SERONO S A
Form 6-K
December 21, 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 December

Commission File Number **1-15096**

Serono S.A.

(Translation of registrant s name into English)

15 bis, Chemin des Mines
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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):

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 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 BEGIN PHASE 2 CLINICAL TRIAL WITH ATACICEPT IN RHEUMATOID ARTHRITIS

Seattle, USA and Geneva, Switzerland, December 20, 2006 ZymoGenetics, Inc. (NASDAQ: ZGEN) and Serono (virt-x: SEO and NYSE: SRA) today announced the start of a Phase 2 clinical trial in which atacicept therapy will be evaluated in patients with rheumatoid arthritis (RA). The randomized, double-blind, multi-center study will investigate the efficacy of atacicept in patients with an inadequate response to prior treatment with TNF inhibitors. The efficacy of atacicept will be evaluated according to the American College of Rheumatology (ACR) criteria for defining clinical improvement in RA patients.

Data from our Phase 1b RA study indicate that atacicept has potential as a treatment for rheumatoid arthritis, said Bruce L. A. Carter, Ph.D., President and Chief Executive Officer of ZymoGenetics. A clear patient need still exists for new therapies. The Phase 2 study should provide a clear signal as to the efficacy of atacicept and this will enable us to make an informed decision about targeting the RA market with atacicept.

This Phase 2 study is part of a broad Phase 2 clinical trial program in rheumatoid arthritis. It also marks an important step toward bringing innovative treatments to patients whose medical needs are unmet by current therapies, said Franck Latrille, Senior Executive Vice President, Corporate Global Product Development at Serono.

The study will enroll 320 patients who have had active RA for more than one year and who have had an inadequate response to at least 3 months of TNF inhibitor therapy. Patients will be randomized into groups receiving one of three dose levels (25 mg, 75 mg or 150 mg) of atacicept or placebo, in addition to background methotrexate therapy, and they will be treated for twenty-five weeks. Loading doses will be given twice weekly for 4 weeks, followed by 21 weekly maintenance doses. A follow-up visit will occur 13 weeks after the last dose.

The primary endpoint will be the rate of ACR 20 response(1) at week 26. Secondary objectives include further characterizing the efficacy, safety, tolerability and pharmacologic profile of atacicept at each of these dose levels. ACR 50 and 70 responses and DAS 28(2) will be used as secondary measures of efficacy.

(1) ACR 20 response = the percentage of patients who achieve at least a 20% improvement in the ACR-specified measures of disease activity

(2) DAS = Disease Activity Score; a measure of the activity of rheumatoid arthritis

ZymoGenetics and Serono are also 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.

Earlier this year, the companies completed Phase 1b studies with atacicept in systemic lupus erythematosus (SLE) and rheumatoid arthritis.

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.

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 $2.6 billion. 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 December 21, 2006

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