SERONO S A
Form 6-K
July 10, 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 July

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

EUROPEAN COMMISSION APPROVES
REVISION OF THERAPEUTIC INDICATION FOR REBIF®

Throughout the European Union, multiple sclerosis patients can now benefit from Rebif®
as soon as their diagnosis of MS is confirmed

Geneva, Switzerland, July 10, 2006 Serono (virt-x:SEO and NYSE: SRA) announced today that the European Commission has approved an update of the Summary of Product Characteristics (SmPC) of Rebif® (interferon beta-1a), in order to align it with current medical practice. Throughout the European Union, Rebif® can now be prescribed after the diagnosis of multiple sclerosis (MS) has been confirmed based on one attack and subsequent positive magnetic resonance imaging (MRI) scans.

The therapeutic indication section of the SmPC of Rebif® now takes into account the McDonald criteria, which are the current reference criteria for the diagnosis of MS. The SmPC of Rebif® was previously based on the Poser criteria, which were in use at the time of Rebif® approval in the European Union in 1998, and Rebif® was consequently indicated for MS patients who had experienced at least two attacks. Compared with the Poser criteria, the McDonald criteria utilize MRI evidence as an alternative to a second attack, and allow the same patients to be diagnosed with more sensitivity and specificity. Current understanding of the disease supports that it is critical to initiate treatment as soon as the diagnosis of MS is established to ensure the best possible outcome for the patients.

We are delighted with the European Commission decision, said Roberto Gradnik, Senior Executive Vice President Europe at Serono. MS has an initial stage when clinical manifestations are not pronounced but irreversible neurological damage is taking place. This neurological damage determines the relative risk of progression of the disease. People with MS living in Europe will be able to benefit from the proven efficacy of Rebif® as soon as MS is diagnosed, when it is needed most .

Rebif® is proven effective on the following three key measures of treatment effectiveness: MRI lesion area and activity, relapse rates, and disability progression. The safety and efficacy of Rebif® are supported by eight-year follow-up data and 12 years of patient experience from around the world.

The European Commission decision means that the updated SmPC of Rebif® is valid immediately in all 25 member states of the European Union. In most other regions of the world, the therapeutic indication of Rebif® already takes into account the McDonald criteria.

About Rebif®

Rebif® (interferon beta-1a) is a disease-modifying drug used to treat relapsing forms of multiple sclerosis 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(1). 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 Neurology

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 therapy options are currently under development at Serono, including cladribine tablets, currently in Phase III studies and potentially the first oral therapy for treatment of MS, as well as osteopontin, an MMP-12 inhibitor, a JNK inhibitor and interferon beta:Fc, in early-stage development for MS. 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. To-date, 80 genes associated with MS have been identified, based on a 40% scan. The project is due to be completed in 2006 and will improve understanding of the causes of MS and the appropriate therapeutic targets for the disease.

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.

(1) The exact relationship between MRI findings and the clinical status of patients 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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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 government investigations and litigation 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 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. Currently, there are more than 25 on-going development projects.

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 July 10, 2006	By:	/s/ Stuart Grant
	Name:	Stuart Grant
	Title:	Chief Financial Officer