

Edgar Filing: SERONO S A - Form 6-K

SERONO S A
Form 6-K
October 30, 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)

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

(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

Edgar Filing: SERONO S A - Form 6-K

EUROPEAN COMMISSION APPROVES SERONO'S OVITRELLE(R) SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE FOR TREATMENT OF INFERTILITY

OVITRELLE(R) - THE WORLD'S ONLY RECOMBINANT, FILLED-BY-MASS AND CONSISTENT HCG IS NOW AVAILABLE IN A READY-TO-USE PRE-FILLED SYRINGE THAT WILL ALLOW PATIENTS TO ADMINISTER HCG WITH ONE SIMPLE STEP

GENEVA, SWITZERLAND, OCTOBER 30, 2003 - Serono S.A. (virt-x: SEO and NYSE: SRA), announced today that the European Commission has approved its new pre-filled syringe for Ovitrelle(R) (choriogonadotropin alfa).

Designed to make infertility treatment easier for patients, the new Ovitrelle(R) Solution for Injection is designed so that patients can administer their r-hCG in one single step. Unlike other hCG treatments, the Ovitrelle(R) Solution for Injection 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, Ovitrelle(R) triggers ovulation in women being treated for infertility.

"hCG administration is a single, once only injection and therefore getting it right is essential to the success of the cycle," said Professor Matts Wikland M.D, PhD of the Fertility Center at Carlanderska Hospital, Gothenburg, Sweden. "Having Ovitrelle(R) as a liquid in a ready to use pre-filled syringe will make the process significantly easier for patients and help to ensure that they do not incorrectly reconstitute or administer this crucial injection."

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

"We are extremely pleased that the European Commission has approved the Ovitrelle(R) Solution for Injection in a pre-filled syringe," said Hans Christian Rohde, Corporate Vice President, Reproductive Health, Serono. "We are constantly striving to introduce the most consistent products and to deliver them in the most accurate devices to help to increase the treatment efficiency in assisted cycles."

1/3

Serono expects Ovitrelle(R) Solution for Injection in a pre-filled syringe to be available in December, replacing the currently available powder form of Ovitrelle(R).

ADDITIONAL PRODUCT INFORMATION

Ovitrelle(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.

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 10 million Europeans, 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.

Edgar Filing: SERONO S A - Form 6-K

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) FbM (follitropin alfa for injection filled-by-mass), 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) (cetrotorelix acetate for injection) to control hormonal surges; Ovitrelle(R) (choriogonadotropin alfa for injection), to help follicles mature and release eggs; and Crinone(R) (progesterone gel), to help establish and maintain a pregnancy.

For more information on infertility and full prescribing information for Serono's marketed fertility products visit www.serono.com.

###

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.

###

2/3

ABOUT SERONO

Serono is a global biotechnology leader. The Company has six recombinant products on the market, Gonal-f(R), Luveris(R), Ovidrel(R)/Ovitrelle(R), Rebif(R), Serostim(R) and Saizen(R) (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 Helix 2003 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 US\$ 1.538 billion, and a net income of US\$321 million, making it the third largest biotech company in the world. The Company operates in 44 countries, and its products are sold in 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).

Edgar Filing: SERONO S A - Form 6-K

FOR MORE INFORMATION, PLEASE CONTACT:

SERONO IN GENEVA, SWITZERLAND:

MEDIA RELATIONS:

Tel: +41-22-739 36 00

Fax: +41-22-739 30 85

<http://www.serono.com>

INVESTOR RELATIONS:

Tel: +41-22-739 36 01

Fax: +41-22-739 30 22

Reuters: SEOZ.VX / SRA.N

Bloomberg: SEO VX / SRA
US

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

3/3

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 30, 2003

By: /s/ Allan Shaw

Name: Allan Shaw

Title: Chief Financial Officer