SERONO S A
Form 6-K
April 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 April

Commission File Number 1-15096

Serono S.A.

(Translation of registrant s name into English)

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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

SERONO SUBMITS NEW FORMULATION OF REBIF®

FOR APPROVAL IN THE UNITED STATES AND IN EUROPE

Trial Data Show New Formulation of Rebif® Offers Substantial Improvement in Overall Tolerability and Reduction in Antibody Formation

Geneva, Switzerland, and Rockland, MA, April 4, 2006 Serono (virt-x:SEO and NYSE: SRA) announced today the submission of a supplemental Biologics Licence Application (sBLA) to the US Food and Drug Administration (FDA) and of a variation to the current Marketing Authorization to the European Medicines Agency (EMEA) for a new formulation of Rebif® (interferon beta-1a) as a treatment of multiple sclerosis (MS).

Data from a Phase III clinical trial in patients with relapsing forms of MS show that the new formulation of Rebif® results in a substantial improvement in overall tolerability, as measured by pre-specified parameters including injection site reactions, which are an important factor for patients when choosing an MS therapy. The trial data also show that the incidence of antibody formation with the new formulation of Rebif® is reduced. Serono expects data on the new formulation of Rebif® to be presented at a major medical conference in the second half of 2006.

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. While Rebif® is well established in the treatment of relapsing forms of multiple sclerosis, results from this clinical trial show that the new formulation offers promising improvements which could translate into additional benefits to the patient.

Serono is focused upon providing multiple sclerosis patients with enhanced therapeutic solutions, said Franck Latrille, Senior Executive Vice President Global Product Development. This is supported by innovative development and manufacturing technology platforms that we have implemented to deliver world-leading biotech therapies.

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 new Rebiject II auto-injector to facilitate injections; a 29 gauge-needle pre-filled syringe, the thinnest needle in a ready-to-use pre-filled syringe for the treatment of MS; a titration pack designed to make starting on Rebif® therapy easier and more convenient.

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.

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

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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 April 4, 2006

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