

## Theravance Biopharma, Inc. Reports Fourth Quarter and Full-Year 2019 Financial Results and Provides Business Update

February 24, 2020

- YUPELRI<sup>®</sup> (revefenacin) is realizing strong customer acceptance and market uptake, in partnership with Mylan
- Phase 1 of TD-5202 single-ascending dose and multiple-ascending dose studies evaluated the safety and tolerability of TD-5202 in healthy subjects; data showed TD-5202 was generally well tolerated, supporting advancement
- Full-year operating loss, excluding share-based compensation expense, was lower than the Company's previously stated financial guidance for 2019 [1]
- Multiple potential value-driving catalysts expected in 2020 and beyond

DUBLIN, Feb. 24, 2020 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today reported financial results for the fourth quarter and full year ended December 31, 2019. Revenue for the fourth quarter and full year 2019 was \$29.5 million and \$73.4 million, respectively. Full-year operating loss was \$251.9 million or \$191.5 million excluding share-based compensation expense. Cash, cash equivalents and marketable securities totaled \$285.8 million as of December 31, 2019.



Rick E Winningham, Chairman and Chief Executive Officer, commented: "2019 was a year of achievement for Theravance Biopharma across our business. We successfully launched YUPELRI with Mylan and advanced our development- and research-stage pipeline, further building a diversified portfolio with promising, differentiated programs in every stage of development. Our roster of partnerships continued to strengthen, with ongoing successful collaborations with Mylan for YUPELRI and Janssen for TD-1473 and TD-5202. In addition, we entered into a new agreement with Pfizer to out-license our skin-selective pan-JAK inhibitor program. Our partnerships complement and expand our capabilities and execution and underscore our potential to transform the treatment of serious diseases."

"As we look ahead, 2020 will be an important year for our Company. We have established a strong capital position, augmented by our partnerships, as well as TRELEGY ELLIPTA royalties and YUPELRI commercialization. We are optimistic about future data readouts, especially our wholly owned programs -- amprelosetine in nOH and TD-8236 in asthma -- which could both represent new treatment paradigms for patients with debilitating chronic diseases. The combined strengths of our research engine, pipeline, proven development expertise and commercial infrastructure have set the stage for a data- and catalyst-rich 2020 -- a year that we believe can deliver meaningful value for stakeholders."

### Corporate Highlights

Partnered with Mylan:

YUPELRI<sup>®</sup> (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)
- One year post-launch -- continued strong customer acceptance across key market metrics; combined Theravance Biopharma/Mylan sales infrastructures covering the hospital, hospital discharge, and home health settings
  - Data as of October 2019 show that YUPELRI achieved an 86% share of the nebulized LAMA market and a 10.7% share of the long-acting nebulized market (including Durable Medical Equipment)

Partnered with Janssen:

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

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 planned for late-2020

Amprelosetine (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 expected in late 2020
  - 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 mid-2020
- Phase 2 lung allergen challenge initiated in 4Q 2019; data expected in mid-2020

TRELEGY ELLIPTA (first once-daily single inhaler triple therapy for COPD)<sup>2</sup>:

- 4Q 2019 net sales of \$221.5 million and full-year 2019 net sales of \$661.3 million; Theravance Biopharma entitled to approximately 5.5% to 8.5% (tiered) of worldwide net sales of the product
- Product now launched for COPD in 38 markets, including China
- GSK filed sNDA 2Q 2019 for mortality benefit compared with ANORO in COPD and sNDA for use in patients with asthma in 3Q 2019

Notes:

<sup>1</sup> Theravance Biopharma's full-year operating loss, excluding share-based compensation expense, was below the 2019 guidance of \$200 million to \$210 million operating loss excluding share-based compensation due to the Pfizer upfront payment of \$10 million being recognized as revenue in late December.

<sup>2</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, 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 PhaRMA<sup>SM</sup> notes, 25% of income from Company's investment in TRC is retained by Company.

#### Fourth Quarter and Full Year Financial Results

- **Revenue:** Revenue for the fourth quarter of 2019 was \$29.5 million, comprised of collaboration revenue of \$9.6 million primarily attributed to the upfront payment from Janssen for TD-1473, licensing revenue of \$10.0 million related to the upfront payment from Pfizer for rights to our skin-selective pan-JAK inhibitor program, and revenue from the Mylan collaboration agreement of \$9.9 million. Revenue for the fourth quarter represents a \$13.8 million increase over the same period in 2018. The increase was primarily due to licensing revenue associated with the upfront payment from Pfizer and an increase in revenue from the Mylan collaboration agreement, partially offset by a decrease in product sales which resulted from the sale of VIBATIV<sup>®</sup> to Cumberland Pharmaceuticals in late-2018. Full-year 2019 revenue was \$73.4 million, comprised of collaboration revenue of \$31.3 million primarily associated with our global collaboration with Janssen, licensing revenue of \$28.5 million related to upfronts from Pfizer and Mylan and revenue from the Mylan collaboration of \$13.7 million.
- **Research and Development Expenses:** Research and Development (R&D) expenses for the fourth quarter of 2019 were \$67.0 million, compared to \$52.3 million in the same period in 2018. The increase was primarily due to an increase in employee-related costs and share-based compensation related to long-term retention and incentive awards, plus external-related costs associated with the progression of our key programs. Full-year 2019 R&D expenses were \$219.2 million, or \$190.3 million excluding non-cash share-based compensation.
- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses for the fourth quarter of 2019 were \$33.0 million, compared to \$25.5 million in the same period in 2018. The increase was primarily due to an increase in share-based compensation related to long-term retention and incentive awards. Full-year 2019 SG&A expenses were \$106.1 million, or \$74.6 million excluding non-cash share-based compensation.
- **Cash, Cash Equivalents and Marketable Securities** Cash, cash equivalents and marketable securities totaled \$285.8 million as of December 31, 2019.

