

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

FORM 8-K

CURRENT REPORT

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

Date of Report: May 06, 2014  
(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))

**Item 2.02. Results of Operations and Financial Condition**

The information in this Current Report (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Securities Exchange Act of 1934"), or otherwise subject to the liabilities of that Section. The information in this Current Report (including Exhibit 99.1) shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

On May 6, 2014 Theravance, Inc. ("Theravance") issued a press release announcing the record date of May 15, 2014 for the dividend of ordinary shares of Theravance Biopharma, Inc. to be paid to Theravance stockholders to effect the separation of Theravance into two independent, publicly traded companies. Each Theravance stockholder of record as of 5:00 p.m. Eastern Time on May 15, 2014 will receive shares of Theravance Biopharma, Inc. on the issue date, currently expected to be June 2, 2014. In addition, the press release announced that Theravance intends to initiate a quarterly cash dividend of \$0.25 per share to Theravance stockholders beginning in the third quarter of 2014. The press release also covered Theravance's financial results for the quarter ended March 31, 2014. A copy of the press release is furnished as Exhibit 99.1 to this Current Report.

**Item 9.01. Financial Statements and Exhibits**

**(d) Exhibits**

99.1 [Press Release dated May 06, 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.

Dated: May 06, 2014

**THERAVANCE, INC.**

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

---

<b><u>Exhibit No.</u></b>	<b>Exhibit Index</b>	<b><u>Description</u></b>
99.1		Press Release dated May 06, 2014

## **Theravance, Inc. Announces May 15 Record Date and June 2 Share Issue Date for Separation Into Two Companies via a Stock Dividend**

Announces Intention to Initiate \$0.25 per Share Quarterly Cash Dividend to Theravance, Inc. Stockholders in Third Quarter 2014; Reports First Quarter 2014 Financial Results

SOUTH SAN FRANCISCO, CA -- (Marketwired - May 06, 2014) - Theravance, Inc. (NASDAQ: THRX) (the "Company" or "Theravance") has announced the record date of May 15, 2014 for the Company's strategic separation into two independent, publicly traded companies via a stock dividend. Each Theravance stockholder of record as of 5:00 p.m. Eastern Time on May 15, 2014 will receive shares of Theravance Biopharma, Inc. on the issue date, currently expected to be June 2, 2014. In addition, the Company announced that it intends to initiate a quarterly cash dividend to stockholders of Theravance of \$0.25 per share beginning in the third quarter of 2014.

"I am very pleased with our team's progress in 2014 on both the tactical and strategic level," said Rick E Winningham, Chief Executive Officer. "The completion of the separation will be a major milestone on the path toward creating two separate successful companies, each aligned with distinct stockholder objectives. Theravance's strategy will align with stockholders who seek capital returns from dividend payouts, which we intend to grow over time, and potential future share repurchases. Theravance Biopharma shareholders, on the other hand, have the potential to benefit primarily from capital appreciation associated with progress in the research, development and commercialization activities in our product pipeline."

### **Corporate Developments**

Separation Strategy To Be Accomplished via Stock Dividend of Theravance Biopharma

In April 2013, Theravance announced that it would separate late-stage partnered respiratory assets from its biopharmaceutical research and development (R&D) operations and create two companies, Theravance, Inc. (the royalty management company) and Theravance Biopharma, Inc. (the R&D company) to unlock value and facilitate capital returns to stockholders. This strategic separation is expected to be completed on June 2, 2014 subject to various legal and regulatory conditions, including the effectiveness of the Form 10 Registration Statement filed with the U.S. Securities and Exchange Commission.

Theravance, Inc., A Royalty Management Company, will focus on managing all development and commercial responsibilities under its respiratory partnership agreements with GlaxoSmithKline plc (GSK) and associated royalty revenues, including royalties from RELVAR®/BREO® ELLIPTA® and ANORO™ ELLIPTA®, with the intention of providing capital returns to stockholders. The R&D company, Theravance Biopharma, Inc., will be a biopharmaceutical company focused on discovery, development and commercialization of small molecule product candidates in the bacterial infections, central nervous system (CNS)/pain, respiratory disease, and gastrointestinal (GI) motility dysfunction therapeutic areas. The separation will create two independent, publicly traded companies with different business models, enabling investors to align their investment philosophies with the strategic opportunities and financial objectives of the two independent enterprises.

