

ASTRAZENECA PLC
Form 6-K
November 06, 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 November 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 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 STRENGTHENS CARDIOVASCULAR AND METABOLIC DISEASE PORTFOLIO WITH
ACQUISITION OF
ZS PHARMA

AstraZeneca to acquire ZS Pharma for \$90 per share

Acquisition includes potential best-in-class hyperkalaemia treatment currently under US FDA regulatory review

Acquisition expected to contribute Product Sales from 2016 and benefit AstraZeneca's return to growth strategy

AstraZeneca announced today that it has entered into a definitive agreement to acquire ZS Pharma (NASDAQ: ZSPH), a biopharmaceutical company based in San Mateo, California. ZS Pharma uses its proprietary ion--trap technology to develop novel treatments for hyperkalaemia (high potassium levels), a serious condition of elevated potassium in the bloodstream, typically associated with chronic kidney disease (CKD) and chronic heart failure (CHF).

The transaction will give AstraZeneca access to the potassium-binding compound ZS-9, a potential best-in-class treatment for hyperkalaemia, a condition associated with increased mortality in CKD and CHF. ZS-9 is under regulatory review by the US Food and Drug Administration with a Prescription Drug User Fee Act goal date of 26 May 2016. A submission for European Marketing Application Authorisation is planned by the end of 2015. Current estimates for global peak year sales of ZS-9 exceed \$1 billion.

The acquisition continues AstraZeneca's track record of targeted business development with a focus on three main therapy areas. ZS Pharma represents a strong fit with AstraZeneca's pipeline and portfolio in Cardiovascular & Metabolic Disease, one of the company's three main therapy areas. AstraZeneca's strategy focuses on reducing morbidity, mortality and organ damage by addressing multiple risk factors across cardiovascular disease, diabetes and chronic kidney disease. ZS-9 complements the company's increasing focus on CKD and CHF, including the investigational medicine roxadustat, which is currently in Phase III development for patients with anaemia associated with CKD, as well as its leading diabetes portfolio.

Pascal Soriot, Chief Executive Officer of AstraZeneca, said: "Hyperkalaemia can be a life-threatening condition for patients with chronic kidney disease and chronic heart failure, however the risk is underappreciated and prevalence is increasing. This acquisition complements our strategic focus on Cardiovascular and Metabolic Disease by adding a potential best-in-class treatment to our portfolio of innovative medicines. We look forward to welcoming the ZS Pharma team to AstraZeneca."

Under the terms of the agreement, AstraZeneca will acquire all of the outstanding capital stock of ZS Pharma for \$90 per share in an all-cash transaction, or approximately \$2.7 billion in aggregate transaction value.

Upon completion, ZS Pharma, which has around 200 employees across three sites in California, Texas and Colorado, will become a wholly owned subsidiary of AstraZeneca. The transaction does not impact AstraZeneca's financial guidance for 2015. It is expected to generate Product Sales from 2016, with minimal earnings dilution over 2016 and 2017, becoming accretive to AstraZeneca's core earnings from 2018.

Robert Alexander, Chief Executive Officer, ZS Pharma, said: "This agreement will allow us to maximize the potential of ZS-9, drawing on AstraZeneca's long-standing expertise in developing and commercializing medicines for cardiovascular and metabolic diseases. We look forward to joining AstraZeneca and to working together to bring this important treatment for hyperkalaemia to the global market, helping to meet an important unmet medical need for patients."

Terms of the acquisition

The acquisition is structured as an all-cash tender offer for all outstanding shares of ZS Pharma common stock at a price of \$90 per share, followed by a merger in which each remaining untendered share of ZS Pharma common stock

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would be converted into the same \$90 cash per share consideration as in the tender offer.

Under the terms of the merger agreement, AstraZeneca will commence a tender offer to acquire all outstanding shares of ZS Pharma's common stock. The Board of Directors of ZS Pharma has unanimously approved the terms of the agreement.

