

Theravance Biopharma, Inc. Reports Third Quarter 2017 Financial Results and Provides Business Update

November 7, 2017

Inflection Points for Key Development Programs Anticipated Throughout 2018 Trelegy Ellipta Launch Expected by Year-End 2017

DUBLIN, Nov. 7, 2017 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today reported financial results for the third quarter ended September 30, 2017. Revenue for the third quarter of 2017 was \$4.3 million. The third quarter operating loss was \$57.0 million, or \$46.3 million excluding non-cash share-based compensation expense of \$10.7 million. Cash, cash equivalents, and marketable securities totaled \$434.4 million as of September 30, 2017.

(PRNewfoto/Theravance Biopharma, Inc.)

Rick E Winningham, Chairman and Chief Executive Officer, commented: "In 2017, we continue to demonstrate the potential of our portfolio with encouraging clinical data across multiple key programs. Looking forward, we are positioned to achieve numerous clinical and regulatory milestones, with a plan to deliver on the promise of developing differentiated medicines for patients in need."

Recent Updates¹

- Trelegy Ellipta (the combination of fluticasone furoate, umeclidinium, and vilanterol, previously referred to as the Closed Triple) approved in the US for the treatment of chronic obstructive pulmonary disease (COPD) in appropriate patients
- European Medicines Agency's Committee for Medicinal Products for Human Use issued a positive opinion of Trelegy Ellipta, recommending marketing authorization for the product
- Landmark IMPACT study met primary endpoint showing reduction in exacerbations with Trelegy Ellipta compared to dual therapies in patients with COPD; safety findings were consistent with the known profile of individual medicines and their dual combinations; regulatory filings for IMPACT data expected in 2018

Expected Upcoming Milestones and Events

- Revefenacin (TD-4208, a once-daily nebulized long-acting muscarinic antagonist (LAMA) for COPD): NDA filing anticipated in 4Q 2017; potential regulatory approval in the US for COPD in 2018; Phase 3b PIFR study, designed to support commercialization, expected to complete in 1Q 2018
- Trelegy Ellipta¹: Commercial launch expected mid-November 2017; economic interest related to Trelegy Ellipta entitles Theravance Biopharma to upward tiering royalty of 5.5% to 8.5% on worldwide net sales; potential regulatory approval in the EU for COPD in late 2017; Phase 3 CAPTAIN study in asthma patients expected to complete in 2018
- TD-1473 (intestinally restricted pan-Janus kinase (JAK) inhibitor): Data from the remaining cohorts of the Phase 1b study in patients with ulcerative colitis in 2018; targeting initiation of large, multi-dose induction and maintenance study in 2018
- TD-9855 (norepinephrine serotonin reuptake inhibitor (NSRI)): Data from the Phase 2a study in patients with nOH in first half of 2018
- VIBATIV: Televancin Observational Use Registry (TOURTM) data to be published in 2018; data from the Phase 3 registrational bacteremia study in 2018 or 2019

Notes:

¹ As reported by Glaxo Group Limited or one of its affiliates (GSK)

Third Quarter Financial Results

Revenue

Revenue for the third quarter of 2017 was \$4.3 million, primarily related to US net product sales of VIBATIV[®] of \$4.1 million. In the same period in 2016, net product sales of VIBATIV[®] were \$3.9 million and revenue from collaborative arrangements was \$15.2 million, primarily driven by non-recurring revenue of \$15.1 million associated with the Takeda collaboration.

Research and Development (R&D) Expenses

R&D expenses for the third quarter of 2017 were \$39.3 million representing an increase of \$7.4 million compared to the same period in 2016. The increase is driven by costs associated with the progression of our key programs as well as employee-related costs. Third quarter R&D expenses include non-cash share-based compensation expense of \$5.0 million.

Selling, General and Administrative (SG&A) Expenses

SG&A expenses for the third quarter of 2017 were \$20.9 million, representing an increase of \$0.7 million compared to the same period in 2016. The increase is primarily due to employee-related costs and share-based compensation, partially offset by a reduction in external expenses related to commercialization activities. Third quarter SG&A expenses include non-cash share-based compensation expense of \$5.7 million.

Other-than-Temporary Impairment Loss

In the third quarter, a non-cash impairment charge of \$8.0 million was recorded to write off the full carrying value of the non-marketable equity securities of Trek

Therapeutics, PBC (TREKtx). These securities were received in 2015, pursuant to a license agreement granting TREKtx rights to TD-6450, an internally discovered NS5A inhibitor.

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities, excluding restricted cash, totaled \$434.4 million as of September 30, 2017.

2017 Financial Guidance

The Company's guidance on operating loss excluding non-cash share-based compensation for the full-year of 2017 remains unchanged at \$205.0 million to \$215.0 million. The actual amount could be above or below this forecast as a result of a variety of factors impacting our business, including the timing and cost of clinical and non-clinical studies associated with our key programs and net product sales of VIBATIV®.

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, using the confirmation code 96855845. 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 7, 2017. An audio replay will also be available through 8:00 pm ET on November 14, 2017 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 96855845.

