THERAVANCE INC
Form 8-K
September 09, 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): **September 8, 2013**

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):

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 September 8, 2013 at the European Respiratory Society (ERS) Annual Congress 2013 in Barcelona, Spain, GlaxoSmithKline (GSK) presented posters containing information from Phase 3 studies of umeclidinium/vilanterol (UMEC/VI) in chronic obstructive pulmonary disease (COPD). UMEC/VI is a combination of two investigational bronchodilator molecules - GSK573719 or umeclidinium, a long-acting muscarinic antagonist (LAMA) and vilanterol (VI), a long-acting beta2 agonist (LABA), administered using the ELLIPTA inhaler. UMEC/VI is under regulatory review by the U.S. Food and Drug Administration (FDA), European Medicines Agency and the Japanese Ministry of Health, Labor and Welfare. Marketing applications for UMEC/VI have been submitted to regulatory authorities in a number of other countries worldwide.

In addition, GSK presented data on ELLIPTA from Phase 3 asthma studies of FF/VI, the treatment combination of fluticasone furoate (FF), an inhaled corticosteroid, and VI, and FF monotherapy. FF/VI, known in the United States as BREO ELLIPTA (100/25mcg), is approved by the FDA as an inhaled long-term, once-daily maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. It is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations. It is not indicated for the relief of acute bronchospasm or the treatment of asthma. FF/VI is not currently approved or licensed in the European Union or anywhere outside of the U.S. and Canada.

GSK also presented a poster containing information from a Phase 2 study of GSK961081 in patients with COPD. GSK961081 (081) is an investigational, single molecule bifunctional bronchodilator with both muscarinic antagonist and beta2 receptor agonist activities.

UMEC/VI and FF/VI are in development under the LABA collaboration agreement between Glaxo Group Limited and Theravance, Inc. 081 is in development under the strategic alliance between Glaxo Group Limited and Theravance, Inc.

The posters are filed as Exhibits 99.1 to 99.4 to this report and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
Exhibit 99.1	Long-term safety and tolerability of umeclidinium/vilanterol and umeclidinium in COPD
Exhibit 99.2	Effects of a combination of vilanterol and umeclidinium on exercise endurance in subjects with COPD: two randomised clinical trials
Exhibit 99.3	Ease of use of a two-strip dry powder inhaler (DPI) to deliver fluticasone furoate/vilanterol (FF/VI) and FF alone in asthma
Exhibit 99.4	

Population pharmacokinetics and pharmacodynamics of GSK961081 (MABA) in patients with moderate to severe COPD

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 8, 2013

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

EXHIBIT INDEX

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99.4	Population pharmacokinetics and pharmacodynamics of GSK961081 (MABA) in patients with moderate to severe COPD