

Theravance Biopharma, Inc. Reports First Quarter 2019 Financial Results and Provides Business Update

May 7, 2019

- Late-stage clinical studies of TD-1473 and ampreloxadine underway
- Phase 1 results including biomarker data in asthmatics for lung-selective inhaled pan-JAK inhibitor TD-8236 expected in third quarter 2019
 - Product launch of YUPELRI® (revefenacin) inhalation solution progressing in partnership with Mylan
 - GSK announced positive data from Phase 3 CAPTAIN study of TRELEGY ELLIPTA in patients with asthma
 - Company has initiated arbitration against Innoviva to enforce its full TRELEGY ELLIPTA royalty rights

DUBLIN, May 7, 2019 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today reported financial results for the first quarter ended March 31, 2019. Revenue for the first quarter of 2019 was \$5.3 million. First quarter operating loss was \$73.7 million or \$61.4 million excluding share-based compensation expense. Cash, cash equivalents, and marketable securities totaled \$434.1 million as of March 31, 2019.



Rick E Winningham, Chief Executive Officer, commented: "As we continue to make progress in 2019, we remain highly focused on implementing our strategy to discover, develop and commercialize transformational medicines with the potential to address important unmet patient, payor and caregiver needs.

"The Phase 2 Crohn's disease and Phase 2b/3 ulcerative colitis studies of TD-1473, our gut-selective pan-JAK inhibitor, are actively enrolling patients. Our registrational Phase 3 clinical program of ampreloxadine in symptomatic nOH is also underway, and we plan to present supportive five-month data from the completed Phase 2 study at scientific meetings in mid-2019. The Phase 1 study of TD-8236, our lung-selective JAK inhibitor, in healthy volunteers and asthmatic patients is ongoing and we expect to report results from the study in the third quarter of 2019.

"The YUPELRI launch is progressing following the commencement of formal sales and marketing efforts earlier this year in partnership with Mylan. In addition, sales of GSK's TRELEGY ELLIPTA for COPD continue to accelerate supported by product approvals and launches in additional geographies, including the recent approval in Japan. We were pleased to see GSK's recent announcement that the Phase 3 CAPTAIN study of TRELEGY ELLIPTA in patients with asthma met its primary endpoint, and GSK plans to submit the full dataset for regulatory review.

"Our strong cash position enables us to drive forward key programs in TD-1473, ampreloxadine, TD-8236, and YUPELRI, and to advance novel, organ-selective research programs toward the clinic. We intend to continue to build momentum throughout the year with a line-up of important milestones leading toward additional catalysts over the next 12 to 18 months as our late-stage trials mature, earlier-stage programs advance, and our commercial efforts gain traction," concluded Mr. Winningham.

Program Updates

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

- Supplemental data from the Phase 1b study of TD-1473 in patients with ulcerative colitis to be shared in an oral presentation at Digestive Disease Week (DDW) in May 2019
- Phase 2 DIONE induction study in Crohn's disease and registrational Phase 2b/3 RHEA induction and maintenance study in ulcerative colitis underway

Ampreloxadine (TD-9855, norepinephrine reuptake inhibitor (NRI)):

- 5-month data from the Phase 2 study in patients with neurogenic orthostatic hypotension (nOH) to be presented at the International Association of Parkinsonism and Related Disorders (IAPRD) in June 2019 and selected for oral presentation at the 32nd European Neurology Congress (ENC) in July 2019
- Ongoing registrational Phase 3 program in symptomatic nOH comprised of two studies:
 - 4-week treatment study; and
 - 4-month open label study followed by a 6-week randomized withdrawal phase to demonstrate durability of response

TD-8236 (novel, lung-selective inhaled pan-JAK inhibitor for serious respiratory diseases):

- Phase 1 data expected in the third quarter of 2019; study designed to evaluate safety and provide biomarker data of TD-8236 in healthy volunteers and asthmatic patients
 - Program goal in asthma is the prevention of exacerbations and the improvement of symptoms in patients uncontrolled by steroids despite compliance
 - TD-8236 shown to potentially inhibit targeted mediators of Th2-high and Th2-low asthma in human cells in preclinical studies

