

Edgar Filing: SERONO S A - Form 6-K

SERONO S A  
Form 6-K  
March 24, 2003

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, 2003

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

[GRAPHIC OMITTED]  
serono

Media Release

FOR IMMEDIATE RELEASE

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

-----  
PHASE III RAPTIVA(TM) STUDY RESULTS IN THE TREATMENT OF PSORIASIS PRESENTED AT  
ANNUAL AAD MEETING

GENEVA, SWITZERLAND - MARCH 21, 2003 - SERONO S.A. (virt-x: SEO and NYSE: SRA) Serono today announced positive results from a randomized Phase III clinical trial with Raptiva(TM) (efalizumab) that studied efficacy and safety in the treatment of adults with moderate-to-severe plaque psoriasis. The study results were presented by Kenneth Gordon, M.D., Associate Professor of Medicine, Division of Dermatology at Loyola University in Chicago, Illinois during a session on emerging biologic therapies for psoriasis at the 61st annual American Academy of Dermatology (AAD) meeting in San Francisco.

Results from the 556-patient, placebo-controlled study were consistent with data obtained from previous Phase III Raptiva studies and were included as part of a Marketing Authorization Application (MAA) in February 2003 to the European Agency for the Evaluation of Medicinal Products (EMEA) and are currently under review.

After 12 weeks of Raptiva therapy, 27 percent (98/369) of study patients demonstrated 75 percent or greater Psoriasis Area and Severity Index (PASI) score improvement, versus 4 percent (8/187) of patients on placebo, and 59 percent (216/369) achieved 50 percent or greater PASI score improvement, versus 14 percent (26/187) in the placebo group.

"The three large Phase III trials and a long-term open label trial demonstrate clinically meaningful response in a majority of patients," said Andrew Galazka, M.D., Serono's Senior Vice President Scientific Affairs. "We believe that these efficacy results together with Raptiva's rapid onset of action and its safety profile in more than 2,100 Raptiva-treated patients, means that Raptiva has significant potential as a once-weekly treatment for moderate-to-severe psoriasis."

Data from 15 months of an open-label multicenter trial evaluating the safety and tolerability of Raptiva as a potential continuous treatment in patients with moderate-to-severe psoriasis will be presented by Alice Gottlieb, M.D., director of the Clinical Research Center at the Robert Wood Johnson Medical School at the University of Medicine and Dentistry of New Jersey on Saturday, March 22.

-more-

### EFFICACY AND QUALITY OF LIFE DATA PRESENTED

In the double blind, placebo-controlled, multicenter study, 556 patients were randomized in a 2 to 1 ratio to receive weekly subcutaneous doses of 1 mg/kg Raptiva (n=369) or placebo (n=187) for a 12-week period. The study's primary endpoint was to compare the percentage of patients who achieved 75 percent or greater improvement in PASI scores (PASI 75) after 12 weeks of Raptiva therapy with patients receiving placebo. Secondary endpoints include the percentage of patients who achieved 50 percent or greater improvement in PASI scores (PASI 50); the Overall Lesion Severity scale (OLS), which is a static measure of global physician assessment on psoriasis; patient-reported outcomes such as the Dermatology Life Quality Index (DLQI), which measures impairment from a skin condition, and the Psoriasis Symptom Assessment (PSA).

At week 12, mean improvement in DLQI scores with Raptiva treatment was 47 percent, versus 14 percent for patients on placebo. The study results with Raptiva showed improvement on each of the eight PSA subsets: pain, burning or

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

stinging, itching, bothered by water, irritation, sensitivity, bleeding and scaling.

"The reduction in disease severity and rapid onset of action observed in Raptiva-treated study patients along with the positive impact on these patients' quality of life measurements provide further support for Raptiva as a potential treatment option for psoriasis patients," said Dr. Gordon.

The most common adverse events in patients receiving Raptiva compared with those in the placebo group included headache, chills, pain, fever, and myalgia (muscle pain). These events occurred principally following the first two injections of Raptiva. For the third and subsequent doses, the incidence of acute adverse events was similar between the Raptiva and placebo groups. The only serious unexpected adverse event reported as study drug related by the investigators was one case of myelitis.

