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): November 19, 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)

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):

□ 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 November 19, 2014, GlaxoSmithKline plc (GSK) and Theravance, Inc. distributed a press release in Manchester, United Kingdom, that patient recruitment in the Salford Lung Study in chronic obstructive pulmonary disease (COPD) has completed. The Salford Lung Study is being conducted in the unique 'research city' setting of Salford, Greater Manchester. Approximately 2,800 people with COPD living in Salford and the surrounding area have signed up to be part of a one-year study to explore the effectiveness of RELVAR[®] ELLIPTA[®] (fluticasone furoate 'FF'/vilanterol 'VI'100/25 mcg) compared to other COPD treatments when used in a broad group of people living and managing their COPD on a day-to-day basis. The Salford Lung Study (NCT01551758) is a Phase 3 multicenter, randomized open-label study in patients being treated in primary care who have been diagnosed and receive regular treatment for COPD in Salford. The primary endpoint is the mean annual rate of moderate and severe exacerbations while secondary endpoints will assess safety, contact with healthcare professionals and patient reported outcomes. The 12-month COPD study is expected to complete at the end of 2015 with the first results expected in 2016. FF/VI has been developed under the 2002 Long-Acting Beta₂ Agonist (LABA) collaboration between Glaxo Group Limited and Theravance, Inc. FF/VI, under the trade name RELVAR[®] ELLIPTA[®], is approved in Europe for COPD and asthma. In the United States, FF/VI under the trade name BREO[®] ELLIPTA[®] is not indicated for the relief of acute bronchospasm or the treatment of asthma in the United States. 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.

ExhibitDescriptionExhibit 99.1Press Release dated November 19, 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: November 19, 2014

By: <u>/s/ Michael W. Aguiar</u> Michael W. Aguiar Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u> 99.1 <u>Description</u> Press Release dated November 19, 2014



Issued: 19 November 2014

Patient recruitment completed in a world-first COPD lung study being conducted in the unique 'research city' setting of Salford, Greater Manchester

Approximately 2,800 people with Chronic Obstructive Pulmonary Disease (COPD) living in Salford and the surrounding area have signed up to be part of a one-year study to explore the effectiveness of Relvar[®] ▼ Ellipta[®] (fluticasone furoate 'FF'/vilanterol 'VI'100/25 mcg) compared to other COPD treatments when used in a broad group of people living and managing their COPD on a day-to-day basis.

Traditionally, medicines are evaluated through randomised controlled trials (RCTs) which are vital in helping understand the efficacy and safety of medicines. RCTs are carefully controlled and include specific patient populations to allow scientists to accurately assess exactly what effect a medicine is having, and, as such, may exclude patients with additional conditions or those who are receiving other medicines which may influence the outcome. So there is a need for additional information, to complement the findings from RCTs, in order to better understand the potential of a medicine when used by people in the real world.

The Salford Lung Study has been specifically designed to provide this type of information. It includes a broader range of people who are more representative of the population in which the medicine would be prescribed in 'real life', for example more patients with different disease severities or with co-existing illnesses. These patients are asked to manage their COPD and other conditions as normal via their GP, Pharmacist and Specialist, without additional interventions.

The Salford Lung Study is the first 'real-world' study of its kind in the world, being initiated on a medicine prior to approval, conducted in just one geographic location and run by GSK in collaboration with the local healthcare providers and academia, including North West e-Health (NWEH), The University of Manchester, Salford Royal NHS Foundation Trust, NHS Salford, and over 2000 GP and community pharmacy staff.

The study also utilises Salford's sophisticated electronic health record system which links patients' records across GP surgeries and hospitals. This allows patients to be closely monitored in real-time over the course of the study, but with minimal intrusion into their everyday lives, unlike RCTs which require multiple interventions.

David Leather, Relvar Global Medical Affairs Leader, GSK said, "The Salford Lung Study is a new and exciting way of studying a medicine which maintains the robustness of a randomised controlled trial while more closely reflecting the real world in which the medicine is used. We have already gained so many valuable insights in establishing the study and creating a research city in Salford that allows us to better evaluate COPD patients' real-life treatment experience. We look forward to the results of the study and to better understanding the real-world value of the 24-hour efficacy of Relvar Ellipta for patients with COPD who are at risk of exacerbations."

The Salford Lung Study (NCT01551758) is a Phase 3 multi-centre, randomised open-label study in patients being treated in primary care who have been diagnosed and receive regular treatment for COPD in Salford. The primary endpoint is the mean annual rate of moderate and severe exacerbations while secondary endpoints will assess safety, contact with healthcare professionals and patient reported outcomes.

The 12 month COPD study is expected to complete at the end of 2015 with the first results expected in 2016.

A second part of the Salford Lung Study is being conducted in patients with asthma and aims to evaluate the effectiveness and safety of Relvar Ellipta 100/25 and 200/25 mcg compared with existing maintenance therapy. Recruitment of asthma patients is ongoing.

ENDS

As is customary for most newly licensed medicines, Relvar Ellipta (fluticasone furoate/vilanterol) follows the EU-wide black triangle monitoring scheme: This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions

About the Salford Lung Study

The Salford Lung Study is intended to enable healthcare decision makers to more fully assess the potential value of fluticasone furoate/vilanterol (FF/VI) by providing data collected in a real-world setting which is representative of how healthcare professionals and patients may use the medicine in everyday life. It will add to the existing data set from RCTs for the medicine which, while critical to establishing the safety and efficacy of a medicine, are conducted in a highly controlled environment and enrol a more highly selected patient population than would be expected in the real world.

