GLAXOSMITHKLINE PLC
Form 6-K
December 03, 2018

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 03 December 2018

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 x 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 x

Issued: 3 December 2018, London UK - LSE Announcement

GSK reaches agreement to acquire TESARO, an oncology focused biopharmaceutical company

GlaxoSmithKline plc (LSE/NYSE: GSK) and TESARO Inc (NASDAQ: TSRO) today announced that the Companies have entered into a definitive agreement pursuant to which GSK will acquire TESARO, an oncology-focused company based in Waltham, Massachusetts, for an aggregate cash consideration of approximately $5.1 billion (£4.0 billion). The proposed transaction will significantly strengthen GSK's pharmaceutical business, accelerating the build of GSK's pipeline and commercial capability in oncology.

TESARO is a commercial-stage biopharmaceutical company, with a major marketed product, Zejula (niraparib), an oral poly ADP ribose polymerase (PARP) inhibitor currently approved for use in ovarian cancer. PARP inhibitors are transforming the treatment of ovarian cancer, notably demonstrating marked clinical benefit in patients with and without germline mutations in a BRCA gene (gBRCA). Zejula is currently approved in the US and Europe as a treatment for adult patients with recurrent ovarian cancer who are in response to platinum-based chemotherapy, regardless of BRCA mutation or biomarker status.

Clinical trials to assess the use of Zejula in "all-comers" patient populations, as a monotherapy and in combinations, for the significantly larger opportunity of first line maintenance treatment of ovarian cancer are also underway. These ongoing trials are evaluating the potential benefit of Zejula in patients who carry gBRCA mutations as well as the larger population of patients without gBRCA mutations whose tumours are HRD-positive and HRD-negative. Results from the first of these studies, PRIMA, are expected to be available in the second half of 2019.

GSK also believes PARP inhibitors offer significant opportunities for use in the treatment of multiple cancer types. In addition to ovarian cancer, Zejula is currently being investigated for use as a possible treatment in lung, breast and prostate cancer, both as a monotherapy and in combination with other medicines, including with TESARO's own anti-PD-1 antibody (dostarlimab, formerly known as TSR-042).

In addition to Zejula, TESARO has several oncology assets in its pipeline including antibodies directed against PD-1, TIM-3 and LAG-3 targets.

Emma Walmsley, Chief Executive Officer, GSK, said: "The acquisition of TESARO will strengthen our pharmaceuticals business by accelerating the build of our oncology pipeline and commercial footprint, along with providing access to new scientific capabilities. This combination will support our aim to deliver long-term sustainable growth and is consistent with our capital allocation priorities. We look forward to working with TESARO's talented team to bring valuable new medicines to patients."

Hal Barron, Chief Scientific Officer and President, R&D, GSK, said: "Our strong belief is that PARP inhibitors are important medicines that have been under appreciated in terms of the impact they can have on cancer patients. We are optimistic that Zejula will demonstrate benefit in patients with ovarian cancer beyond those who are BRCA-positive as front-line treatment. We are also very excited that through this transaction, we will have the opportunity to work with an outstanding Boston-based oncology group with deep clinical development expertise and together we will explore Zejula's efficacy beyond ovarian cancer into multiple tumour types to help many more patients."

Lonnie Moulder, Chief Executive Officer, TESARO, said: "This transaction marks the beginning of a new global partnership that will accelerate our oncology business and allow our mission of delivering transformative products to individuals living with cancer to endure. Our Board and Management team are very pleased to announce this transaction, and we are grateful to the management team at GSK for their tremendous vision and the opportunity to

preserve and build upon the impact we have had in the cancer community to date."

Mary Lynne Hedley, President and Chief Operating Officer, TESARO, said: "This partnership marks an evolution in the way we live out the TESARO mission and will allow us to more rapidly deliver on our commitment to patients. I am excited to be partnering with our new colleagues at GSK as together we advance innovative scientific and drug development strategies that ultimately enable us to provide more time for more patients."

Financial highlights

The acquisition price of $75 per share in cash represents a 110% premium to TESARO's 30 day Volume Weighted Average Price of $35.67 and an aggregate consideration of approximately $5.1 billion (£4.0 billion) including the assumption of TESARO's net debt.

Zejula's revenues in its current approved indication as second-line maintenance treatment for ovarian cancer were $166 million for the 9 months ended 30 September 2018.

