

Edgar Filing: SERONO S A - Form 6-K

SERONO S A  
Form 6-K  
February 12, 2004

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 February, 2004

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.)

(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-\_\_\_\_\_)

SERONO  
[GRAPHIC OMITED]

MEDIA RELEASE

FOR IMMEDIATE RELEASE

Edgar Filing: SERONO S A - Form 6-K

-----  
LOW DOSE MAINTENANCE THERAPY WITH RECOMBINANT HUMAN GROWTH HORMONE MAY SUSTAIN  
PREVIOUS SEROSTIM(R) TREATMENT IN HIV POSITIVE PATIENTS WITH HARS

NEW DATA PRESENTED AT A RECENT MEDICAL MEETING ON HIV AND INFECTIOUS DISEASES

ROCKLAND, MA, FEBRUARY 12, 2004 - Serono, Inc., the US affiliate of Serono (virt-x: SEO and NYSE: SRA), announced new clinical data on Serostim(R) [somatropin (rDNA origin) for injection] as a potential maintenance therapy to sustain reductions in excess visceral fat accumulation in patients with HIV-associated adipose redistribution syndrome (HARS) who had previously received Serostim(R) (1) induction therapy. The data was recently presented at a medical meeting on HIV and infectious diseases. HARS is a debilitating medical condition experienced by people being treated for HIV and for which there is currently no medical treatment. The visceral adipose tissue accumulation seen in HARS may be associated with an adverse risk profile.

"Based on its efficacy and safety profile, a low dose of Serostim(R) merits additional investigation as a maintenance therapy for HIV patients with HARS," said study lead investigator, Donald P. Kotler, M.D., St. Luke's Roosevelt Hospital, New York.

A prospective, multi-center, randomized, dose-finding extension trial evaluated the safety and efficacy of Serostim(R) maintenance therapy, administered at a dose of 1 or 2 mg daily, to sustain reductions in excess trunk fat in patients with HARS following treatment with Serostim(R) at a higher dose. Laboratory measurements of potential metabolic conditions occurring with HARS, such as lipid profiles, were also included.

Serono has previously reported positive findings of Serostim(R) for the Treatment of Adipose Redistribution Syndrome (STARS) study, a double-blind, placebo-controlled study, designed to evaluate Serostim(R) as a potential HARS therapy. The study results showed that Serostim(R) 4mg administered daily for 12 weeks decreased visceral adipose tissue and trunk fat as compared to placebo

-----  
1 Serostim(R) is currently not approved for the treatment of HARS.

(p)