SERONO S A
Form 6-K
October 08, 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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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

Media Release

FOR IMMEDIATE RELEASE

FDA APPROVES SERONO'S OVIDREL(R) PREFILLED SYRINGE
FOR TREATMENT OF INFERTILITY

OVIDREL(R) PREFILLED SYRINGE IS THE FIRST READY-TO-INJECT LIQUID INFERTILITY TREATMENT APPROVED BY THE FDA

ROCKLAND, MA, OCTOBER 8, 2003 - Serono, Inc., the US affiliate of Serono S.A. (virt-x: SEO and NYSE: SRA), announced today that the United States Food and Drug Administration (FDA) has approved its new pre-filled syringe for Ovidrel(R) (choriogonadotropin alfa injection), making it the first liquid, ready-to-inject therapy for infertility treatment in the US.

Designed to make infertility treatment easier for patients, the new Ovidrel(R) Pre-Filled Syringe is the only liquid infertility treatment approved by the FDA that patients can administer in one single step. Unlike other infertility treatments, the Ovidrel(R) PreFilled Syringe does not require patients to mix medication prior to injection. It is also the only available recombinant version of human chorionic gonadotropin (hCG), one of three hormones required to treat infertility. Essentially equivalent in structure to naturally occurring hCG, Ovidrel(R) triggers ovulation in women being treated for infertility.

"The administration of the hormone medication needed to trigger ovulation is one of the most crucial steps in the infertility treatment cycle," said Raymond W. Ke, MD, Associate Professor of Obstetrics and Gynecology at the University of Tennessee and Director of IVF for Fertility Associates of Memphis, Tennessee. "Having Ovidrel(R) in a pre-filled syringe will make that step easier for patients and may alleviate some of the difficulties and stresses associated with infertility treatment."

The new pre-filled syringe for Ovidrel(R) will continue to carry the same indication as the currently marketed product for triggering ovulation in women undergoing infertility treatment.

"We are very pleased that the FDA has approved the Ovidrel(R) PreFilled Syringe," said Bharat Tewarie, MD, Executive Vice President, Reproductive Health, Serono, Inc. "We are committed to advancing infertility treatment by developing safe, effective and patient-friendly products manufactured using state-of-the-art technology."

Serono expects Ovidrel(R) PreFilled Syringe to be available in November, replacing the currently available powder form of Ovidrel(R).

ADDITIONAL PRODUCT INFORMATION
Ovidrel(R) is one of a complete line of widely prescribed Serono infertility therapies used to promote follicle growth, ovulation and maturation of eggs in the ovaries of women undergoing assisted reproductive technologies (ART), such as in vitro fertilization, and to induce ovulation in women with infertility due to anovulation.

Ovidrel(R) PreFilled Syringe is well tolerated. Side effects may include injection site bruising, pain or inflammation, tiredness, nausea, headache and abdominal pain. With all assisted reproduction there is a risk of ovarian hyperstimulation syndrome, multiple pregnancy or miscarriage.

Infertility is defined as the inability of a couple to achieve pregnancy after one year of regular, unprotected intercourse (six months if the woman is over 35). It affects about 6.1 million Americans, representing about 10 percent of

couples in their childbearing years. Infertility is just as likely to be related to male factors as female factors, which each account for about a third of infertility problems. The remaining third are either a combination of male and female factors or are unexplained.

SERONO AND INFERTILITY TREATMENT

Serono, the world leader in reproductive health, 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.)(1) 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

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

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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Reuters: SEOZ.VX / SRA.N
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 8, 2003

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