

Theravance Biopharma, Inc. Reports Fourth Quarter and Full Year 2014 Financial Results

VIBATIV(R) (Telavancin) Commercial Team Expanded in Target Geographies, Registry Study Initiated and Telavancin Phase 3 Bacteremia Study Underway; Pipeline Progressing; TD-4208 Advancing to Phase 3 Registrational Program, and Partnered With Mylan in Broad Development and Commercialization Collaboration

GEORGE TOWN, GRAND CAYMAN -- (Marketwired) -- 03/10/15 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today reported financial results for the fourth quarter and year ending December 31, 2014. Revenue for the fourth quarter of 2014 was \$1.4 million. Net loss for the fourth quarter of 2014 was \$64.3 million or \$2.02 per share. Cash, cash equivalents, and marketable securities, excluding restricted cash, totaled \$306.0 million as of December 31, 2014.

Rick E Winningham, Chairman and Chief Executive Officer, commented: "In 2014, we successfully separated Theravance Biopharma from Theravance, Inc., creating an independent biopharmaceutical company with a valuable research, development and commercial portfolio. We established a commercial infrastructure to market VIBATIV[®] in the U.S., and to support future initiatives focused on the acute care setting. We advanced our late-stage pipeline, led by TD-4208 which is moving toward a Phase 3 registrational program in COPD, and progressed exciting new compounds from our research efforts toward the clinic. Our accomplishments in 2014 created a strong foundation for continued progress and the opportunity for achievement of important milestones."

Recent Highlights

- With VIBATIV, the Company expanded the field force supporting the commercial launch, initiated a Phase 3 bacteremia registrational study and initiated a patient registry study.
- The Company held discussions with the FDA on the design of a Phase 3 program for TD-4208 in COPD and announced plans to initiate the Phase 3 program later this year.
- The Company announced an important strategic collaboration with Mylan to develop and, if approved, commercialize the nebulized formulation of TD-4208.
- The Company successfully co-formulated axelopran with the opiate OxyContin[®] as a fixed-dose combination in a Phase 1 study.
- GSK and Theravance, Inc. announced initiation of a second global Phase 3 study to evaluate the effects of the Closed Triple in patients with COPD.
- In collaboration with partner Alfa Wassermann, the Company prepared to initiate a Phase 2b study in gastroparesis with velusetrag.

Theravance Biopharma Programs

VIBATIV[®] (telavancin)

VIBATIV is a bactericidal, once-daily injectable antibiotic to treat patients with serious, life-threatening infections due to *Staphylococcus aureus* and other Gram-positive bacteria, including methicillin-resistant (MRSA) strains. VIBATIV is approved in the U.S. and Canada for the treatment of adult patients with complicated skin and skin structure infections (cSSSI) caused by susceptible Gram-positive bacteria. VIBATIV is also approved in the U.S. for the treatment of adult patients with hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Staphylococcus aureus* when alternative treatments are not suitable. VIBATIV is approved in the European Union for the treatment of adults with nosocomial pneumonia, including ventilator-associated pneumonia, known or suspected to be caused by MRSA when other alternatives are not suitable.

In 2014, we implemented a phased launch strategy for VIBATIV in the U.S. that focused on a small number of targeted

geographic territories across the country. We have since expanded our sales force and medical affairs presence to include additional territories in the U.S. with the goal of strengthening our commercial infrastructure comprised of experienced sales representatives and a significant medical information component focused on the acute care market.

Initiated in February 2015, the 1,000-patient TOUR observational use registry study is designed to assess the manner in which VIBATIV is used by healthcare practitioners to treat patients. By broadly collecting and examining data related to VIBATIV treatment patterns, as well as clinical and safety outcomes in the real world, we aim to create an expansive knowledge base to guide future development and optimal use of the drug.

As part of our effort to explore additional settings in which VIBATIV may offer patients therapeutic benefit, in February 2015, we initiated a Phase 3 registrational study for the treatment of patients with *Staphylococcus aureus* bacteremia. The 250-patient registrational study is a multicenter, randomized, open-label study designed to evaluate the non-inferiority of telavancin in treating *Staphylococcus aureus* bacteremia as compared to standard therapy. Key secondary outcome measures of the study include an assessment of the duration of bacteremia post-randomization and the incidence of development of metastatic complications, as compared to standard therapy.

TD-4208: Long-Acting Muscarinic Antagonist (LAMA)

TD-4208 is an investigational, long-acting muscarinic antagonist (LAMA) in development for the treatment of chronic obstructive pulmonary disease (COPD). We believe that TD-4208 may become a valuable addition to the COPD treatment regimen and that it represents a significant commercial opportunity. Our market research indicates approximately 9% of the treated COPD patients in the U.S. either need or prefer nebulized delivery for maintenance therapy. LAMAs are a cornerstone of maintenance therapy for COPD, but existing LAMAs are only available in handheld devices that may not be suitable for every patient. TD-4208 has the potential to be a best-in-class once-daily single-agent product for COPD patients who require, or prefer, nebulized therapy. The therapeutic profile of TD-4208, together with its physical characteristics, suggest that this LAMA could serve as a foundation for combination products and for delivery in metered dose inhaler and dry powder inhaler products.

