ASTRAZENECA PLC
Form 6-K
December 17, 2015

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 December 2015

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 X 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 X

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

ASTRAZENECA ENHANCES LONG TERM GROWTH THROUGH ONCOLOGY INVESTMENT IN ACERTA PHARMA

Transaction includes late-stage, potential best-in-class irreversible small molecule BTK inhibitor, acalabrutinib

Opportunity for first regulatory submissions in haematological malignancies in 2016

Investment establishes in-house expertise in blood cancers and complements strategic use of immunotherapy in haematological malignancies and solid tumours

AstraZeneca today announced that it has entered into an agreement to invest in a majority equity stake in Acerta Pharma, a privately-owned biopharmaceutical company based in the Netherlands and US. The transaction provides AstraZeneca with a potential best-in-class irreversible oral Bruton's tyrosine kinase (BTK) inhibitor, acalabrutinib (ACP-196), currently in Phase III development for B-cell blood cancers and in Phase I/II clinical trials in multiple solid tumours.

Pascal Soriot, Chief Executive Officer of AstraZeneca, said: "The investment is consistent with our focus on long-term growth and reflects the role targeted business development plays in our business model. We are boosting a key area in our comprehensive oncology portfolio with a late-stage, potential best-in-class medicine that could transform treatment for patients across a range of blood cancers."

"Acalabrutinib provides us with a small molecule presence in blood cancers to complement our existing immunotherapy approach, in collaboration with Celgene in haematological malignancies. Furthermore, we look forward to working closely with the Acerta team and benefiting from the considerable clinical expertise they bring in this complex area of medicine."

Under the terms of the agreement, AstraZeneca will acquire 55% of the entire issued share capital of Acerta for an upfront payment of $2.5 billion. A further unconditional payment of $1.5 billion will be paid either on receipt of the first regulatory approval for acalabrutinib for any indication in the US, or the end of 2018, depending on which is first. The agreement also includes options which, if exercised, provide the opportunity for Acerta shareholders to sell, and AstraZeneca to buy, the remaining 45% of shares in Acerta. The options can be exercised at various points in time, conditional on the first approval of acalabrutinib in both the US and Europe and when the extent of the commercial opportunity has been fully established, at a price of approximately $3 billion net of certain costs and payments incurred by AstraZeneca and net of agreed future adjusting items, using a pre-agreed pricing mechanism.

An extensive development programme is underway for acalabrutinib with the opportunity for initial regulatory submissions in the second half of 2016 for the treatment of patients with specific types of haematological malignancies. Expanding further into B-cell cancers, acalabrutinib is estimated to reach potential peak-year sales in excess of $5 billion globally. AstraZeneca will also benefit from the substantial expertise in haematological cancers offered by Acerta's approximately 150 employees.

The BTK inhibitor class is transforming the treatment of B-cell blood cancers, allowing a potentially more effective treatment option with limited side effects, replacing current chemotherapy and antibody-containing regimens. Acalabrutinib is a highly selective, irreversible, next-generation small molecule oral BTK inhibitor supported by strong clinical evidence, with approximately 1,000 patients treated to date, of whom more than 600 were on the potential medicine as monotherapy. Data indicate that acalabrutinib offers enhanced BTK inhibition. Phase I/II data presented at the recent American Society of Haematology Annual Meeting 2015 showed a 95% response rate in patients with relapsed chronic lymphocytic leukaemia, the most prevalent form of adult leukaemia, and a 100% overall response rate in the difficult-to-treat 17p deletion patients1.

In addition, acalabrutinib has the potential to address an unmet medical need for patients who are intolerant to or unsuitable for first generation BTK inhibitor treatment. Currently 20-30% of patients discontinue first-generation

therapy due to tolerability issues2.

John C. Byrd MD, Professor and Director, Division of Haematology, Department of Medicine, at The Ohio State University School of Medicine, said: "The BTK inhibitor class has been transformational in the management of B-cell cancers but a portion of patients treated with ibrutinib (the first generation BTK inhibitor), can't tolerate the side effects and sadly discontinue their treatment. The acalabrutinib data are highly encouraging as they show that high selectivity, a short half-life and an optimised dosing schedule result in very high efficacy and a significantly better tolerability profile with very low discontinuation rates. Acalabrutinib may potentially offer improved long-term benefit over other options available for these patients."

