

Theravance Biopharma, Inc. Reports Fourth Quarter and Full Year 2015 Financial Results

Priority Programs Advancing; Multiple Data Read-Outs in 2016

DUBLIN, IRELAND -- (Marketwired) -- 03/09/16 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today reported financial results for the fourth quarter and full year ended December 31, 2015. Revenue for the fourth quarter and full year of 2015 was \$3.9 million and \$42.1 million, respectively. In line with the Company's expectation, the full year 2015 operating loss excluding share-based compensation was \$127.8 million, or \$181.9 million including share-based compensation of \$54.1 million. Cash, cash equivalents, and marketable securities totaled \$215.3 million as of December 31, 2015. The year-end cash balance excludes \$35.2 million in receivables from collaborative arrangements and a \$15.0 million milestone payment from Mylan for recently achieving 50% enrollment in the Phase 3 twelve-month safety study of revefenacin (TD-4208).

Rick E Winningham, Chairman and Chief Executive Officer, commented: "In 2015, we made significant progress in advancing our priority programs to key inflection points, setting the stage for multiple value-creating events in 2016. We recently reported positive results, including positive biomarker data, from the Phase 1 clinical trial of our neprilysin inhibitor, and we expect to report top-line data from the full Phase 1 study in the second half of 2016. The Phase 1 trial of our GI-targeted pan-JAK inhibitor for ulcerative colitis is underway and should yield data in the first half of 2016 that could pave the way to a Phase 1b trial in patients later this year. The Phase 3 program for revefenacin in COPD recently surpassed 50% enrollment in all three studies, and the Phase 3 efficacy studies remain on track to have data read out in the third quarter of 2016. On the commercial front, with our sales force expansion completed, we look forward to building on the momentum of VIBATIV[®] sales we achieved in the fourth quarter of 2015. We also look forward to a PDUFA date in the second quarter of 2016 for the concurrent bacteremia indications. Looking ahead, we expect to achieve key clinical and regulatory milestones in 2016, including numerous data read-outs. We believe our Company is well-positioned to generate significant value for both patients and shareholders in the near- and long-term."

Recent Highlights

- | Neprilysin (NEP) Inhibitor Program (TD-0714):
 - | Phase 1 single-ascending dose study met key objectives, including positive biomarker data, with favorable tolerability, maximal and sustained target engagement, potential for once-daily dosing and very low renal elimination. Results met Company's target product profile and support further development in a broad range of cardiovascular and renal indications.
 - | Phase 1 multiple ascending dose trial underway.
- | JAK Inhibitor Program (TD-1473):
 - | Phase 1 single-ascending and multiple-ascending dose studies underway for GI-targeted pan-Janus kinase (JAK) inhibitor to treat ulcerative colitis.
 - | Results from preclinical colitis models suggest a GI-targeted JAK inhibitor, such as TD-1473, may provide clinical benefit without systemically-mediated adverse effects; data to be presented in two posters at the European Crohn's and Colitis Organisation (ECCO) Conference in Amsterdam (March 16-19, 2016).
- | Revefenacin (TD-4208): Phase 3 program in COPD progressing well. 50% enrollment surpassed in two replicate efficacy studies and twelve-month long-term safety study. \$15.0 million milestone payment earned from partner Mylan.
- | VIBATIV[®] (telavancin):
 - | Net product sales of VIBATIV for the full year of 2015 were \$9.4 million, including U.S. net product sales of \$8.8 million and \$0.6 million in net product sales from global partnerships.
 - | sNDA under review by FDA for cases of concurrent *Staphylococcus aureus* bacteremia and complicated skin

and skin structure infections (cSSSI) or hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP).

Enrollment in the Phase 3 registrational study in bacteremia is ongoing.

Upcoming 2016 Key Data and Regulatory Milestones

- ┆ TD-0714 (NEP inhibitor): Phase 1 study
- ┆ TD-1473 (JAK inhibitor): Phase 1 study
- ┆ VIBATIV[®] (telavancin): Concurrent bacteremia and cSSSI or HABP/VABP PDUFA
- ┆ Revefenacin (TD-4208): Two Phase 3 efficacy studies in COPD
- ┆ Closed Triple: Phase 3 FULFIL study in COPD¹
- ┆ Closed Triple: EU regulatory filing¹

Fourth Quarter Financial Results

Revenue

Revenue for the fourth quarter of 2015 was \$3.9 million, including revenue from collaborative arrangements and net product sales of VIBATIV[®] (telavancin). Revenue from collaborative arrangements for the fourth quarter of 2015 was \$0.2 million. Net product sales of VIBATIV for the fourth quarter of 2015 was \$3.7 million, consisting of net product sales in the U.S. of \$3.1 million and ex-U.S. of \$0.6 million.

Cost of Goods Sold

Cost of goods sold for the fourth quarter of 2015 totaled \$3.2 million, which includes a charge of \$1.9 million for write down of inventory due to dating of the product.

Research and Development (R&D) Expenses

R&D expenses for the fourth quarter of 2015 were \$32.4 million, representing a decrease of \$9.8 million compared to the same period in 2014. The decrease was primarily due to non-recurring long-term retention and incentive awards and a decrease in program-related expense due to the reimbursement of expenses associated with the Mylan collaboration for revefenacin (TD-4208). Total R&D share-based compensation expense for the fourth quarter of 2015 was \$5.4 million.

