

3-1-02



02012163

1117399

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13a-16 OR 15d-16 OF  
THE SECURITIES EXCHANGE ACT OF 1934



For the month of March, 2002.

Serono S.A.  
(Registrant's Name)

15 bis, Chemin des Mines  
Case Postale 54  
CH-1211 Geneva 20  
Switzerland  
(Address of Principal Executive Offices)

1-15096  
(Commission File No.)

PROCESSED  
MAR 21 2002  
P THOMSON  
FINANCIAL

(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 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 REBIF<sup>®</sup> RECEIVES FDA APPROVAL

**Rebif<sup>®</sup> gains marketing approval under terms of Orphan Drug Act by demonstrating clinical superiority over Avonex<sup>®</sup> at 24 weeks in the EVIDENCE head-to-head study**

**Rebif<sup>®</sup> will now be available to patients with relapsing forms of multiple sclerosis in the US**

Rockland, MA, March 8, 2002 — Serono, S.A. (SWX Swiss Exchange: SEO and NYSE: SRA) announced today that the US Food and Drug Administration (FDA) has approved Rebif<sup>®</sup> (interferon beta-1a) for the treatment of relapsing forms of multiple sclerosis. This approval was based upon the results of two large multi-center studies in patients with relapsing remitting multiple sclerosis (RRMS). The data collected in the PRISMS and EVIDENCE studies, along with years of clinical experience with Rebif<sup>®</sup> outside the US, have shown that Rebif<sup>®</sup> provides significant treatment benefits for people with relapsing forms of MS.

"This is an important milestone for our company. The FDA approval, based upon all the evidence, enables us to make Rebif<sup>®</sup> available to people in the US with multiple sclerosis," said Ernesto Bertarelli, Chief Executive Officer of Serono. "This is a great day to celebrate Serono's commitment to science and clinical advancement."

In the treatment of relapsing forms of multiple sclerosis, Rebif<sup>®</sup> decreases the frequency of clinical exacerbations and delays the accumulation of physical disability.<sup>1</sup> Until now, Rebif<sup>®</sup> could not be marketed in the US due to the Orphan Drug status of another interferon beta-1a product, Avonex<sup>®</sup>, whose exclusivity under the Orphan Drug Act (ODA) was granted in 1996 and will not expire until May 2003. Rebif<sup>®</sup> was able to gain marketing approval under the terms of the ODA by demonstrating clinical superiority over Avonex<sup>®</sup> at 24 weeks in the EVIDENCE head-to-head study.<sup>2</sup>

"The approval of Rebif<sup>®</sup> is good news for people with multiple sclerosis in the US," said Patricia K. Coyle, MD, Health Science Center, State University of New

---

<sup>1</sup> PRISMS (Prevention of Relapses and disability by Interferon beta-1a Subcutaneously in MS) Study Group. Randomized, double-blind, placebo-controlled study of interferon beta-1a in relapsing/remitting multiple sclerosis. *Lancet* 1998; 352: 1498-1504.

<sup>2</sup> EVIDENCE: Evidence for Interferon Dose-response European-North American Comparative Efficacy.

York at Stony Brook. "Physicians are now free to prescribe Rebif<sup>®</sup> to patients in the US who have relapsing forms of multiple sclerosis."

### **About MS**

Multiple sclerosis is a chronic, inflammatory condition of the central nervous system. It is the most common non-traumatic disease of the central nervous system in young adults and today affects approximately 350,000 people in the US. While symptoms can vary from person to person affected by MS, common symptoms include: blurred vision, numbness and tingling in the limbs and problems with strength and coordination. The relapsing forms of the disease are the most common forms of MS.

### **Clinical Studies of Rebif<sup>®</sup> in Multiple Sclerosis**

The EVIDENCE study<sup>3</sup> is the largest prospective, randomized comparative study of two disease modifying drugs in RRMS to date. The open-label, assessor-blinded study included 677 patients with RRMS who had not been treated with interferon before, ages 18-55, at 56 centers in the US, Canada and Europe. Patients underwent repeated clinical and MRI assessments while taking either Rebif<sup>®</sup> (44 mcg three times weekly, subcutaneously) or Avonex<sup>®</sup> (30 mcg once weekly, intramuscularly). During the study, assessing neurologists and radiologists were blinded from knowing which drug the patients were taking.

Results showed statistically significant differences in favor of Rebif<sup>®</sup> on all primary and secondary efficacy measures at 24 weeks. The primary endpoint of the study was based on a comparison of the proportion of patients who did not experience a relapse of MS during the first 24 weeks of treatment. Approximately 75% of the patients in the EVIDENCE study who received Rebif<sup>®</sup> did not have a relapse, compared to 63% of patients in the study who received Avonex<sup>®</sup>. This reflects a 32% relative reduction in the proportion of Rebif<sup>®</sup> patients who experienced relapses during the study period.

The main secondary endpoint of the study was an assessment of combined unique active lesions as measured by magnetic resonance imaging (MRI). Those patients treated with Rebif<sup>®</sup> had an average of 0.8 active lesions per scan while patients treated with Avonex<sup>®</sup> had an average of 1.2 active lesions per scan, a reduction of approximately one-third in lesion activity for Rebif<sup>®</sup> patients.

