THERAVANCE INC
Form 8-K
September 08, 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 8, 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 8, 2015, GlaxoSmithKline plc (GSK) and Theravance, Inc. distributed a press release announcing initial data from the **S**tudy to **U**nderstand **M**ortality and **M**orbid**IT**y (SUMMIT) survival study of RELVAR®/BREO® ELLIPTA® 100/25mcg (fluticasone furoate/vilanterol or FF/VI). The aim of the study was to prospectively evaluate the effect of FF/VI 100/25mcg compared with the placebo on survival in chronic obstructive pulmonary disease (COPD) patients with moderate airflow limitation and a history or risk of cardiovascular disease (CVD).

SUMMIT showed that for the primary end point of the study, the risk of dying was 12.2% lower in patients taking FF/VI 100/25mcg versus placebo however this was not statistically significant (p=0.137). Results from the two secondary endpoints, showed that FF/VI 100/25mcg reduced the rate of lung function decline in FEVI (forced expiratory volume in one second) by 8mL per year compared with placebo (p=0.019) and also reduced the risk of on-treatment cardiovascular (CV) event (CV death, myocardial infarction, stroke, unstable angina and transient ischemic attack) at any time in the same patient population by 7.4% versus placebo (p=0.475). As the primary endpoint was not met, statistical significance cannot be inferred from these results.

FF/VI has been developed under the 2002 Long-Acting Beta 2 Agonist (LABA) collaboration between Glaxo Group Limited and Theravance, Inc. FF/VI 100/25mcg, under the brand name RELVAR® ELLIPTA®, is approved in Europe for the symptomatic treatment of adults with COPD with a FEV1<70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy. In the United States, FF/VI 100/25mcg, under the brand name BREO® ELLIPTA®, is indicated for long-term, once-daily, maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema and to reduce exacerbations of COPD in patients with a history of exacerbations.

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 8, 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 8, 2015	By:	/s/ Eric d Esparbes Eric d Esparbes Chief Financial Officer