Subject to customary conditions, including the tender of a majority of the outstanding ZS Pharma shares and the expiration or earlier termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, the transaction is expected to close by the end of 2015. The transaction is not subject to a financing condition.

Conference call for investors and analysts

AstraZeneca will host a conference call for investors and analysts at 14:00 GMT / 09:00 EST on 6 November 2015. A presentation will be available for download from the Investor Relations section of astrazeneca.com (Our company > Investor Relations) before the conference call starts.

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Listen-only dial-in details for media:

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

SOME OF THE STATEMENTS CONTAINED IN THIS ANNOUNCEMENT ARE FORWARD LOOKING STATEMENTS, INCLUDING STATEMENTS REGARDING THE EXPECTED CONSUMMATION OF THE ACQUISITION, WHICH INVOLVES A NUMBER OF RISKS AND UNCERTAINTIES, INCLUDING THE SATISFACTION OF CLOSING CONDITIONS FOR THE ACQUISITION, SUCH AS REGULATORY APPROVAL FOR THE TRANSACTION, THE TENDER OF A MAJORITY OF THE OUTSTANDING SHARES OF COMMON STOCK OF ZS PHARMA, THE POSSIBILITY THAT THE TRANSACTION WILL NOT BE COMPLETED AND OTHER RISKS AND UNCERTAINTIES DISCUSSED IN ZS PHARMA'S PUBLIC FILINGS WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION (SEC), INCLUDING THE "RISK FACTORS" SECTIONS OF ZS PHARMA'S ANNUAL REPORT ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2014 AND SUBSEQUENT QUARTERLY REPORTS ON FORM 10-Q, AS WELL AS THE TENDER OFFER DOCUMENTS TO BE FILED BY SUBSIDIARIES OF ASTRAZENECA AND THE

SOLICITATION/RECOMMENDATION TO BE FILED BY ZS PHARMA. THESE STATEMENTS ARE BASED ON CURRENT EXPECTATIONS, ASSUMPTIONS, ESTIMATES AND PROJECTIONS, AND INVOLVE KNOWN AND UNKNOWN RISKS, UNCERTAINTIES AND OTHER FACTORS THAT MAY CAUSE RESULTS, LEVELS OF ACTIVITY, PERFORMANCE OR ACHIEVEMENTS TO BE MATERIALLY DIFFERENT FROM ANY FUTURE STATEMENTS. THESE STATEMENTS ARE GENERALLY IDENTIFIED BY WORDS OR PHRASES SUCH AS "BELIEVE," "ANTICIPATE," "EXPECT," "INTEND," "PLAN," "WILL," "MAY," "SHOULD," "ESTIMATE," "PREDICT," "POTENTIAL," "CONTINUE" OR THE NEGATIVE OF SUCH TERMS OR OTHER SIMILAR EXPRESSIONS. IF UNDERLYING ASSUMPTIONS PROVE INACCURATE OR UNKNOWN RISKS OR UNCERTAINTIES MATERIALIZE, ACTUAL RESULTS AND THE TIMING OF EVENTS MAY DIFFER MATERIALLY FROM THE RESULTS AND/OR TIMING DISCUSSED IN THE FORWARD-LOOKING STATEMENTS, AND YOU SHOULD NOT PLACE UNDUE RELIANCE ON THESE STATEMENTS. ASTRAZENECA AND ZS PHARMA DISCLAIM ANY INTENT OR OBLIGATION TO UPDATE ANY FORWARD-LOOKING STATEMENTS AS A RESULT OF DEVELOPMENTS OCCURRING AFTER THE DATE HEREOF OR OTHERWISE.