#### 2020 Financial Guidance

- **Operating Expenses:** The Company 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

Note: timing and cost of clinical studies associated with key programs, among other factors, could impact financial guidance.

Additionally, as announced on February 11th, 2020, we closed our public offering of 5,500,000 ordinary shares at a price to the public of \$27.00 per share. The gross proceeds to Theravance Biopharma from the offering are approximately \$148.5 million, before deducting underwriting discounts and commissions and estimated offering expenses.

### **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 (2:00 pm PT / 10:00 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 5775588. 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.

A replay of the conference call will be available on Theravance Biopharma's website for 30 days through March 25, 2020. An audio replay will also be available through 8:00 pm ET on March 2, 2020 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 5775588.

### **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](http://www.theravance.com).

THERAVANCE® and the Cross/Star logo are registered trademarks of the Theravance Biopharma group of companies. YUPELRI® is a United States registered trademark of Mylan Specialty L.P. Trademarks, trade names or service marks of other companies appearing on this press release are the property of their respective owners.

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 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: 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. Other risks affecting Theravance Biopharma are in the company's Prospectus Supplement filed with the Securities and Exchange Commission (SEC) on February 12, 2020, Form 10-Q filed with the SEC on November 8, 2019, 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.

Contact:

Gail B. Cohen

Corporate Communications and Investor Relations

917-214-6603

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

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
<b>Revenue:</b>	<b>(Unaudited)</b>		<b>(Unaudited)</b>	
Product sales	\$ -	\$ 2,415	\$ -	\$ 15,304
Collaboration revenue	9,584	10,047	31,250	41,791
Licensing revenue	10,000	-	28,500	-
Mylan collaboration agreement	9,915	3,275	13,664	3,275
Total revenue	<u>29,499</u>	<u>15,737</u>	<u>73,414</u>	<u>60,370</u>
<b>Costs and expenses:</b>				
Cost of goods sold	-	632	-	715
Research and development <sup>(2)</sup>	67,025	52,269	219,248	201,348
Selling, general and administrative <sup>(2)</sup>	33,046	25,457	106,081	97,058
Total costs and expenses	<u>100,071</u>	<u>78,358</u>	<u>325,329</u>	<u>299,121</u>
Loss from operations	(70,572)	(62,621)	(251,915)	(238,751)
Income from investment in TRC, LLC	11,913	5,428	33,705	11,182
Interest expense	(8,035)	(4,071)	(31,862)	(10,482)
Interest and other income, net	1,137	7,822	8,395	11,966
Loss before income taxes	(65,557)	(53,442)	(241,677)	(226,085)
Provision for income tax benefit (expense)	(49)	3,256	5,222	10,561
<b>Net loss</b>	<u>\$ (65,606)</u>	<u>\$ (50,186)</u>	<u>\$ (236,455)</u>	<u>\$ (215,524)</u>
Net loss per share:				
Basic and diluted net loss per share	<u>\$ (1.17)</u>	<u>\$ (0.92)</u>	<u>\$ (4.25)</u>	<u>\$ (3.99)</u>
Shares used to compute basic and diluted net loss per share	<u>56,102</u>	<u>54,555</u>	<u>55,610</u>	<u>53,969</u>

(1) The condensed consolidated statement of operations for the year ended 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.

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

<b>(In thousands)</b>	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Research and development	\$ 10,615	\$ 5,806	\$ 28,953	\$ 25,563
Selling, general and administrative	13,297	5,908	31,497	25,750
Total share-based compensation expense	<u>\$ 23,912</u>	<u>\$ 11,714</u>	<u>\$ 60,450</u>	<u>\$ 51,313</u>

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

	December 31, 2019	December 31, 2018
<b>Assets</b>	<b>(Unaudited)</b>	<b>(1)</b>
Current assets:		
Cash and cash equivalents and short-term marketable securities	\$ 280,831	\$ 505,276
Receivables from collaborative arrangements	11,996	10,053
Receivables from licensing arrangements	10,000	-
Amounts due from TRC, LLC	28,574	5,422
Other prepaid and current assets	7,087	12,072
Total current assets	<u>338,488</u>	<u>532,823</u>
Property and equipment, net	12,644	13,176
Long-term marketable securities	4,985	11,869
Operating lease assets	46,604	-
Restricted cash	833	833
Other assets	5,272	1,534
Total assets	<u>\$ 408,826</u>	<u>\$ 560,235</u>
<b>Liabilities and Shareholders' Deficit</b>		
Current liabilities	\$ 111,703	\$ 98,554
Convertible senior notes due 2023, net	225,890	224,818
Non-recourse notes due 2033, net	219,300	229,535

Long-term operating lease liabilities	47,725	-
Other long-term liabilities	28,048	58,917
Shareholders' deficit	<u>(223,840)</u>	<u>(51,589)</u>
Total liabilities and shareholders' deficit	<u>\$ 408,826</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.

 View original content to download multimedia: <http://www.prnewswire.com/news-releases/theravance-biopharma-inc-reports-fourth-quarter-and-full-year-2019-financial-results-and-provides-business-update-301009967.html>

SOURCE Theravance Biopharma, Inc.