

## **Theravance Biopharma, Inc. Reports Third Quarter 2015 Financial Results and Provides Business Update**

DUBLIN, IRELAND -- (Marketwired) -- 11/09/15 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today reported financial results for the third quarter ending September 30, 2015. Revenue for the third quarter of 2015 was \$10.7 million. Net loss for the third quarter of 2015 was \$47.3 million, or \$1.40 per share. Cash, cash equivalents, and marketable securities, excluding restricted cash, totaled \$196.0 million as of September 30, 2015. The quarter-end cash balance excludes \$55.0 million of gross proceeds from the recently completed sale of ordinary shares by the Company and \$19.6 million in receivables from collaborative arrangements.

"We continue to make important progress advancing key programs in our pipeline and executing our commercial strategy for VIBATIV<sup>®</sup>," said Rick E Winningham, Chairman and Chief Executive Officer. "We filed two INDs for novel product candidates -- our neprilysin inhibitor TD-0714 for cardiovascular and renal diseases and our GI-targeted pan-JAK inhibitor TD-1473 for ulcerative colitis -- both of which are advancing to Phase 1 studies late in 2015 or early 2016. We initiated all three studies comprising the Phase 3 program for revefenacin, previously known as TD-4208, in chronic obstructive pulmonary disease, or COPD. We completed the hiring and training of additional VIBATIV sales representatives and medical science liaisons, all of whom were deployed in the field by the beginning of the fourth quarter. In summary, we are pleased with our performance to date and are excited to enter 2016. With six Phase 3 studies expected to read out in 2016 and 2017, multiple Phase 2 programs advancing, high value research programs progressing into the clinic, a productive research organization and a strong financial position, the Company is well positioned for near- and long-term growth."

### **Upcoming Clinical Catalysts**

- Multiple mid- and late-stage clinical studies expected to read out in 2016 and 2017:
  - Revefenacin: Two Phase 3 efficacy studies in COPD (2016)
  - Closed Triple: Phase 3 FULFIL study in COPD (2016)<sup>1</sup>
  - TD-6450: Phase 2a study in hepatitis C virus (HCV) (2016)
  - Revefenacin: Phase 3 long-term safety study in COPD (2017)
  - Telavancin: Phase 3 registrational study in bacteremia (2017)
  - Velusetrag: Phase 2b study in gastroparesis (2017)
  - Closed Triple: Phase 3 IMPACT study in COPD (2017)<sup>1</sup>

### **Business Update**

- VIBATIV<sup>®</sup> (telavancin)
  - Total VIBATIV revenues were \$2.7 million, consisting of revenue from collaborative arrangements of \$0.4 million and net product sales of \$2.3 million. Net product sales increased 9% over the prior quarter.
  - Expanded sales force fully deployed by the beginning of the fourth quarter 2015.
  - FDA accepted for review a supplemental New Drug Application (sNDA) to expand the current label for VIBATIV to include treatment of cases of concurrent *Staphylococcus aureus* bacteremia and hospital-acquired or ventilator-associated bacterial pneumonia (HABP/VABP) or complicated skin and skin structure infections (cSSSI).
- Revefenacin: Phase 3 program in COPD initiated and enrolling patients.
- TD-0714: IND application filed for TD-0714, the lead compound in a series of novel neprilysin inhibitor development candidates for cardiovascular and renal diseases. Phase 1 study expected to start fourth quarter 2015.
- TD-1473: IND application filed for TD-1473, a GI-targeted pan-Janus kinase (JAK) inhibitor designed for targeted activity in the GI-tract with minimal systemic exposure. Development candidate has the potential to treat a range of inflammatory intestinal disorders, including ulcerative colitis. Phase 1 study expected to start by early 2016.

