SERONO S A
Form 6-K
September 28, 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 September

Commission File Number 1-15096

Serono S.A.

(Translation of registrant s name into English)

15 bis, Chemin des Mines
Case Postale 54
CH-1211 Geneva 20
Switzerland

(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

ONE-YEAR DATA FROM PHASE III TRIAL SHOW THAT NEW FORMULATION OF REBIF® OFFERS SUBSTANTIAL IMPROVEMENT

IN TOLERABILITY AND IMMUNOGENICITY PROFILES

Data Presented at 22nd ECTRIMS Congress in Madrid

Madrid, Spain, September 28, 2006 Serono (virt-x: SEO and NYSE: SRA) announced today data from an ongoing two-year (96 weeks) Phase IIIb trial show that the new formulation of Rebif® (interferon beta-1a) 44 mcg subcutaneously (sc) three times weekly (tiw) for the treatment of relapsing forms of multiple sclerosis (MS) offers substantial improvement in tolerability and reduction in antibody formation observed at one year (48 weeks), compared with historical data from patients. Historical data for the currently available formulation of Rebif® is the EVIDENCE study. These data are presented today at a satellite symposium at the 22nd Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Madrid, Spain.

These results are promising news for patients with multiple sclerosis, said Prof Per Soelberg Sørensen, from the Danish MS Research Center, Copenhagen University Hospital, Rigshospitalet and an investigator of the trial. If approved the new formulation of Rebif® potentially represents an improvement in the treatment of patients with multiple sclerosis.

The incidence of injection site reactions with the new formulation of Rebif® at 48 weeks was nearly three-fold less than in the EVIDENCE study (29.6% versus 83.8%). Injection site reactions are one of the reasons why some patients discontinue MS treatment. Treatment enhancements resulting in a decrease of injection site reactions are usually associated with improved compliance and adherence to treatment.

The primary endpoint of the study is the proportion of neutralizing antibody positive patients at the last assessment. At 48 weeks, the data showed that 13.9% of patients treated with the new formulation of Rebif® were neutralizing antibody positive. In the EVIDENCE study at 48 weeks, 24.4% of the patients were positive. Persistent neutralizing antibodies were detected in 2.5% of the patients treated with the new formulation of Rebif® at 48 weeks. In the EVIDENCE study at 48 weeks, the rate of persistent neutralizing antibodies observed was 14.3%.

The new formulation of Rebif® has been developed by an innovative approach, using state-of-the-art technologies, with a major focus on the molecule s structural and functional integrity , said Franck Latrille, Senior Executive Vice President Global Product Development at Serono. Based on the improvements in tolerability and immunogenicity, the new formulation of Rebif® could lead to an improved benefit-to-risk profile .

The new formulation of Rebif® is the latest of many product developments from Serono to continually enhance the convenience and tolerability of Rebif®. Other enhancements have included the Rebiject II auto-injector to facilitate injections; a 29 gauge-5 bevel needle pre-filled syringe, the thinnest needle in a ready-to-use pre-filled syringe for the treatment of MS; and a titration pack designed to make starting on Rebif® therapy easier and more convenient. The new formulation of Rebif® is currently under regulatory review by the European Medicines Agency, the US Food and Drug Administration and other healthcare authorities.

The results presented today are the 48-week results from a 96-week, Phase IIIb, multicenter, single-arm, open-label study evaluating the safety and immunogenicity of the new formulation of Rebif® 44 mcg sc tiw in 260 patients with relapsing forms of MS. The primary objective of the study was to compare the antigenicity of new formulation Rebif to historical data.

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 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. 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.

###

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.

###

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).

For more information, please contact:

Corporate Media Relations:
Tel: +41 22 739 36 00
Fax: +41 22 739 30 85
http://www.serono.com

Corporate Investor Relations:
Tel: +41 22 739 36 01
Fax: +41 22 739 30 22
Reuters: SEO.VX / SRA.N
Bloomberg: SEO VX / SRA US

Media Relations, USA:
Tel: +1 781 681 2340
Fax: +1 781 681 2935
http://www.seronousa.com

Investor Relations, USA:
Tel: +1 781 681 2552
Fax: +1 781 681 2912

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 September 28, 2006

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