

Theravance Biopharma, Inc. Reports Fourth Quarter and Full Year 2017 Financial Results and Provides Business Update

February 27, 2018

Multiple Programs Poised to Advance in 2018

DUBLIN, Feb. 27, 2018 /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, 2017. Revenue for the fourth quarter and full year 2017 was \$4.5 million and \$15.4 million, respectively. Full year operating loss was \$260.1 million or \$211.0 million excluding share-based compensation expense, in line with the Company's previously stated financial guidance. Cash, cash equivalents, and marketable securities totaled \$390.2 million as of December 31, 2017.



Rick E Winningham, Chairman and Chief Executive Officer, commented: "2018 will be an important year for the Company, as we intensify our focus on our strategic priorities, drive clinical execution, and advance programs from our validated research platform towards clinical development. With Trelegy Ellipta launched in the US and multiple strategic partners secured to complement our internal efforts, we are well positioned to execute on the most important opportunities in our portfolio, including optimizing development of our intestinally restricted JAK inhibitor, TD-1473, with Janssen Biotech; advancing our drug for neurogenic orthostatic hypertension, TD-9855, towards a registrational program; launching our nebulized LAMA revefenacin, if approved, with our partner Mylan; and progressing a new program – an inhaled JAK inhibitor for serious respiratory disease – into the clinic."

Anticipated Near-Term Milestones and Events

- TD-1473 (intestinally restricted pan-Janus kinase (JAK) inhibitor): Initiations of Phase 2b/3 induction and maintenance study in ulcerative colitis and Phase 2 induction study in Crohn's disease in second half of 2018
- TD-9855 (norepinephrine serotonin reuptake inhibitor (NSRI)): Data from exploratory Phase 2a study in patients with symptomatic neurogenic orthostatic hypotension (nOH) at the end of the first half of 2018
- Revefenacin (TD-4208, nebulized long-acting muscarinic antagonist (LAMA)): Potential regulatory approval in the US for chronic obstructive pulmonary disease (COPD), with assigned Prescription Drug User Fee Act (PDUFA) target action date of November 13, 2018
- Progression of inhaled JAK inhibitor, the next program from our research platform aimed at discovering localized medicines that target diseased tissues without systemic exposure, into first-in-human studies in late 2018 or early 2019
- Trelegy Ellipta (Company entitled to approximately 5.5% to 8.5% of worldwide net sales): Potential label expansion in COPD to include IMPACT study data and completion of Phase 3 CAPTAIN study in asthma patients, both expected in 2018¹

Program Updates

- Recently announced global collaboration with Janssen Biotech, Inc. (Janssen) to jointly develop and commercialize TD-1473 in inflammatory intestinal diseases, including ulcerative colitis and Crohn's disease. Theravance Biopharma eligible to receive up to \$1 billion in potential payments, including \$100 million upfront payment received in February 2018 following execution of the agreement; additionally, companies sharing profits and expenses in the US, and Theravance Biopharma would receive double-digit tiered royalties on ex-US sales
- Recently announced acceptance by US Food and Drug Administration (FDA) of New Drug Application (NDA) for revefenacin for the treatment of COPD and PDUFA target action date of November 13, 2018
- Completed Phase 3b study of revefenacin, designed to assess nebulized revefenacin versus handheld tiotropium via Handihaler® in improving lung function in COPD patients with suboptimal peak inspiratory flow rate (PIFR)
 - Primary endpoint of improvement in lung function in COPD patients with suboptimal PIFR, as measured by trough forced expiratory volume in one second (FEV1) after 4 weeks of treatment
 - While numerical improvements for revefenacin over tiotropium were not statistically significant for the primary endpoint, the study provided important insights for the use of the product (if approved) in patients with COPD
 - In the pre-specified subgroup of severe and very severe (GOLD 3/4) COPD patients (representing approximately 80% of the patients in the study), revefenacin demonstrated nominally statistically significant and clinically relevant improvements in FEV1 versus tiotropium

