

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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)
December 21, 2019

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
(IRS Employer
Identification No.)

PO Box 309
Ugland House, South Church Street
George Town, Grand Cayman, Cayman Islands KY1-1104
(Address of principal executive offices) (Zip Code)

(650) 808-6000
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Share \$0.00001 Par Value	TBPH	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §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 DEFINITIVE AGREEMENT.

On December 21, 2019, 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 Agreement (the “License Agreement”) with Pfizer Inc. (“Pfizer”). Under the License Agreement, Theravance Biopharma provides Pfizer with a global license for Theravance Biopharma’s preclinical program for skin-targeted, locally-acting pan-Janus kinase (JAK) inhibitors that can be rapidly metabolized. Under the License Agreement, Pfizer will have an exclusive license to develop, manufacture and commercialize certain Company compounds for all uses other than gastrointestinal, ophthalmic and respiratory applications. The License Agreement provides that Theravance Biopharma will receive an upfront cash payment of \$10 million and will be eligible to receive up to an additional \$240 million in development and sales milestone payments from Pfizer. In addition, Theravance Biopharma will be eligible to receive a tiered marginal royalty on worldwide net sales of any potential products under the license at percentage royalty rates ranging from mid single-digits to low double-digits.

The foregoing is a summary of the terms of the License Agreement and is qualified in its entirety by reference to the License Agreement, a copy of which will be filed as an exhibit to the Company’s Annual Report on Form 10-K for the year ending December 31, 2019.

ITEM 8.01. OTHER EVENTS.

On December 23, 2019, the Company issued a press release announcing the License Agreement with Pfizer. A copy of the Company’s press release is attached hereto as exhibit 99.1.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits.

[99.1 Press Release dated December 23, 2019 titled, “Pfizer and Theravance Biopharma Enter Global License Agreement for Skin-Targeted, Locally-Acting Pan-Janus Kinase \(JAK\) Inhibitor Program”](#)

104 Cover Page Interactive Data File (cover page XBRL tags embedded within the Inline XBRL document)

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.

By: _____
/s/ Andrew Hindman
Andrew Hindman
Senior Vice President and Chief Financial Officer

Date: December 26, 2019



Theravance Biopharma and Pfizer Inc. Enter Global License Agreement for Skin-Targeted, Locally-Acting Pan-Janus Kinase (JAK) Inhibitor Program

Topically-Applied, Skin-Selective Pan-JAK Inhibitors Specifically Designed to Target Pro-Inflammatory Pathways with Minimal Systemic Exposure

DUBLIN, IRELAND AND NEW YORK – December 23, 2019 – Theravance Biopharma Ireland Limited, a subsidiary of Theravance Biopharma, Inc. (NASDAQ: TBPH) (“Theravance Biopharma”) and Pfizer Inc. (NYSE: PFE) (“Pfizer”) today announced that the companies have entered into a global license agreement for Theravance Biopharma’s preclinical program for skin-targeted, locally-acting pan-Janus kinase (JAK) inhibitors that can be rapidly metabolized. The compounds in this program target validated pro-inflammatory pathways and are specifically designed to possess skin-selective activity with minimal systemic exposure.

Under the terms of the agreement, Theravance Biopharma will receive an upfront cash payment of \$10 million and will be eligible to receive up to an additional \$240 million in development and sales milestone payments from Pfizer. In addition, Theravance Biopharma will be eligible to receive royalties on worldwide net sales of any potential products emerging from the program.

“We believe that this global agreement with Pfizer provides further validation of our unique expertise in the discovery and development of innovative, organ-selective JAK inhibitors. As a clear global leader in the field of JAK inhibition, Pfizer is ideally positioned to advance this program and unlock its therapeutic potential,” said Rick E Winningham, chief executive officer of Theravance Biopharma.

“Theravance Biopharma’s skin-targeted JAK inhibitor program will nicely complement Pfizer’s portfolio of preclinical and clinical-stage molecules, which have unique selectivity profiles and are matched to conditions in which we believe they have the greatest potential to address unmet need,” said Michael Vincent, chief scientific officer, Inflammation & Immunology, Pfizer. “Topical JAK inhibitors that can be rapidly metabolized have potential to reach more patients with mild-to-moderate skin conditions, for whom treatment is currently limited.”

About Organ-Selective Pan-Janus (JAK) Kinase Inhibition

JAK inhibitors function by inhibiting the activity of one or more of the Janus kinase family of enzymes (JAK1, JAK2, JAK3, TYK2) that play a key role in cytokine signaling. Inhibiting these JAK enzymes interferes with the JAK/STAT signaling pathway and, in turn, modulates the activity of a wide range of pro-inflammatory cytokines. JAK inhibitors are currently approved for the treatment of a range of inflammatory diseases including rheumatoid arthritis, psoriatic arthritis, myelofibrosis, and ulcerative colitis.

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.

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This press release contains "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 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 described under the heading "Risk Factors" contained in Theravance Biopharma's Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 8, 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.

Pfizer Inc.: Breakthroughs that Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, YouTube and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

PFIZER DISCLOSURE NOTICE: *The information contained in this release is as of December 23, 2019. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.*

This release contains forward-looking information about a global license agreement between Pfizer and Theravance Biopharma, and Theravance Biopharma's program for skin-targeted, locally-acting pan-Janus kinase (JAK) inhibitors that can be rapidly metabolized, including its potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in any jurisdictions for any of the product candidates with Theravance Biopharma's JAK inhibitors; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether any of the product candidates with Theravance Biopharma's JAK inhibitors will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of any of the product candidates with Theravance Biopharma's JAK inhibitors; and competitive developments. A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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