In February 2015, Mylan Inc., which is now a subsidiary of Mylan N.V., and we established a strategic collaboration for the development and, subject to FDA approval, commercialization of TD-4208. Partnering with a world leader in nebulized respiratory therapies enables us to expand the breadth of our TD-4208 development program and extend our commercial reach beyond the acute care setting where we currently market VIBATIV. Funding of the Phase 3 registrational program by Mylan strengthens our capital position and enhances our financial flexibility to advance other high-value pipeline assets alongside TD-4208.

In December 2014, following the announcement of positive top-line results of our Phase 2b program, we conducted an end-of-Phase 2 meeting with the FDA to discuss the design of the Phase 3 registrational program. We are progressing TD-4208 into a Phase 3 registrational program that will include two replicate three-month efficacy studies and a single twelve-month safety study. Based on our discussion with the FDA, the studies will include approximately 2,200 patients. The studies will test two doses: 88 mcg and 175 mcg administered once-daily. We expect to initiate the Phase 3 program in 2015.

Other Late-Stage Programs: Axelopran (TD-1211), Velusetrag, Closed Triple

Axelopran is an investigational, once-daily, oral peripherally active mu opioid receptor antagonist for opioid-induced constipation (OIC). The axelopran Phase 2 program demonstrated a clinically meaningful treatment effect in OIC patients compared to placebo. The goal for this program is to demonstrate the ability to normalize bowel function without impacting analgesia and improve a variety of GI symptoms associated with constipation, which could provide axelopran with a competitive advantage in the OIC market if demonstrated in Phase 3 studies and approved by regulatory authorities. We have developed a patient reported outcomes tool designed to measure patient symptoms which would be used in a Phase 3 registrational program and potentially generate data that could differentiate the product from the competition. We are currently refining our development and commercial strategy for axelopran.

In December 2014, we completed a Phase 1 study to determine the relative bioavailability of OxyContin[®] (oxycodone) and axelopran after oral administration as a fixed dose combination (FDC) relative to the individual components administered together. The study examined a spray-coat application of axelopran to an opioid, OxyContin, to determine the effect of axelopran on OxyContin exposure. The study compared exposure of OxyContin alone, axelopran alone, OxyContin and axelopran administered as two separate tablets, and OxyContin spray-coated with axelopran in a FDC. Study results demonstrated that axelopran does not significantly alter systemic exposure to OxyContin when delivered as a FDC relative to when co-administered as individual tablets. A FDC of axelopran and an opioid could present an important market opportunity, as it has the potential to provide pain relief without constipation in a single abuse-deterrent pill for patients using opioids on a chronic basis.

Velusetrag is an oral, investigational medicine developed for gastrointestinal motility disorders. It is a highly selective agonist

with high intrinsic activity at the human 5-HT4 receptor. Velusetrag is being developed in collaboration with Alfa Wassermann S.p.A. ("Alfa Wassermann") in a two-part Phase 2 program to test the efficacy, safety and tolerability of velusetrag in the treatment of patients with gastroparesis. Positive top-line results from the initial Phase 2 proof-of-concept study under this partnership, which evaluated gastric emptying, safety and tolerability of multiple doses of velusetrag, were announced in April 2014. Based on these results, we have agreed with Alfa Wassermann to advance velusetrag into a Phase 2b study. Pursuant to our agreement with Alfa Wassermann, the first Phase 2 study was, and the bulk of the Phase 2b study will be, funded by Alfa Wassermann.

The "Closed Triple" program seeks to provide the activity of fluticasone furoate, umeclidinium, and vilanterol (FF/UMEC/VI) in a single delivery device. We have an 85% economic interest in future payments that may be made by Glaxo Group Limited ("GSK") pursuant to its agreements with Theravance, Inc. ("Theravance") relating to certain drug programs, including the closed triple. The royalty rates applicable to worldwide net sales of the closed triple are upward-tiering from 6.5% to 10%. In July 2014, GSK and Theravance announced the initiation of a large, global Phase 3 program for the closed triple in patients with COPD. In February 2015, GSK and Theravance announced the start of a second global Phase 3 study to evaluate the effects of the closed triple in patients with COPD.

2014 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 herein may not necessarily reflect the financial profile of Theravance Biopharma in the future or what it would have been had Theravance Biopharma been an independent, publicly traded company during the periods presented.

Revenue

Revenue for the quarter ended December 31, 2014 totaled \$1.4 million, primarily resulting from the recognition of product sales for VIBATIV of \$1.3 million.

Cost of goods sold for the quarter ended December 31, 2014 totaled \$3.2 million, which includes a charge of \$2.9 million for write down of inventory due to dating of the product. We continue to hold this inventory for sale as of December 31, 2014.

