SERONO S A
Form 6-K
May 27, 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 May, 2004

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

Media Release

FOR IMMEDIATE RELEASE

SERONO RECEIVES FDA APPROVAL FOR GONAL-F(R) PEN
TO TREAT INFERTILITY

FIRST AND ONLY PREFILLED DEVICE WITH NEW LIQUID FORMULATION DEVELOPED TO MAKE INFERTILITY TREATMENT EASIER FOR PATIENTS

GENEVA, SWITZERLAND AND ROCKLAND, MA, MAY 27, 2004 - Serono, Inc., the US affiliate of Serono (virt-x: SEO and NYSE: SRA), announced today that the United States Food and Drug Administration (FDA) has approved a prefilled device that delivers a new liquid formulation of the most prescribed gonadotropin in the world: Gonal-f(R) RFF Pen (follitropin alfa injection).

Gonal-f(R) RFF Pen is the first and only prefilled and ready-to-use multi-dose FSH (follicle stimulating hormone) in the US. It will be available in three sizes that deliver either 300 IU, 450 IU or 900 IU of liquid Gonal-f(R) filled-by-mass, which can be administered in multiple doses. Developed to make infertility treatment easier, it provides patients with a new way to administer Gonal-f(R) by simply dialing the correct dose without the need to mix medication or load cartridges. It was designed specifically for the treatment of infertility to allow patients to easily and accurately deliver a precise daily dose of medication.

"We are proud to be the first company to offer a prefilled and ready-to-use pen, providing a new option for infertility patients that is easy and simple to use," said Bharat Tewarie, MD, Executive Vice President, Reproductive Health, Serono, Inc. "Serono is the world leader in reproductive health, and we are again demonstrating our commitment to continually improve the patient experience. Gonal-f(R) RFF Pen, in addition to our multi-dose and single-dose vial presentations, gives us the most extensive and complete portfolio of infertility products to allow for enhanced dosing flexibility and individualized treatment." Serono expects Gonal-f(R) RFF Pen to be available in the US in Q3 of this year.

RFF stands for revised formulation female, the new Gonal-f(R) presentations approved by the FDA.

Gonal-f(R) RFF Pen is indicated for induction of ovulation and pregnancy in anovuluatory infertile women in whom the cause of infertility is functional and not due to primary ovarian failure. It is also indicated for the development of multiple follicles in ovulatory women participating in an Assisted Reproductive Technology (ART) program.

Gonal-f(R) is a highly consistent, filled-by-mass recombinant human follicle stimulating hormone (r-hFSH) prescribed to supplement or replace naturally occurring FSH, which stimulates the development of follicles in the ovaries. The Gonal-f(R) prefilled pen was previously approved by the European Commission, the Swiss and the Australian Regulatory Authorities and launch is underway.

Infertility is defined as the inability 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, which represents about 10 percent of couples in their childbearing years. About 70% of patients who are treated

succeed in having children.

ADDITIONAL INFORMATION

Side effects may occur with the use of infertility medications and, therefore, they should only be prescribed by physicians who are thoroughly familiar with infertility problems and their management. Ovarian hyperstimulation syndrome (OHSS) with or without vascular and pulmonary complications, can occur with the use of infertility drugs. Reports of multiple births have been associated with gonadotropin treatment. Side effects in women using Gonal-f(R) RFF Pen for infertility treatment may include headache, stomach pain, bloating, nausea and injection site bruising.

ABOUT SERONO, INC. AND INFERTILITY

Serono, Inc. is dedicated to providing patient-friendly, innovative products to help couples build families. It is the only company to offer a full portfolio of infertility medications for every stage of the reproductive cycle and recombinant versions of two hormones needed to treat infertility.

ABOUT SERONO

Serono, Inc., located in Rockland, MA, is the US affiliate of Serono, a global biotechnology leader, headquartered in Geneva, Switzerland. Serono has seven recombinant products, Rebif(R) (interferon beta-1a), Gonal-f(R) (follitropin alfa for injection), Luveris(R) (lutropin alfa), Ovidrel PreFilled Syringe(R)/Ovitrelle(R) (choriogonadotropin alfa injection), Serostim(R) [somatropin (rDNA origin) for injection], Saizen(R) [somatropin (rDNA origin) for injection] and Zorbtive(TM) [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. Serono'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).

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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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FOR MORE INFORMATION, PLEASE CONTACT:

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Reuters: SEO.VX / SRA.N
Bloomberg: SEO VX / SRA US

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

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)

May 27, 2004

By: /s/ Francois Naef
Name: Francois Naef
Title: Secretary