
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): December 1, 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))
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Item 8.01 Other Events.

On December 1, 2014, GlaxoSmithKline plc (GSK) and Theravance, Inc. (Theravance) announced that ANORO[®] ELLIPTA[®] (umeclidinium/vilanterol) will be reimbursed via the Australian Pharmaceutical Benefits Scheme (PBS) as a long-term once-daily, maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). The reimbursement will be effective beginning December 1, 2014. ANORO[®] is a once-daily combination treatment comprising two bronchodilators, umeclidinium (UMEC), a long-acting muscarinic antagonist (LAMA), and vilanterol (VI), a long-acting beta₂ agonist (LABA), in a single inhaler, the ELLIPTA[®]. In addition, GSK and Theravance also announced that BREO[®] ELLIPTA[®] (fluticasone furoate/ vilanterol) will be added to the PBS listing for treatment of asthma and COPD beginning December 1, 2014. BREO[®] is a combination of an inhaled corticosteroid, fluticasone furoate (FF) and a long-acting bronchodilator, VI, administered using the ELLIPTA[®]. UMEC/VI and FF/VI have been developed under the 2002 LABA collaboration between Glaxo Group Limited and Theravance. The press releases are filed as Exhibit 99.1 and Exhibit 99.2 to this report and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit</u>	<u>Description</u>
Exhibit 99.1	ANORO [®] ELLIPTA [®] Press Release dated December 1, 2014
Exhibit 99.2	BREO [®] ELLIPTA [®] Press Release dated December 1, 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: December 1, 2014

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

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	ANORO® ELLIPTA® Press Release dated December 1, 2014
99.2	BREO® ELLIPTA® Press Release dated December 1, 2014



THERAVANCE, INC.
A ROYALTY MANAGEMENT COMPANY

1 December 2014 – Sydney, Australia.

Anoro® Ellipta® (umeclidinium/vilanterol) to be reimbursed in Australia for Chronic Obstructive Pulmonary Disease

- **Administered using a new dry powder inhaler called Ellipta¹**
- **Listed on the Pharmaceutical Benefits Scheme (PBS) on 1st December, 2014**

GlaxoSmithKline (GSK) and Theravance, Inc. (NASDAQ: THRX) have welcomed news that Anoro Ellipta (umeclidinium/vilanterol) will be reimbursed via the Australian Pharmaceutical Benefits Scheme (PBS) as a long-term once-daily, maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

The reimbursement will be effective from December 1st 2014.

Anoro is a once-daily combination treatment comprising two bronchodilators, umeclidinium (UMEC), a long-acting muscarinic antagonist (LAMA), and vilanterol (VI), a long-acting beta₂ agonist (LABA), in a single inhaler, the Ellipta.

Senior respiratory physician and clinical researcher Professor Peter Frith from Repatriation General Hospital said he welcomed the improved access to new treatments that results from PBS reimbursement.

“I certainly welcome better access to effective treatment options in COPD that can alleviate symptoms and improve quality of life. Combined drugs of this nature promise to add significantly to patient well-being,” said Professor Frith.

GSK Medical Director, Dr Andrew Weekes says the reimbursement underscores the breadth of GSK’s growing respiratory portfolio in Australia.

“This reimbursement coincides with the PBS listing of Incruse® Ellipta® (umeclidinium) for COPD. These dual developments are testimony to our determination to bring new respiratory options to the market. GSK is committed to developing a range of therapeutic options to provide physicians choice when considering individual patient needs.”

“We are delighted by the Australian PBS listing of Anoro Ellipta which provides a new alternative for COPD patients for whom dual bronchodilator treatment in a single inhaler may be appropriate,” said Dr Weekes.

Michael W. Aguiar, President and Chief Executive Officer of Theravance said he is pleased to see Anoro Ellipta being reimbursed in Australia for the treatment of COPD.

“We believe this will be an important treatment option for appropriate patients with COPD and is a further positive outcome from the collaboration between Theravance and GSK to bring to market new respiratory medicines that meet patient needs.”

The evidence supporting the reimbursement was based upon results of 7 clinical studies in 5,968 patients with COPD.