GSK expects the acquisition of TESARO and associated R&D and commercial investments will impact Adjusted EPS for the first two years by mid to high single digit percentages, reducing thereafter with the acquisition expected to start to be accretive to Adjusted EPS by 2022.

GSK's guidance for full-year 2018 Adjusted EPS growth remains unchanged at 8 to 10% at CER. GSK continues to expect to deliver on its previously published Group Outlooks to 2020, but following the acquisition of TESARO now expects Adjusted EPS growth at CER for the period 2016-2020 to be at the bottom end of the mid to high single digit percentage CAGR range.

Guidance and Group Outlooks are given on the bases set out on pages 37 and 38 of GSK's Q3 2018 results, including definitions of CER growth and Adjusted results.

GSK confirms no change to its current dividend policy and continues to expect to pay 80p in dividends for 2018.

GSK expects to fund the acquisition from cash resources and drawing under a new acquisition facility.

Structure and Terms of the Transaction

Under the terms of the merger agreement between GSK and TESARO, unanimously approved by TESARO's Board of Directors, an indirect subsidiary of GSK will commence a tender offer within the next 10 business days to acquire all of the issued and outstanding shares of TESARO common stock for a price of $75 per share in cash upon completion of the offer. The transaction is expected to complete in the first quarter of 2019, subject to satisfaction of customary closing conditions, including the tender by TESARO stockholders of at least one share more than 50% of the issued and outstanding shares of TESARO and required regulatory approvals, including clearance by the US Federal Trade Commission. Following closing of the tender offer, GSK will acquire any shares of TESARO that are not tendered in the tender offer through a second-step merger under Delaware law at the tender offer price.

The value of the gross assets of TESARO to be acquired (as at 30 September 2018) is $711 million (£555 million at the rate of £1 = $1.28, being the 30 November spot rate). The net losses of the business were $466 million for the 9 months ended 30 September 2018 (£345 million, at the rate of £1 = $1.35, being the average rate for the 9 months ended 30 September 2018).

GSK is in discussions with several key executives of TESARO to ensure their continued employment with the company.

Additional information and where to find it

This press announcement is for informational purposes only and is neither an offer to purchase nor a solicitation of an offer or a recommendation to sell securities, nor is it a substitute for the tender offer materials that GSK and its indirect subsidiary, Adriatic Acquisition Corporation, will file with the Securities and Exchange Commission (the "SEC"). The tender offer for the outstanding shares of TESARO's common stock described in this press announcement has not commenced. At the time the tender offer is commenced, GSK and Adriatic Acquisition Corporation will file, or will cause to be filed, a Schedule TO Tender Offer Statement with the SEC, and, thereafter, TESARO will file a Schedule 14D-9 Solicitation/Recommendation Statement with the SEC, in each case with respect to the tender offer. The Schedule TO Tender Offer Statement (including an offer to purchase, a related letter of transmittal and other offer documents) and the Schedule 14D-9 Solicitation/Recommendation Statement will contain important information that should be read carefully before any decision is made with respect to the tender offer. Those materials (once they become available) will be made available to TESARO's stockholders at no expense to them by the information agent for the tender offer, which will be announced. In addition, those materials and all other documents filed by or caused to be filed by TESARO or GSK with the SEC will be available at no charge on the SEC's website at www.sec.gov . In addition to the Schedule 14D-9 Solicitation/Recommendation Statement and Schedule TO Offer Statement (once each becomes available), TESARO and GSK file or furnish, as applicable, annual, quarterly and current reports and other information with the SEC. You may read and copy any reports or other information filed by TESARO at the SEC public reference room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-0330 for further information on the public reference room. TESARO's and GSK's filings with the SEC are also available to the public from commercial document-retrieval services and at the SEC's website at www.sec.gov.

This announcement contains inside information for the purposes of Article 7 of EU Regulation 596/2014. The person responsible for arranging the release of this announcement on behalf of GSK is V.A. Whyte, Company Secretary.

