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): **March 19, 2015**

THERAVANCE, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**000-30319**	**94-3265960**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

951 Gateway Boulevard
South San Francisco, California 94080
(650) 238-9600
(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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 March 19, 2015, GlaxoSmithKline plc. and Theravance, Inc. issued a press release regarding the outcome of a joint meeting of the Pulmonary-Allergy Drug Advisory Committee and Drug Safety and Risk Management Advisory Committee of the United States Food and Drug Administration ("FDA") regarding the supplemental New Drug Application ("sNDA") for BREO® ELLIPTA® (fluticasone furoate/vilanterol FF/VI) as a once-daily inhaled treatment for asthma in patients aged 12 years and older.

For more information about the Committee meeting and the vote, please see the press release attached as Exhibit 99.1 to this Current Report on Form 8-K which is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated March 19, 2015.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

THERAVANCE, INC.

Date: March 19, 2015

By: /s/ Michael W. Aguiar
Michael W. Aguiar
President and Chief Executive Officer

PRESS RELEASE

Issued: 19 March 2015, London, UK, and South San Francisco, CA, USA

GSK and Theravance announce outcome of US FDA Advisory Committee on BREO® ELLIPTA® in asthma

GlaxoSmithKline plc (LSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced the outcome of the joint meeting of the Pulmonary-Allergy Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee of the United States (US) Food and Drug Administration (FDA) regarding the supplemental New Drug Application (sNDA) for BREO® ELLIPTA® (fluticasone furoate/vilanterol [FF/VI]) as a once-daily inhaled treatment for asthma in patients aged 12 years and older.

The FDA Advisory Committee voted that the efficacy and safety data for FF/VI 100/25 mcg and 200/25 mcg once daily in asthma support approval in adults 18 years of age and older (16 for, 4 against). The Committee voted that the efficacy data provides substantial evidence of a clinically meaningful benefit in adults (18 for, 2 against) and that the safety in this population has been adequately demonstrated (17 for, 3 against).

The Committee voted against approval for the proposed indication in 12-17 year olds (2 for, 18 against)*. The Committee voted that the efficacy data was not sufficient to demonstrate the benefit (4 for, 16 against) and the safety (1 for, 19 against) has not been adequately demonstrated in this sub-population.

The Committee recommended that a large LABA safety trial with FF/VI should be required in adults (13 yes, 7 no) and in 12-17 year olds (17 yes, 2 no and 1 no-vote), similar to the ongoing LABA safety trials being conducted as an FDA Post-Marketing Requirement by each of the manufacturers of LABA containing asthma treatments.

FDA Advisory Committees provide non-binding recommendations for consideration by the FDA. Based on these opinions and the data presented, the FDA will make its final decision on approval, which is expected on 30 April 2015 (the Prescription Drug User Fee Act goal date).

Breo, a fixed-dose combination of the inhaled corticosteroid FF and the long-acting $beta_2$-agonist VI, is administered with the Ellipta dry powder inhaler device. The sNDA for Breo Ellipta in asthma was submitted to the FDA in June 2014 for two once-daily dose regimens, 100/25 mcg and 200/25 mcg.

Darrell Baker, SVP & Head, GSK Global Respiratory Franchise, said: “We recognise the Advisory Committee’s thoroughness in reviewing the data related to Breo Ellipta for asthma. We will continue to work closely with the FDA while it considers the Committee’s recommendations and our aim is to answer any outstanding questions to enable them to make a fully informed decision.”

Michael W. Aguiar, President and Chief Executive Officer of Theravance, Inc., said: “We remain committed to the ongoing review process and will be fully cooperating with the FDA to ensure it has all it needs to consider the sNDA for Breo Ellipta in asthma. We look forward to the final outcome expected in April.”

*One panel member indicated that he intended to vote no, however a vote cannot be changed once read into the official FDA records.

PRESS RELEASE

About asthma

Asthma is a chronic lung disease that inflames and narrows the airways.(1) Approximately 26 million people in the USA currently have asthma.(2) Despite medical advances, more than half of patients continue to experience poor control and significant symptoms.(3)

The causes of asthma are not completely understood but likely involve an interaction between a person’s genetic make-up and the environment. Key environmental risk factors for the development of asthma are allergens, respiratory infections and airway irritants.