Product Information is available at <http://www.gsk.com.au/anoro>

About COPD

The prevalence of COPD in Australia is difficult to determine because accurate diagnosis requires clinical testing. It is estimated that COPD affects approximately 529,000 Australians (2%).²

About Anoro Ellipta¹

Anoro is a combination treatment comprising two bronchodilators, umeclidinium, a long-acting muscarinic antagonist (LAMA), and vilanterol (VI), a long-acting beta₂ agonist (LABA), in a single inhaler, the Ellipta[®]. The registered strength of Anoro Ellipta is 62.5/25mcg.

Anoro Ellipta was well tolerated in clinical trials. Anoro Ellipta is intended for the long-term maintenance bronchodilator treatment of COPD and should not be used for the relief of acute symptoms.

Adverse events included: Cough, pharyngitis, constipation, dry mouth, UTI, URTI.

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 Peter Frith has served on advisory boards sponsored by GSK for which an honorarium was received. In relation to this GSK media announcement, no honorarium was provided to Professor Peter Frith, and the opinions expressed are his own. Professor Peter Frith has been briefed by GSK on the approved use of this product.

If you are an Australian healthcare professional please visit www.health.gsk.com for more information on Anoro[®] Ellipta[®].

You can follow GSK on Twitter for more Australian updates [@GSK_AU](https://twitter.com/GSK_AU).

References:

1. Anoro[®] Ellipta[®] Approved Product information July 2014.
2. Australian Institute of Health and Welfare Report *Australia's Health 2014*.p138

PBS Information: Authority required (STREAMLINED). Refer to PBS Schedule for full authority information.

STREAMLINED AUTHORITY CODE 4655

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

ANORO[®] ELLIPTA[®] (umeclidinium bromide/vilanterol trifenate)

62.5 mcg umeclidinium/25 mcg vilanterol inhalation powder

INDICATIONS: As a long-term once daily maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

CONTRAINDICATIONS: Hypersensitivity to the active ingredient or any excipients, patients with severe milk-protein allergy.

PRECAUTIONS: Should not be used in asthma. Can cause paradoxical bronchospasm - if it occurs, treatment should be discontinued and alternative therapy instituted if necessary. Should not be used for the relief of acute symptoms of bronchospasm. Use with caution in patients with severe cardiovascular disorders, particularly cardiac arrhythmias. See full PI. Use with caution in patients with narrow-angle glaucoma or urinary retention. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Pregnancy – Cat B3, Lactation – unknown whether umeclidinium or vilanterol are excreted in human milk. Paediatric – should not be used in children.

INTERACTIONS: Beta-blockers, strong CYP3A4 inhibitors, P-glycoprotein inhibitors.

ADVERSE EFFECTS: Cough, pharyngitis, constipation, dry mouth, UTI, URTI. Others see full PI.

DOSAGE: One oral inhalation via Anoro Ellipta inhaler (umeclidinium/vilanterol 62.5/25 mcg), once a day. Do not use Anoro Ellipta more than once every 24 hours. Should be taken at the same time every day. No dosage adjustment is required in elderly, impaired renal function, mild or moderate hepatic impairment. This product should not be used in children.

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.

Anoro, Incruse and Ellipta are registered trademarks 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. 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 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.

ENDS

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

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investor.relations@thrxinc.com

GSK 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 2013.

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 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)



THERAVANCE, INC.
A ROYALTY MANAGEMENT COMPANY

1 December 2014 – Sydney, Australia

Breo® Ellipta® (fluticasone furoate/vilanterol) to gain PBS listing for the treatment of asthma and COPD

- **First combination of an inhaled corticosteroid and a long-acting beta₂ agonist administered once daily for asthma and COPD¹**
- **Administered using a new dry powder inhaler called Ellipta¹**

Affordable treatment options for Australian patients with asthma and chronic obstructive pulmonary disease (COPD) are set to expand with GlaxoSmithKline (GSK) and Theravance, Inc. (NASDAQ: THRX) announcing the listing of Breo Ellipta on the Pharmaceutical Benefits Scheme (PBS) from 1st December 2014.

Breo Ellipta is a combination of an inhaled corticosteroid, fluticasone furoate and a long-acting bronchodilator, vilanterol, administered using the new Ellipta dry powder inhaler (DPI).

Breo Ellipta is listed on the PBS for the treatment of asthma in Australian patients aged 12 years and over. The registered strengths of Breo Ellipta for the treatment of moderate to severe asthma are 100/25mcg and 200/25mcg.

Breo Ellipta is also listed on the PBS for the treatment of COPD. The registered strength for Breo Ellipta for COPD is 100/25mcg.