Analyst conference call details
14:00 UK / 09:00 EST Monday 3 December

UK Direct: 01296 480 100
UK freephone: 0800 783 0906

US Direct: +1 718 354 1175
US freephone: + 1866 804 8688

Passcode: 177 245 38

Rest of world dial in numbers:
http://www.btconferencing.com/globalaccess/?bid=54_attended

TESARO portfolio and pipeline
Zejula is an orally active and potent poly ADP-ribose polymerase (PARP) inhibitor. PARP is a family of proteins involved in many functions in a cell, including DNA repair, gene expression, cell cycle control, intracellular trafficking and energy metabolism. PARP proteins play key roles in single strand break repair through the base excision repair pathway. PARP inhibitors have shown activity as a monotherapy against tumours with existing DNA repair defects, such as BRCA1 and BRCA2, and as a combination therapy when administered together with anti-cancer agents that induce DNA damage or activate the immune system.

TESARO's development pipeline also has a number of novel oncology candidates that modulate the function of the immune system via different mechanisms. By blocking the interaction of PD-1, TIM-3 and LAG-3 with their respective ligands, antibodies to these targets aim to restore immune anti-cancer function in patients across a variety of tumour types.

Compound	Indication	Phase
Niraparib	Ovarian cancer maintenance (PRIMA)	Phase 3
Niraparib + dostarlimab (anti-PD-1 mAb)	First-line ovarian cancer treatment (FIRST)	Phase 3
Niraparib + anti-PD-1 mAb	Advanced NSCLC, squamous cell carcinoma of the lung	Phase 2
Niraparib + bevacizumab	First-line ovarian cancer maintenance (OVARIO)	Phase 2
Niraparib + bevacizumab	Recurrent ovarian cancer (AVANOVA) (in collaboration with ENGOT, the European Network for Gynaecological Oncological Trial groups)	Phase 2
Niraparib + pembrolizumab	Triple negative breast or ovarian cancer (TOPACIO)	Phase 2
Dostarlimab (anti-PD-1 mAb)	MSI-H tumours including metastatic endometrial cancer (GARNET)	Phase 1
Niraparib + chemotherapy	Ewing's sarcoma (in collaboration with SARC, the Sarcoma Alliance for Research through Collaboration)	Phase 1
Dostarlimab (anti-PD-1 mAb)	Various tumour types	Phase 1
Dostarlimab +/- bevacizumab + niraparib or carboplatin-paclitaxel	Advanced or metastatic cancer	Phase 1
TSR-022 (anti-TIM-3 mAb)	Various tumour types (AMBER)	Phase 1
TSR-033 (anti-LAG-3 mAb	Various tumour types (CITRINO)	Phase 1
Anti-LAG-3/PD-1 bispecific antibody	Various tumour types	Discovery
Undisclosed small molecule and antibody I-O candidates	Various tumour types	Discovery

Advisors
GSK is being advised by PJT Partners and additionally by Bank of America Merrill Lynch, who is also acting as corporate broker. Legal advice is being provided by Shearman & Sterling LLP, with Slaughter and May advising on the acquisition facility.

Citi is serving as TESARO's lead financial advisor, with Centerview Partners also providing financial advice. Legal advice is being provided by Ropes & Gray LLP, and Hogan Lovells.

Notes to editors:

About TESARO
TESARO is an oncology-focused biopharmaceutical company devoted to providing transformative therapies to people facing cancer. The company is based in Boston and has 763 associates. For more information, visit www.tesarobio.com, and follow us on Twitter and LinkedIn.

About GSK
GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. For further information please visit www.gsk.com.

About GSK Oncology
GSK is focused on delivering transformational therapies for cancer patients. GSK's pipeline is focused on immuno-oncology, cell therapy, and epigenetics. Our goal is to achieve a sustainable flow of new treatments for

cancer patients based on a diversified portfolio of investigational medicines utilising modalities such as small molecules, antibodies, multi-specific molecules, adjuvants and cells, either alone or in combination.

About Zejula (niraparib)
Zejula (niraparib) is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. In preclinical studies, Zejula concentrates in the tumour relative to plasma, delivering greater than 90% durable inhibition of PARP 1/2 and a persistent antitumour effect. Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML), including some fatal cases, was reported in patients treated with Zejula. Discontinue Zejula if MDS/AML is confirmed. Hematologic adverse reactions (thrombocytopenia, anemia and neutropenia), as well as cardiovascular effects (hypertension and hypertensive crisis) have been reported in patients treated with Zejula. Monitor complete blood counts to detect hematologic adverse reactions, as well as to detect cardiovascular disorders, during treatment. Zejula can cause fetal harm and females of reproductive potential should use effective contraception. Please see full prescribing information, including additional important safety information, available at www.zejula.com.