- TD-6450:
  - License granted to Trek Therapeutics (TREKtx) for TD-6450, a next-generation investigational NS5A inhibitor in development to treat patients with HCV. In exchange, the Company received \$8.0 million in the form of TREKtx's Series A preferred stock and is eligible to receive future royalties on net sales of TD-6450.
  - Phase 2a study initiated by TREKtx to evaluate TD-6450 in combination with faldaprevir, an HCV protease inhibitor, and ribavirin in patients infected with HCV genotype 4 in the US.
- Closed Triple: EU regulatory filing planned end of 2016 and US regulatory filing planned first-half of 2018<sup>1</sup>

## **Financial Results**

### Revenue

Total revenue for the third quarter of 2015 totaled \$10.7 million. Total revenue consisted of net product sales of VIBATIV<sup>®</sup> (telavancin) of \$2.3 million, an increase of \$0.2 million or 9% over the prior quarter, and revenue from collaborative arrangements of \$8.4 million. Revenue from collaborative arrangements is related to the license granted to TREKtx for TD-6450 and VIBATIV collaborations outside the US.

### Cost of Goods Sold

Cost of goods sold for the third quarter of 2015 totaled \$0.6 million.

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

R&D expenses for the third quarter of 2015 decreased to \$30.4 million compared to \$38.3 million for the same period in 2014. The decrease was primarily due to non-recurring long-term retention and incentive awards that impacted the third quarter of 2014 and a decrease in program-related expense due to the reimbursement of expenses associated with the Mylan collaboration for revefenacin. Total R&D share-based compensation expense was \$6.0 million in the third quarter of 2015.

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

SG&A expenses for the third quarter of 2015 were \$22.8 million compared with \$17.7 million for the same period in 2014. The increase was primarily due to costs associated with VIBATIV commercialization. Total share-based compensation expense in SG&A was \$6.2 million in the third quarter of 2015.

### Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities, excluding restricted cash, totaled \$196.0 million as of September 30, 2015. The quarter-end cash balance excludes proceeds related to the recently completed sale of ordinary shares by the Company for the aggregate sale price of \$55.0 million.

### Receivables from Collaborative Arrangements

Receivables from collaborative arrangements totaled \$19.6 million as of September 30, 2015, and include \$16.9 million in receivables associated with the Mylan collaboration.

### Basis of Presentation

On June 1, 2014, Theravance, Inc. separated its late-stage respiratory assets partnered with GSK from its biopharmaceutical operations by transferring its discovery, development and commercialization operations (the "Biopharmaceutical Business") and contributing \$393.0 million of cash, cash equivalents and marketable securities into its then wholly-owned subsidiary, Theravance Biopharma. On June 2, 2014, Theravance made a pro rata dividend distribution to its stockholders of record on May 15, 2014 of one ordinary share of Theravance Biopharma for every three and one half shares of Theravance common stock outstanding on the record date (the "Spin-Off"). The Spin-Off resulted in Theravance Biopharma operating as an independent, publicly-traded company. Prior to June 2, 2014, Theravance operated the Biopharmaceutical Business.

The financial statements of Theravance Biopharma for periods prior to the Spin-Off were derived from Theravance's historical consolidated financial statements, with expenses allocated through a specific identification basis or another reasonable allocation methodology. As such, the financial information included herein for periods prior to the Spin-Off may not necessarily reflect the financial profile of what Theravance Biopharma would have been had it been an independent, publicly traded

company during those periods.

Notes:

<sup>1</sup>Regulatory and clinical milestones as reported by GSK

Conference Call Today at 5:00 pm ET

Theravance Biopharma will hold a conference call today at 5:00 pm ET to discuss its third quarter 2015 financial results and recent business activities. 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 65819430. 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 9, 2015. An audio replay will also be available through 11:59 pm ET on November 16, 2015 by dialing (855) 859-2056 from the US, or (404) 537-3406 for international callers, and then entering confirmation code 65819430.

### **About Theravance Biopharma**

The mission of Theravance Biopharma (NASDAQ: TBPH) is to create value from a unique and diverse set of assets: an approved product; a development pipeline of late-stage assets; and a productive research platform designed for long-term growth.