Selling, General and Administrative (SG&A) Expenses

SG&A expenses for the fourth quarter of 2015 were \$24.1 million, representing an increase of \$2.3 million compared to the same period in 2014. The increase was primarily due to costs associated with VIBATIV commercialization. Total share-based compensation expense in SG&A for the fourth quarter of 2015 was \$6.1 million.

Provision for Income Taxes

In the fourth quarter of 2015, the Company recognized an income tax provision benefit of \$10.8 million primarily due to changes in the Company's transfer pricing.

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities, excluding restricted cash, totaled \$215.3 million as of December 31, 2015. The year-end cash balance excludes receivables from collaborative arrangements noted below and a \$15.0 million milestone payment from Mylan for recently achieving 50% enrollment in the Phase 3 twelve-month safety study of revefenacin.

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 \$35.2 million as of December 31, 2015, and include \$33.2 million in receivables associated with the Mylan collaboration.

2016 Financial Guidance

The Company anticipates that 2016 operating loss, excluding share-based compensation, will be in the range of \$120.0 to \$130.0 million.

Basis of Presentation

On June 1, 2014, Innoviva, Inc. ("Innoviva") (known as Theravance, Inc. prior to January 7, 2016) separated its late-stage respiratory assets partnered with GSK from its biopharmaceutical operations (the "Spin-Off") by transferring its discovery, development and commercialization operations to Theravance Biopharma. The Spin-Off resulted in Theravance Biopharma operating as an independent, publicly-traded company.

The financial statements of Theravance Biopharma for periods prior to the Spin-Off were derived from Innoviva's historical consolidated financial statements, with expenses allocated through a specific identification basis or another reasonable allocation methodology.

Notes:

¹ *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 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 60136860. 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 April 9, 2016. An audio replay will also be available through 11:59 pm ET on March 16, 2016 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 60136860.

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[®] (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 GI-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 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).

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, 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) and the Company's expectations for product sales. 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[®] (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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 12, 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
(In thousands, except per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2015	2014	2015	2014
	<i>(Unaudited)</i>		<i>(Unaudited)</i>	
Revenue:				
Product sales	\$ 3,693	\$ 1,309	\$ 9,408	\$ 4,418
Revenue from collaborative arrangements	200	124	32,718	7,270
Total revenue	3,893	1,433	42,126	11,688
Costs and expenses:				
Cost of goods sold	3,200	3,222	4,657	4,058
Research and development (2)	32,403	42,192	129,165	168,522
Selling, general and administrative (2)	24,064	21,772	90,203	71,647
Total costs and expenses	59,667	67,186	224,025	244,227
Loss from operations	(55,774)	(65,753)	(181,899)	(232,539)
Interest and other income	110	983	631	1,865
Loss before income taxes	(55,664)	(64,770)	(181,268)	(230,674)
Provision for income taxes	(10,836)	(460)	951	6,364
Net loss	<u>\$ (44,828)</u>	<u>\$ (64,310)</u>	<u>\$ (182,219)</u>	<u>\$ (237,038)</u>
Net loss per share:				
Basic and diluted net loss per share	<u>\$ (1.23)</u>	<u>\$ (2.02)</u>	<u>\$ (5.34)</u>	<u>\$ (7.46)</u>
Shares used to compute basic and diluted net loss per share	<u>36,513</u>	<u>31,782</u>	<u>34,150</u>	<u>31,755</u>

(1) The condensed consolidated statement of operations for the year ended December 31, 2014 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, 2014.

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

<i>(In thousands)</i>	Three Months Ended December 31,		Year Ended December 31,	
	2015	2014	2015	2014
Research and development	\$ 5,437	\$ 7,145	\$ 25,770	\$ 21,191
Selling, general and administrative	6,074	7,275	28,280	22,043
Total share-based compensation expense	<u>\$ 11,511</u>	<u>\$ 14,420</u>	<u>\$ 54,050</u>	<u>\$ 43,234</u>

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

	December 31,	
	2015	2014
	<i>(Unaudited)</i>	<i>(1)</i>
Assets		
Current assets:		
Cash and cash equivalents and marketable securities	\$ 215,294	\$ 306,010
Receivables from collaborative arrangements (2)	35,232	1,840
Prepaid taxes	12,764	-
Inventories	10,005	12,546
Other prepaid and current assets	7,037	6,373
Restricted cash	833	833
Property and equipment, net	9,873	9,663
Other assets	9,078	506
Total assets	<u>\$ 300,116</u>	<u>\$ 337,771</u>
Liabilities and Shareholders' Equity		
Current liabilities (3)	49,470	41,256
Long-term liabilities	7,581	6,728
Shareholders' equity	243,065	289,787
Total liabilities and shareholders' equity	<u>\$ 300,116</u>	<u>\$ 337,771</u>

(1) The condensed consolidated balance sheet at December 31, 2014 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, 2014.

(2) Receivables from collaborative arrangements at December 31, 2015 includes \$33.2 million in receivables associated with the Mylan collaboration.

(3) Amounts include the current portion of deferred revenue of \$0.1 million at December 31, 2015 and 2014.

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