

THERAVANCE INC  
Form 8-K  
September 08, 2015

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

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**FORM 8-K**

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**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**

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**THERAVANCE, INC.**

(Exact Name of Registrant as Specified in its Charter)

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**Delaware**  
(State or Other Jurisdiction of  
Incorporation)

**000-30319**  
(Commission File Number)

**94-3265960**  
(I.R.S. Employer Identification  
Number)

**951 Gateway Boulevard**  
**South San Francisco, California 94080**

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(650) 238-9600

(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

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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))
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**Item 8.01. Other Events.**

On September 8, 2015, GlaxoSmithKline plc (GSK) and Theravance, Inc. distributed a press release announcing initial data from the Study to Understand Mortality and Morbidity (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 FEV1 (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