

**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): **May 17, 2011**

**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  
(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.**

Today at the American Thoracic Society International Conference in Denver, Colorado, GlaxoSmithKline plc presented a poster presentation on a Phase 2b study: Dose-Related Efficacy and Optimal Once-Daily Dosing Interval of the Long-Acting Beta<sub>2</sub> Agonist (LABA), Vilanterol Trifenatate (VI), in Adults with Persistent Asthma. VI is the LABA in RELOVAIR™. RELOVAIR™ is an investigational product being developed under the LABA collaboration between GSK and Theravance, Inc. as a once-daily medicine that combines Fluticasone Furoate, and the LABA VI for the treatment of patients with chronic obstructive pulmonary disease or asthma. The poster presentation is filed as Exhibit 99.1 to this report and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit</u>	<u>Description</u>
Exhibit 99.1	Dose-Related Efficacy and Optimal Once-Daily Dosing Interval of the Long-Acting Beta <sub>2</sub> Agonist (LABA), Vilanterol Trifenatate (VI), in Adults with Persistent Asthma

**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: May 17, 2011

By: /s/ Michael W. Aguiar

**Michael W. Aguiar**  
**Chief Financial Officer**

3

---

**EXHIBIT INDEX**

<u>Exhibit</u>	<u>Description</u>
Exhibit 99.1	Dose-Related Efficacy and Optimal Once-Daily Dosing Interval of the Long-Acting Beta <sub>2</sub> Agonist (LABA), Vilanterol Trifenatate (VI), in Adults with Persistent Asthma

4

---

Poster No. C81

**Dose-related efficacy and optimal once-daily dosing interval of the long-acting beta<sub>2</sub> agonist (LABA), vilanterol trifenatate (VI), in adults with persistent asthma**

*Sterling R,(1) Lim J,(2) Frith L,(2) Snowise NG,(2)  
Jacques L,(2) Haumann B(2)*

*(1)Carolina Research, Respiratory Medicine, Orangeburg, SC, USA;  
(2)Respiratory Medicines Development Centre, GlaxoSmithKline, Uxbridge, UK*

**INTRODUCTION**

- Patients with asthma may remain symptomatic despite controller therapy.
- Addition of a LABA to an ICS is recommended for patients symptomatic on ICS alone.(1),(2)
- Combination therapy is currently licensed for twice-daily use; once-daily therapy may increase treatment adherence.
- VI (GW642444M) is a LABA with inherent 24h activity in development as a once-daily treatment in combination with the novel ICS, fluticasone furoate, for asthma and COPD.

**OBJECTIVES**

1. To evaluate the relative effects in trough FEV<sub>1</sub> versus placebo of VI at doses of 6.25mcg once daily, 6.25mcg twice daily, 12.5mcg once daily and 25mcg once daily, each administered for 7 days.
2. To evaluate the relative effects versus placebo on weighted mean for 24h serial FEV<sub>1</sub> of selected doses and dose intervals of VI.
3. To assess the safety of VI at selected doses and dose intervals of VI.

**METHODS**

- Multicenter, randomized, double-blind, placebo-controlled, five-period crossover study in adult patients (≥18 years old) with persistent asthma.
- Eligible patients had asthma according to NIH criteria,(1) FEV<sub>1</sub> reversibility of ≥12% and ≥200mL following albuterol and had been taking ICS at a stable dose for ≥4 weeks prior to screening.
- Patients were randomized to one of five treatment sequences with each 7 (+3)-day treatment period separated by a 7 (-3/+7)-day wash-out period; all patients received VI 6.25mcg twice daily (morning and evening), VI 6.25mcg once daily, VI 12.5mcg once daily, VI 25mcg once daily and placebo. All VI once-daily doses were given in the evening.
- VI was given via a novel single-step activation dry powder inhaler.

**Efficacy endpoints and safety measures**

- Primary: trough (pre-bronchodilator and pre-dose) FEV<sub>1</sub> at the end of the 7-day treatment period (mean of 23h and 24h assessments post-evening dose).
- Secondary: weighted mean for 24h serial FEV<sub>1</sub> on Day 7.
- Exploratory analysis: repeated measures analysis of serial FEV<sub>1</sub> on Day 7.
- Analyses of trough and weighted mean serial FEV<sub>1</sub> were performed using mixed effects analysis of covariance (ANCOVA) models with fixed effects for treatment period, sex and age. Subject was fitted as a random effect and the period baseline measurement (pre-dose FEV<sub>1</sub> on Day 1) was included as part of a bivariate response.
- AE terms were coded using the Medical Dictionary for Regulatory Activities (MedDRA) dictionary.

