THERAVANCE INC
Form 8-K
February 19, 2013

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: February 19, 2013
(Date of earliest event reported)

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
(IRS Employer
Identification Number)
901 Gateway Boulevard, South San Francisco, CA
(Address of principal executive offices) 94080
(Zip Code)
650-808-6000
(Registrant's telephone number, including area code)
Not Applicable
(Former Name or Former Address, if changed since last report)

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:

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 February 19, 2013, GlaxoSmithKline plc (GSK) and Theravance, Inc. (Company) issued a press release announcing that the New Drug Application (NDA) for the investigational once-daily LAMA/LABA combination medicine, UMEC/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 December 18, 2013. GSK and Theravance also announced that the Marketing Authorization Application (MAA) for UMEC/VI for COPD has been validated for assessment by the European Medicines Agency (EMA). UMEC/VI, with proposed brand name ANORO(TM), is a combination of two investigational bronchodilator molecules - GSK573719 or umeclidinium bromide (UMEC), a long-acting muscarinic antagonist (LAMA) and vilanterol (VI), a long-acting beta2 agonist (LABA), administered using the ELLIPTA(TM) inhaler. UMEC/VI is 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

99.1 Press Release of Theravance, Inc. dated February 19, 2013

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.

Dated: February 19, 2013
THERAVANCE, INC.

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

Exhibit Index **Exhibit No.** **Description** 99.1 Press Release of Theravance, Inc. dated February 19, 2013