

Edgar Filing: SERONO S A - Form 6-K

SERONO S A  
Form 6-K  
March 29, 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 March, 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  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-            )

-----

[GRAPHIC OMITTED]

Serono

# Edgar Filing: SERONO S A - Form 6-K

Media Release

FOR IMMEDIATE RELEASE  
-----

SERONO RECEIVES FDA APPROVAL FOR NEW PRESENTATIONS OF GONAL-F(R) TO TREAT  
INFERTILITY

NEW PRESENTATIONS ALLOW FOR MAXIMUM DOSING FLEXIBILITY AND EASE OF USE

ROCKLAND, MA, MARCH 29, 2003 - SERONO (VIRT-X: SEO AND NYSE: SRA) -Serono, Inc., the US affiliate of Serono, announced today that the US Food and Drug Administration (FDA) has approved new presentations of Gonal-f(R) (follitropin alfa for injection) including a 450 IU multi-dose vial and a 75 IU mono-dose vial. Serono is the leader in reproductive health, and Gonal-f(R) is the most prescribed gonadotropin in the world.

The new presentations of Gonal-f(R) expand Serono's portfolio of infertility treatments to allow for maximum dosing flexibility and ease of use. "We are very pleased with the approval of the new presentations of Gonal-f(R)," said Bharat Tewarie, MD, Executive Vice President, Reproductive Health, Serono, Inc. "We believe these products will provide our customers with the optimal flexibility they require to tailor treatment to individual patient needs and all treatment protocols."

The new 450 IU multi-dose vial will be available in addition to the currently marketed multi-dose presentation, while the new 75 IU mono-dose vial will replace the current ampules. Gonal-f(R) is indicated for induction of ovulation and pregnancy as part of hormonal treatment for infertility and development of multiple follicles as part of an assisted reproductive technology program. Serono expects the new Gonal-f(R) presentations to be introduced in the US in Q2.

Gonal-f(R) is a highly consistent recombinant human follicle stimulating hormone (r-hFSH) prescribed to supplement or replace naturally occurring FSH, which stimulates the development of follicles in the ovaries. It is the only FSH available in multi-dose and mono-dose vials for maximum dosing flexibility and individualized treatment.

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.

- more -

## ADDITIONAL INFORMATION

Side effects may occur with the use of infertility drugs 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 Gonal-f(R) treatment. Side effects in women using Gonal-f(R) for ovulation induction may include headache, ovarian cysts and nausea.

## 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 fertility drugs for every stage of the reproductive cycle and recombinant

## Edgar Filing: SERONO S A - Form 6-K

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(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.)(1) 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).

###

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.

###

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

FOR MORE INFORMATION, PLEASE CONTACT:

SERONO, INC., ROCKLAND, MA  
MEDIA RELATIONS:  
Tel. +1 781 681 2340  
Fax: +1 781 681 2935  
<http://www.seronousa.com>  
-----

INVESTOR RELATIONS:  
Tel. +1 781 681 2552  
Fax: +1 781 681 2912

SERONO IN GENEVA, SWITZERLAND:  
MEDIA RELATIONS:

INVESTOR RELATIONS:

Edgar Filing: SERONO S A - Form 6-K

Tel: +41-22-739 36 00  
Fax: +41-22-739 30 85  
http://www.serono.com  
-----

Tel: +41-22-739 36 01  
Fax: +41-22-739 30 22  
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)

March 29, 2004

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