ADDITIONAL INFORMATION AND WHERE TO FIND IT

THIS COMMUNICATION IS FOR INFORMATIONAL PURPOSES ONLY AND DOES NOT CONSTITUTE AN OFFER TO PURCHASE OR A SOLICITATION OF AN OFFER TO SELL ZS PHARMA COMMON STOCK. THE OFFER TO BUY ZS PHARMA COMMON STOCK WILL ONLY BE MADE PURSUANT TO A TENDER OFFER STATEMENT (INCLUDING THE OFFER TO PURCHASE, LETTER OF TRANSMITTAL AND OTHER RELATED TENDER OFFER MATERIALS). INVESTORS AND SECURITY HOLDERS ARE URGED TO READ BOTH THE TENDER OFFER STATEMENT (WHICH WILL BE FILED BY SUBSIDIARIES OF ASTRAZENECA WITH THE SEC AND THE SOLICITATION/RECOMMENDATION STATEMENT ON SCHEDULE 14D-9 WITH RESPECT TO THE TENDER OFFER (WHICH WILL BE FILED BY ZS PHARMA WITH THE SEC) WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION, INCLUDING THE TERMS AND CONDITIONS OF THE OFFER. INVESTORS AND SECURITY HOLDERS MAY OBTAIN A FREE COPY OF THESE MATERIALS (WHEN AVAILABLE) AND OTHER DOCUMENTS FILED BY ASTRAZENECA AND ZS PHARMA WITH THE SEC AT THE WEBSITE MAINTAINED BY THE SEC AT WWW.SEC.GOV. THE TENDER OFFER STATEMENT AND RELATED MATERIALS, AND THE SOLICITATION/RECOMMENDATION STATEMENT, MAY ALSO BE OBTAINED (WHEN AVAILABLE) FOR FREE BY CONTACTING ASTRAZENECA INVESTOR RELATIONS - SEE CONTACT DETAILS BELOW.

COPIES OF THESE MATERIALS AND ANY DOCUMENTATION RELATING TO THE TENDER OFFER ARE NOT BEING, AND MUST NOT BE, DIRECTLY OR INDIRECTLY, MAILED OR OTHERWISE FORWARDED, DISTRIBUTED OR SENT IN, INTO OR FROM ANY JURISDICTION WHERE TO DO SO WOULD BE UNLAWFUL.

About Hyperkalaemia

Hyperkalaemia, or high potassium levels, occurs in 23-47% of patients with chronic kidney disease and/or chronic heart failure, and can lead to cardiac arrest and death (mortality up to 20%). Treatment with common heart medicines can also be responsible for increases in hyperkalaemia. Current therapeutic options are limited, leaving high unmet medical need, in particular for treatments with rapid onset of action and no significant drug-drug interaction risk.

About ZS-9

ZS-9 is a proprietary zirconium silicate compound and is manufactured as odourless, tasteless crystals. It acts as a highly selective potassium trap, is administered orally in 5 to 15g doses mixed with three tablespoons of water, is not systemically absorbed and is excreted in faeces. Clinical studies indicate that ZS-9 is stable at room temperature and

has a rapid onset of action. Current estimates for global peak year sales of ZS-9 exceed \$1 billion. Pending and granted patents, some under license, have expiries out to 2032 and beyond.

About ZS Pharma

ZS Pharma, founded in 2008, is a publicly traded biopharmaceutical company dedicated to challenging the status quo in disease states where therapeutic options have been limited. The company has been focused on using its proprietary ion-trap technology to develop new treatments of kidney and liver diseases that are focused on addressing unmet needs in the medical community. For more information, please visit: www.zspharma.com.

About AstraZeneca in Cardiovascular & Metabolic Disease (CVMD)

Cardiovascular, metabolic disease and chronic kidney disease are key areas of focus for AstraZeneca as part of the company's strategy for achieving scientific leadership and returning to growth. Our patient-led strategy is focused on addressing the multiple risk factors facing CVMD and CKD patients at different stages of their disease, with the goal of reducing morbidity and mortality through life changing medicines. One of the innovative medicines currently in Phase III development is roxadustat as a potential therapy for anaemia associated with chronic kidney disease, in patients on dialysis and those who are not on dialysis. The global development programme is being conducted by FibroGen in collaboration with AstraZeneca and Astellas.

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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