### ABOUT RAPTIVA(TM)

As a targeted T-cell modulator, Raptiva (efalizumab) is designed to block the activation of T-cells that cause psoriasis, without destroying them. Raptiva has been studied as a once-weekly therapy for the continuous treatment of moderate-to-severe plaque psoriasis. In clinical trials, Raptiva was administered via subcutaneous injection and in several of the trials was self-administered by some patients in their homes.

Raptiva(TM), a recombinant humanized monoclonal antibody, is designed to inhibit the adhesion of T-lymphocytes to other cell types by inhibiting the binding of LFA-1 to ICAM-1. This mechanism of action has a number of effects depending upon the cell type, which include: (1) inhibition of T-lymphocyte interactions with tissue-specific cells, (2) inhibition of T-lymphocyte migration, (3) inhibition of T-lymphocyte activation, proliferation and cytokine release. In the clinical Phase III studies, Raptiva(TM) was given as a once-a-week subcutaneous injection. Raptiva(TM) is potentially the first and only once-a-week subcutaneous treatment for psoriasis. Raptiva(TM) is currently in Phase II trials in Rheumatoid Arthritis and is being also evaluated for the treatment of Psoriatic Arthritis.

-more-

Serono has the rights to develop and market Raptiva(TM) worldwide outside of the United States and Japan. Development and marketing rights in the United States remain with Genentech Inc. (NYSE:DNA) and its U.S. partner XOMA (Nasdaq: XOMA), who filed a Biologics License Application (BLA) with the FDA in December 2002.

### ABOUT PSORIASIS

Psoriasis is a chronic skin disease that affects approximately 5.7 million Europeans. Psoriasis occurs when new skin cells grow abnormally, resulting in thick, red, scaly, inflamed patches. Plaque psoriasis, the most common form of the disease, is characterized by inflamed patches of skin ("lesions") topped with silvery white scales. Psoriasis can be limited to a few spots or involve extensive areas of the body, appearing most commonly on the scalp, knees, elbows and trunk. Although it is highly visible, psoriasis is not a contagious disease. While there are a number of medications that may help control the symptoms of psoriasis, there currently is no known cure.

### ABOUT SERONO

Serono is a global biotechnology leader. The Company has six recombinant products on the market, Gonal-F(R), Luveris(R), Ovidrel(R)/Ovitrelle(R),

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

Rebif(R), Serostim(R) and Saizen(R) (Luveris(R) is not approved in the USA). 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 over 30 projects in development.

Serono was awarded the International James D. Watson Helix 2003 Award from the Biotechnology Industry Organization (BIO) in recognition of the Company's outstanding leadership and highest standards of scientific and product achievement.

In 2002, Serono achieved worldwide revenues of US\$1.546 billion, and a net income of US\$321 million, making it the third largest biotech company in the world. 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 virt-x (SEO) and its American Depositary 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 May 21 2002. 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.

###

-more-

FOR MORE INFORMATION, PLEASE CONTACT:

SERONO IN GENEVA, SWITZERLAND:

MEDIA RELATIONS:

Tel: +41-22-739 36 00

Fax: +41-22-739 30 85

<http://www.serono.com>

-----

INVESTOR RELATIONS:

Tel: +41-22-739 36 01

Fax: +41-22-739 30 22

Reuters: SEOZ.VX/SRA.N

Bloomberg: SEO VX/SRA US

SERONO, INC., ROCKLAND, MA

MEDIA RELATIONS:

Tel. +1 781 681 2340

Fax: +1 781 681 2935

<http://www.seronousa.com>

-----

INVESTOR RELATIONS:

Tel. +1 781 681 2552

Fax: +1 781 681 2912

GENENTECH:

MEDIA CONTACT:

