
**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): July 10, 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))
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Item 8.01 Other Events.

On July 10, 2013, GlaxoSmithKline plc and Theravance, Inc. issued a press release announcing that BREO™ ELLIPTA™ (fluticasone furoate/vilanterol) has been approved in Canada for the long-term once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema, and to reduce exacerbations of COPD in patients with a history of exacerbations. BREO™ ELLIPTA™ 100/25 mcg is a combination of the inhaled corticosteroid (ICS) fluticasone furoate and the long-acting beta₂-agonist (LABA) vilanterol, administered by the new ELLIPTA™ dry powder inhaler (DPI). BREO™ ELLIPTA™ 100/25 mcg contains 100 micrograms of fluticasone furoate (FF) and 25 micrograms of vilanterol (VI) as trifenate. BREO™ ELLIPTA™ was developed by Glaxo Group Limited in collaboration with 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.

<u>Exhibit</u>	<u>Description</u>
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Exhibit 99.1	Press Release dated July 10, 2013
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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: July 10, 2013

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

EXHIBIT INDEX

<u>Exhibit No</u>	<u>Description</u>
99.1	Press Release dated July 10, 2013

**PRESS
RELEASE****BREO™ ELLIPTA™ APPROVED FOR COPD TREATMENT IN CANADA**

Mississauga, ON – July 10, 2013 – BREO™ ELLIPTA™ (fluticasone furoate/vilanterol) has been approved in Canada for the long-term once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema, and to reduce exacerbations of COPD in patients with a history of exacerbations.¹

BREO™ ELLIPTA™ 100/25 mcg is a combination of the inhaled corticosteroid (ICS) fluticasone furoate and the long-acting beta₂-agonist (LABA) vilanterol, administered by the new ELLIPTA™ dry powder inhaler (DPI). BREO™ ELLIPTA™ 100/25 mcg contains 100 micrograms of fluticasone furoate (FF) and 25 micrograms of vilanterol (VI) as trifenate. BREO™ ELLIPTA™ has been shown to reduce airflow obstruction in patients with COPD and to reduce exacerbations of COPD, or lung attacks, in patients with a history of exacerbations.

Recent research has shown that a significant number of COPD patients prefer a once-daily medication, relative to having a more frequent dosing regimen of two or four times daily.²

“When a person is affected by COPD, it can be debilitating, and the simple act of taking a breath can be challenging. With the approval of BREO™ ELLIPTA™100/25 mcg, we can now offer COPD patients a once-daily option,” said Glenn Crater, Country Medical Director for GlaxoSmithKline Inc. “Through research we’ve learned that when treatment administration is simplified, patients are more likely to use it regularly and ultimately that can help improve the management of their disease.”

The data submitted in support of the use of BREO™ ELLIPTA™100/25 mcg in the treatment of COPD included results from a comprehensive program of non-clinical studies, 52 clinical pharmacology studies of 1,406 patients, and 11 clinical studies of 7,851 patients with COPD. Of these, there were four primary COPD studies: two 6-month lung-function studies and two 1-year exacerbation studies.¹

“For over forty years, GlaxoSmithKline has been at the forefront of delivering medicines to patients with respiratory diseases,” commented Paul Lirette, President, GlaxoSmithKline Inc. “We are committed to responding to patients’ needs and are very pleased to be expanding our respiratory portfolio with the introduction of BREO™ ELLIPTA™ 100/25 mcg once-daily for the treatment of COPD in Canada.”

BREO™ ELLIPTA™ was developed by Glaxo Group Limited in collaboration with Theravance, Inc.

“We are very pleased with the approval of BREO™ ELLIPTA™ as a once-daily treatment for COPD in Canada,” said Rick E. Winningham, Theravance’s Chief Executive Officer. “We believe that BREO™ ELLIPTA™ has the potential to be an important new treatment option for doctors and patients dealing with this debilitating disease.”

