

Theravance Biopharma, Inc. Reports First Quarter 2018 Financial Results and Provides Business Update

May 8, 2018

Focusing on Advancement of Highest Priority Programs

DUBLIN, May 8, 2018 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today reported financial results for the first quarter ended March 31, 2018. Revenue for the first quarter of 2018 was \$8.3 million. The Company's first quarter operating loss was \$65.0 million or \$51.0 million excluding share-based compensation expense. Cash, cash equivalents, and marketable securities totaled \$435.5 million as of March 31, 2018 and includes the \$100 million upfront payment associated with the global development and commercialization agreement with Janssen Biotech, Inc. (Janssen) for TD-1473.



Rick E Winningham, Chairman and Chief Executive Officer, commented: "We are very pleased with our achievements in the first quarter of 2018, led by our global collaboration with Janssen for the development and commercialization of TD-1473 in inflammatory intestinal diseases. As we look to the remainder of 2018, we are enhancing our focus on the most important strategic priorities for the Company, which are those programs where we think there is the greatest opportunity to create transformational medicines. For revefenacin, our commercial readiness activities are underway in anticipation of approval in the US for COPD later this year. With TD-1473 for ulcerative colitis and Crohn's disease and TD-9855 for neurogenic orthostatic hypotension, we are advancing two highly differentiated assets through mid-stage development. In research, we are preparing to progress a novel inhaled JAK inhibitor for serious respiratory diseases into the clinic. These assets, combined with our strong balance sheet and emerging cash flows from our economic interest in Trelegy Ellipta, position us to advance all segments of our business – from research to commercial – with the goal of creating transformational medicines."

Program Updates

- Trelegy Ellipta (first once-daily single inhaler triple therapy for chronic obstructive pulmonary disease (COPD))¹: GSK reported first quarter 2018 net sales of \$14.6 million; Theravance Biopharma entitled to approximately 5.5% to 8.5% of worldwide net sales of the product
 - U.S. Food and Drug Administration (FDA) approved an expanded indication of Trelegy Ellipta for treatment of a broader population of COPD patients with airflow limitation or who have experienced an acute worsening of respiratory symptoms
 - Expanded indication based on the positive results of the landmark 10,355 patient IMPACT study, which was recently published in the *New England Journal of Medicine*
 - Boxed warning removed from Trelegy Ellipta prescribing information
- Velusetrag (TD-5108; 5-HT₄ agonist): Collaboration partner Alfasigma S.p.A. (Alfasigma), which funded majority of Phase 2 gastroparesis program costs, has exercised its option to develop and commercialize velusetrag
 - Alfasigma opt-in decision results in \$10 million payment to Company and right to receive future potential development, regulatory and sales milestone payments and royalties
 - Theravance Biopharma has elected not to pursue further development of velusetrag, based on the Company's planned pipeline investments and in light of the current FDA requirement that a chronically administered gastroparesis product in this class complete a large Phase 3 safety study
 - Global rights to develop, manufacture and commercialize velusetrag will transfer to Alfasigma, under the terms of the existing collaboration agreement
- Revefenacin (TD-4208, nebulized long-acting muscarinic antagonist (LAMA)): Mid-cycle review meeting with FDA is complete
 - FDA reiterated no Advisory Committee meeting planned for revefenacin
 - Prescription Drug User Fee Act (PDUFA) date remains on track as November 13, 2018

Anticipated Near-Term Milestones and Events

- TD-1473 (intestinally restricted pan-Janus kinase (JAK) inhibitor): Initiations of Phase 2 induction study in Crohn's disease and Phase 2b/3 induction and maintenance study in ulcerative colitis planned in the second half of 2018
- TD-9855 (norepinephrine serotonin reuptake inhibitor (NSRI)): Data from exploratory Phase 2a study in patients with

symptomatic neurogenic orthostatic hypotension (nOH) by end of July 2018

- Revefenacin (TD-4208, nebulized long-acting muscarinic antagonist (LAMA)): Potential regulatory approval in the US for COPD, with assigned PDUFA date of November 13, 2018
- Novel inhaled JAK inhibitor: Progression into first-in-human studies in late 2018 or early 2019
- Trelegy Ellipta¹: Potential label expansion in EU expected in 2018, supported by submission of IMPACT data to European Medicines Agency; completion of Phase 3 CAPTAIN study in asthma patients expected in early 2019

Notes:

¹ As reported by Glaxo Group Limited or one of its affiliates (GSK); reported sales converted to USD; economic interest related to Trelegy Ellipta (the combination of fluticasone furoate, umeclidinium, and vilanterol, (FF/UMEC/VI), jointly developed by GSK and Innoviva, Inc.) entitles Company to upward tiering payments equal to approximately 5.5% to 8.5% on worldwide net sales of the product

First Quarter Financial Results

Revenue

Revenue for the first quarter of 2018 was \$8.3 million, comprised of revenue from collaborative arrangements and US net product sales of VIBATIV[®]. This represents an increase of \$5.2 million over the same period in 2017. The increase is primarily related to revenue recognized from the non-refundable, upfront payment associated with the global development and commercialization agreement with Janssen for TD-1473, which will be recognized over the course of the TD-1473 Phase 2 program.

Research and Development (R&D) Expenses

R&D expenses for the first quarter of 2018 were \$47.8 million, compared to \$40.6 million in the same period in 2017. The increase is primarily due to an increase in employee-related costs, share-based compensation and allocated expenses. First quarter R&D expenses include non-cash share-based compensation of \$6.6 million.