About Breo Ellipta

Breo Ellipta (FF/VI 100/25 mcg) was licensed by the US Food and Drug Administration under the brand name Breo Ellipta in May 2013 as a prescription medication for the long-term, once-daily, maintenance treatment of airflow obstruction and for reducing exacerbations in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Breo Ellipta is not indicated for the relief of acute bronchospasm or the treatment of asthma in the US.

Full US prescribing information, including BOXED WARNING and Medication Guide is available at us.gsk.com or US Prescribing Information Breo Ellipta.

Important Safety Information (ISI) for Breo Ellipta in the US

The following ISI is based on the Highlights section of the US Prescribing Information for Breo Ellipta for the maintenance treatment of airflow obstruction in patients with COPD and to reduce exacerbations of COPD in patients with a history of exacerbations. Please consult the full Prescribing Information for all the labelled safety information for Breo Ellipta.

Long-acting beta$_2$-adrenergic agonists (LABAs), such as vilanterol, one of the active ingredients in Breo Ellipta, increase the risk of asthma-related death. A placebo-controlled trial with another LABA (salmeterol) showed an increase in asthma-related deaths in subjects receiving salmeterol. This finding with salmeterol is considered a class effect of all LABAs, including vilanterol. In the US, the safety and efficacy of Breo Ellipta in patients with asthma have not been established and therefore Breo Ellipta is not indicated for the treatment of asthma.

Breo Ellipta is contraindicated in patients with severe hypersensitivity to milk proteins or who have demonstrated hypersensitivity to either fluticasone furoate, vilanterol, or any of the excipients.

Breo Ellipta should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD, or as rescue therapy for the treatment of acute episodes of bronchospasm. Acute symptoms should be treated with an inhaled, short-acting beta$_2$-agonist.

Breo Ellipta should not be used more often than recommended, at higher doses than recommended, or in conjunction with other medications containing LABAs, as an overdose may result.

Oropharyngeal candidiasis has occurred in patients treated with Breo Ellipta. Patients should rinse their mouth with water without swallowing after inhalation to help reduce this risk.

An increase in the incidence of pneumonia has been observed in subjects with COPD receiving the fluticasone furoate/vilanterol combination, including Breo Ellipta 100 mcg/25 mcg, in clinical trials. There was also an increased incidence of pneumonias resulting in hospitalization. In some incidences these pneumonia events were fatal.

Patients who use corticosteroids are at risk for potential worsening of existing tuberculosis; fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex. A more serious or even fatal course of chickenpox or measles may occur in susceptible patients.

PRESS RELEASE

Particular care is needed for patients who have been transferred from systemically active corticosteroids to inhaled corticosteroids because deaths due to adrenal insufficiency have occurred in patients with asthma during and after transfer from systemic corticosteroids to less systemically available inhaled corticosteroids.

Hypercorticism and adrenal suppression may occur with very high dosages or at the regular dosage of inhaled corticosteroids in susceptible individuals.

Caution should be exercised when considering the coadministration of Breo Ellipta with long-term ketoconazole and other known strong CYP3A4 inhibitors because increased systemic corticosteroid and cardiovascular adverse effects may occur.

As with other inhaled medicines, Breo Ellipta can produce paradoxical bronchospasm which may be life-threatening. Vilanterol, the LABA in Breo Ellipta, can produce clinically significant cardiovascular effects in some patients as measured by increases in pulse rate, systolic or diastolic blood pressure, and also cardiac arrhythmias. Decreases in bone mineral density have been observed with long-term administration of products containing inhaled corticosteroids, as have glaucoma, increased intraocular pressure, and cataracts.

Breo Ellipta should be used with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, ketoacidosis, and in patients who are unusually responsive to sympathomimetic amines.

Beta-adrenergic agonist medicines may produce significant hypokalemia in some patients. Beta-adrenergic agonist medicines may produce transient hyperglycemia in some patients.

