

THERAVANCE INC  
Form 8-K  
September 04, 2012

**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): **September 3, 2012**

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**THERAVANCE, INC.**

(Exact Name of Registrant as Specified in its Charter)

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**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**

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(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):

- 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 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 |

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- 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**

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