

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: February 19, 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))

Item 8.01. Other Events

On February 19, 2013, GlaxoSmithKline plc (GSK) and Theravance, Inc. (Company) issued a press release announcing that the New Drug Application (NDA) for the investigational once-daily LAMA/LABA combination medicine, UMEC/VI, for patients with chronic obstructive pulmonary disease (COPD), has been accepted by the U.S. Food and Drug Administration (FDA), indicating that the application is sufficiently complete to permit a substantive review. The Prescription Drug User Fee Act (PDUFA) goal date has also been confirmed as December 18, 2013. GSK and Theravance also announced that the Marketing Authorization Application (MAA) for UMEC/VI for COPD has been validated for assessment by the European Medicines Agency (EMA). UMEC/VI, with proposed brand name ANORO(TM), is a combination of two investigational bronchodilator molecules - GSK573719 or umeclidinium bromide (UMEC), a long-acting muscarinic antagonist (LAMA) and vilanterol (VI), a long-acting beta2 agonist (LABA), administered using the ELLIPTA(TM) inhaler. UMEC/VI is in development under the LABA collaboration between GSK and the Company. A copy of the press release is filed as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 [Press Release of Theravance, Inc. dated February 19, 2013](#)

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: February 19, 2013

THERAVANCE, INC.

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

| <u>Exhibit No.</u> | Exhibit Index | <u>Description</u> |
|---------------------------|----------------------|---|
| 99.1 | | Press Release of Theravance, Inc. dated February 19, 2013 |

GSK and Theravance Announce FDA Acceptance of New Drug Application (NDA) Submission in the US for ANORO ELLIPTA(TM) for COPD

LONDON and SOUTH SAN FRANCISCO, CA -- (Marketwire - February 19, 2013) - GlaxoSmithKline plc (LSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced that the New Drug Application (NDA) for the investigational once-daily LAMA/LABA combination medicine, UMEC/VI, for patients with chronic obstructive pulmonary disease (COPD), has been accepted by the U.S. Food and Drug Administration (FDA) indicating that the application is sufficiently complete to permit a substantive review. The Prescription Drug User Fee Act (PDUFA) goal date has also been confirmed as 18 December 2013.

In December 2012 and January 2013, GSK and Theravance announced the submission by GSK of regulatory applications in the United States and the European Union, respectively, for UMEC/VI for patients with COPD. The Marketing Authorisation Application (MAA) for UMEC/VI has been validated for assessment by the European Medicines Agency (EMA).

UMEC/VI, with proposed brand name ANORO™, is a combination of two investigational bronchodilator molecules - GSK573719 or umeclidinium bromide (UMEC), a long-acting muscarinic antagonist (LAMA) and vilanterol (VI), a long-acting beta2 agonist (LABA), administered using the ELLIPTA™ inhaler.

Future Regulatory Submissions:

Regulatory submissions for UMEC/VI are planned in other countries during the course of 2013. In addition, GSK intends to commence global regulatory submissions for UMEC monotherapy, administered using the ELLIPTA™ inhaler, for COPD patients later this year.

Other Respiratory Development Programmes:

UMEC/VI is one of several late-stage assets in the GSK respiratory development portfolio, which includes fluticasone furoate/vilanterol (FF/VI, with proposed brand names RELVAR™ and BREO™), VI monotherapy and MABA (GSK961081), developed in collaboration with Theravance, as well as GSK's investigational medicines FF monotherapy, UMEC monotherapy and anti-IL5 MAb (mepolizumab). These investigational medicines are not currently approved anywhere in the world.

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

GlaxoSmithKline - one of the world's leading research-based pharmaceutical and healthcare companies - is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com.

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™ or BREO™ (FF/VI), ANORO™ (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.

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

Cautionary statement regarding forward-looking statements

Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK's operations are described under 'Risk Factors' in the 'Business Review' in the company's Annual Report on Form 20-F for 2011.

Theravance forward-looking statement

This press release contains certain "forward-looking" statements as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding, among other things, statements relating to goals, plans, objectives and future events. Theravance intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. Examples of such statements include statements relating to the status and timing of clinical studies, data analysis and communication of results, statements regarding the potential benefits and mechanisms of action of drug candidates, statements concerning the timing of seeking regulatory approval of our product candidates, statements concerning the enabling capabilities of Theravance's approach to drug discovery and its proprietary insights, and statements concerning expectations for the discovery, development and commercialization of our product candidates. These statements are based on the current estimates and assumptions of the management of Theravance as of the date of this press release and are subject to risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results of Theravance to be materially different from those reflected in its forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, among others, risks related to delays or difficulties in commencing or completing clinical and non-clinical studies, the potential that results of clinical or non-clinical studies indicate product candidates are unsafe or ineffective, our dependence on third parties in the conduct of our clinical studies, delays or failure to achieve regulatory approvals for product

candidates, risks of relying on third-party manufacturers for the supply of our product and product candidates and risks of collaborating with third parties to discover, 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 October 31, 2012 and in Theravance's prospectus supplement filed with the SEC on January 18, 2013 pursuant to Rule 424(b)(5). 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-G)

GlaxoSmithKline Enquiries:

UK Media enquiries:

David Mawdsley

+44 (0) 20 8047 5502

(London)

Stephen Rea

+44 (0) 20 8047 5502

(London)

Sarah Spencer

+44 (0) 20 8047 5502

(London)

David Daley

+44 (0) 20 8047 5502

(London)

US Media enquiries:

Kevin Colgan

+1 919 483 2933

(North Carolina)

Melinda Stubbee

+1 919 483 2510

(North Carolina)

Sarah Alspach

+1 202 715 1048

(Washington, DC)

Jennifer Armstrong

+1 215 751 5664

(Philadelphia)

Analyst/Investor enquiries:

Sally Ferguson

+44 (0) 20 8047 5543

(London)

Tom Curry

+ 1 215 751 5419

(Philadelphia)

Gary Davies

+ 44 (0) 20 8047 5503

(London)

James Dodwell

+ 44 (0) 20 8047 2406

(London)

Jeff McLaughlin

+ 1 215 751 7002

(Philadelphia)

Ziba Shamsi

+ 44 (0) 20 8047 3289

(London)

Theravance Inc. Enquiries

Michael W. Aguiar

Investor.relations@theravance.com

(650) 808 4100

(San Francisco)