

GLAXOSMITHKLINE PLC

Form 6-K

August 24, 2012

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of  
the Securities Exchange Act of 1934

For period ending August 2012

GlaxoSmithKline plc  
(Name of registrant)

980 Great West Road, Brentford, Middlesex, TW8 9GS  
(Address of principal executive offices)

Indicate by check mark whether the registrant files or  
will file annual reports under cover Form 20-F or Form 40-F

Form 20-F  Form 40-F

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Indicate by check mark whether the registrant by furnishing the  
information contained in this Form is also thereby furnishing the  
information to the Commission pursuant to Rule 12g3-2(b) under the  
Securities Exchange Act of 1934.

Yes No

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This press release is intended for business journalists and analysts/investors. Please note that this release may not have been issued in every market in which GSK operates.

Issued: Friday 24 August 2012, London UK and South San Francisco, CA

GSK and Theravance announce completion of the Phase III programme for once-daily LAMA/LABA (UMEC/VI) in COPD

GSK confirms its intention to commence global filings from the end of 2012

GlaxoSmithKline plc (GSK) and Theravance, Inc. (NASDAQ: THRX) today announced the completion of the phase III programme of an investigational LAMA/LABA involving approximately 6,000 patients with chronic obstructive pulmonary disease (COPD).

LAMA/LABA 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. UMEC/VI is a once-daily investigational medicine currently under development for the maintenance treatment of COPD.

On 2 July 2012, GSK and Theravance announced the completion of four pivotal studies for UMEC/VI. The pivotal programme for UMEC/VI also includes a 52-week safety study, which is now complete. Two non-pivotal 12-week crossover exercise studies will also be included in the registrational package as they are now also complete.

These recently completed studies support GSK's plans to commence global regulatory submissions for UMEC/VI from the end of 2012.

The full results of all these studies, together with additional data from phase IIb dose-ranging studies of UMEC, will be presented at future scientific meetings.

#### About the LAMA/LABA Studies

The 52-week parallel group safety study evaluated the long-term safety and tolerability of UMEC 125mcg alone and the combination UMEC/VI 125/25mcg compared to placebo in approximately 500 patients. The two replicate 12-week crossover exercise studies of approximately 300 patients each, evaluated the lung function and exercise endurance time of UMEC/VI 125/25mcg and 62.5/25mcg, UMEC 125mcg and 62.5mcg, and VI 25mcg compared to placebo. The co-primary endpoints of these studies were 3-hour post-dose exercise endurance time and trough FEV1.

#### Other Respiratory Development Programmes

The data from these studies will also contribute to the future regulatory submissions for GSK's UMEC monotherapy, with global filings commencing in 2013.

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.

V A Whyte  
Company Secretary  
24 August 2012

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™ or BREO™ (FF/VI), umeclidinium bromide/vilanterol (UME/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™

and ELLIPTA™ are trademarks of the GlaxoSmithKline group of companies. The use of these brand names has not yet been approved by any regulatory authority.

GlaxoSmithKline

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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 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, 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.

Registered in England & Wales:

No. 3888792

Registered Office:

980 Great West Road

Brentford, Middlesex

TW8 9GS

SIGNATURES

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, thereunto duly authorised.

GlaxoSmithKline plc  
(Registrant)

Date: August 24, 2012

By: VICTORIA WHYTE  
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Victoria Whyte  
Authorised Signatory for and on  
behalf of GlaxoSmithKline plc