Following its authorization for use in the treatment of COPD, it is anticipated BREO™ ELLIPTA™ 100/25 mcg will be made available in Canada by GlaxoSmithKline in the fall of 2013.

About COPD

Chronic obstructive pulmonary disease (COPD) refers to two lung diseases, chronic bronchitis and emphysema, which are characterised by the obstruction of airflow that interferes with normal breathing. More than 770,000 Canadians have been diagnosed with this serious disease.³ COPD is the leading cause of hospitalizations in Canada.⁴ It is also the fourth leading cause of death in Canada⁵ and the world.⁶ It is estimated COPD costs the Canadian health care system between \$646 million to \$736 million per year.⁷

Long-term exposure to lung irritants that damage the lungs and the airways are usually the cause of COPD. Cigarette smoke, breathing in second hand smoke, air pollution, chemical fumes, or dust from the environment or workplace can all contribute to COPD.⁸ Most people who have COPD are at least 40 years old when symptoms begin.⁹ COPD symptoms vary over time and among patients, but they can include chronic cough, shortness of breath and an increase of phlegm.¹⁰ When symptoms get worse or a new, persistent symptom comes on, patients experience an exacerbation or lung attack.¹¹ As COPD worsens over time, exacerbations can become more frequent, potentially lead to hospitalization, restricted mobility and can increase the risk of death.^{12,13,14}

COPD can have a significant impact on the lives of patients and their families. Patients begin to accept their condition as normal, often understating its severity and the ways it has an impact on their daily life.¹⁵ The long-term and progressive nature of symptoms can reduce the quality of life in people with COPD, including the ability to work, socialize and remain active.¹⁶

About BREO™ ELLIPTA™

BREO™ ELLIPTA™ 100/25 mcg is a long-term once-daily, inhaled corticosteroid/long-acting beta₂ agonist (ICS/LABA) combination treatment approved for COPD in Canada. BREO™ ELLIPTA™ contains 100 micrograms of fluticasone furoate (FF) and 25 micrograms of vilanterol (VI) as trifenate, administered by the new ELLIPTA™ dry powder inhaler (DPI).

Canadian prescribing Information for BREO™ ELLIPTA™ 100/25 mcg, **including BOXED WARNING and Consumer Information** will be available soon at www.gsk.ca. Prior to the label being posted online, health care providers may request a copy of the complete Product Monograph by calling GSK's Medical Information department at 1-800-387-7374.

Important safety information

BREO™ ELLIPTA™ is contraindicated in patients who are hypersensitive to fluticasone furoate, vilanterol, or any ingredient in the formulation or component of the container; and patients with severe hypersensitivity to milk proteins.

BREO™ ELLIPTA™ is not indicated for use in children and therefore should not be used in patients under 18 years of age. BREO™ ELLIPTA™ is also not indicated for the relief of acute bronchospasm in COPD. Patients should be prescribed a rapid onset, short duration inhaled bronchodilator to relieve acute symptoms.

ASTHMA-RELATED DEATH: Long-acting beta₂-adrenergic agonist (LABA) increase the risk of asthma-related death. Data from a large, placebo-controlled US study that compared the safety of another long-acting beta₂-adrenergic agonist (salmeterol) to placebo added to usual asthma therapy, showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with salmeterol is considered a class effect of LABA, including vilanterol, the active ingredient in BREO™ ELLIPTA™.

BREO™ ELLIPTA™ is only indicated for COPD. The safety and efficacy of BREO™ ELLIPTA™ in patients with asthma have not been established. BREO™ ELLIPTA™ is not indicated for the treatment of asthma.

BREO™ and ELLIPTA™ are trademarks of the GlaxoSmithKline group of companies.

About GlaxoSmithKline Inc.

GlaxoSmithKline (GSK) is a leading research-based pharmaceutical company with a challenging and inspiring mission: to improve the quality of human life by enabling people to do more, feel better, and live longer. This mission gives GSK the purpose to develop innovative medicines, vaccines and healthcare solutions that help millions of people. Discover more at GSK.ca.

