

**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 20, 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)

**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.**

On May 20, 2014 at the American Thoracic Society (ATS) 2014 International Conference held in San Diego, California, GlaxoSmithKline (GSK) presented a poster containing data from a Phase 3 study, "Efficacy and Safety of Once-Daily Fluticasone Furoate/Vilanterol (FF/VI) and FF Over 12 Weeks In Patients With Persistent Asthma". BREO<sup>®</sup> ELLIPTA<sup>®</sup> is the proprietary name in the United States (U.S.), Canada and Australia for FF/VI. BREO<sup>®</sup> ELLIPTA<sup>®</sup> is not indicated for the relief of acute bronchospasm or for the treatment of asthma in the U.S. and Canada. RELVAR<sup>®</sup> ELLIPTA<sup>®</sup> is the proprietary name for FF/VI outside of the U.S. and Canada. RELVAR<sup>®</sup>/BREO<sup>®</sup> ELLIPTA<sup>®</sup> is a combination of the inhaled corticosteroid, FF, and the long-acting beta<sub>2</sub>-agonist (LABA), VI, in a single inhaler. FF/VI has been developed under the 2002 LABA collaboration between Glaxo Group Limited and Theravance, Inc. The poster is filed as Exhibits 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	Efficacy and safety of once-daily fluticasone furoate/vilanterol (FF/VI) and FF over 12 weeks in patients 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 20, 2014

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

3

---

**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Efficacy and safety of once-daily fluticasone furoate/vilanterol (FF/VI) and FF over 12 weeks in patients with persistent asthma

4

---

**Efficacy and safety of once-daily fluticasone furoate/vilanterol (FF/VI)  
and FF over 12 weeks in patients with persistent asthma**

Poster #407

*Bernstein DI(1), Bateman ED(2), Woodcock A(3), Toler WT(4), Forth R(5), Jacques L(6), Nunn C(6), O'Byrne PM(7)*

(1)College of Medicine, University of Cincinnati, Cincinnati, OH, USA; (2)Department of Medicine, University of Cape Town, Cape Town, South Africa; (3)Institute of Inflammation and Repair, University of Manchester, Manchester, UK; (4)Respiratory Medicines Development Center, GlaxoSmithKline, RTP, NC, USA; (5)Quantitative Sciences Division, GlaxoSmithKline, RTP, NC, USA; (6)Respiratory Medicines Development Centre, GlaxoSmithKline, London, UK; (7)Michael G DeGroot School of Medicine, Hamilton, ON, Canada

**INTRODUCTION**

- Treatment guidelines for persistent asthma in patients not controlled with inhaled corticosteroid (ICS) therapy alone recommend an ICS with a long-acting beta<sub>2</sub> agonist (LABA),(1) leading to improved lung function and asthma symptom control compared with ICS monotherapy.(2)
- FF is an ICS in development as a once-daily (OD) monotherapy and available as a combination therapy with the LABA VI (FF/VI) for the treatment of COPD in the USA and for COPD and asthma in the EU and a number of other countries.(3),(4)
- FF/VI 200/25mcg OD significantly improves lung function and symptomatic endpoints compared with FF alone,(5) while numeric benefits have been reported for FF/VI 100/25mcg compared with FF 100mcg.(6)

**OBJECTIVES**

- To compare the efficacy and safety of OD FF/VI 100/25mcg with FF 100mcg in patients with moderate-to-severe, persistent bronchial asthma over 12 weeks.
- To assess the relative efficacy of FF/VI 100/25mcg with FF/VI 200/25mcg in these patients (descriptive comparison only).

**METHODS**

- Phase III, multicenter, randomized, double-blind, parallel-group study.
- Patient inclusion criteria: ≥12 years of age; FEV<sub>1</sub> 40–80% predicted; demonstrated ≥12% and ≥200mL reversibility to albuterol; receiving ICS for ≥12 weeks pre-study and stable with a mid-to-high dose ICS or mid-dose ICS/LABA for 4 weeks pre-study.
- Following a 4-week run-in without LABA, patients symptomatic or using rescue on ≥4 of the last 7 days of run-in were randomized 1:1:1 (stratified by baseline forced expiratory volume in one second [FEV<sub>1</sub>], ≤65% versus >65%) to FF 100mcg, FF/VI 100/25mcg or FF/VI 200/25mcg administered in the evening via the ELLIPTA™ dry powder inhaler OD for 12 weeks.
- Primary and secondary endpoints were analyzed using ANCOVA (covariates of baseline, region, sex, age and treatment) with a step-down statistical hierarchy for FF 100mcg versus FF/VI 100/25mcg.

**RESULTS**

- Of 2019 patients screened, 1039 were randomized and received at least one dose of study medication (intent-to-treat [ITT] population; Table 1), with 90% of patients completing the study.

**Table 1. Baseline demographics (ITT population)**

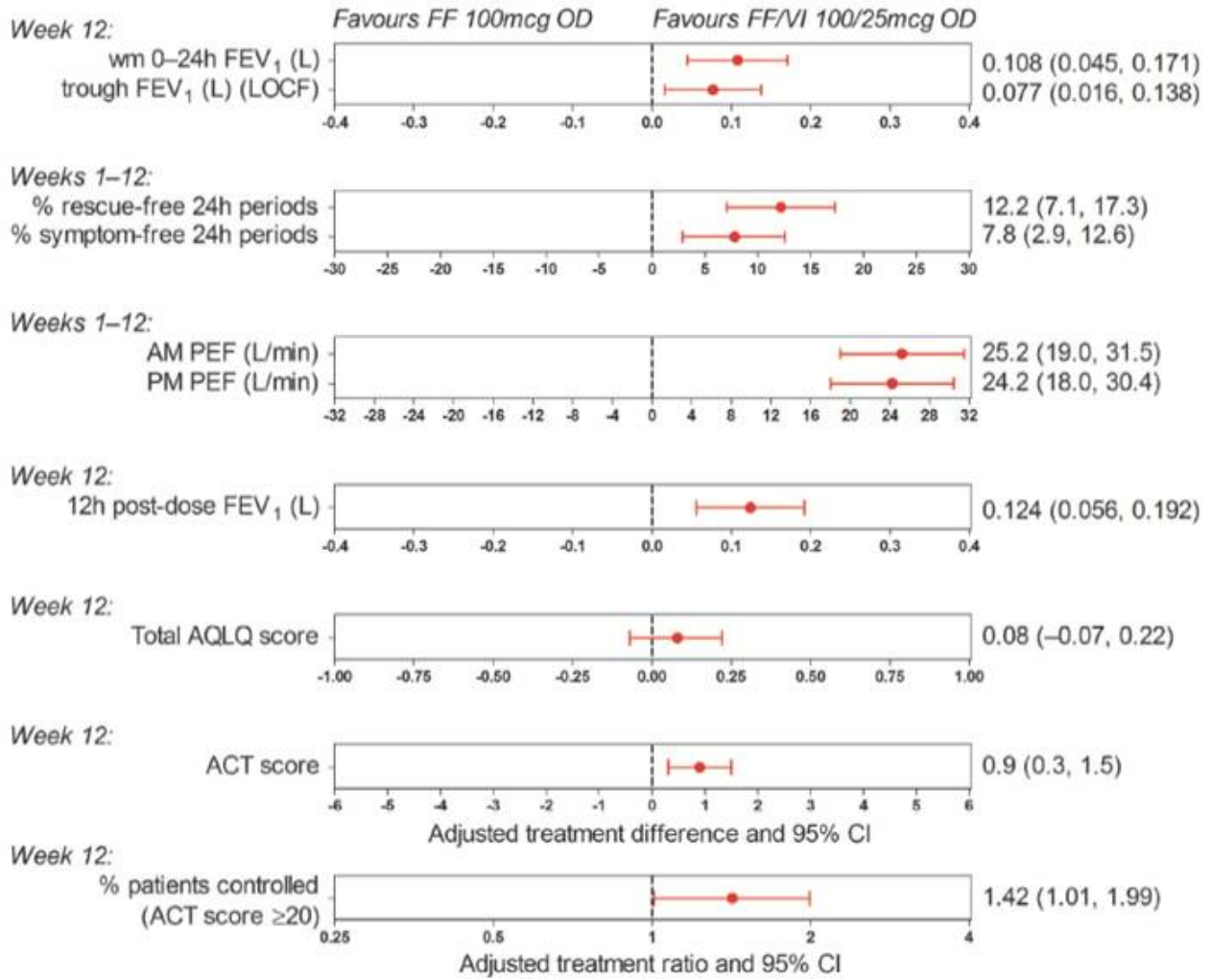
	FF 100mcg N=347	FF/VI 100/25mcg N=346	FF/VI 200/25mcg N=346
Age, years	44.7 (15.89)	45.9 (16.14)	46.6 (14.72)
Female sex, n (%)	199 (57)	205 (59)	224 (65)
Pre-bronchodilator FEV <sub>1</sub> , L	1.965 (0.5980)(a)	1.985 (0.5563)(a)	1.954 (0.5819)(b)
Percent predicted FEV <sub>1</sub>	61.13 (10.348)(a)	62.64 (10.148)(a)	62.12 (10.050)(b)
Percent reversibility	30.79 (19.153)(c)	29.10 (16.537)(a)	29.33 (15.701)(b)
Rescue-free 24-h periods, %	4.4 (12.07)	4.4 (12.58)	5.8 (16.00)
Symptom-free 24-h periods, %	4.8 (14.63)	3.8 (14.38)	4.6 (15.44)

Values are mean (SD) unless otherwise stated. (a)n=342; (b)n=344; (c)n=346

**Efficacy endpoints**

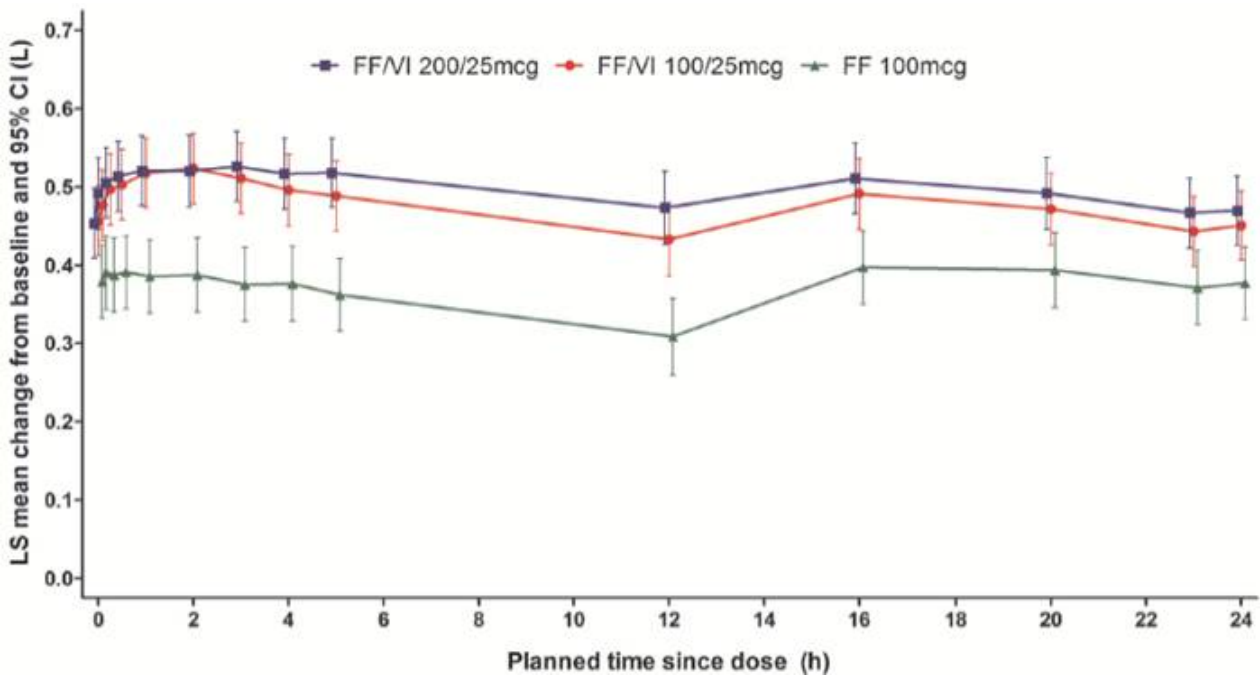
- There were statistically significant improvements with FF/VI 100/25mcg versus FF 100mcg for the primary endpoint of weighted mean 0–24h FEV<sub>1</sub> (Figs. 1–2) and the secondary and ‘other’ endpoints, except for AQLQ score (Fig. 1).
- There were numerical improvements for all efficacy endpoints with FF/VI 200/25mcg versus FF/VI 100/25mcg (Fig. 3).

