

THERAVANCE BIOPHARMA, INC.

FORM 8-K (Current report filing)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

Current Report Pursuant
to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): February 27, 2017

THERAVANCE BIOPHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Cayman Islands
(State or Other Jurisdiction of Incorporation)

001-36033
(Commission File Number)

98-1226628
(I.R.S. Employer Identification Number)

PO Box 309
Ugland House, South Church Street
George Town, Grand Cayman, Cayman Islands KY1-1104
(650) 808-6000

(Addresses, including zip code, and telephone number, including area code, of principal executive offices)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02. Results of Operations and Financial Condition.

On February 27, 2017, Theravance Biopharma, Inc. issued a press release and is holding a conference call regarding its financial results for the quarter and year ended December 31, 2016 and a business update. A copy of the press release is furnished as Exhibit 99.1 to this Current Report.

The information in Item 2.02 and in Item 9.01 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Securities Exchange Act of 1934"), or otherwise subject to the liabilities of that Section, nor shall it be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release dated February 27, 2017

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

THERAVANCE BIOPHARMA, INC.

Date: February 27, 2017

By: /s/ Renee D. Gala
Renee D. Gala
Senior Vice President and Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated February 27, 2017

Theravance Biopharma, Inc. Reports Fourth Quarter and Full Year 2016 Financial Results and Provides Business Update

Key Program Milestones Anticipated in 2017 and 2018

DUBLIN, Feb. 27, 2017 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today reported financial results for the fourth quarter and full year ended December 31, 2016. Revenue for the fourth quarter and full year of 2016 was \$5.7 million and \$48.6 million, respectively. Full year 2016 operating loss was \$180.5 million. Full year operating loss excluding share-based compensation was \$139.3 million, in line with the Company's previously stated guidance of approximately \$140 million. Cash, cash equivalents, and marketable securities totaled \$592.7 million as of December 31, 2016.

Rick E Winningham, Chairman and Chief Executive Officer, commented: "2016 was a year of significant progress for Theravance Biopharma. We made important clinical gains in multiple programs, including advancements for our JAK inhibitor program in ulcerative colitis and our Phase 3 revefenacin program in COPD, as well as in two of our mid-stage assets – TD-9855 in neurogenic orthostatic hypotension (nOH) and velusetrag in gastroparesis. We continued to focus on executing our commercial and label expansion strategies for VIBATIV[®], and reported positive data from our TOUR[™] study. We significantly strengthened our cash reserve positioning us to drive key programs through important value inflection points.

"We are focused on continuing our momentum from 2016, and we have an extensive line up of milestones anticipated in 2017 and 2018. We believe the programs we are pursuing will provide valuable and differentiated therapeutic options for patients with unmet needs. With our pipeline of proprietary and partnered assets, combined with our economic interest in the GSK closed triple program and strong balance sheet, we believe we are well-positioned to generate significant value for patients and shareholders in the near- and long-term."

Pipeline Update and Recent Highlights

- Intestinally Restricted Pan-Janus Kinase (JAK) Inhibitor Program for Ulcerative Colitis and Other Inflammatory Bowel Diseases:
 - TD-1473: Enrollment underway in a Phase 1b trial in patients with moderate to severe ulcerative colitis, following results of the Phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) studies in healthy volunteers demonstrating favorable tolerability and minimal systemic exposure.
- Advancing Mid-Stage Assets: TD-9855 and Velusetrag
 - TD-9855 (dual norepinephrine and serotonin reuptake inhibitor (NSRI)): Enrollment underway in a Phase 2a study in patients with nOH; the study protocol is being amended to allow patients who respond to continue beyond a single dose.
 - Velusetrag (5-HT4 agonist): Enrollment recently completed in the Phase 2b study in idiopathic and diabetic gastroparesis patients; Fast Track designation granted by US Food and Drug Administration (FDA) in Q4 2016.
- Nepirilysin (NEP) Inhibitor Program for Cardiovascular and Renal Diseases:
 - TD-0714: Results announced from a Phase 1 MAD study in healthy volunteers in Q4 2016. Phase 1 program complete and results supportive of further compound development.
 - TD-1439: Phase 1 SAD study in healthy volunteers completed in Q1 2017. Results support program objectives, with TD-1439 demonstrating sustained 24-hour target engagement, low levels of renal elimination and a favorable tolerability profile.
- Revefenacin (TD-4208) Program: Once-Daily Nebulized Long-Acting Muscarinic Antagonist (LAMA) for Chronic Obstructive Pulmonary Disease (COPD) partnered with Mylan:
 - Results announced in two pivotal three-month Phase 3 efficacy studies in patients with COPD in Q4 2016. Both studies met their primary endpoint, demonstrating statistically significant and clinically meaningful improvements in trough lung function after 12 weeks of dosing revefenacin, both in patients who had no other COPD medications and in those who were also using background COPD treatments (including LABA and LABA/ICS). Revefenacin was also shown to be generally well-tolerated at both doses studied (88 mcg and 175 mcg).
 - Preparing to initiate a Phase 3b study of revefenacin in patients with low peak inspiratory flow rate (PIFR), designed to support commercialization.
- VIBATIV[®] (telavancin):
 - For the full year, U.S. net product sales of VIBATIV increased 100% to \$17.6 million.
 - Enrollment complete in the Telavancin Observational Use Registry (TOUR[™]) study in Q1 2017. Initial data show positive clinical responses in patients with bacteremia, endocarditis, osteomyelitis, skin and respiratory infections.
- Closed Triple (the combination of fluticasone furoate, umeclidinium, and vilanterol)¹:
 - Regulatory filings complete in the US and EU for COPD, and Phase 3 CAPTAIN trial in asthma initiated, all in Q4 2016.

Expected Upcoming Milestones

- TD-1439 (NEP inhibitor): Completion of the Phase 1 MAD study in healthy volunteers in 1H 2017.
- TD-1473 (JAK inhibitor): Data from the Phase 1b study in patients with ulcerative colitis in mid-2017.
- TD-3504 (JAK inhibitor): Initiation of a Phase 1 study expected in 1H 2017.
- Velusetrag (TD-5108): Completion of the Phase 2b study in patients with gastroparesis in mid-2017.
- TD-9855 (NSRI): Data from a Phase 2a study in patients with nOH in 2017.
- Revefenacin (TD-4208): Completion of the 12-month Phase 3 safety study in patients with COPD in mid-2017; potential NDA filing in late 2017; completion of the Phase 3b PIFR study in early 2018; potential regulatory approval in the US for COPD in 2018.
- VIBATIV: TOUR[™] study data to be published throughout 2017; completion of the Phase 3 registrational bacteremia study in 2018, to be followed by potential sNDA submission in the US for bacteremia.
- Closed Triple¹: Completion of the Phase 3 IMPACT study in 2017; potential regulatory approval in the US and EU for COPD in late 2017; Phase 3 CAPTAIN study completion in asthma patients and supplementary regulatory submissions for asthma in 2018.

Notes:

¹ As reported by Glaxo Group Limited or one of its affiliates (GSK)

Fourth Quarter Financial Results

Revenue

Revenue for the fourth quarter of 2016 was \$5.7 million, primarily related to U.S. net product sales of VIBATIV[®] of \$5.0 million. This represents an increase of \$1.9 million over the same period in 2015. Full year 2016 revenue was \$48.6 million, comprised of \$31.0 million in revenue from collaborative arrangements and U.S. net product sales of VIBATIV[®] of \$17.6 million.

Research and Development (R&D) Expenses

R&D expenses for the fourth quarter of 2016 were \$42.0 million representing an increase of \$9.6 million compared to the same period in 2015. The increase is primarily attributed to costs associated with the progression of our priority programs. Full year R&D expenses were \$141.7 million, or \$121.5 million excluding share-based compensation.

Selling, General and Administrative (SG&A) Expenses

SG&A expenses for the fourth quarter were \$20.4 million, representing a decrease of \$3.7 million compared to the same period in 2015. The decrease is driven by lower costs associated with share-based compensation and lower external sales and marketing expenses. Full year SG&A expenses were \$84.5 million, or \$63.5 million excluding shared-based compensation expense.

Cash, Cash Equivalents and Marketable Securities

Cash and cash equivalents, and marketable securities totaled \$592.7 million as of December 31, 2016, an increase of \$377.4 million as compared to December 31, 2015. The increase is primarily due to net proceeds received by the Company related to financing activities completed in 2016, offset by funds used in operations.

2017 Financial Guidance

We expect to fund advancements across all stages of our development pipeline, including investment towards the key program milestones anticipated in 2017 and 2018. We anticipate our full year 2017 operating loss, excluding share-based compensation, will be in the range of \$195.0 to \$205.0 million. The actual amount could be above or below this forecast as a result of a variety of factors impacting our business, including business development transactions, the timing and cost of clinical and non-clinical studies associated with our priority programs, and net product sales of VIBATIV[®].

Conference Call Today at 5:00 pm ET

Theravance Biopharma will hold a conference call today at 5:00 pm ET. To participate in the live call by telephone, please dial (855) 296-9648 from the U.S., or (920) 663-6266 for international callers, using the confirmation code 56971538. 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 March 29, 2017. An audio replay will also be available through 8:00 pm ET on March 6, 2017 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 56971538.

About Theravance Biopharma

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.

Our pipeline of internally discovered product candidates includes potential best-in-class medicines to address the unmet needs of patients being treated for serious conditions primarily in the acute care setting. VIBATIV[®] (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the U.S. Europe and certain other countries for certain difficult-to-treat infections. Revedfenacin (TD-4208) is a long-acting muscarinic antagonist (LAMA) being developed as a potential once-daily, nebulized treatment for chronic obstructive pulmonary disease (COPD). Our neprilysin (NEP) inhibitor program is designed to develop selective NEP inhibitors for the treatment of a range of major cardiovascular and renal diseases, including acute and chronic heart failure, hypertension and chronic kidney diseases, such as diabetic nephropathy. Our research efforts are focused in the areas of inflammation and immunology, with the goal of designing medicines that provide targeted drug delivery to tissues in the lung and gastrointestinal tract in order to maximize patient benefit and minimize risk. The first program to emerge from this research is designed to develop intestinally restricted-targeted pan-Janus kinase (JAK) inhibitors for the treatment of a range of inflammatory intestinal diseases.

