

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549



REC'D S.E.C.  
SEP 17 2002  
1086

FORM 6-K

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

1-15896

For the month of September, 2002.

Serono S.A.  
(Registrant's Name)

REC'D S.E.C.  
SEP 17 2002  
1086

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

P.E.  
9/1/02

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

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# Media Release

## FOR IMMEDIATE RELEASE

### SERONO CONFIRMS INTENTION TO FILE RAPTIVA™ IN EUROPE DURING FIRST QUARTER 2003

**GENEVA, Switzerland – September 17, 2002 – Serono S.A. (virt-x: SEO and NYSE: SRA).** Following the announcement today by Genentech and XOMA of positive and consistent results in a third Phase III efficacy study for the psoriasis treatment Raptiva™ (efalizumab), Serono confirmed that it plans to submit a marketing authorization application in Europe for Raptiva during the first quarter of 2003. Serono received an exclusive license from Genentech in August 2002 to market Raptiva internationally outside of the United States, Japan, and certain other Asian countries.

“We are delighted with these positive results for Raptiva, and will include the data from this Phase III study in our submission to European authorities early next year”, said Ernesto Bertarelli, Chief Executive Officer. “We believe Raptiva will be an important treatment option for patients suffering from psoriasis.”

Genentech Inc (NYSE:DNA) and its US partner XOMA (US) LLC (Nasdaq: XOMA) today announced that Raptiva had met its primary efficacy endpoint in a third Phase III study. The results from this study using Genentech material are consistent with data obtained from previous Phase III studies with Raptiva, conducted with both XOMA and Genentech material.

Genentech and XOMA plan to include data from this study as part of a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) by the end of 2002. Genentech and XOMA plan to present the data from this study at an upcoming medical meeting.

This double-blind, placebo-controlled, multicenter efficacy study enrolled 556 patients with moderate-to-severe plaque psoriasis who were randomized in a 2 to 1 ratio to receive 12 weekly subcutaneous injections of 1 mg/kg of Raptiva or placebo. The primary endpoint of the study was to compare the percentage of patients who achieved 75 percent or greater improvement in Psoriasis Area and Severity Index (PASI) scores (PASI 75) after 12 weeks of Raptiva therapy with patients receiving placebo.

The trial also measured several secondary endpoints at 12 weeks, including the Overall Lesion Severity (OLS) scale, the percentage of patients achieving 50 or greater improvement in PASI scores (PASI 50) and the percentage of PASI improvement over time. Data from these secondary endpoints are consistent with results obtained from previous Phase III Raptiva studies.

The safety profile in this study was similar to previous Raptiva studies conducted with both Genentech and XOMA material. Adverse events that occurred more often in the Raptiva arm included mild-to-moderate headache, general aches/pains, chills, nausea and fever.

### **About Raptiva**

A humanized monoclonal antibody, Raptiva is a targeted T-cell modulator designed to inhibit three key inflammatory processes in the cascade of events that are associated with psoriasis. These processes are: (1) binding of T-cells through interactions with adhesion molecules on the endothelial cell surface; (2) trafficking of T-cells into the skin; and (3) activation of T-cells, all of which may be linked to the abnormal growth of skin cells and the painful, elevated scaly patches of skin (lesions) typical among psoriasis sufferers. Raptiva is administered subcutaneously (under the skin) once per week.

Raptiva is being developed in the U.S. for the treatment of moderate-to-severe psoriasis through a partnership between Genentech and XOMA. Raptiva is also in Phase II clinical testing in patients with rheumatoid arthritis. In August 2002, Serono received the exclusive license from Genentech to market Raptiva in these and any other future indications internationally outside of the United States, Japan and certain other Asian countries.

### **Psoriasis Background**

Psoriasis is a chronic autoimmune disease that affects approximately 5.7 million patients in Europe and approximately 4.5 million people in the U.S. Psoriasis is characterized by the abnormal growth of new skin cells, resulting in thick, red, scaly, inflamed patches. Psoriasis is not a contagious disease.

Psoriasis may be one of several types: plaque psoriasis, pustular psoriasis, erythrodermic psoriasis, guttate psoriasis, or inverse psoriasis. 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. Psoriasis is categorized as mild, moderate or severe, depending on the percentage of body surface area involved and the impact of the patient's quality of life.

Existing treatments for psoriasis are topical (applied to the skin), systemic (taken internally), or phototherapeutic (ultraviolet light applied to the skin). While some current treatments may help control the symptoms of psoriasis, their benefits are not long lasting and may be associated with serious side effects. There currently is no known cure.

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*The statements made in this press release relating to the regulatory filing time frame for Raptiva in the U.S. and Europe are forward-looking and actual results could differ materially. Among other things, the regulatory filing time frame in the U.S. or Europe could be affected by unexpected safety or efficacy issues, manufacturing issues, additional time requirements for data analysis, preparation of the BLA or the regulatory filing in Europe, discussions with the FDA or the EMEA, slow enrollment in clinical studies or additional clinical studies.*

*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.*

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### **About Serono**

Serono is a global biotechnology leader. The Company has six recombinant products on the market, Gonal-F®, Luveris®, Ovidrel®/Ovitrelle®, Rebif®, Serostim® and Saizen® [somatropin. (Luveris® 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 seventeen new molecules in development.

In 2001, Serono achieved worldwide revenues of U.S. \$1.38 billion, and a net income of U.S. \$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 virt-x (SEO) and its American Depository Shares are traded on the New York Stock Exchange (SRA).

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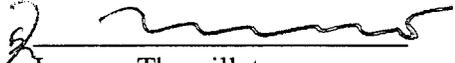
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## SIGNATURES

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)

September 17, 2002

By:   
Name: Jacques Theurillat  
Title: Deputy Chief Executive Officer and  
Chief Financial Officer