Theravance Biopharma, Inc. Reports First Quarter 2020 Financial Results and Provides Business Update

May 6, 2020

- TD-0903, an investigational lung-selective nebulized Janus kinase inhibitor (JAKi) with the potential to treat Acute Lung Injury in hospitalized patients with COVID-19, has progressed to Phase 1 clinical testing

- Pipeline momentum impacted by COVID-19 disruption, studies continue to enroll; ampreloxetine and TD-1473 study readouts expected to move into 2021

- YUPELRI® (revefenacin) growth continued in first quarter 2020, in partnership with Mylan; trajectory could be affected by COVID-19 in second quarter

- Maintains 2020 financial guidance

DUBLIN, May 6, 2020 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today reported financial results for the first quarter ended March 31, 2020. Revenue for the first quarter 2020 was $19.9 million. Operating loss was $72.5 million, or $57.2 million excluding share-based compensation expense. Cash, cash equivalents and marketable securities totaled $492.1 million as of March 31, 2020.

"As we are each challenged by COVID-19 – personally and professionally, I want to thank our employees who have supported the communities we serve: the most vulnerable with respiratory illness and immune deficiencies, healthcare professionals across the globe and each other in extremely troublesome times. I could not be prouder," said Rick E Winningham, Chief Executive Officer. "Theravance Biopharma moved to remote working conditions in early March 2020 for the vast majority of our workforce. Our past investment in technology infrastructure is enabling us to rapidly shift and service our business. Our geographic diversification of clinical trial sites as well as supply chain is minimizing impact on our clinical trial programs. The commitment of our lab-based personnel to work in our laboratories during this time has been crucial to continued progress of our pipeline programs."

"Our commercial team remains focused on delivering YUPELRI to the COPD community – always a vulnerable community and especially during this pandemic – to both the people with COPD and the healthcare professionals that treat them; our team has been continuously available to support them with YUPELRI. As the only once-daily nebulized maintenance therapy for COPD, we believe YUPELRI has made a difference for the community during these challenging times."

"We are well-capitalized to continue our pipeline momentum. We have significantly accelerated internal research and development efforts on TD-0903, a lung-selective nebulized JAKi with the potential to treat hospitalized patients with Acute Lung Injury (ALI) caused by COVID-19 to prevent progression to Acute Respiratory Distress Syndrome (ARDS) and the need for assisted ventilation. The learnings from the early clinical experience of TD-0903 will not only benefit the program in its potential for the treatment of COVID-19 lung hyperinflammation but will inform the broader clinical program in other severe inflammatory conditions of the lung. We are working in close collaboration with our partner, Janssen, on TD-1473, a gut-selective oral JAKi in development for inflammatory intestinal disease and TD-5202, gut-selective irreversible JAK3 inhibitor in development for inflammatory intestinal diseases. TD-8236, our lung-selective dry powder inhaler pan-JAK inhibitor in development for inflammatory lung disease, continues to progress. Ampreloxetine, a norepinephrine reuptake inhibitor (NRI) is under evaluation for treatment of symptomatic neurogenic orthostatic hypotension (nOH), a rare disease, in a Phase 3 clinical program. We continue to move these programs forward despite the significant hurdles imposed by social distancing and government lockdowns around the world."

"As we look ahead, as a company with a legacy in developing respiratory medicines, we hope our inhaled JAK inhibitor program can help make a meaningful contribution to the COVID-19 story as we continue to progress our other high priority programs of TD-1473 and ampreloxetine."

