

ASTRAZENECA PLC
Form 6-K
January 25, 2019

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 January 2019

Commission File Number: 001-11960

AstraZeneca PLC

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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. Completion of divestment of US Synagis rights

25 January 2019 14:00 GMT

Completion of the divestment of US Synagis rights to Sobi

AstraZeneca and its global biologics research and development arm, MedImmune, has completed the agreement to sell its US rights to Synagis (palivizumab), used for the prevention of serious lower respiratory tract infection (LRTI) caused by respiratory syncytial virus (RSV), to Swedish Orphan Biovitrum AB (publ) (Sobi).

Sobi will commercialise Synagis in the US and around 130 AstraZeneca employees have transferred to Sobi as part of the transaction.

Sobi will also have the right to participate in payments from the US profits or losses for potential new medicine MEDI8897 in development for RSV-induced LRTI. AstraZeneca will continue to develop MEDI8897 in collaboration with Sanofi Pasteur, the vaccines division of Sanofi S.A.

Financial considerations

Under the terms of the agreement, AstraZeneca has received a total consideration of \$1.6bn, consisting of \$1.0bn in cash and \$590m in ordinary shares of Sobi, equating to an ownership interest of 8%. AstraZeneca has committed to retaining the shares for 12 months.

The majority of the consideration is allocable to the divestment of the US rights to Synagis and, after netting off an appropriate derecognition of the intangible asset, will be reported within Other Operating Income & Expense in the Group's financial statements in the first quarter of 2019. A financial liability will be recognised for the consideration received in relation to MEDI8897. Further details will be included in the Q1 2019 financial disclosures once an exercise to allocate the fair value of the consideration between the two assets has been completed.

AstraZeneca will also receive sales-related payments for Synagis and profit- and development-related milestones and non-contingent payments for MEDI8897 from Sobi.

As stated previously in the agreement, for the purposes of the UK Listing Authority's Listing Rule LR 10.4.1 R (Notification of class 2 transactions), the total book value of gross assets attributable to the RSV franchise were \$2.2bn at 31 December 2017, of which approximately \$1.0bn was attributable to Synagis in the US. In the year to 31 December 2017, the pre-tax profits attributable to Synagis in the US were approximately \$118m.

About Synagis

Synagis is indicated for the prevention of serious LRTI caused by RSV in infants and young children at high risk of RSV disease. RSV is the most-prevalent cause of LRTI among infants and young children. Synagis is an RSV F protein inhibitor monoclonal antibody (mAb) that acts as a prophylaxis against serious RSV disease¹. It is the only medicine approved for the prevention of serious RSV disease². AstraZeneca has an agreement with AbbVie Inc. for the distribution of Synagis outside the US, which is not impacted by the transaction with Sobi.

About MEDI8897

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MEDI8897 is a single dose extended half-life anti-RSV (F) mAb being developed for the prevention of LRTI caused by RSV in all infants entering their first RSV season and children with chronic lung disease or congenital heart disease entering their first and second RSV season. It is being developed for the passive immunisation of a broad infant population and has been engineered to have a long half-life so that only one dose will be needed for the entire RSV season³. The current development plan includes initiation of a Phase III trial in healthy full-term and late pre-term infants. MEDI8897 received Fast Track Designation from the US FDA in March 2015.

In March 2017, AstraZeneca and Sanofi Pasteur announced an agreement to develop and commercialise MEDI8897. Under the agreement, AstraZeneca is responsible for all development activity through initial approvals, as well as manufacturing of MEDI8897, while Sanofi Pasteur leads commercialisation activities. The two companies share all costs and profits equally.

About Sobi

Sobi is a leading integrated biopharmaceutical company focused on rare diseases and specialty healthcare products, headquartered in Solna, Sweden; it has approximately 850 employees. The company operates in over 20 countries in Europe and the Middle East, as well as in the US and Canada.

About MedImmune

MedImmune is the global biologics research and development arm of AstraZeneca, a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of small molecule and biologic prescription medicines. MedImmune is pioneering innovative research and exploring novel pathways across Oncology, Respiratory, Cardiovascular, Renal and Metabolic Diseases, and Infection and Vaccines. The MedImmune headquarters is located in Gaithersburg, Md., one of AstraZeneca's three global R&D centres, with additional sites in Cambridge, UK and South San Francisco, CA. For more information, please visit www.medimmune.com.

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 therapy areas - Oncology, Cardiovascular, Renal & Metabolism and Respiratory. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit astrazeneca.com and follow us on Twitter @AstraZeneca.

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Adrian Kemp
Company Secretary
AstraZeneca PLC

References

1. Synagis US prescribing information, May 2017.
2. Villafana, T. et al. Expert Review of Vaccines 2017.
3. Zhu et al. Science Translational Medicine 2017.

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: 25 January 2019

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