In April 2014, Theravance announced that it had entered into certain note purchase agreements relating to the private placement of \$450.0 million aggregate principal amount of non-recourse 9% fixed rate term notes due 2029 issued by our wholly-owned subsidiary. The notes are secured by a security interest in a segregated bank account established to receive 40% of royalties from global net sales occurring on or after April 1, 2014 and ending upon the earlier of full repayment of principal or May 15, 2029 of RELVAR®/BREO® ELLIPTA®, ANORO™ ELLIPTA® and, if filed, approved and commercialized, VI monotherapy, due to Theravance under the collaboration agreement with GSK. The Company currently plans to utilize the net proceeds from this transaction to support the initiation of a capital return strategy to its stockholders, to pay remaining approval and launch milestones to GSK under the collaboration agreement, and to fund the Company's operations following the separation. Theravance may redeem the notes at any time prior to maturity, in whole or in part, subject to the terms of the indenture.

Intention to Initiate Cash Dividend

Theravance intends to initiate a \$0.25 per share quarterly dividend to stockholders of Theravance during the third quarter of 2014, following the separation of Theravance Biopharma, Inc. from the Company. This decision was based upon Theravance's strong capital position and confidence in the respiratory programs partnered with GSK, RELVAR®/BREO® ELLIPTA® and ANORO™ ELLIPTA®. Following the separation, Theravance will be capitalized with the net proceeds of approximately \$434.3 million from the recently completed private placement of non-recourse PHARMA(SM) royalty notes less any milestones paid to GSK prior to the separation. The dividend is intended to grow over time.

### **Program Highlights**

Respiratory Programs with GlaxoSmithKline plc (GSK)

RELVAR®/BREO® ELLIPTA® (fluticasone furoate/vilanterol "FF/VI")

RELVAR®/BREO® ELLIPTA® has been approved in 42 countries for marketing and has been launched in 12 countries, including the U.S., Canada, Japan, and U.K., as of April 25, 2014.

In April 2014, GSK announced that it expects Medicare Part D coverage to exceed 70% from May 1, 2014 and that 50 percent of patients are insured through commercial plans.

In April 2014, GSK and Theravance announced that the Therapeutic Goods Administration (TGA) has approved BREO™ ELLIPTA® for the treatment of patients with asthma or COPD in Australia.

In April 2014, GSK announced its intention to file BREO® for asthma in the U.S. in 2014.

BREO® ELLIPTA® is the proprietary name in the U.S., Canada and Australia for the once-daily combination medicine of an inhaled corticosteroid (ICS), fluticasone furoate "FF", and a long-acting beta2-agonist (LABA), vilanterol "VI" (FF/VI) administered using the ELLIPTA®, a dry powder inhaler (DPI). RELVAR® ELLIPTA® is the proprietary name for FF/VI outside of the U.S., Canada and Australia. BREO® ELLIPTA® is not indicated for the relief of acute bronchospasm or for the treatment of asthma in the U.S. or Canada.

In April 2014, GSK and Theravance announced the start of a Phase 3 efficacy and safety study of FF/VI evaluating the contribution of the ICS component on lung function, in patients with COPD. Positive results from this study will help support a potential filing of FF/VI for the treatment of patients with COPD in Japan.

In March 2014, GSK and Theravance announced that recruitment of patients into the "Study to Understand Mortality and Morbidity", known as SUMMIT, has completed enrollment of 16,000 patients. The aim of this study is to determine the impact of RELVAR®/BREO® ELLIPTA® (FF/VI) on all-cause mortality amongst patients with moderate COPD who have cardiovascular disease (CVD) or are at increased risk for CVD. As an event-driven study, the exact duration of the treatment phase will depend on the mortality rate within the study. However, it is anticipated that each patient will participate in the study in the range of 16-53 months.