Corporate Highlights

Partnered with Mylan:

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

- First and only once-daily, nebulized bronchodilator approved in the U.S. for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), reimbursed by Part B Medicare program
- Data as of January 2020 show that YUPELRI achieved an 87% share of the nebulized LAMA market and a 13.7% share of the long-acting nebulized market (including Durable Medical Equipment)
- YUPELRI is manufactured in the United States and supply chains are monitored regularly; no disruption of supply is currently anticipated
- In-person field calls on YUPELRI ceased as of mid-March 2020; as with most pharmaceuticals, sales momentum has been affected by COVID-19; the team is leveraging established relationships, digital technology, and non-personal promotion to continue the dialogue with stakeholders to continue sales growth; an "Insight and Innovation Think Tank" has been established to evolve "next practices" during the peri- and post-COVID-19 period

Key Pipeline Progress

The COVID-19 pandemic is a significant threat to public health throughout the world and the Company has been diligently monitoring and adapting to the threat. Theravance Biopharma has been evaluating each of its clinical trial programs to determine necessary modifications and working closely with regulators, ethics committees, sites, CROs and data safety monitoring boards. The Company appreciates the pragmatism, collaboration and the ongoing prioritization of the clinical trial participants and all of those caring for them. Given the significant strains on the healthcare system across the globe, Theravance Biopharma took the decision in mid-March to temporarily suspend adding new patients to the screening phase for its TD-1473 and ampreloxetine trials for 4 weeks, in order to prioritize ongoing support for patients who were already in screening and those patients who were already randomized. As a result, the studies were able to continue randomizing existing screened patients into the studies and the randomized patients were able to continue to receive study medication per the protocol requirements. Screening of new patients is now resuming in some countries in a controlled and measured fashion as individual sites confirm their ability to support the study requirements and new patients are able to be assessed for their eligibility to participate in the studies. The global nature of the TD-1473 and ampreloxetine clinical programs will allow for flexibility as COVID-19 control measures evolve in different countries. The situation is expected to continue to change at different rates in different countries around the world in response to COVID-19 interventions, and as a result it is not possible to provide an accurate re-estimation of expected completion dates for these programs at this time outside of our guidance of shifting data delivery to 2021.

In light of the COVID-19 pandemic, the Company is implementing mitigation plans to ensure patients in the clinical trials have continued access to drug supply and regular visits with their physicians for study visits per trial protocols. The Company continues to develop strategies to reduce patient needs to travel to sites in hopes of avoiding unnecessary exposure while balancing safety monitoring of investigational products. The Company is working closely with regulators and Ethics Committees and taking steps to ensure protection of patients, site personnel and clinical trial integrity.

Partnered with Janssen Biotech, Inc.:
TD-1473 (gut-selective oral pan-Janus kinase (JAK) inhibitor for inflammatory intestinal diseases):

- Phase 2b/3 induction and maintenance study in ulcerative colitis (RHEA) and Phase 2 induction study in Crohn's disease (DIONE) progressing
- Data from the Phase 2b portion of the ulcerative colitis and Phase 2 Crohn's disease studies originally planned for late-2020 and now expected in 2021

TD-5202 (gut-selective irreversible JAK3 inhibitor for inflammatory intestinal diseases):

- TD-5202 was generally well tolerated as a single oral dose up to 2000 milligrams and as a twice-daily oral dose up to 2000 milligrams total per day given for 10 consecutive days in healthy subjects

Ampreloxetine (TD-9855, norepinephrine reuptake inhibitor (NRI) for symptomatic nOH):

- Ongoing registrational program in symptomatic neurogenic orthostatic hypertension (nOH) comprised of two studies:
  - Phase 3 four-week treatment study (SEQUOIA) to demonstrate efficacy, with data originally planned for late-2020 and now expected in 2021
  - Phase 3 four-month open label study followed by a six-week randomized withdrawal phase (REDWOOD) to demonstrate durability of response

TD-8236 (lung-selective inhaled pan-JAK inhibitor for inflammatory lung diseases):

- Part C extension portion of the Phase 1 trial assessing additional biomarkers in more severe asthmatics underway with results expected in 2H 2020
- Phase 2 lung allergen challenge initiated in 4Q 2019; data expected 2H 2020

TD-0903 (lung-selective nebulized pan-JAK inhibitor for treatment of Acute Lung Injury caused by COVID-19)

