

Edgar Filing: SERONO S A - Form 6-K

SERONO S A  
Form 6-K  
June 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 June, 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

-----

### SERONO ANNOUNCES PROMISING RESULTS FOR EMFILERMIN, A NEW DRUG FOR IMPROVING IMPLANTATION OF EMBRYOS

GENEVA, SWITZERLAND - JUNE 30TH, 2003 - SERONO S.A. (VIRT-X: SEO AND NYSE: SRA) Serono announced today at the ESHRE (European Society for Human Reproduction and Embryology) Congress in Madrid positive results of a first proof of concept study of emfilermin (r-hLIF) for improving embryo implantation in women with recurrent implantation failure (RIF).

"This study indicates that emfilermin has good prospects of increasing pregnancy rates in those women in whom embryos have previously failed to implant, helping more couples to fulfill their dream of having a child," said Peter Brinsden, Medical Director of Bourn Hall in Cambridgeshire, England. "The results of this exploratory study confirmed that those patients who had a suspected problem with purely embryo implantation may benefit most from emfilermin."

Amongst this group, which is characterized by patients requiring normal in-vitro fertilization (IVF) rather than intra cytoplasmic sperm injection, (ICSI) none of the eight patients on placebo achieved a clinical pregnancy compared with eight of the 17 (47%) treated with LIF.

The results of this trial were based on a relatively small sample size; Serono is undertaking a larger proof of concept study focusing on recurrent implantation failure in IVF. This study started this year in Europe and Australia using this protein which was developed by Australian company AMRAD and has been exclusively licensed to Serono.

1/3

#### FURTHER INFORMATION

1. One in six couples worldwide experience some form of infertility problems.
2. LIF is a substance that is produced in the female reproductive tract and is naturally secreted by the endometrium during the secretory phase (time of embryo implantation). There is good evidence that if LIF is not secreted properly during the time of implantation, the embryo may not implant and the pregnancy may fail. Since LIF appears to play an important role during embryo implantation, it is thought that giving recombinant human LIF to infertile women for several days from embryo transfer might increase their chances of successful implantation.
3. The study participants were all pre-menopausal women aged between 21 and 36 years who required treatment by IVF or ICSI. All had a history of at least three implantation failures, defined as failure of at least three transfers of at least two fresh or frozen/thawed morphologically normal embryos, and with no other known cause of previous IVF failure.
4. In the overall population from the placebo-controlled study, 11 out of 39 patients on emfilermin (28%) achieved clinical pregnancies. This compared with 4 out of 20 patients on placebo (20%).
5. Emfilermin was generally safe and well-tolerated when co-administered with paracetamol administration. Most adverse events were mild in severity and no serious adverse events with possible / probable causal relationship with emfilermin were observed. Some mild, asymptomatic, transient and reversible laboratory changes which are related to the cytokine-induced acute phase response were observed. Most injection site reactions were mild in severity.

ABOUT SERONO

Serono is a global biotechnology leader. The Company has six recombinant products on the 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 US\$1.546 billion, and a net income of US\$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).

###

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.

###

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

Edgar Filing: SERONO S A - Form 6-K

SERONO, INC., ROCKLAND, MA

MEDIA RELATIONS:

Tel. +1 781 681 2340

Fax: +1 781 681 2935

<http://www.seronusa.com>  
-----

INVESTOR RELATIONS:

Tel. +1 781 681 2552

Fax: +1 781 681 2912

---

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

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)

June 30, 2003

By: /s/ Allan Shaw  
-----

Name: Allan Shaw  
Title: Chief Financial Officer