**RESULTS**

- Seventy-five patients were randomized (intent-to-treat population [ITT]); 96% of patients completed the study.
- Mean treatment compliance was ≥98% in each treatment group.
- Table 1 shows demographic and baseline clinical characteristics.

**Table 1. Patient baseline demographics and screening lung function (ITT population).**

	N=75
Age, years	38.9 (14.37)
Female, n (%)	47 (63)
Race, n (%)	
White	51 (68)
African American/African heritage	23 (31)
Asian	1 (1)

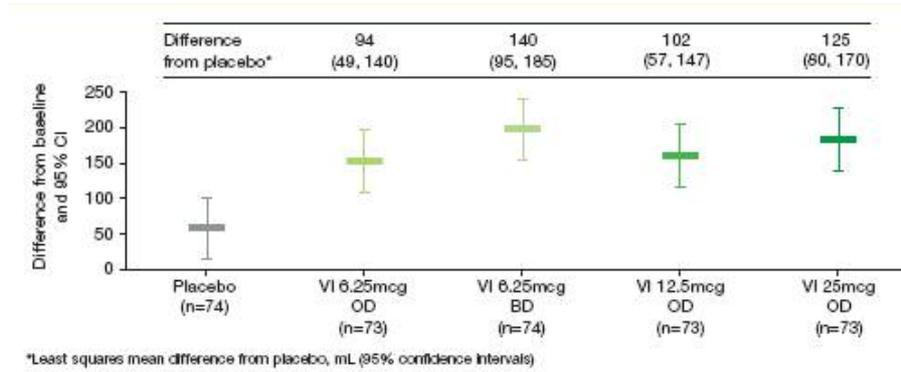
Screening lung function	
Percent predicted FEV <sub>1</sub> (%)	66.4 (10.37)
Percent reversibility in FEV <sub>1</sub> (%)	27.9 (15.24)

Values are mean (standard deviation) unless otherwise stated

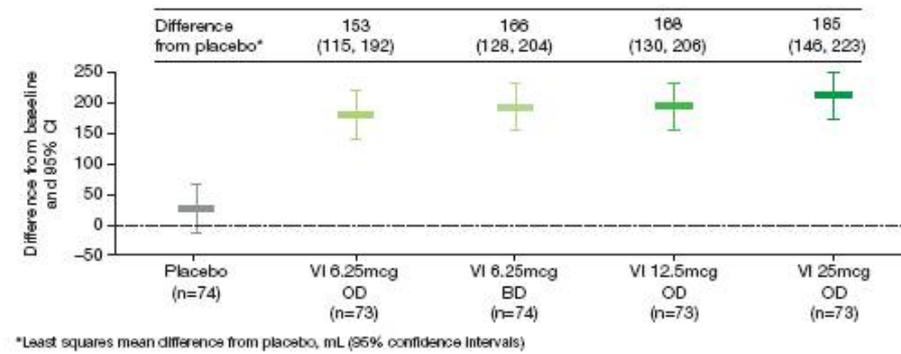
### Efficacy

- VI was associated with statistically significant increases in trough FEV<sub>1</sub> versus placebo (p<0.001; Figure 1).
- VI was associated with statistically significant increase in weighted mean serial 24h FEV<sub>1</sub> versus placebo (p<0.001; Figure 2).

