

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: May 13, 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:

- 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 7.01. Regulation FD Disclosure**

On May 13, 2013 Theravance, Inc. ("Theravance") and Elan Corporation, plc ("Elan") announced that they entered into a royalty participation agreement wherein Elan will purchase a participation interest in potential future royalty payments related to four respiratory programs partnered with GlaxoSmithKline plc (GSK): RELVAR(TM) ELLIPTA(TM)/BREO(TM) ELLIPTA(TM), ANORO(TM) ELLIPTA(TM), MABA (Bifunctional Muscarinic Antagonist-Beta2 Agonist) monotherapy (GSK961081), and vilanterol (VI) monotherapy. Under the terms of the agreement, Elan will make a one-time cash payment of \$1.0 billion to Theravance in exchange for a 21% participation interest in the potential future royalty payments from the four programs when, as and if received by Theravance. The transaction is not subject to any material conditions, other than approval by Elan's shareholders. Elan plans to promptly prepare the required documentation to enable a shareholder vote, which Elan has agreed to hold within 35 days. A copy of the press release is furnished 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 May 13, 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: May 13, 2013

**THERAVANCE, INC.**

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

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**Exhibit Index**

**Exhibit No.**

99.1

**Description**

Press Release dated May 13, 2013

## **Theravance and Elan Enter Into a \$1.0 Billion Royalty Participation Agreement**

Theravance to receive \$1.0 billion upfront payment upon closing; Elan to receive a 21% participation interest in potential future royalty payments associated with four respiratory programs

SOUTH SAN FRANCISCO, CA and DUBLIN, IRELAND -- (Marketwire - May 13, 2013) - Theravance, Inc. (NASDAQ: THRX) and Elan Corporation, plc (NYSE: ELN) today announced that they have entered into a royalty participation agreement wherein Elan will purchase a participation interest in potential future royalty payments related to four respiratory programs partnered with GlaxoSmithKline plc (GSK): RELVAR™ ELLIPTA™/Breo™ ELLIPTA™, ANORO™ ELLIPTA™, MABA (Bifunctional Muscarinic Antagonist-Beta2 Agonist) monotherapy (GSK961081, or MABA '081), and vilanterol (VI) monotherapy. Under the terms of the agreement, Elan will make a one-time cash payment of \$1.0 billion to Theravance in exchange for a 21% participation interest in the potential future royalty payments from the four programs when, as and if received by Theravance.

"We are very excited to partner with Elan in a transaction that recognizes the significant value of four programs from our GSK collaborations targeted at respiratory disease," said Rick E Winningham, Theravance's Chief Executive Officer. "This agreement complements our strategy to facilitate and accelerate the return of capital to our stockholders and build value, consistent with our recently announced plan to separate Theravance into two entities, Royalty Management Company and Theravance Biopharma."

Mr Kelly Martin, Chief Executive Officer of Elan commented, "This transaction, upon closing, will immediately diversify our business with an investment in four high quality and late stage clinical assets within a large and growing therapeutic area. This diversification should benefit our shareholders by spreading the inherent risk embedded in any one specific asset. In addition, the long term and future potential cash flow streams and net income will be shared with investors both directly -- through a dividend pass through -- and indirectly through overall after tax earnings."

Mr Martin added, "Being involved, even indirectly, with an important therapeutic area that addresses the needs of millions of patients who suffer from respiratory disease is particularly meaningful to all of us at Elan."

RELVAR™ ELLIPTA™/Breo™ ELLIPTA™ (fluticasone furoate (FF)/vilanterol (VI)), ANORO™ ELLIPTA™ (umeclidinium bromide (UMEC)/VI) and VI monotherapy have been developed under the LABA collaboration with GSK. For RELVAR™ ELLIPTA™/Breo™ ELLIPTA™ and VI, Theravance is entitled to receive royalties from GSK of 15% of the first \$3.0 billion of combined annual global net sales, and 5% of combined annual global net sales above \$3.0 billion. If ANORO™ ELLIPTA™ is approved and commercialized, royalties on annual global net sales are upward tiering and range from the mid-single digits to 10%. The transaction does not include any royalty participation interest associated with UMEC/VI/FF, an investigational medicine also in development under the LABA collaboration with GSK.

MABA '081 is an investigational medicine in development under the strategic alliance between Theravance and GSK. If MABA '081 is successfully developed and commercialized as monotherapy, Theravance is entitled to receive royalties from GSK of between 10% and 20% of the first \$3.5 billion of annual global net sales, and 7.5% of all annual global net sales above \$3.5 billion. The transaction does not include any royalty participation interest associated with MABA '081 in combination with any other therapeutically active component, including an inhaled corticosteroid, or any other MABA compound as monotherapy or in combination.

The transaction is not subject to any material conditions, other than approval by Elan's shareholders. Elan plans to promptly prepare the required documentation to enable a shareholder vote, which Elan has agreed to hold within 35 days. If approved by Elan's shareholders, the parties expect the transaction to be consummated by the end of June 2013.

### **Theravance Tax Treatment and Use of Proceeds**

Theravance does not expect to pay significant income taxes associated with the transaction.

As previously disclosed, Theravance intends to separate its biopharmaceutical operations and its late stage partnered respiratory assets into two independent publicly traded companies, referred to as Theravance Biopharma and Royalty Management Co, respectively. We intend for Royalty Management Co to be the primary vehicle for the return of capital and that the proceeds from this transaction will facilitate and accelerate returns to its stockholders following the separation. Theravance Biopharma will be primarily focused on the discovery, development and commercialization of small-molecule medicines in areas of significant unmet medical need. This transaction does not change the overall structure of the planned separation, including which assets are expected to be in each company. Additionally, we do not plan to increase 2013 research and development spending above what was included in our 2013 expense guidance. Theravance is currently evaluating the optimal strategies to return capital to stockholders of Royalty Management Co following completion of the separation, including through dividends or the repurchase of shares and/or convertible debt.

Centerview Partners LLC is acting as financial advisor and Skadden, Arps, Slate, Meagher & Flom LLP and Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP are acting as legal advisors to Theravance in connection with the transaction.

Evercore Partners and Ondra Partners are acting as financial advisors to Elan. Cadwalader, Wickersham & Taft LLP and A&L Goodbody are acting as legal advisors to Elan in connection with the transaction.

### **Conference Call and Webcast Information**

Theravance will discuss this announcement at 8:30 a.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, 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 12, 2013. An audio replay will also be available through 11:59 p.m. Eastern Daylight Time on May 20, 2013 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and entering confirmation code 71715858.

For more information, please visit Theravance's website at [www.theravance.com](http://www.theravance.com).

### **About Four Respiratory Programs**

RELVAR™ ELLIPTA™/BREO™ ELLIPTA™, ANORO™ ELLIPTA™, VI monotherapy and MABA monotherapy (GSK961081, or MABA '081), are assets developed in collaboration with GlaxoSmithKline plc (GSK).

In November 2002, Theravance entered into its LABA collaboration with GSK to develop and commercialize once-daily long-acting beta2 agonist (LABA) products for the treatment of chronic obstructive pulmonary disease (COPD) and asthma. For the treatment of COPD, the collaboration is developing two combination products: (1) RELVAR™ ELLIPTA™ or BREO™ ELLIPTA™ (FF/VI), an investigational once-daily combination medicine consisting of a LABA, vilanterol (VI), and an inhaled corticosteroid (ICS), fluticasone furoate (FF) and (2) ANORO™ ELLIPTA™ (UMEC/VI), a once-daily investigational medicine combining a long-acting muscarinic antagonist (LAMA), umeclidinium bromide (UMEC), with a LABA, VI. For the treatment of asthma, the collaboration is developing FF/VI. BREO™ ELLIPTA™ 100/25 mcg is approved in the United States as an inhaled long-term, once-daily maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. It is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations. RELVAR™ ELLIPTA™ for the treatment of COPD and asthma patients is currently under review by the European Medicines Agency (EMA) and Japan. FF/VI is not approved or licensed in the European Union or anywhere outside of the United States. ANORO™ ELLIPTA™ for the treatment of COPD patients is currently under review by the U.S. Food and Drug Administration, the EMA and Japan. The Prescription Drug User Fee Act goal date for ANORO™ ELLIPTA™ is December 18, 2013. ANORO™ ELLIPTA™ (UMEC/VI) is an investigational medicine and is not currently approved anywhere in the world.

In March 2004, Theravance entered into its strategic alliance with GSK. Under this alliance, GSK received an option to license exclusive development and commercialization rights to product candidates from certain of Theravance's discovery programs on predetermined terms and on an exclusive, worldwide basis. In 2005, GSK licensed Theravance's MABA program for the treatment of COPD. GSK961081 ('081), the lead MABA, is an investigational, single molecule bifunctional bronchodilator with both muscarinic antagonist and beta2 receptor agonist activities. Based on the results from a Phase 2b study, GSK and Theravance plan to advance '081 monotherapy into Phase 3 and the '081/FF combination into Phase 3-enabling studies, later in 2013.

### **Important Safety Information**

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, which 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.

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.

Inhaled medicines can produce paradoxical bronchospasm, which may be life-threatening. Vilanterol, the LABA in BREO ELLIPTA, can produce clinically significant cardiovascular effects in some patients. 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.

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.

BREO ELLIPTA is not indicated for the relief of acute bronchospasm or the treatment of asthma. The safety and efficacy of BREO ELLIPTA in patients with asthma have not been established. 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.

## **About Elan**

Elan Corporation, plc is a biotechnology company, headquartered in Ireland, committed to making a difference in the lives of patients and their families by dedicating itself to bringing innovations in science to fill significant unmet medical needs that continue to exist around the world. Elan shares trade on the New York and Irish Stock Exchanges. For additional information about Elan, please visit [www.elan.com](http://www.elan.com).

As required by the Irish Takeover Rules, the Directors of Elan accept responsibility for the information contained in this announcement. To the best of their knowledge and belief (having taken all reasonable care to ensure such is the case); the information contained in this announcement is in accordance with the facts and does not omit anything likely to affect the import of such information.

