

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

Date of Report: September 20, 2013  
(Date of earliest event reported)

**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**  
(IRS Employer  
Identification Number)

**901 Gateway Boulevard, South San Francisco,  
CA**  
(Address of principal executive offices)

**94080**  
(Zip Code)

**650-808-6000**  
(Registrant's telephone number, including area code)

**Not Applicable**

(Former Name or Former Address, if changed since last report)

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 September 20, 2013, GlaxoSmithKline plc (GSK) and Theravance, Inc. issued a press release announcing that the Japanese Ministry of Health, Labor and Welfare (MHLW) has approved RELVAR(TM) ELLIPTA(TM) for the treatment of bronchial asthma (in cases where concurrent use of inhaled corticosteroid and long-acting inhaled beta2 agonist is required). Relvar Ellipta is not indicated for the treatment of chronic obstructive pulmonary disease in Japan. Relvar is a combination of the inhaled corticosteroid, fluticasone furoate "FF", and the long-acting beta2 agonist, vilanterol "VI". The MHLW has approved two doses of FF/VI - 100/25 mcg and 200/25 mcg. Both strengths will be administered using the Ellipta, a new dry powder inhaler. FF/VI is in development under the LABA collaboration agreement between Glaxo Group Limited and Theravance, Inc. A copy of 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**

99.1 [Press Release dated September 20, 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.

Dated: September 20, 2013

**THERAVANCE, INC.**

By: /s/ Michael W. Aguiar

Michael W. Aguiar

*Chief Financial Officer*

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**Exhibit No.**

99.1

**Exhibit Index**

**Description**

Press Release dated September 20, 2013

## RELVAR(TM) ELLIPTA(TM) Gains Approval in Japan for the Treatment of Asthma

LONDON, UNITED KINGDOM and SOUTH SAN FRANCISCO, CA -- (Marketwired - September 20, 2013) - GlaxoSmithKline plc (LSE: GSK) (NYSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) has approved RELVAR™ ELLIPTA™ for the treatment of bronchial asthma (in cases where concurrent use of inhaled corticosteroid and long-acting inhaled beta2 agonist is required). Relvar Ellipta is not indicated for the treatment of chronic obstructive pulmonary disease (COPD) in Japan.

Relvar is a combination of the inhaled corticosteroid (ICS), fluticasone furoate "FF", and the long-acting beta2 agonist (LABA), vilanterol "VI". The MHLW has approved two doses of FF/VI - 100/25 mcg and 200/25 mcg. Both strengths will be administered once-daily using the Ellipta, a new dry powder inhaler (DPI).

Darrell Baker, SVP & Head, GSK Global Respiratory Franchise, said, "The approval of Relvar Ellipta in Japan means that, for the first time, people with asthma will be able to benefit from a once-daily ICS/LABA that delivers continuous 24-hour efficacy. Throughout the development programme, GSK focused on the needs of patients to develop a medicine that may help address some of the existing treatment challenges. We are delighted by this approval, which means that healthcare professionals in Japan will soon have another treatment option for appropriate asthma patients."

"The approval of Relvar Ellipta will provide Japanese physicians with a new, important once-daily, inhaled treatment option for their asthma patients," said Rick E Winningham, Chief Executive Officer of Theravance. "This first approval of Relvar Ellipta in asthma represents yet another significant milestone in the respiratory partnership between Theravance and GSK."

Under the terms of the 2002 LABA collaboration agreement, Theravance is obligated to make a milestone payment of \$10 million (USD) to GSK following MHLW approval of Relvar Ellipta in Japan.

FF/VI is not approved or licensed anywhere outside of Japan for the treatment of asthma.

### About asthma

Asthma is a chronic lung disease that inflames and narrows the airways, causing recurring periods of wheezing, chest tightness, shortness of breath and coughing which often occurs at night or early in the morning. The Japanese MHLW estimate that 8% of the 127 million people in Japan have asthma.(i,ii)

The causes of asthma are not completely understood however the key risk factors are inhaled substances that provoke allergic reactions or irritate the airways. These include smoke and allergens like dust mites and pets.

Despite medical advances, more than half of patients (53.5%) have poor control of their asthma, representing a significant area of unmet medical need.(iii)

### About Relvar Ellipta

Relvar Ellipta (FF/VI) is the first once-daily, inhaled corticosteroid/long-acting beta agonist (ICS/LABA) combination for the regular treatment of asthma in adults and adolescents aged 12 years and older approved in Japan. Relvar Ellipta contains the ICS fluticasone furoate (FF) and the LABA vilanterol (VI) and may be prescribed in two doses -- 100/25 mcg and 200/25 mcg. Both dosages are administered using the Ellipta, a new dry powder inhaler (DPI).

Japanese Drug Information will be available soon at <http://glaxosmithkline.co.jp/healthcare/>. Prior to the label being posted online, a copy of the label may be requested from one of the GSK Media or Investor Relations contacts listed in the "GlaxoSmithKline Inquiries" section at the end of this document.

### Important Safety Information for Relvar Ellipta in Japan

FF/VI is contraindicated in patients with hypersensitivity to fluticasone furoate, vilanterol, or any of the excipients and in patients with infections or deep mycosis against which there is no effective anti-bacterial agent (symptoms may be exacerbated due to steroid effects).

Because FF/VI is not intended for immediate relief of symptoms that have occurred, the product should not be used to relieve acute symptoms. Any other appropriate drug such as short-acting inhaled beta2 agonist (e.g. inhaled salbutamol sulphate) should be used for relief of acute symptoms.

