SERONO S A
Form 6-K
October 02, 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 October

Commission File Number 1-15096

Serono S.A.

(Translation of registrant s name into English)

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(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

FINAL DATA FROM TWO PHASE II TRIALS INDICATE ACTIVITY OF ADECATUMUMAB (MT201) IN BREAST AND PROSTATE CANCER

Carlsbad, CA, and Geneva, Switzerland, October 2, 2006, Micromet, Inc. (NASDAQ: MITI), a biopharmaceutical company focusing on the development of novel, proprietary antibody-based products for cancer, inflammatory and autoimmune diseases, and Serono (virt-x: SEO and NYSE: SRA) today reported on the outcome of two phase II trials testing the activity of adecatumumab (MT201) in metastatic breast cancer and in prostate cancer, respectively. Adecatumumab originated at Micromet and is developed in collaboration between Micromet and Serono. The product candidate, a fully human monoclonal antibody targeting tumor cells overexpressing the epithelial cell adhesion molecule (EpCAM), was assessed as a single agent for efficacy and safety in patients with EpCAM-positive metastatic breast cancer (N=109) and in patients with prostate cancer (N=84). The studies tested adecatumumab at two dose levels in patients with high and low EpCAM expression. The results suggested dose dependent activity of adecatumumab as well as a dependency on relevant levels of target expression.

Final results from a phase II trial with adecatumumab in metastatic breast cancer were reported at the 31st Congress of the European Society of Medical Oncology (ESMO) in Istanbul, Turkey. This randomized, open label study was conducted in 5 European countries with 26 centers participating. Patients were stratified according to EpCAM expression into two groups, one with low EpCAM expression and another with high level EpCAM expression. Each group was then randomised into two arms treated every two weeks by intravenous infusion at either 2 mg adecatumumab per kg body weight (2 mg/kg) or at 6 mg adecatumumab per kg body weight (6 mg/kg). Patients were treated until disease progression with full tumor assessments every 6 weeks according to standardized RECIST criteria.

While the primary endpoint of the study (i.e., 25 percent clinical benefit rate at week 24) was not reached, secondary end point analysis showed a significant prolongation of time-to-progression (TTP) in patients treated with the higher dose of adecatumumab (p=0.0465) compared to patients receiving the lower dose. In addition, the importance of target presence was underscored by a trend towards increased TTP in patients expressing high EpCAM levels as opposed to patients with low or moderate EpCAM expression on their primary tumor tissue. Patients receiving the high dose of adecatumumab and expressing high EpCAM (high/high) on their tumor tissue had a significantly longer TTP compared to patients with low EpCAM on their tumor tissue and treated with the low dose of adecatumumab (low/low) (p=0.0057). Progression-free survival was 336 days, 128 days and 49 days for 10%, 25% and 50% (median) of patients in the high/high group with those numbers being 112 days, 59 days and 42 days in the low/low group.

This phase II study indicates activity of adecatumumab in metastatic breast cancer based on progression-free survival analysis , commented the principal investigator, Dr. Ahmad Awada, Head of the Medical Oncology Unit at Institute Jules Bordet in Bruxelles, Belgium. If this activity can be confirmed in additional trials, adecatumumab may offer a treatment option for patients with breast cancers highly overexpressing EpCAM. This finding is important because normally this patient population is believed to have a reduced overall survival compared to patients with low or no EpCAM expression .

The second trial, a placebo-controlled phase II study in relapse of prostate cancer, used serum PSA levels as the main readout for biological and clinical activity (n=84). The primary endpoint of this study was mean change in PSA at week 24 compared to baseline. While the primary end point was not reached, the analysis of the final data of the study indicated that treatment with 6 mg/kg adecatumumab had a beneficial trend when compared to placebo (0.46 ng/ml versus 1.24 ng/ml; p=0.0879). In a further exploration this trend was only seen for patients having high EpCAM expression levels (p=0.0884), but not for patients with low EpCAM expression (p=0.7947). The patients included in this trial had a high variability of PSA at study start (variation by a factor of 100 with baseline PSA values ranging from 0.2 to 20 ng/ml in serum). The clinical experts advising the company in connection with this trial determined that this high variability of PSA may have confounded the results and recommended that a retrospective sub-group analysis of the primary endpoint should be performed in a more homogeneous patient population. According to the experts, predominantly patients with PSA levels ≤1 ng/ml at baseline would define a minimal residual disease setting. The retrospective sub-group analysis for this specific patient population with high EpCAM expression (n=23) showed that both high (6 mg/kg) and low adecatumumab dose (2 mg/kg) given every other week for seven weeks led to a statistically significant smaller increase in PSA (0.38 ng/ml; p=0.0356, and 0.21 ng/ml; p=0.0014, respectively) compared to the placebo group (0.76 ng/ml) in patients with a high EpCAM expression.