About Theravance

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. 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.

For more information, please contact:

Jennifer Gordon / Shaday Livingston
jgordon@environicspr.com / slivingston@environicspr.com
416-969-2665 / 416-969-2759

Michelle Smolenaars Hunter
Manager, Corporate Communications
GlaxoSmithKline
(905) 819-3475
Michelle.J.Smolenaars-Hunter@gsk.com

Michael W. Aguiar
Investor Relations
Theravance Inc. Enquiries
+1 650 808 4100
investor.relations@theravance.com

Cautionary statement regarding GSK forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK's operations are described under 'Risk factors' in the Annual Report for GlaxoSmithKline plc.

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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 1, 2013 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.

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- ¹ BREO™ ELLIPTA™ Product Monograph, GlaxoSmithKline Inc., July 2013
- ² Price D, Lee AJ et al. Characteristics of patients preferring once-daily controller therapy for asthma and COPD: a retrospective cohort study. *Primary Care Respiratory Journal*. 2013;22 <http://dx.doi.org/10.4104/pcrj.2013.00017>
- ³ Public Health Agency of Canada. Fast Facts About Chronic Obstructive Pulmonary Disease. Available at: <http://www.phac-aspc.gc.ca/cd-mc/publications/copd-mpoc/ff-rr-2011-eng.php> [Last accessed: June 20 2013]
- ⁴ Canadian Institute for Health Information. A Snapshot of Health Care in Canada as Demonstrated by Top 10 List. P.6. Available at https://secure.cihi.ca/free_products/Top10ReportEN-Web.pdf [Last accessed: June 20, 2013]
- ⁵ Statistics Canada. Leading Cause of Death by Sex. Available at: <http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/hlth36a-eng.htm> [Last accessed: June 20, 2013]
- ⁶ Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) [online] 2013. Available from: http://www.goldcopd.org/uploads/users/files/GOLD_Report_2013_Feb20.pdf [Last accessed: April 2013]
- ⁷ N. Mittmann et. Al. The cost of moderate and severe COPD exacerbations to the Canadian healthcare system. Available at [http://www.resmedjournal.com/article/S0954-6111\(07\)00432-5/fulltext](http://www.resmedjournal.com/article/S0954-6111(07)00432-5/fulltext) [Last accessed: June 20 2013]
- ⁸ Canadian Lung Association. What is COPD. Available at: http://www.lung.ca/diseases-maladies/copd-mpoc/what-quoi/index_e.php [Last accessed: June 20, 2013]
- ⁹ World Health Organization. Chronic respiratory diseases: Diagnosis of COPD 2013. Available at: <http://www.who.int/respiratory/copd/diagnosis/en/index.html> [Last accessed: June 20, 2013]
- ¹⁰ Canadian Lung Association. COPD Signs & Symptoms. Available at http://www.lung.ca/diseases-maladies/copd-mpoc/signs-signes/index_e.php [Last accessed: June 20 2013]
- ¹¹ Global Initiative for Chronic Obstructive Lung Disease (GOLD). Pocket guide to COPD diagnosis, management and prevention
- ¹² Soler-Cataluna, JJ, et al. (2005) Severe acute exacerbations and mortality in patients with chronic obstructive pulmonary disease. *Thorax* 60, 925-931.
- ¹³ Cote, CG, Dordelly, LJ, Celli, BR (2007) Impact of COPD exacerbations on patient-centered outcomes. *Chest*, 131(3); 696-704
- ¹⁴ Ibid.
- ¹⁵ Rennard S, Decramer M et al. Impact of COPD in North America and Europe in 2000: subjects' perspective of Confronting COPD International Survey. *European Respiratory Journal*. 2002;20:799–805
- ¹⁶ Canadian Lung Association. The Human and Economic Burden of COPD. Pg 5. Available at: http://www.lung.ca/cts-sct/pdf/COPDReport_E.pdf [Last accessed: June 21, 2013]
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