ASTRAZENECA PLC
Form 6-K
June 04, 2013

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 June 2013

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 X 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 X

If “Yes” is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b): 82-_____

ASTRAZENECA ANNOUNCES TOP-LINE RESULTS FROM PHASE III OSKIRA TRIALS OF FOSTAMATINIB AND DECISION NOT TO PROCEED WITH REGULATORY FILINGS

Rights to the compound will be returned to Rigel Pharmaceuticals

AstraZeneca today announced top-line results from OSKIRA-2 and OSKIRA-3, the remaining pivotal Phase III clinical trials investigating fostamatinib, the first oral spleen tyrosine kinase (SYK) inhibitor in development as an oral treatment for rheumatoid arthritis (RA).

In the OSKIRA-2 study of patients inadequately responding to disease modifying anti-rheumatic drugs (DMARDs), fostamatinib in combination with DMARDs showed statistically significant improvements in ACR20 response rates at 24 weeks in both the 100mg twice daily group and the group receiving 100mg twice daily for four weeks followed by 150mg once daily (39.6%, $p<0.001$ both arms) compared to placebo (24.5%).

In the OSKIRA-3 study of patients inadequately responding to methotrexate (MTX) and a single TNF-alpha antagonist, fostamatinib in combination with MTX showed statistically significant improvements in ACR20 response rates at 24 weeks in the 100mg twice daily group (36.2%, $p=0.004$) but not in the group given 100mg twice daily for four weeks followed by 150mg once daily (27.8%, $p=0.168$) compared to placebo (21.1%).

The safety and tolerability findings for fostamatinib observed in the OSKIRA Phase III programme were generally consistent with those previously reported in earlier studies. The most commonly reported adverse events in the OSKIRA programme include hypertension, diarrhoea, nausea, headache and nasopharyngitis (common cold).

Based on the totality of results from the OSKIRA Phase III programme, including the data previously reported from OSKIRA-1, AstraZeneca has decided not to proceed with regulatory filings for fostamatinib. AstraZeneca will return the rights to the compound to Rigel Pharmaceuticals which will decide whether it will continue the ongoing studies and pursue regulatory filings.

Briggs Morrison, MD, Executive Vice President of Global Medicines Development and Chief Medical Officer, said: "The results of the late stage trials did not measure up to the promising results we saw earlier in development. We remain committed to the search for new treatments for patients with rheumatic and inflammatory diseases with Phase II compounds in rheumatoid arthritis and lupus and Phase III compounds in gout and psoriasis."

As a result of this decision, AstraZeneca will incur a pre-tax impairment charge of approximately $140 million to R&D expense in the second quarter of 2013 for the intangible assets relating to fostamatinib. Since intangible asset impairments (except for IS-related intangibles) are excluded from the company's Core financial measures, this impairment will have no impact on the company's financial guidance for 2013, which is provided on a Core financial measures basis. As AstraZeneca will continue to incur some Core R&D costs associated with the completion of ongoing studies for fostamatinib, there is no change to the company's guidance that it expects to hold Core operating costs for 2013 (combined Core SG&A and Core R&D) to a slight increase compared with 2012 on a constant currency basis.

AstraZeneca announced an exclusive worldwide license agreement with Rigel Pharmaceuticals in February 2010 for the global development and commercialisation of fostamatinib. AstraZeneca intends to publish a more detailed analysis of the OSKIRA clinical programme in due course.

About ACR20

The American College of Rheumatology (ACR) score represents a percentage improvement in symptoms (tenderness and swelling in the joints). 28 joints are evaluated for tenderness and swelling respectively (prior to taking any required analgesic that day if possible). To qualify for an ACR20 score, a person with RA must have at least 20% fewer tender joints and at least 20% fewer swollen joints. He or she must also show a 20% improvement in at least three of the following five areas: 1) the person's overall (global) assessment of his or her own RA, 2) the physician's global assessment of the person's RA, 3) the person's assessment of his or her own pain, 4) the person's assessment of his or her own physical functioning, and 5) the results of an erythrocyte sedimentation rate or C-reactive protein blood test (both of which test for inflammation).

About the OSKIRA programme

The (Oral SYK Inhibition in Rheumatoid Arthritis) OSKIRA programme was designed to investigate fostamatinib as a potential new oral treatment option for rheumatoid arthritis and an alternative to injectable therapies for patients with an inadequate response to conventional Disease Modifying Anti-Rheumatic Drugs (DMARDs), including methotrexate (OSKIRA-1 and OSKIRA-2) and those with an inadequate response to TNF- antagonists (OSKIRA-3).

OSKIRA-1 was a 12-month study with ~900 patients, examining the effect of fostamatinib (100mg twice-daily or 100mg twice-daily for one month followed by 150mg once-daily) compared with placebo over a 24 week period, in patients responding inadequately to methotrexate. OSKIRA-1 had co-primary endpoints of ACR20 (composite endpoint assessing signs and symptoms of rheumatoid arthritis) and mTSS (x-ray endpoint assessing structural progression) at 24 weeks.

OSKIRA-2 was a 12-month study with ~900 patients, examining the effect of fostamatinib (100mg twice-daily or 100mg twice-daily for one month followed by 150mg once-daily) compared with placebo over a 24 week period, in patients responding inadequately to DMARDs. OSKIRA-2 had a primary endpoint of ACR20 at 24 weeks.

OSKIRA-3 was a six-month study of ~320 patients assessing the effect of fostamatinib (100mg twice-daily or 100mg twice-daily for one month followed by 150mg once-daily) compared with placebo in patients responding inadequately to TNF- antagonist therapy. The primary endpoint of OSKIRA-3 was ACR20 at 24 weeks.

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

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4 June 2013

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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: 04 June 2013

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