Tara Cooper: +1 (650) 225-5505

Edgar Filing: SERONO S A - Form 6-K

INVESTOR CONTACT:  
Kathee Littrell: +1 (650) 225-1034  
www.gene.com  
-----

-end-

[GRAPHIC OMITTED]  
Serono

Media Release

FOR IMMEDIATE RELEASE  
-----

PRELIMINARY RESULTS FROM OPEN-LABEL RAPTIVA(TM) STUDY SUGGEST CONTINUED BENEFIT  
WITH LONG-TERM TREATMENT

OVER 64 PERCENT OF PATIENTS CONTINUING TREATMENT FOR 15 MONTHS SHOWED PASI 75  
OR GREATER RESPONSE WITH WEEKLY RAPTIVA THERAPY

GENEVA, SWITZERLAND - MARCH 24, 2003 - Serono S.A. (virt-x: SEO and NYSE: SRA)  
Serono today announced preliminary results from an open-label, multicenter trial  
evaluating the long-term safety and tolerability of continuous Raptiva(TM)  
(efalizumab) treatment in patients with moderate-to-severe psoriasis.

"The findings from this important open label study on the long-term safety and  
efficacy of Raptiva are very encouraging and further support Raptiva's potential  
to address the unmet medical need of patients with moderate-to-severe  
psoriasis", said Andrew Galazka, M.D., Serono's Senior Vice President Scientific  
Affairs.

Alice Gottlieb, M.D., director of the Clinical Research Center at the Robert  
Wood Johnson Medical School at the University of Medicine and Dentistry of New  
Jersey presented data for patients receiving continuous Raptiva treatment for  
one-year following an initial three months of treatment. The data were presented  
on Saturday, March 22 at the 61st annual American Academy of Dermatology meeting  
being held in San Francisco.

RESPONSE RATES WITH CONTINUED RAPTIVA TREATMENT

A total of 339 patients were enrolled in this continuing open-label, multicenter  
study. 41 percent of patients (140/339) achieved 75 percent or greater  
improvement in Psoriasis Area and Severity Index (PASI) scores (PASI 75) and 82  
percent (278/339) achieved PASI 50 or greater improvement after 12 weeks of 2  
mg/kg/week Raptiva therapy. Patients who achieved PASI 50 or OLS (Overall Lesion  
Severity scale) of clear, minimal or mild at week 12 were eligible to enter the  
continuous treatment period. Of the original 339 patients, 290 patients who met  
the entry criteria for the maintenance period entered the continuous treatment  
phase of the study. For each successive three-month period of treatment,  
dropouts during that cohort period were counted as non-responders for that  
cohort, but were excluded from the subsequent cohorts.

-more-

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

Starting from week 13, the weekly subcutaneous doses in patients were reduced to 1 mg/kg Raptiva. At weeks 13-24 (n=290) more than 77 percent of patients who continued on therapy achieved PASI 50 and more than 51 percent achieved PASI 75. Of which, more than 22 percent of patients achieved PASI 90. At weeks 49-60 (n=228), more than 79 percent of patients who continued on therapy achieved PASI 50 and over 64 percent achieved PASI 75. Of which, more than 31 percent achieved PASI 90.

"The data from this study suggest that for some patients, Raptiva may present an option for continuous treatment of moderate-to-severe psoriasis," said Dr. Gottlieb. "As a chronic disease, the opportunity for an efficacious treatment with a favorable safety profile is of interest to clinicians as we explore potential therapies for this devastating disease."

The most common adverse events during the first 12 weeks of treatment were headache, non-specific infection (e.g., common colds), chills, pain, nausea, asthenia (weakness), and fever. These events principally occurred following the first two injections of Raptiva. No new adverse events emerged during continuous Raptiva therapy. Over time, among those patients who continued on therapy, the percentage of patients who experienced at least one adverse event decreased from 57 percent during weeks 13-24 to 47 percent during weeks 49-60. The occurrence of serious adverse events during the 15 months of treatment was infrequent, which is consistent with data from previous Raptiva Phase III studies.

### ABOUT RAPTIVA(TM)

In February 2003, Serono filed a Marketing Authorization Application (MAA) to the European Agency for the Evaluation of Medicinal Products (EMEA) for Raptiva(TM) (efalizumab) for the treatment of adult patients with moderate-to-severe plaque psoriasis. The MAA submission included data from over 2,100 patients with moderate-to-severe plaque psoriasis treated with Raptiva.

