

Theravance Biopharma, Inc. Reports First Quarter 2015 Financial Results

VIBATIV(R) Commercial Activities Gaining Momentum; TD-4208 Phase 3 Program to Commence Second Half 2015; New Product Candidates Advancing Towards the Clinic; Lowering Operating Loss Guidance for 2015

GEORGE TOWN, GRAND CAYMAN -- (Marketwired) -- 05/07/15 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today reported financial results for the first quarter ending March 31, 2015. Revenue for the first quarter of 2015 was \$20.4 million. Net loss for the first quarter of 2015 was \$42.5 million, or \$1.29 per share. Cash, cash equivalents, and marketable securities, excluding restricted cash, totaled \$274.8 million as of March 31, 2015.

Rick E Winningham, Chairman and Chief Executive Officer, commented: "We achieved our objectives and made good progress in advancing key programs during the first quarter. The expansion of our field force, and the initiation of the TOUR and bacteremia studies are helping to build the VIBATIV[®] (telavancin) brand, and plans are underway for additional commercial expansion this year to further drive market uptake. We are on track to initiate a Phase 3 registrational program in TD-4208 in COPD later this year, in collaboration with Mylan. Additional progress includes the initiation of a Phase 2b study of velusetrag, partnered with Alfa Wassermann, in gastroparesis. Underscoring the innovation and productivity of our research platform, we continue to make strides in advancing product candidates toward the clinic. We believe that we are on track to meet our 2015 milestones, and achieve an exciting year of growth for our company."

First Quarter 2015 Highlights and Business Update

- *Expanded field force driving market uptake of VIBATIV:* commencing further expansion of sales force to 50 representatives, based on steady account growth, new formulary wins and sales growth in target regions.
- *Phase 3 bacteremia registrational study enrolling patients:* designed to support regulatory filing for telavancin as a treatment for *Staphylococcus aureus* bacteremia.
- *TOUR patient registry study enrolling:* designed to generate real-world data to guide future development and optimal use of VIBATIV.
- *TD-4208 Phase 3 registrational program in COPD to begin in the second half 2015:* plan includes two replicate three-month efficacy studies and a single twelve-month safety study.
- *Velusetrag Phase 2b study progressing:* testing the efficacy, safety and tolerability of velusetrag in the treatment of patients with gastroparesis.
- *Novel neprilysin inhibitor development candidates for heart failure moving from research into IND-enabling toxicology studies:* targeting initiation of Phase 1 in late 2015/early 2016.
- *Ulcerative colitis development candidate advancing into IND-enabling toxicology studies;* targeting initiation of Phase 1 in late 2015/early 2016.

First Quarter 2015 Financial Results

On June 1, 2014, Theravance 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 was the parent for 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.

Revenue

Product sales of VIBATIV for the quarter ended March 31, 2015 totaled \$1.3 million.

Revenue from collaborative arrangements for the quarter ended March 31, 2015 was \$19.1 million primarily due to the recognition of upfront payments related to the delivery of the license and technological know-how to Mylan during the period.

Cost of goods sold for the quarter ended March 31, 2015 totaled \$0.4 million.

Research and Development (R&D)

R&D expenses for the quarter ended March 31, 2015 decreased to \$36.0 million compared to \$42.6 million for the same period in 2014. The decrease was primarily due to lower costs associated with the long-term retention and incentive awards that were granted in 2011 and a decrease in program-related net expense due to the reimbursement of costs associated with the Mylan collaborative arrangement. Total research and development share-based compensation expense was \$7.5 million in the first quarter of 2015 compared with \$5.6 million for the same period in 2014, with the increase primarily related to new equity awards issued by the company in 2015.

Selling, General and Administrative (SG&A)

SG&A expenses for the quarter ended March 31, 2015 were \$21.7 million compared with \$18.2 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 \$8.1 million in the first quarter of 2015 compared with \$7.1 million for the same period in 2014, with the increase primarily related to new equity awards issued by the company in 2015.

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities, excluding restricted cash, totaled \$274.8 million as of March 31, 2015.

Revised 2015 Financial Guidance

The Company is lowering its full year 2015 operating loss guidance to \$120-\$130 million, excluding share-based compensation. The prior 2015 operating loss guidance was \$150-\$160 million, excluding share-based compensation.

The updated guidance reflects a reduction in operating loss due to revenues and reimbursements received from Mylan, offset by an increase in investment in both VIBATIV commercialization and early development programs. The Company is investing in VIBATIV by expanding its sales force commencing in Q2 2015. The investment in early development programs reflects the decision to advance multiple product candidates from the Company's neprilysin inhibitor and ulcerative colitis programs towards the clinic.

The Company is targeting VIBATIV net sales of approximately \$20.0 million. As stated in the Company's last earnings call, VIBATIV sales are expected to build through the second half of the year.

Conference Call Today at 5:00 pm ET

Theravance Biopharma will hold a conference call today at 5:00 pm EDT to discuss its first quarter 2015 financial results. To participate in the live call by telephone, please dial (855) 296-9648 from the U.S., or (920) 663-6266 for international callers. 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. To listen to the live call via the internet, please go to the website 15 minutes prior to its start 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 7, 2015. An audio replay will also be available through 11:59 pm EDT on May 14, 2015 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and entering confirmation code 31476865.

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[®] (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the U.S. and Europe for certain difficult-to-treat infections. TD-4208 is an investigational long-acting muscarinic antagonist (LAMA) being developed as a potential once-daily, nebulized treatment for 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 GSK pursuant to its agreements with Theravance, Inc. relating to certain drug development programs, including the combination of fluticasone furoate, umeclidinium, and vilanterol (or 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.

