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SERONO S A  
Form 6-K  
May 03, 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.

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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    X    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).)

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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)(7).)

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(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  
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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-            )

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Media Release

FOR IMMEDIATE RELEASE

NEW ADVANCE FOR INFERTILE COUPLES

SERONO'S INNOVATIVE GONAL-F(R) (FbM) PREFILLED PEN IS PHYSICIANS',  
NURSES' AND PATIENTS' PREFERRED CHOICE IN FERTILITY TREATMENT

GENEVA, SWITZERLAND, MAY 3, 2004 - Serono (virt-x: SEO and NYSE: SRA) announced today that the new GONAL-f(R) Filled-by-Mass (FbM) Prefilled Pen is considered as the preferred choice for fertility treatment following an expert meeting held this weekend in Lisbon, Portugal, on the initial experience of physicians, nurses and patients with the innovative pre-filled pen.

The GONAL-f(R) (FbM) Prefilled Pen has recently been approved by the European Commission, the Swiss and the Australian Authority. Through its combination of an accurate and easy-to-use delivery device - the Prefilled Pen - with GONAL-f(R) (FbM), the most consistent follicle-stimulating hormone available, it represents a significant advance for physicians, nurses and patients in fertility treatment. Infertility is defined as the inability of a couple to achieve pregnancy after one year of regular, unprotected intercourse and it affects according to WHO around 60 - 80 million people worldwide.

In a phase IIIb study that compared the GONAL-f(R) (FbM) Prefilled Pen with another pen available on the market, twice as many of the treated patients preferred the GONAL-f(R) (FbM) Prefilled pen, as it required less time for training, less time to prepare their daily injections and also gives patients more confidence that they have injected the right dose of FSH. "The GONAL-f(R) (FbM) Prefilled Pen ensures an accurate dosing and correct administration, as it is ready-to-use and easy for patients to inject themselves, making the treatment more acceptable for them", said Professor Dr. Christoph Keck from the Department of Obstetrics and Gynecology of the University of Freiburg, Germany. (1)

In Australia, the country with most experience to date with the GONAL-f(R) (FbM) Prefilled Pen, nurses reported a significant reduction in the time to train patients, and it also reduced patient confusion. "My nurses have told me how much less time they have to spend with patients and that fewer mistakes are being made due to incorrect dosing, as patients do not have to reconstitute the medication or to load a cartridge", explained Dr. Ric Porter, director from IVF Australia's Northshore Unit in Chatswood.

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1) Serono Data on File, Phase IIIb study, University of Freiburg, Germany.

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The GONAL-f (FbM) (R) Prefilled Pen is specifically designed for fertility treatment and is available in three multidose strengths, allowing individualized dosing in Ovulation Induction and Assisted Reproductive Techniques. Delivering the most consistent recombinant FSH - GONAL-f(R) (Filled-by-Mass) - it results in a greater and more predictable control over ovarian stimulation (2) and increases treatment efficiency in terms of a reduction of the number of stimulation days (3) (4), and the number of cancelled cycles (3).

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### ADDITIONAL PRODUCT INFORMATION

GONAL-f(R) Filled-by-Mass (follitropin alfa) 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 the latest advance which takes advantage of a standardized, highly consistent manufacturing process to ensure batch-to-batch and vial-to-vial consistency in dosage, resulting in the most consistent FSH and therefore in optimal control over treatment cycles. GONAL-f(R) 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 90 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 infertility problems. The remaining third are either a combination of male and female factors or are unexplained.

### SERONO AND FERTILITY 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), 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).

2) Hugues et al.; Improvement in consistency of response to ovarian stimulation with recombinant human follicle hormone resulting from a new method for calibrating the therapeutic preparation, RBM online, December 2002, Vol. 6, No. 2, pp 185 - 190

3) Tredway et al.; Improvement of clinical profile with GONAL-f Filled-by-Mass in ovulation induction, 7th Congress of the Latin American Federation of the Sterility and Fertility Societies (FLASEF), Montevideo, Uruguay, November 2002.

4) Balasch et al.; Outcome from consecutive assisted reproduction cycles in patients treated with recombinant follitropin alfa filled-by-bioassay and those treated with recombinant follitropin alfa filled-by-mass, RBM online, April 2004, Vol. 8, No. 4.

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### ABOUT SERONO

Serono is a global biotechnology leader. The Company has seven recombinant

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products, Rebif(R), Gonal-f(R), Luveris(R), Ovidrel(R)/Ovitrelle(R), Serostim(R), Saizen(R) and Zorbitive(TM) (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 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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### 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.

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a Swiss corporation  
(Registrant)

May 3, 2004

By: /s/ Francois Naef

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Name: Francois Naef

Title: Secretary