- Initiated Phase 1 study to assess the safety, tolerability and pharmacokinetics of single- and multiple-ascending doses (SAD/MAD) in healthy volunteers
- The program will then initially move to a nested Phase 2 study in hospitalized patients with COVID-19 with the first part (an ascending dose study) being conducted in the same clinical setting in the UK as the Phase 1 study; the Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom approved the Phase 2 study today
- The second part of the Phase 2 study will be a larger, multi-center study conducted at hospital-based clinical sites in the UK, and potentially other clinical sites in the European Union and United States; both of the latter territories would join the Phase 2 study program subject to review and approval of the relevant regulatory approvals required by the relevant EU National Competent Authorities and Food and Drug Administration (FDA)

Economic Interest

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

- 1Q 2020 net sales of $249 million; Theravance Biopharma entitled to approximately 5.5% to 8.5% (tiered) of worldwide net sales of the product
- GSK sNDA for asthma expected 2H 2020; The European Medicines Agency accepted the regulatory submission for the treatment of asthma in adults supported by the Phase III CAPTAIN study; FDA postponed Advisory Committee Meeting originally scheduled for April 21, 2020 regarding mortality sNDA and no additional public information available at this time

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, aclidinium, 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 Theravance Respiratory Company, LLC ("TRC LLC") expenses paid and the amount of cash, if any, expected to be used in TRC over the next four fiscal quarters). 75% of the income from Company's investment in TRC is pledged to service outstanding notes, 25% of income from Company's investment in TRC is retained by Company.

First Quarter Financial Results

- **Revenue:** Revenue for the first quarter of 2020 was $19.9 million, comprised of collaboration revenue of $6.6 million primarily attributed to the Janssen collaboration agreement for TD-1473 and $11.7 million in Mylan collaboration revenue related to YUPELRI. Revenue for the first quarter represents a $14.5 million increase over the same period in 2019. The increase was primarily due to an increase in Mylan collaboration revenue related to YUPELRI and a larger portion of recognized revenue related to the $100.0 million upfront payment from the Janssen collaboration agreement that was entered into in February 2018.
- **Research and Development Expenses:** Research and Development (R&D) expenses for the first quarter of 2020 were $66.0 million, compared to $53.8 million in the same period in 2019. The $12.2 million increase was primarily due to a $12.4 million increase in external-related expenses related to the advancement of our priority programs, notable TD-1473, ampreloxetine, and TD-8236, a $1.7 million increase in share-based compensation expense, and a $2.2 million decrease in employee-related expenses. First quarter R&D expenses included non-cash share-based compensation of $7.9 million.
- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses for the first quarter of 2020 were $26.3 million, compared to $25.2 million in the same period in 2019. The $1.1 million increase was primarily attributed to a $1.4 million increase in share-based compensation expense, a $0.8 million increase in employee-related expenses, and a $0.6 million increase in external-related expenses. These increases were partially offset by a $1.4 million decrease related to collaboration expenses payable to Mylan in connection with the commercialization of YUPELRI which was formally launched in the first quarter of 2019. First quarter SG&A expenses included non-cash share-based compensation of $7.4 million.
- **Cash, Cash Equivalents and Marketable Securities** Cash, cash equivalents and marketable securities totaled $492.1 million as of March 31, 2020.

2020 Financial Guidance

- **Operating Loss** (excluding share-based compensation)**:** The Company is not changing financial guidance and expects full-year 2020 operating loss, excluding share-based compensation, of $205 million to $225 million. Operating loss guidance does not include:
    - Royalty income for TRELEGY ELLIPTA which the Company recognizes in its statement of operations as "income from investment in TRC, LLC;" or
    - Potential future business development collaborations

Additionally, as previously announced, the Company closed its public offering of 5,500,000 ordinary shares at a price to the public of $27.00 per share on February 14, 2020. The gross proceeds to Theravance Biopharma from the offering are approximately $148.5 million, before deducting underwriting discounts and commissions and estimated offering expenses.

