

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

DUBLIN, IRELAND -- (Marketwired) -- 08/08/16 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today reported financial results for the second quarter ended June 30, 2016. Revenue for the second quarter 2016 was \$5.5 million. The second quarter operating loss excluding share-based compensation was \$37.6 million, or \$47.5 million including share-based compensation of \$9.9 million. Cash, cash equivalents, and marketable securities totaled \$302.0 million as of June 30, 2016. The quarter-end cash balance excludes \$35.1 million in receivables from collaborative arrangements. Also excluded from quarter-end cash is a \$15.0 million upfront payment expected in the third quarter from Takeda Pharmaceuticals associated with the TD-8954 license agreement, which received Hart-Scott Rodino clearance in the third quarter.

Rick E Winningham, Chairman and Chief Executive Officer, commented: "2016 is unfolding as a pivotal year in Theravance Biopharma's growth and development. We are delivering on our goals and milestones, our priority programs are advancing as planned, and our performance is on track for the year.

"We reported positive Phase 1 results for TD-1473, our oral GI-targeted pan-JAK inhibitor, and look forward to the important milestone of initiating a Phase 1b study in patients with ulcerative colitis later this year. We reported positive biomarker data from our single-ascending dose study of our lead next-generation NEP inhibitor TD-0714 to treat cardiovascular and renal diseases, and expect to complete the multiple-ascending dose study later this year. We anticipate the revefenacin Phase 3 program in COPD will read out data from the replicate three-month efficacy studies early in the fourth quarter of this year, followed by the twelve-month safety study read-out and planned NDA filing in 2017. We continue to make good progress implementing our commercial and label expansion strategies for VIBATIV®.

"Our growing pipeline of partnered assets and our economic interest in certain respiratory programs being developed by GSK and Innoviva, in which we are eligible to receive royalties on worldwide net sales, represent valuable near- and mid-term opportunities. Last month, GSK and Innoviva announced positive top-line results from the pivotal Phase 3 FULFIL study of the Closed Triple in COPD patients, in addition to the acceleration of the U.S. regulatory filing from 2018 to 2016. With our strong cash position, maturing product portfolio and full slate of upcoming milestones, we are building a strong foundation to develop differentiated therapies for patients with serious illness and create meaningful value for shareholders."

Recent Highlights

- | GI-Targeted Pan-Janus Kinase (JAK) Inhibitor Program (TD-1473): Reported positive Phase 1 results showing favorable safety and tolerability of single-ascending and multiple-ascending oral doses and achieving target pharmacokinetic profile. Phase 1b study in patients with ulcerative colitis anticipated to begin later this year, with data expected in 2017.
- | Nephilysin (NEP) Inhibitor Program (TD-0714): Reported favorable safety, pharmacokinetic and biomarker data from single-ascending dose study, and expect to complete multiple-ascending dose study later this year. Goal is to develop a potential best-in-class therapeutic, with the differentiating feature of non-renal clearance, for cardiovascular and renal diseases.
- | Revefenacin (TD-4208): Phase 3 efficacy data expected early-fourth quarter 2016. Data from the twelve-month safety study expected in 2017, followed by a planned NDA filing in late 2017.
- | VIBATIV® (telavancin):
 - | U.S. net product sales of VIBATIV for the second quarter of 2016 were \$5.4 million, representing a 152% increase over the same period in 2015.
 - | Mutual decision reached with Clinigen Group to return commercial rights to market and distribute VIBATIV in the EU to Theravance Biopharma. Companies collaborating to transition EU-focused commercial rights and activities for VIBATIV to ensure product remains accessible to physicians and patients. Theravance Biopharma in discussion with potential collaborators with the goal of establishing a new strategic commercial partnership in

the EU.

- | Closed Triple (the combination of fluticasone furoate, umeclidinium, and vilanterol) GlaxoSmithKline (GSK) and Innoviva, Inc. last month disclosed:
 - | Positive top-line results from the pivotal Phase 3 FULFIL study of the Closed Triple in COPD. Data demonstrated superiority for the Closed Triple as compared to Symbicort® Turbohaler® in improving lung function and health-related quality of life in COPD patients.
 - | U.S. regulatory filing of Closed Triple accelerated from early 2018 to late 2016.
 - | EU regulatory filing also expected in 2016.
- | TD-8954: Global license agreement established with Takeda Pharmaceuticals for development and commercialization of TD-8954, selective 5-HT4 receptor agonist being investigated for potential use in the treatment of gastrointestinal motility disorders, including enteral feeding intolerance.

