

Theravance Biopharma, Inc. Reports First Quarter 2016 Financial Results and Provides Business Update

DUBLIN, IRELAND -- (Marketwired) -- 05/09/16 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today reported financial results for the first quarter ended March 31, 2016. Revenue for the first quarter 2016 was \$18.4 million. The first quarter operating loss excluding share-based compensation was \$30.3 million, or \$41.6 million including share-based compensation of \$11.3 million. Cash, cash equivalents, and marketable securities totaled \$214.5 million as of March 31, 2016. The quarter-end cash balance excludes \$37.5 million in receivables from collaborative arrangements and approximately \$107.7 million in net proceeds from the Company's recent public offering of its ordinary shares.

Rick E Winningham, Chairman and Chief Executive Officer, commented: "We continue to make significant progress in advancing our priority programs to key milestones. The Phase 1 clinical study of our NEP inhibitor is progressing well. We reported encouraging safety, PK and biomarker data from the Phase 1 single ascending dose study and expect the Phase 1 multiple ascending dose study to read out in the second half of this year. The Phase 1 study of our GI-targeted pan-JAK inhibitor should yield data in the second quarter, which could pave the way to a Phase 1b study in patients with ulcerative colitis later this year. The Phase 3 program for revefenacin in COPD is approaching full enrollment. We expect the two efficacy studies to read out late-third quarter or early-fourth quarter of 2016, and the twelve-month safety study to read out in 2017, leading to a potential NDA filing in late 2017.

"On the commercial front, we have made progress implementing our commercial and label expansion strategies for VIBATIV[®]. Today we announced that the FDA approved our sNDA to expand the product's label to include data describing the treatment of patients with concurrent bacteremia in cases of cSSSI and HAP/VABP. In addition, our ongoing Phase 3 registrational study in primary bacteremia continues to enroll and we expect the study to complete in 2017 or 2018.

"Looking ahead, we remain focused on achieving our key clinical and regulatory milestones in 2016. We have a durable and robust business model, a strong balance sheet, which includes proceeds from our recent public offering and significant funding from partners, a rich portfolio of assets at various stages of development and a proven track record of success which we intend to build upon this year and in years to come."

Recent Highlights

- | Completed Public Offering: The Company issued 5,479,750 of its ordinary shares, including 714,750 shares pursuant to the underwriters' option to purchase additional shares, at a public offering price of \$21.00 per share, resulting in net proceeds from the offering of approximately \$107.7 million (after deducting the underwriting discount and estimated offering expenses).
- | Neprilysin (NEP) Inhibitor Program (TD-0714): Ongoing Phase 1 multiple ascending dose study expected to read out in the second half of 2016. Phase 1 single ascending dose study met key objectives: positive biomarker data, favorable tolerability, maximal and sustained target engagement, potential for once-daily dosing, and very low renal elimination.
- | GI-Targeted Pan-Janus Kinase (JAK) Inhibitor Program (TD-1473): Ongoing Phase 1 single ascending and multiple ascending dose studies expected to read out in the second quarter of 2016. Phase 1b study in patients could follow later this year.
- | Revefenacin (TD-4208): Phase 3 program in COPD progressing well. Data from the two replicate three-month efficacy studies is expected late-third quarter or early-fourth quarter 2016. Data from the twelve-month safety study is expected in 2017, followed by a potential NDA filing in late 2017.
- | VIBATIV (telavancin):
 - | U.S. net product sales of VIBATIV for the first quarter of 2016 were \$3.3 million, representing an increase of approximately 9% over the prior quarter.
 - | FDA approved expanded label for VIBATIV. Updated label includes data describing VIBATIV use in concurrent

bacteremia in both complicated skin and skin structure infections (cSSSI) and hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP).

- Phase 3 registrational study in primary bacteremia continues to enroll patients. Data expected in 2017 or 2018.

