

## **Theravance Biopharma, Inc. Reports Third Quarter 2016 Financial Results and Provides Business Update**

DUBLIN, Nov. 8, 2016 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today reported financial results for the third quarter ended September 30, 2016. Revenue for the third quarter 2016 was \$19.1 million. The third quarter operating loss was \$33.5 million, or \$23.5 million excluding share-based compensation expense of \$9.9 million. Cash, cash equivalents, and marketable securities totaled \$289.3 million as of September 30, 2016. The quarter-end cash balance excludes \$22.7 million in receivables from collaborative arrangements. The quarter end cash balance also excludes net proceeds of approximately \$316.2 million from the Company's concurrent public offerings of ordinary shares and convertible senior notes, which closed on November 2, 2016.



Rick E Winningham, Chairman and Chief Executive Officer, commented: "2016 continues to unfold as an important year for Theravance Biopharma. We were extremely pleased to announce positive top-line results from two pivotal Phase 3 studies of revefenacin for the treatment of COPD. The revefenacin program exemplifies our strategy of discovering and developing localized medicines for localized diseases and is a testament to our ability to execute on our goals and milestones.

"We are also excited by the progress of our two early stage programs - TD-1473, our intestinally restricted JAK inhibitor, for which we initiated a Phase 1b study in ulcerative colitis patients, and TD-0714, our potential best-in-class NEP inhibitor which successfully completed a Phase 1 MAD study clearing the way for further development.

"We remained focused on executing our commercial and label expansion strategies for VIBATIV® and are pleased with the data emerging from our TOUR registry study which highlight real-world experience with VIBATIV in a range of difficult-to-treat infections. We believe our pipeline of proprietary and partnered assets and our economic interest in certain respiratory programs being developed by GSK and Innoviva, combined with a strong balance sheet and numerous upcoming milestones, are enabling us to build a strong foundation for developing differentiated therapies and creating meaningful value for shareholders."

### **Recent Highlights**

- | Completed Public Offerings: The Company announced the closing of its concurrent public offerings of ordinary shares and convertible senior notes with net proceeds of approximately \$316.2 million (after deducting underwriting discounts and commissions and other estimated transaction expenses), which closed on November 2, 2016.
- | Revefenacin (TD-4208) Program: Once-Daily Nebulized Long-Acting Muscarinic Antagonist (LAMA) for Chronic Obstructive Pulmonary Disease (COPD):
  - | Two replicate three-month Phase 3 studies met primary efficacy endpoints demonstrating statistically significant and clinically meaningful improvements in trough lung function of revefenacin after 12 weeks of dosing and was generally well-tolerated at both doses studied.
  - | 12-month safety study fully enrolled. Data expected in 2017, followed by a planned NDA filing by the end of 2017.
- | Intestinally Restricted Pan-Janus Kinase (JAK) Inhibitor Program for Ulcerative Colitis and Other Inflammatory Bowel Diseases:
  - | TD-1473: Reported positive Phase 1 results of single-ascending and multiple-ascending oral doses that demonstrated the compound to be generally well-tolerated and the achievement of target pharmacokinetic

- profile. Initiated Phase 1b study in patients with moderate to severe ulcerative colitis; data expected mid-2017.
- TD-3504: Announced a second JAK inhibitor compound, chemically distinct from TD-1473. Designed to release active tofacitinib directly into the intestinal tract. Company plans to initiate a Phase 1b study of TD-3504 in ulcerative colitis patients in the first half of 2017.
- Neprilysin (NEP) Inhibitor Program for Cardiovascular and Renal Diseases:
  - TD-0714: Completed Phase 1 multiple-ascending dose study. Results demonstrated sustained target engagement, low levels of renal elimination and a favorable safety and tolerability profile. Company plans to advance an intravenous formulation into a Phase 1 study in early 2017.
  - TD-1439: Announced a second NEP inhibitor compound, structurally distinct from TD-0714. Phase 1 single-ascending and multiple-ascending dose studies underway in healthy volunteers; data expected in first half of 2017.
- VIBATIV<sup>®</sup> (telavancin):
  - U.S. net product sales of VIBATIV for the third quarter of 2016 were \$3.9 million.
  - TOUR patient registry study enrolling rapidly with over 600 of 1,000 patients enrolled to date. First TOUR data presented in poster presentations at ID Week highlighting real-world experience with VIBATIV in a range of difficult-to-treat infections.
- Closed Triple (the combination of fluticasone furoate, umeclidinium, and vilanterol):
  - In September, GlaxoSmithKline (GSK) and Innoviva reported positive top-line results from the pivotal Phase 3 FULFIL study of the Closed Triple in COPD. Data demonstrated superiority for the Closed Triple as compared to Symbicort<sup>®</sup> Turbuhaler<sup>®</sup> in improving lung function and health-related quality of life in COPD patients.
  - In October, GSK stated that U.S. and EU regulatory filings for COPD are on track to be filed in Q4 2016.
  - In November, GSK disclosed that it is recruiting patients in a Phase 3 study of the Closed Triple for the treatment of asthma.
- TD-8954 (TAK-954): Upfront payment of \$15.0 million recognized in the third quarter, related to the recently announced collaboration agreement with Takeda.