The study is made possible through a unique collaboration between GSK, North West e-Health (NWEH), The University of Manchester, Salford Royal NHS Foundation Trust, University Hospital of South Manchester (UHSM), NHS Salford and GPs and community pharmacists in Salford, Trafford and South Manchester.

Salford, Greater Manchester was chosen after an extensive global search revealed its information systems and organisational networks are best suited to this particular type of study.

About COPD

Chronic obstructive pulmonary disease is a term referring to two lung diseases, chronic bronchitis and emphysema, that are characterised by obstruction to airflow that interferes with normal breathing.

Long-term exposure to lung irritants that damage the lungs and the airways are usually the cause of COPD.¹ Cigarette smoke, breathing in second hand smoke, air pollution, chemical fumes or dust from the environment or workplace can all contribute to COPD.¹ Most people who have COPD are at least 40 years old when symptoms begin.

COPD-related exacerbations are typically defined as a worsening of symptoms that require medical intervention.¹

About Relvar Ellipta

Relvar Ellipta was approved by the European Medicines Agency (EMA) in November 2013 for the symptomatic treatment of adults with chronic obstructive pulmonary disease (COPD) with a $FEV_1 < 70\%$ predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy. One strength has been licensed for the treatment of COPD (92/22 mcg) and is administered once-daily using Ellipta, a dry powder inhaler (DPI).

European Medicines Agency (EMA) European public assessment report including summary of product characteristics.

Important safety information for Relvar Ellipta in Europe

FF/VI is contraindicated in patients with hypersensitivity to either fluticasone furoate, vilanterol, or any of the excipients.

FF/VI should not be used to treat acute asthma symptoms or an acute exacerbation in COPD, for which a short-acting bronchodilator is required. Increasing use of short-acting bronchodilators to relieve symptoms indicates deterioration of control and patients should be reviewed by a physician.

Patients should not stop therapy with FF/VI in asthma or COPD, without physician supervision since symptoms may recur after discontinuation.

Asthma-related adverse events and exacerbations may occur during treatment with FF/VI. Patients should be asked to continue treatment but to seek medical advice if asthma symptoms remain uncontrolled or worsen after initiation of treatment with FF/VI.

Paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. This should be treated immediately with a short-acting inhaled bronchodilator. FF/VI should be discontinued immediately, the patient assessed and alternative therapy instituted if necessary.

Cardiovascular effects, such as cardiac arrhythmias e.g. supraventricular tachycardia and extrasystoles may be seen with sympathomimetic medicinal products including FF/VI. Therefore fluticasone furoate/vilanterol should be used with caution in patients with severe cardiovascular disease.

For patients with moderate to severe hepatic impairment, the 92/22 mcg dose should be used and patients should be monitored for systemic corticosteroidrelated adverse reactions. FF/VI 184/22 mcg is not indicated for patients with COPD. There is no additional benefit of the 184/22 mcg dose compared to the 92/22 mcg dose and there is a potential increased risk of pneumonia and systemic corticosteroid-related adverse reactions.

An increase in the incidence of pneumonia has been observed in subjects with COPD receiving FF/VI. There was also an increased incidence of pneumonias resulting in hospitalisation. In some incidences these pneumonia events were fatal.

The incidence of pneumonia in patients with asthma was common at the higher dose. The incidence of pneumonia in patients with asthma taking FF/VI 184/22 mcg was numerically higher compared with those receiving FF/VI 92/22 mcg or placebo.

Hyperglycaemia: There have been reports of increases in blood glucose levels in diabetic patients and this should be considered when prescribing to patients with a history of diabetes mellitus.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

Systemic effects may occur with any inhaled corticosteroid, particularly at high doses prescribed for long periods. These effects are much less likely to occur than with oral corticosteroids. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, decrease in bone mineral density, growth retardation in children and adolescents, cataract and glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).

FF/VI should be administered with caution in patients with pulmonary tuberculosis or in patients with chronic or untreated infections. Data from large asthma and COPD clinical trials were used to determine the frequency of adverse reactions associated with FF/VI.

Very common adverse reactions (occurring in >1/10 patients) with FF/VI were headache and nasopharyngitis. Common adverse reactions (occurring in >1/100 to <1/10 patients) were pneumonia, upper respiratory tract infection, bronchitis, influenza, candidiasis of mouth and throat, oropharyngeal pain, sinusitis, pharyngitis, rhinitis, cough, dysphonia, abdominal pain, arthralgia, back pain, fractures and pyrexia. Extrasystoles were observed as an uncommon adverse reaction (occurring in >1/1,000 to <1/100 patients). With the exception of pneumonia and fractures, the safety profile was similar in patients with asthma and COPD. During clinical studies, pneumonia and fractures were more frequently observed in patients with COPD.

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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 <u>www.gsk.com</u>.

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 Beta₂ 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-Beta₂ 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 website at www.thrxinc.com.

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

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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 strategies, plans and objectives of the company, the timing, manner, amount and planned growth of anticipated potential capital returns to stockholders (including without limitation statements, expectations of future cash dividends and the potential for 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 filed with the Securities and Exchange Commission (SEC) on November 4, 2014. 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 forwardlooking 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.

¹ Global Initiative for Chronic Obstructive Lung Disease (GOLD). Pocket guide to COPD diagnosis, management and prevention