About Theravance Biopharma

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.

Our pipeline of internally discovered product candidates includes potential best-in-class medicines to address the unmet needs of patients being treated for serious conditions primarily in the acute care setting. VIBATIV® (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the U.S., Europe and certain other countries for certain difficult-to-treat infections. Revefenacin (TD-4208) is a long-acting muscarinic antagonist (LAMA) being developed as a potential once-daily, nebulized treatment for chronic obstructive pulmonary disease (COPD). Our neprilysin (NEP) inhibitor program is designed to develop selective NEP inhibitors for the treatment of a range of major cardiovascular and renal diseases, including acute and chronic heart failure, hypertension and chronic kidney diseases, such as diabetic nephropathy. Our research efforts are focused in the areas of inflammation and immunology, with the goal of designing medicines that provide targeted drug delivery to tissues in the lung and gastrointestinal tract in order to maximize patient benefit and minimize risk. The first program to emerge from this research is designed to develop intestinally restricted pan-Janus kinase (JAK) inhibitors for the treatment of a range of inflammatory intestinal diseases.

In addition, we have an economic interest in future payments that may be made by Glaxo Group Limited or one of its affiliates (GSK) pursuant to its agreements with Innoviva, Inc. relating to certain drug development programs, including Trelegy Ellipta (the combination of fluticasone furoate, umeclidinium, and vilanterol in a single ELLIPTA® inhaler, previously referred to as the Closed Triple), currently approved in the US for the treatment of appropriate COPD patients and in development for the treatment of COPD in several other countries. The product is also currently in development for the treatment of asthma.

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

THERAVANCE®, the Cross/Star logo, and VIBATIV® are registered trademarks of the Theravance Biopharma group of companies. 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 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 2017 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), the feasibility of undertaking future clinical trials for our product candidates based on FDA policies and feedback, 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, risks associated with establishing and maintaining sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure, and risks of developing an institutional customer mix for VIBATIV® (telavancin) that meet the Company's plan for the product. 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 9, 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.

Contact Information:

Alexander Dobbin
Head of Investor Relations
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,	
	2017	2016	2017	2016
	(Unaudited)		(Unaudited)	
Revenue:				
Product sales	\$ 4,140	\$ 3,901	\$ 10,664	\$ 12,571
Revenue from collaborative arrangements	135	15,174	207	30,385
Total revenue	<u>4,275</u>	<u>19,075</u>	<u>10,871</u>	<u>42,956</u>
Costs and expenses:				
Cost of goods sold	985	332	2,914	1,748
Research and development (1)	39,343	31,951	122,835	99,698
Selling, general and administrative (1)	20,944	20,286	66,069	64,143
Total costs and expenses	<u>61,272</u>	<u>52,569</u>	<u>191,818</u>	<u>165,589</u>
Loss from operations	(56,997)	(33,494)	(180,947)	(122,633)
Interest expense	(2,136)	-	(6,410)	-
Other-than-temporary impairment loss	(8,000)	-	(8,000)	-
Interest and other income (expense), net	1,124	344	3,579	839
Loss before income taxes	(66,009)	(33,150)	(191,778)	(121,794)
Provision for income taxes	868	812	6,705	1,542
Net loss	<u>\$ (66,877)</u>	<u>\$ (33,962)</u>	<u>\$ (198,483)</u>	<u>\$ (123,336)</u>
Net loss per share:				
Basic and diluted net loss per share	<u>\$ (1.27)</u>	<u>\$ (0.73)</u>	<u>\$ (3.80)</u>	<u>\$ (2.86)</u>
Shares used to compute basic and diluted net loss per share	<u>52,611</u>	<u>46,470</u>	<u>52,165</u>	<u>43,080</u>

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

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Research and development	\$ 5,005	\$ 4,933	\$ 15,023	\$ 15,052
Selling, general and administrative	5,680	4,962	16,329	16,077
Total share-based compensation expense	<u>\$ 10,685</u>	<u>\$ 9,895</u>	<u>\$ 31,352</u>	<u>\$ 31,129</u>

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

	September 30,	December 31,
	2017	2016
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents and short-term marketable securities	\$ 335,001	\$ 501,096
Receivables from collaborative arrangements	11,547	9,076
Prepaid taxes	289	3,060
Inventories	15,258	12,220
Other prepaid and current assets	5,038	3,051
Property and equipment, net	8,618	8,460
Long-term marketable securities	99,399	91,565
Tax receivable	8,070	-
Restricted cash	833	833
Other assets	2,106	9,893
Total assets	<u>\$ 486,159</u>	<u>\$ 639,254</u>
Liabilities and Shareholders' Equity		
Current liabilities	48,786	49,268
Long-term liabilities	253,256	239,755
Shareholders' equity	<u>184,117</u>	<u>350,231</u>

Total liabilities and shareholders' equity	<u>\$ 486,159</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.

View original content with multimedia:<http://www.prnewswire.com/news-releases/theravance-biopharma-inc-reports-third-quarter-2017-financial-results-and-provides-business-update-300551260.html>

SOURCE Theravance Biopharma, Inc.