Serono has the rights to develop and market Raptiva(TM) worldwide outside of the United States and Japan. Development and marketing rights in the United States remain with Genentech Inc. (NYSE:DNA) and its U.S. partner XOMA (Nasdaq: XOMA), who filed a Biologics License Application (BLA) with the FDA in December 2002.

As a targeted T-cell modulator, Raptiva is designed to block the activation of T-cells that cause psoriasis, without destroying them. Raptiva has been studied as a once-weekly therapy for the continuous treatment of moderate-to-severe plaque psoriasis. In clinical trials, Raptiva was administered via subcutaneous injection and in several of the trials was self-administered by some patients in their homes.

Raptiva(TM), a recombinant humanized monoclonal antibody, is designed to inhibit the adhesion of T-lymphocytes to other cell types by inhibiting the binding of LFA-1 to ICAM-1. This mechanism of action has a number of effects depending upon the cell type, which include: (1) inhibition of T-lymphocyte interactions with tissue-specific cells, (2) inhibition of T-lymphocyte migration, (3) inhibition of T-lymphocyte activation, proliferation and cytokine release. In the clinical Phase III studies, Raptiva(TM) was given as a once-a-week subcutaneous injection. Raptiva(TM) is potentially the first and only once-a-week subcutaneous treatment for psoriasis. Raptiva(TM) is currently in Phase II trials in Rheumatoid Arthritis and is being also evaluated for the treatment of Psoriatic Arthritis.

-more-

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

### ABOUT PSORIASIS

Psoriasis is a chronic skin disease that affects approximately 5.7 million Europeans. Psoriasis occurs when new skin cells grow abnormally, resulting in thick, red, scaly, inflamed patches. Plaque psoriasis, the most common form of the disease, is characterized by inflamed patches of skin ("lesions") topped with silvery white scales. Psoriasis can be limited to a few spots or involve extensive areas of the body, appearing most commonly on the scalp, knees, elbows and trunk. Although it is highly visible, psoriasis is not a contagious disease. While there are a number of medications that may help control the symptoms of psoriasis, there currently is no known cure.

### ABOUT SERONO

Serono is a global biotechnology leader. The Company has six recombinant products on the market, Gonal-F(R), Luveris(R), Ovidrel(R)/Ovitrelle(R), Rebif(R), Serostim(R) and Saizen(R) (Luveris(R) is not approved in the USA). 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 over 30 projects in development.

Serono was awarded the International James D. Watson Helix 2003 Award from the Biotechnology Industry Organization (BIO) in recognition of the Company's outstanding leadership and highest standards of scientific and product achievement.

In 2002, Serono achieved worldwide revenues of US\$1.546 billion, and a net income of US\$321 million, making it the third largest biotech company in the world. 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 virt-x (SEO) and its American Depositary 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 May 21 2002. 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.

###

-more-

FOR MORE INFORMATION, PLEASE CONTACT:

SERONO IN GENEVA, SWITZERLAND:

Edgar Filing: SERONO S A - Form 6-K

MEDIA RELATIONS:

Tel: +41-22-739 36 00

Fax: +41-22-739 30 85

<http://www.serono.com>

-----

INVESTOR RELATIONS:

Tel: +41-22-739 36 01

Fax: +41-22-739 30 22

Reuters: SEOZ.VX/SRA.N

Bloomberg: SEO VX / SRA US

SERONO, INC., ROCKLAND, MA

MEDIA RELATIONS:

Tel. +1 781 681 2340

Fax: +1 781 681 2935

<http://www.seronusa.com>

-----

INVESTOR RELATIONS:

Tel. +1 781 681 2552

Fax: +1 781 681 2912

GENENTECH:

MEDIA CONTACT:

Tara Cooper: +1 (650) 225-5505

INVESTOR CONTACT:

Kathee Littrell: +1 (650) 225-1034

[www.gene.com](http://www.gene.com)

-----

-end-

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 24, 2003

By: /s/ Allan Shaw

-----  
Name: Allan Shaw

Title: Chief Financial Officer