

**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): **June 24, 2013**

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 June 24, 2013 at the European Academy of Allergy and Clinical Immunology & World Allergy Organization World Allergy & Asthma Congress 2013, Milan, Italy, GlaxoSmithKline plc ("GSK") presented a poster on qualitative assessment of ELLIPTA™, a dry powder inhaler for chronic obstructive pulmonary disease (COPD) and asthma, by patients who participated in Phase 3 clinical trials of FF/VI, the treatment combination of fluticasone furoate (FF), an inhaled corticosteroid, and vilanterol (VI), a long-acting beta₂ agonist, and a Phase 3 clinical trial of FF monotherapy. FF/VI, known in the United States as BREO™ ELLIPTA™ (100/25mcg), recently gained U.S. Food and Drug Administration approval as an inhaled long-term, once-daily maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. It is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations. It is not indicated for the relief of acute bronchospasm or the treatment of asthma. FF/VI remains in development elsewhere in the world for the maintenance treatment of asthma and COPD, with pending marketing authorization applications in a number of countries. It is not currently approved or licensed in the European Union or anywhere outside of the U.S. FF/VI is in development under the LABA collaboration agreement between GSK and Theravance, Inc. The poster 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	Qualitative assessment of a two-strip dry powder inhaler (ELLIPTA™) for COPD and 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: June 24, 2013

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

3

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Qualitative assessment of a two-strip dry powder inhaler (ELLIPTA™) for COPD and asthma

4

**Qualitative assessment of a two-strip dry powder inhaler
(ELLIPTA™) for COPD and asthma**

Poster No. 1976

Woepse M(1), Dale P(2), Garrill K(3), Svendsater H(4), Walker R(5)

(1)Strategic Eye, Inc., Wayne, PA, USA; (2)HEOR Solutions, London, UK; (3)Medicine and Process Delivery, (4)Global Health Outcomes, (5)Product Development, GlaxoSmithKline, Uxbridge, UK

INTRODUCTION

- COPD and asthma are chronic respiratory disorders associated with significant morbidity(1),(2) commonly treated with inhaled therapies, usually delivered via a handheld inhaler.
- Poor adherence to inhaled therapies may be associated with inferior treatment outcomes in COPD and asthma.(3),(4) Guidelines recommend that patient preference, convenience and ability to use the device correctly should be considered when choosing an inhaler.(5)
- Fluticasone furoate (FF) is a novel corticosteroid in development as a once-daily monotherapy for asthma and in combination with vilanterol (VI), a novel long-acting beta₂ agonist, as a once-daily therapy for COPD and asthma.
- In clinical trials, FF/VI and FF have been delivered via the ELLIPTA™ dry powder inhaler (DPI), which is in development for the delivery of these treatments.

OBJECTIVES

- To assess perception of the ELLIPTA DPI among patients who participated in phase 3 clinical trials of FF/VI and FF.
- To assess preference for the ELLIPTA DPI compared with other inhalers currently used by study participants.
- To understand any specific attributes of the ELLIPTA DPI associated with patient satisfaction and inhaler preference.

METHODS

- Patients (aged ≥18 years, recruited from US study sites, had English as their primary language) with COPD or asthma who completed one of six phase 3 studies of FF/VI or FF using the ELLIPTA DPI (Figure 1) participated in qualitative interviews.

Figure 1. Unlabelled (blank) ELLIPTA DPI used in clinical trials



- Telephone interviews were conducted ≤4 weeks after completion of the clinical study. Visual stimuli, including images of the ELLIPTA DPI, patient instructions and illustrations of ways in which users had been observed to open and grip the DPI, were made available to participants via a password-protected website and used as prompts.
- Interviews focused on the inhaler and followed a semi-structured format based upon a discussion guide:
 - introduction: history of disease and inhaler use
 - ELLIPTA inhaler discussion: patient perception of, and preference for the ELLIPTA DPI compared with other inhalers they were currently using (participant-reported); evaluation of ELLIPTA DPI on key performance measures
 - follow-up queries: issues previously identified or recognised during the interview.

RESULTS

- See Table 1 for patient demographics; details of the studies the patients participated in are presented in Table 2.

Table 1. Patient demographics

	Asthma population (n=33)	COPD population (n=42)
Age, years	41	61
Duration of disease, years	22.1	7.1
Self-reported disease severity*	5.0	5.6

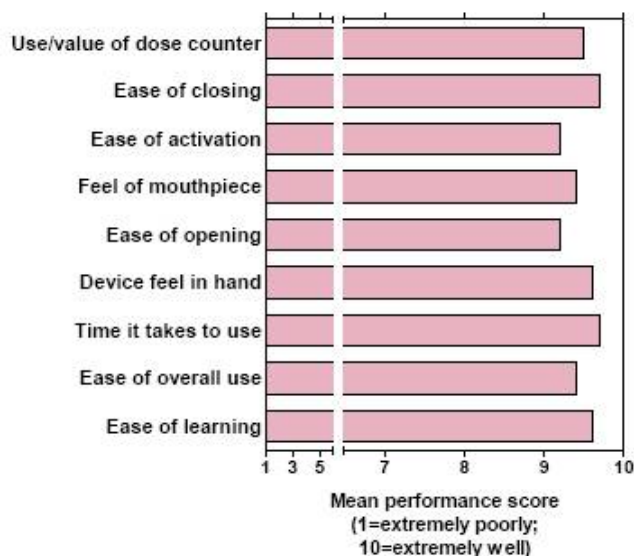
*Qualitative 1–10 scale: 1 = least severe, 10 = most severe