About Ovarian Cancer
Approximately 22,000 women are diagnosed with ovarian cancer each year in the US, and more than 65,000 women are diagnosed annually in Europe. Ovarian cancer is the fifth leading cause of cancer death among women. Despite high-response rates to platinum-based chemotherapy in the second-line advanced treatment setting, approximately 85% of patients with advanced ovarian cancer will experience recurrence. Once ovarian cancer recurs, it's considered incurable. From there, with each recurrence, the time a woman may spend without her cancer progressing until the next recurrence gets shorter.

About PARP Inhibitor/PARP-1 and PARP-2 Inhibitors
PARP, or poly(ADP-ribose) polymerase, is a family of proteins that helps repair damaged DNA in cells. A PARP inhibitor like Zejula may prevent cancer cells from repairing their damaged DNA, which can cause cancer cells to die. This may slow the return or progress of cancer. Zejula can also impact other cells and tissues in the body

About BRCA / HRD
BRCA is a gene that is linked to increased risk for cancer. Mutations in this gene can prevent DNA repair. Mutations or aberrations in BRCA or other genes that prevent DNA repair result in a state of homologous recombination deficiency, or "HRD". Cancer cells with HRD are especially sensitive to PARP inhibitors, which have been shown to shrink tumours in patients with HRD and increase the time in which patients are free from cancer progression. The genomic tests used to define HRD are evolving. To date, clinical studies of PARP inhibitors have primarily relied on tests for BRCA gene mutations to select patients for treatment with a PARP inhibitor. Other tests, such as MyChoice and FoundationOne have been used in clinical trials of ovarian cancer to identify patients whose tumors have HRD and are sensitive to PARP inhibitors. However, more sensitive tests involving such things as whole genome screening and functional genomic analyses are needed to identify additional patients with cancer who might benefit from treatment with PARP inhibitors.

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Cautionary statements 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. Such factors include, but are not limited to, those described under Item 3.D Principal risks and uncertainties in the company's Annual Report on Form 20-F for 2017. Guidance and Group Outlooks are given on the bases set out on pages 37 and 38 of GSK's Q3 2018 results, including definitions of CER growth and Adjusted results. This communication also includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 related to TESARO and the acquisition of TESARO by GSK that are subject to risks, uncertainties and other factors. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including all statements regarding the intent, belief or current expectation of TESARO and members of its senior management team and can typically be identified by words such as "believe," "expect," "estimate," "predict," "target," "potential," "likely," "continue," "ongoing," "could," "should," "intend," "may," "might," "plan," "seek," "anticipate," "project" and similar expressions, as well as variations or negatives of these words. Forward-looking statements include, without limitation, statements regarding the business combination, similar transactions, prospective performance, future plans, events, expectations, performance, objectives and opportunities and the outlook for TESARO's business; the commercial success of TESARO's products; the anticipated timing of clinical data; the possibility of unfavorable results from clinical trials; filings and approvals relating to the transaction; the expected timing of the completion of the transaction; the ability to complete the transaction considering the various closing conditions; and the accuracy of any assumptions underlying any of the foregoing. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties and are cautioned not to place undue reliance on these forward-looking statements. Actual results may differ materially from those currently anticipated due to a number of risks and uncertainties. Risks and uncertainties that could cause the actual results to differ from expectations contemplated by forward-looking statements include: uncertainties as to the timing of the tender offer and merger; uncertainties as to how many of TESARO's stockholders will tender their stock in the offer; the possibility that various closing conditions for the transaction may not be satisfied or waived, including that a governmental entity may prohibit, delay or refuse to grant approval for the consummation of the transaction; the occurrence of any event, change or other circumstance that could give rise to the termination of the merger agreement; the effects of the transaction (or the announcement thereof) on relationships with associates, customers, other business partners or governmental entities; transaction costs; the risk that the merger will divert management's attention from TESARO's ongoing business operations; changes in TESARO's businesses during the period between now and the closing; risks associated with litigation; and other risks and uncertainties detailed from time to time in documents filed with the Securities and Exchange Commission by TESARO, including current reports on Form 8-K, quarterly reports on Form 10-Q and annual reports on Form 10-K, as well as the Schedule 14D-9 to be filed by TESARO. All forward-looking statements are based on information currently available to TESARO, and TESARO assumes no obligation to update any 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: December 03, 2018

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc