THERAVANCE INC
Form 8-K
November 12, 2013

# 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): **November 12, 2013**

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# THERAVANCE, INC.

(Exact Name of Registrant as Specified in its Charter)

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| **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)

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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))

**Item 8.01 Other Events.**

On November 12, 2013 at the 18th Congress of the Asian Pacific Society of Respirology, Yokohama, Japan, GlaxoSmithKline plc ( GSK ) presented a poster 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, (FF/VI 200/25 mcg) in asthma patients of Asian ancestry. 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 chronic obstructive pulmonary disease (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 poster 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 | Efficacy and safety of once-daily fluticasone furoate/vilanterol 200/25mcg compared with twice-daily fluticasone propionate 500mcg in asthma patients of Asian ancestry |

**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 12, 2013

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

**EXHIBIT INDEX**

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