YUPELRI® (revefenacin) inhalation solution (lung-selective nebulized long-acting muscarinic antagonist (LAMA)):

- First and only once-daily, nebulized bronchodilator approved in the US for the maintenance treatment of patients with COPD
- Launch underway with partner Mylan; combined sales infrastructures covering the hospital, hospital discharge, and home health settings

TRELEGY ELLIPTA (first once-daily single inhaler triple therapy for COPD)¹:

- First quarter 2019 net sales of \$112.7 million; Theravance Biopharma entitled to approximately 5.5% to 8.5% (tiered) of worldwide net sales of the product
- Phase 3 CAPTAIN study in patients with asthma met primary endpoint:
 - TRELEGY demonstrated statistically significant 110mL improvement in lung function compared with RELVAR/BREO
 - GSK plans to submit data for regulatory review once full dataset is available
- Marketing authorization granted in Japan for the treatment for COPD; product now launched in 30 markets with the potential for an approval in China later this year

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 (net of TRC LLC expenses paid and the amount of cash, if any, expected to be used in TRC over the next four fiscal quarters). RELVAR/BREO ELLIPTA (the combination of fluticasone furoate and vilanterol)

First Quarter Financial Results

Revenue

Revenue from collaborative arrangements for the first quarter of 2019 was \$5.3 million compared to \$4.6 million in the same period in 2018. Total revenue decreased by approximately \$3.0 million as compared to the first quarter of 2018. The decrease in total revenue resulted primarily from no product sales being recognized in the first quarter of 2019 following the sale of VIBATIV® to Cumberland Pharmaceuticals in late 2018.

Research and Development (R&D) Expenses

R&D expenses for the first quarter of 2019 were \$53.8 million, compared to \$47.8 million in the same period in 2018. The increase was primarily due to an increase in external and employee-related expenses. The increase in employee-related expenses includes the impact of the reduction in force announced in the first quarter of 2019. First quarter R&D expenses included non-cash share-based compensation of \$6.2 million.

Selling, General and Administrative (SG&A) Expenses

SG&A expenses for the first quarter of 2019 were \$25.2 million, compared to \$24.7 million in the same period in 2018. The increase was primarily due to higher collaboration and employee-related expenses. The increase in employee-related expenses includes the impact of the reduction in force announced in the first quarter of 2019. First quarter SG&A expenses included non-cash share-based compensation of \$6.1 million.

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities, excluding restricted cash, totaled \$434.1 million as of March 31, 2019.

2019 Financial Guidance

The Company's guidance on operating loss excluding non-cash share-based compensation for the full year of 2019 remains unchanged at \$210.0 million to \$230.0 million. Operating loss guidance does not include royalty income for TRELEGY ELLIPTA which the Company recognizes as non-operating income. The Company's share of US profits and losses related to the commercialization of YUPELRI, potential future business development collaborations as well as the timing and cost of clinical studies associated with its key programs, among other factors, could impact the Company's financial guidance.

Arbitration Against Innoviva

As noted in the Innoviva, Inc. ("Innoviva") Quarterly Report on Form 10-Q for the three months ended March 31, 2019² filed with the Securities and Exchange Commission on May 1, 2019, no distributions were made to Theravance Biopharma with respect to its 85% economic interest in Theravance Respiratory Company, LLC ("TRC LLC") for the quarter ended December 31, 2018. As a result of this unjustified withholding of cash and Innoviva's statement to Theravance Biopharma that it intends to cause TRC LLC to withhold making further cash distributions through calendar 2019, the Company has initiated an arbitration against Innoviva and TRC LLC regarding Innoviva's material breach of its obligations to cause TRC LLC to make contractually-required distributions to the Company from royalties paid to TRC LLC by GlaxoSmithKline and its affiliates (collectively, "GSK")

related to GSK's net sales of TRELEGY ELLIPTA.

