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SERONO S A  
Form 6-K  
February 25, 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 February, 2004

Serono S.A.

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(Registrant's Name)

15 bis, Chemin des Mines  
Case Postale 54  
CH-1211 Geneva 20  
Switzerland

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(Address of Principal Executive Offices)

1-15096

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(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   
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(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   
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(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

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EUROPEAN COMMISSION APPROVES GONAL-F(R) FILLED-BY-MASS  
PREFILLED PEN

THE MOST CONSISTENT FSH IS NOW AVAILABLE IN AN ACCURATE AND  
EASY-TO-USE PRE-FILLED PEN

GENEVA, SWITZERLAND - FEBRUARY 25, 2004 - Serono (virt-x: SEO and NYSE: SRA) announced today that the European Commission has approved its GONAL-f(R) Filled-by-Mass solution for injection in a pre-filled pen, which delivers the company's market-leading recombinant human follicle-stimulating hormone.

"As the worldwide leader in infertility treatment, Serono is committed to developing innovative products," said Ernesto Bertarelli, Chief Executive Officer of Serono. "The GONAL-f(R) (FbM) Prefilled Pen delivers the most consistent FSH in the only ready-to-use pre-filled pen available on the market."

To make infertility treatment easier and more accurate for patients, the new GONAL-f(R) (FbM) Prefilled Pen is specifically designed for infertility treatment and will be available in 3 multidose presentations; 300 IU/0.5 ml (22 mcg/0.5 ml), 450 IU/0.75 ml (33 mcg/0.75 ml) and 900 IU/1.5 ml (66 mcg/1.5 ml).

"This is the first ready-to-use pen that enables us to combine the efficacy of the most consistent FSH with the flexibility to individualize the dosing in ovulation induction and Assisted Reproductive Techniques for each patient," said Professor Christoph Keck, M.D., from the Department of Obstetrics and Gynecology of the University of Freiburg, Germany. "Having GONAL-f(R) (FbM) in a pre-filled, ready-to-use pen will make the administration easier for the patients, and help them to ensure that they have injected the right dose."

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The GONAL-f(R) (FbM) Prefilled Pen will continue to carry the same indications as the currently marketed product for a) anovulation in women who have been unresponsive to treatment with clomiphene citrate, b) stimulation of multifollicular development in patients undergoing superovulation for assisted reproductive technologies, c) in association with a luteinising hormone (LH) preparation for the stimulation of follicular development in women with severe LH and FSH deficiency and d) for stimulation of spermatogenesis in men who have congenital or acquired hypogonadotropic hypogonadism.

Serono expects the GONAL-f(R) (FbM) Prefilled Pen to be introduced in Europe during the first half of this year.

### ADDITIONAL PRODUCT INFORMATION

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GONAL-f(R) Filled-by-Mass (follitropin alpha) is a recombinant human follicle-stimulating hormone, which is equivalent in its structure to the naturally occurring human FSH in the body. GONAL-f(R) (FbM) is used in clinical practice to treat infertile women and men with low or lacking naturally occurring FSH. It is the world's leading treatment for male and female infertility and is registered in more than 80 countries around the world. 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

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infertility problems. The remaining third are either a combination of male and female factors or are unexplained.

### SERONO AND INFERTILITY TREATMENT

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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), to stimulate the ovaries and produce eggs; Luveris(R) (lutropin alfa), to stimulate follicular development in women who are profoundly LH deficient; Cetrotide(R) (cetrotorelix acetate) to prevent a premature ovulation; Ovitrelle(R) (choriogonadotropin alfa), to help follicles mature and release eggs; and Crinone(R) (progesterone gel), to help establish and maintain a pregnancy.

For more information on infertility visit [www.fertility.com](http://www.fertility.com) and for Serono's marketed fertility products visit [www.serono.com](http://www.serono.com) (1).

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(1) These websites are not intended for US residents. US residents should consult the Serono Inc. fertility website at [www.seronofertility.com](http://www.seronofertility.com) or [www.seronousa.com](http://www.seronousa.com).

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### ABOUT SERONO

Serono is a global biotechnology leader. The Company has seven recombinant products, Rebif(R), Gonadotropin alfa (Gonal-f(R)), Luveris(R), Ovidrel(R)/Ovitrelle(R), Serostim(R), Saizen(R) and Zorbtive (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.

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

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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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Bloomberg: SEO VX / SRA US

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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)

February 25, 2004

By: /s/ Allan Shaw

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Name: Allan Shaw  
Title: Chief Financial Officer