

GLAXOSMITHKLINE PLC

Form 6-K

August 02, 2013

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 2013

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: 2 August 2013, London UK

Regulatory update: albiglutide US PDUFA date extended by three months

GlaxoSmithKline plc (LSE:GSK) today announced that the US Prescription Drug User Fee Act (PDUFA) goal date for albiglutide, an investigational once-weekly treatment for adult patients with type 2 diabetes, has been extended by three months to 15 April 2014 to provide time for a full review of information submitted by GSK in response to the Food and Drug Administration's requests.

GSK announced the submission of a Biologics Licence Application to the US FDA for albiglutide on 14 January 2013 and this was followed by the submission of a Marketing Authorisation Application to the European Medicines Agency (EMA) on 7 March 2013. The EMA filing is progressing to schedule. Albiglutide is not approved for use anywhere in the world.

V A Whyte

Company Secretary

2 August 2013

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

GlaxoSmithKline

Enquiries:

UK Media enquiries:	David Mawdsley	+44 (0) 20 8047 5502	(London)
	Simon Steel	+44 (0) 20 8047 5502	(London)
	David Daley	+44 (0) 20 8047 5502	(London)
	Catherine Hartley	+44 (0) 20 8047 5502	(London)
US Media enquiries:	Stephen Rea	+1 215 751 4394	(Philadelphia)
	Kevin Colgan	+1 919 483 2933	(North Carolina)
		+1 919 483 2510	

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Melinda Stubbee		(North Carolina)
Mary Anne Rhyne	+1 919 483 0492	(North Carolina)
Sarah Alspach	+1 202 715 1048	(Washington, DC)
Jennifer Armstrong	+1 215 751 5664	(Philadelphia)
Analyst/Investor enquiries:		
Ziba Shamsi	+ 44 (0) 20 8047 3289	(London)
Lucy Budd	+44 (0) 20 8047 2248	(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)

Cautionary statement regarding forward-looking statements

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 Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2012.

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 02, 2013

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc