

Theravance Biopharma, Inc.
Form 8-K
February 09, 2018

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 5, 2018**

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

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Ugland House, South Church Street

George Town, Grand Cayman, Cayman Islands KY1-1104

(650) 808-6000

(Addresses, including zip code, and telephone numbers, 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01 Entry into a Material Agreement.

On February 5, 2018, Theravance Biopharma Ireland Limited, an Irish company limited by shares (Theravance Biopharma) and wholly-owned subsidiary of Theravance Biopharma, Inc. (the Company), entered into a License and Collaboration Agreement (the Agreement) with Janssen Biotech, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, (Janssen), in order to establish a collaboration for the development and commercialization of TD-1473 and related back-up compounds for inflammatory intestinal diseases, including ulcerative colitis and Crohn's disease. TD-1473 is a novel, potent, orally administered and intestinally restricted pan-Janus kinase (JAK) inhibitor in clinical development, with the potential to treat a range of inflammatory intestinal diseases.

Under the terms of the Agreement, Theravance Biopharma will receive an upfront payment of \$100 million and will be eligible to receive up to an additional \$900 million in potential payments, if Janssen elects to remain in the collaboration following the completion of certain Phase 2 activities, as described below. Upon such election, Theravance Biopharma together with Janssen will jointly develop and commercialize TD-1473 in inflammatory intestinal diseases, with the two companies sharing profits and losses in the US, as well as development expenses related to a potential Phase 3 program (67% to Janssen; 33% to Theravance Biopharma). In addition, Theravance Biopharma would receive double-digit tiered royalties on ex-US sales.

In 2018, Theravance Biopharma plans to initiate a large, Phase 2b/3 adaptive design induction and maintenance study in ulcerative colitis with TD-1473, as well as a Phase 2 study in Crohn's disease. Following completion of the Phase 2 Crohn's study and the Phase 2b induction portion of the ulcerative colitis study, Janssen can obtain an exclusive license to develop and commercialize TD-1473 and certain related compounds by paying Theravance Biopharma a fee of \$200 million, the closing of which portion of the transaction is also subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act (HSR Act). After Phase 2, Janssen would lead subsequent development of TD-1473 in Crohn's disease if it makes such election. Theravance Biopharma will lead development of TD-1473 in ulcerative colitis through completion of the Phase 2b/3 program. If TD-1473 is commercialized, Theravance Biopharma has the option to co-commercialize in the US, and Janssen would have sole commercialization responsibilities outside the US. Theravance Biopharma would be eligible to receive up to an additional \$700 million in development and commercialization milestone payments.

The foregoing is a summary of the terms of the Agreement and is qualified in its entirety by reference to the Agreement, a copy of which will be filed as an exhibit to a future amendment of this Current Report on Form 8-K or as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending March 31, 2018.

Item 2.02. Results of Operations and Financial Condition.

The information in Item 2.02 of this Current Report on Form 8-K 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.

In connection with a conference call Theravance Biopharma held on February 7, 2018 to discuss the collaboration with Janssen, Theravance Biopharma disclosed that it expects to report approximately \$390 million in cash, cash equivalents and marketable securities as of December 31, 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 9, 2018

By:

/s/ Renee D. Gala

Renee D. Gala

Senior Vice President and Chief Financial Officer