The PRISMS study examined the long-term efficacy and safety of Rebif<sup>®</sup> versus placebo in RRMS. Statistical significance was achieved on the study's endpoints at two years measuring delay in progression of disability, reduction in number and severity of relapses and reduction in burden of disease and MS activity as shown on brain scans. The PRISMS two-year data formed the basis for the initial approvals of Rebif<sup>®</sup> outside the US. Additional data from the PRISMS study at four years was published in the journal *Neurology* in 2001.<sup>4</sup>

---

<sup>3</sup> See Rebif<sup>®</sup> full prescribing information.

<sup>4</sup> The PRISMS (Prevention of Relapses and Disability by Interferon beta-1a Subcutaneously in Multiple Sclerosis) Study Group and the University of British Columbia MS/MRI Analysis Group.

## ***Additional Product Information***

Rebif® is recommended for use at a dosage of 44 mcg three times per week injected subcutaneously, just below the skin. Rebif® is supplied in single-use, pre-filled syringes. Most commonly reported side effects are injection site disorders, flu-like symptoms, abdominal pain, depression, elevation of liver enzymes and blood cell abnormalities. Rebif® is contraindicated in patients with hypersensitivity to natural or recombinant interferon, human albumin, or any other component of the formulation. Caution is advised in patients with depression, pre-existing seizure disorders, liver disease, alcohol abuse or elevated liver enzyme levels. Women who are or are planning to become pregnant should not take Rebif® without consulting their doctor.

A comparison of safety based on the EVIDENCE study indicates that both Rebif® and Avonex® are associated with a similar overall side effect profile. Consistent with the higher and more frequent dose of interferon used in Rebif® therapy, injection site reactions, liver function disorders and reduced white blood cell counts were observed with greater frequency with Rebif®. When considering severe side effects, no difference between patients taking Rebif® and Avonex® was seen and such side effects usually responded to dose adjustment.

Rebif® was approved in Europe in 1998 and is registered for use in more than 70 countries worldwide. During 2001, Rebif® increased its leading position as the treatment of choice for patients with relapsing forms of MS with a market share of 38% in value terms and sales of \$379.6 million outside the US.

People living in the US with relapsing forms of MS can find more information about Rebif® in the full prescribing information, on line at [www.rebif.com](http://www.rebif.com) or by calling MS LifeLines at 1-877-44REBIF. Patients should be instructed to read the Medication Guide accompanying the product.

## ***Conference Call and Webcast***

Serono will hold a conference call on Monday, March 11, 2002, from 10:30 to 11:30 am Eastern Standard Time (4:30 to 5:30 pm Central European Time). To join the telephone conference, please dial +1 412 858 4600 (from the US), +41 91 610 41 11 (from Europe), and 091 610 41 11 (from Switzerland). Telephone playback will be available one hour after the conference call and until Wednesday, March 13, 5 pm Central European Time. Please dial +41 91 610 2500 and enter the PIN code 079# from a touch tone telephone for access.

The event will also be relayed by live webcast which interested parties may access via Serono's Corporate home page. Please go to [www.serono.com](http://www.serono.com), click on the related ticker announcement, and follow the instructions. The webcast will be available for replay until close of business on March 28, 2002.

**About Serono**

Serono, Inc., located in Rockland, MA, is the US affiliate of Serono, S.A., a global biotechnology leader, headquartered in Geneva, Switzerland. The Company has six recombinant products on the market, Gonal-F® (follitropin alfa for injection), Luveris® (lutropin alfa), Ovidrel®/Ovitrelle® (choriogonadotropin alfa for injection), Rebif® (interferon beta-1a), Serostim® [somatropin (rDNA origin) for injection] and Saizen® [somatropin (rDNA origin) for injection]. (Luveris® is not approved in the USA).<sup>5</sup> In addition to being the world leader in reproductive health, Serono has strong market positions in neurology, metabolism and growth. The Company's research programs are focused on growing these businesses and on establishing new therapeutic areas. Currently, there are fifteen new molecules in development.

In 2001, Serono achieved worldwide revenues of US\$1.38 billion, and a net income of US\$317 million, making it the third largest biotech company in the world based on revenues. The Company operates in 45 countries, and its products are sold in over 100 countries. Bearer shares of Serono S.A., the holding company, are traded on the SWX Swiss Exchange (SEO) and its American Depository Shares are traded on the New York Stock Exchange (SRA).

###

*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 April 23, 2001. 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, 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.*

###

For more information, please contact:

**Media Relations**  
Serono, Inc., Rockland, MA

Tel: +1 781 681 2340  
Fax: +1 781 681 2935  
[www.seronousa.com](http://www.seronousa.com)

**Investor Relations**  
MontRidge, LLC

Tel: +1 203 894 8038  
Fax: +1 203 894 8039

**Feinstein Kean Healthcare**  
**Media Relations**

Tel: +1 617 761 6791  
Fax: +1 617 577 8985  
[www.fkhealth.com](http://www.fkhealth.com)

**Serono, Geneva,**  
**Switzerland:**

Tel: +41-22 739 36 00  
Fax +41-22-739 30 85  
[www.serono.com](http://www.serono.com)

-end-

---

<sup>5</sup> Package inserts for the company's US products are available at [www.seronousa.com](http://www.seronousa.com) or by calling 1-888-275-7376.

## SIGNATURES

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)

March            8, 2002

By: \_\_\_\_\_

Name: Jacques Theurillat

Title: Chief Financial Officer