

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

August 1, 2018

TD-1473 Advancing into Phase 2b/3 Study in Ulcerative Colitis in Fourth Quarter Following Completion of Phase 1b Study and Successful Dialogues with FDA and EMA

TD-1473 Advancing into Phase 2 Study in Crohn's Disease in Third Quarter

TD-9855 Advancing into Phase 3 Program in nOH in Late 2018 or Early 2019 Following Positive Data from Phase 2 Study and Successful Dialogue with FDA

DUBLIN, Aug. 1, 2018 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today reported financial results for the second quarter ended June 30, 2018. Revenue for the second quarter of 2018 was \$23.5 million. The Company's second quarter operating loss was \$48.7 million or \$34.8 million excluding share-based compensation expense. Cash, cash equivalents, and marketable securities totaled \$371.2 million as of June 30, 2018.



Rick E Winningham, Chairman and Chief Executive Officer, commented: "We have made exciting progress across our portfolio. Positive data from the TD-1473 Phase 1b study in ulcerative colitis and TD-9855 Phase 2 study in nOH provide strong clinical rationale for the progression into registrational programs, and with regulatory dialogues recently completed, each program now has a clear path into late-stage studies. For YUPELRI™, our brand name for revefenacin, we and our partner Mylan are finalizing launch readiness activities in anticipation of a potential FDA approval later this year. In our early stage pipeline, we are preparing to advance TD-8236, our novel inhaled JAK inhibitor for serious respiratory diseases, into the clinic. These recent pipeline advancements along with a strong balance sheet and emerging cash flows from Trelegy Ellipta position us to continue to deliver growth across our business – from research to commercial – to drive value for shareholders and maximize the impact we can make on patients' lives."

Program Updates and Upcoming Milestones

TD-1473 (intestinally restricted pan-Janus kinase (JAK) inhibitor):

- Phase 1b study in 40 patients with ulcerative colitis complete; results demonstrate localized biologic activity and minimal systemic exposure, with a favorable safety and tolerability profile
 - Rates of clinical response were higher on all active doses (20, 80, 270 mg) compared with placebo using both partial and total Mayo definitions, with greatest effect seen at the 270 mg dose
 - Rectal bleeding scores improved above placebo at the 80 and 270 mg doses
 - Endoscopic improvements and mucosal healing were reported in all active arms, none in placebo arm
 - Plasma pharmacokinetic (PK) levels were low and consistent with data from healthy volunteers; local GI tissue PK levels above JAK inhibitory concentrations (IC50) for 80 and 270 mg dose
 - TD-1473 was generally well tolerated at all doses
 - Company and partner Janssen Biotech, Inc. plan to present full results from the Phase 1b study at a future medical meeting
- Initiation of Phase 2 induction study in Crohn's disease planned in third quarter of 2018
- Initiation of Phase 2b/3 induction and maintenance study in ulcerative colitis planned in fourth quarter of 2018, following completion of the Phase 1b study and successful dialogues with U.S. Food and Drug Administration (FDA) and European Medicines Authority (EMA)

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

- Positive data from the Phase 2 study in patients with neurogenic orthostatic hypotension (nOH), as detailed in a separate press release this morning. The Phase 2 trial was designed to evaluate the effect of TD-9855 in improving key symptoms and blood pressure
 - 27 of 34 (79%) patients who were enrolled in the single-ascending portion of the study demonstrated an improvement in blood pressure or standing time
 - A statistically significant difference of 30 mm Hg ($p = 0.011$) was observed in systolic blood pressure between active ($n=5$) and placebo ($n=5$) at the four-hour time point post-dose in the single dose placebo-controlled portion of

the study. These patients had a lower than normal mean SBP at baseline, consistent with nOH

- Of the 21 patients who started the repeat-dose portion of the study, 16 (76%) remained on therapy after four weeks
- Durable improvements in nOH symptom severity were observed as measured by OHSA Question #1 (a measure of dizziness, light-headedness or the sensation of being about to black out): the improvement was 2.4 points at the four-week time point¹
- 13 of the 16 patients who completed four weeks of dosing entered the trial with OHSA #1 of ≥ 4 (a threshold that will be applied in the registrational studies), and these patients reported a mean OHSA #1 reduction of 3.8 points at four weeks
- Consistent increases in systolic blood pressure (SBP), including clinically meaningful improvements in standing SBP (7 mm Hg or greater) after standing for three minutes at all assessment time points and at all weekly visits over four weeks
- TD-9855 was generally well tolerated, with no new safety findings attributable to drug observed in the study
- Initiation of a registrational Phase 3 program in nOH planned in late 2018 or early 2019 following positive data from the Phase 2 study and successful dialogue with FDA
- Presentation of preclinical TD-9855 findings at the Movement Disorders Congress in October

YUPELRI™ (revefenacin, TD-4208, nebulized long-acting muscarinic antagonist (LAMA)):

- Prescription Drug User Fee Act (PDUFA) date remains on track as November 13, 2018
- Oral presentation of the effect of revefenacin on reducing exacerbation rates in chronic obstructive pulmonary disease (COPD) based on the Phase 3 clinical program at European Respiratory Society (ERS) Paris 2018 International Congress in September

Trelegy Ellipta (first once-daily single inhaler triple therapy for COPD)²:

