SERONO S A
Form 6-K
October 01, 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 October, 2003

Serono S.A.
(Registrant's Name)

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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

FDA ADVISORY COMMITTEE ISSUES FAVORABLE RECOMMENDATION FOR EFFICACY OF LUVERIS(R) IN FOLLICULAR DEVELOPMENT

ROCKLAND, MA, SEPTEMBER 30, 2003 - Serono, Inc. announced today that the Reproductive Health Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) issued a favorable recommendation for Luveris(R) in Serono's proposed indication of follicular development. Luveris(R) (lutropin alfa for injection) administered with follitropin alfa for injection, is proposed for the indication of stimulation of follicular development in infertile hypogonadotropic hypogonadal (HH) women with profound luteinizing hormone deficiency (LH <1.2 IU/L). HH is a rare endocrine deficiency affecting between 2,800 and 5,600 women in the US and can range from mild to severe.

The FDA had previously recommended that Serono study an endpoint of ovulation rates, an endpoint frequently used for products in ovulation induction. However, the Committee agreed that in this rare patient population the endpoint of follicular development was appropriate.

"We are very pleased with the recommendation of the Advisory Committee supporting the efficacy of Luveris(R) for follicular development in this rare patient population and will continue to work closely with the FDA as it finalizes its review of this important new treatment," said Paul Lammers, MD, Chief Medical Officer, Serono, Inc. "Serono's development of Luveris(R) is part of our ongoing commitment to reproductive health and our leadership role in this area. Luveris(R) is the third of three recombinant fertility hormones developed exclusively by Serono."

Luveris(R) is a recombinant form of luteinizing hormone (LH), a naturally occurring fertility hormone. It is the first and only drug product to contain LH exclusively that can address the unmet medical need for fertility treatment by profoundly LH deficient women. Women whose opportunities for pregnancy are limited by profound LH deficiency have no available treatment approved specifically for their condition. These women lack the ability to produce the hormones needed for full development of follicles in the ovaries, ovulation, and growth of the lining of the uterus sufficient to support implantation of a fertilized egg and early pregnancy.

The Advisory Committee's recommendation was based on a review of the clinical development program conducted in patients with this rare condition, including a phase III confirmatory, double-blind, placebo-controlled, randomized trial. In this trial, patients were treated with either Luveris(R) or placebo, co-administered with Serono's recombinant follicle stimulating hormone (r-hFSH), Gonal-f(R) (follitropin alfa for injection). In the Luveris(R) and Gonal-f(R) treatment group, 17 patients (65.4%) achieved the primary endpoint of follicular development compared to two patients (15.4%) in the placebo and Gonal-f(R) group. The four-fold difference between the two groups was both clinically meaningful and statistically significant (p=0.006).

In these studies, Luveris(R) was well tolerated with reported adverse events similar to those of other currently approved recombinant gonadotropin products.

The Advisory Committee recommendation is considered by the FDA in making its decision regarding Luveris(R), which is expected before the end of this year. Luveris(R) received an Orphan Drug Designation from the FDA and is currently approved for the treatment of women with profound LH deficiency in 46 countries worldwide, including countries of the European Union such as France, Germany and

the United Kingdom.

SERONO AND INFERTILITY TREATMENT

Serono, the global leader in infertility, is dedicated to providing patient-friendly, innovative products to help couples build families. Serono is the only company to offer a full portfolio of fertility drugs for every stage of the reproductive cycle and recombinant versions of the three hormones needed to treat infertility: Gonal-f(R) (follitropin alfa for injection), to stimulate the ovaries and produce eggs; Luveris(R) (lutropin alfa for injection), to stimulate follicular development in women who are profoundly LH deficient; Cetrotide(R) (cetrorelix acetate for injection) to control hormonal surges; Ovidrel(R) (choriogonadotropin alfa for injection), to help follicles mature and release eggs; and Crinone(R) (progesterone gel), to help establish and maintain a pregnancy. (Luveris(R) is not approved in the US.)

For more information on infertility and full prescribing information for Serono's US marketed fertility products visit www.seronofertility.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 worldwide 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 $1.546 billion, and a net income of $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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Bloomberg: SEO VX / SRA US

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 1, 2003

By: /s/ Allan Shaw
Name: Allan Shaw
Title: Chief Financial Officer