Rick E Winningham, chairman and chief executive officer of Theravance Biopharma, commented: "Theravance Biopharma intends to aggressively enforce all aspects of its agreement with Innoviva and TRC LLC to ensure we continue receiving our stipulated 85% share of royalties linked to TRELEGY ELLIPTA net sales. We firmly believe there is no justification or legal basis for Innoviva to cause TRC LLC to withhold the Q4 2018 distributions, the 2019 distributions or any material amount of cash. We are confident that Theravance Biopharma will prevail in this dispute and retain all rights to its full portion of the TRELEGY ELLIPTA royalties paid to TRC LLC by GSK."

In connection with Theravance Biopharma's spin-off from Innoviva in 2014, the two companies (collectively, and including Theravance Biopharma affiliates who became members, the "Members") entered into a limited liability company agreement (the "TRC LLC Agreement") that established TRC LLC. TRC LLC is jointly owned by the two companies despite being managed by Innoviva, and its purpose is to collect and disburse royalties from GSK's sales of certain products, including TRELEGY ELLIPTA, to the Members. The terms of the Agreement plainly state that Member interests owned by Theravance Biopharma entitle it to 85% of the royalties paid to TRC LLC by GSK as a result of GSK's net sales of TRELEGY ELLIPTA (net of TRC LLC expenses paid and the amount of cash, if any, expected to be used in TRC LLC over the next four fiscal quarters). The TRC LLC Agreement imposes express fiduciary duties on Innoviva equal to those of directors of a for-profit corporation and those of a controlling shareholder. To ensure that Innoviva causes TRC LLC to fulfill its contractual duties to distribute royalties, and to discharge its own fiduciary duties, the TRC LLC Agreement imposes significant limitations on Innoviva's authority as manager, including requiring Theravance Biopharma's consent before taking actions or omitting to take actions that would reasonably be expected to have a direct or indirect material and adverse effect on the Company's economic interest in TRC LLC or its rights, preferences, privileges or obligations.

On November 30, 2018, an affiliate of Theravance Biopharma named Triple Royalty Sub LLC (the "Issuer") closed a private placement of \$250 million aggregate principal amount of non-recourse Triple PharmaSM 9% Fixed Rate Term notes due on or before April 15, 2033 (the "Notes"). The Notes are secured by, and the primary source of funds to make payments on the Notes is, the Issuer's 63.75% economic interest in any future payments made by GSK to TRC LLC (net of TRC LLC expenses paid and the amount of cash, if any, expected to be used in TRC LLC over the next four fiscal quarters).

The Notes bear an annual interest rate of 9%, with interest and principal payable quarterly beginning April 15, 2019. Through October 15, 2020, the terms of the Notes provide that to the extent there are insufficient funds to satisfy the Issuer's scheduled quarterly interest obligations, the shortfall shall be added to the principal amount of the Notes without a default or event of default occurring. The terms of the Notes also provide that, at Theravance Biopharma's option, the quarterly interest payment obligations can be satisfied by making a capital contribution to the Issuer, but not for more than four (4) consecutive quarterly interest payment dates or for more than six (6) quarterly interest payment dates during the term of the Notes. For the April 15, 2019 interest payment date, Theravance Biopharma R&D, Inc. (parent entity of Issuer) made a capital contribution to satisfy the interest payment obligations for that scheduled payment. If necessary, interest may be paid in-kind or Theravance Biopharma may exercise its capital contribution option in the near future while we arbitrate this dispute with Innoviva.

Rick E Winningham concluded:

"As we work to resolve this dispute in our favor, we will continue to execute on our go-forward strategy. Again, we firmly believe there is no justification or legal basis for Innoviva to cause TRC LLC to withhold any material amount of cash. We are confident that Theravance Biopharma will prevail in this dispute and retain all rights to its full portion of the TRELEGY ELLIPTA royalties paid to TRC LLC by GSK. We believe the arbitration process provided for under the Agreement will enable us to pursue and achieve a favorable resolution in a relatively timely manner."

Quinn Emanuel Urquhart & Sullivan, LLP is serving as external counsel to Theravance Biopharma in this matter.

Notes

² As disclosed in *Innoviva's Condensed Consolidated Statement of Cash Flows and the Condensed Consolidated Statements of Stockholders' Equity in the Form 10-Q for the three months ended March 31, 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 9890346. 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, 2019. An audio replay will also be available through 8:00 pm ET on May 14, 2019 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 9890346.

