THERAVANCE INC
Form 8-K
September 24, 2015

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): **September 24, 2015**

THERAVANCE, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**000-30319**	**94-3265960**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

951 Gateway Boulevard
South San Francisco, California 94080

(650) 238-9600

(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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. **Other Events.**

On September 24, 2015, GlaxoSmithKline plc (GSK) and Theravance, Inc. issued a press release announcing the intention to file a supplemental Japanese New Drug Application (sJNDA) for Relvar® Ellipta® (fluticasone furoate FF /vilanterol VI or FF/VI) for the treatment of chronic obstructive pulmonary disease (COPD) with the Japanese regulatory authority during the first quarter of 2016. This decision follows results from Study 200820, a global phase III efficacy and safety study designed to provide additional data for the combination FF/VI in Japanese patients with COPD. The study which included 1,620 patients with COPD, of whom 370 were from Japan, showed that patients who received FF/VI 100/25mcg achieved a statistically significant improvement in lung function (as measured by change from baseline in trough FEV1) compared with VI 25mcg at 12 weeks (p=0.001).

FF/VI is not currently indicated for the treatment of COPD in Japan. FF/VI was approved by the Japanese Ministry of Health, Labor and Welfare for the regular treatment of asthma in patients aged 15 and over in September 2013. Relvar® Ellipta® has been developed under the 2002 LABA collaboration agreement between Glaxo Group Limited and Theravance, Inc.

The press release is filed as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated September 24, 2015.

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, INC.

Date: September 24, 2015	By:	/s/ Eric d Esparbes Eric d Esparbes Chief Financial Officer