In February 2014, GSK submitted a regulatory application to the China Food and Drug Administration (CFDA) for FF/VI, administered using the ELLIPTA® inhaler, for asthma and COPD.

On May 20, 2014, GSK will be presenting data from a Phase 3 study, "Efficacy and Safety of Once-Daily Fluticasone Furoate/Vilanterol (FF/VI) and FF Over 12 Weeks In Patients With Persistent Asthma," and the protocol of the Phase 3 Salford Lung Study of FF/VI in asthma at the American Thoracic Society (ATS) 2014 International Conference held in San Diego, California.

ANORO™ ELLIPTA® (umeclidinium bromide/vilanterol, UMEC/VI)

On April 28, 2014, GSK and Theravance announced that ANORO™ ELLIPTA®, the first once-daily product approved in the U.S. that combines two long-acting bronchodilators in a single inhaler for the maintenance treatment of COPD, is now available in U.S. retail pharmacies. The FDA-approved strength of ANORO™ ELLIPTA® is UMEC/VI 62.5 mcg/25 mcg.

In February 2014, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion recommending marketing authorization for UMEC/VI under the proposed brand name ANORO® as a once-daily, maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. The proposed strength is UMEC/VI 55 mcg / 22 mcg.

UMEC/VI is also under regulatory review by a number of other regulatory authorities, including Japanese Ministry of Health, Labour and Welfare.

In March 2014, GSK and Theravance announced positive results from three Phase 3 studies. Two studies comparing the efficacy and safety of ANORO™ ELLIPTA® with inhaled corticosteroid/long-acting beta2-adrenergic agonist combination, ADVAIR® DISKUS® (fluticasone propionate/salmeterol 'FSC 250/50') and the third comparing the efficacy and safety of ANORO™ ELLIPTA® with SERETIDE® DISKUS® 'FSC 500/50' in patients with COPD and no history of moderate to severe COPD exacerbations in the last year. In each of the studies UMEC/VI achieved a statistically significant improvement in lung function, measured as weighted mean forced expiratory volume in one second (wm FEV1) over 0-24 hours at the end of the 12 week study (Day 84), compared to either dose of FSC.

Inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist (MABA) - GSK961081

GSK961081 ('081) is an investigational, single molecule bifunctional bronchodilator discovered by Theravance with both muscarinic antagonist and beta2 receptor agonist activities. Preclinical Phase 3-enabling studies and a Phase 1 study with healthy volunteers of the combination '081/FF are ongoing to explore its potential as a once-daily medicine delivered in the ELLIPTA® inhaler.

Theravance Respiratory Program

Long-Acting Muscarinic Antagonist (LAMA) - TD-4208

In April 2014, Theravance initiated a dose-ranging Phase 2b study with TD-4208 as a nebulized aqueous solution in patients with moderate to severe COPD. TD-4208 is an investigational inhaled LAMA discovered using Theravance's multivalent approach to drug design. The Phase 2b study will evaluate the bronchodilator effect, safety and tolerability of four doses of TD-4208 and placebo in patients with moderate to severe COPD. Approximately 350 patients will be randomized to receive one of four doses of TD-4208 inhalation solution (44 mcg, 88 mcg, 175 mcg, 350 mcg) or placebo once daily via a jet nebulizer for 28 days in a double-blind, parallel group study. The primary endpoint of the study is trough forced expiratory volume in one second (FEV1) after the

28-day treatment period. Secondary endpoints include measurements of serial FEV1 on Day 28 and Day 1 and safety and tolerability assessments.