Research and Development (R&D)

R&D expenses for the quarter ended December 31, 2014 were \$42.2 million compared with \$32.5 million for the same period in 2013. The increase was primarily due to progression of our key programs, and long-term retention and incentive awards granted in 2011. Program expenses included start-up costs associated with our telavancin Phase 3 registrational study in Staph aureus bacteremia and our TOUR study with VIBATIV, as well as progression of our early-stage programs towards the clinic.

Selling, General and Administrative (SG&A)

SG&A expenses for the quarter ended December 31, 2014 were \$21.8 million compared with \$11.8 million for the same period in 2013. The increase was primarily due to costs associated with VIBATIV commercialization and share-based compensation expense associated with long-term retention and incentive awards granted in 2011.

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities, excluding restricted cash, totaled \$306.0 million as of December 31, 2014.

Conference Call Today at 5:00 pm ET

Theravance Biopharma will hold a conference call today at 5:00 pm ET to discuss 2014 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 April 10, 2015. An audio replay will also be available through 11:59 pm ET on March 17, 2015 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and entering confirmation code 95998632.

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 umeclidinium, vilanterol and fluticasone furoate (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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 12, 2014. 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.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
	<i>(Unaudited)</i>		<i>(Unaudited)</i>	
				<i>(1)</i>
Revenue:				
Product sales	\$ 1,309	\$ -	\$ 4,418	\$ -
Revenue from collaborative arrangements (2)	124	175	7,270	226
Total revenue	<u>1,433</u>	<u>175</u>	<u>11,688</u>	<u>226</u>
Costs and expenses:				
Cost of goods sold	3,222	-	4,058	-
Research and development (3)	42,192	32,470	168,522	120,579
Selling, general and administrative (3)	21,772	11,785	71,647	35,931
Total costs and expenses	<u>67,186</u>	<u>44,255</u>	<u>244,227</u>	<u>156,510</u>
Loss from operations	(65,753)	(44,080)	(232,539)	(156,284)
Interest and other income	983	-	1,865	-
Loss before income taxes	(64,770)	(44,080)	(230,674)	(156,284)
Provision (benefit) for income taxes	(460)	-	6,364	-
Net loss	<u>\$ (64,310)</u>	<u>\$ (44,080)</u>	<u>\$ (237,038)</u>	<u>\$ (156,284)</u>
Net loss per share:				
Basic and diluted net loss per share	<u>\$ (2.02)</u>	<u>\$ (1.39)</u>	<u>\$ (7.46)</u>	<u>\$ (4.92)</u>
Shares used to compute basic and diluted net loss per share	<u>31,782</u>	<u>31,741</u>	<u>31,755</u>	<u>31,741</u>

(1) The condensed consolidated statement of operations amounts for the year ended December 31, 2013 are derived from the audited combined December 31, 2013 financial statements and notes thereto included in the information statement filed as an exhibit to our Registration Statement on Form 10 filed with the Securities and Exchange Commission on May 7, 2014.

(2) Revenue recognized from collaborative arrangements is as follows:

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
	<i>(Unaudited)</i>		<i>(Unaudited)</i>	
				<i>(1)</i>
Clinigen Group plc	\$ -	\$ -	\$ 5,011	\$ -
R-Pharm CJSC	124	-	2,259	-
Other	-	175	-	226
Total revenue from collaborative arrangements	<u>\$ 124</u>	<u>\$ 175</u>	<u>\$ 7,270</u>	<u>\$ 226</u>

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

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
	<i>(Unaudited)</i>		<i>(Unaudited)</i>	
				<i>(1)</i>
Research and development	\$ 7,145	\$ 3,373	\$ 21,191	\$ 15,444
Selling, general and administrative	7,275	1,786	22,043	7,032
Total share-based compensation expense	<u>\$ 14,420</u>	<u>\$ 5,159</u>	<u>\$ 43,234</u>	<u>\$ 22,476</u>

Theravance Biopharma, Inc.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except per share data)

December 31,

	<u>2014</u>	<u>2013</u>
	<i>(Unaudited)</i>	<i>(1)</i>
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 306,010	\$ -
Prepaid and other current assets	8,213	3,700
Inventories	12,546	10,406
Restricted cash	833	833
Property and equipment, net	9,663	10,238
Other assets	506	-
Total assets	<u>\$ 337,771</u>	<u>\$ 25,177</u>
Liabilities, shareholders' equity and parent company deficit		
Current liabilities (2)	41,256	36,853
Long-term liabilities	6,728	5,359
Shareholders' equity and parent company deficit	289,787	(17,035)
Total liabilities, shareholders' equity and parent company deficit	<u>\$ 337,771</u>	<u>\$ 25,177</u>

- (1) The condensed consolidated balance sheet amounts at December 31, 2013 are derived from the audited combined December 31, 2013 financial statements and notes thereto included in the information statement filed as an exhibit to our Registration Statement on Form 10 filed with the Securities and Exchange Commission on May 7, 2014.
- (2) Amounts include the current portion of deferred revenue of \$0.1 million and \$8.2 million as of December 31, 2014 and 2013.

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Source: Theravance Biopharma

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