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SERONO S A
Form 6-K
February 24, 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 February, 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 Form 40-F
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(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
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(If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-_____)

SERONO

INDEX
Pharmaceuticals AB

Media Release

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FOR IMMEDIATE RELEASE

SERONO AND SWEDISH BIOTECH COMPANY INDEX PHARMACEUTICALS SIGN WORLDWIDE AGREEMENT TO DEVELOP AND COMMERCIALIZE NOVEL ULCERATIVE COLITIS TREATMENT

AGREEMENT FOR NOVEL GASTROENTEROLOGY THERAPY CURRENTLY IN PHASE II

GENEVA, SWITZERLAND AND STOCKHOLM, SWEDEN - FEBRUARY 24, 2004 -

Serono (virt-x: SEO and NYSE: SRA) and InDex Pharmaceuticals AB ("InDex") announced today that they have signed an agreement under which Serono receives exclusive worldwide rights to develop and commercialize InDex' product Kappaproct(R) for the treatment of ulcerative colitis and potentially other inflammatory diseases. Kappaproct(R) is an antisense inhibitor of the p65 protein, a key activator of the pro-inflammatory NF-kappa B pathway.

Under the terms of the agreement, InDex will receive an initial fee upon the effective date of the agreement and potential milestone payments related to development progress, regulatory submissions and approvals, as well as research and development funding. If Kappaproct(R) is successfully developed and registered worldwide in at least one indication, the aggregate amount of these payments could reach USD35 million. InDex will also receive undisclosed royalties on sales of Kappaproct(R).

"Ulcerative colitis is a severe debilitating disease and represents a high unmet medical need," said Franck Latrille, Serono's Senior Executive Vice President Global Product Development. "Kappaproct(R) has the potential to be a significant breakthrough by inducing clinical remission in patients with active ulcerative colitis without compromising safety."

"As one of the world's leading biotechnology companies, Serono has an impressive track record in the development and marketing of innovative therapeutics," said Svante Rasmuson, CEO of InDex Pharmaceuticals. "We are confident that in Serono we have found a strong and committed partner for completing development of this novel approach to the treatment of ulcerative colitis".

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Kappaproct(R) is currently being tested in a Phase II clinical trial for active ulcerative colitis which will involve 150 patients. In a completed proof-of-concept, double-blind placebo-controlled clinical trial in patients with therapy-resistant inflammatory bowel disease, it was shown that the majority of these patients responded positively to a single dose of Kappaproct(R). Patients receiving Kappaproct(R) experienced only mild adverse effects.

Kappaproct(R) is being developed for the treatment of ulcerative colitis, a chronic inflammatory condition involving the large bowel. This disease mainly affects young people, with disease onset typically occurring between the ages of 20 and 30 years. The most common symptoms of ulcerative colitis are abdominal discomfort and frequent loose stools. Patients may also experience fatigue, weight loss, loss of appetite, rectal bleeding, loss of body fluids and nutrients. Severely affected patients experience fever, bloody diarrhea, nausea, and abdominal cramps. Ulcerative colitis may also cause non-intestinal problems

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such as arthritis, inflammation of the eye, liver disease and anemia. Disease management is a long-term commitment for both patient and physician, since there is currently no cure for this condition. In a majority of cases, the disease may be controlled with conventional drugs, including 5-aminosalicylic acid (5-ASA) and glucocorticosteroids. However, between 25 and 40 percent of ulcerative colitis patients are unresponsive to such treatment, and ultimately require surgical resection of the colon. Patients with long-standing ulcerative colitis disease are at considerable risk of developing colorectal cancer.

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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 April 17, 2003. 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 INDEX PHARMACEUTICALS

Index Pharmaceuticals develops antisense therapeutics and diagnostic/prognostic tools for unmet medical needs within inflammation and cancer. The company, located at Karolinska Institutet in Stockholm, was incorporated in December 2000 and has currently a staff of 26 people. Main shareholders are SEB Foretagsinvest and Life Equity Sweden.

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The company's corporate mission is to break new ground in innovative therapies and thus become a preferred R&D partner to large industry players in the biopharmaceutical area. The first product Kappaproct(R), developed for the treatment of inflammatory bowel disease, has entered into phase II clinical trials for active ulcerative colitis.

Research activities are focused on development of antisense drugs. Antisense represents an expansion of conventional pharmacology in combination with new findings within molecular biology. Consequently, a new class of drugs has been created with a different approach, but the antisense technology itself also implies a more rational design of new drugs.

FOR MORE INFORMATION, PLEASE CONTACT:

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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)

February 24, 2004

By: /s/ Allan Shaw

Name: Allan Shaw

Title: Chief Financial Officer

