

## **Theravance Biopharma, Inc. Reports Third Quarter 2018 Financial Results and Provides Business Update**

November 6, 2018

### **PDUFA date for YUPELRI™ (revefenacin) inhalation solution on November 13**

### **TD-1473 and TD-9855 entering late-stage clinical development programs; TD-8236 advancing from research into clinic Company to host R&D Day on December 12 in New York City**

DUBLIN, Nov. 6, 2018 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today reported financial results for the third quarter ended September 30, 2018. Revenue for the third quarter of 2018 was \$12.8 million. The Company's third quarter operating loss was \$62.5 million or \$50.7 million excluding share-based compensation expense. Cash, cash equivalents, and marketable securities totaled \$320.6 million as of September 30, 2018.

Rick E Winningham, chairman and chief executive officer, commented: "The steps we have taken over the course of the year reflect a focus on our strategic priorities, placing us in an optimal position as we approach 2019. The decision to sell VIBATIV® to Cumberland Pharmaceuticals allows our commercial organization to concentrate exclusively on the potential launch of YUPELRI, which if approved will be the first once-daily nebulized LAMA for the treatment of COPD. We are eager to bring this potential medicine to patients and remain on track with an assigned PDUFA date of November 13. Meanwhile, the rapid uptake in scripts for GSK's Trelegy Ellipta in its first full year on the market remains extremely impressive. Our economic interest in the first and only once-daily single-inhaler triple therapy represents an important strategic asset to the Company. Earlier this year, we established proof of concept in patients with highly encouraging clinical results for TD-1473 in ulcerative colitis and TD-9855 in nOH, and we are driving both programs to begin late-stage studies in the near term. We also approach the first-in-human studies of TD-8236, our novel inhaled JAK inhibitor for serious respiratory diseases. Finally, we look forward to discussing the insight and innovation in our early-stage assets at our 2018 R&D Day next month."

#### **Program Updates and Upcoming Milestones**

YUPELRI™ (revefenacin, nebulized long-acting muscarinic antagonist (LAMA)):

- Prescription Drug User Fee Act (PDUFA) date on track as November 13, 2018. Final launch readiness activities with partner Mylan ongoing
- Phase 3 clinical program data in chronic obstructive pulmonary disease (COPD) shared in oral presentation at European Respiratory Society (ERS) Paris 2018 International Congress. Descriptive data showed reductions in the rates of COPD exacerbations in moderate to very severe COPD patients administered once-daily YUPELRI for up to 52 weeks as compared to placebo and tiotropium (Spiriva® HandiHaler®)

TD-1473 (gut-selective pan-Janus kinase (JAK) inhibitor):

- Results from the Phase 1b study of TD-1473 in patients with ulcerative colitis recently presented in an oral late-breaker session at United European Gastroenterology (UEG) Week 2018. Data demonstrated four weeks of TD-1473 treatment led to localized biologic activity and localized target engagement with minimal systemic exposure, and a favorable safety and tolerability profile
- Patient screening underway for Phase 2 induction study in Crohn's disease
- Site initiation underway for Phase 2b/3 induction and maintenance study in ulcerative colitis, with patient dosing expected to begin in late 2018 or early 2019

TD-9855 (norepinephrine serotonin reuptake inhibitor (NSRI)):

- Positive four-week data reported from the Phase 2 study in patients with neurogenic orthostatic hypotension (nOH) in August 2018. Majority of patients enrolled in single ascending dose portion demonstrated response to TD-9855; durable improvements in nOH symptom severity observed as measured by OHSA Question #1 (a measure of dizziness, light-headedness or the sensation of being about to black out)
- Initiation of the registrational Phase 3 program in symptomatic nOH underway, with patient dosing expected to begin in late 2018 or early 2019

TD-8236 (novel inhaled JAK inhibitor for serious respiratory diseases):

- Progression into first-in-human studies this year, leveraging expertise in respiratory diseases and JAK inhibition
  - Multiple JAK-dependent pathways clinically validated in asthma and COPD
  - Potentially broad activity with JAK inhibition across a range of respiratory indications and phenotypes

VIBATIV® (telavancin):

- Proprietary antibiotic VIBATIV® sold to Cumberland Pharmaceuticals, Inc.; transaction is expected to close in mid-November, pending satisfaction of customary closing conditions

Trelegy Ellipta (first once-daily single inhaler triple therapy for COPD)<sup>1</sup>:

- GSK reported third quarter 2018 net sales of \$56 million; Theravance Biopharma entitled to approximately 5.5% to 8.5% (tiered) of worldwide net sales of the product
- Trelegy Ellipta is currently available in 16 countries, with an additional nine expected over the course of 2019; more recent regulatory filings include Japan and China
- Potential label expansion in EU, as European Medicines Agency's Committee for Medicinal Products for Human Use recently issued a positive opinion supporting the use of Trelegy Ellipta in patients not adequately treated by a long-acting muscarinic receptor antagonist and long-acting  $\beta_2$ -agonist; also referenced the effect on exacerbations based on data from the IMPACT study
- Completion of Phase 3 CAPTAIN study in asthma patients anticipated in early 2019

