SERONO S A
Form 6-K
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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 October

Commission File Number 1-15096

Serono S.A.

(Translation of registrant s name into English)

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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 x Form 40-F o

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): o

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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 o No x

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Media Release

FOR IMMEDIATE RELEASE

24-WEEK CLEAR STUDY RESULTS CONFIRM SUSTAINED EFFICACY AND SAFETY OF RAPTIVA® IN MODERATE-TO-SEVERE PSORIASIS PATIENTS WITH CO-MORBIDITIES

Extended Therapy Maintains and Improves Clinical Responses

Geneva, Switzerland October 31, 2006 Serono (virt-x: SEO and NYSE: SRA) announced today that the 24-week data from the clinical study CLEAR (**CL**inical **E**xperience **A**cquired with **R**aptiva®), evaluating moderate-to-severe psoriasis patients, as well as refractory patients, was published in this month s edition of the Journal of the German Society of Dermatology.(1) The data confirms the efficacy and safety of Raptiva® seen during the initial 12-week treatment period and demonstrates a continued improvement in clinical response for patients following an extended treatment. Also, Raptiva® was found to be equally effective in the subgroup of patients refractory to at least two systemic therapies compared to the overall moderate-to-severe patient population. Refractory patients had suffered from psoriasis for a longer time, had a more severe disease and a greater past history of co-morbidities, such as psoriatric arthritis, hypertension, metabolic and nutritional disorders, and hepatobiliary disorders(2).

Extended treatment with Raptiva® resulted in a sustained clinical improvement for psoriasis patients, including refractory patients who had a significant high unmet medical need, said Professor Wolfram Sterry, Director of the Department of Dermatology, Venerology and Allergology at the University Hospital Charité Berlin, Germany. These patients did not respond to or could not take traditional therapies and had in many cases additional co-morbidities.

The aim of the CLEAR study was to evaluate the efficacy and safety of Raptiva® compared to placebo in patients who either continued after an initial 12-week therapy to receive treatment up to 24 weeks, or who received re-treatment for an additional 12 weeks following a treatment-free observation period.

Key Study Findings:

After 12 weeks of treatment, Raptiva® met its primary endpoint and showed a favourable safety and efficacy profile with a statistically significantly higher PASI 75 rate(3) demonstrating clinical superiority over placebo:

- 31.4% of patients treated with Raptiva® in the overall, non-refractory patient population (267/793) reached a ≥ 75% PASI improvement compared to 4.2% of those treated with placebo ($p < 0.0001$)

- 29.5% of patients treated with Raptiva® in the refractory patient group (526/793) reached a PASI 75 rate compared to 2.7% of those treated with placebo ($p < 0.0001$).

(1) Sterry et al., Clinical Experience Acquired with Raptiva (CLEAR) trial in patients with moderate-to-severe plaque psoriasis: results from extended treatment in an international, Phase III, placebo-controlled trial, JDDG Vol. 4, Issue 11, Page 947, November 2006

(2) Prinz JC, Henninger E, Patient Characteristics and Drug Exposure in High-Need Patients: The CLEAR Experience, EADV Spring Symposium, Sofia, Bulgaria, May 2005, Poster

(3) Psoriasis Area and Severity Index; most commonly used clinical scoring system to assess disease severity in clinical trials

After 24 weeks of treatment, the results of the CLEAR study confirm the efficacy and safety of Raptiva® demonstrated in the initial 12-week treatment period:

- Following the extended treatment period, 47.5% of patients with an initial PASI improvement of ≥ 50% but < 75% at week 12 continued to improve over time and achieved PASI 75

- Median time to relapse during the observation period was 58 days for patients who achieved a PASI 75 response after an initial 12-week treatment with Raptiva®

- The safety profile of Raptiva® is consistent with previous experience and no new safety concerns were identified

For psoriasis patients often requiring a lifelong treatment, these results are encouraging and demonstrate that Raptiva® provides an innovative, effective and safe treatment paradigm for a continuous management of the chronic disease. said Professor Sterry.

CLEAR is the only multinational, randomized, double-blind, placebo-controlled, parallel-group trial demonstrating the efficacy of a biological therapy in an international refractory patient population, where other systemic therapies were inappropriate due to contraindications or intolerance, or where patients failed to respond to them. CLEAR prospectively and uniquely demonstrates that Raptiva® is an effective therapy in moderate-to-severe plaque psoriasis patients regardless of previous systemic treatments.

In North-American studies, Raptiva® was also demonstrated to be equally effective in overweight patients, another common co-morbidity with psoriasis(4).

Globally, more than 30,000 patients have received Raptiva®, both during clinical trials and post registration. This represents more than 22,500 patient years of exposure, creating one of the largest existing databases of patients taking a biological therapy for psoriasis.

About the CLEAR Study

CLEAR (**CL**inical **E**xperience **A**cquired with **R**aptiva®) is the first multinational, randomized, double blind, placebo-controlled, parallel-group trial designed to evaluate the safety and efficacy of Raptiva® compared to placebo. Patients with moderate-to-severe plaque psoriasis, including refractory patients, defined as those for whom at least two systemic therapies were unsuitable because of lack of efficacy, intolerance or contraindication, were randomized in a 2:1 ratio to receive either once weekly for 12 weeks 1mg/kg Raptiva® or placebo. 793 patients were included in this prospective trial, thereof 529 were randomized to Raptiva® and 264 to placebo. Amongst the 793 patients, 526 were refractory patients.

The CLEAR trial comprised four discrete periods: a double-blind, first treatment (FT) period, in which patients were randomized 2:1 to Raptiva® or placebo for 12 weeks; an observation (OB) period, in which those patients who achieved a PASI-75 response were observed, without treatment, for up to 24 weeks or until they had a relapse; an open-label, re-treatment (RT) period, in which, following relapse or completion of the OB period, patients were re-started on open-label treatment with Raptiva® for 12 weeks; and an open-label, extended-treatment (ET) period, in which patients who did not achieve a PASI 75-response at the end of the FT period continued to receive open-label treatment with Raptiva® for up to 24 weeks without intervening OB period.

The primary endpoint of the CLEAR study was to evaluate the safety and efficacy of Raptiva® 1mg/kg given subcutaneously once a week for 12 weeks compared to placebo. The secondary endpoint was to evaluate the safety and efficacy of Raptiva® during the extended treatment, observation and re-treatment periods.

Overall, the safety profile of Raptiva® in the CLEAR study is consistent with that reported in previous US phase III clinical studies and no new safety concerns were identified. The most frequent adverse

(4) Lebwohl M. et al., Efficacy and Safety of efalizumab in patients with high body weight: pooled results from randomized phase III trials, Summer AAD 2005, Chicago, USA, Poster

events were consistent with the syndrome of acute adverse events known to be associated with initial Raptiva® treatment, including headache, chills, fever, nausea, or myalgia occurring within 48 hours of injection.

Full data on the initial 12-week treatment period has been published in the *British Journal of Dermatology* in June 2006.(5)

About Raptiva®

Raptiva® (efalizumab) is a humanized therapeutic antibody designed to selectively and reversibly block the activation, reactivation and trafficking of T-cells that lead to the development of psoriasis symptoms. Raptiva® is designed to be administered once weekly via subcutaneous injection and can be self-administered by patients at home.

Raptiva® received EU approval for the *Treatment of adult patients with moderate to severe chronic plaque psoriasis who have failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including cyclosporine, methotrexate and PUVA* .

Adverse events observed with Raptiva® include headache, non-specific infection (e.g., common colds), chills, pain, nausea, asthenia (weakness), and fever, all of which diminished after the first 1-2 doses. There is no evidence of accumulation or cumulative toxicity to date.

Serono has the rights to develop and market Raptiva® worldwide outside of the United States and Japan. To date, Raptiva® is available in over 50 countries, amongst them many countries in Europe, Latin America, Asia as well as Australia. Development and marketing rights in the United States, where Raptiva® has been available since November 2003, remain with Genentech, Inc.

About Psoriasis

Psoriasis is a T-cell mediated disease, which occurs when 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 knees, elbows, trunk, and scalp. 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 permanent cure.

Background material

For free B-roll, video and other content for Serono and its products, please visit the Serono Media Center 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.

About Serono

Serono is a global biotechnology leader. The Company has eight biotechnology products, Rebif®, Gonal-f®, Luveris®, Ovidrel®/Ovitrelle®, Serostim®, Saizen®, Zorbtive 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. Currently, there are more than 25 on-going development projects.

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(5) Dubertret L, Sterry W, Bos JD, Chimenti S, Shumack S, Larsen CG, Shear NH, Papp KA, CLEAR Multinational Study Group. Clinical Experience acquired with the efalizumab (Raptiva) CLEAR trial in patients with moderate-to-severe plaque psoriasis: results from a phase III international randomized, placebo-controlled trial. *Br J Dermatol 155:170-181*

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).

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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 government investigations and litigation 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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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 October 31, 2006

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