Table 2. Participant involvement in clinical trials*

Study number	Study treatments	n	Duration (weeks)
COPD			
HZC102871/ HZC102970	FF/VI 50/25mcg, 100/25mcg, 200/25mcg and VI 25mcg once daily	27	52
HZC112206	FF/VI 50/25mcg, FF/VI 100/25mcg, FF 100mcg, VI 25mcg and placebo once daily	12	24
HZC112207	FF/VI 100/25mcg, FF/VI 200/25mcg, FF 100mcg, FF 200mcg, VI 25mcg and placebo once daily	3	24
Asthma			
HZA106827	FF/VI 100/25mcg, FF 100mcg and placebo once daily	22	12
FFA114496	FF 200mcg and FF 100mcg once daily	11	24

*A two-strip configuration of the ELLIPTA DPI was used in all studies listed except for FFA114496, in which a single-strip ELLIPTA DPI was used

Figure 2. Overall* ELLIPTA DPI performance scores



*Scores are combined for patients with COPD and asthma

Table 3. Patient inhaler preference (ELLIPTA DPI versus specified other)

Comparator inhaler	No. patients using comparator inhaler	No. (%) of patients preferring ELLIPTA DPI to comparator	Key features rated as positive attributes of the ELLIPTA DPI compared with comparator
COPD			
HandiHaler	20	19 (95)	<ul style="list-style-type: none"> Simple mode of action; no need to insert a capsule into device before inhalation Increased confidence that a complete dose of medication was received
DISKUS	21	18 (86)	<ul style="list-style-type: none"> Ease of handling and operation Ease of reading the dose counter Mouthpiece provides a better seal with the lips
MDI/HFA	20	17 (85)	<ul style="list-style-type: none"> Ease of operation; requires less effort and fewer puffs Co-ordination of activation of the DPI with the inhalation is not required Readable dose counter
Asthma			

DISKUS	21	15 (71)	<ul style="list-style-type: none"> · The shape of the mouthpiece · The larger size of the dose counter · Ease of handling and operation
MDI/HFA	10	6 (60)	<ul style="list-style-type: none"> · Ease of operation; requires less effort and fewer puffs · Co-ordination of activation of the DPI with the inhalation is not required · Readable dose counter

MDI/HFA = metered dose inhaler/hydrofluoroalkane (propellant)

- Participants reported high levels of satisfaction with, and a very positive experience of, using the ELLIPTA DPI.
- Ease of use, dose count awareness, comfortable and well-shaped mouthpiece design, confidence in delivery of the medication, small size and ergonomic shape, the easy to open and integrated cover, and ease of handling were cited as positive attributes of the ELLIPTA DPI.
- The majority of participants with asthma ($\geq 60\%$) and overwhelming majority of participants with COPD ($\geq 85\%$) preferred the ELLIPTA DPI to the inhaler used to deliver their current medication (as prescribed after the end of the clinical study) (Table 3).
- Average performance scores (on a 1–10 scale) were >9 on all attributes. This was observed for patients with asthma and with COPD, as well as when the COPD and asthma data were combined (Figure 2).

CONCLUSIONS

- The ease, simplicity and security of use of the ELLIPTA inhaler were its most frequently commended attributes.
- The ELLIPTA DPI was preferred over currently-used inhalers by the majority of COPD and asthma phase 3 trial patients who participated in the qualitative interviews.
- These findings suggest that patients appreciate and are satisfied with the ELLIPTA DPI, and that it meets the needs of patients with COPD and asthma.

REFERENCES

- (1) Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention 2012. <http://www.ginasthma.org/Guidelines/guidelines-resources.html> (accessed 8 May 2013).
- (2) Halbert RJ, et al. *Eur Respir J* 2006;28:523–32.
- (3) Bender BG, et al. *Curr Opin Allergy Clin Immunol* 2004;3:191–5.
- (4) Lareau SC, et al. *Int J COPD* 2010;5:401–6.
- (5) Dolovich MB, et al. *Chest* 2005;127:335–71.

ACKNOWLEDGEMENTS

- The presenting author, Henrik Svedstater, has the following competing interests: is employed by and holds stock in GlaxoSmithKline.
- This research was sponsored by GlaxoSmithKline. GSK study codes (clinicaltrials.gov): HZC112206 (NCT01053988); HZC112207 (NCT01054885); HZC102871 (NCT01009463); HZC102970 (NCT01017952); HZA106827 (NCT01165138); FFA114496 (NCT01431950).
- Editorial support (in the form of writing assistance, assembling tables and figures, collating author comments, grammatical editing and referencing) was provided by Laura Maguire, MChem and David Cutler, PhD at Gardiner-Caldwell Communications (Macclesfield, UK) and was funded by GlaxoSmithKline.

ELLIPTA™ is a trade mark of the
GlaxoSmithKline group of companies



Presented at the European Academy of Allergy and Clinical Immunology & World Allergy Organization World Allergy & Asthma Congress 2013, Milan, Italy, 22–26 June 2013