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VIBATIV[®] Important Safety Information (U.S.)

Mortality

Patients with pre-existing moderate/severe renal impairment (CrCl \leq 50 mL/min) who were treated with VIBATIV for hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia had increased mortality observed versus vancomycin. Use of VIBATIV in patients with pre-existing moderate/severe renal impairment (CrCl \leq 50 mL/min) should be considered only when the anticipated benefit to the patient outweighs the potential risk.

Nephrotoxicity

New onset or worsening renal impairment occurred in patients who received VIBATIV. Renal adverse events were more likely to occur in patients with baseline comorbidities known to predispose patients to kidney dysfunction and in patients who received concomitant medications known to affect kidney function. Monitor renal function in all patients receiving VIBATIV prior to initiation of treatment, during treatment, and at the end of therapy. If renal function decreases, the benefit of continuing VIBATIV versus discontinuing and initiating therapy with an alternative agent should be assessed.

Fetal Risk

Women of childbearing potential should have a serum pregnancy test prior to administration of VIBATIV. Avoid use of VIBATIV during pregnancy unless the potential benefit to the patient outweighs the potential risk to the fetus. Adverse developmental outcomes observed in three animal species at clinically relevant doses raise concerns about potential adverse developmental outcomes in humans. If not already pregnant, women of childbearing potential should use effective contraception during VIBATIV treatment.

Contraindication

Intravenous unfractionated heparin sodium is contraindicated with VIBATIV administration due to artificially prolonged activated partial thromboplastin time (aPTT) test results for up to 18 hours after VIBATIV administration.

VIBATIV is contraindicated in patients with a known hypersensitivity to the drug.

Hypersensitivity Reactions

Serious and potentially fatal hypersensitivity reactions, including anaphylactic reactions, may occur after first or subsequent doses. VIBATIV should be used with caution in patients with known hypersensitivity to vancomycin.

Geriatric Use

Telavancin is substantially excreted by the kidney, and the risk of adverse reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection in this age group.

Infusion Related Reactions

VIBATIV is a lipoglycopeptide antibacterial agent and should be administered over a period of 60 minutes to reduce the risk of infusion-related reactions. Rapid intravenous infusions of the glycopeptide class of antimicrobial agents can cause "Red-man Syndrome" like reactions including: flushing of the upper body, urticaria, pruritus, or rash.

QTc Prolongation

Caution is warranted when prescribing VIBATIV to patients taking drugs known to prolong the QT interval. In a study involving healthy volunteers, VIBATIV prolonged the QTc interval. Use of VIBATIV should be avoided in patients with congenital long QT syndrome, known prolongation of the QTc interval, uncompensated heart failure, or severe left ventricular hypertrophy.

Most Common Adverse Reactions

The most common adverse reactions (greater than or equal to 10% of patients treated with VIBATIV) were diarrhea, taste disturbance, nausea, vomiting, and foamy urine.

Full Prescribing Information, including Boxed Warning and Medication Guide in the U.S., is available at www.VIBATIV.com.

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 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 and risks associated with establishing and maintaining sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure. Other risks affecting Theravance Biopharma are described under the heading "Risk Factors" contained in Theravance Biopharma's Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 13, 2015. In addition to the risks described above and in Theravance Biopharma's other 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)

	Three Months Ended March 31,	
	2015	2014
Revenue:		
Product sales	\$ 1,280	\$ 945
Revenue from collaborative arrangements	19,121	-

Total revenue	20,401	945
Costs and expenses:		
Cost of goods sold	371	188
Research and development (1)	36,019	42,558
Selling, general and administrative (1)	21,748	18,217
Total costs and expenses	58,138	60,963
Loss from operations	(37,737)	(60,018)
Interest and other income	211	-
Loss before income taxes	(37,526)	(60,018)
Provision for income taxes	4,948	-
Net loss	<u>\$ (42,474)</u>	<u>\$ (60,018)</u>
Net loss per share:		
Basic and diluted net loss per share	<u>\$ (1.29)</u>	<u>\$ (1.89)</u>
Shares used to compute basic and diluted net loss per share	<u>32,830</u>	<u>31,741</u>

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

(In thousands)	Three Months Ended March 31,	
	2015	2014
Research and development	\$ 7,482	\$ 5,556
Selling, general and administrative	8,144	7,145
Total share-based compensation expense	<u>\$ 15,626</u>	<u>\$ 12,701</u>

THERAVANCE BIOPHARMA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except per share data)

	March 31, 2015 (Unaudited)	December 31, 2014 (1)
Assets		
Current assets:		
Cash and cash equivalents and marketable securities	\$ 274,757	\$ 306,010
Receivables from collaborative arrangements (2)	19,660	1,840
Prepaid and other current assets	7,323	6,373
Inventories	12,337	12,546
Restricted cash	833	833
Property and equipment, net	9,305	9,663
Other assets	686	506
Total assets	<u>\$ 324,901</u>	<u>\$ 337,771</u>
Liabilities and Shareholders' Equity:		
Current liabilities (3)	\$ 28,852	\$ 41,256
Long-term liabilities	6,934	6,728
Shareholders' equity	289,115	289,787
Total liabilities and shareholders' equity	<u>\$ 324,901</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 March 31, 2015 includes \$19.1million 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 March 31, 2015 and December 31, 2014.

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Source: Theravance Biopharma

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