## Bacterial Infections Program

### VIBATIV® (telavancin)

In March 2014, Theravance was informed by its partner, Clinigen Group plc ("Clinigen") that it had received a notification that the European Commission (EC) lifted the Europe-wide suspension of the Marketing Authorization for VIBATIV® (telavancin) for the treatment of adults with nosocomial pneumonia (hospital-acquired), including ventilator-associated pneumonia, known or suspected to be caused by methicillin resistant *Staphylococcus aureus* (MRSA) when other alternatives are not suitable. Theravance and Clinigen have an exclusive commercialization agreement in the European Union and certain other European countries (including Switzerland and Norway) for VIBATIV®.

On May 1, 2014, Theravance announced that data from multiple studies of VIBATIV® will be presented at the 24th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Barcelona, Spain, on May 10 - 13, 2014. New and retrospectively analyzed data on the product's in vitro potency, efficacy and safety will be discussed as part of one oral and three poster presentations.

## Central Nervous System (CNS)/Pain Program

### Norepinephrine and Serotonin Reuptake Inhibitor - TD-9855

In April 2014, Theravance announced positive results from a Phase 2 study of TD-9855, an investigational norepinephrine and serotonin reuptake inhibitor (NSRI), in patients with fibromyalgia (FM). The Phase 2 randomized, double-blind, parallel-group, placebo-controlled study evaluated the safety and efficacy of two doses of TD-9855 (5 mg and 20 mg) in 392 patients. Study medication was administered once-daily for up to 6 weeks. The primary endpoint of the study was improvement in pain. Secondary endpoints assessed improvement in core symptoms of fibromyalgia using established fibromyalgia measures, the Fibromyalgia Impact Questionnaire (FIQ) and the Patient Global Impression of Change scale (PGIC). Impact on common symptoms of fibromyalgia was also evaluated as exploratory endpoints. The study demonstrated statistically significant and clinically meaningful improvements in the primary and secondary endpoints at the 20 mg dose of TD-9855 compared to placebo. The 5 mg dose did not meet statistical significance for the primary endpoint. Both doses were generally well tolerated. The five most common treatment-emergent adverse events reported were headache, nausea, dizziness, insomnia and constipation. Changes in heart rate and blood pressure with TD-9855 were within the range of those seen in approved drugs in this class. Two serious adverse events were reported in TD-9855 treatment groups, with one assessed as possibly treatment related in the 5 mg group. Topline results support further development of TD-9855.

## GI Motility Dysfunction Programs

### Velusetrag

In April 2014, Theravance announced the positive topline results from a Phase 2 study with velusetrag for the treatment of patients with diabetic or idiopathic gastroparesis. Velusetrag is an oral, once-daily, investigational 5-HT4 selective agonist discovered by Theravance and partnered with Alfa Wassermann S.p.A. (Alfa Wassermann). Improvement in gastric emptying time was observed with all doses of velusetrag (5, 15, 30 mg). The primary endpoint of the study was the proportion of patients with at least a 20 percent improvement in gastric emptying (GE) as measured by half-time ( $t_{1/2}$ ), the time to half-emptying of the stomach of the biomarker, on Day 7 of each treatment period. Forty-seven percent more of the patients in the 30 mg velusetrag group demonstrated at least a 20% improvement in gastric emptying (GE  $t_{1/2}$ ) compared to patients in the placebo group (velusetrag 30 mg 52%, placebo 5%;  $p < 0.001$ ), which is a statistically significant increase. All doses of velusetrag improved gastric emptying  $t_{1/2}$  by 34-52 minutes versus 13 minutes for placebo. The 30 mg dose demonstrated statistically significant differences relative to placebo in percentage change and absolute change in minutes. Similar treatment effects were observed in both diabetic and idiopathic gastroparetic patients treated with velusetrag. All doses of velusetrag were generally well tolerated. The two most common adverse events were diarrhea and headache. One serious adverse event of pyelonephritis was observed during post-treatment follow-up on velusetrag 30 mg and was assessed as not related to study drug by the investigator. Based on these results, Theravance and Alfa Wassermann have agreed to advance velusetrag into a Phase 2b study later this year.

