SERONO S A
Form 6-K
May 04, 2004

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 6-K

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

For the month of May, 2004

Serono S.A.
(Registrant's Name)

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

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 X Form 40-F

(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 No X

(If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-)

[GRAPHIC OMITED]

Media Release

FOR IMMEDIATE RELEASE

4SC AG AND SERONO SIGN WORLDWIDE AGREEMENT
TO DEVELOP AND COMMERCIALIZE ORALLY ACTIVE COMPOUNDS
FOR THE TREATMENT OF AUTOIMMUNE DISORDERS

LEAD COMPOUND SC12267 COMPLETING PHASE I CLINICAL TRIALS

MARTINSRIED, GERMANY AND GENEVA, SWITZERLAND - MAY 4, 2004 - 4SC AG ("4SC"), a German-based drug discovery and development company, and Serono (virt-x: SEO and NYSE: SRA) announced today that they have signed an agreement under which 4SC grants Serono exclusive worldwide rights to develop and commercialize 4SC's program of dihydroorotate dehydrogenase (DHODH) inhibitors. This program comprises a series of small molecules with potential as orally active treatments in autoimmune disorders, such as rheumatoid arthritis and multiple sclerosis. The agreement covers lead compound SC12267, which is currently completing Phase I clinical trials, as well as further back-up compounds and related intellectual property.

Under the terms of the agreement, 4SC will receive an upfront payment, research funding and potential milestone payments related to development progress, regulatory submissions, marketing authorizations and commercial sales achievements. If products are successfully developed, registered and commercialized 4SC could receive up to USD 67 million from Serono. 4SC will also receive undisclosed royalties on product sales.

4SC will be responsible for completion of the current multiple dose Phase I study on SC12267, while Serono will be solely responsible for further development, regulatory approvals and commercialization, both of SC12267 and of any other products deriving from the collaboration.

Dr Ulrich Dauer, CEO of 4SC commented "Gaining Serono as a partner committed to strongly expanding its presence in autoimmune disorders demonstrates the success of our business model in providing attractive drug candidates to major companies". He added "Revenues resulting from this partnership will contribute to the sustainable growth of our small molecule drug discovery and development pipeline".

"This partnership with 4SC will further strengthen our development portfolio in autoimmune diseases, building on Serono's existing commitment to this area of significant medical need" said Franck Latrille, Serono's Head of Product Development.

ABOUT SC12267

SC12267, a novel, selective and orally available, small molecule inhibitor of dihydroorotate dehydrogenase (DHODH), interferes with cell proliferation through blocking the synthesis pathway of pyrimidines. Its mode-of-action is of therapeutic relevance for the treatment of autoimmune disorders such as rheumatoid arthritis and multiple sclerosis. 4SC was able to reach clinical

trials with SC12267 in less than 3 years through application of its proprietary virtual screening platform and state of the art discovery capabilities in medicinal chemistry and relevant disciplines. SC12267 has shown activity in in vitro and in vivo models. Ongoing Phase I studies indicate favorable pharmacokinetic properties, suggesting a likely once daily dosing regime of the well tolerated compound.

ABOUT AUTOIMMUNE DISORDERS

Autoimmune disorders are a severe medical problem. In general they are caused by an over reactive immune response. Examples of this kind of disorder are multiple sclerosis (MS) and rheumatoid arthritis (RA). MS is a disease of the central nervous system (CNS), which includes the brain, the spinal cord and the optic nerves. It is usually diagnosed between the ages of 20 and 40 and is twice as common in women as in men. RA is a very common disease affecting almost 6 million people around the world. It is characterized by inflammation of multiple joints, cartilage loss and bone erosion, which leads to joint destruction and ultimately reduced joint function. Fewer than 50% of patients diagnosed with RA can continue to work or function normally on a day to day basis after ten years.

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Serono forward-looking statements
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 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 March 25, 2004. 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 seven recombinant products, Rebif(R), Gonal-F(R), Luveris(R), Ovidrel(R)/Ovitrelle(R), Serostim(R), Saizen(R) and Zorbtive(TM) (Luveris(R) 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 approximately 30 ongoing development projects.

In 2003, Serono achieved worldwide revenues of US$2,018.6 million, and a net income of US$390.0 million, making it the third largest biotech company in the world. Its products are sold in over 90 countries. 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 4SC
4SC is a drug discovery and development company that uses its

cheminformatics-based technological platform for the discovery and development of new drug candidates. By combining the disciplines of chemistry and biology with the proprietary virtual High Throughput Screening technology, 4SCan(R), the time and cost of advancing a drug candidate to the development phase can be significantly reduced. The company's therapeutic focus centers on hyperproliferative and infectious diseases. The drug candidate SC12267 for treatment of rheumatoid arthritis from 4SC's most advanced project is currently being tested in clinical Phase I. Additional research programs in disease areas of cancer, inflammation, and bacterial infections are currently at the discovery and preclinical evaluation stage. 4SC, which was founded in 1997, today employs 60 people and is based in Martinsried, near Munich, Germany.

