total share-based compensation expense	$ 11,714	$ 17,793	$ 51,313	$ 49,145

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

	December 31, 2018	December 31, 2017
Assets	**(Unaudited)**	**(1)**
Current assets:		
Cash and cash equivalents and short-term marketable securities	$ 505,276	$ 348,566
Receivables from collaborative arrangements	10,053	7,109
Other prepaid and current assets	17,494	6,244
Inventories	-	16,830
Total current assets	532,823	378,749
Property and equipment, net	13,176	10,157
Long-term marketable securities	11,869	41,587
Tax receivable	-	8,191
Restricted cash	833	833
Other assets	1,534	1,883
Total assets	$ 560,235	$ 441,400
Liabilities and Shareholders' (Deficit) Equity		
Current liabilities	$ 98,554	$ 62,552
Convertible senior notes due 2023, net	224,818	223,746
Non-recourse notes due 2033, net	229,535	-
Other long-term liabilities	58,917	39,924
Shareholders' (deficit) equity	(51,589)	115,178
Total liabilities and shareholders' (deficit) equity	$ 560,235	$ 441,400

(1) The condensed consolidated balance sheet at December 31, 2017 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, 2017.

View original content to download multimedia:http://www.prnewswire.com/news-releases/theravance-biopharma-inc-reports-fourth-quarter-and-full-year-2018-financial-results-and-provides-business-update-300802552.html

SOURCE Theravance Biopharma, Inc.