

THERAVANCE INC
Form 8-K
September 04, 2012

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 3, 2012**

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)

901 Gateway Boulevard
South San Francisco, California 94080

Edgar Filing: THERAVANCE INC - Form 8-K

(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))
-

Item 8.01 Other Events.

On September 3, 2012 at the European Respiratory Society (ERS) Annual Congress 2012 in Vienna, Austria, GlaxoSmithKline (GSK) presented posters containing information from Phase 2 and Phase 3 studies of the combination treatment fluticasone furoate/vilanterol (FF/VI) and its component, FF, and from the Phase 2b study of umeclidinium bromide (UMEC). FF/VI, with proposed brand names of Relvar and Breo, is an investigational once-daily inhaled corticosteroid (ICS)/long-acting beta-agonist (LABA) combination treatment for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD) and patients with asthma. UMEC, a long-acting muscarinic antagonist (LAMA), combined with VI, a LABA, is a once-daily investigational medicine for the maintenance treatment of patients with COPD. FF/VI and UMEC/VI are in development under the LABA collaboration agreement between GSK and the Theravance, Inc. (the Company). The Company also presented a poster containing information on a Phase 2a study of TD-4208, its internally-discovered investigational LAMA for the treatment of COPD. The posters are filed as Exhibits 99.1 to 99.16 to this report and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
Exhibit 99.1	Efficacy of the novel inhaled corticosteroid, fluticasone furoate (FF)/long-acting beta2-agonist vilanterol (VI) combination in reducing COPD exacerbations
Exhibit 99.2	Safety of fluticasone furoate (FF), an inhaled corticosteroid in combination with vilanterol (VI), a long-acting beta agonist in management of COPD exacerbations
Exhibit 99.3	Lung function effects and safety of fluticasone furoate (FF)/vilanterol (VI) in patients with COPD: mid-high dose assessment
Exhibit 99.4	Efficacy of combination fluticasone furoate/vilanterol (FF/VI) and salmeterol/fluticasone propionate (SFC) over 12 weeks in patients with COPD
Exhibit 99.5	Effect of fluticasone furoate (FF)/vilanterol (VI) once daily on risk of severe exacerbations in asthma
Exhibit 99.6	Efficacy and safety of fluticasone furoate/vilanterol (FF/VI) once-daily for 24 weeks in persistent asthma
Exhibit 99.7	Efficacy and safety of fluticasone furoate (FF)/vilanterol (VI) compared with fluticasone propionate/salmeterol combination (FP/SAL) in adults and adolescents with persistent asthma

Edgar Filing: THERAVANCE INC - Form 8-K

- Exhibit 99.8 Efficacy of fluticasone furoate (FF) as a monotherapy and in combination with vilanterol (VI) over 12 weeks in patients with persistent asthma
- Exhibit 99.9 Safety and tolerability of the novel inhaled corticosteroid (ICS) fluticasone furoate (FF) in combination with the long-acting beta2 agonist (LABA) vilanterol (VI) administered once daily in patients with asthma
- Exhibit 99.10 Efficacy and safety of once-daily fluticasone furoate (FF) in patients with persistent asthma: a 24-week randomised trial
- Exhibit 99.11 The pharmacokinetics (PK) and pharmacodynamics (PD) of the fluticasone furoate (FF) and vilanterol (VI) combination in subjects with severe renal impairment
- Exhibit 99.12 The pharmacokinetics (PK) and pharmacodynamics (PD) of the fluticasone furoate (FF) and vilanterol (VI) combination in subjects with hepatic impairment
- Exhibit 99.13 The efficacy of inhaled fluticasone furoate (FF) and vilanterol (VI) administered in combination in asthma is comparable when administered in the morning or evening
- Exhibit 99.14 Efficacy of fluticasone furoate (FF) and vilanterol (VI), separately and in combination (FF/VI), in an allergen challenge model
- Exhibit 99.15 Umeclidinium (GSK573719) dose response and dosing interval in COPD
- Exhibit 99.16 A Randomized, Crossover Study to Examine the Pharmacodynamics and Safety of a New Antimuscarinic TD-4208 in Patients with 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 4, 2012

By:

/s/ Michael W. Aguiar

Michael W. Aguiar
Chief Financial Officer

EXHIBIT INDEX

Exhibit	Description
Exhibit 99.1	Efficacy of the novel inhaled corticosteroid, fluticasone furoate (FF)/long-acting beta2-agonist vilanterol (VI) combination in reducing COPD exacerbations
Exhibit 99.2	Safety of fluticasone furoate (FF), an inhaled corticosteroid in combination with vilanterol (VI), a long-acting beta agonist in management of COPD exacerbations
Exhibit 99.3	Lung function effects and safety of fluticasone furoate (FF)/vilanterol (VI) in patients with COPD: mid-high dose assessment
Exhibit 99.4	Efficacy of combination fluticasone furoate/vilanterol (FF/VI) and salmeterol/fluticasone propionate (SFC) over 12 weeks in patients with COPD
Exhibit 99.5	Effect of fluticasone furoate (FF)/vilanterol (VI) once daily on risk of severe exacerbations in asthma
Exhibit 99.6	Efficacy and safety of fluticasone furoate/vilanterol (FF/VI) once-daily for 24 weeks in persistent asthma
Exhibit 99.7	Efficacy and safety of fluticasone furoate (FF)/vilanterol (VI) compared with fluticasone propionate/salmeterol combination (FP/SAL) in adults and adolescents with persistent asthma
Exhibit 99.8	Efficacy of fluticasone furoate (FF) as a monotherapy and in combination with vilanterol (VI) over 12 weeks in patients with persistent asthma
Exhibit 99.9	Safety and tolerability of the novel inhaled corticosteroid (ICS) fluticasone furoate (FF) in combination with the long-acting beta2 agonist (LABA) vilanterol (VI) administered once daily in patients with asthma
Exhibit 99.10	Efficacy and safety of once-daily fluticasone furoate (FF) in patients with persistent asthma: a 24-week randomised trial
Exhibit 99.11	The pharmacokinetics (PK) and pharmacodynamics (PD) of the fluticasone furoate (FF) and vilanterol (VI) combination in subjects with severe renal impairment
Exhibit 99.12	The pharmacokinetics (PK) and pharmacodynamics (PD) of the fluticasone furoate (FF) and vilanterol (VI) combination in subjects with hepatic impairment

Edgar Filing: THERAVANCE INC - Form 8-K

- Exhibit 99.13 The efficacy of inhaled fluticasone furoate (FF) and vilanterol (VI) administered in combination in asthma is comparable when administered in the morning or evening
- Exhibit 99.14 Efficacy of fluticasone furoate (FF) and vilanterol (VI), separately and in combination (FF/VI), in an allergen challenge model
- Exhibit 99.15 Umeclidinium (GSK573719) dose response and dosing interval in COPD
- Exhibit 99.16 A Randomized, Crossover Study to Examine the Pharmacodynamics and Safety of a New Antimuscarinic TD-4208 in Patients with COPD