In addition, we have an economic interest in future payments that may be made by Glaxo Group Limited or one of its affiliates (GSK) pursuant to its agreements with Innoviva, Inc. relating to certain drug development programs, including the Closed Triple (the combination of fluticasone furoate, umeclidinium, and vilanterol), currently in development for the treatment of COPD and asthma.

For more information, please visit www.theravance.com.

THERAVANCE[®], the Cross/Star logo, and VIBATIV[®] are registered trademarks of the Theravance Biopharma group of companies. 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 timing of clinical studies and the timing of announcement of data or results from clinical studies, the potential 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), product sales and the Company's expectations for its 2017 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 or completing clinical studies, variability in rates of enrollment and associated spending for planned or ongoing clinical studies, the potential that results from clinical and 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), the feasibility of undertaking future clinical trials for our product candidates based on FDA policies and feedback, 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, risks associated with establishing and maintaining sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure, and risks of developing an institutional customer mix for VIBATIV[®] (telavancin) that meet the Company's plan for the product. 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 November 9, 2016. In addition to the risks described above and in Theravance Biopharma filings with the SEC, other unknown or unpredictable factors also could affect Theravance Biopharma's results. No forward-looking statements can be guaranteed as 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 Information:

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

	<u>Three Months Ended December 31,</u>		<u>Year Ended December 31,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
	(Unaudited)		(Unaudited)	(1)
Revenue:				
Product sales	\$ 5,032	\$ 3,693	\$ 17,603	\$ 9,408
Revenue from collaborative arrangements	660	200	31,045	32,718
Total revenue	<u>5,692</u>	<u>3,893</u>	<u>48,648</u>	<u>42,126</u>
Costs and expenses:				
Cost of goods sold	1,146	3,200	2,894	4,657
Research and development (2)	42,013	32,403	141,712	129,165
Selling, general and administrative (2)	20,366	24,064	84,509	90,203
Total costs and expenses	<u>63,526</u>	<u>59,667</u>	<u>229,115</u>	<u>224,025</u>
Loss from operations	(57,834)	(55,774)	(180,467)	(181,899)
Interest expense	(185)	-	(1,404)	-
Interest and other income	(745)	110	1,312	631
Loss before income taxes	(58,764)	(55,664)	(180,559)	(181,268)
Provision for income taxes	8,568	(10,836)	10,110	951
Net loss	<u>\$ (67,332)</u>	<u>\$ (44,828)</u>	<u>\$ (190,669)</u>	<u>\$ (182,219)</u>
Net loss per share:				
Basic and diluted net loss per share	<u>\$ (1.36)</u>	<u>\$ (1.23)</u>	<u>\$ (4.26)</u>	<u>\$ (5.34)</u>
Shares used to compute basic and diluted net loss per share	<u>49,570</u>	<u>36,513</u>	<u>44,711</u>	<u>34,150</u>

(1) The condensed consolidated statement of operations for the year ended December 31, 2015 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, 2015.

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

<u>(In thousands)</u>	<u>Three Months Ended December 31,</u>		<u>Year Ended December 31,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Research and development	\$ 5,150	\$ 5,437	\$ 20,202	\$ 25,770
Selling, general and administrative	4,890	6,074	20,967	28,280
Total share-based compensation expense	<u>\$ 10,040</u>	<u>\$ 11,511</u>	<u>\$ 41,169</u>	<u>\$ 54,050</u>

THERAVANCE BIOPHARMA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

	<u>December 31,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
Assets	(Unaudited)	(1)
Current assets:		
Cash and cash equivalents and short-term marketable securities	\$ 501,096	\$ 172,434
Receivables from collaborative arrangements (2)	9,076	35,232
Prepaid taxes	3,060	12,764
Inventories	12,220	10,005
Other prepaid and current assets	3,051	7,037
Property and equipment, net	8,460	9,873
Long-term marketable securities	91,565	42,860
Restricted cash	833	833
Other assets	9,893	9,078
Total assets	<u>\$ 639,254</u>	<u>\$ 300,116</u>
Liabilities and Shareholders' Equity		
Current liabilities	49,268	49,470
Long-term liabilities	239,755	7,581
Shareholders' equity	350,231	243,065
Total liabilities and shareholders' equity	<u>\$ 639,254</u>	<u>\$ 300,116</u>

(1) The condensed consolidated balance sheet at December 31, 2015 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, 2015.

(2) Receivables from collaborative arrangements includes \$7.8 million and \$33.2 million in receivables associated with the Mylan collaboration at December 31, 2016 and 2015, respectively.