

THERAVANCE INC
Form 8-K
November 13, 2013

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): **November 13, 2013**

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)

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**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))
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Item 8.01 Other Events.

On November 13, 2013 at the 18th Congress of the Asian Pacific Society of Respiriology, Yokohama, Japan, GlaxoSmithKline plc (GSK) presented an oral presentation on a Phase 3 study of the once-daily treatment combination of fluticasone furoate (FF), an inhaled corticosteroid, and vilanterol (VI), a long-acting beta2 agonist, in Asian patients with chronic obstructive pulmonary disease (COPD). In addition, GSK presented a poster on an ethnic sensitivity assessment of FF/VI in asthma patients in Japan and Korea. In September 2013, the Japanese Ministry of Health, Labour and Welfare (MHLW) approved FF/VI for the treatment of bronchial asthma (in cases where concurrent use of inhaled corticosteroid and long-acting inhaled beta2 agonist is required). FF/VI is not indicated for the treatment of COPD in Japan. The MHLW has approved two doses of FF/VI - 100/25 mcg and 200/25 mcg. Both strengths will be administered once-daily using the ELLIPTA, a new dry powder inhaler. RELVAR® ELLIPTA is the trade name in Japan. FF/VI remains in development elsewhere in the world for the maintenance treatment of asthma and COPD, with pending marketing authorization applications in a number of countries. FF/VI for the treatment of COPD is approved in the United States and Canada. FF/VI is not indicated for the relief of acute bronchospasm or the treatment of asthma in the United States or Canada. FF/VI is not approved or licensed anywhere outside of the United States, Japan and Canada. FF/VI is in development under the LABA collaboration agreement between Glaxo Group Limited and Theravance, Inc. The slide presentation and poster are filed as Exhibit 99.1 and 99.2 to this report and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
Exhibit 99.1	The efficacy and safety of inhaled fluticasone furoate (FF)/vilanterol (VI) in Asian patients with COPD
Exhibit 99.2	Ethnic sensitivity assessment of fluticasone furoate (FF)/vilanterol (VI) in asthma patients in Japan and Korea: a pre-specified subgroup analysis

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: November 13, 2013

By:

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

EXHIBIT INDEX

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