

GLAXOSMITHKLINE PLC  
Form 6-K  
January 09, 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 January, 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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Issued: 9 January 2012, London UK and South San Francisco, CA, USA

GSK and Theravance announce initial outcomes from pivotal Phase III studies for once-daily Relovair™\* in COPD and asthma

GSK intends to commence global regulatory filings in COPD and asthma from mid-2012

GlaxoSmithKline (GSK) and Theravance, Inc. (NASDAQ: THRX) today announced the completion of the phase III registration programme for the once-daily investigational medicine Relovair™\* (fluticasone furoate "FF"/vilanterol "VI") in patients with chronic obstructive pulmonary disease (COPD) and of all but one of the pivotal studies in patients with asthma.

For COPD, GSK intends to submit regulatory applications in the US and Europe in mid-2012. For asthma, GSK plans to submit an application in Europe in mid-2012 and will continue discussions with the FDA on the regulatory requirements for a US asthma indication.

Darrell Baker, SVP Respiratory Portfolio Optimisation Leader at GSK said: "We are pleased to have reached this milestone for Relovair™, one of the important assets in our respiratory development portfolio. Having undertaken an initial assessment of these data we believe they support our plan to seek global approvals of this once-daily medicine for the treatment of patients with COPD and asthma."

Rick E Winningham, Chief Executive Officer of Theravance said: "We are very excited with the new data and GSK's plan to submit regulatory applications for Relovair™ in the US and Europe this year. Relovair™ is one of our three respiratory programs with GSK."

The full results of these pivotal studies will be presented at future scientific meetings.

#### COPD Programme

The COPD programme included two replicate 52-week exacerbation studies each of which randomised approximately 1,620 patients. The studies were powered to compare each of 3 doses of FF/VI (200/25mcg, 100/25mcg and 50/25mcg) to VI 25mcg alone in a step-wise manner, starting at the highest dose. In both studies, all doses of FF/VI demonstrated reductions in the annual rate of moderate to severe exacerbations compared with VI alone. In the first study, the reductions were statistically significant at all doses (200/25mcg  $p < 0.001$ , 100/25mcg  $p = 0.024$ , 50/25mcg  $p = 0.040$ ). In the second study, the reductions were not statistically significant at the highest dose (200/25mcg). The p-values in this study were  $p = 0.109$  (200/25mcg),  $p < 0.001$  (100/25mcg) and  $p = 0.181$  (50/25mcg). GSK and Theravance believe that it is appropriate to request that regulatory authorities review the totality of the exacerbation data, including the effects seen across both studies for the 100/25mcg dose.

In both exacerbation studies, all doses of FF/VI demonstrated numerical increases in lung function compared with VI, but not all increases were significant.

Across these two studies, the most common adverse events in the FF/VI arms included nasopharyngitis, upper respiratory tract infection, oral candidiasis, headache, COPD, back pain, pneumonia, bronchitis and sinusitis. GSK is investigating reports of fatal pneumonia on FF/VI primarily at the 200/25mcg dose. An integrated safety and tolerability analysis is underway.

A 4-week detailed lung function profile study in 54 patients demonstrated that all doses of FF/VI (50/25mcg, 100/25mcg, and 200/25mcg) statistically significantly increased weighted mean FEV1 versus placebo.

In a non-pivotal 12-week superiority study of FF/VI 100/25mcg once daily compared with Seretide® (fluticasone propionate/salmeterol (FP/SAL)) 500/50mcg twice daily, FF/VI did not meet the predefined threshold for superiority on 0-24 hour weighted mean FEV1 (p=0.282). There was no statistical difference between FF/VI and FP/SAL.

GSK anticipates filing the FF/VI 100/25mcg dose for COPD on a global basis starting in mid-2012.

#### Asthma Programme

GSK has also completed asthma studies, which form the majority of the phase III registration programme for FF/VI.

An exacerbation study, which randomised approximately 2,000 patients for up to 76 weeks, demonstrated that FF/VI 100/25mcg significantly increased time to first severe exacerbation (p=0.036) and significantly decreased annual rate of severe exacerbations (p=0.014) compared to FF. The study also found that FF/VI improved trough FEV1 at all pre-defined time points over the 76-week treatment period (p<0.001 vs. FF), demonstrating a contribution by VI to the improvement in lung function of FF/VI.

In this study, the most frequent adverse events were headache, nasopharyngitis, upper respiratory tract infection, bronchitis, cough, oropharyngeal pain and influenza. There were no differences in the number of asthma-related hospitalisations between the treatment arms. There were no asthma-related deaths. An integrated safety and tolerability analysis is underway.

