SERONO S A
Form 6-K
July 28, 2003

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 July, 2003

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

NEW DATA SUPPORT RAPTIVA(TM) AS A POTENTIAL LONG-TERM TREATMENT FOR MODERATE-TO-SEVERE PLAQUE PSORIASIS

GENEVA, SWITZERLAND - JULY 26, 2003 - Serono S.A. (virt-x: SEO and NYSE: SRA) today announced positive results from two clinical studies evaluating the long-term safety and efficacy of treatment with Raptiva(TM) (efalizumab) in adults with moderate-to-severe plaque psoriasis. Study investigators will present data from these studies on Monday, July 28 from 2- 5 p.m. during a peer-reviewed session at the American Academy of Dermatology ACADEMY 2003 meeting in Chicago.

Findings highlighted during the session will include data at 24 weeks from an open-label, extended treatment period following the first-time treatment with Raptiva in a randomized, double blind, placebo-controlled Phase III study. By the end of the extended treatment , 44 percent (161/368) of patients treated continuously with 1mg/kg Raptiva for up to 24 weeks achieved a 75 percent or greater improvement in Psoriasis Area and Severity Index (PASI) scores (PASI 75).

Additionally, 21-months (84 weeks) of data from an open-label study evaluating the long-term safety and tolerability of continuous Raptiva will be presented. The 21-month data analysis showed that 67 percent (130/194) of patients achieving a PASI 75 score with weekly Raptiva therapy.

"These data further support the sustained and potentially increased clinical benefit of Raptiva when administered continuously for the treatment of moderate-to-severe plaque psoriasis," said Dr Andrew Galazka, Serono's Senior Vice President Scientific Affairs.

NEW EFFICACY DATA AT 24 WEEKS OF TREATMENT

Data evaluating efficacy at 24 weeks from an open-label, extended treatment period following 12 weeks of treatment with Raptiva in a randomized, double blind, placebo-controlled Phase III study will be presented. In this study a total of 368 patients received at least one dose of Raptiva during the first 12 weeks of the study and were eligible to receive once-weekly 1mg/kg doses of Raptiva for an additional 12 weeks.

At week 24, 44 percent (161/368) of patients who had received at least one dose of Raptiva during the first 12 weeks achieved PASI 75 response. As previously reported, at week 12, 27 percent (98/369) of the patients receiving Raptiva had achieved PASI 75, suggesting an improvement in the reduction of symptoms with continued treatment. Furthermore, at week 24, 67 percent of patients (245/368) achieved a 50 percent or greater PASI improvement (PASI 50) versus 59 percent of patients (216/369) at week 12. Furthermore, 15 percent (55/368) of patients achieved a 90 percent or greater PASI improvement (PASI 90).

No new adverse events emerged during the extended 12 weeks of Raptiva treatment. The most common events that were reported in greater than or equal to five percent of patients included non-specific infection, headache, and arthritis.

"These results show a high percentage of patients experiencing a clinically meaningful response to Raptiva with 24 weeks of continuous therapy," said Kenneth Gordon, M.D., associate professor of Medicine, Division of Dermatology at Loyola University in Chicago, Illinois. "Further, Raptiva continued to be well-tolerated by patients suggesting a positive overall clinical profile."

LONG-TERM STUDY SUGGESTS CONTINUED BENEFIT WITH 21-MONTHS OF TREATMENT

Preliminary results from 21 months (84 weeks) of an open-label, multicenter trial evaluating the long-term safety and tolerability of continuous Raptiva treatment will be presented.

In this study, patients received 2 mg/kg Raptiva weekly for an initial 12 weeks and subsequently received a once-weekly dose of 1mg/kg Raptiva starting at week 13. For each successive three-month period of treatment, dropouts during that period were analyzed using their last available PASI assessment, but were excluded from the subsequent cohorts. Among the 194 patients who remained in the trial through Week 84, 67 percent (130/194) of patients achieved a PASI 75 response and 86 percent (167/194) of patients achieved a PASI 50 response. Further, 34 percent of patients (66/194) achieved a 90 percent or greater PASI improvement (PASI 90).

The most common adverse events during the first 12 weeks of treatment were headache, non-specific infection (e.g., common colds), chills, pain, nausea, asthenia (weakness), and fever of which headache, chills, nausea, and fever are protocol-defined acute adverse events that mostly occurred following the first two injections of Raptiva. During continuous therapy, the incidence of adverse events decreased over time from 57 percent during Weeks 13-24 to 47.9% during Weeks 73-84. The occurrence of serious adverse events was infrequent, which is consistent with data from previous Raptiva Phase III studies.

ABOUT RAPTIVA(TM)

As a targeted T-cell modulator, Raptiva is designed to block the activation of T-cells that cause psoriasis without destroying them.

Raptiva has been studied as a once-weekly therapy for the continuous treatment of moderate-to-severe plaque psoriasis. In clinical trials, Raptiva was administered via subcutaneous injection and in several of the trials was self-administered by some patients in their homes.

Serono has the rights to develop and market Raptiva(TM) 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). The two companies filed a Biologics License Application (BLA) with the U.S. Food and Drug Administration in December 2002 for Raptiva for the treatment of moderate-to-severe plaque psoriasis in patients 18 years or older. More than 2,700 patients have been treated with Raptiva to date, creating the largest existing database of patients treated with a biologic therapy for psoriasis.

ABOUT PSORIASIS

Psoriasis occurs when new 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.

ABOUT SERONO

Serono is a global biotechnology leader. The Company has six recombinant products on the market, Gonal-F(R) (follitropin alfa for injection), Luveris(R) (lutropin alfa), Ovidrel(R)/Ovitrelle(R) (choriogonadotropin alfa for injection), Rebif(R) (interferon beta-1a), Serostim(R) [somatropin (rDNA origin) for injection] and Saizen(R) [somatropin (rDNA origin) for injection]. (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. The Company's research programs are focused on growing these businesses and on establishing new therapeutic areas. Currently, there are over 30 projects in development.

Serono was awarded the International James D. Watson 2003 Helix Award from the Biotechnology Industry Organization (BIO) in recognition of the Company's outstanding leadership and highest standards of scientific and product achievement.

In 2002, Serono achieved worldwide revenues of US$1.546 billion, and a net income of US$321 million, making it the third largest biotech company in the world. The Company operates in 45 countries, and its products are sold in over 100 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 April 17, 2003. 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)

July 28, 2003

By: /s/ Allan Shaw

Name: Allan Shaw
Title: Chief Financial Officer