### TD-8954

TD-8954 is a selective 5-HT4 receptor agonist. Theravance recently initiated a Phase 2a study to evaluate the safety, tolerability and pharmacodynamics of a single-dose of TD-8954 administered intravenously compared to metoclopramide in critically ill patients with enteral feeding intolerance. The objective of the study is assessment of adverse events and the ability to tolerate feeding.

## Financial Results

### Revenue

Product sales in the first quarter of 2014 were \$0.9 million and resulted from the recognition of VIBATIV® product sales, which includes amounts that were previously deferred. Royalty revenue earned in the first quarter of 2014 was \$0.7 million and is related

to net sales of RELVAR®/BREO® ELLIPTA® from GSK. Royalty revenue was reduced by amortization expense for intangible assets of \$1.8 million.

## Research and Development (R&D)

Research and development expenses for the first quarter of 2014 were \$43.4 million compared with \$26.4 million for the same period in 2013. The increase in the first quarter over the same period last year was primarily due to higher employee-related costs and external R&D costs. Employee-related costs increased primarily due to the achievement of certain performance conditions under a special long-term retention and incentive equity and cash bonus awarded to certain employees in 2011, which resulted in additional stock-based compensation expense and cash bonus expense in the first quarter of 2014 of \$9.3 million. External R&D costs for first quarter of 2014 increased primarily as a result of continuing progression of clinical trials for our key programs. Total external R&D costs for the first quarter of 2014 were \$12.0 million compared with \$7.1 million for the same period in 2013. Total R&D stock-based compensation expense for the first quarter of 2014 was \$5.4 million, compared with \$3.8 million for the same period in 2013.

## Selling, General and Administrative

Selling, general and administrative expenses for the first quarter of 2014 were \$22.8 million compared with \$8.3 million for the same period in 2013. The increase in the first quarter over the same period last year was primarily due to higher employee-related costs and higher external costs related to the Company's separation strategy and VIBATIV® commercialization activities. Employee-related expenses increased primarily due to the achievement of certain performance conditions under a special long-term retention and incentive equity and cash bonus awarded to certain employees in 2011, which resulted in additional stock-based compensation expense and cash bonus expense in the first quarter of 2014 of \$6.6 million. Total selling, general and administrative stock-based compensation expenses for the first quarter of 2014 were \$8.1 million compared with \$2.3 million for the same period in 2013. Total external costs related to the proposed separation were \$3.6 million for the first quarter of 2014.

## Cash and Cash Equivalents, Short-Term Investments and Marketable Securities

Cash and cash equivalents, short-term investments and marketable securities totaled \$430.8 million as of March 31, 2014, a decrease of \$89.7 million compared to December 31, 2013. This decrease was primarily due to registrational and launch-related milestone payments to GSK of \$55.0 million and cash used in operations, partially offset by net proceeds of \$18.3 million received from issuances of our common stock. The March 31, 2014 cash and cash equivalents, short-term investments and marketable securities balance does not include the proceeds of approximately \$434.3 million from the issuance of \$450.0 million Pharma royalty notes completed in April 2014.

## Conference Call and Webcast Information

As previously announced, Theravance has scheduled a conference call to discuss this announcement beginning at 5:00 p.m. Eastern Daylight Time today. To participate in the live call by telephone, please dial (877) 837-3908 from the U.S., or (973) 890-8166 for international callers. Those interested in listening to the conference call live via the internet may do so by visiting Theravance's web site at [www.theravance.com](http://www.theravance.com). To listen to the live call via the internet, please go to the web site 15 minutes prior to its start to register, download, and install any necessary audio software.

A replay of the conference call will be available on Theravance's web site for 30 days through June 5, 2014. An audio replay will also be available through 11:59 p.m. Eastern Daylight Time on May 13, 2014 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and entering confirmation code 18905066.

## 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. Theravance's key programs include: RELVAR®/BREO® ELLIPTA® (FF/VI), ANORO™ ELLIPTA® (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta2 Agonist) GSK961068, each partnered with GlaxoSmithKline plc (GSK), and its Long-Acting Muscarinic Antagonist program. 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).

THERAVANCE®, the Theravance logo, and MEDICINES THAT MAKE A DIFFERENCE® are registered trademarks of Theravance, Inc.

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

VIBATIV® is a registered trademark of Theravance, Inc.

## BREO® ELLIPTA® Important Safety Information (U.S.)

The following ISI is based on the Highlights section of the U.S. Prescribing Information for BREO® ELLIPTA®. Please consult the full Prescribing Information for all the labeled safety information for BREO® ELLIPTA®.

Long-acting beta2-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. 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® 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 beta2-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.

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 ( $\geq 3\%$  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  $\geq 3\%$  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.

### **ANORO™ ELLIPTA® Important Safety Information (U.S.)**

The following Important Safety Information (ISI) is based on the Highlights section of the Prescribing Information for ANORO™ ELLIPTA®. Please consult the full Prescribing Information for all the labeled safety information for ANORO™ ELLIPTA®.

Long-acting beta2-adrenergic agonists (LABAs), such as vilanterol, one of the active ingredients in ANORO™ 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. The safety and efficacy of ANORO™ ELLIPTA® in patients with asthma have not been established. ANORO™ ELLIPTA® is not indicated for the treatment of asthma.

ANORO™ ELLIPTA® is contraindicated in patients with severe hypersensitivity to milk proteins or who have demonstrated hypersensitivity to either umeclidinium, vilanterol, or any of the other ingredients.

ANORO™ 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, which should be treated with an inhaled, short-acting beta2-agonist.

ANORO™ ELLIPTA® should not be used more often than recommended, at higher doses than recommended, or in conjunction with additional medicine containing a LABA, as an overdose may result.

ANORO™ ELLIPTA® should be used with caution when considering coadministration with long-term ketoconazole and other known strong cytochrome P450 3A4 inhibitors because increased cardiovascular adverse effects may occur.

As with other inhaled medicines, ANORO™ ELLIPTA® can produce paradoxical bronchospasm, which may be life-threatening.

ANORO™ ELLIPTA® should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

ANORO™ 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.

ANORO™ ELLIPTA® should be used with caution in patients with narrow-angle glaucoma. Instruct patients to contact a physician immediately should any signs or symptoms of narrow-angle glaucoma occur.

ANORO™ ELLIPTA® should be used with caution in patients with urinary retention, especially in patients with prostatic hyperplasia or bladder neck obstruction. Instruct patients to contact a physician immediately should any signs or symptoms of urinary retention occur.

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

The most common adverse reactions (incidence  $\geq 1\%$  and more common than placebo) reported in four 6-month clinical trials with ANORO™ ELLIPTA® (and placebo) were pharyngitis, 2% ( $< 1\%$ ); sinusitis 1% ( $< 1\%$ ); lower respiratory tract infection, 1% ( $< 1\%$ ); constipation, 1% ( $< 1\%$ ); diarrhea, 2% (1%); pain in extremity 2% (1%); muscle spasms, 1% ( $< 1\%$ ); neck pain, 1% ( $< 1\%$ ); and chest pain 1% ( $< 1\%$ ). In addition to the 6-month efficacy trials with ANORO™ ELLIPTA®, a 12-month trial evaluated the safety of umeclidinium/vilanterol 125 mcg/25 mcg in subjects with COPD. Adverse reactions (incidence  $\geq 1\%$  and more common than placebo) in subjects receiving umeclidinium/vilanterol 125 mcg/25 mcg were: headache, back pain, sinusitis, cough, urinary tract infection, arthralgia, nausea, vertigo, abdominal pain, pleuritic pain, viral respiratory tract infection, toothache, and diabetes mellitus.

Use of beta2-agonists, such as vilanterol should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval or within 2 weeks of discontinuation of such agents, because the effect of adrenergic agonists on the cardiovascular system may be potentiated.

Use beta-blockers with caution as they not only block the pulmonary effect of beta-agonists, such as vilanterol, but may produce severe bronchospasm in patients with COPD.

