SERONO S A
Form 6-K
October 08, 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 October, 2004

Serono S.A.
(Registrant's Name)

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Case Postale 54
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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

FOUR YEAR DATA SHOWS 54% REDUCTION IN RELAPSE RATE AND 76% OF MS PATIENTS REMAIN FREE OF DISEASE PROGRESSION WITH REBIF(R)

SUSTAINED EFFICACY OF REBIF(R) FURTHER DEMONSTRATED IN LONG TERM DATA FROM PRISMS STUDY PRESENTED AT THE 20TH ECTRIMS CONGRESS

SERONO (VIRT-X: SEO AND NYSE: SRA) -VIENNA, AUSTRIA, OCTOBER 8, 2004 - Patients with relapsing-remitting multiple sclerosis (RRMS) who were on placebo and then treated with Rebif(R) in the PRISMS study showed substantial clinical benefits with a 54% relative reduction in relapse rate, Serono announced at the 20th congress of the European Committee for Treatment and Research In Multiple Sclerosis (ECTRIMS) meeting in Vienna, Austria.

The data also showed a significant improvement in MRI results for patients treated with Rebif(R) 44 mcg. There was a highly, statistically significant relative reduction in the mean number of brain lesions(1) of 67%. In addition, 76% of patients treated with Rebif(R) 44 mcg remained free of disease progression.

"Our results show the immediate and long-term benefits of treatment with Rebif(R) in controlling MS," said Dr Paul Lammers, Head of Neurology Product Development at Serono. "This is important news for patients with MS, as these data further demonstrate that treatment with high-dose, high-frequency interferon beta-1a can slow disease progression and enable people with relapsing MS to have an active life longer."

This data is based on a prospective pre-planned analysis of the progress of patients who received two years of placebo therapy followed by two years of Rebif(R) in the PRISMS study. The four year PRISMS study demonstrated significant improvements in the three key efficacy measures of MS: reductions in MRI lesion area and activity(2), reduced frequency of relapses, and delayed disability progression. Rebif(R) is the only disease-modifying drug with proven efficacy in all three measures.

The most frequently reported adverse events were flu-like symptoms and injection-site reactions, the majority of which were mild. No new safety issues were noted.

These results are consistent with the PRISMS long-term follow up study, which showed that patients who started on high-dose and high-frequency Rebif(R) from the start did the best in terms of disease progression over eight years.

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(1) Number of T2 active lesions per patient per scan

(2) The exact relationship between MRI findings and the clinical status of patients is unknown

ABOUT THE PRISMS STUDY

The placebo-crossover data come from the PRISMS study, a double blind, placebo-controlled study, which began in 1994, and involved 560 patients with RRMS 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, patients who had received placebo were then re-randomized to receive the active drug at a dose of 22 mcg or 44 mcg sc tiw; all patients were followed for a further two years. For the placebo-crossover analysis presented today at the 20th ECTRIMS Congress, only placebo patients with data in both years 1-2 and years 3-4 (n=172/187) were included for analyses in order to permit within-patient comparisons.

The two-year results from the PRISMS study showed that both doses of interferon beta-1a significantly reduced MRI activity and area, relapse rates, as well as reduced progression of Expanded Disability Status Scale (EDSS) scores. Dose-blinded extension data to four years demonstrated sustained treatment benefit over time, with increasing evidence of a dose-effect that favored Rebif(R) 44 mcg. The Long-Term Follow Up (LTFU) assessment was then performed on the seventh or eighth anniversary of patients' enrollment in the original PRISMS study, and these data provided a comprehensive long-term clinical and MRI assessment of cohort of MS patients on therapy with interferon. The LTFU results support the long-term effectiveness of Rebif(R) 44 mcg in the treatment of RRMS.

ABOUT REBIF(R)

Rebif(R) (interferon beta-1a) is a disease-modifying drug used to treat relapsing forms of multiple sclerosis 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-marketed by Serono, Inc. and Pfizer Inc. Rebif(R) has been proven to reduce MRI lesion activity and area(3), reduce the frequency of relapses, and delay the progression of disability. Rebif(R) is available in a 22 mcg and 44 mcg ready-to-use pre-filled syringe and can be stored at room temperature for up to 30 days if a refrigerator is not available.

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 treatment with Rebif(R) with their doctors.

ABOUT MULTIPLE SCLEROSIS

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

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(3) The exact relationship between MRI findings and the clinical status of patients is unknown

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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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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).

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)

October 8, 2004

By: /s/ Francois Naef

Name: Francois Naef
Title: Secretary