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SERONO S A
Form 6-K
October 15, 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 October, 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
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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

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FDA APPROVES SERONO'S LUVERIS(R) FOR CONCOMITANT USE WITH GONAL-F(R)

APPROVAL EXPANDS SERONO'S RECOMBINANT PORTFOLIO IN THE UNITED STATES

GENEVA, SWITZERLAND AND ROCKLAND, MA, OCTOBER 15, 2004 - SERONO (VIRT-X SEO AND NYSE: SRA) - Serono announced today that the US Food and Drug Administration (FDA) has approved Luveris(R) (lutropin alfa for injection) for concomitant use with Gonal-f(R) (follitropin alfa for injection) for stimulation of follicular development in infertile hypogonadotropic hypogonadal (HH) women with profound LH deficiency (LH < 1.2 IU/L).

HH is a rare endocrine deficiency. Women with HH are unable to produce the hormones needed for full development of follicles in the ovaries, ovulation and growth of the lining of the uterus sufficient to support implantation of a fertilized egg and early pregnancy.

Luveris(R) is the first and only approved recombinant human form of luteinizing hormone (LH), a naturally occurring fertility hormone. The Luveris(R) approval makes Serono the only company to offer three recombinant fertility hormones, part of its long-term global strategy to develop a 100% recombinant human gonadotropin portfolio. By the end of this year, Serono will complete a systematic commercial phase out of its older-generation urinary products, with the exception of Japan.

"The Luveris(R) approval is a result of Serono's strong dedication to research and development of products in reproductive health," said Bharat Tewarie, MD, Executive Vice President, Reproductive Health, Serono, Inc. "We recognized the additional endocrine needs of this special population of patients and developed recombinant human LH specifically for them as part of our continued commitment to advancing infertility treatment." Data on Luveris(R) are being presented at the 60th Annual Meeting of the American Society for Reproductive Medicine in Philadelphia later this month. For patients and healthcare providers who would like additional information on Luveris(R) and other Serono products, a toll-free educational service called Fertility LifeLines(TM) (1-866-538-7879) is available.

"Luveris(R), in conjunction with Gonal-f(R), helps individualize treatment for a special population of infertile patients," said Zev Rosenwaks, MD, Director, Center for Reproductive Medicine and Infertility at New York Weill Cornell. "It provides an option for women who specifically do not produce or secrete LH."

Luveris(R) addresses an unmet medical need and has also received Orphan Drug designation from the FDA Office of Orphan Products Development. It is currently approved in over 60 countries worldwide, including countries in the European Union, Asia, Latin America and Australia.

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ADDITIONAL INFORMATION

Side effects may occur with the use of infertility drugs and, therefore, 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 gonadotropin treatments. The most common side effects in women using Luveris(R) include headache, abdominal pain, nausea, OHSS, breast pain, and ovarian cyst. Please see full prescribing information for product details.

ABOUT SERONO, INC. AND FERTILITY

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Serono, Inc., a subsidiary of Serono S.A., is a leader in fertility health, dedicated to developing patient-friendly, innovative products that help people build families. It is the only company to offer a full portfolio of fertility medications for every stage of the reproductive cycle and recombinant versions of three hormones used in the treatment of infertility, including the newly approved Gonal-f(R) RFF Pen (follitropin alfa injection). For more information, please contact Fertility LifeLines(TM), a toll-free educational service that offers customized information and support to people with fertility health concerns, available at 1-866-LETS-TRY (1-866-538-7879).

ABOUT SERONO S.A.

Serono is a global biotechnology leader. The Company has eight biotechnology products, Rebif(R) (interferon beta-1a), Gonal-f(R) (follitropin alfa for injection), Luveris(R) (lutropin alfa for injection), Ovidrel(R)/Ovitrelle(R) (choriogonadotropin alfa injection), Serostim(R) [somatropin (rDNA origin) for injection], Saizen(R) [somatropin (rDNA origin) for injection], Zorbtive(TM) [somatropin (rDNA origin) for injection] and Raptiva(R) (efalizumab). In addition to being the world leader in reproductive health, Serono has strong market positions in neurology, metabolism and growth and has recently entered the psoriasis area. The Company'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).

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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.

Package inserts for Serono's US marketed products are available at www.seronusa.com or by calling 1-888-275-7376.

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FOR MORE INFORMATION, PLEASE CONTACT:
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Reuters: SEOZ.VX / SRA.N
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)

October 15, 2004

By: /s/ Francois Naef

Name: Francois Naef
Title: Secretary