Respiratory specialist and senior scientist Professor Phil Bardin said he welcomed the availability of new options in asthma management.

“Remembering to take medications is a major problem for many people. I welcome contemporary treatments for asthma that need only be taken once a day since this strategy gives healthcare professionals additional options for suitable patients,” said Professor Bardin.

GSK Medical Director, Dr Andrew Weekes says the listing represents a milestone for the company which is dedicated to improving respiratory health in Australia and continuing the development of new treatments for patients with asthma and COPD.

“We are delighted with this new listing in Australia. GSK is committed to making medicines available and affordable to our Australian patients.

“The listing of Breo Ellipta reinforces GSK’s commitment to innovation in respiratory health and we are proud to make this treatment option available for prescribers and their patients,” said Dr Weekes.

“The Australian PBS reimbursement of Breo Ellipta is yet another important achievement reflecting the strength of our partnership with GSK,” said **Michael W. Aguiar, President and Chief Executive Officer of Theravance** “We, like GSK, are pleased to make Breo Ellipta available for appropriate patients in Australia.”

Prescribing Information is available at www.gsk.com.au/breo

About Asthma

Asthma is a condition of the airways when the muscles become tight (bronchoconstriction), swollen and irritated (inflammation). Symptoms include shortness of breath, wheezing, chest tightness and cough.² Asthma affects approximately 1 in 10 Australians.³

About COPD

The prevalence of COPD in Australia is difficult to determine because accurate diagnosis requires clinical testing. It is estimated that COPD affects approximately 529,000 Australians (2%).⁴

Important Safety Information for Breo Ellipta in Australia¹

Breo Ellipta is registered for use in the regular treatment of moderate to severe asthma requiring medium to high dose inhaled corticosteroid with a long-acting bronchodilator 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

Breo Ellipta is indicated in adults and adolescents aged 12 years and over.¹

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, influenza, oral candidiasis of mouth and throat, extrasystoles, oropharyngeal pain, sinusitis, pharyngitis, rhinitis, cough, dysphonia, abdominal pain, arthralgia, back pain, pyrexia. Fractures and pneumonia 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:

The information contained within this media release does not contain all the available information. It does not take the place of talking to healthcare professionals.

If you are an Australian healthcare professional please visit www.health.gsk.com for more information on Breo Ellipta.

Professor Phil Bardin 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 Phil Bardin, and the opinions expressed are his own. Professor Phil Bardin has been briefed by GSK on the approved use of this product.

You can follow GSK on Twitter for more Australian updates [@GSK_AU](https://twitter.com/GSK_AU).

PBS Information – Restricted Benefit: Asthma

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids. Patient must be 12 years or older.

PBS Information – Restricted Benefit: COPD

Symptomatic treatment of COPD where the FEV1 is < 50% predicted normal and there is a history of repeated exacerbations with significant symptoms despite regular β 2-agonist bronchodilator therapy. Note: Patient must not be on a concomitant single agent long acting β 2-agonist. Product is not indicated for initiation of bronchodilator therapy in COPD.

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 β 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, formoterol, 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.

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

Adverse Reactions: Very common: headache, nasopharyngitis. Common: URTI, bronchitis, influenza, oral candidiasis of mouth and throat, extrasystoles, oropharyngeal pain, sinusitis, pharyngitis, rhinitis, cough, dysphonia, abdominal pain, arthralgia, back pain, pyrexia. Fractures and 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 v2.0. For full product information please contact GlaxoSmithKline Australia Pty Ltd. PO Box 18095, Melbourne, VIC 8003. ABN 47 100 162 481. Breo® and Ellipta® are registered trademarks of the GSK Group of Companies. AUS/FFT/0001/14a Date of Approval: October 2014

References:

1. Breo Ellipta Product information 9 July 2014
2. Australian Centre for Asthma Monitoring 2011. Asthma in Australia 2011. AIHW Asthma Series no. 4. Cat. no. ACM 22. Canberra: AIHW.
3. National Health survey 2007-8; adults. Prevalence in adults stable (AIHW: Asthma in Australia 2011; COPD in Australia p14; p164)
4. Australian Institute of Health and Welfare Report. *Australia's Health 2014*. p138

Breo and Ellipta are registered trademarks 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. For further information please visit www.gsk.com

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GSK Cautionary statement regarding forward-looking statements

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