SERONO S A
Form 6-K
November 13, 2006

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 November

Commission File Number **1-15096**

Serono S.A.

(Translation of registrant s name into English)

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Switzerland

(Address of principal executive office)

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

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

ZYMOGENETICS AND SERONO REPORT DETAILED POSITIVE RESULTS FROM ATACICEPT PHASE 1B CLINICAL TRIAL IN PATIENTS WITH LUPUS

Clear biologic activity, tolerability and trends toward efficacy observed

Seattle, USA and Geneva, Switzerland, November 13, 2006 ZymoGenetics, Inc. (NASDAQ: ZGEN) and Serono (virt-x: SEO and NYSE: SRA) today presented positive results at the American College of Rheumatology (ACR) annual meeting from a Phase 1b study in systemic lupus erythematosus (SLE) patients treated with atacicept(1). The results showed that atacicept was well tolerated across all dose levels and schedules in the study. In addition, atacicept therapy was associated with clear biologic activity, as shown by dose-dependent reductions in several biologic markers, consistent with atacicept s proposed mechanism of action.

ZymoGenetics and Serono are striving to develop an effective therapy for patients who suffer from lupus, said Bruce L.A. Carter, President and Chief Executive Officer of ZymoGenetics. We believe atacicept has the potential to help people with this debilitating disease.

The primary objective of the dose-escalating Phase 1b clinical trial, which included 49 patients with SLE in 6 cohorts, was to determine the safety and tolerability of atacicept administered subcutaneously. Secondary objectives included examining the effects of various dose and schedule regimens on markers of biologic activity and disease activity.

The Phase 1b results are very encouraging and we are looking forward to moving the clinical development of atacicept in patients with SLE to Phase 2, said Franck Latrille, Senior Executive Vice President, Corporate Global Product Development at Serono.

ZymoGenetics and Serono are in dialogue with the FDA regarding the SLE Phase 2 clinical development program. The companies are planning to initiate the trial in SLE in mid-2007.

Key Study Findings:

Clear biologic activity:

Consistent with the mode of action:

- Immunoglobulins showed prompt dose-related decreases with atacicept treatment.

- Among patients treated with the highest study dose of atacicept (9mg/kg), median IgA, IgG and IgM levels were reduced by 32, 16 and nearly 50 percent relative to baseline. Patients treated with placebo showed average reductions of only four percent.

- Repeated doses were associated with greater decreases in immunoglobulin (Ig) levels than single equivalent doses.

- Following treatment cessation, Ig levels returned towards baseline.

- Mature and total B-cells showed a sustained, dose-related reduction.

(1) Trial of Atacicept in Patients with Systemic Lupus Erythematosus (SLE) (poster L19/499), ACR/ARHP Poster Session B Late-Breaking Posters, November 13, 2006, American College of Rheumatology Annual Meeting

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Tolerability:

- No serious adverse events were reported in patients treated with atacicept.

- There was no evidence of increased infection risk among treated subjects, and no binding antibodies to atacicept were detected.

Positive trend towards efficacy:

- Although the study was not designed to evaluate efficacy, compared to placebo an overall positive trend in SELENA-SLEDAI scores(2) and complement levels was seen in patients treated with multiple doses of atacicept.

A separate poster(3) presented at ACR reviewed findings from a Phase 1b study with atacicept in patients with rheumatoid arthritis, as announced earlier this year. The companies are planning to initiate the Phase 2 study with atacicept in RA patients before the end of 2006.

About the Study

The double blind, placebo-controlled, dose escalating, multi-site Phase 1b trial enrolled forty-nine patients with mild-to-moderate SLE. Six cohorts, consisting of eight patients each, were treated with either atacicept or placebo. Cohorts 1 through 4 received a single subcutaneous dose of 0.3, 1, 3, or 9 mg/kg of atacicept respectively. Cohorts 5 and 6 received four weekly doses of 1 mg/kg or 3 mg/kg respectively. Patients were followed for either six weeks (cohorts 1-4) or nine weeks (cohorts 5-6). All patients were monitored during and for several weeks after dosing for safety purposes.

The primary outcome measure was the systemic and local tolerability of atacicept administered subcutaneously. The secondary measures included pharmacokinetics and pharmacodynamics, as well as measures of SLE disease activity.

Atacicept was well tolerated by patients with SLE at all doses investigated. There was a clear demonstration of biologic activity consistent with the mechanism of action of atacicept and positive trends towards efficacy were observed.

Overall, the results demonstrated a favorable tolerability profile. The predominant adverse event noted was a mild to moderate local injection site reaction (redness of skin or pain at the injection site), which was observed in 50% of atacicept subjects and less frequently in the placebo and 0.3 mg/kg groups. Few notable differences were observed between atacicept and placebo in the nature, severity or frequency of adverse events.

About Atacicept

ZymoGenetics and Serono are developing atacicept (formerly referred to as TACI-Ig) for the treatment of autoimmune diseases and B-cell malignancies. Atacicept contains the soluble TACI receptor that binds to the cytokines BLyS and APRIL. These cytokines, in turn, are members of the tumor necrosis factor (TNF) family that promote B-cell survival and autoantibody production associated with certain autoimmune diseases such as systemic lupus erythematosus (SLE). Current data indicates that levels of BLyS and APRIL are elevated in patients with rheumatoid arthritis, SLE and B-cell malignancies. Atacicept has been shown to affect several stages of B-cell development and may inhibit the survival of cells responsible for making antibodies.

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(2) SELENA-SLEDAI: SLE Disease Activity Index; The original SLEDAI is a weighted, cumulative index of lupus disease activity, and the SELENA SLEDAI represents a further refinement.

(3) A Phase Ib Study to Investigate Atacicept (TACI-Ig) In Patients With Rheumatoid Arthritis (poster L36/516). ACR/ARHP Poster Session B Late-Breaking Posters, November 13, 2006, American College of Rheumatology Annual Meeting

Posters

The abstracts and posters are available at www.zymogenetics.com in the What s New section on the home page.

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.

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Forward-looking Statements

For ZymoGenetics

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on the current intent and expectations of the management of ZymoGenetics. These statements are not guarantees of future performance and involve risks and uncertainties that are difficult to predict. ZymoGenetics actual results and the timing and outcome of events may differ materially from those expressed in or implied by the forward-looking statements because of risks associated with our unproven discovery strategy, preclinical and clinical development, regulatory oversight, intellectual property claims and litigation and other risks detailed in the company s public filings with the Securities and Exchange Commission, including the company s Annual Report on Form 10-K for the year ended December 31, 2005. Except as required by law, ZymoGenetics undertakes no obligation to update any forward-looking or other statements in this press release, whether as a result of new information, future events or otherwise.

For Serono

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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About ZymoGenetics

ZymoGenetics creates novel protein drugs with the potential to significantly help patients fight their diseases. The Company is developing a diverse pipeline of potential proprietary product candidates that are moving into and through clinical development. These candidates span a wide array of clinical opportunities that include bleeding, autoimmune diseases and cancer. ZymoGenetics intends to commercialize these product candidates through internal development, collaborations with partners, and out-licensing of patents from its extensive patent portfolio. For further information, visit www.zymogenetics.com.

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.

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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ZymoGenetics

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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 November 13, 2006

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