

Theravance Biopharma, Inc. Reports Second Quarter 2015 Financial Results and Provides Business Update

DUBLIN, IRELAND -- (Marketwired) -- 08/10/15 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today reported financial results for the second quarter ending June 30, 2015. Revenue for the second quarter of 2015 was \$7.1 million. Net loss for the second quarter of 2015 was \$47.6 million, or \$1.42 per share. Cash, cash equivalents, and marketable securities, excluding restricted cash, totaled \$228.8 million as of June 30, 2015.

Rick E Winningham, Chairman and Chief Executive Officer, commented: "In the first half of 2015, we have focused on executing our strategies to advance TD-4208 to a registrational Phase 3 program, creating an acute care commercial organization in the U.S., while positioning VIBATIV[®] (telavancin) as an important treatment for patients with life-threatening infections, and advancing our two high-value research programs towards the clinic. We are pleased with the progress achieved with our programs to date, and believe we have multiple opportunities to generate value across our entire portfolio."

Continued Mr. Winningham: "Building VIBATIV into a global brand is a key component of our Company's strategy to create a portfolio of high-value, innovative medicines that create value for both patients and shareholders. We are pleased by our achievements in establishing revenue-generating partnerships for VIBATIV outside the U.S. and the 66% quarter-over-quarter gain in VIBATIV U.S. net sales from the first quarter to the second quarter. We are also pleased with the underlying fundamentals we saw in the second quarter, including formulary wins, sales in new accounts and increased volume overall. In a relatively short period, we have created a national acute care focused organization staffed with excellent sales and medical professionals, and we remain on track to complete the sales force expansion to 50 representatives late in the third quarter. However, some recent issues have caused us to reduce our projected U.S. sales ramp for VIBATIV in the second half of 2015. We are working aggressively to address these issues, which include a greater percentage of our sales being made to Public Health Service institutions at a much lower price point, as mandated by the federal government, and the integration of new representatives into our sales force. While we believe it is prudent to reduce our full-year U.S. net sales guidance for VIBATIV, our outlook on the product's commercial potential remains quite positive. We remain committed to the ongoing clinical and commercial development of VIBATIV to serve physicians who treat life-threatening infections. Going forward, we intend to report on all VIBATIV-related revenues, including U.S. net sales, revenue from ex-U.S. sales, and sales and milestones generated from our ex-U.S. partnerships, which we believe more accurately reflect the overall value VIBATIV contributes to our Company."

Second-Quarter Summary and Business Update

- VIBATIV[®] (telavancin)
 - Total VIBATIV revenues of \$7.1 million, consisting of revenue from collaborative arrangements of \$5.0 million and net product sales of \$2.1 million. Net product sales increased 66% over the prior quarter.
 - Partnership agreement established with SciClone Pharmaceuticals for development and commercialization of VIBATIV in China.
 - Marketing approvals for VIBATIV achieved in Russia and Canada.
 - Sales force expansion to 50 representatives on track for completion in the third quarter 2015.
- TD-4208 Phase 3 registrational program in COPD to initiate in the second half of 2015.
- Multiple novel neprilysin inhibitor development candidates for heart failure and chronic kidney disease advancing towards Phase 1 in late 2015/early 2016.
- Colon restricted ulcerative colitis development candidate advancing towards Phase 1 in late 2015/early 2016.
- FDA Fast Track designation received for TD-8954, an investigational highly selective 5HT₄ receptor agonist for potential treatment of enteral feeding intolerance (EFI) in critically ill patients.
- Multiple mid-to late-stage clinical studies underway with target read-outs in 2016 and 2017, including the velusetrag Phase 2b study in gastroparesis, the telavancin Phase 3 registrational study in bacteremia, and the two Phase 3 studies of the Closed Triple combination for COPD being conducted by GlaxoSmithKline plc.

Financial Results

Revenue

Total revenue for the second quarter of 2015 totaled \$7.1 million. Total revenue consisted of net product sales of VIBATIV[®] (telavancin) of \$2.1 million, an increase of \$0.8 million or 66% over the prior quarter, and revenue from VIBATIV-related collaborative arrangements of \$5.0 million. Revenue from collaborations included a \$3.0 million upfront payment from SciClone Pharmaceuticals for execution of a development and commercialization agreement for VIBATIV in China and a \$2.0 million regulatory milestone payment from R-Pharm for marketing approval of VIBATIV in Russia.

Cost of Goods Sold

Cost of goods sold for the second quarter of 2015 totaled \$0.5 million.