The most common adverse reactions (≥3% and more common than in placebo) reported in two 6-month clinical trials with Breo Ellipta (and placebo) were nasopharyngitis, 9% (8%); upper respiratory tract infection, 7% (3%); headache, 7% (5%); and oral candidiasis, 5% (2%). In addition to the events reported in the 6-month studies, adverse reactions occurring in ≥3% of the subjects treated with Breo Ellipta in two 1-year studies included COPD, back pain, pneumonia, bronchitis, sinusitis, cough, oropharyngeal pain, arthralgia, hypertension, influenza, pharyngitis, diarrhea, peripheral edema, and pyrexia.

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, Inc. — is focused on maximizing the potential value of the respiratory assets partnered with Glaxo Group Limited (GSK), including RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®, with the intention of providing capital returns to stockholders. Under the Long-Acting Beta$_2$ Agonist (LABA) Collaboration Agreement with GSK, Theravance is eligible to receive the associated royalty revenues from RELVAR®/BREO® ELLIPTA® (fluticasone furoate/vilanterol, "FF/VI"), ANORO® ELLIPTA® (umeclidinium bromide/vilanterol, "UMEC/VI") and if approved and commercialized, VI monotherapy. Theravance is also entitled to a 15% economic interest in any future payments made by GSK under agreements entered into prior to the spin-off of Theravance Biopharma, and since assigned to Theravance Respiratory Company, LLC, relating to the combination of UMEC/VI/FF and the Bifunctional Muscarinic Antagonist-Beta$_2$ Agonist (MABA) program, as monotherapy and in combination with other therapeutically active components, such as an inhaled corticosteroid, and any other product or combination of products that may be discovered and developed

in the future under these agreements with GSK (other than RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and VI monotherapy). For more information, please visit Theravance's web site at www.thrxinc.com.

ANORO®, RELVAR®, BREO® and ELLIPTA® are trademarks of the GlaxoSmithKline group of companies.

PRESS RELEASE

References:

(1) Global Initiative for Asthma. Pocket Guide for asthma management and prevention. Updated 2014.
(2) American Lung Association, Epidemiology and Statitics Unit, Research and Program Services Division,Trends in Asthma Morbidity and Mortality, September 2012, http://www.lung.org/finding-cures/our-research/trend-reports/asthma-trend-report.pdf (Last accessed March 2015)
(3) Demoly et al. Eur Respir Rev. 2012 Mar 1;21(123):66-74. doi: 10.1183/09059180.00008111.

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Cautionary statement regarding 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. Such factors include, but are not limited to, those described under Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2014.

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. Such forward-looking statements involve substantial risks, uncertainties and assumptions. Examples of such statements include statements relating to: the US FDA following the joint advisory committee's recommendations, the strategies, plans and objectives of the company, the timing, manner and amount of anticipated potential capital returns to stockholders (including without limitation, expectations of future cash dividends or future share repurchases), the status and timing of clinical studies, data analysis and communication of results, the potential benefits and mechanisms of action of product candidates, expectations for product candidates through development and commercialization, the timing of seeking regulatory approval of product candidates, 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 the 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: the disruption of operations during the transition period following the spin-off, including the diversion of managements' and employees' attention, disruption of relationships with collaborators and increased employee turnover, lower than expected future royalty revenue from respiratory products partnered with GSK, delays or difficulties in commencing or completing clinical studies, the potential that results from clinical or non-clinical studies indicate product candidates are unsafe or ineffective, dependence on third parties to conduct its clinical studies, delays or failure to achieve and maintain regulatory approvals for product candidates, and risks of collaborating with third parties to discover, develop and commercialize products. Other risks affecting Theravance are described

under the headings “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” contained in Theravance’s Annual Report on Form 10-K for the year ended December 31, 2014 filed with the Securities and Exchange Commission (SEC) on

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February 27, 2015. In addition to the risks described above and in Theravance’s other filings with the SEC, other unknown or unpredictable factors also could affect Theravance’s results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Theravance assumes no obligation to update its forward-looking statements on account of new information, future events or otherwise, except as required by law. (THRX-G)

(THRX-G)

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