On March 2, 2020 Theravance Biopharma announced the closing of a private placement of $400 million in aggregate principal amount of non-recourse 9.5% fixed rate term notes. The notes are secured by a portion of the future payments the Company expects to receive related to royalties due on net sales of TRELEGY ELLIPTA, with 75% of such payments to be used to satisfy the debt obligations until the notes are repaid and the remaining 25% of such payments being directed to benefit the Company on an ongoing basis. The Company used a portion of the net proceeds from this transaction to repay in full the remaining outstanding balance of the $250 million Triple PhaRMA^{SM} 9.0% fixed rate term notes due 2033 and intends to use the remainder of the net proceeds to support continued execution of its key development programs.

Conference Call and Live Webcast Today at 5 pm ET

Theravance Biopharma will hold a conference call and live webcast accompanied by slides today at 2 pm PT / 9 pm GMT). 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 8371418. 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.

A replay of the conference call will be available on Theravance Biopharma's website for 30 days through June 5, 2020. An audio replay will also be available through 8:00 pm ET on May 13, 2020 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 8371418.

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 Limited 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.

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 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 2020 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: potential future disagreements with Innoviva, Inc. and TRC LLC, the uncertainty of arbitration and litigation and the possibility that an arbitration award or litigation result 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. In addition, while we expect the COVID-19 pandemic to continue to adversely impact our business operations and financial results, the extent of the impact on our ability to generate revenue from YUPELRI, our clinical development programs (in particular our later stage clinical programs for TD-1473 and Ampreloxetine) and the value of and market for our common shares, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time. These potential future developments include, but are not limited to, the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the U.S. and in other countries, and the effectiveness of actions taken globally to contain and treat the disease. Other risks affecting Theravance Biopharma are in the company's Form 10-K filed with the SEC on February 27, 2020 and other periodic reports filed 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 BALANCE SHEETS
(In thousands)

	March 31, 2020	December 31, 2019
Assets	**(Unaudited)**	**(1)**
Current assets:		
Cash and cash equivalents and short-term marketable securities	$ 487,031	$ 280,831
Receivables from collaborative arrangements	14,214	11,996
Receivables from licensing arrangements	1,200	10,000
Amounts due from TRC, LLC	26,282	28,574
Other prepaid and current assets	5,491	7,087
Total current assets	534,218	338,488
Property and equipment, net	13,905	12,644
Long-term marketable securities	5,067	4,985

Operating lease assets	46,106	46,604
Restricted cash	833	833
Other assets	5,280	5,272
Total assets	$ 605,409	$ 408,826
Liabilities and Shareholders' Deficit		
Current liabilities	$ 98,040	$ 111,703
Convertible senior notes due 2023, net	226,158	225,890
Non-recourse notes due 2035, net	373,854	-
Non-recourse notes due 2033, net	-	219,300
Long-term operating lease liabilities	47,199	47,725
Other long-term liabilities	18,094	28,048
Shareholders' deficit	(157,936)	(223,840)
Total liabilities and shareholders' deficit	$ 605,409	$ 408,826

(1) The condensed consolidated balance sheet as of December 31, 2019 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, 2019.

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

	Three Months Ended March 31,	
	2020	2019
	(Unaudited)	
Revenue:		
Collaboration revenue	$ 6,632	$ 5,338
Licensing revenue	1,500	-
Mylan collaboration agreement	11,730	-
Total revenue	19,862	5,338
Costs and expenses:		
Research and development (1)	66,013	53,818
Selling, general and administrative (1)	26,325	25,186
Total costs and expenses	92,338	79,004
Loss from operations	(72,476)	(73,666)
Income from investment in TRC, LLC	13,515	6,229
Interest expense	(9,941)	(7,858)
Loss on extinguishment of debt	(15,464)	-
Interest and other income, net	1,460	2,795
Loss before income taxes	(82,906)	(72,500)
Provision for income tax expense	(147)	(80)
Net loss	$ (83,053)	$ (72,580)
Net loss per share:		
Basic and diluted net loss per share	$ (1.40)	$ (1.32)
Shares used to compute basic and diluted net loss per share	59,463	54,938

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

	Three Months Ended March 31,	
(In thousands)	2020	2019
Research and development	$ 7,865	$ 6,159
Selling, general and administrative	7,411	6,061
Total share-based compensation expense	$ 15,276	$ 12,220

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