
**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): April 22, 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))
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Item 8.01 Other Events.

On April 22, 2014, GlaxoSmithKline plc and Theravance, Inc. issued a press release announcing that the Therapeutic Goods Administration (TGA) has approved BREO™ ELLIPTA® (fluticasone furoate/vilanterol trifenate) for the treatment of patients with asthma or chronic obstructive pulmonary disease (COPD) in Australia. BREO™ ELLIPTA® is a combination of the inhaled corticosteroid, fluticasone furoate (FF), and the long-acting beta₂-agonist (LABA), vilanterol (VI). Two strengths of BREO™ ELLIPTA® have been licensed for the treatment of asthma (100/25 mcg and 200/25 mcg) and one strength has been licensed for the treatment of COPD (100/25 mcg). Both strengths will be administered once-daily using the new ELLIPTA® dry powder inhaler. FF/VI has been developed under the 2002 LABA collaboration between Glaxo Group Limited and Theravance, Inc. The press release is filed as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit**Description**

[Exhibit 99.1](#)

Press Release dated April 22, 2014

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: April 22, 2014

By: /s/ **Michael W. Aguiar**

Michael W. Aguiar
Chief Financial Officer

EXHIBIT INDEX

Exhibit No.
[99.1](#)

Description
Press Release dated April 22, 2014

Issued: 22 April 2014, Sydney Australia

Breo™ Ellipta® (fluticasone furoate/vilanterol trifenate) approved in Australia for Asthma and Chronic Obstructive Pulmonary Disease

- **First combination of an inhaled corticosteroid and a long-acting beta₂-agonist administered once daily¹**
- **Administered using a new dry powder inhaler called Ellipta¹**

GSK Australia and Theravance, Inc. (NASDAQ: THRX) announced today that the Therapeutic Goods Administration (TGA) has approved Breo Ellipta for the treatment of patients with asthma or chronic obstructive pulmonary disease (COPD) in Australia¹.

Breo Ellipta is a combination of the inhaled corticosteroid (ICS), fluticasone furoate (FF), and the long-acting beta₂-agonist (LABA), vilanterol (VI). Two strengths of Breo Ellipta have been licensed for the treatment of asthma (100/25 mcg and 200/25 mcg) and one strength has been licensed for the treatment of COPD (100/25 mcg)¹.

Both strengths will be administered once-daily using the new Ellipta dry powder inhaler¹.

Respiratory specialist Professor Grant Waterer welcomed the new registration saying the availability of a once-daily corticosteroid with a once-daily long acting beta-agonist in the same inhaler is an exciting development for patients and their doctors.

“In both COPD and asthma there is significant potential to improve patient outcomes especially where compliance with twice daily regimens has been problematic,” said Professor Waterer.

GSK Medical Director Dr Andrew Yeates says the company had been focused for many years on the development of new treatments for patients with asthma or COPD.

“We are delighted that Breo Ellipta is now approved in Australia. GSK is committed to supporting innovation in respiratory medicine and has a strong pipeline of products which will help us to deliver this to our Australian patients. We are proud that healthcare professionals in Australia will, for the first time, have the option of prescribing an effective once daily ICS/LABA combination which is delivered in our new Ellipta inhaler device,¹” said Dr Yeates.

“The Australian approval of Breo Ellipta is yet another important achievement and is testament to our successful partnership with GSK in respiratory disease,” said Rick E Winningham, Chief Executive Officer of Theravance. “We are delighted that the TGA has approved Breo Ellipta for the treatment of asthma and COPD and look forward to seeing the benefits of this effective once-daily treatment option in these patient populations.”

It is estimated that approximately 10% of Australians have asthma².

The prevalence of COPD in Australia is difficult to determine because accurate diagnosis requires clinical testing. The prevalence of self-reported emphysema/bronchitis in Australians over 55 was reported to be approx 5%².

