

ASTRAZENECA PLC

Form 6-K

October 18, 2016

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 October 2016

Commission File Number: 001-11960

AstraZeneca PLC

1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge CB2 0AA
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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 PLC

INDEX TO EXHIBITS

1 A accepts for review ZS-9 NDA for hyperkalaemia dated 18th October 2016

18 October 2016 [07:00]

FDA ACCEPTS FOR REVIEW NEW DRUG APPLICATION
FOR SODIUM ZIRCONIUM CYCLOSILICATE (ZS-9) FOR THE TREATMENT OF HYPERKALAEMIA

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AstraZeneca today announced that the US Food and Drug Administration (FDA) has accepted a complete re-submission of a New Drug Application (NDA) for sodium zirconium cyclosilicate (ZS-9), a potential new medicine for the treatment of hyperkalaemia (high potassium level in the blood serum) by ZS Pharma, a wholly-owned subsidiary of AstraZeneca. The FDA has indicated that this is a complete class 2 response.

Interactions with other health authorities in the European Union and Australia are ongoing with decisions expected in the first half of 2017.

About sodium zirconium cyclosilicate (ZS-9) for oral suspension

Sodium zirconium cyclosilicate (ZS-9) is an insoluble, non-absorbed compound with a structure that was designed to preferentially capture potassium ions. Sodium zirconium cyclosilicate has been studied in three double-blind, placebo controlled trials and in one ongoing 12-month open label clinical trial in patients with hyperkalaemia which represents over 1,600 patients treated. Sodium zirconium cyclosilicate is an investigational medicine that is not currently approved for any indication in any market.

About hyperkalaemia

Hyperkalaemia (potassium levels > 5.0 mEq/L in the blood serum) commonly occurs in patients with advanced chronic kidney disease and/or chronic heart failure, and may lead to cardiac arrest and death. Treatment with common heart medicines (RAAS inhibitors) can also be responsible for increases in hyperkalaemia. Current therapeutic options are limited, leaving a high unmet medical need in these patients.

About ZS Pharma

ZS Pharma was founded in 2008, became a public company in 2014 and, in December 2015, joined the AstraZeneca Group. ZS Pharma is focused on the development and commercialisation of highly selective, non-absorbed drugs to treat renal, cardiovascular and metabolic disorders. Additional information about ZS Pharma is available at 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.

About AstraZeneca

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - Oncology, Cardiovascular & Metabolic Diseases and Respiratory. The Company also is selectively active in the areas of autoimmunity, neuroscience and infection. 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 and follow us on Twitter @AstraZeneca.

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Adrian Kemp
Company Secretary, AstraZeneca PLC

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: 18 October 2016 By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary