

ASTRAZENECA PLC  
Form 6-K  
September 01, 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 September 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 AND VALEANT PHARMACEUTICALS TO PARTNER  
ON BRODALUMAB

AstraZeneca continues to sharpen focus on main therapy areas as collaboration with expert in dermatology is expected to accelerate the development of brodalumab for patients with psoriasis where there is high unmet need

US and EU regulatory submission planned in moderate-to-severe psoriasis in Q4 2015

AstraZeneca today announced that it has entered into a collaboration agreement with Valeant Pharmaceuticals International, Inc. under which it will grant an exclusive license for Valeant to develop and commercialise brodalumab.

Brodalumab is an IL-17 receptor monoclonal antibody in development for patients with moderate-to-severe plaque psoriasis and psoriatic arthritis. Under the agreement, Valeant will hold the exclusive rights to develop and commercialise brodalumab globally, except in Japan and certain other Asian countries where rights are held by Kyowa Hakko Kirin Co., Ltd under a prior arrangement with Amgen Inc., the originator of brodalumab. Valeant will assume all development costs associated with the regulatory approval for brodalumab. Regulatory submission in US and EU for brodalumab in moderate-to-severe psoriasis is planned for the fourth quarter of 2015.

Under the terms of the agreement, Valeant will make an up-front payment to AstraZeneca of \$100 million as well as additional pre-launch milestones of up to \$170 million and further sales related milestone payments of up to \$175 million following launch. After approval, AstraZeneca and Valeant will share profits.

Brodalumab is supported by data from the three AMAGINE Phase III pivotal studies<sup>1</sup>. The results highlighted that brodalumab has an effective mechanism of action that delivers clinical benefit and could help a significant number of moderate-to-severe plaque psoriasis patients achieve total clearance of their skin disease. At the 210 mg dose, brodalumab was shown to be efficacious in total skin clearance of psoriasis compared to placebo and superior to ustekinumab at week 12 in two replicate comparator trials involving over 3,500 patients.

Pascal Soriot, Chief Executive Officer, said: "Our agreement will help to bring brodalumab to patients with psoriasis who need new treatment options through Valeant's expert focus on dermatology."

J. Michael Pearson, Chairman and Chief Executive Officer of Valeant, said, "We are delighted we were able to reach a licensing agreement with AstraZeneca to commercialize brodalumab, which is potentially the most efficacious therapy yet for moderate-to-severe plaque psoriasis. We remain fully committed to dermatology and will continue to advance our pipeline of internally developed and acquired products."

The transaction is expected to complete in the fourth quarter of 2015, subject to customary closing conditions, and it does not materially impact AstraZeneca's financial guidance for 2015. As AstraZeneca continues to retain a significant interest in brodalumab, the upfront payment and any potential subsequent milestone payments are expected to be reported as Externalisation Revenue.

NOTES TO EDITORS

[1] AstraZeneca and Amgen press release 11 November 2014:

<http://www.astrazeneca.com/Media/Press-releases/Article/11112014--amgen-and-astrazeneca-announce-positive-results>

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AstraZeneca and Amgen press release 25 November 2014:

<http://www.astrazeneca.com/Media/Press-releases/Article/20141125-amgen-and-astrazeneca-positive-results-brodalumab>

AstraZeneca and Amgen press release 11 December 2014:

<http://www.astrazeneca.com/Media/Press-releases/Article/20141211-astrazeneca-amgen-amagine1-brodalumab>

### About brodalumab

Brodalumab is a novel human monoclonal antibody that binds to the interleukin-17 (IL-17) receptor and inhibits inflammatory signaling by blocking the binding of several IL-17 ligands to the receptor. By stopping IL-17 ligands from activating the receptor, brodalumab prevents the body from receiving signals that may lead to inflammation. The IL-17 pathway plays a central role in inducing and promoting inflammatory disease processes.

### About the Amgen and AstraZeneca Collaboration

In April 2012, Amgen and AstraZeneca formed a collaboration to jointly develop and commercialise six monoclonal antibodies from Amgen's clinical inflammation portfolio, including brodalumab. Following Amgen's decision to discontinue development of brodalumab on 22 May 2015, AstraZeneca has terminated its contractual relationship with Amgen with regard to brodalumab as at the end of August 2015. The collaboration arrangements remain in place for the other programmes.

### About Valeant

Valeant Pharmaceuticals International, Inc. (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](http://www.valeant.com).

### 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](http://www.astrazeneca.com)

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Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease,  
ING - Infection, Neuroscience and Gastrointestinal

1 September 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: 01 September 2015

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