Use with caution in patients taking non-potassium-sparing diuretics, as electrocardiographic changes and/or hypokalemia associated with non-potassium-sparing diuretics may worsen with concomitant beta-agonists.

Avoid co-administration of ANORO™ ELLIPTA® with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic adverse effects such as cardiovascular effects, worsening of narrow-angle glaucoma, and worsening of urinary retention.

## **VIBATIV® Important Safety Information (U.S.)**

### **Mortality**

Patients with pre-existing moderate/severe renal impairment (CrCl  $\leq 50$  mL/min) who were treated with VIBATIV® for hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia had increased mortality observed versus vancomycin. Use of VIBATIV® in patients with pre-existing moderate/severe renal impairment (CrCl  $\leq 50$  mL/min) should be considered only when the anticipated benefit to the patient outweighs the potential risk.

### **Nephrotoxicity**

New onset or worsening renal impairment occurred in patients who received VIBATIV®. Renal adverse events were more likely to occur in patients with baseline comorbidities known to predispose patients to kidney dysfunction and in patients who received concomitant medications known to affect kidney function.

Monitor renal function in all patients receiving VIBATIV® prior to initiation of treatment, during treatment, and at the end of therapy. If renal function decreases, the benefit of continuing VIBATIV® versus discontinuing and initiating therapy with an alternative agent should be assessed.

### **Fetal Risk**

Women of childbearing potential should have a serum pregnancy test prior to administration of VIBATIV®. Avoid use of VIBATIV® during pregnancy unless the potential benefit to the patient outweighs the potential risk to the fetus. Adverse



developmental outcomes observed in three animal species at clinically relevant doses raise concerns about potential adverse developmental outcomes in humans. If not already pregnant, women of childbearing potential should use effective contraception during VIBATIV® treatment.

#### Contraindication

VIBATIV® is contraindicated in patients with a known hypersensitivity to the drug.

#### Hypersensitivity Reactions

Serious and potentially fatal hypersensitivity reactions, including anaphylactic reactions, may occur after first or subsequent doses. VIBATIV® should be used with caution in patients with known hypersensitivity to vancomycin.

#### Geriatric Use

Telavancin is substantially excreted by the kidney, and the risk of adverse reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection in this age group.

#### Infusion Related Reactions

VIBATIV® is a lipoglycopeptide antibacterial agent and should be administered over a period of 60 minutes to reduce the risk of infusion-related reactions. Rapid intravenous infusions of the glycopeptide class of antimicrobial agents can cause "Red-man Syndrome" like reactions including: flushing of the upper body, urticaria, pruritus, or rash.

#### QTc Prolongation

Caution is warranted when prescribing VIBATIV® to patients taking drugs known to prolong the QT interval. In a study involving healthy volunteers, VIBATIV® prolonged the QTc interval. Use of VIBATIV® should be avoided in patients with congenital long QT syndrome, known prolongation of the QTc interval, uncompensated heart failure, or severe left ventricular hypertrophy.

#### Most Common Adverse Reactions

The most common adverse reactions (greater than or equal to 10% of patients treated with VIBATIV®) were diarrhea, taste disturbance, nausea, vomiting, and foamy urine.

Full Prescribing Information, including Boxed Warning and Medication Guide in the U.S., is available at [www.VIBATIV.com](http://www.VIBATIV.com).

