SERONO S A
Form 6-K
September 22, 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 September, 2003

Serono S.A.
(Registrant's Name)

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(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 POSITIVE LONG-TERM RESULTS FOR
REBIF(R) MULTIPLE SCLEROSIS TREATMENT PRESENTED AT ECTRIMS

EIGHT-YEAR DATA IN RELAPSING REMITTING MS SUPPORT USE OF REBIF(R)

GENEVA, SWITZERLAND, SEPTEMBER 19, 2003-SERONO, S.A. (VIRT-X: SEO AND NYSE: SRA)

New data from a long-term assessment of a cohort of patients with relapsing-remitting multiple sclerosis (RRMS) on Rebif(R) (interferon beta-1a) therapy will be presented today at the 19th Congress of the European Committee for Treatment and Research In Multiple Sclerosis (ECTRIMS) in Milan, Italy. The data will be included in a poster session presented by Professor Ludwig Kappos of the Neurologische Universitatsklinik und Poliklinik in Basel, Switzerland.

The results support the long-term benefit of Rebif(R) 44 mcg subcutaneously (sc) three times weekly (tiw), in the treatment of RRMS on relapses, disability and magnetic resonance imaging (MRI) outcomes measured, with a favorable risk benefit profile through eight years. The exact relationship between MRI findings and clinical outcomes for patients is unknown.

"These are very important data and good news for the multiple sclerosis (MS) community, said Dr. Donald W. Paty of the University of British Columbia, Vancouver, Canada, an investigator in the PRISMS(1) trial. "These findings support Rebif(R)'s effectiveness and show that it is generally well-tolerated for eight years duration of treatment and that it appears to modify the natural course of the disease. These data provide additional support to the concept of treating MS patients with high dose high frequency interferon beta in order to gain maximum benefit and prevent disease progression."

In those patients returning for long-term follow-up (LTFU) assessment, approximately 1 in 5 progressed to secondary progressive multiple sclerosis (SPMS). Natural history data from two population-based studies in Canada and Sweden suggest that approximately 1 in 2 patients would have been expected to have progressed to SPMS without treatment.(2) However, differences between study patients and natural history cohorts may exist.

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(1) PRISMS (Prevention of Relapses and disability by Interferon beta-1a Subcutaneously in MS)

(2) B.G. Weinshenker et al. "The natural history of multiple sclerosis: a geographically based study." Brain (1989), 112: 133-146 B. Runmarker et al. "Prognostic factors in a multiple sclerosis incidence cohort with twenty-five years of follow-up" Brain (1993), 116: 117-134

The eight-year extension data come from an open-label follow-up of the PRISMS study, a double-blind, placebo-controlled study, which began in 1994, and involved 560 patients at 22 centers in 9 countries. Patients were originally randomized to receive Rebif(R) 44 mcg sc tiw (184 patients), Rebif(R) 22 mcg sc tiw (189 patients) or placebo (187 patients). After the first two years, placebo patients were re-randomized to receive one of the two active doses, while patients already on active treatment continued with the same dose.

A LTFU assessment was performed to coincide with the seventh or eighth anniversary of the first patient visit after enrollment in the original study. Safety, efficacy and antigenicity evaluations were performed as well as retrospective collection of efficacy outcomes since the last evaluative visit in

PRISMS. Patients originally randomized to placebo have received active therapy for the intervening time until the LTFU assessment.

A total of 68% (382/560) of the patients in the original randomized cohort returned for the LTFU visit including 74% (136/184) of the patients originally randomized to Rebif(R) 44 mcg sc tiw. Of these, almost three-quarters were being treated with Rebif(R) tiw at the time of the LTFU visit, reflecting long-term compliance to high dose, high frequency interferon beta treatment.

Rebif(R) was generally well tolerated in those seen at the LTFU visit. The most frequently reported adverse events at the time of the LTFU visit were flu-like symptoms and injection-site reactions, the majority of which were mild. Other adverse events generally associated with interferon beta therapy occurred infrequently.

Neutralizing antibody (NAb) rate was 12% (22/184) at the last available assessment in patients randomized to Rebif(R) 44 mcg sc tiw. The clinical implications of NAb development in patients with relapsing forms of MS have not been fully studied and remain unknown.

Benefit for patients initially randomized to Rebif(R) 44 mcg sc tiw, compared with those patients initially randomized to placebo and who had been on IFN therapy for up to 5-6 years, was seen on time to progression on a disability scale, time to SPMS, annualized relapse rate, and change in lesion area as measured in MRI. Given that patients initially randomized to placebo have been treated for up to 75% of the observation period with active drug, and that patients could have changed doses or medications, the power of the study to detect differences between original randomization groups is limited.

ADDITIONAL INFORMATION

Rebif(R) (interferon beta-1a) is a disease-modifying drug used to treat relapsing forms of MS and is similar to the interferon beta protein produced by the human body. Interferon helps modulate the body's immune system, fight disease and reduce inflammation.

Rebif(R), which was approved in Europe in 1998 and in the US in 2002, is registered in more than 80 countries worldwide. In the United States, Rebif(R) is co-promoted by Serono and Pfizer Inc.

People in the US with relapsing forms of MS can find more information about Rebif(R) in the full prescribing information, online at www.mslifelines.com or by calling MS LifeLines(TM) toll-free at 1-877-44REBIF. Patients should be instructed to read the Medication Guide accompanying the product. Most commonly reported side effects are injection site disorders, flu-like symptoms, elevation of liver enzymes and blood cell abnormalities. Patients, especially those with depression, seizure disorders, or liver problems, should discuss with their doctors whether Rebif(R) is right for them.

MS is a chronic, inflammatory condition of the nervous system and is the most common, non-traumatic, neurological disease in young adults. MS may affect approximately two million people worldwide. While symptoms can vary, the most common symptoms of MS include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of MS are the most common.

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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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ABOUT SERONO

Serono is a global biotechnology leader. The Company has six recombinant products on the market, Gonal-F(R), Luveris(R), Ovidrel(R)/Ovitrelle(R), Rebif(R), Serostim(R) and Saizen(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. 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 Helix 2003 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).

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 22, 2003

By: /s/ Allan Shaw

Name: Allan Shaw
Title: Chief Financial Officer