THERAVANCE INC
Form 8-K
September 26, 2012

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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 26, 2012

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)

901 Gateway Boulevard
South San Francisco, California 94080
(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.

On September 26, 2012, GlaxoSmithKline plc (GSK) and Theravance, Inc. (the "Company") issued a press release announcing that the New Drug Application (NDA) for the once-daily investigational medicine fluticasone furoate "FF"/vilanterol "VI" (FF/VI) for patients with chronic obstructive pulmonary disease (COPD), has been accepted by the U.S. Food and Drug Administration (FDA) indicating that the application is sufficiently complete to permit a substantive review. The Prescription Drug User Fee Act (PDUFA) goal date has also been confirmed as May 12, 2013. GSK and Theravance also announced that the Marketing Authorization Application (MAA) for FF/VI for COPD and asthma has been validated by the European Medicines Agency (EMA). GSK also submitted a Japanese New Drug Application (JNDA) for FF/VI for patients with COPD and asthma on September 25, 2012. FF/VI is administered by a new dry powder inhaler called Ellipta™. FF/VI has the proposed brand name Relvar™ in Europe and Japan and Breo™ in the U.S. FF/VI is currently in development under the LABA collaboration between GSK and the Company. A copy of 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

Exhibit	Description
Exhibit 99.1	Press Release Dated September 26, 2012

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 26, 2012

/s/ Michael W. Aguiar
Michael W. Aguiar
Chief Financial Officer

EXHIBIT INDEX

Exhibit	Description
Exhibit 99.1	Press Release Dated September 26, 2012