SERONO S A
Form 6-K
June 26, 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 June, 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

SERONO ANNOUNCES RESULTS OF FDA ADVISORY COMMITTEE ON SEROSTIM(R) FOR USE IN PATIENTS WITH SHORT BOWEL SYNDROME

ROCKLAND, MA, JUNE 25, 2003 - Serono, Inc. announced that the Gastrointestinal Drugs Advisory Committee for the U.S Food and Drug Administration (FDA) did not recommend approval at this time of Serostim(R) [somatropin (rDNA origin) for injection] for use in the treatment of short bowel syndrome (SBS) in patients receiving specialized nutritional support.

The committee's view was based, in part, on the fact that the majority of study patients were treated in a single specialty treatment center.

"Serono is disappointed with the recommendation of the Advisory Committee," said Dr. Joseph Gertner, Vice President and Head of Metabolic Endocrinology Clinical Development, Serono, Inc. "There is a substantial clinical need to provide more effective treatments to patients with short bowel syndrome, a rare orphan condition. We will evaluate our next steps and will continue to work closely with the FDA to fully understand and address the outstanding issues."

The Advisory Committee recommendation is considered by the FDA in making its decision. This committee recommendation does not impact the current use of Serostim(R) in the approved indication of AIDS wasting.

SBS is a rare, serious and potentially life-threatening condition that follows extensive surgical removal of the small intestine as a treatment for acute or chronic disorders of the intestine. Removal of a large portion of the bowel results in impaired absorption of nutrients. Currently the standard treatment for SBS involves careful management of dietary intake, or where appropriate, a process referred to as parenteral nutrition in which patients are fed through an intravenous tube. Surgical transplant of the intestine may also be performed for this condition. There are an estimated 10,000-20,000 patients in the United States who are receiving long-term intravenous parenteral nutrition for SBS.

At the committee meeting, Serono presented data from a pivotal study to evaluate the change in total parenteral nutrition requirements in adult patients with SBS who are dependent on parenteral nutrition. In the double-blind, controlled, parallel group Phase III study, 41 patients were randomly assigned to

one of three study arms: a specialized diet supplemented with oral glutamine alone; Serostim(R) with a specialized diet alone; or Serostim(R) with a specialized diet with glutamine.

The results of the study were positive with total parenteral nutrition volume, total parenteral nutrition calories, and frequency of infusion decreasing significantly more in the Serostim(R) plus specialized diet group as compared to the glutamine supplemented specialized diet group (p values 0.043, 0.005, and 0.025 respectively). The corresponding reductions in the Serostim(R) plus glutamine supplemented diet group as compared to the glutamine supplemented specialized diet group were larger and all were highly significant (p values less than 0.001).

Serostim(R) was granted an orphan drug designation for use alone or in combination with glutamine in the treatment of patients with short bowel syndrome by the FDA Office of Orphan Products Development.

Serostim(R) is currently approved by the FDA for the treatment of AIDS wasting or cachexia.

ABOUT SEROSTIM(R)

Serostim(R) [somatropin (rDNAorigin) for injection] is the only growth hormone approved by the US Food and Drug Administration for the treatment of AIDS wasting or cachexia. Serostim(R) received FDA accelerated approval in 1996 based upon the analysis of changes in body weight and lean body mass in surrogate endpoints in clinical studies up to 12 weeks in duration. Serostim(R) is now on the market in 12 countries.

Serostim(R), when taken as currently prescribed in 6mg doses over 12 weeks, is generally well tolerated. The most common adverse reactions to Serostim(R) are increased tissue turgor (generally swelling of hands and feet) and musculoskeletal discomfort (pain, swelling or stiffness). Generally mild to moderate in severity, these symptoms usually resolve spontaneously with continued treatment or are effectively managed with analgesic therapy or after reducing the weekly dose. Elevations in mean blood glucose levels can also occur. Patients with other risk factors for glucose intolerance should be monitored closely. When used in patients with HIV disease, Serostim(R) must be used in conjunction with antiretroviral therapy. Full prescribing information for Serostim(R) is available at www.aidswasting.com.

ABOUT SERONO

Serono, Inc., located in Rockland, MA, is the US affiliate of Serono, 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).

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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)

June 26, 2003 By: /s/ Allan Shaw

Name: Allan Shaw
Title: Chief Financial Officer