## Expected 2016-2018 Key Milestones

- Closed Triple: U.S. and EU regulatory filings for COPD by GSK and Innoviva (2016)<sup>1</sup>
- Closed Triple: Initiation of a Phase 3 study in asthma by GSK and Innoviva (2016)<sup>1</sup>
- TD-1473 (JAK inhibitor): Complete Phase 1b study in ulcerative colitis patients (2017)
- TD-0714 (NEP inhibitor): Advance IV formulation into Phase 1 clinical study (2017)
- Velusetrag (TD-5108): Complete Phase 2b study in gastroparesis (2017)
- Revefenacin (TD-4208): Complete long-term safety study in COPD and file NDA (2017)
- VIBATIV<sup>®</sup>: Complete Phase 3 bacteremia study (2018)

Notes:

<sup>1</sup>As reported by Glaxo Group Limited or one of its affiliates (GSK)

## Third Quarter 2016 Financial Results

### Revenue

Revenue for the third quarter of 2016 was \$19.1 million comprised of revenue from collaborative arrangements totaling \$15.2 million and U.S. net product sales of VIBATIV<sup>®</sup> of \$3.9 million. Revenue from collaborative arrangements is principally due to the recognition of a \$15.0 million upfront payment from Takeda for the license of TD-8954.

### Research and Development (R&D) Expenses

R&D expenses for the third quarter of 2016 were \$32.0 million representing an increase of \$1.6 million compared to the same period in 2015. The increase is primarily attributed to costs associated with the progression of our priority programs. Total R&D share-based compensation expense for the third quarter of 2016 was \$4.9 million.

### Selling, General and Administrative (SG&A) Expenses

SG&A expenses for the third quarter of 2016 were \$20.3 million, representing a decrease of \$2.6 million compared to the same period in 2015. The decrease is due to lower costs associated with share-based compensation and timing of other expenses. Total share-based compensation expense in SG&A for the third quarter of 2016 was \$5.0 million.

### Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities, excluding restricted cash, totaled \$289.3 million as of September 30, 2016. The quarter-end cash balance excludes \$22.7 million in receivables from collaborative arrangements, as noted below. The quarter-end cash balance also excludes net proceeds of approximately \$316.2 million (after deducting underwriting discounts and commissions and other estimated transaction expenses) from the Company's recent concurrent public offerings of ordinary shares and convertible senior notes.

#### Receivables from Collaborative Arrangements

Certain collaborative arrangements entered into by the Company result in reimbursement of expenses in the quarter after they are incurred. Total receivables from collaborative arrangements totaled \$22.7 million as of September 30, 2016, and include \$18.6 million in receivables associated with the Mylan collaboration.

#### 2016 Financial Guidance

We anticipate our operating loss, excluding share-based compensation, will be approximately \$140.0 million for the full year of 2016. Our actual operating loss, excluding share-based compensation, could be above or below our forecast as a result of a variety of factors, including the rate of enrollment in clinical studies, spending rates to prepare for planned clinical studies and fourth quarter revenue.

#### 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 96306659. 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](http://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 8, 2016. An audio replay will also be available through 8:00 pm ET on November 15, 2016 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 96306659.

#### **About Theravance Biopharma**

Theravance Biopharma is a diversified biopharmaceutical company with the core purpose of creating medicines that make a difference in 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<sup>®</sup> (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-targeted 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, umecclidinium, and vilanterol), currently in development for the treatment of COPD and asthma.

For more information, please visit [www.theravance.com](http://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, 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 2016 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 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 and commercialize products, risks associated with establishing and maintaining sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure, risks of developing an institutional customer mix for VIBATIV<sup>®</sup> (telavancin) that meet the Company's plan for the product and risks related to the variability of rates of enrollment in clinical studies, spending rates to prepare for planned clinical studies and fourth quarter revenue. 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 Aug 9, 2016, Theravance Biopharma's prospectus supplements filed with the SEC on October 31, 2016 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. CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited) (In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue:				
Product sales	\$ 3,901	\$ 2,312	\$ 12,571	\$ 5,716
Revenue from collaborative arrangements	15,174	8,386	30,385	32,517
Total revenue	19,075	10,698	42,956	38,233
Costs and expenses:				
Cost of goods sold	332	581	1,748	1,456
Research and development <sup>(1)</sup>	31,951	30,367	99,698	96,763
Selling, general and administrative <sup>(1)</sup>	20,286	22,845	64,143	66,139
Total costs and expenses	52,569	53,793	165,589	164,358
Loss from operations	(33,494)	(43,095)	(122,633)	(126,125)
Interest and other income	344	104	839	518
Loss before income taxes	(33,150)	(42,991)	(121,794)	(125,607)
Provision for income taxes	812	4,323	1,542	11,786
Net loss	\$ (33,962)	\$ (47,314)	\$ (123,336)	\$ (137,393)
Net loss per share:				
Basic and diluted net loss per share	\$ (0.73)	\$ (1.40)	\$ (2.86)	\$ (4.12)
Shares used to compute basic and diluted net loss per share	46,470	33,689	43,080	33,353

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

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development	\$ 4,933	\$ 6,035	\$ 15,052	\$ 20,334
Selling, general and administrative	4,962	6,216	16,077	22,205
Total share-based compensation expense	\$ 9,895	\$ 12,251	\$ 31,129	\$ 42,539

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

	September 30, 2016	December 31, 2015
<b>Assets</b>		
Current assets:		
Cash and cash equivalents and short-term marketable securities	\$ 230,482	\$ 172,434
Receivables from collaborative arrangements <sup>(1)</sup>	22,713	35,232
Prepaid taxes	3,168	12,764
Inventories	12,480	10,005
Other prepaid and current assets	5,192	7,037
Property and equipment, net	8,832	9,873
Long-term marketable securities	58,769	42,860
Restricted cash	833	833
Other assets	13,820	9,078
Total assets	<u>\$ 356,289</u>	<u>\$ 300,116</u>
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities	45,410	49,470
Long-term liabilities	13,006	7,581
Shareholders' equity	297,873	243,065
Total liabilities and shareholders' equity	<u>\$ 356,289</u>	<u>\$ 300,116</u>

(1) Receivables from collaborative arrangements includes \$18.6 million and \$33.2 million in receivables associated with the Mylan collaboration at September 30, 2016 and December 31, 2015, respectively.

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