

THERAVANCE INC
Form 8-K
September 08, 2014

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 7, 2014**

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)

Edgar Filing: THERAVANCE INC - Form 8-K

**951 Gateway Boulevard
South San Francisco, California 94080**

(650) 238-9600

(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 7, 2014 at the European Respiratory Society (ERS) Annual Congress, Munich, Germany, GlaxoSmithKline plc (GSK) presented posters containing information from Phase 3 studies of umeclidinium/vilanterol (UMEC/VI) and Phase 1 studies of the closed triple combination fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI). ANORO® ELLIPTA® is a once-daily combination treatment comprising two bronchodilators, UMEC, a long-acting muscarinic antagonist (LAMA), and VI, a long-acting beta2 agonist (LABA), in a single inhaler, the ELLIPTA®. FF/UMEC/VI is being investigated as a once-daily closed triple combination treatment of an inhaled corticosteroid, a LAMA and a LABA in patients with COPD. A Phase 3 study of FF/UMEC/VI is currently ongoing. FF/UMEC/VI is not approved anywhere in the world. UMEC/VI has been developed and UMEC/FF/VI is being developed under the 2002 LABA collaboration between Glaxo Group Limited and Theravance, Inc. The posters are filed as Exhibits 99.1 to 99.5 to this report and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
Exhibit 99.1	Umeclidinium/vilanterol (UMEC/VI) once daily (OD) vs fluticasone/salmeterol combination (FSC) twice daily (BD) in patients with moderate-to-severe COPD and infrequent COPD exacerbations
Exhibit 99.2	Evaluating lung function response to umeclidinium/vilanterol (UMEC/VI) 62.5/25mcg, UMEC 62.5mcg and VI 25mcg in COPD patients
Exhibit 99.3	Effect of the once-daily long-acting bronchodilator combination umeclidinium/vilanterol (UMEC/VI) and bronchodilator monotherapy on dyspnoea as measured by the transitional dyspnoea index (TDI) in COPD
Exhibit 99.4	Pharmacokinetic (PK) analysis of fluticasone furoate (FF), umeclidinium (UMEC) and vilanterol (VI) following triple therapy in healthy subjects
Exhibit 99.5	Pharmacokinetic (PK) analysis of fluticasone furoate (FF), umeclidinium (UMEC) and vilanterol (VI) following triple therapy at two UMEC doses in healthy subjects

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 7, 2014

By:

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Umeclidinium/vilanterol (UMEC/VI) once daily (OD) vs fluticasone/salmeterol combination (FSC) twice daily (BD) in patients with moderate-to-severe COPD and infrequent COPD exacerbations
99.2	Evaluating lung function response to umeclidinium/vilanterol (UMEC/VI) 62.5/25mcg, UMEC 62.5mcg and VI 25mcg in COPD patients
99.3	Effect of the once-daily long-acting bronchodilator combination umeclidinium/vilanterol (UMEC/VI) and bronchodilator monotherapy on dyspnoea as measured by the transitional dyspnoea index (TDI) in COPD
99.4	Pharmacokinetic (PK) analysis of fluticasone furoate (FF), umeclidinium (UMEC) and vilanterol (VI) following triple therapy in healthy subjects
99.5	Pharmacokinetic (PK) analysis of fluticasone furoate (FF), umeclidinium (UMEC) and vilanterol (VI) following triple therapy at two UMEC doses in healthy subjects