- Revefenacin was generally well tolerated and no new safety issues were identified
 - Study conducted to support commercialization and is not required for FDA approval
- Expect to provide an update in the first half of 2018 regarding dialogue with US and EU regulators on Phase 3 requirements for velusetrag (TD-5108; 5-HT4 agonist) program in gastroparesis
 - Alfasigma S.p.A. evaluating option under existing collaboration agreement to further develop and potentially commercialize velusetrag in the EU (and certain other markets); opt-in by Alfasigma would result in \$10 million payment to the Company and right to receive certain future milestones and royalties
- Phase 3 bacteremia study of VIBATIV® (telavancin) discontinued following recent interim analysis conducted by independent review committee and company-wide review of investment priorities
 - Committee concluded the study is underpowered and therefore unlikely to achieve the primary study objective without a significant increase in study size beyond the planned enrollment of 250 patients
 - In light of incremental investment required, Company is closing the study
 - No new safety issues identified; all currently enrolled patients allowed to complete dosing
 - Data generated from study to be shared with regulators and submitted for future scientific publication
- Trelegy Ellipta launched by GSK in November 2017¹
 - Commercial and Medicare Part D coverage at several top national payers secured since early January 2018¹
 - Landmark IMPACT data submitted to FDA and European Medicines Agency (EMA) to support expanded label for Trelegy Ellipta¹

Notes:

¹ As reported by Glaxo Group Limited or one of its affiliates (GSK); Economic interest related to Trelegy Ellipta (the combination of fluticasone furoate, umeclidinium, and vilanterol) entitles Company to upward tiering payments equal to approximately 5.5% to 8.5% on worldwide net sales of the product

Fourth Quarter and Full Year Financial Results

Revenue

Revenue for the fourth quarter of 2017 was \$4.5 million, primarily related to US net product sales of VIBATIV® of \$4.1 million. This represents a decrease of \$1.2 million over the same period in 2016, largely due to the impact of generic competition. Full year 2017 revenue was \$15.4 million, comprised primarily of US net product sales of VIBATIV® of \$14.3 million.

Research and Development (R&D) Expenses

R&D expenses for the fourth quarter of 2017 were \$51.1 million representing an increase of \$9.0 million compared to the same period in 2016. The increase is primarily due to an increase in employee-related costs, share-based compensation, and other expenses of \$14.3 million. These increases were partially offset by a decrease in external costs of \$5.3 million. Full year R&D expenses were \$173.9 million, or \$151.2 million excluding share-based compensation.

Selling, General and Administrative (SG&A) Expenses

SG&A expenses for the fourth quarter of 2017 were \$29.5 million, representing an increase of \$9.2 million compared to the same period in 2016. The increase is primarily due to higher expenses related to employee-related costs and share-based compensation. Full year SG&A expenses were \$95.6 million, or \$69.1 million excluding shared-based compensation expense.

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities, excluding restricted cash, totaled \$390.2 million as of December 31, 2017. This amount excludes the \$100 million upfront payment received in February 2018, from the recently announced global collaboration with Janssen.

2018 Financial Guidance

The Company anticipates full year 2018 operating loss, excluding share-based compensation, will be in the range of \$180.0 to \$200.0 million. The actual amount could be above or below this forecast as a result of a variety of factors impacting our business, including the amount of revenue recognized in 2018 related to the global collaboration agreement with Janssen (currently expected to be less than \$25 million), the timing and cost of clinical studies associated with our key programs, and net product sales of VIBATIV®. Operating loss, excluding share-based compensation does not include potential royalties for Trelegy Ellipta.

Conference Call Today at 5:00 pm ET

Theravance Biopharma will hold a conference call 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 3999284. 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 29, 2018. An audio replay will also be available through 8:00 pm ET on March 6, 2018 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 3999284.

About Theravance Biopharma

Theravance Biopharma, Inc. ("Theravance Biopharma") is a diversified biopharmaceutical company with the core purpose of creating medicines that

help improve the lives of patients suffering from serious illness.