FF/VI should be administered with caution in patients with tuberculosis or infections, patients with severe cardiac disease, and patients with hepatic impairment.

Patients should be cautioned to visit a medical institution as soon as possible to seek medical treatment if they notice increasing use or insufficient effect of the short-acting inhaled beta2 agonist because asthma management may be inadequate.

Patients should be instructed not to stop inhaling FF/VI on their own since symptoms may be exacerbated after discontinuation of the product.

As with other inhaled drugs, paradoxical bronchospasm may occur with an increase in wheezing after inhalation of FF/VI. In such a case, FF/VI should be discontinued immediately, and treatment with a short-acting inhaled bronchodilator should be given. The patient should be assessed and alternative therapy should be considered if necessary.

Asthma-related events and asthma exacerbations may occur during treatment with FF/VI. Patients should be instructed not to stop inhaling FF/VI on their own but to seek medical advice if asthma symptoms remain uncontrolled or are exacerbated after initiation of treatment with the product.

Systemic effects (including Cushing's syndrome, Cushingoid symptoms, adrenal suppression, growth retardation in children, decrease in bone mineral density, cataract, and glaucoma) may occur with inhaled steroids although these effects are less likely than with systemic steroids. Therefore, inhaled steroids should be used at the lowest dose to effectively control asthma for each patient. Particularly, patients who are treated at high doses for long periods should be monitored with regular examinations; in case systemic effects occur, appropriate measures should be taken while monitoring the patient's asthmatic symptoms.

It has been reported in a global clinical study and overseas clinical studies in patients with chronic obstructive pulmonary disease that the incidence of pneumonia showed a fluticasone furoate/vilanterol dose-dependent increase. Caution should be exercised when FF/VI is administered to patients who are generally at potentially high risk for developing pneumonia.

Caution should be exercised when considering the coadministration of FF/VI with long-term ketoconazole and other known strong CYP3A4 inhibitors because increased systemic corticosteroid and cardiovascular adverse effects may occur. Caution should also be exercised when considering the coadministration of FF/VI with beta-blockers which may weaken the effect of FF/VI.

In three global phase III clinical studies, adverse reactions including laboratory abnormalities were reported in 100 (7.1%) of a total of 1,407 patients (including 61 Japanese patients) treated with FF/VI. The common adverse reactions were dysphonia and oral candidiasis reported in 19 (1.4%) and 12 (0.9%) patients, respectively. Of 61 Japanese patients, adverse reactions including laboratory abnormalities were reported in 7 patients (11.5%). The common adverse reactions were dysphonia and oral candidiasis reported in 3 (4.9%) and 2 (3.3%) patients, respectively (at the time of approval).

In a Japanese long-term administration study, adverse reactions including laboratory abnormalities were reported in 40 (26.1%) of a total of 153 patients treated with FF/VI. The common adverse reactions were oral candidiasis and dysphonia reported in 16 (10.5%) and 10 (6.5%) patients, respectively (at the time of approval).

An anaphylactic reaction may occur (incidence unknown). Patients treated with Relvar Ellipta should be monitored closely, and if an abnormality is observed, the treatment should be discontinued and appropriate measures should be taken.

#### **Other FF/VI Regulatory Activity:**

In June 2012, a regulatory application for FF/VI was submitted in the European Union under the trade name RELVAR™ ELLIPTA™ for the treatment of patients with COPD and asthma. FF/VI is not approved or licensed in the European Union or anywhere outside of the US, Canada and Japan.

FF/VI is not approved or licensed anywhere outside of Japan for the treatment of asthma. In the US, BREO ELLIPTA is not indicated for the treatment of asthma. Full US Prescribing Information, including BOXED WARNING and Medication Guide is available at [us.gsk.com](http://us.gsk.com) or **US Prescribing information BREO ELLIPTA**.

#### **GSK Respiratory Development Programmes:**

The GSK respiratory development portfolio includes LAMA/LABA (umeclidinium bromide (UMEC)/VI), with proposed brand name ANORO™ ELLIPTA™, VI monotherapy and MABA (GSK961081), developed in collaboration with Theravance, as well as GSK's investigational medicines FF monotherapy, UMEC monotherapy and anti-IL5 MAb (mepolizumab). These investigational medicines are not currently approved anywhere in the world.

RELVAR™, BREO™, ANORO™ and ELLIPTA™ are trademarks of the GlaxoSmithKline group of companies. The use of the brand name ANORO™ is not approved by any regulatory authorities.

**GlaxoSmithKline** -- 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](http://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 programmes include: RELVAR™ ELLIPTA™ or BREO™ ELLIPTA™ (FF/VI), ANORO™ ELLIPTA™ (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta2 Agonist), GSK961081, each partnered with GlaxoSmithKline plc, and its oral Peripheral Mu Opioid Receptor Antagonist programme. 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](http://www.theravance.com).

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#### **GlaxoSmithKline 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. Factors

that may affect GSK's operations are described under Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2012.

### **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 August 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. (THRX-G)

(i) Ministry of Health, Labour and Welfare (MHLW)

(ii) Statista. Available from <http://www.statista.com/statistics/263746/total-population-in-japan/> [Last accessed September 2013]

(iii) Demoly, P et al. Repeated cross-sectional survey of patient-reported asthma control in Europe in the past 5 years. *European Respiratory Review*. 2012;21(123):66-24.

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