About Theravance Biopharma

Theravance Biopharma, Inc. ("Theravance Biopharma") is a diversified biopharmaceutical company primarily focused on the discovery, development and commercialization of organ-selective medicines. Our purpose is to create transformational medicines to improve the lives of patients suffering from serious illnesses. Our research is focused in the areas of inflammation and immunology.

In pursuit of our purpose, we apply insights and innovation at each stage of our business and utilize our internal capabilities and those of partners around the world. We apply organ-selective expertise to biologically compelling targets to discover and develop medicines designed to treat underserved localized diseases and to limit systemic exposure, in order to maximize patient benefit and minimize risk. These efforts leverage years of experience in developing lung-selective medicines to treat respiratory disease, including FDA-approved YUPELRI[®] (revefenacin) inhalation solution indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Our pipeline of internally discovered programs is targeted to address significant patient needs.

We have an economic interest in potential future payments from 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 current dispute with Innoviva and TRC LLC, 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 potential that the Company's research programs will progress product candidates into the clinic, the Company's expectations for product candidates through development, potential regulatory approval and commercialization (including their differentiation from other products or potential products), product sales or profit share revenue and the Company's expectations for its 2019 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: the nature of the current dispute with Innoviva and TRC LLC, the uncertainty of arbitration and litigation and the possibility that an arbitration award or litigation result involving the current dispute could be adverse to the Company, delays or difficulties in commencing, enrolling or completing clinical studies, the potential that results from clinical or non-clinical studies indicate the Company's compounds or product candidates are unsafe or ineffective, 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, 2019 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 March 31,</u>	
	<u>2019</u>	<u>2018</u>
	<u>(Unaudited)</u>	
Revenue:		
Product sales	\$ -	\$ 3,679
Collaboration revenue	5,338	4,640
Total revenue	<u>5,338</u>	<u>8,319</u>
Costs and expenses:		
Cost of goods sold	-	826
Research and development (1)	53,818	47,765
Selling, general and administrative (1)	25,186	24,704
Total costs and expenses	<u>79,004</u>	<u>73,295</u>
Loss from operations	(73,666)	(64,976)
Income from investment in TRC, LLC	6,229	686
Interest expense	(7,858)	(2,137)
Interest and other income, net	2,795	1,484
Loss before income taxes	(72,500)	(64,943)
Provision for income tax expense	(80)	(144)

Net loss	<u>\$ (72,580)</u>	<u>\$ (65,087)</u>
Net loss per share:		
Basic and diluted net loss per share	<u>\$ (1.32)</u>	<u>\$ (1.22)</u>
Shares used to compute basic and diluted net loss per share	<u>54,938</u>	<u>53,256</u>

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

(In thousands)	Three Months Ended March 31,	
	2019	2018
Research and development	\$ 6,159	\$ 6,559
Selling, general and administrative	6,061	7,439
Total share-based compensation expense	<u>\$ 12,220</u>	<u>\$ 13,998</u>

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

	March 31, 2019	December 31, 2018
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents and short-term marketable securities	\$ 434,058	\$ 505,276
Receivables from collaborative arrangements	7,824	10,053
Other prepaid and current assets	25,351	17,494
Total current assets	467,233	532,823
Property and equipment, net	12,899	13,176
Long-term marketable securities	-	11,869
Operating lease assets	48,861	-
Restricted cash	833	833
Other assets	1,439	1,534
Total assets	<u>\$ 531,265</u>	<u>\$ 560,235</u>
Liabilities and Shareholders' Deficit		
Current liabilities	\$ 113,542	\$ 98,554
Convertible senior notes due 2023, net	225,086	224,818
Non-recourse notes due 2033, net	221,402	229,535
Operating lease liabilities	48,493	-
Other long-term liabilities	35,994	58,917
Shareholders' deficit	(113,252)	(51,589)
Total liabilities and shareholders' deficit	<u>\$ 531,265</u>	<u>\$ 560,235</u>

(1) The condensed consolidated balance sheet as of December 31, 2018 has been derived from the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

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