PRESS RELEASE



About Breo Ellipta¹

Breo Ellipta is registered for use in the regular treatment of moderate to severe asthma and in the symptomatic treatment of COPD where the FEV₁ <70% predicted normal (post-bronchodilator) and there is a history of exacerbations despite regular bronchodilator therapy.¹

Following TGA registration GSK's next focus is to make Breo Ellipta available to prescribers.

Breo Ellipta was well tolerated in clinical trials. As with all ICS therapy, patients should rinse their mouth with water after use to minimise the local adverse effects. To minimise adverse reactions, ICS should be used at the lowest dose that maintains symptom control.¹

Adverse events included; headache, nasopharyngitis, URTI, bronchitis, oropharyngeal, pain, cough, sinusitis, back pain, influenza, pharyngitis, dysphonia, rhinitis allergic, abdominal pain upper pyrexia, oral candidiasis, extrasystoles, nasopharyngitis, fractures. Pneumonia has been reported in patients with COPD.¹

Healthcare professionals are advised to refer to the Full Product Information for further information regarding the safety of the product, including contraindications and precautions.

Additional notes:

Professor Grant Waterer has served on advisory boards and been involved in clinical trials sponsored by GSK for which compensation was received. In relation to this GSK media announcement, no compensation was provided to Professor Grant Waterer, and the opinions expressed are their own. Dr Grant Waterer has been briefed by GSK on the approved use of this product.

References:

1. Breo[™] Ellipta[®] Product information, 17 April 2014
2. National Health survey 2007-8; adults. Prevalence in adults stable (AIHW: Asthma in Australia 2011; COPD in Australia p14; p164)

PBS Information – This product is not listed on the PBS

**PLEASE REVIEW FULL PRODUCT INFORMATION BEFORE PRESCRIBING.
The product information can be accessed at www.gsk.com.au**

Breo[™] Ellipta[®] (fluticasone furoate/vilanterol trifenate) Minimum Product Information.

Indications: Asthma: Regular treatment of moderate to severe asthma in patients requiring medium to high dose inhaled corticosteroid combined with long acting β_2 -agonist. COPD: symptomatic treatment of patients with COPD with a FEV₁ <70% predicted normal (post-bronchodilator) in patients with an exacerbation history despite regular bronchodilator therapy. Breo[™] Ellipta[®] is not indicated for the initiation of bronchodilator therapy in COPD.

Contraindications: Severe milk-protein allergy or hypersensitivity to any of the actives and any excipients.

Precautions: Long acting beta(2) agonists (LABAs) as a class can be associated with an increased risk of asthma death. Patients using Breo[™] Ellipta[®] should not use another medicine containing a LABA (e.g., salmeterol, eformoterol, indacaterol) for any reason. Cannot be used to relieve acute symptoms of asthma or COPD (short acting β_2 -agonists should be used for acute attacks). As with other inhalation therapy, the possible occurrence of paradoxical bronchospasm immediately after dosing should be treated with short acting β_2 -agonists. As with sympathomimetic drugs, Breo[™] Ellipta[®] should be used with caution in patients with cardiovascular disease. As with all sympathomimetic amines, Breo[™] Ellipta[®] should be used with caution in patients with convulsive disorders or hyperthyroidism. To minimise adverse reactions, inhaled corticosteroids should be used at the lowest dose that maintains symptom control. Inhaled corticosteroids should be used with caution in patients with active or quiescent tuberculosis infections of the respiratory tract; systemic fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex. An increase in pneumonia has been observed in patients with COPD. Beta-adrenergic agonists may produce significant hypokalaemia in some patients, which has the potential to produce adverse cardiovascular effects. Beta-agonist agents may produce transient hyperglycaemia in some patients. Other: fertility, pregnancy (category B3), lactation.

