SERONO S A
Form 6-K
December 02, 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 December, 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
[GRAPHIC OMITTED]

Media Release

FOR IMMEDIATE RELEASE

FDA APPROVES SERONO'S ZORBTIVE(TM) FOR USE IN PATIENTS WITH SHORT BOWEL SYNDROME

USE OF RECOMBINANT HUMAN GROWTH HORMONE IN PATIENTS WITH SHORT BOWEL SYNDROME PROVIDES BENEFIT TO PEOPLE WITH THIS RARE CONDITION

ROCKLAND, MA, DECEMBER 2, 2003 - Serono, Inc., the US affiliate of Serono S.A. (virt-x: SEO and NYSE: SRA), announced today that the U.S Food and Drug Administration (FDA) has approved Zorbtive(TM)(1) [somatropin (rDNA origin) for injection] for use in the treatment of short bowel syndrome (SBS).

"We are delighted that the FDA has approved Zorbtive(TM) for treatment of short bowel syndrome," said James Sapirstein, Executive Vice President, Metabolic Endocrinology, Serono, Inc. "There has been a substantial clinical need for additional effective treatment options for patients with this rare condition. We are pleased that continued discussions with the FDA following an Advisory Committee meeting in June have resulted in our being able to bring this product to patients."

SBS is a rare, serious and potentially life-threatening condition that follows extensive surgical removal of portions 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 and hydration, or where appropriate, a process referred to as parenteral nutrition in which patients are fed through an intravenous tube. On rare occasions, 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 intravenous parenteral nutrition for SBS.

In a randomized double-blind, controlled, parallel group Phase III clinical study, Serono's recombinant human growth hormone administered with specialized nutritional support was shown to significantly reduce patient dependence on total parenteral nutrition as measured by total volume, total calories and frequency of

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(1) Zorbtive(TM) [somatropin (rDNA origin) for injection] is a new trade name for Serono's recombinant human growth hormone.

infusion. Serono's recombinant human growth hormone was granted an orphan drug designation for use in the treatment of patients with short bowel syndrome by the FDA Office of Orphan Products Development.

ADDITIONAL PRODUCT INFORMATION

The most common adverse events associated with growth hormone therapy are mild to moderate muscle and joint pain and swelling/edema, which occur in a dose-related manner and often subside with continued treatment or dose reduction. Cases of new onset impaired glucose intolerance, new onset type 2 diabetes mellitus and exacerbation of preexisting diabetes mellitus have been reported. Some patients develop diabetic ketacidosis and diabetic coma. In some patients, therapy with growth hormone necessitates initiation or adjustment of anti-diabetic treatment. Patients with a history of hyperglycemia or other risk factors for glucose intolerance should be monitored closely. Transient increases in glucose levels occur early in treatment and should be monitored.

Use of growth hormone is contraindicated in treatment of patients in intensive

care units due to complications following open-heart surgery or abdominal surgery, multiple accidental trauma or acute respiratory failure; patients with active neoplasia; and patients with known hypersensitivity to growth hormone.

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 worldwide market, Gonal-F(R) (follitropin alfa for injection), Luveris(R) (lutropin alfa), Ovidrel(R)/Ovitrelle(R) (choriogonadotropin alfa 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.)(2) 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 $1.538 billion, and a net income of $321 million, making it the third largest biotech company in the world. The Company operates in 44 countries, and its products are sold in over 94 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

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(2) Package inserts for Serono's US marketed products are available at www.seronousa.com or by calling 1-888-275-7376.

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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)

December 2, 2003

By: /s/ Allan Shaw

Name: Allan Shaw
Title: Chief Financial Officer