

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

Key Program Milestones Anticipated in Remainder of 2017 and 2018

DUBLIN, May 9, 2017 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today reported financial results for the first quarter ended March 31, 2017. Revenue for the first quarter of 2017 was \$3.1 million. The first quarter operating loss was \$58.8 million, or \$48.5 million excluding non-cash share-based compensation expense of \$10.3 million. Cash, cash equivalents, and marketable securities totaled \$540.7 million as of March 31, 2017.



Rick E Winningham, Chairman and Chief Executive Officer, commented: "As we progress into mid-2017, we are on track to deliver clinical results at every stage of development through the remainder of this year and into 2018. This unprecedented period for the Company underscores the depth and breadth of our portfolio, the productivity of our internal R&D engine, and our robust business model. In addition, the Closed Triple for COPD represents an important strategic asset and a promising potential source of income for Theravance Biopharma in both the near and long-term. With a strong cash position and an extensive set of milestones ahead of us, we believe we are well-positioned to improve the lives of patients and create meaningful value for our shareholders."

Pipeline Update

- ▮ Phase 3b low peak inspiratory flow rate (PIFR) study initiated with revefenacin (TD-4208), the Company's once-daily nebulized long-acting muscarinic antagonist (LAMA) for chronic obstructive pulmonary disease (COPD), partnered with Mylan. Study is designed to support commercialization and will enroll approximately 200 GOLD¹ 2, 3, and 4 COPD patients with low PIFR, to compare the effects of nebulized revefenacin versus inhaled tiotropium.
- ▮ Phase 2a protocol for TD-9855 (dual norepinephrine and serotonin reuptake inhibitor (NSRI)) amended in neurogenic orthostatic hypotension (nOH) study to include a treatment extension of up to 20 weeks of therapy to assess durability of treatment effects in patients, following encouraging treatment responses in the majority of patients tested to date in the study.
- ▮ Phase 1 multiple-ascending dose (MAD) study completed in healthy volunteers with TD-1439, the second compound in the neprilysin (NEP) inhibitor program for cardiovascular and renal diseases. Positive study results demonstrated sustained target engagement, low levels of renal elimination and a favorable safety and tolerability profile, in-line with program objectives.

Expected Upcoming Milestones

- ▮ TD-1473 (intestinally restricted pan-janus kinase (JAK) inhibitor): Data from the Phase 1b study in patients with ulcerative colitis in mid-2017.
- ▮ Velusetrag (5-HT₄ agonist; TD-5108): Data from the Phase 2b study in patients with gastroparesis in mid-2017.
- ▮ TD-9855 (NSRI): Data from a Phase 2a study in patients with nOH in 2017.
- ▮ Revefenacin (TD-4208): Completion of the 12-month Phase 3 safety study in patients with COPD in mid-2017; potential NDA filing in late 2017; completion of the Phase 3b PIFR study in early 2018; potential regulatory approval in the US for COPD in 2018.

- ▮ VIBATIV: Televancin Observational Use Registry (TOURTM) data to be published throughout 2017; completion of the Phase 3 registrational bacteremia study in 2018, to be followed by potential sNDA submission in the US for bacteremia.
- ▮ Closed Triple (the combination of fluticasone furoate, umeclidinium, and vilanterol)²: Completion of the Phase 3 IMPACT study in 2017; potential regulatory approval in the US and EU for COPD in late 2017; Phase 3 CAPTAIN study completion in asthma patients and supplementary regulatory submissions for asthma in 2018.

Notes:

¹ *Global Initiative for Chronic Obstructive Lung Disease guidelines*

² *As reported by Glaxo Group Limited or one of its affiliates (GSK)*

First Quarter Financial Results

Revenue

Revenue for the first quarter of 2017 was \$3.1 million, primarily related to U.S. net product sales of VIBATIV[®]. This represents a decrease of \$15.3 million from the same period in 2016, which consisted primarily of revenue from collaborative arrangements.

Research and Development (R&D) Expenses

R&D expenses for the first quarter of 2017 were \$40.6 million representing an increase of \$4.9 million compared to the same period in 2016. The increase is primarily attributed to costs associated with the progression of our key programs. First quarter R&D expenses include non-cash share-based compensation expense of \$5.1 million.

Selling, General and Administrative (SG&A) Expenses

SG&A expenses for the first quarter of 2017 were \$20.8 million, representing a decrease of \$2.8 million compared to the same period in 2016. The decrease is due to a reduction in external costs and lower non-cash share-based compensation expense. First quarter SG&A expenses include non-cash share-based compensation expense of \$5.2 million.

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities, excluding restricted cash, totaled \$540.7 million as of March 31, 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 \$195.0 million to \$205.0 million. The actual amount could be above or below this forecast as a result of a variety of factors impacting our business, including business development transactions, 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 U.S., or (920) 663-6266 for international callers, using the confirmation code 13732779. 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 June 8, 2017. An audio replay will also be available through 8:00 pm ET on May 16, 2017 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 13732779.

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. Revedfenacin (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 the Closed Triple (the combination of fluticasone furoate, umeclidinium, and vilanterol), currently in development for the treatment of COPD and asthma.

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 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-K filed with the Securities and Exchange Commission (SEC) on March 1, 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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(In thousands, except per share data)

	Three Months Ended March 31,	
	2017	2016
	(Unaudited)	
Revenue:		
Product sales	\$ 3,050	\$ 3,311
Revenue from collaborative arrangements	37	15,099
Total revenue	<u>3,087</u>	<u>18,410</u>
Costs and expenses:		
Cost of goods sold	565	778
Research and development ⁽¹⁾	40,565	35,678
Selling, general and administrative ⁽¹⁾	<u>20,786</u>	<u>23,596</u>
Total costs and expenses	<u>61,916</u>	<u>60,052</u>
Loss from operations	(58,829)	(41,642)
Interest expense	(2,137)	-
Interest and other income	<u>1,030</u>	<u>186</u>
Loss before income taxes	(59,936)	(41,456)
Provision for income taxes	<u>5,383</u>	<u>694</u>
Net loss	<u>\$ (65,319)</u>	<u>\$ (42,150)</u>
Net loss per share:		
Basic and diluted net loss per share	<u>\$ (1.27)</u>	<u>\$ (1.10)</u>
Shares used to compute basic and diluted net loss per share	<u>51,617</u>	<u>38,326</u>

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

(In thousands)	Three Months Ended March 31,	
	2017	2016
Research and development	\$ 5,101	\$ 5,160
Selling, general and administrative	5,168	6,170
Total share-based compensation expense	<u>\$ 10,269</u>	<u>\$ 11,330</u>

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

	March 31,	December 31,
	2017	2016
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents and short-term marketable securities	\$ 392,768	\$ 501,096
Receivables from collaborative arrangements	7,639	9,076
Prepaid taxes	3,083	3,060
Inventories	13,215	12,220
Other prepaid and current assets	4,799	3,051
Property and equipment, net	8,251	8,460
Long-term marketable securities	147,885	91,565
Restricted cash	833	833
Other assets	9,566	9,893
Total assets	<u>\$ 588,039</u>	<u>\$ 639,254</u>
Liabilities and Shareholders' Equity		
Current liabilities	48,984	49,268
Long-term liabilities	245,109	239,755

Shareholders' equity	293,946	350,231
Total liabilities and shareholders' equity	<u>\$ 588,039</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.

To view the original version on PR Newswire, visit:<http://www.prnewswire.com/news-releases/theravance-biopharma-inc-reports-first-quarter-2017-financial-results-and-provides-business-update-300454610.html>

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