- GSK reported second quarter 2018 net sales of \$36.5 million; Theravance Biopharma entitled to approximately 5.5% to 8.5% (tiered) of worldwide net sales of the product
- In April, 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; boxed warning removed from Trelegy Ellipta prescribing information
- Regulatory application recently submitted to Japanese Ministry of Health, Labor and Welfare (MHLW) for the treatment of adults with chronic COPD
- Potential label expansion in EU and regulatory approval in Japan expected; completion of Phase 3 CAPTAIN study in asthma patients anticipated in early 2019

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

- Progression into first-in-human studies in late 2018, 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

2018 R&D Day

- Planned in December to focus on Theravance Biopharma research and next programs potentially progressing into clinic

Notes:

¹OHSA (Orthostatic Hypotension Symptom Assessment) is a validated scale assessing the presence of a range of symptoms in patients with nOH including dizziness, weakness, problems with vision, fatigue, trouble concentrating and head/neck discomfort

² 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

Second Quarter Financial Results

Revenue

Revenue for the second quarter of 2018 was \$23.5 million, comprised of revenue from collaborative arrangements of \$18.1 million and product sales of VIBATIV® of \$5.4 million. Revenue in the second quarter represents an increase of approximately \$20.0 million over the same period in 2017. The increase is primarily related to revenue recognized from both the opt-in payment received from Alfasigma for velusetrag and the upfront payment associated with the global collaboration agreement with Janssen for TD-1473. The upfront payment from Janssen is expected to be recognized over the course of the Phase 2 program.

Research and Development (R&D) Expenses

R&D expenses for the second quarter of 2018 were \$48.6 million, compared to \$42.9 million in the same period in 2017. The increase is primarily due to higher share-based compensation, external-related expenses, and other allocated expenses. Second quarter R&D expenses include non-cash

share-based compensation of \$6.9 million.

Selling, General and Administrative (SG&A) Expenses

SG&A expenses for the second quarter of 2018 were \$25.0 million, compared to \$24.3 million in the same period in 2017. Second quarter SG&A expenses include non-cash share-based compensation of \$7.0 million.

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities, excluding restricted cash, totaled \$371.2 million as of June 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.

Conference Call and Live Webcast Today at 8:00 am ET

Theravance Biopharma will hold a conference call and live webcast accompanied by slides today at 8:00 am 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 8316649. 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 August 31, 2018. An audio replay will also be available through 8:00 pm ET on August 8, 2018 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 8316649.

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-Q filed with the Securities and Exchange Commission (SEC) on May 9, 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)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
	(Unaudited)		(Unaudited)	
Revenue:				
Product sales	\$ 5,361	\$ 3,474	\$ 9,040	\$ 6,524
Revenue from collaborative arrangements	<u>18,115</u>	<u>35</u>	<u>22,755</u>	<u>72</u>
Total revenue	23,476	3,509	31,795	6,596
Costs and expenses:				
Cost of goods sold	(1,448)	1,364	(622)	1,929
Research and development ⁽¹⁾	48,621	42,927	96,386	83,492
Selling, general and administrative ⁽¹⁾	<u>25,007</u>	<u>24,339</u>	<u>49,711</u>	<u>45,125</u>
Total costs and expenses	<u>72,180</u>	<u>68,630</u>	<u>145,475</u>	<u>130,546</u>
Loss from operations	(48,704)	(65,121)	(113,680)	(123,950)
Income from investment in TRC, LLC	1,949	-	2,635	-
Interest expense	(2,137)	(2,137)	(4,274)	(4,274)
Interest and other income	<u>1,284</u>	<u>1,425</u>	<u>2,768</u>	<u>2,455</u>
Loss before income taxes	(47,608)	(65,833)	(112,551)	(125,769)
Provision for income tax (benefit)	<u>(6,790)</u>	<u>454</u>	<u>(6,646)</u>	<u>5,837</u>
Net loss	<u>\$ (40,818)</u>	<u>\$ (66,287)</u>	<u>\$ (105,905)</u>	<u>\$ (131,606)</u>
Net loss per share:				
Basic and diluted net loss per share	<u>\$ (0.76)</u>	<u>\$ (1.27)</u>	<u>\$ (1.98)</u>	<u>\$ (2.53)</u>
Shares used to compute basic and diluted net loss per share	<u>53,799</u>	<u>52,255</u>	<u>53,529</u>	<u>51,938</u>

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

<u>(In thousands)</u>	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>

Research and development	\$ 6,904	\$ 4,917	\$ 13,463	\$ 10,018
Selling, general and administrative	<u>6,951</u>	<u>5,481</u>	<u>14,390</u>	<u>10,649</u>
Total share-based compensation expense	<u>\$ 13,855</u>	<u>\$ 10,398</u>	<u>\$ 27,853</u>	<u>\$ 20,667</u>

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

	<u>June 30, 2018</u>	<u>December 31, 2017</u>
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents and short-term marketable securities	\$ 352,903	\$ 348,566
Receivables from collaborative arrangements	3,865	7,109
Prepaid taxes	944	291
Other prepaid and current assets	11,075	5,953
Inventories	17,906	16,830
Property and equipment, net	10,677	10,157
Long-term marketable securities	18,252	41,587
Tax receivable	3,143	8,191
Restricted cash	833	833
Other assets	<u>1,766</u>	<u>1,883</u>
Total assets	<u>\$ 421,364</u>	<u>\$ 441,400</u>
Liabilities and Shareholders' Equity		
Current liabilities	93,480	62,552
Long-term liabilities	293,497	263,670
Shareholders' equity	<u>34,387</u>	<u>115,178</u>
Total liabilities and shareholders' equity	<u>\$ 421,364</u>	<u>\$ 441,400</u>

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

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