Selling, General and Administrative (SG&A) Expenses

SG&A expenses for the first quarter of 2018 were \$24.7 million, compared to \$20.8 million in the same period in 2017. The increase is primarily due to higher expenses in G&A related to external-related expenses, employee-related costs, and share-based compensation. First quarter SG&A expenses include non-cash share-based compensation of \$7.4 million.

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities, excluding restricted cash, totaled \$435.5 million as of March 31, 2018. This amount includes the \$100 million upfront payment associated with the global development and commercialization agreement with Janssen and excludes \$10.0 million payment from Alfasigma associated with exercise of its option for velusetrag.

2018 Financial Guidance

The Company's guidance on operating loss excluding non-cash share-based compensation for the full year of 2018 remains unchanged at \$180.0 to \$200.0 million. The actual amount could be above or below this forecast as a result of a variety of factors impacting the business, including the amount of revenue recognized in 2018 related to the global collaboration agreement with Janssen (currently expected to be less than \$25 million), the timing and cost of clinical studies associated with Company's key programs, and net product sales of VIBATIV[®]. The Company's financial guidance for 2018 does not include income related to Trelegy Ellipta.

Conference Call and Live Webcast Today at 5:00 pm ET

Theravance Biopharma will hold a conference call and live webcast accompanied by slides today at 5:00 pm ET. To participate in the live call by telephone, please dial (855) 296-9648 from the US, or (920) 663-6266 for international callers, and use the confirmation code 5379419. 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 7, 2018. An audio replay will also be available through 8:00 pm ET on May 15, 2018 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 5379419.

About Theravance Biopharma

Theravance Biopharma, Inc. ("Theravance Biopharma") is a diversified biopharmaceutical company with the core purpose of creating medicines that help improve the lives of patients suffering from serious illness.

In our relentless pursuit of this objective, we strive to apply insight and innovation at each stage of our business, including research, development and commercialization, and utilize both internal capabilities and those of partners around the world. Our research efforts are focused in the areas of inflammation and immunology. Our research goal is to design localized medicines that target diseased tissues, without systemic exposure, in order to maximize patient benefit and minimize risk. These efforts leverage years of experience in developing localized medicines for the lungs to treat respiratory disease. The first potential medicine to emerge from our research focus on immunology and localized treatments is an oral, intestinally restricted pan-Janus kinase (JAK) inhibitor, currently in development to treat a range of inflammatory intestinal diseases. Our pipeline of internally discovered product candidates will continue to evolve with the goal of creating transformational medicines to address the significant needs of patients.

In addition, we have an economic interest in future payments that may be made by Glaxo Group or one of its affiliates (GSK) pursuant to its agreements with Innoviva, Inc. relating to certain programs, including Trelegy Ellipta.

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 (including the data therefrom), the potential characteristics, 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 their differentiation from other products or potential products), product sales and the Company's expectations for its 2018 operating loss, excluding share-based compensation. 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, enrolling 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), risks that product candidates do not obtain approval from regulatory authorities, the feasibility of undertaking future clinical trials for our product candidates based on policies and feedback from regulatory authorities, 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, manufacture 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 Form 10-K filed with the Securities and Exchange Commission (SEC) on February 28, 2018 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.

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

	Three Months Ended March 31,	
	2018	2017
	(Unaudited)	
Revenue:		
Product sales	\$ 3,679	\$ 3,050
Revenue from collaborative arrangements	4,640	37
Total revenue	<u>8,319</u>	<u>3,087</u>
Costs and expenses:		
Cost of goods sold	826	565
Research and development (1)	47,765	40,565
Selling, general and administrative (1)	24,704	20,786
Total costs and expenses	<u>73,295</u>	<u>61,916</u>
Loss from operations	(64,976)	(58,829)
Interest expense	(2,137)	(2,137)
Interest and other income	2,170	1,030
Loss before income taxes	(64,943)	(59,936)
Provision for income taxes	144	5,383
Net loss	<u>\$ (65,087)</u>	<u>\$ (65,319)</u>
Net loss per share:		
Basic and diluted net loss per share	<u>\$ (1.22)</u>	<u>\$ (1.27)</u>
Shares used to compute basic and diluted net loss per share	<u>53,256</u>	<u>51,617</u>

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

(In thousands)	Three Months Ended March 31,	
	2018	2017
Research and development	\$ 6,559	\$ 5,101
Selling, general and administrative	7,439	5,168
Total share-based compensation expense	<u>\$ 13,998</u>	<u>\$ 10,269</u>

THERAVANCE BIOPHARMA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	March 31, 2018	December 31, 2017
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents and short-term marketable securities	\$ 418,531	\$ 348,566
Receivables from collaborative arrangements	2,845	7,109
Prepaid taxes	926	291
Other prepaid and current assets	7,299	5,953
Inventories	17,217	16,830
Property and equipment, net	10,329	10,157
Long-term marketable securities	16,999	41,587
Tax receivable	3,324	8,191
Restricted cash	833	833
Other assets	1,805	1,883
Total assets	<u>\$ 480,108</u>	<u>\$ 441,400</u>
Liabilities and Shareholders' Equity		
Current liabilities	105,179	62,552
Long-term liabilities	311,522	263,670
Shareholders' equity	<u>63,407</u>	<u>115,178</u>
Total liabilities and shareholders' equity	<u>\$ 480,108</u>	<u>\$ 441,400</u>

(1) The condensed consolidated balance sheet at December 31, 2017 has been derived from the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

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