PRESS RELEASE



Interactions: Beta-blockers, P-glycoprotein inhibitors, CYP3A4 inhibitors, sympathomimetic medicinal products, monoamine oxidase inhibitors, tricyclic antidepressants

Adverse Reactions: Common: headache, nasopharyngitis, URTI, bronchitis, oropharyngeal, pain, cough, sinusitis, back pain, influenza, pharyngitis, dysphonia, rhinitis allergic, abdominal pain upper pyrexia, oral candidiasis, extrasystoles, nasopharyngitis, fractures. Other: pneumonia in patients with COPD

Dosage: Prescribers should be aware that 100 mcg of fluticasone furoate is a medium dose of inhaled corticosteroid and 200 mcg of fluticasone furoate is a high dose of inhaled corticosteroid. Asthma: (Adults and Adolescents \geq 12 years): 1 inhalation once daily (100/25mcg or 200/25mcg). In patients whose asthma is well controlled and stable the Breo™ Ellipta® dose may carefully be down-titrated to the lowest strength of Breo™ Ellipta®. The next step should consider the cessation of Breo™ Ellipta® and transfer to an appropriate inhaled corticosteroid containing regimen. COPD: 1 inhalation once daily (100/25mcg only). Breo™ Ellipta® 200/25 mcg is not indicated for patients with COPD. Specific patient population: Elderly patients: due to limited data in patients with asthma aged 75 years and older, Breo™ Ellipta® 200/25mcg is not recommended. Moderate to Severe Hepatic Impairment: once daily maximum dose of 100/25mcg.

Min PI v1.0. For full product information, information on GSK products or to report an adverse event involving a GSK product, please contact GSK Medical Information on 1800 033 109. GlaxoSmithKline Australia Pty Ltd. ABN 47 100 162 481. Melbourne, VIC.
AUS/FFT/0004/14 Date of Approval: 09/04/2014

BREO™ ELLIPTA® is a trade mark of the GSK group of companies.

GSK – one of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com.

Theravance – is a biopharmaceutical company with a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. Theravance is focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections, and central nervous system (CNS)/pain. Theravance's key programs include: RELVAR®/BREO® ELLIPTA® (FF/VI), ANORO™ ELLIPTA™ (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta₂ Agonist) GSK961081, each partnered with GlaxoSmithKline plc (GSK), and its Long-Acting Muscarinic Antagonist program. By leveraging its proprietary insight of multivalency to drug discovery, Theravance is pursuing a best-in-class strategy designed to discover superior medicines in areas of significant unmet medical need. For more information, please visit Theravance's web site at www.theravance.com.

THERAVANCE®, the **Theravance** logo, and **MEDICINES THAT MAKE A DIFFERENCE®** are registered trademarks of Theravance, Inc.

PRESS RELEASE



Theravance forward-looking statements

This press release contains certain "forward-looking" statements as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding, among other things, statements relating to goals, plans, objectives and future events. Theravance intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. Examples of such statements include statements relating to the status and timing of clinical studies, data analysis and communication of results, statements regarding the potential benefits and mechanisms of action of drug candidates, statements concerning the timing of seeking regulatory approval of our product candidates, statements concerning the enabling capabilities of Theravance's approach to drug discovery and its proprietary insights and statements concerning expectations for product candidates through development and commercialization and projections of revenue, expenses and other financial items. These statements are based on the current estimates and assumptions of the management of Theravance as of the date of this press release and are subject to risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results of Theravance to be materially different from those reflected in its forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, among others, risks related to delays or difficulties in commencing or completing clinical studies, the potential that results of clinical or non-clinical studies indicate product candidates are unsafe or ineffective, our dependence on third parties in the conduct of our clinical studies, delays or failure to achieve regulatory approvals for product candidates, risks of relying on third-party manufacturers for the supply of our product and product candidates and risks of collaborating with third parties to develop and commercialize products. These and other risks are described in greater detail under the heading "Risk Factors" contained in Theravance's Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 3, 2014 and the risks discussed in our other periodic filings with the SEC. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Theravance assumes no obligation to update its forward-looking statements. (THR-X-G)

This media release has been issued by Palin Communications on behalf of GSK.

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