Our pipeline of internally discovered product candidates includes potential best-in-class opportunities in underserved markets in the acute care setting, representing multiple opportunities for value creation. VIBATIV<sup>®</sup> (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the US, Europe and certain other countries for certain difficult-to-treat infections. Revefenacin (TD-4208) is an investigational long-acting muscarinic antagonist (LAMA) being developed as a potential once-daily, nebulized treatment for chronic obstructive pulmonary disease (COPD). Axelopran (TD-1211) is an investigational potential once-daily, oral treatment for opioid-induced constipation (OIC). Our earlier-stage clinical assets represent novel approaches for potentially treating diseases of the lung and gastrointestinal tract and infectious disease. 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 Theravance, Inc. relating to certain drug development programs, including the combination of fluticasone furoate, umeclidinium, and vilanterol (the "Closed Triple").

With our successful drug discovery and development track record, commercial infrastructure, experienced management team and efficient corporate structure, we believe that we are well positioned to create value for our shareholders and make a difference in the lives of patients.

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 and commercialization (including their potential as components of combination therapies). 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 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 and risks of developing an institutional customer mix for VIBATIV 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 13, 2015 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.

**THERAVANCE BIOPHARMA, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
*(Unaudited)*

*(In thousands, except per share data)*

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Revenue:				
Product sales	\$ 2,312	\$ 1,303	\$ 5,716	\$ 3,109
Revenue from collaborative arrangements	8,386	5,033	32,517	7,146
Total revenue	<u>10,698</u>	<u>6,336</u>	<u>38,233</u>	<u>10,255</u>
Costs and expenses:				
Cost of goods sold	581	369	1,456	836
Research and development (1)	30,367	38,324	96,763	126,330
Selling, general and administrative (1)	22,845	17,705	66,139	49,875
Total costs and expenses	<u>53,793</u>	<u>56,398</u>	<u>164,358</u>	<u>177,041</u>
Loss from operations	(43,095)	(50,062)	(126,125)	(166,786)
Interest and other income	104	668	518	882
Loss before income taxes	(42,991)	(49,394)	(125,607)	(165,904)
Provision for income taxes	4,323	5,101	11,786	6,824
Net loss	<u>\$ (47,314)</u>	<u>\$ (54,495)</u>	<u>\$ (137,393)</u>	<u>\$ (172,728)</u>
Net loss per share:				
Basic and diluted net loss per share	<u>\$ (1.40)</u>	<u>\$ (1.72)</u>	<u>\$ (4.12)</u>	<u>\$ (5.44)</u>
Shares used to compute basic and diluted net loss per share	<u>33,689</u>	<u>31,754</u>	<u>33,353</u>	<u>31,746</u>

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

<i>(In thousands)</i>	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Research and development	\$ 6,035	\$ 5,132	\$ 20,334	\$ 14,046
Selling, general and administrative	6,216	4,218	22,205	14,768
Total share-based compensation expense	<u>\$ 12,251</u>	<u>\$ 9,350</u>	<u>\$ 42,539</u>	<u>\$ 28,814</u>

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

*(In thousands, except per share data)*

	<u>September 30, 2015</u>	<u>December 31, 2014</u>
	<i>(Unaudited)</i>	<i>(1)</i>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents and marketable securities	\$ 195,970	\$ 306,010

Receivables from collaborative arrangements (2)	19,640	1,840
Prepaid and other current assets	10,488	6,373
Inventories	12,141	12,546
Restricted cash	833	833
Property and equipment, net	9,513	9,663
Other assets	8,921	506
Total assets	<u>\$ 257,506</u>	<u>\$ 337,771</u>
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities (3)	\$ 27,430	\$ 41,256
Long-term liabilities	7,531	6,728
Shareholders' equity	222,545	289,787
Total liabilities and shareholders' equity	<u>\$ 257,506</u>	<u>\$ 337,771</u>

*Note 1: The condensed consolidated balance sheet at December 31, 2014 has been derived from the audited consolidated financial statements at that date included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2014.*

*Note 2: Receivables from collaborative arrangements at September 30, 2015 includes \$16.9 million in receivables associated with Mylan collaboration.*

*Note 3: Amounts include the current portion of deferred revenue of \$0.3 million and \$0.1 million as September 30, 2015 and December 31, 2014, respectively.*

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Source: Theravance Biopharma

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