**Figure 1. Least squares mean change from baseline in trough FEV<sub>1</sub> (mL) on Day 7 (ITT population).**

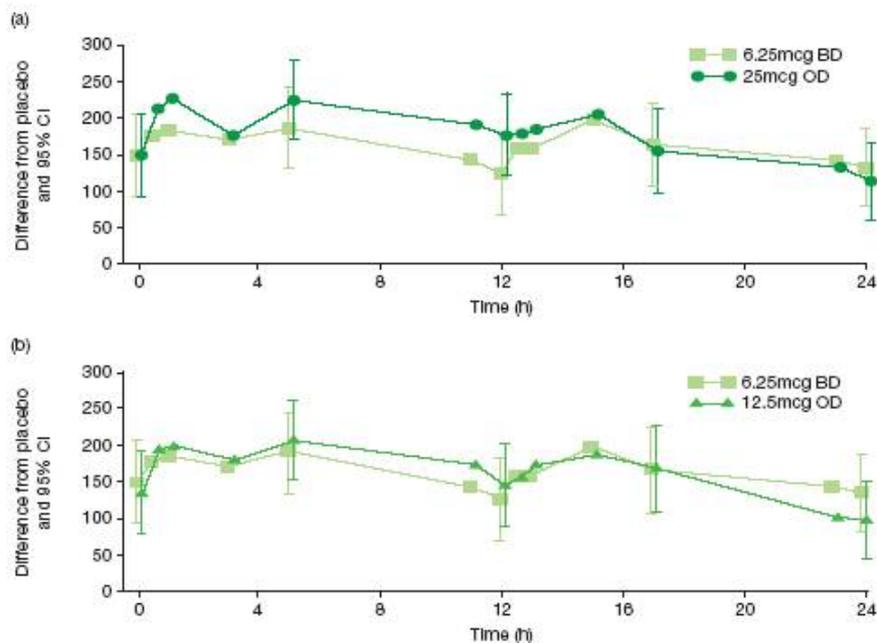


**Figure 2. Weighted mean 24h serial FEV<sub>1</sub> (mL) on Day 7 (ITT population).**



- Repeated measures analysis (difference from placebo in change from period baseline in FEV<sub>1</sub> with VI over 0–24h on Day 7)
  - there were greater changes in lung function with VI 25mcg once daily than 6.25mcg twice daily at 0-13h; the changes were similar during the 13–23h period (Figure 3a)
  - there were greater changes with 12.5mcg once daily than 6.25mcg twice daily during the first 12h but the overall 24h profiles were similar for the two dosing regimens (Figure 3b).

**Figure 3. Repeated measures analysis of serial FEV<sub>1</sub> (0-24h) on Day 7 (ITT population), treatment differences (mL) from placebo; (a) 6.25mcg twice daily and 25mcg once daily (b) 6.25mcg twice daily and 12.5mcg once daily.**



## Safety

- VI was well tolerated at all doses; incidence of AEs was low in each VI treatment group and not dose dependent (5–9%; placebo = 18%) (Table 2).
- No drug-related AEs or serious AEs were reported.

**Table 2. Summary of most common on-treatment AEs ( $\geq 3\%$  in any treatment group) (ITT population).**

	Placebo (n=74)	6.25mcg OD (n=73)	6.25mcg BD (n=74)	12.5mcg OD (n=73)	25mcg OD (n=73)
Any event, n (%)	13 (18)	5 (7)	7 (9)	4 (5)	6 (8)
Number of patients with most frequent event (%)	4 (5)	5 (7)	4 (5)	2 (3)	4 (5)
Nasopharyngitis	0	1 (1)	1 (1)	2 (3)	1 (1)
Upper respiratory tract infection	1 (1)	0	3 (4)	0	0
Road traffic accident	0	0	0	0	3 (4)
Back pain	2 (3)	0	0	0	0
Headache	1 (1)	2 (3)	1 (1)	0	0
Rhinitis perennial	0	2 (3)	0	0	0

## CONCLUSIONS

- All doses of VI were associated with significant improvements in trough FEV<sub>1</sub> and weighted mean 24h serial FEV<sub>1</sub> versus placebo.
- The greatest numerical improvements in trough FEV<sub>1</sub> were seen with VI 6.25mcg twice daily; the greatest numerical improvements in weighted mean 24h serial FEV<sub>1</sub> were seen with 25mcg once daily.
- Once-daily dosing with VI is supported by the observation of a sustained benefit over 24h; no substantial difference in weighted mean 24h serial FEV<sub>1</sub> was seen between a total daily dose of 12.5mcg given once daily (168mL) or twice daily (166mL) versus placebo.

## REFERENCES

- (1) NIH. Expert Panel Report 3. Guidelines for the Diagnosis and Management of Asthma. Full report 2007. NIH publication No. 07-4051. <http://www.nhlbi.nih.gov>.
- (2) GINA. Global Strategy for Asthma Management and Prevention - updated 2009. [www.ginasthma.org](http://www.ginasthma.org).

## ACKNOWLEDGMENTS

- This study was funded by GlaxoSmithKline. ClinicalTrials.gov: NCT00980200; protocol number: HZA113310.
- Richard Sterling (lead author) has no conflicting interests to declare.
- Editorial support (in the form of writing assistance, assembling tables and figures, collating author comments, grammatical editing and referencing) was provided by Lisa Moore at Gardiner-Caldwell Communications and was funded by GlaxoSmithKline.