Expected 2016 Key Clinical and Regulatory Milestones

- TD-0714 (NEP inhibitor): Phase 1 study completion
- TD-1473 (JAK inhibitor): Phase 1 study completion
- Revefenacin (TD-4208): Complete two Phase 3 efficacy studies in COPD
- Closed Triple¹: Complete Phase 3 FULFIL study in COPD²
- Closed Triple¹: EU regulatory filing²

Notes:

¹Combination of fluticasone furoate, umeclidinium, and vilanterol

²Regulatory and clinical milestones as reported by Glaxo Group Limited or one of its affiliates (GSK)

First Quarter 2016 Financial Results

Revenue

Revenue for the first quarter of 2016 was \$18.4 million, including revenue from collaborative arrangements and net product sales of VIBATIV. Revenue from collaborative arrangements for the first quarter of 2016 was \$15.1 million, primarily driven by a \$15.0 million milestone received from Mylan related to the Company's collaboration for revefenacin. Net product sales of VIBATIV for the first quarter of 2016 were \$3.3 million, all from sales in the U.S.

Research and Development (R&D) Expenses

R&D expenses for the first quarter of 2016 were \$35.7 million representing a decrease of \$0.3 million compared to the same period in 2015. Total R&D share-based compensation expense for the first quarter of 2016 was \$5.2 million.

Selling, General and Administrative (SG&A) Expenses

SG&A expenses for the first quarter of 2016 were \$23.6 million, representing an increase of \$1.8 million compared to the same period in 2015. The increase was primarily due to costs associated with VIBATIV commercialization. Total share-based compensation expense in SG&A for the first quarter of 2016 was \$6.2 million.

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities, excluding restricted cash, totaled \$214.5 million as of March 31, 2016. The quarter-end cash balance excludes receivables from collaborative arrangements noted below and approximately \$107.7 million in net proceeds (after deducting the underwriting discount and estimated offering expenses) from the Company's recent public offering of its ordinary shares.

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 \$37.5 million as of March 31, 2016, and include \$35.2 million in receivables associated with the Mylan collaboration.

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 3895267. 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 June 9, 2016. An

audio replay will also be available through 11:59 pm ET on May 16, 2016 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 3895267.

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. Revedfenacin (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 (GSK) 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), currently in development for the treatment of COPD and asthma.

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 Form 10-K filed with the Securities and Exchange Commission (SEC) on March 11, 2016, in Theravance Biopharma's prospectus supplement filed with the SEC on April 29, 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.

TERAVANCE BIOPHARMA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except per share data)

	Three Months Ended March 31,	
	2016	2015
Revenue:		
Product sales	\$ 3,311	\$ 1,280
Revenue from collaborative arrangements	15,099	19,121
Total revenue	18,410	20,401
Costs and expenses:		
Cost of goods sold	778	371
Research and development ⁽¹⁾	35,678	36,019
Selling, general and administrative ⁽¹⁾	23,596	21,748
Total costs and expenses	60,052	58,138
Loss from operations	(41,642)	(37,737)
Interest and other income	186	211
Loss before income taxes	(41,456)	(37,526)
Provision for income taxes	694	4,948
Net loss	\$ (42,150)	\$ (42,474)
Net loss per share:		
Basic and diluted net loss per share	\$ (1.10)	\$ (1.29)
Shares used to compute basic and diluted net loss per share	38,326	32,830

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

(In thousands)	Three Months Ended March 31,	
	2016	2015
Research and development	\$ 5,160	\$ 7,482
Selling, general and administrative	6,170	8,144
Total share-based compensation expense	\$ 11,330	\$ 15,626

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

	March 31,	December 31,
	2016	2015
Assets		
Current assets:		
Cash and cash equivalents and short-term marketable securities	\$ 179,876	\$ 172,434
Receivables from collaborative arrangements ⁽¹⁾	37,536	35,232
Prepaid taxes	242	12,764
Inventories	9,406	10,005
Other prepaid and current assets	11,692	7,037
Property and equipment, net	10,119	9,873
Long-term marketable securities	34,598	42,860

Restricted cash	833	833
Other assets	8,823	9,078
Total assets	<u>\$ 293,125</u>	<u>\$ 300,116</u>
Liabilities and Shareholders' Equity		
Current liabilities ⁽²⁾	\$ 46,401	\$ 49,470
Long-term liabilities	8,187	7,581
Shareholders' equity	238,537	243,065
Total liabilities and shareholders' equity	<u>\$ 293,125</u>	<u>\$ 300,116</u>

(1) Receivables from collaborative arrangements includes \$35.2 million and \$33.2 million in receivables associated with the Mylan collaboration at March 31, 2016 and December 31, 2015, respectively.

(2) Current liabilities include the current portion of deferred revenue of \$1.1 million and \$0.1 million at March 31, 2016 and December 31, 2015, respectively.

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