2018 R&D Day:

- Company to host R&D Day on December 12, 2018, in New York City

Notes:

<sup>1</sup> 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 (net of TRC LLC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters)

### Third Quarter Financial Results

#### Revenue

Revenue for the third quarter of 2018 was \$12.8 million, comprised of revenue from collaborative arrangements of \$9.0 million and product sales of VIBATIV® of \$3.8 million. Revenue in the third quarter represents an increase of approximately \$8.6 million over the same period in 2017. The increase is primarily related to revenue recognized from the upfront payment associated with the global collaboration agreement with Janssen for TD-1473.

#### Research and Development (R&D) Expenses

R&D expenses for the third quarter of 2018 were \$52.7 million, compared to \$39.3 million in the same period in 2017. The increase is primarily due to higher external and employee-related expenses to support our key programs, and share-based compensation expense. Third quarter R&D expenses include non-cash share-based compensation of \$6.3 million.

#### Selling, General and Administrative (SG&A) Expenses

SG&A expenses for the third quarter of 2018 were \$21.9 million, compared to \$20.9 million in the same period in 2017. Third quarter SG&A expenses include non-cash share-based compensation of \$5.5 million.

#### Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities totaled \$320.6 million as of September 30, 2018.

#### 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. The Company's financial guidance for 2018 does not include income related to Trelegy Ellipta.

### Annual Meeting

The Company will hold its 2019 Annual General Meeting on April 30, 2019.

### 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 8172459. 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](http://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 December 6, 2018. An audio replay will also be available through 8:00 pm ET on November 13, 2018 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 8172459.

## 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, gut-selective 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](http://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 expected closing date for the sale of VIBATIV<sup>®</sup>, 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-Q filed with the Securities and Exchange Commission (SEC) on August 2, 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(Unaudited)		(Unaudited)	
Revenue:				
Product sales	\$ 3,849	\$ 4,140	\$ 12,889	\$ 10,664
Revenue from collaborative arrangements	8,989	135	31,744	207
Total revenue	12,838	4,275	44,633	10,871
Costs and expenses:				
Cost of goods sold	705	985	83	2,914
Research and development <sup>(1)</sup>	52,693	39,343	149,079	122,835
Selling, general and administrative <sup>(1)</sup>	21,890	20,944	71,601	66,069
Total costs and expenses	75,288	61,272	220,763	191,818

Loss from operations	(62,450)	(56,997)	(176,130)	(180,947)
Income from investment in TRC, LLC	3,119	-	5,754	-
Interest expense	(2,137)	(2,136)	(6,411)	(6,410)
Other-than-temporary impairment loss	-	(8,000)	-	(8,000)
Interest and other income, net	1,376	1,124	4,144	3,579
Loss before income taxes	(60,092)	(66,009)	(172,643)	(191,778)
Provision for income tax (benefit)	(659)	868	(7,305)	6,705
Net loss	<u>\$ (59,433)</u>	<u>\$ (66,877)</u>	<u>\$ (165,338)</u>	<u>\$ (198,483)</u>

Net loss per share:

Basic and diluted net loss per share	<u>\$ (1.10)</u>	<u>\$ (1.27)</u>	<u>\$ (3.07)</u>	<u>\$ (3.80)</u>
Shares used to compute basic and diluted net loss per share	<u>54,248</u>	<u>52,611</u>	<u>53,771</u>	<u>52,165</u>

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

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	\$ 6,294	\$ 5,005	\$ 19,757	\$ 15,023
Selling, general and administrative	5,452	5,680	19,842	16,329
Total share-based compensation expense	<u>\$ 11,746</u>	<u>\$ 10,685</u>	<u>\$ 39,599</u>	<u>\$ 31,352</u>

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

	September 30, December 31,	
	2018	2017
	(Unaudited)	(1)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents and short-term marketable securities	\$ 300,409	\$ 348,566
Receivables from collaborative arrangements	3,907	7,109
Prepaid taxes	314	291
Other prepaid and current assets	10,053	5,953
Inventories	17,923	16,830
Property and equipment, net	12,415	10,157
Long-term marketable securities	20,217	41,587
Tax receivable	3,131	8,191
Restricted cash	833	833
Other assets	1,762	1,883
Total assets	<u>\$ 370,964</u>	<u>\$ 441,400</u>
<b>Liabilities and Shareholders' Equity (Deficit)</b>		
Current liabilities	102,029	62,552
Long-term liabilities	282,380	263,670
Shareholders' equity (deficit)	(13,445)	115,178
Total liabilities and shareholders' equity (deficit)	<u>\$ 370,964</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.

View original content to download multimedia: <http://www.prnewswire.com/news-releases/theravance-biopharma-inc-reports-third-quarter-2018-financial-results-and-provides-business-update-300745099.html>

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