



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

August 8, 2017

Meaningful Clinical Readouts Underpin Progress in Key Programs Additional Milestones Anticipated in Remainder of 2017 and 2018

DUBLIN, Aug. 8, 2017 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today reported financial results for the second quarter ended June 30, 2017. Revenue for the second quarter of 2017 was \$3.5 million. The second quarter operating loss was \$65.1 million, or \$54.7 million excluding non-cash share-based compensation expense of \$10.4 million. Cash, cash equivalents, and marketable securities totaled \$498.3 million as of June 30, 2017.



Rick E Winningham, Chairman and Chief Executive Officer, commented: "We are incredibly pleased with our progress to date in 2017, which includes the delivery of meaningful clinical data across a number of our key pipeline programs. We are in an unprecedented period at Theravance Biopharma, driven by the depth and breadth of our portfolio, the talents and insights of our team, and the overall productivity of our R&D engine."

Recent Pipeline Updates

- Positive results announced from a 12-month Phase 3 safety study of revefenacin (TD-4208), the Company's once-daily nebulized long-acting muscarinic antagonist (LAMA) for chronic obstructive pulmonary disease (COPD), partnered with Mylan.
- Positive results announced in the 5 mg treatment arm of velusetrag (5-HT4 agonist; TD-5108) from a Phase 2b study in patients with gastroparesis.
- Early evidence of localized target engagement announced from first cohort of Phase 1b study of TD-1473 (intestinally restricted pan-Janus kinase (JAK) inhibitor) in patients with ulcerative colitis.

Expected Upcoming Milestones and Events

- Revefenacin (TD-4208): NDA filing anticipated in 4Q 2017; completion of the Phase 3b PIFR study in the first quarter of 2018, designed to support commercialization; potential regulatory approval in the US for COPD in 2018.
- Closed Triple (the combination of fluticasone furoate, umeclidinium, and vilanterol)¹: Results from 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 potential supplementary regulatory submissions for asthma in 2018.
- VIBATIV: Televancin Observational Use Registry (TOURTM) data to be published throughout remainder of 2017; data from the Phase 3 registrational bacteremia study in 2018 or 2019.
- TD-1473: Data from the remaining cohorts of the Phase 1b study in patients with ulcerative colitis in 2018; targeting initiation of induction and maintenance study in 2018.
- TD-9855 (NSRI): Data from the Phase 2a study in patients with nOH in first half of 2018.

Notes:

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

Second Quarter Financial Results

Revenue

Revenue for the second quarter of 2017 was \$3.5 million, primarily related to U.S. net product sales of VIBATIV[®]. This represents a decrease of \$2.0

million from the same period in 2016, reflecting the impact of generic competitive products in the outpatient market.

Research and Development (R&D) Expenses

R&D expenses for the second quarter of 2017 were \$42.9 million representing an increase of \$10.9 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 increased employee-related costs. Second quarter R&D expenses include non-cash share-based compensation expense of \$4.9 million.

Selling, General and Administrative (SG&A) Expenses

SG&A expenses for the second quarter of 2017 were \$24.3 million, representing an increase of \$4.1 million compared to the same period in 2016. The increase is due to employee-related costs, external expenses related to G&A, and share-based compensation, partially offset by a reduction in external expenses related to commercialization activities. Second quarter SG&A expenses include non-cash share-based compensation expense of \$5.5 million.

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities, excluding restricted cash, totaled \$498.3 million as of June 30, 2017.

2017 Financial Guidance

The Company is revising its guidance for operating loss excluding non-cash share-based compensation for the full-year of 2017 to a range of \$205.0 million to \$215.0 million. The increase in guidance is primarily driven by the Company's decision to accelerate spending associated with the next phase of development in the JAK inhibitor program. 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 U.S., or (920) 663-6266 for international callers, using the confirmation code 41381031. 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 September 7, 2017. An audio replay will also be available through 8:00 pm ET on August 15, 2017 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 41381031.

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 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-Q filed with the Securities and Exchange Commission (SEC) on May 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.

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
	(Unaudited)		(Unaudited)	
Revenue:				
Product sales	\$ 3,474	\$ 5,359	\$ 6,524	\$ 8,670
Revenue from collaborative arrangements	35	112	72	15,211
Total revenue	<u>3,509</u>	<u>5,471</u>	<u>6,596</u>	<u>23,881</u>
Costs and expenses:				
Cost of goods sold	1,364	638	1,929	1,416
Research and development ⁽¹⁾	42,927	32,069	83,492	67,748
Selling, general and administrative ⁽¹⁾	24,339	20,261	45,125	43,857
Total costs and expenses	<u>68,630</u>	<u>52,968</u>	<u>130,546</u>	<u>113,021</u>
Loss from operations	(65,121)	(47,497)	(123,950)	(89,140)
Interest expense	(2,137)	-	(4,274)	-
Interest and other income (loss), net	1,425	308	2,455	495
Loss before income taxes	(65,833)	(47,189)	(125,769)	(88,645)
Provision for income taxes	454	36	5,837	730
Net loss	<u>\$ (66,287)</u>	<u>\$ (47,225)</u>	<u>\$ (131,606)</u>	<u>\$ (89,375)</u>
Net loss per share:				
Basic and diluted net loss per share	<u>\$ (1.27)</u>	<u>\$ (1.06)</u>	<u>\$ (2.53)</u>	<u>\$ (2.16)</u>
Shares used to compute basic and diluted net loss per share	<u>52,255</u>	<u>44,407</u>	<u>51,938</u>	<u>41,366</u>

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

<u>(In thousands)</u>	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Research and development	\$ 4,917	\$ 4,959	\$ 10,018	\$ 10,119
Selling, general and administrative	5,481	4,945	10,649	11,115
Total share-based compensation expense	<u>\$ 10,398</u>	<u>\$ 9,904</u>	<u>\$ 20,667</u>	<u>\$ 21,234</u>

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

	<u>June 30,</u>	<u>December 31,</u>
	<u>2017</u>	<u>2016</u>
	(Unaudited)	
Assets		
Current assets:		

Cash and cash equivalents and short-term marketable securities	\$ 361,820	\$ 501,096
Receivables from collaborative arrangements	5,318	9,076
Prepaid taxes	242	3,060
Inventories	12,126	12,220
Other prepaid and current assets	5,376	3,051
Property and equipment, net	8,679	8,460
Long-term marketable securities	136,445	91,565
Restricted cash	833	833
Other assets	13,047	9,893
Total assets	<u>\$ 543,886</u>	<u>\$ 639,254</u>

Liabilities and Shareholders' Equity

Current liabilities	57,103	49,268
Long-term liabilities	245,656	239,755
Shareholders' equity	241,127	350,231
Total liabilities and shareholders' equity	<u>\$ 543,886</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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