SERONO S A
Form 6-K
May 04, 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 May

Commission File Number 1-15096

Serono S.A.

(Translation of registrant s name into English)

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Case Postale 54
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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 ý 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 ý

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

PHASE III TRIAL OF ORAL CLADRIBINE,
A NOVEL INVESTIGATIONAL THERAPY FOR MULTIPLE SCLEROSIS,
BEGINS IN THE UNITED STATES

Nationwide Recruitment Begins at Sites Across the U.S.

Rockland, Massachusetts, and Geneva, Switzerland, May 4, 2006 - Serono (virt-x: SEO and NYSE: SRA) announced today that recruitment in the U.S. is beginning for the Phase III CLARITY study (**CLA**d**RI**bine **T**ablets in Treating MS Orall**Y** Study) of oral cladribine for the treatment of patients with relapsing forms of multiple sclerosis (MS). This multi-national study was successfully initiated outside the U.S. in 2005, and will now expand to include 17 clinical trial sites in the U.S. The study is one of the largest MS trials ever conducted, and enrollment is on track to be completed in 2006.

CLARITY is a two-year, double-blind, placebo-controlled Phase III study of more than 1,200 patients. It is designed to assess patients clinical relapses, disability progression and MRI (magnetic resonance imaging) brain activity. Previous clinical trials using cladribine administered by injection in patients with MS showed positive effects in reduction of new lesion development in the brain as seen on MRI scans; reductions in relapses were also observed.

The Phase III CLARITY trial is enrolling at a strong pace, and the addition of US sites will accelerate this pace and bring us one step closer to our goal of making the first oral MS therapy available for people living with this debilitating condition, underscoring our fundamental and long-term commitment to the MS community, said Dr. Paul Lammers, Chief Medical Officer at Serono, Inc. The formulation of oral cladribine, combined with the proposed short dosing regimen, should help patients to be more compliant with their MS therapy and lighten the patient s treatment burden associated with chronic MS.

We all are looking forward to the day when there is an FDA approved oral therapy that can affect the underlying disease process in MS, said

Dr. John Richert vice president research and clinical programs at the National MS Society. Clinical studies, such as CLARITY, are an important part of the process leading to the development of these new medications. Those interested in determining whether they are eligible to participate in the clinical trial should speak with their healthcare provider.

Trial Recruitment Taking Place in 15 States

Currently, there are 17 clinics, medical centers, universities and hospitals recruiting patients to participate in the study in 15 major cities across the country, including:

Medford, OR
Newark, NJ
Boulder, CO
Las Vegas, NV
Fort Wayne, IN
Durham, NC
Baltimore, MD
Charleston, WV
Ann Arbor, MI
Oklahoma City, OK
Charleston, SC
Columbus, OH
Chicago, IL
Edmonds, WA
Atlanta, GA

Further clinical trail site information is available at www.TheCLARITYStudy.com, or the U.S. National Institutes of Health clinical trial information website at www.ClinicalTrials.gov.

We are excited to further evaluate oral cladribine for the treatment of MS, said Dr. Dusan Stefoski, M.D., associate professor of the Rush Multiple Sclerosis Center and a clinical investigator for the CLARITY trial. From my clinical experience, the addition of an oral therapy for MS could improve compliance among patients and potentially change the MS treatment paradigm.

It is estimated that approximately 400,000 Americans are affected with MS, a chronic, progressive autoimmune disease of the central nervous system (CNS). Relapsing forms of MS are the most common. While symptoms of MS are unpredictable and can vary, the most common symptoms of MS include blurred vision, numbness or tingling in the limbs and problems with strength and coordination.

About Oral Cladribine

Oral cladribine is a proprietary oral tablet formulation of cladribine that is being studied in an effort to demonstrate possible benefits as a treatment for patients with relapsing forms of MS. Cladribine is a purine nucleoside analogue that interferes with the behavior and the proliferation of certain white blood cells, particularly lymphocytes, which are involved in the pathological process of MS. Through its differentiated mechanism of action, cladribine tablets may offer an effective new option to patients with MS.

About Serono Neurology

Currently, Serono has two therapies available for the treatment of MS: Rebif (interferon beta-1a), indicated for relapsing forms of MS, and Novantrone (mitoxantrone for injection concentrate), the only therapy approved for worsening forms of MS. Full prescribing information for these products can be obtained by contacting Serono or visiting the Serono website at www.seronousa.com. Additional therapy options beyond cladribine tablets are currently under development at Serono, including 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.

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 seven biotechnology products in the U.S., Rebif® (interferon beta-1a), Gonal-f® (follitropin alfa for injection), Luveris® (lutropin alfa), Ovidrel PreFilled Syringe®/Ovitrelle® (choriogonadotropin alfa injection), Serostim® [somatropin (rDNA origin) for injection], Saizen® [somatropin (rDNA origin) for injection] and Zorbtive™ [somatropin (rDNA origin) for injection].(1) 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).

For more information, please contact:

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http://www.seronousa.com

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

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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 May 4, 2006

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