In addition to blood cancers, acalabrutinib is currently being explored in Phase I/II studies in combination with immunotherapy or chemotherapies in a range of solid tumours. Pre-clinical data show that acalabrutinib has an immune-modulatory effect that, as monotherapy and alongside PD-1/PD-L1 antibodies, has the potential to enhance anti-tumour activity.

Acerta will initially be a majority owned subsidiary of AstraZeneca; if AstraZeneca acquires the remaining shares of the company in the future, Acerta would become a wholly-owned subsidiary. The transaction will be accounted for as a business combination and is expected to complete by the end of the first quarter of 2016, subject to customary closing conditions. The initial acquisition payment of $2.5 billion will be funded from cash and debt. The agreement is expected to be moderately dilutive to AstraZeneca's core earnings in the near term.

For the purposes of the UK Listing Authority's Listing Rule LR 10.4.1 R (Notification of class 2 transactions), the fair value of gross assets acquired with the transaction is estimated to be $5.7 billion and, in view of the development phase of the medicine, a pre-tax loss of $80 million was attributable to Acerta during the year to 31 December 2014.

Full Year 2016 guidance is expected to be provided at Full Year 2015 results on 4 February 2016.

Conference call for investors and analysts

AstraZeneca will host a conference call for investors and analysts at 13:00 GMT on 17 December 2016. A presentation will be available for download from the Investor Relations section of astrazeneca.com (Our company/Investors) one hour before the conference call starts.

Telephone dial-in details for investors and analysts:

UK Freephone: 0800 694 2573
International standard: +44 (0) 1452 580 733
Sweden: 0200 883 198
US: 877 391 1148

Conference code: 8984139

A replay will be available from 17 December at 15:00 GMT to 30 December 15:00 GMT, the dial-in details are:

UK Freephone: 0800 953 1533
International standard: +44 (0) 1452 550000

US: 866 247 4222

Conference code: 8984139

NOTES TO EDITORS

1 John C. Byrd, M.D. et al, NEJM, DOI: 10.1056/NEJMoa1509981 Published online 7 December. http://www.nejm.org/doi/full/10.1056/NEJMoa1509981.

2 Maddocks et al, JAMA Oncol. DOI:10.1001/jamaoncol.2014.218 Published online February 26, 2015.

About Acalabrutinib
Acalabrutinib is a highly selective, irreversible, second generation BTK inhibitor, with approximately 1,000 patients treated to date in clinical studies across the entire development programme. More than 600 patients have been treated with acalabrutinib monotherapy. Phase I/II data showing a favourable safety profile and strong efficacy in relapsed/refractory chronic lymphocytic leukaemia patients was presented at the American Society of Hematology Annual Meeting & Exposition in December 2015, with simultaneous publication in the New England Journal of Medicine.

Potentially registrational studies in haematological malignancies are expected to be submitted for regulatory filings in second half 2016. In addition, a head-to-head study versus ibrutinib in high risk chronic lymphocytic leukaemia patients is currently ongoing.

Acalabrutinib is also currently being tested in multiple Phase I/II studies in solid tumours, as monotherapy or in combination with immune checkpoint inhibitors or other standard of care regimens.

About Acerta Pharma
Acerta is a leader in the field of covalent binding technology and is applying this technology to create novel selective therapies intended for the treatment of cancer and autoimmune diseases. Acerta's lead molecule, acalabrutinib (ACP-196), is a selective and potent inhibitor of BTK. Acerta is also developing ACP-319, a novel isoform selective inhibitor of phosphoinositide 3-kinase (PI3K) delta. The company has operations in Oss, the Netherlands and multiple U.S. sites. The U.S. headquarters is in Redwood City, CA.

About AstraZeneca in Oncology
Oncology is a therapeutic area in which AstraZeneca has a deep-rooted heritage. It will be potentially transformational for the company's future, becoming the sixth growth platform. Our vision is to help patients by redefining the cancer treatment paradigm and one day eliminate cancer as a cause of death. By 2020, we are aiming to bring six new cancer medicines to patients.

Our broad pipeline of next-generation medicines is focused on four main disease areas - ovarian, lung, breast and haematological cancers. These are being targeted through four key platforms - immuno-oncology, the genetic drivers of cancer and resistance, DNA damage repair and antibody drug conjugates.

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 diseases in three main therapy areas - respiratory, inflammation, autoimmune disease, cardiovascular and metabolic disease and oncology - as well as in infection and neuroscience. 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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Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease, ING - Infection, Neuroscience and Gastrointestinal

17 December 2015

-ENDS-

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: 17 December 2015

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