

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 (Date of earliest event Reported): September 26, 2012

**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)

**901 Gateway Boulevard**  
**South San Francisco, California 94080**  
**(650) 808-6000**

(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)  
 Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)  
 Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))  
 Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

---

**Item 8.01. Other Events.**

On September 26, 2012, GlaxoSmithKline plc (GSK) and Theravance, Inc. (the "Company") issued a press release announcing that the New Drug Application (NDA) for the once-daily investigational medicine fluticasone furoate "FF"/vilanterol "VI" (FF/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 May 12, 2013. GSK and Theravance also announced that the Marketing Authorization Application (MAA) for FF/VI for COPD and asthma has been validated by the European Medicines Agency (EMA). GSK also submitted a Japanese New Drug Application (JNDA) for FF/VI for patients with COPD and asthma on September 25, 2012. FF/VI is administered by a new dry powder inhaler called Ellipta™. FF/VI has the proposed brand name Relvar™ in Europe and Japan and Breo™ in the U.S. FF/VI is currently 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

<u>Exhibit</u>	<u>Description</u>
Exhibit 99.1	Press Release Dated September 26, 2012

---

**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: September 26, 2012

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

---

**EXHIBIT INDEX**

<u>Exhibit</u>	<u>Description</u>
Exhibit 99.1	Press Release Dated September 26, 2012

## **GSK and Theravance Announce FDA Acceptance of FF/VI New Drug Application (NDA) Submission in the US for COPD**

### **Japanese New Drug Application (JNDA) Submitted for COPD and Asthma**

LONDON and SOUTH SAN FRANCISCO, Calif., Sept. 26, 2012 (GLOBE NEWSWIRE) -- GlaxoSmithKline plc (GSK) and Theravance, Inc. (Nasdaq:THRX) today announced that the New Drug Application (NDA) for the once-daily investigational medicine fluticasone furoate "FF"/vilanterol "VI" (FF/VI) for patients with chronic obstructive pulmonary disease (COPD), has been accepted by the US 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 12<sup>th</sup> May 2013.

On 13<sup>th</sup> July 2012, GSK and Theravance announced the submission by GSK of regulatory applications in the US and European Union for FF/VI for patients with COPD and a regulatory application for asthma in the European Union. The Marketing Authorisation Application (MAA) for FF/VI for COPD and asthma has been validated by the European Medicines Agency (EMA).

GSK also submitted a Japanese New Drug Application (JNDA) for FF/VI for patients with COPD and asthma on 25<sup>th</sup> September 2012.

FF/VI is one of several late-stage assets in the GSK respiratory development portfolio, which also includes the investigational LAMA/LABA combination umeclidinium bromide/vilanterol (UMEC/VI), 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).

FF/VI is administered by a new dry powder inhaler called Ellipta<sup>TM</sup>. FF/VI has the proposed brand name Relvar<sup>TM</sup> in Europe and Japan and Breo<sup>TM</sup> in the US. FF/VI is an investigational medicine and is not currently approved anywhere in the world. Relvar<sup>TM</sup>, Breo<sup>TM</sup> and Ellipta<sup>TM</sup> are trademarks of the GlaxoSmithKline group of companies. The use of these brand names has not yet been approved by any regulatory authority.

**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](http://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<sup>TM</sup> or Breo<sup>TM</sup> (FF/VI), umeclidinium bromide/vilanterol (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta<sub>2</sub> 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.

### **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 Exchange Act and the Private Securities Litigation Reform Act of 1995. Examples of such statements include statements relating to the status and timing of data analysis and communication of results from clinical studies, 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 enabling capabilities of Theravance's approach to drug discovery and its proprietary insights, and statements concerning expectations for product candidates through development and commercialization. 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 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 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 August 1, 2012 and the risks discussed in our other period filings with 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.

**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**

Investor.relations@theravance.com	Michael W. Aguiar	(650) 808 4100	(San Francisco)
-----------------------------------	-------------------	----------------	-----------------