# 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): **October 25, 2016**

# THERAVANCE BIOPHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

| **Cayman Islands** | **001-36033** | **98-1226628** |
|---|---|---|
| (State or Other Jurisdiction of Incorporation) | (Commission File Number) | (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 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))

**Item 8.01. Other Events.**

*The following information in this Item 8.01 of this Current Report on Form 8-K, including Exhibit 99.1, is being "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934.*

On October 25, 2016, Theravance Biopharma, Inc. (the "Company") issued a press release announcing positive results, including biomarker data, from its Phase 1 multiple-ascending dose clinical trial of TD-0714, the lead molecule in the Company's neprilysin (NEP) inhibitor program for the treatment of a range of major cardiovascular and renal diseases. A copy of the press release is filed as Exhibit 99.1 hereto and incorporated by reference into this Current Report on Form 8-K.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

99.1 Press Release Dated October 25, 2016

**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: October 25, 2016

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

**EXHIBIT INDEX**

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press Release Dated October 25, 2016 |

**Exhibit 99.1**

**Theravance Biopharma Announces Positive Results Including Biomarker Data from Phase 1 Multiple-Ascending Dose Study of TD-0714, an Inhibitor of Neprilysin (NEP)**

*Study Findings Consistent with Single-Ascending Dose (SAD) Data, Demonstrating Sustained Target Engagement, Low Levels of Renal Elimination, Favorable Safety and Tolerability Profile*

**DUBLIN, IRELAND — October 25, 2016** — Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today announced positive results, including biomarker data, from its Phase 1 multiple-ascending dose (MAD) clinical trial of TD-0714, the lead molecule in the Company's neprilysin (NEP) inhibitor program for the treatment of a range of major cardiovascular and renal diseases. The trial in healthy adult (50, 100, 200 mg and 10 mg) and elderly (100 mg) volunteers was designed to assess the safety, tolerability, and pharmacokinetics (PK) of TD-0714 administered once daily for 14 days, as well as to measure biomarker evidence of target engagement and the amount of the drug that is eliminated via the kidneys.

Study results were consistent with data from the Company's previously completed single-ascending dose (SAD) trial of TD-0714, which showed robust and sustained inhibition of the NEP target over a 24-hour period. The biological effect was demonstrated by dose-related increases in the levels of cyclic GMP (a well-precedented biomarker of NEP target engagement). The 50 mg, 100 mg and 200 mg doses (including the elderly cohort) produced maximal increases, while 10 mg was sub-maximal, thereby providing a more complete assessment of the dose response for cGMP target engagement for TD-0714. Theravance Biopharma believes that these findings showing the sustained nature of the drug's biological activity support the potential for once-daily dosing with TD-0714.

This trial also confirmed the low levels of renal elimination for TD-0714 reported in the SAD study, which showed that less than one percent of the total TD-0714 dose was eliminated through the kidneys.

All doses in the study were generally well-tolerated and no serious adverse events were reported at any dose in the study. One subject in the 10 mg dose group had a transient increase in certain liver function enzymes, and this subject's dosing was discontinued as a precaution. The same subject was subsequently re-dosed with 10 mg once daily for the full 14 days with no changes in liver enzymes, suggesting that factors other than treatment with TD-0714 were likely implicated in the initial findings. The subject remained asymptomatic during both dosing periods. There were no clinically relevant changes seen in any laboratory measures (including liver function enzymes) in any other subjects in the study.

“Consistent with our previously reported SAD data, these MAD study results met our target product profile for TD-0714. We are encouraged by the sustained levels of NEP inhibition after repeat dosing, which continues to build clinical support for the drug’s potential for once-daily dosing. We have also confirmed that TD-0714 is not dependent on the kidney for its elimination, suggesting that dose adjustment may not be needed in patients with low or variable renal function and differentiating TD-0714 from current NEP-inhibitor-based therapy which is cleared by the kidneys and requires dose adjustment in these patients,” said Brett Haumann, MD, Chief Medical Officer at Theravance Biopharma. “An additional potential advantage for TD-0714 is the flexibility that we believe it may provide in combination with other important treatments, including angiotensin receptor blockers and therapies with complimentary mechanisms of action. This product attribute also has the potential of increasing the number and type of patients that may be appropriate for treatment with TD-0714. These include patients with acute decompensated heart failure, for whom an IV NEP inhibitor may be beneficial. As a result, we expect to progress the IV formulation of TD-0714 into a Phase 1 study in the first half of 2017.”

***About the Multiple-Ascending Dose Study***

The Phase 1 clinical trial of TD-0714 was a randomized, double-blind, placebo-controlled, multiple-ascending dose study. The study investigated the safety and tolerability, pharmacokinetics, and pharmacodynamics (as defined by biomarker target engagement) of oral doses of TD-0714 (50, 100, 200 and 10 mg) administered once-daily for 14 days in 50 healthy adult and elderly volunteers. The study was designed to allow for the addition of the 10 mg dose group to characterize the bottom of the dose response curve for target engagement, once it had been confirmed that the 50, 100 and 200 mg doses produced maximal responses.

***About Neprilysin (NEP) Inhibition***

Neprilysin (NEP) is an enzyme that degrades natriuretic peptides. These peptides exert protective cardiac and renal effects including vasodilation, diuresis, natriuresis, reversal of maladaptive changes in heart, blood vessels and kidney, prevention of fibrosis, and prevention of end-organ damages. By elevating levels of natriuretic peptides, NEP inhibitors may have the potential to treat a range of major cardiovascular and renal diseases, including acute and chronic heart failure and chronic kidney disease. Roughly 26 million Americans suffer from chronic kidney disease, including diabetic nephropathy. In the U.S. alone, there are six million patients diagnosed with chronic heart failure and approximately one million hospitalizations annually for acute heart failure.(1)

***About Theravance Biopharma***

Theravance Biopharma is a diversified biopharmaceutical company with the core purpose of creating medicines that make a difference in 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. Revefenacin (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 intestinal tract in order to maximize patient benefit and minimize risk. The first program to emerge from this research is designed to develop intestinally restricted 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.



*This press release contains 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, 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) and the company's expectations for product sales. 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: delays or difficulties in commencing or completing clinical studies, the potential that results from clinical or 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 and commercialize product and product candidates, 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 August 9, 2016 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.*

**References:**



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