

ASTRAZENECA PLC
Form 6-K
July 01, 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 July 2016

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 ENTERS LICENSING AGREEMENTS WITH LEO PHARMA IN SKIN DISEASES

Agreement for development and commercialisation of tralokinumab for atopic dermatitis supports sharper focus on main therapy areas

AstraZeneca also licenses European rights to LEO Pharma for brodalumab, a potential new medicine for psoriasis

AstraZeneca today announced that it has entered into agreements that support its strategic focus on three main therapy areas; Respiratory, Inflammation and Autoimmunity, Cardiovascular and Metabolic disease and Oncology. The agreements include two of AstraZeneca's potential new medicines for dermatitis and psoriasis, allowing the Company to further simplify and sharpen focus on innovative new medicines in the main therapy areas.

Agreement for tralokinumab for dermatology

AstraZeneca has entered into an agreement with LEO Pharma A/S (LEO Pharma), a specialist in dermatology care, for the global licence to tralokinumab in skin diseases. Tralokinumab is a potential new medicine (an anti-IL-13 monoclonal antibody) that has completed a Phase IIb trial for the treatment of patients with atopic dermatitis, an inflammatory skin disease resulting in itchy, red, swollen and cracked skin.

Under the terms of the agreement, LEO Pharma will make an upfront payment to AstraZeneca of \$115 million for the exclusive, global rights to tralokinumab in atopic dermatitis and any future additional dermatology indications. LEO Pharma will also pay AstraZeneca up to \$1 billion in commercially-related milestones and up to mid-teen tiered percentage royalties on Product Sales. AstraZeneca will manufacture and supply tralokinumab to LEO Pharma. Tralokinumab is also in Phase III development for patients with severe asthma. AstraZeneca will retain all rights to tralokinumab in respiratory disease and any other indications outside of dermatology.

Luke Miels, Executive Vice President, Global Product and Portfolio Strategy, AstraZeneca, said: "This agreement allows us to concentrate our efforts on tralokinumab's potential for patients with severe asthma, a priority area for AstraZeneca, while benefitting from LEO Pharma's expertise in dermatology for the continued development and commercialisation of tralokinumab in atopic dermatitis and other dermatology conditions."

Agreements for brodalumab in Europe

AstraZeneca and an affiliate of Valeant Pharmaceuticals International, Inc. (Valeant) have agreed to terminate the licence for Valeant's right to develop and commercialise brodalumab in Europe. Simultaneously, AstraZeneca has entered into an agreement with LEO Pharma for the exclusive licence to brodalumab in Europe. Brodalumab is an IL-17 receptor monoclonal antibody under regulatory review for patients with moderate-to-severe plaque psoriasis (a skin disease that causes red patches of skin covered with silvery scales) and in development for psoriatic arthritis (inflammation of the joints associated with psoriasis).

In September 2015, AstraZeneca and Valeant entered an agreement granting Valeant an exclusive licence to develop and commercialise brodalumab globally, outside Japan and certain other Asian countries where the rights are held by Kyowa Hakko Kirin Co., Ltd. Valeant will continue to lead development and commercialisation of brodalumab in the US and all other markets included in the original agreement.

LEO Pharma will gain the European rights to brodalumab under similar terms to those agreed with Valeant. Additionally, Amgen will continue to receive a low single-digit inventor royalty.

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Luke Miels added: "These agreements allow us to capitalise on LEO's strong track record of bringing new dermatological treatments to patients in Europe, while enabling Valeant to focus on bringing brodalumab to market in the US and other key markets. We are confident that working with both partners, we can maximise the reach of this potential new medicine to help psoriasis patients across the globe."

Gitte Aabo, President and CEO, LEO Pharma, said: "LEO Pharma has secured a unique position to help people with skin diseases as a result of our strategic partnership with AstraZeneca, a global healthcare company at the forefront of science-led innovation. By expanding our portfolio to include both biologics and topicals, LEO Pharma is set to become the world dermatology leader - offering the most diverse range of treatment solutions to meet the individual needs of people with skin diseases."

Financial considerations

The agreement with LEO Pharma for tralokinumab is subject to customary closing conditions and is expected to complete in the third quarter of 2016. As AstraZeneca will retain a significant ongoing interest in dermatology indications for tralokinumab, the upfront consideration of \$115 million, future commercial milestone and royalty payments will be reported as Externalisation Revenue in the Company's financial statements.

The agreements with Valeant and LEO Pharma for brodalumab became effective at signing and incremental payments received from LEO Pharma will be reported as Externalisation Revenue, in line with the prior arrangement.

The agreements do not impact AstraZeneca's financial guidance for 2016.

About LEO Pharma

LEO Pharma helps people achieve healthy skin. By offering care solutions to patients in more than 100 countries globally, LEO Pharma supports people in managing their skin conditions. Founded in 1908 and owned by the LEO Foundation, the healthcare company has devoted decades of research and development to delivering products and solutions to people with skin conditions. LEO Pharma is headquartered in Denmark and employs around 5,000 people worldwide. For more information please visit: www.leo-pharma.com

About Valeant

Valeant (NYSE/TSX:VRX) is a multinational specialty pharmaceutical company that develops, manufactures and markets a broad range of pharmaceutical products primarily in the areas of dermatology, gastrointestinal disorder, eye health, neurology and branded generics. More information about Valeant can be found at www.valeant.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 main therapy areas - Respiratory and Autoimmunity, Cardiovascular and Metabolic disease, and Oncology. We are also active in inflammation, infection and neuroscience through collaborations. 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

01 July 2016

-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: 01 July 2016

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