SERONO S A
Form 6-K
September 23, 2004

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16 OF
THE SECURITIES EXCHANGE ACT OF 1934

For the month of September, 2004

Serono S.A.
(Registrant's Name)

15 bis, Chemin des Mines
Case Postale 54
CH-1211 Geneva 20
Switzerland
(Address of Principal Executive Offices)

1-15096
(Commission File No.)

(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-_____)

Serono

Media Release

FOR IMMEDIATE RELEASE

SERONO RECEIVES MARKETING AUTHORISATION FROM THE EUROPEAN COMMISSION FOR NEW BIOLOGICAL PSORIASIS PRODUCT RAPTIVA(R)

Product launches to commence in the EU during fourth quarter of 2004

GENEVA, SWITZERLAND - SEPTEMBER 23, 2004 - Serono (virt-x: SEO and NYSE: SRA) announced today that it has received European Commission Marketing Authorisation for its product Raptiva(R) (efalizumab) for people with moderate-to-severe chronic plaque psoriasis for whom other systemic treatments or phototherapy have been inadequate or inappropriate.

Raptiva is the first new biological treatment for psoriasis to be authorised for marketing in the 25 countries of the European Union (EU). Serono plans to launch the treatment in several countries including Germany and the United Kingdom before the end of the year and throughout the rest of the EU during 2005.

"The approval of Raptiva provides an effective therapy for those psoriasis patients in the EU whose needs are not met by current treatments," said Ernesto Bertarelli, Chief Executive Officer of Serono. "With other approvals in Switzerland, Argentina, Mexico and Brazil, our new, fourth therapeutic area of Dermatology has made a very strong start."

According to Prof. Saurat, Chairman of the Dermatology Department at the University Hospital of Geneva and President of EADV (European Academy of Dermatology and Venerology), "a new era is opening in the treatment of psoriasis."

"Biological treatments such as Raptiva give us new hope of providing patients with improved therapies that will be easier to manage and will provide effective and safe, long-term control of their condition," he added.

ABOUT RAPTIVA(R)

Raptiva(R) is a humanized therapeutic antibody designed to selectively and reversibly block the activation, reactivation and trafficking of T-cells that lead to the development of psoriasis symptoms. Raptiva is designed to be administered once weekly via subcutaneous injection and can be self-administered by patients at home after training by a healthcare professional.

Raptiva received EU approval for the 'Treatment of adult patients with moderate to severe chronic plaque psoriasis who have failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including cyclosporine, methotrexate and PUVA'.

Serono has already launched Raptiva(R) in Switzerland and Argentina, has recently received approval in Mexico and Brazil and a positive recommendation for approval in Australia. Raptiva(R) has also been available since November 2003 in the U.S., where it is marketed by Genentech for the treatment of moderate to severe chronic plaque psoriasis in adults aged 18 or older who are candidates for systemic therapy or phototherapy.

Serono has the rights to develop and market Raptiva worldwide outside of the United States and Japan.

Development and marketing rights in the United States remain with Genentech Inc. (NYSE:DNA) and its U.S. partner XOMA (Nasdaq: XOMA).

More than 3,500 patients in the U.S. and Europe have been included in Raptiva

trials to date, creating the largest existing database of patients taking part in studies with a biological therapy for psoriasis, with about 200 of these treated continuously for more than 2-and-a-half years.
Adverse events observed with Raptiva include headache, non-specific infection (e.g., common colds), chills, pain, nausea, asthenia (weakness), and fever, all of which diminished after the first 1-2 doses. Further, there was no evidence of accumulation or cumulative toxicity. At 30-months, the occurrence of serious adverse events was infrequent which is consistent with data from previous Raptiva Phase III studies.

ABOUT PSORIASIS
Psoriasis is a T-cell mediated disease which occurs when skin cells grow abnormally, resulting in thick, red, scaly, inflamed patches. Plaque psoriasis, the most common form of the disease is characterized by inflamed patches of skin ("lesions") topped with silvery white scales. Psoriasis can be limited to a few spots or involve extensive areas of the body, appearing most commonly on the scalp, knees, elbows and trunk. Although it is highly visible, psoriasis is not a contagious disease. While there are a number of medications that may help control the symptoms of psoriasis, there currently is no known cure.

BACKGROUND MATERIAL
For free B-roll, video and other content about Raptiva, psoriasis and Serono, please visit the Serono Media Center www.thenewsmarket.com/Serono. You can
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download print-quality images and receive broadcast-standard video digitally or by tape from this site. Registration and video is free to the media.

ABOUT SERONO
Serono is a global biotechnology leader. The Company has eight biotechnology products, Rebif(R), Gonal-F(R), Luveris(R), Ovidrel(R)/Ovitrelle(R), Serostim(R), Saizen(R), Zorbtive(TM) and Raptiva(R) (Luveris(R) is not approved in the USA). In addition to being the world leader in reproductive health, Serono has strong market positions in neurology, metabolism and growth and has recently entered the psoriasis area. The Company's research programs are focused on growing these businesses and on establishing new therapeutic areas. Currently, there are approximately 30 ongoing development projects.

In 2003, Serono achieved worldwide revenues of US$2,018.6 million, and a net income of US$390.0 million, making it the third largest biotech company in the world. Its products are sold in over 90 countries. Bearer shares of Serono S.A., the holding company, are traded on the virt-x (SEO) and its American Depositary Shares are traded on the New York Stock Exchange (SRA).

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Some of the statements in this press release are forward looking. Such statements are inherently subject to known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements of Serono S.A. and affiliates to be materially different from those expected or anticipated in the forward-looking statements. Forward-looking statements are based on Serono's current expectations and assumptions, which may be affected by a number of factors, including those discussed in this press release and more fully described in Serono's Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission on March 25, 2004. These factors include any failure or delay in Serono's ability to develop new products, any failure to receive anticipated regulatory approvals, any problems in commercializing current products as a result of competition or other factors, our ability to obtain reimbursement coverage for our products, and government regulations limiting our ability to sell our products. Serono has no responsibility to

update the forward-looking statements contained in this press release to reflect events or circumstances occurring after the date of this press release.

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FOR MORE INFORMATION, PLEASE CONTACT:

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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.

SERONO S.A.
a Swiss corporation
(Registrant)

September 23, 2004

By: /s/ Francois Naef

Name: Francois Naef
Title: Secretary