Prof. Axel Heidenreich, Head of the Urological Clinic at the University Hospital of Cologne, Germany, commented: While the primary end point was not reached likely due to high inter-patient variability of PSA, the analysis of the minimal residual disease subset showed an encouraging effect on PSA progression, although patient numbers are limited. The fact that these effects were seen in patients with high EpCAM expression further validates the concept of adecatumumab being a true targeted therapy.

Adecatumumab was generally well tolerated in both trials with the observation of a dose-dependent incidence of adverse events (AE) in both trials. The most frequent AE were fever, chills, diarrhea, hypertension, lymphopenia, and elevation of pancreatic enzymes, and most AE were of mild to moderate severity.

The partners continue to investigate opportunities for further development. Adecatumumab is being explored for tolerability in combination with docetaxel in an ongoing phase Ib study in Europe. The information from the current trials will be used to further refine the targeted patient populations and dosing regimens as well as to explore other solid tumor settings.

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.

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).

About Micromet, Inc. (www.micromet-inc.com)

Micromet, Inc. is a biopharmaceutical company focusing on the development of novel, proprietary antibody-based products for cancer, inflammatory and autoimmune diseases. Two product candidates are currently in clinical trials. For adecatumumab (MT201), a recombinant human monoclonal antibody, two Phase 2 clinical trials for the treatment of patients with breast cancer and prostate cancer have been completed in Q3 2006. MT103 (MEDI-538), a BiTE® product candidate, is being studied in a Phase 1 clinical trial for the treatment of patients with Non Hodgkin Lymphoma. Micromet has established a drug development platform based on its BiTE® technology, a unique, antibody-based format that leverages the cytotoxic potential of T cells, the most powerful killer cells of the human immune system. Micromet has established collaborations with MedImmune, Inc. and Serono.

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Forward-Looking Statements

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 any government investigations and litigation. Serono is providing this information as of the date of this press release, and 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.

For Micromet:

This release contains certain forward-looking statements that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Such forward-looking statements include statements regarding the company s clinical development activities; the observation of clinical activity of MT201 in metastatic breast cancer, based on the observed prolongation of TTP in patients treated with the higher dose of MT201, compared to patients receiving the lower dose and the progression free survival rates observed in the high EpCAM / high dose group, compared to the low EpCAM / low dose group; the potential for such clinical activity to be confirmed in additional clinical trials; the potential for adecatumumab to offer a treatment option for patients with high EpCAM overexpression; the observation in the prostate cancer trial of the potential benefit of MT201 in patients with high EpCAM expression levels; the belief that the variability in baseline PSA for the trial subjects may have impacted the results of the prostate cancer trial; Micromet s and Serono s intention to continue the development of adecatumumab for the treatment of metastatic breast cancer in combination with docetaxel; the evaluation of other solid tumor settings for additional development opportunities; and Micromet s and Serono s intention to continue to explore the future development opportunities; and Micromet s and Serono s intention to continue to explore the future development of MT201 as a single agent in prostate cancer or breast cancer.. Factors that may cause actual results to differ materially include the risk that product candidates that appeared promising in early research and clinical trials do not demonstrate safety and/or efficacy in larger-scale or later clinical trials, the risk that encouraging results from clinical trials may not be confirmed upon further analysis of the detailed results of a trial and additional information relating to the safety, efficacy or tolerability of our product candidates may be discovered upon further analysis of the trial data, the risk that we will not obtain approval to market our product candidates, the risks associated with reliance on outside financing to meet capital requirements, and the risks associated with reliance on collaborative partners, including Serono, for further clinical trials, development and commercialization of product candidates, including MT201. You are urged to consider statements that include the words ongoing , may , will , would , could , should , believes , estimates , projects , potential , expects , suggests , plans , anticipates , intends , continues , forecast , designed , goal , or the negative of those words or other comparable words to be uncertain and forward-looking. These factors and others are more fully discussed in our periodic reports and other filings with the SEC.

Any forward-looking statements are made pursuant to Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and, as such, speak only as of the date made. Micromet, Inc. undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

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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 2, 2006

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