In our relentless pursuit of this objective, we strive to apply insight and innovation at each stage of our business, including research, development and commercialization, and utilize both internal capabilities and those of partners around the world. Our research efforts are focused in the areas of inflammation and immunology. Our research goal is to design localized medicines that target diseased tissues, without systemic exposure, in order to maximize patient benefit and minimize risk. These efforts leverage years of experience in developing localized medicines for the lungs to treat respiratory disease. The first potential medicine to emerge from our research focus on immunology and localized treatments is an oral, intestinally restricted pan-Janus kinase (JAK) inhibitor, currently in development to treat a range of inflammatory intestinal diseases. Our pipeline of internally discovered product candidates will continue to evolve with the goal of creating transformational medicines to address the significant needs of patients.

In addition, we have an economic interest in future payments that may be made by Glaxo Group or one of its affiliates (GSK) pursuant to its agreements with Innoviva, Inc. relating to certain programs, including Treligy Ellipta.

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 benefits and mechanisms of action of the Company's product and product candidates, the Company's expectations for product candidates through development, potential regulatory approval and commercialization (including their potential as components of combination therapies), product sales and the Company's expectations for its 2018 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 product candidates are unsafe or ineffective (including when our product candidates are studied in combination with other compounds), 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, 2017 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.

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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,	
	2017	2016	2017	2016
	(Unaudited)		(Unaudited)	(1)
Revenue:				
Product sales	\$ 4,124	\$ 5,032	\$ 14,788	\$ 17,603
Revenue from collaborative arrangements	391	660	598	31,045
Total revenue	4,515	5,692	15,386	48,648
Costs and expenses:				

Cost of goods sold	3,116	1,146	6,030	2,894
Research and development (2)	51,051	42,014	173,887	141,712
Selling, general and administrative (2)	29,524	20,366	95,592	84,509
Total costs and expenses	83,691	63,526	275,509	229,115
Loss from operations	(79,176)	(57,834)	(260,123)	(180,467)
Interest expense	(2,137)	(1,404)	(8,547)	(1,404)
Other-than-temporary impairment loss	-	-	(8,000)	-
Interest and other income (expense), net	1,379	474	4,959	1,312
Loss before income taxes	(79,934)	(58,764)	(271,711)	(180,559)
Provision for income taxes	6,988	8,568	13,694	10,110
Net loss	(86,922)	\$ (67,332)	\$ (285,405)	\$ (190,669)
Net loss per share:				
Basic and diluted net loss per share	\$ (1.64)	\$ (1.36)	\$ (5.45)	\$ (4.26)
Shares used to compute basic and diluted net loss per share	52,908	49,570	52,352	44,711

(1) The condensed consolidated statement of operations for the year ended December 31, 2016 has been derived from the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

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

(In thousands)	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
Research and development	\$ 7,668	\$ 5,150	\$ 22,691	\$ 20,202
Selling, general and administrative	10,125	4,890	26,454	20,967
Total share-based compensation expense	\$ 17,793	\$ 10,040	\$ 49,145	\$ 41,169

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

	December 31,	
	2017	2016
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents and short-term marketable securities	\$ 348,566	\$ 501,096
Receivables from collaborative arrangements	7,109	9,076
Prepaid taxes	291	3,060
Other prepaid and current assets	5,953	3,051
Inventories	16,830	12,220
Property and equipment, net	10,157	8,460
Long-term marketable securities	41,587	91,565
Tax receivable	8,191	-
Restricted cash	833	833
Other assets	1,883	9,893

Total assets	<u>\$ 441,400</u>	<u>\$ 639,254</u>
Liabilities and Shareholders' Equity		
Current liabilities	62,552	49,268
Long-term liabilities	263,670	239,755
Shareholders' equity	<u>115,178</u>	<u>350,231</u>
Total liabilities and shareholders' equity	<u>\$ 441,400</u>	<u>\$ 639,254</u>

(1) The condensed consolidated balance sheet at December 31, 2016 has been derived from the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

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