

THERAVANCE INC
Form 8-K
April 30, 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): **April 30, 2015**

THERAVANCE, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

000-30319
(Commission File Number)

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

951 Gateway Boulevard

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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):

- 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))
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Item 8.01. Other Events.

On April 30, 2015, GlaxoSmithKline plc. and Theravance, Inc. issued a press release announcing that the U.S. Food and Drug Administration (FDA) has approved BREO® ELLIPTA® (fluticasone furoate/vilanterol [FF/VI]) as a once-daily inhaled treatment for asthma in patients aged 18 years and older. In addition, the FDA issued a complete response letter related to the proposed use of BREO® ELLIPTA® in patients aged 12-17 stating that the data submitted do not show adequate risk benefit to support the approval in these patients. BREO® is a fixed-dosed combination of the inhaled corticosteroid fluticasone furoate (FF) and the long-acting beta2-agonist vilanterol (VI). Two strengths have been approved in the U.S. for use in asthma, 100/25mcg and 200/25mcg and will be administered once-daily using the ELLIPTA® dry powder inhaler.

For more information about the FDA approval and the complete response letter, please see the press release attached as Exhibit 99.1 to this Current Report on Form 8-K which is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated April 30, 2015.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

THERAVANCE, INC.

Date: April 30, 2015

By:

/s/ Eric d Esparbes

Eric d Esparbes

Vice President and Chief Financial Officer