A 24-week study in approximately 600 moderate to severe asthmatics demonstrated superiority of FF/VI 200/25mcg over FF 200mcg on both trough FEV1 (p<0.001) and weighted mean FEV1 (p=0.048), demonstrating a contribution by VI to the improvement in lung function of FF/VI. FF 200mcg dosed once daily was non-inferior to fluticasone propionate (FP) 500mcg dosed twice daily on trough FEV1.

A 12-week placebo-controlled study evaluating lung function in approximately 600 mild to moderate asthmatics given FF/VI 100/25mcg, did not demonstrate statistically significant improvements compared to FF 100mcg on either trough FEV1 (p=0.405) or weighted mean FEV1 (p=0.06). Both FF/VI and FF demonstrated statistically significant improvements against placebo on the same endpoints (p<0.001).

In a 12-week study conducted in approximately 340 patients receiving inhaled corticosteroids throughout the study, once-daily VI 25mcg and twice-daily salmeterol (SAL) 50mcg showed no statistically significant difference on 24-hour weighted mean FEV1 compared to placebo. The lack of numerical improvement of SAL (the active control) over placebo in this study was unexpected and confounded interpretation of the study.

A 24-week study in approximately 330 patients comparing the efficacy of FF and FP to placebo is currently ongoing and will be completed during the first half of 2012.

In a non-pivotal 24-week superiority study of FF/VI 100/25mcg once daily compared with Seretide® (fluticasone propionate/salmeterol (FP/SAL)) 250/50mcg twice daily, FF/VI did not meet the predefined threshold for superiority on 0-24 hour weighted mean FEV1 (p=0.162). There was no statistical difference between FF/VI and FP/SAL.

A 6-week HPA axis study and a 52-week safety study to evaluate the safety profile of FF/VI in asthma have also been completed. The results from both studies support the planned regulatory filings.

These recently completed Phase III studies evaluated approximately 9,000 patients with COPD and asthma. The totality of the data provides GSK with the confidence to proceed with global registration for Relovair in COPD and asthma beginning in mid-2012.

#### Ongoing Development Programme

The development programmes for FF/VI in COPD and asthma will continue as planned and include an outcomes study of 16,000 patients to prospectively evaluate the effect of the combination (FF/VI 100/25mcg) compared with placebo on survival in COPD patients with moderate disease and a history of, or at risk from, cardiovascular disease. In addition, GSK is in the process of setting up pre-registration real-world effectiveness studies to investigate the potential effects of FF/VI versus the standards of care in asthma and COPD. These studies are expected to commence shortly.

FF/VI is one of several late-stage assets in the GSK respiratory development portfolio, which includes LAMA/LABA (GSK573719/VI) and MABA (GSK961081), developed in collaboration with Theravance, as well as FLAP-inhibitor (GSK2190915), p-38 kinase inhibitor (losmapimod) and anti-IL5 MAb (mepolizumab). The phase III programme for LAMA/LABA is expected to complete in 2012.

V A Whyte  
Company Secretary  
9 January 2012

\*Relovair™

is a once-daily inhaled corticosteroid (ICS)/long-acting beta-agonist (LABA) combination treatment, comprising fluticasone furoate and vilanterol (FF/VI), currently in development for the treatment of COPD and asthma. This investigational medicine is not currently approved anywhere in the world.

Relovair™ is a trademark of the GlaxoSmithKline group of companies. The use of the brand name Relovair™ for FF/VI is not approved by regulatory authorities around the world. Seretide® and Advair® are registered trademarks of GSK.

#### Theravance Analyst Conference Call and Webcast Information

Theravance has scheduled an analyst conference call to discuss this announcement today at 8:30 a.m. Eastern Standard Time. Analysts who wish 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 [ww.theravance.com](http://ww.theravance.com). To listen to the live call and to download the slide presentation, please go to Theravance's 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 February 8, 2012. An audio replay will also be available through 11:59 p.m. Eastern Standard Time on January 16, 2012 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and entering confirmation code 41442579.

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: Relovair™, LAMA/LABA ('719/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta2 Agonist), each partnered with GlaxoSmithKline plc, and its oral Peripheral Mu Opioid Receptor Antagonist (PμMA) 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).

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GlaxoSmithKline 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 2010.

Theravance forward-looking statement

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 Exchange Act 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 and product commercialization, 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, statements concerning expectations for product candidates through development and commercialization and projections of revenue, expenses 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 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 preclinical 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 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 November 2, 2011 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.

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: January 9, 2012

By: VICTORIA WHYTE

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Victoria Whyte  
Authorised Signatory for and on  
behalf of GlaxoSmithKline plc