Any holder of 1% or more of any class of relevant securities of Elan may have disclosure obligations under Rule 8.3 of the Irish Takeover Panel Act, 1997, Takeover Rules 2007 (as amended).

## **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 programmes include: RELVAR™ ELLIPTA™ or BREO™ ELLIPTA™ (FF/VI), ANORO™ ELLIPTA™ (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta2 Agonist), each partnered with GlaxoSmithKline plc, and its oral Peripheral Mu Opioid Receptor 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. The use of the brand names ANORO™ and RELVAR™ has not yet been approved by any regulatory authority.

## **Theravance Forward-Looking Statements**

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 the expected timing of the Elan shareholder vote on the transaction and the outcome of such vote, the expected timing for consummating the transaction if Elan shareholder approval is obtained, the effect of the transaction if it is consummated on the strategies, plans and objectives of Theravance, the timing, manner and amount of anticipated potential returns of capital to stockholders if the transaction and/or Theravance's previously announced planned separation is consummated, the timing, plans and objectives of and the possible impact of the transaction on Theravance's previously announced, planned separation, 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 product candidates, statements concerning the enabling capabilities of Theravance's approach to drug discovery and its proprietary insights, statements concerning expectations for product candidates through development and commercialization and projections of the tax effects of the transaction 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 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

delays or difficulties encountered in obtaining, or the failure to obtain, the approval of Elan's shareholders for the transaction, the possibility that intervening events could arise which could alter the timing, or the ability to consummate, the transaction, the anticipated separation of Theravance into two independent companies or the intended return of capital to stockholders, the risk that third parties could challenge the transaction, the risk that Theravance's net operating loss may not be available to offset taxes from the transaction, 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 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 May 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.

## **Elan Forward-Looking Statements**

This press release contains forward-looking statements that involve substantial risks and uncertainties. You can identify these statements by the fact that they use words such as "anticipate", "estimate", "project", "target", "intend", "plan", "will", "believe", "expect" and other words and terms of similar meaning in connection with any discussion of future financial performance or events. Among the factors that could cause actual results to differ materially from those described or projected herein are the following: risks related to delays or difficulties encountered in obtaining, or the failure to obtain, the approval of Elan's shareholders for the transaction; the possibility that intervening events could arise which could alter the timing, or the ability to consummate the transaction if Elan shareholder approval is obtained; the risk that third parties could challenge the transaction, even if the transaction is approved by Elan shareholders and consummated; risks related to the development, approval and commercialization of the products or potential products that underlie the royalty participation interest; whether this agreement will provide diversification benefits to Elan shareholders; whether any cash flow streams will result from this agreement; as Elan's principal source of revenue may remain a royalty on sales of Tysabri, the potential of Tysabri, which may be severely constrained by increases in the incidence of serious adverse events (including death) associated with Tysabri (in particular, by increases in the incidence rate for cases of PML), or by competition from existing or new therapies (in particular, oral therapies), and the potential for the successful development and commercialization of products, whether internally or by acquisition, especially given the separation of the Prothena business which left Elan with no material pre-clinical research programs or capabilities; Elan's ability to maintain sufficient cash, liquid resources, and investments and other assets capable of being monetized to meet its liquidity requirements; the success of our development activities, and research and development activities in which Elan retains an interest, including, in particular, the impact of the announced discontinuation of the development of bapineuzumab intravenous in mild to moderate Alzheimer's disease; failure to comply with anti-kickback, bribery and false claims laws in the United States, Europe and elsewhere; difficulties or delays in manufacturing and supply of Tysabri; trade buying patterns; the impact of potential biosimilar competition, the trend towards managed care and health care cost containment, including Medicare and Medicaid; legislation and other developments affecting pharmaceutical pricing and reimbursement (including, in particular, the dispute in Italy with respect to Tysabri sales), both domestically and internationally; failure to comply with Elan's payment obligations under Medicaid and other governmental programs; exposure to product liability (including, in particular, with respect to Tysabri) and other types of lawsuits and legal defense costs and the risks of adverse decisions or settlements related to product liability, patent protection, securities class actions, governmental investigations and other legal proceedings; Elan's ability to protect its patents and other intellectual property; claims and concerns that may arise regarding the safety or efficacy of Elan's product candidates; interest rate and foreign currency exchange rate fluctuations and the risk of a partial or total collapse of the euro; governmental laws and regulations affecting domestic and foreign operations, including tax obligations; whether Elan is deemed to be an Investment Company or a Passive Foreign Investment Company; general changes in United States and International generally accepted accounting principles; growth in costs and expenses; and the impact of acquisitions, divestitures, restructurings, product withdrawals and other unusual items. A further list and description of these risks, uncertainties and other matters can be found in Elan's Annual Report on Form 20-F for the fiscal year ended December 31, 2012, and in its Reports of Foreign Issuer on Form 6-K filed with the SEC. Elan assumes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

(THR-X-G)

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