**Figure 1. Adjusted treatment differences and ratios for efficacy endpoints: FF/VI 100/25mcg versus FF 100mcg (ITT population)**



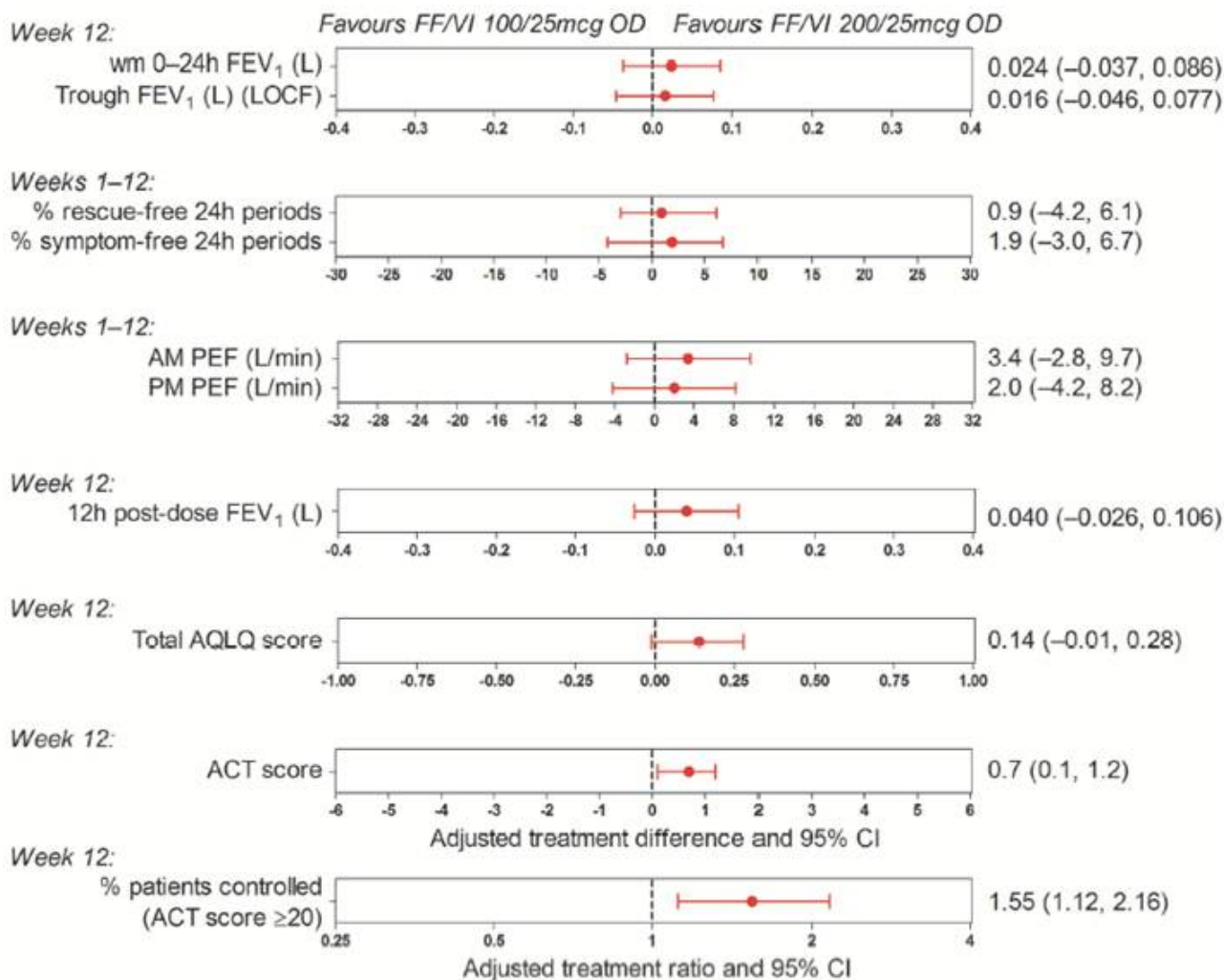
ACT = Asthma Control Test™; AQLQ = Asthma Quality of Life Questionnaire; CI = confidence interval; PEF = peak expiratory flow; wm = weighted mean

