

ASTRAZENECA PLC
Form 6-K
April 26, 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 April 2016

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 ENTERS INTO US LICENSING AGREEMENT WITH IRONWOOD PHARMACEUTICALS
FOR LESINURAD

Agreement includes US rights to Zurampic and lesinurad/allopurinol fixed-dose combination in gout

AstraZeneca today announced that it has entered into a licensing agreement with Ironwood Pharmaceuticals for the exclusive US rights to Zurampic® (lesinurad). Zurampic was approved by the US Food and Drug Administration (FDA) in December 2015, in combination with a xanthine oxidase inhibitor (XOI), for the treatment of hyperuricemia associated with uncontrolled gout.

Under the terms of the agreement, Ironwood will acquire exclusive US rights to Zurampic. In addition, Ironwood will gain the exclusive US rights to the fixed-dose combination of lesinurad and allopurinol. AstraZeneca plans to submit the fixed-dose combination programme for regulatory review in the second half of 2016. Ironwood will pay AstraZeneca sales-related and other milestone payments of up to \$265 million and tiered single-digit royalties on Product Sales. AstraZeneca will manufacture and supply Zurampic, provide certain support and services to Ironwood and undertake the FDA post-approval commitment on their behalf.

Luke Miels, Executive Vice President, Global Product and Portfolio Strategy, AstraZeneca, said: "We're pleased to be entering into this agreement with Ironwood, a company with whom we already have a number of successful commercial partnerships. Our new agreement with Ironwood will ensure the successful launch of Zurampic in the US, while allowing us to concentrate our resources on the innovative medicines in our main therapy areas."

Tom McCourt, Chief Commercial Officer of Ironwood, said: "This transaction enables Ironwood to leverage our strong commercial capabilities to advance a durable franchise of innovative medicines addressing a significant unmet need in which patients are highly motivated and seeking relief. With focused investment into the gout franchise over time, we believe we can maximize cash flows and accelerate our efforts to build a top-performing commercial biotechnology company."

Gout is a serious, progressive and debilitating form of inflammatory arthritis. Approximately two million patients in the US on urate lowering therapy remain inadequately controlled, as XOI treatment alone is not sufficient to achieve their treatment goals.

The development of AstraZeneca's gout portfolio is led by Ardea Biosciences, a wholly owned subsidiary. The transaction does not include the transfer of any AstraZeneca or Ardea employees or facilities. AstraZeneca also retains the rights to the rest of the Ardea portfolio, including RDEA3170, a Phase IIb ready, potent selective uric acid reabsorption inhibitor. Under the terms of the agreement, Ironwood will have certain rights to potentially access RDEA3170 in gout indications in the US. The licensing agreement is expected to close in the second quarter of 2016, subject to antitrust approval in the US.

Financial considerations

Revenue from the licensing agreement will provide AstraZeneca with recurring Externalisation Revenue from any expected milestone payments and tiered single-digit royalty payments on Product Sales. The agreement does not impact AstraZeneca's financial guidance for 2016.

About Zurampic

ZURAMPIC® (lesinurad) is the first in a new class of medicines called Selective Uric Acid Reabsorption Inhibitors (SURI) that work selectively to complement xanthine oxidase inhibitors (XOIs) in the treatment of hyperuricemia associated with uncontrolled gout. ZURAMPIC is not recommended for the treatment of asymptomatic hyperuricemia and should not be used as monotherapy. XOIs reduce the production of uric acid; ZURAMPIC increases the excretion of uric acid. Together, the combination of ZURAMPIC and an XOI provides a dual mechanism of action that both decreases production and increases excretion of uric acid, thereby lowering serum uric acid (sUA) levels in patients who have not achieved target serum acid levels with XOI treatment alone. ZURAMPIC selectively inhibits the function of transporter proteins urate transporter (URAT1) and organic anion transporter 4 (OAT4), involved in uric

acid reabsorption in the kidney. In people, it does not inhibit OAT1 and OAT3, which are drug transporters in the kidney associated with drug-drug interactions. The efficacy of ZURAMPIC was established in three Phase III clinical trials that evaluated a once daily dose of ZURAMPIC in combination with the XOI allopurinol or febuxostat compared to XOI alone.

About Ironwood

Ironwood Pharmaceuticals (NASDAQ: IRWD) is a commercial biotechnology company focused on creating medicines that make a difference for patients, building value for our fellow shareholders, and empowering our passionate team. We are advancing an innovative pipeline of medicines in multiple areas of significant unmet need, including irritable bowel syndrome with constipation (IBS-C)/chronic idiopathic constipation (CIC), vascular and fibrotic diseases, and refractory gastroesophageal reflux disease, among others. We discovered, developed and are commercializing linaclotide, the U.S. branded prescription market leader in the IBS-C/CIC category, and we are applying our proven R&D and commercial capabilities to advance multiple internally-developed and externally-accessed product opportunities. Ironwood was founded in 1998 and is headquartered in Cambridge, Mass. For more information, please visit www.ironwoodpharma.com or www.twitter.com/ironwoodpharma; information that may be important to investors will be routinely posted in both these locations.

About Ardea Biosciences

Ardea Biosciences is a member of the AstraZeneca Group, located in San Diego, California. Ardea is leading the development of AstraZeneca's gout portfolio, including Zurampic and RDEA3170.

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 diseases in three main therapy areas - respiratory, inflammation, autoimmune disease (RIA), cardiovascular and metabolic disease (CVMD) and oncology - as well as in infection and neuroscience. 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

26 April 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: 26 April 2016

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