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SERONO S A
Form 6-K
December 20, 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 December, 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 ☒

(If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-)

[GRAPHIC OMITTED]
Serono

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FOR IMMEDIATE RELEASE

SERONO ANNOUNCES FDA APPROVAL OF REBIF(R) TITRATION PACK

Titration Pack Designed to Improve Convenience and Dose Accuracy for People Starting Therapy with Rebif

ROCKLAND, MASS., DECEMBER 20, 2004 - Serono, Inc. (virt-x: SEO and NYSE: SRA) announced today that the U.S. Food and Drug Administration (FDA) has approved a new Titration Pack for people who take Rebif(R) (interferon beta-1a) to treat relapsing forms of multiple sclerosis (MS).

The new Titration Pack is designed to provide improved convenience, ease of use and dosing accuracy for people beginning Rebif therapy, as they increase to the full dose during their first month of therapy. The new pack includes one month's supply of Rebif therapy, including a two-week supply of 8.8 mcg and a two-week supply of 22 mcg, both in pre-filled syringes. Rebif is the only therapy currently available in a titration pack.

Rebif is taken by injection to delay the progression of disability associated with relapsing forms of MS. It is the only approved MS therapy proven in a four-year clinical study in all three key measures of treatment effectiveness: reducing MRI lesion area and activity (1), reducing relapses and delaying the progression of disability. Also, the EVIDENCE trial demonstrated that Rebif 44 mcg, taken three times weekly, is superior to Avonex, another MS therapy, in reducing relapses over 48 weeks.

"We are excited about this latest addition to our portfolio of offerings for people living with MS," said James Pusey, M.D., executive vice president of Neurology at Serono, Inc. "Our mission is to make it as easy as possible to start-and stay on-MS therapy for improved outcomes over the long-term. The Titration Pack further demonstrates our commitment to that mission. "

The Titration Pack is the latest offering by Serono in an ongoing commitment to improving the lives of people with MS. The company recently launched the MS LifeLines (TM) Nurses Educators program, providing qualified MS nurses to help educate newly diagnosed MS patients about therapy with Rebif. They also launched the new Rebiject II injection device and 29-gauge needle-the thinnest needle available for any MS therapy-designed to provide improvements in the ease of injections with Rebif. A survey of Rebif patients found that 83 percent preferred the Rebiject II to the original Rebiject device, and 96 percent preferred the new 29-gauge needle to the 27-gauge needle.

The newly approved Titration Pack will be available in the U.S. in early 2005. Patients can learn more about the titration pack and other product offerings by talking with their physician, calling MS LifeLines toll-free at 1-877-447-3243 or visiting www.MSLifeLines.com. More information about Rebif can be found in

the full prescribing information online at www.rebif.com.

(1) The exact relationship between MRI findings and the clinical status of patients is unknown.

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ABOUT THE REBIJECT II AND 29-GAUGE NEEDLE SURVEY

To identify preferences for Rebiject or Rebiject II, a telephone survey was conducted among 59 respondents who had experience using both devices. A similar survey was conducted among 26 patients comparing the 29-gauge and 27-gauge needles. Patients were unaware of the change in needle gauge. Patient responses for both surveys were based on self-assessments after two or more weeks of using the new device and/or needle.

ABOUT MS

MS is a chronic, inflammatory condition of the nervous system and is the most common, non-traumatic, neurological disease in young adults. MS may affect approximately two million people worldwide. While symptoms can vary, the most common symptoms of MS include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of MS are the most common.

ABOUT MS LIFELINES

MS LifeLines is an educational support service for the MS community provided by Serono and Pfizer. Its mission is to offer support to people with MS, people on or considering Rebif(R) therapy, and the care partners who support them.

ABOUT REBIF

Rebif (interferon beta-1a) is a disease-modifying drug (DMD) used to treat relapsing forms of MS to decrease relapses and delay the accumulation of physical disability, and is similar to the interferon beta protein produced by the human body. Interferon beta helps modulate the body's immune system, fight disease and reduce inflammation.

Rebif should be used with caution in patients with a history of depression, seizures or liver problems. Most commonly reported side effects are injection site disorders, flu-like symptoms, elevation of liver enzymes and blood cell abnormalities. Rebif is available in a 22 mcg and 44 mcg ready-to-use pre-filled syringe and can be stored at room temperature for up to 30 days if a refrigerator is not available. Patients should be instructed to read the Medication Guide accompanying the product.

Rebif(R), which was approved in Europe in 1998 and in the US in 2002, is registered in more than 80 countries worldwide. In the United States, Rebif is co-marketed by Serono, Inc. and Pfizer Inc.

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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ABOUT SERONO

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

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.
a Swiss corporation
(Registrant)

December 20, 2004

By: /s/ Francois Naef

Name: Francois Naef

Title: Secretary