This press release contains and the conference call will contain 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: plans for executing the separation of Theravance into two independent companies, the expected timing of the separation, expectations for the amount and estimated duration of the funding of Theravance Biopharma at the time of the separation, the strategies, plans and objectives of the two companies following the separation, the timing, manner, amount and planned growth of anticipated potential capital returns to stockholders (including without limitation statements concerning the intention to initiate a cash dividend in the third quarter of 2014 and expectations of future cash dividend growth), the status and timing of clinical studies, data analysis and communication of results, the potential benefits and mechanisms of action of product candidates, the enabling capabilities of Theravance's approach to drug discovery and its proprietary insights, expectations for product candidates through development and commercialization, and the timing of seeking regulatory approval of product candidates. These statements are based on the current estimates and assumptions of the management of Theravance as of the date of the press release and the conference call 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: difficulties or delays in effecting the registration of Theravance Biopharma as a public company or effecting the separation, changes in the development or operations of Theravance prior to the separation that could affect the plans for the separation of Theravance into two independent companies or the intended provision of capital returns to stockholders, 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, Theravance's dependence on third parties to conduct Theravance's clinical studies, delays or failure to achieve and maintain regulatory approvals for product candidates, risks of collaborating with third parties to discover, develop and commercialize products and risks associated with establishing distribution capabilities for telavancin with appropriate technical expertise and supporting infrastructure. Other risks affecting Theravance are described under the heading "Risk Factors" contained in Theravance's Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 3, 2014 and the risks discussed in Theravance's 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.

(THR-X-F)

	March 31,	
	2014	2013
	(unaudited)	
Revenue:		
Product sales	\$ 945	\$ --
Net royalty revenue	(1,050)	--
Net revenue from collaborative arrangements	270	1,344
Total net revenue (1)	165	1,344
Costs and expenses:		
Cost of goods sold	188	--
Research and development (2)	43,387	26,416
Selling, general and administrative (2)	22,834	8,315
Total costs and expenses	66,409	34,731
Loss from operations	(66,244)	(33,387)
Other income (expense), net	(3)	(1,422)
Interest income	188	185
Interest expense	(1,644)	(2,736)
Net loss	\$ (67,703)	\$ (37,360)
Basic and diluted net loss per share	\$ (0.62)	\$ (0.39)
Shares used to compute basic and diluted net loss per share	109,859	96,379

(1) Net revenue is comprised of the following (in thousands):

	Three Months Ended March 31,	
	2014	2013
	(unaudited)	
Product sales	\$ 945	\$ --
Royalty revenue	730	--
Amortization of intangible assets	(1,780)	--
Net royalty revenue	(1,050)	--
LABA collaboration	--	907
Strategic alliance--MABA program license	270	415
Total net revenue from GSK	(780)	1,322
Revenue from other collaborative arrangements	--	22
Total net revenue	\$ 165	\$ 1,344

(2) Amounts include stock-based compensation expense for the three months ended March 31 as follows (in thousands):

	Three Months Ended March 31,	
	2014	2013
	(unaudited)	
Research and development	\$ 5,439	\$ 3,797
Selling, general and administrative	8,096	2,298
Total stock-based compensation expense	\$ 13,535	\$ 6,095

THERAVANCE, INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(In thousands)

	March 31, 2014	December 31, 2013
	----- (unaudited) -----	----- (1) -----
<b>Assets</b>		
Cash, cash equivalents, short-term investments, and marketable securities	\$ 430,754	\$ 520,499
Other current assets	7,259	7,667
Inventories	11,014	10,406
Property and equipment, net	9,734	10,238
Intangible assets, net	137,477	124,257
Other assets	8,796	8,188
	-----	-----
Total assets	\$ 605,034	\$ 681,255
	=====	=====
<b>Liabilities and stockholders' equity</b>		
Other current liabilities (2)	\$ 44,144	\$ 44,404
Payable to a related-party	-	40,000
Deferred revenue, non-current	5,247	5,455
Convertible subordinated notes	287,500	287,500
Other long-term liabilities	4,891	4,774
Stockholders' equity	263,252	299,122
	-----	-----
Total liabilities and stockholders' equity	\$ 605,034	\$ 681,255
	=====	=====

(1) The condensed consolidated balance sheet amounts at December 31, 2013 are derived from audited financial statements

(2) Amounts include current portion of deferred revenue of \$8.8 million and \$9.3 million as of March 31, 2014 and December 31, 2013, respectively.

**Contact Information:**

Michael W. Aguiar  
Senior Vice President and Chief Financial Officer  
650-808-4100  
investor.relations@theravance.com