SERONO S A
Form 6-K
December 12, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of December

Commission File Number 1-15096

Serono S.A.

(Translation of registrant s name into English)

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(Address of principal executive office)

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 o

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): o

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): o

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 o No x

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

Media Release

FOR IMMEDIATE RELEASE

SERONO ANNOUNCES INITIATION OF THE REFLEX TRIAL TO EVALUATE NEW FORMULATION OF REBIF®
IN PATIENTS AT RISK OF DEVELOPING MULTIPLE SCLEROSIS

First Trial Assessing Therapeutic Benefit of Two Different Dosage Regimens of Disease Modifying Therapy in People with First Clinical Symptoms Suggesting Multiple sclerosis

Geneva, Switzerland, December 12, 2006 Serono (virt-x: SEO and NYSE: SRA) announced today the initiation of a Phase III clinical trial to evaluate the effect of two dosage regimens of the new formulation of Rebif® (interferon beta-1a 44 mcg, three times a week or once a week) on the time to conversion to multiple sclerosis (MS) in people with first clinical symptoms suggestive of the disease. The trial, called the REFLEX study (REbif FLEXible dosing in early MS), will involve 480 patients considered at risk of developing MS because of a recently experienced isolated demyelinating event and of typical magnetic resonance imaging (MRI) brain scans.

It has been demonstrated that early treatment with interferon-beta can reduce the risk of developing multiple sclerosis. Optimizing the impact of such treatment on development of irreversible neurological damage and ascertainment of long term outcomes is still subject of active experimental and clinical research , said Professor Ludwig Kappos, from the Department of Neurology, University Hospital Basel, Switzerland, and a member of the Steering Committee of the REFLEX study. The REFLEX study will determine the respective therapeutic benefit of two different dosage regimens of the new formulation of Rebif® for people at risk of developing multiple sclerosis.

The REFLEX study is a randomized, double-blind, placebo-controlled, multicenter trial. Study participants will receive either the new formulation of Rebif® 44 mcg three times a week (160 patients), or the new formulation of Rebif® 44 mcg once a week (160 patients), or placebo (160 patients) as a subcutaneous injection for a period of 24 months, unless they suffer from a second attack leading to a diagnosis of clinically definite MS. In this case, patients will be offered open label treatment with the new formulation of Rebif® 44 mcg three times a week. The primary endpoint of the study is time to conversion to MS, according to the McDonald criteria. Other endpoints will include assessments of MRI brain scans, clinical relapses and disability progression.

The REFLEX study will also evaluate the effect of the new formulation of Rebif® on cognitive function as measured by the Paced Auditory Serial Addition Test (PASAT)(1). Cognitive dysfunction can occur early in MS and impact memory, ability to process information and learning. A sub-study will assess retinal nerve fiber thickness (a marker of axonal loss) by means of optical coherence tomography (OCT). This sub-study will be conducted in selected centers, equipped with this leading edge technology. In addition, the REFLEX study will aim at identifying genetic/genomic profiles associated with disease and treatment outcomes.

(1) The PASAT is a measure of cognitive function that assesses auditory information processing speed (the ability to attend to orally presented information, process the information in memory, and then formulate a response in a timely fashion) and flexibility, as well as calculation ability.

The new formulation of Rebif® has been developed by an innovative approach, using state-of-the-art technologies. It is under regulatory review by the European Medicines Agency, the US Food and Drug Administration and other healthcare authorities, and is not currently approved.

About Rebif®

Rebif® (interferon beta-1a) is a disease-modifying drug used to treat relapsing forms of multiple sclerosis (MS) and is similar to the interferon beta protein produced by the human body. Interferon helps modulate the body s immune system, fight disease and reduce inflammation.

Rebif®, 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. Rebif® has been proven to delay the progression of disability, reduce the frequency of relapses and reduce MRI lesion activity and area(2). Rebif® is not approved for treatment of chronic progressive MS. Rebif® is available in a 22 mcg and 44 mcg ready-to-use pre-filled syringe and a titration pack, and can be stored at room temperature for up to 30 days if a refrigerator is not available.

Most commonly reported side effects are injection site disorders, flu-like symptoms, elevation of liver enzymes and blood cell abnormalities. Patients, especially those with depression, seizure disorders, or liver problems, should discuss treatment with Rebif® with their doctors.

About Serono and multiple sclerosis

In addition to Rebif®, Serono also offers a second therapy within its US portfolio of multiple sclerosis (MS) therapies: Novantrone® (mitoxantrone for injection concentrate) for worsening forms of MS. Full prescribing information for these products can be obtained by contacting Serono or visiting the Serono website. Additional therapeutic options are currently under development at Serono, including oral cladribine, currently in Phase III studies and potentially the first oral therapy for treatment of MS, as well as several products in early stage development including: osteopontin, an MMP-12 inhibitor, a JNK inhibitor and interferon beta:Fc. Serono also is taking a leading role in developing an understanding of the role of genetics in MS, with a whole genome scan currently underway.

About multiple sclerosis

Multiple sclerosis (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.

(2) The exact correlation between MRI findings and the current or future clinical status of patients, including disability progression, is unknown.

Background material

For free B-roll, video and other content for Serono and its products, please visit the Serono Media Center www.thenewsmarket.com/Serono. You can download print-quality images and receive broadcast-standard video digitally or by tape from this site. Registration and video is free to the media.

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Forward-looking statements

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 February 28, 2006. 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, the outcome of any government investigations and litigation. Serono is providing this information as of the date of this press release, and 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 eight biotechnology products, Rebif®, Gonal-f®, Luveris®, Ovidrel®/Ovitrelle®, Serostim®, Saizen®, Zorbtive and Raptiva®. 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, including oncology and autoimmune diseases.

In 2005, Serono, whose products are sold in over 90 countries, achieved worldwide revenues of US$2,586.4 million. Reported net loss in 2005 was US$106.1 million, reflecting a charge of US$725 million taken relating to the settlement of the US Attorney s Office investigation of Serostim. Excluding this charge as well as other non-recurring items, adjusted net income grew 28.4% to US$565.3 million in 2005. 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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SIGNATURE

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)

Date December 12, 2006

By: /s/ Stuart Grant
Name: Stuart Grant
Title: Chief Financial Officer