Expected 2016-2018 Key Milestones

- | TD-0714 (NEP inhibitor): Complete Phase 1 multiple-ascending dose study (2016)
- | Revefenacin (TD-4208): Complete two Phase 3 efficacy studies in COPD (2016)
- | Closed Triple: EU and U.S. regulatory filings by GSK (2016)¹
- | TD-1473 (JAK inhibitor): Complete Phase 1b study in ulcerative colitis patients (2017)
- | Revefenacin (TD-4208): Complete twelve-month safety study in COPD and file NDA (2017)
- | Velusetrag (TD-5108): Complete Phase 2b study in gastroparesis (2017)
- | VIBATIV®: Complete Phase 3 bacteremia study (2018)

Notes:

¹As reported by Glaxo Group Limited or one of its affiliates (GSK)

Second Quarter 2016 Financial Results

Revenue

Revenue for the second quarter of 2016 was \$5.5 million due primarily to U.S. net product sales of VIBATIV® of \$5.4 million, representing a \$3.3 million increase in U.S. net product sales compared to the same period in 2015. The increase in net product sales is principally due to the expansion of our VIBATIV sales infrastructure.

Research and Development (R&D) Expenses

R&D expenses for the second quarter of 2016 were \$32.1 million representing an increase of \$1.7 million compared to the same period in 2015. The increase is primarily attributed to costs associated with the progression of our priority programs. Total R&D share-based compensation expense for the second quarter of 2016 was \$5.0 million.

Selling, General and Administrative (SG&A) Expenses

SG&A expenses for the second quarter of 2016 were \$20.3 million, representing a decrease of \$1.3 million compared to the same period in 2015. The decrease is largely driven by lower costs associated with share-based compensation expense. Total share-based compensation expense in SG&A for the second quarter of 2016 was \$4.9 million.

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities, excluding restricted cash, totaled \$302.0 million as of June 30, 2016. The quarter-end cash balance excludes a \$15.0 million upfront payment expected in the third quarter from Takeda Pharmaceuticals for the license of TD-8954, in addition to receivables from collaborative arrangements noted below.

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 \$35.1 million as of June 30, 2016, and include

\$31.2 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 56353221. 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 September 8, 2016. An audio replay will also be available through 8:00 pm ET on August 15, 2016 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 56353221.

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 or relying on 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-Q filed with the Securities and Exchange Commission (SEC) on May 10, 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.

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Revenue:				
Product sales	\$ 5,359	\$ 2,124	\$ 8,670	\$ 3,404
Revenue from collaborative arrangements	112	5,010	15,211	24,131
Total revenue	<u>5,471</u>	<u>7,134</u>	<u>23,881</u>	<u>27,535</u>
Costs and expenses:				
Cost of goods sold	638	505	1,416	875
Research and development ⁽¹⁾	32,069	30,377	67,748	66,396
Selling, general and administrative ⁽¹⁾	20,261	21,545	43,857	43,293
Total costs and expenses	<u>52,968</u>	<u>52,427</u>	<u>113,021</u>	<u>110,564</u>
Loss from operations	(47,497)	(45,293)	(89,140)	(83,029)
Interest and other income	308	204	495	414
Loss before income taxes	(47,189)	(45,089)	(88,645)	(82,615)
Provision for income taxes	36	2,514	730	7,463
Net loss	<u>\$ (47,225)</u>	<u>\$ (47,603)</u>	<u>\$ (89,375)</u>	<u>\$ (90,078)</u>
Net loss per share:				
Basic and diluted net loss per share	<u>\$ (1.06)</u>	<u>\$ (1.42)</u>	<u>\$ (2.16)</u>	<u>\$ (2.71)</u>
Shares used to compute basic and diluted net loss per share	<u>44,407</u>	<u>33,532</u>	<u>41,366</u>	<u>33,183</u>

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

<i>(In thousands)</i>	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Research and development	\$ 4,959	\$ 6,817	\$ 10,119	\$ 14,299
Selling, general and administrative	4,945	7,845	11,115	15,989
Total share-based compensation expense	<u>\$ 9,904</u>	<u>\$ 14,662</u>	<u>\$ 21,234</u>	<u>\$ 30,288</u>

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

	<u>June 30,</u>	<u>December 31,</u>
	<u>2016</u>	<u>2015</u>
Assets		
Current assets:		

Cash and cash equivalents and short-term marketable securities	\$ 249,679	\$ 172,434
Receivables from collaborative arrangements ⁽¹⁾	35,080	35,232
Prepaid taxes	3,150	12,764
Inventories	9,810	10,005
Other prepaid and current assets	5,406	7,037
Property and equipment, net	8,811	9,873
Long-term marketable securities	52,316	42,860
Restricted cash	833	833
Other assets	9,403	9,078
Total assets	<u>\$ 374,488</u>	<u>\$ 300,116</u>
<i>Liabilities and Shareholders' Equity</i>		
Current liabilities	44,657	49,470
Long-term liabilities	8,247	7,581
Shareholders' equity	321,584	243,065
Total liabilities and shareholders' equity	<u>\$ 374,488</u>	<u>\$ 300,116</u>

⁽¹⁾ Receivables from collaborative arrangements includes \$31.2 million and \$33.2 million in receivables associated with the Mylan collaboration at June 30, 2016 and December 31, 2015, respectively.

Contact Information:

Renee Gala
Chief Financial Officer
650-808-4045
investor.relations@theravance.com

Source: Theravance Biopharma

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