

ASTRAZENECA PLC
Form 6-K
July 31, 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 the month of July 2013

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

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

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

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 ☒

If "Yes" is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b):
82-_____

ASTRAZENECA AND FIBROGEN COLLABORATE TO DEVELOP AND COMMERCIALISE FG-4592, A
TREATMENT FOR ANAEMIA IN CHRONIC KIDNEY DISEASE
AND END-STAGE RENAL DISEASE

Collaboration to include US, China and selected other markets

AstraZeneca and FibroGen today announced that they have entered into a strategic collaboration to develop and commercialise FG-4592, a first-in-class oral compound in late stage development for the treatment of anaemia associated with chronic kidney disease (CKD) and end-stage renal disease (ESRD).

This broad collaboration focuses on the US, China and all major markets excluding Japan, Europe, the Commonwealth of Independent States, the Middle East and South Africa, which are covered by an existing agreement between FibroGen and Astellas Pharma Inc. The AstraZeneca-FibroGen joint effort will be focused on the development of FG-4592 to treat anaemia in CKD and ESRD, and may be extended to other anaemia indications.

FG-4592 is a small molecule inhibitor of hypoxia-inducible factor (HIF), a protein that responds to oxygen changes in the cellular environment and meets the body's demands for oxygen by inducing erythropoiesis, the process by which red blood cells are produced. FG-4592 has the potential to address the considerable unmet medical need for an effective treatment for anaemia that offers the convenience of oral administration and an improved safety profile as compared to current standards of care. At present, treatment options involve a combination of injectable erythropoiesis-stimulating agents (ESAs) and iron supplements. FG-4592 works through the body's natural oxygen-sensing and response system to help produce red blood cells. This can be compared to the body's natural response to conditions at high altitude, where oxygen levels are low, which is to produce more red blood cells.

In Phase II clinical studies, FG-4592 met its primary objective of demonstrating anaemia correction in treatment-naïve CKD patients not on dialysis as well as maintenance of haemoglobin levels and anaemia correction in patients on dialysis. FG-4592 has demonstrated this efficacy combined with an acceptable safety profile in clinical trials, and has been shown to achieve anaemia correction in the absence of intravenous iron supplementation.

The companies plan to undertake an extensive FG-4592 phase III development programme for the US, and to initiate phase III trials in China, with anticipated regulatory filings in China in 2015 and in the US in 2017.

AstraZeneca will pay FibroGen committed upfront and subsequent non-contingent payments totalling \$350 million, as well as potential future development related milestone payments of up to \$465 million, and potential future sales related milestone payments in addition to tiered royalty payments on future sales on FG-4592 in the low 20% range. Additional development milestones will be payable for any subsequent indications which the companies choose to pursue. AstraZeneca will be responsible for the US commercialisation of FG-4592, with FibroGen undertaking specified promotional activities in the ESRD segment in this market. The companies will also co-commercialise FG-4592 in China where FibroGen will be responsible for clinical trials, regulatory matters, manufacturing and medical affairs, and AstraZeneca will oversee promotional activities and commercial distribution.

Pascal Soriot, Chief Executive Officer, AstraZeneca, said: "Our collaboration with FibroGen on FG-4592 is an important addition to AstraZeneca's growing late-stage portfolio in cardiovascular and metabolic disease, one of our core therapy areas. We know from our research into complications of renal disease that anaemia continues to be a

challenge for patients with chronic kidney disease, due in part to the inconvenience and complexity of existing injectable and intravenous therapies and the safety concerns associated with them. The science behind this compound is compelling. Through our collaboration with FibroGen we aim to offer a first-in-class, convenient treatment option for doctors and patients."

Thomas B. Neff, Chief Executive Officer, FibroGen, said: "FG-4592 has the potential to offer anaemia patients an oral therapy that provides coordinated erythropoiesis, that increases natural erythropoietin within the normal physiological range, and that is effective without intravenous iron supplementation and without an increased risk for hypertension. We are especially pleased that AstraZeneca will share our commitment to making China the first-to-launch country for FG-4592 and join our effort to bring important innovation in anaemia therapy to CKD and ESRD patients in the US and other countries. This agreement secures proper development and commercialisation resources for FG-4592, and ensures US clinical trial efforts are fully funded."

About chronic kidney disease and anaemia

Diabetes, high blood pressure, and other conditions can cause significant damage to the kidneys. If left untreated, those can result in chronic kidney disease and progress to kidney failure. Such deterioration can lead to patients needing a kidney transplant or being placed on dialysis to remove excess fluid and toxins that build up in the body. The progression of CKD also increases the prevalence of anaemia, a condition associated with having fewer of the red blood cells that carry oxygen through the body, and/or lower levels of haemoglobin, the protein that enables red blood cells to carry oxygen. As haemoglobin falls, the lower oxygen-carrying capacity of an anaemic patients' blood results in various symptoms including fatigue, loss of energy, breathlessness, and angina. Anaemia in CKD patients has been associated with increased hospitalisation rates, increased mortality, and reduced quality of life.

CKD is a worldwide critical healthcare problem that affects millions of people and drives significant healthcare cost. In the US, prevalence of CKD has increased dramatically in the past 20 years, from 10% of the adult population (or approximately 20 million US adults) as stated in the National Health and Nutrition Evaluation Survey (NHANES) 1988-1994, to 15% (or approximately 30 million adults) in NHANES 2003-2006. In 2009, total Medicare costs for CKD patients were \$34 billion. China has an estimated 125 million CKD patients, or 5 times the number of CKD patients in the US [Lancet April 2012].

About FG-4592

FG-4592 is an orally administered small molecule inhibitor of hypoxia-inducible factor (HIF) prolyl hydroxylase activity, in development for the treatment of anaemia in patients with chronic kidney disease (CKD). HIF is a protein transcription factor that induces the natural physiological response to conditions of low oxygen, "turning on" erythropoiesis (the process by which red blood cells are produced) and other protective pathways. FG-4592 has been shown to correct anaemia and maintain haemoglobin levels without the need for supplementation with intravenous iron in CKD patients not yet receiving dialysis and in end-stage renal disease patients receiving dialysis. An Independent Data Monitoring Committee has found no signals or trends to date to suggest that treatment with FG-4592 is associated with increased risk of cardiovascular events, thrombosis, or increases in blood pressure requiring initiation or intensification of antihypertensive medications.

Under a licensing agreement between FibroGen, Inc. and Astellas Pharma Inc., Astellas is developing FG-4592 for the treatment of anaemia in CKD and ESRD patients in Europe, Japan, the Commonwealth of Independent States, the Middle East, and South Africa.

About FibroGen

FibroGen, Inc., is a privately-held biotechnology company focused on the discovery, development, and commercialization of therapeutic agents for treatment of fibrosis, anaemia, cancer, and other serious unmet medical needs. FibroGen's FG-3019 monoclonal antibody is in early-stage clinical development for treatment of idiopathic pulmonary fibrosis and other proliferative diseases, including pancreatic cancer and liver fibrosis, and FG-4592 is a small molecule inhibitor of hypoxia-inducible factor (HIF) prolyl hydroxylase currently in clinical development for

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the treatment of anaemia. FibroGen is also currently pursuing the use of proprietary recombinant human type III collagens in synthetic corneas for treatment of corneal blindness. For more information please visit: www.fibrogen.com

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com

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31 July 2013

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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 authorized.

AstraZeneca PLC

Date: 31 July 2013

By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary