

SERONO S A  
Form 6-K  
September 21, 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  Form 40-F

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):

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):

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  No

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 S ORAL CLADRIBINE FOR THE TREATMENT OF MULTIPLE SCLEROSIS  
AWARDED FAST TRACK STATUS BY FDA**

**Geneva, Switzerland, September 21, 2006** - Serono (virt-x: SEO and NYSE: SRA) announced today that oral cladribine has been designated a Fast Track product by the US Food and Drug Administration (FDA). This designation covers patients with relapsing forms of multiple sclerosis.

Serono s proprietary oral formulation of cladribine for the treatment of multiple sclerosis is currently being evaluated in a multi-center, multi-national Phase III study, CLARITY (CLAdRIBine Tablets Treating MS Orally) . It is a two-year, double-blind, placebo-controlled study involving over 1,200 patients. Patient enrollment into this pivotal trial is planned to be completed by the end of 2006.

We are very pleased that oral cladribine has been designated a Fast Track product, said Ernesto Bertarelli, CEO of Serono. As a leader in multiple sclerosis, we are committed to providing new treatment options that can further improve the quality of the lives of people with this serious disease and our objective is to bring to them the first oral disease modifying treatment.

Thanks to decades of research, there are injectible drugs available to treat some forms of MS, but there is certainly a need for more and even better therapies to treat all forms of the disease. Having an effective oral therapy for MS would be a major step forward in improving quality of life for people with MS, said Dr. John Richert, Vice President, Research and Clinical Programs, at the National Multiple Sclerosis Society.

Fast Track programs are designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Under Fast Track designation oral cladribine is eligible for Priority Review and FDA may consider for review portions of the marketing application before the New Drug Application (NDA) is completed.

1

---

**About cladribine**

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 multiple sclerosis. Through its differentiated mechanism of action, oral cladribine may offer an alternative option to patients with multiple sclerosis.

**About multiple sclerosis**

## Edgar Filing: SERONO S A - Form 6-K

Multiple sclerosis is a chronic, inflammatory condition of the nervous system and is the most common, non-traumatic, neurological disease in young adults. Multiple sclerosis affects approximately two million people worldwide. While symptoms can vary, the most common symptoms of multiple sclerosis include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of multiple sclerosis are the most common.

### **Background material**

## Edgar Filing: SERONO S A - Form 6-K

For free B-roll, video and other content for Serono and its products, please visit the Serono Media Center [www.thenewsmarket.com/Serono](http://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®, Zorbitive 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.seronusa.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 21, 2006

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