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[GRAPHIC OMITED]

Media Release

FOR IMMEDIATE RELEASE

SERONO LAUNCHES ZORBTIVE(TM), FIRST DRUG PRODUCT FOR TREATMENT OF SHORT BOWEL SYNDROME

USE OF RECOMBINANT HUMAN GROWTH HORMONE REDUCES PATIENT DEPENDENCE ON PARENTERAL NUTRITION

GENEVA, SWITZERLAND AND ROCKLAND, MA, MAY 4, 2004 - SERONO (VIRT-X: SEO AND NYSE: SRA) -Serono, Inc., the US affiliate of Serono, announced today the launch of Zorbtive(TM) [somatropin (rDNA origin) for injection] for use in the treatment of patients with short bowel syndrome.

Short bowel syndrome (SBS) is a rare and potentially life-threatening condition in which the ability of the small intestine to absorb the nutrition a person needs from food is impaired. Short bowel syndrome can occur after surgical removal of part of the intestine, due to trauma or because the intestine is

diseased.

"Many patients with SBS receive their basic nourishment by parenteral nutrition, which means they can spend eight to ten hours a day hooked up to an intravenous feeding line," says Kareem M. Abu-Elmagd, MD, PhD, FACS, Professor of Surgery, Director of The Intestinal Rehabilitation and Transplant Center at the Thomas E. Starzl Transplantation Institute in Pittsburgh, Pennsylvania. "Reduction in dependence on parenteral nutrition is an important therapeutic goal for patients. Treatment with Zorbtive(TM) may help to achieve this."

Results from a pivotal clinical trial showed that a four-week regimen of Zorbtive(TM), Serono's brand of recombinant human growth hormone for use in SBS given in conjunction with specialized nutritional support, could significantly reduce a person's dependence on intravenous feeding as measured by total volume, total calories and frequency of infusion. Patients taking Zorbtive(TM) and a supplemented specialized diet reduced the average number of days they had to use intravenous nutrition by 4.2 days per week versus baseline, which was a significant reduction compared to the average reduction seen in the control group. Additionally, the proportion of patients who were able to completely discontinue intravenous feeding was greater among those who received Zorbtive(TM). Results persisted at the 12-week post-treatment follow-up assessment.

There are an estimated 10,000-20,000 people in the US who are receiving intravenous parenteral nutrition for SBS who could potentially benefit from Zorbtive(TM) treatment. Zorbtive(TM) was granted a seven-year orphan drug exclusivity for use in the treatment of patients with SBS by the US Food and Drug Administration.

ADDITIONAL PRODUCT INFORMATION
Zorbtive(TM) is the only drug product approved by the US Food and Drug Administration specifically for the treatment of SBS in patients receiving specialized nutritional support. Optimal management of SBS may include dietary adjustments, enteral feedings, parenteral nutrition, and fluid and micronutrient supplements, as needed. The recommended dose is 0.1 mg/kg daily up to a maximum of 8 mg per day for a treatment period of four weeks. Zorbtive(TM) is available in an 8.8 mg vial and is administered by subcutaneous injection.

The most commonly reported adverse events during the clinical trial included mild injection-site reactions, gastrointestinal disturbances, muscle and joint pain, and edema/swelling. Patients with a history of hyperglycemia or other risk factors for glucose intolerance should be monitored closely. Transient increases in glucose levels occur early in treatment and should be monitored.

Use of growth hormone is contraindicated in treatment of patients in intensive care units due to complications following open-heart surgery or abdominal surgery, multiple accidental trauma or acute respiratory failure; patients with active neoplasia; and patients with known hypersensitivity to growth hormone.

More information about Zorbtive(TM) can be found in the full prescribing information and Treatment Guideline available online at www.zorbtive.com or by calling SeroCare at 1-800-714-2437. Patients should be instructed to read the Patient Handbook and the patient package insert leaflet accompanying the product.

ABOUT SERONO

Serono, Inc., located in Rockland, MA, is the US affiliate of Serono, a global biotechnology leader, headquartered in Geneva, Switzerland. Serono has seven recombinant products, Rebif(R) (interferon beta-1a), Gonal-F(R) (follitropin alfa for injection), Luveris(R) (lutropin alfa), Ovidrel(R)/Ovitrelle(R) (choriogonadotropin alfa injection), Serostim(R) [somatropin (rDNA origin) for injection], Saizen(R) [somatropin (rDNA origin) for injection] and Zorbtive(TM) [somatropin (rDNA origin) for injection]. (Luveris(R) is not approved in the USA.)(1) In addition to being the world leader in reproductive health, Serono has strong market positions in neurology, metabolism and growth. Serono's research programs are focused on growing these businesses and on establishing new therapeutic areas. Currently, there are approximately 30 ongoing development projects.

In 2003, Serono achieved worldwide revenues of US$2,018.6 million, and a net income of US$390.0 million, making it the third largest biotech company in the world. Its products are sold in over 90 countries. 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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Reuters: SEO.VX / SRA.N
Bloomberg: SEO VX / SRA US

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(1) Package inserts for Serono's US marketed products are available at www.seronousa.com or by calling 1-888-275-7376.

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)

May 4, 2004 By: /s/ Francois Naef

Name: Francois Naef
Title: Secretary