**Figure 2. Adjusted mean change from baseline of individual serial FEV<sub>1</sub> assessments at Week 12 (ITT population)**



LS = least squares

**Figure 3. Adjusted treatment differences and ratios for efficacy endpoints: FF/VI 200/25mcg versus 100/25mcg (ITT population)**



### Safety (Table 2)

- Incidence of AEs and serious AEs (SAEs) were similar across treatments; there were no post-treatment SAEs and no fatal AEs.

**Table 2. Summary of AE incidence and most commonly reported on-treatment AEs (ITT population)**

n (%)	FF 100mcg N=347	FF/VI 100/25mcg N=346	FF/VI 200/25mcg N=346
<b>AEs</b>			
Any on-treatment	127 (37)	127 (37)	123 (36)
Drug-related(a),(b)	11 (3)	7 (2)	8 (2)
Leading to permanent discontinuation or withdrawal(b)	4 (1)	3 (1)	3 (<1)
<b>Serious AEs</b>			
Any on-treatment	3 (<1)(c)	4 (1)(d)	1 (<1)(e)
Drug-related(a),(b)	1 (<1)	0	0
<b>Most common (≥3%) on-treatment AEs in any treatment group</b>			
Headache	32 (9)	29 (8)	29 (8)
Nasopharyngitis	26 (7)	22 (6)	25 (7)
Upper respiratory tract infection	12 (3)	8 (2)	7 (2)
Influenza	4 (1)	10 (3)	9 (3)

(a)investigator’s judgement of causality; (b)includes on-treatment and post-treatment AEs;

(c)2 pneumonia, 1 borderline mucinous ovarian tumour; (d)biliary colic, acute pancreatitis, thermal burn, occipital neuralgia; (e)abortion threatened

### CONCLUSIONS

- There were statistically significant improvements in lung function and symptoms with FF/VI 100/25mcg versus FF 100mcg after 12 weeks of treatment in patients with moderate-to-severe persistent bronchial asthma.
- Numerical improvements were seen for FF/VI 200/25mcg versus FF/VI 100/25mcg across all endpoints with patients on FF/VI 200/25mcg being 55% more likely to be well controlled than those on FF/VI 100/25mcg.

- No new safety concerns were identified for any of the study treatments.

---

## REFERENCES

- (1) Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention 2012. <http://www.ginasthma.com/Guidelines/guidelines-resources.html> (accessed 3/20/2014).
- (2) Ducharme FM, et al. Cochrane Database Syst Rev 2010;10:CD005533.
- (3) Breo Ellipta Medication Guide. Food and Drug Administration. [www.fda.gov/downloads/drugs/drugsafety/ucm352347.pdf](http://www.fda.gov/downloads/drugs/drugsafety/ucm352347.pdf) (accessed 4/08/2014).
- (4) EPAR Summary For The Public. European Medicines Agency. [www.ema.europa.eu/docs/en\\_GB/document\\_library/EPAR\\_-\\_Summary\\_for\\_the\\_public/human/002673/WC500157636.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Summary_for_the_public/human/002673/WC500157636.pdf) (accessed 4/08/2014).
- (5) O'Byrne PM, et al. Eur Respir J 2014;43:773–82.
- (6) Bleecker ER, et al. J Allergy Clin Immunol Pract 2014; ePub ahead of print (25 April 2014).

## ACKNOWLEDGEMENTS

- The presenting author, WT Toler, is an employee of and holds stock in GlaxoSmithKline.
- This study was funded by GlaxoSmithKline (HZA116863, NCT01686633).
- Editorial support (in the form of writing assistance, assembling tables and figures, collating author comments, grammatical editing and referencing) was provided by David Cutler, PhD at Gardiner-Caldwell Communications (Macclesfield, UK) and was funded by GlaxoSmithKline.

ELLIPTA™ is a trade mark of GlaxoSmithKline



*Presented at the American Thoracic Society Annual Congress, San Diego, CA, USA, 16–21 May 2014*

---