Research and Development (R&D) Expenses

R&D expenses for the second quarter of 2015 decreased to \$30.4 million compared to \$46.3 million for the same period in 2014. The decrease was primarily due to lower costs associated with non-recurring long-term retention and incentive awards that were granted in 2011 and a decrease in program-related net expense due to the reimbursement of expenses associated with the Mylan TD-4208 collaboration. Total R&D share-based compensation expense was \$6.8 million in the second quarter of 2015.

Selling, General and Administrative (SG&A) Expenses

SG&A expenses for the second quarter of 2015 were \$21.5 million compared with \$13.1 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 \$7.8 million in the second quarter of 2015.

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities, excluding restricted cash, totaled \$228.8 million as of June 30, 2015.

Receivables from Collaborative Arrangements

Receivables from collaborative arrangements totaled \$25.5 million as of June 30, 2015, and includes \$23.0 million in receivables associated with Mylan collaboration.

2015 Financial Guidance

The Company is revising 2015 U.S. net sales guidance for VIBATIV and establishing updated guidance that will include the impact of VIBATIV-related revenues worldwide. 2015 total revenue related to VIBATIV is expected to be in the range of \$15 million to \$18 million, with the majority of the revenue coming from net product sales in the U.S., which are now expected to be in range of \$9 million to \$12 million. The Company's non-GAAP operating loss guidance for the full-year of 2015 has remained unchanged at \$120 million to \$130 million. Non-GAAP operating loss guidance includes all revenues and costs and expenses from operations, excluding share-based compensation expense.

Basis of Presentation

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.

Conference Call Today at 5:00 pm ET

Theravance Biopharma will hold a conference call today at 5:00 pm EDT to discuss its second 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 September 10, 2015. An audio replay will also be available through 11:59 pm EDT on August 17, 2015 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and entering confirmation code 94608507.

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., Europe and certain other countries 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 GlaxoSmithKline plc pursuant to its agreements with Theravance, Inc. relating to certain drug development programs, including the combination of fluticasone furoate, umeclidinium, and vilanterol (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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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 guidance regarding revenue and U.S. net sales related to VIBATIV and non-GAAP operating losses, 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, 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 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 May 13, 2015, under the heading "Risk

Factors" contained in the Form S-3 Registration Statement filed by Theravance Biopharma with the SEC on July 9, 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.

THEHAVANCE BIOPHARMA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Revenue:				
Product sales	\$ 2,124	\$ 861	\$ 3,404	\$ 1,806
Revenue from collaborative arrangements	5,010	2,113	24,131	2,113
Total revenue	7,134	2,974	27,535	3,919
Costs and expenses:				
Cost of goods sold	505	279	875	467
Research and development (1)	30,377	46,283	66,396	88,006
Selling, general and administrative (1)	21,545	13,118	43,293	32,170
Total costs and expenses	52,427	59,680	110,564	120,643
Loss from operations	(45,293)	(56,706)	(83,029)	(116,724)
Interest and other income	204	214	414	214
Loss before income taxes	(45,089)	(56,492)	(82,615)	(116,510)
Provision for income taxes	2,514	1,723	7,463	1,723
Net loss	<u>\$ (47,603)</u>	<u>\$ (58,215)</u>	<u>\$ (90,078)</u>	<u>\$ (118,233)</u>
Net loss per share:				
Basic and diluted net loss per share	<u>\$ (1.42)</u>	<u>\$ (1.83)</u>	<u>\$ (2.71)</u>	<u>\$ (3.72)</u>
Shares used to compute basic and diluted net loss per share	33,532	31,768	33,183	31,768

1. Amounts include share-based compensation expense as follows :

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Research and development	\$ 6,817	\$ 4,194	\$ 14,299	\$ 8,914
Selling, general and administrative	7,845	2,570	15,989	10,550
Total share-based compensation expense	<u>\$ 14,662</u>	<u>\$ 6,764</u>	<u>\$ 30,288</u>	<u>\$ 19,464</u>

THEHAVANCE BIOPHARMA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

	June 30, 2015	December 31, 2014
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents and marketable securities	\$ 228,780	\$ 306,010
Receivables from collaborative arrangements (2)	25,488	1,840
Prepaid and other current assets	11,199	6,373

Inventories	12,553	12,546
Restricted cash	833	833
Property and equipment, net	9,609	9,663
Other assets	1,017	506
Total assets	<u>\$ 289,479</u>	<u>\$ 337,771</u>
Liabilities and Shareholders' Equity:		
Current liabilities (3)	\$ 24,477	\$ 41,256
Long-term Liabilities	7,328	6,728
Shareholders' equity	<u>257,674</u>	<u>289,787</u>
Total liabilities and shareholders' equity	<u>\$ 289,479</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 June 30, 2015 includes \$23.0 million 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 June 30, 2015 and December 31, 2014.

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