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SERONO S A
Form 6-K
March 23, 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 March, 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

(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

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

SERONO

IVAX

MEDIA RELEASE

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FOR IMMEDIATE RELEASE

SERONO AND IVAX ANNOUNCE POSITIVE OUTCOME OF PHARMACOKINETIC TRIALS WITH ORAL CLADRIBINE

CLADRIBINE TARGETED TO BECOME FIRST ORAL THERAPY FOR MULTIPLE SCLEROSIS

GENEVA, SWITZERLAND, AND MIAMI, USA - MARCH 23, 2004 - Serono (virt-x: SEO and NYSE: SRA) and IVAX Corporation (AMEX: IVX and LSE: IVX.L) announced today positive results from two clinical trials with a new proprietary oral formulation of cladribine, a potential new treatment for multiple sclerosis (MS). The study results showed that the formulation of oral cladribine which has been developed by Serono and IVAX has met the targets for an orally administered product, with blood levels of cladribine in the expected therapeutic range. Efficacy studies of oral cladribine in MS patients are planned to start late 2004.

Previous Phase II and Phase III clinical trials have demonstrated the positive effect of injectable cladribine in patients with MS. In these trials, cladribine caused a dramatic reduction in new lesion development in the brain as seen on magnetic resonance imaging (MRI) scans. Patients with relapsing remitting MS receiving cladribine also experienced clinical benefits.

"As the originator of Rebif(R), a current reference treatment for multiple sclerosis, Serono has a long-term commitment to patients with multiple sclerosis", said Ernesto Bertarelli, CEO of Serono. "This is a major step in the development of the first oral disease modifying treatment for multiple sclerosis."

Dr. Phillip Frost, CEO and Chairman of IVAX commented, "We are very pleased to report the important progress which has been made with our partner Serono in the development of cladribine as a novel oral therapy for multiple sclerosis. With the successful completion of these clinical trials, another of our products advances in its clinical development."

Cladribine is being developed by Serono and IVAX under a worldwide agreement signed in October 2002.

1/3

ABOUT CLADRIBINE

Cladribine is a purine nucleoside analogue that disrupts the proliferation of certain white blood cells, particularly lymphocytes, which are involved in the pathological process of multiple sclerosis.

ABOUT MULTIPLE SCLEROSIS

Multiple sclerosis is a chronic, inflammatory condition of the nervous system and is the most common, non-traumatic, neurological disease in young adults. Multiple sclerosis affects approximately two million people worldwide. While symptoms can vary, the most common symptoms of multiple sclerosis include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of multiple sclerosis are the most common.

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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 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.

FOR IVAX

This press release contains certain forward-looking statements regarding product development efforts and product performance and other non-historical facts which are being made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements involve risks and uncertainties that cannot be predicted or quantified and, consequentially, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, among others, that development efforts for Cladribine may fail, may not achieve the expected results or effectiveness and/or may not generate data that would support the approval or marketing of this product for the indications being studied or for other indications; that IVAX' patents pertaining to this product may be invalidated or that additional patents may not be issued, and in either case may not succeed in preventing other products; and that others may develop product formulations that are superior to IVAX' formulation. In addition to the risk factors set forth above, IVAX' forward looking statements may also be adversely affected by general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, trade buying patterns, patent positions and litigation, among other things. For further details and discussion of these and other risks and uncertainties, see IVAX' Annual Report on Form 10-K and other filings with the Securities and Exchange Commission.

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2/3

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

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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 IVAX

IVAX is a multinational pharmaceutical company. The company discovers, develops, manufactures and markets branded and brand-equivalent (generic) drugs and veterinary products in the U.S. and abroad. Headquartered in Miami, Florida, IVAX has operations in over 30 countries and its products are sold in more than 80. The company is strategically focused on product diversification and geographic expansion in key pharmaceutical markets in North America; Western, Central and Eastern Europe; Latin America; and Asia. IVAX has more than 700 scientists and researchers involved in research and development.

FOR MORE INFORMATION, PLEASE CONTACT:

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3/3

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)

March 23, 2004

By: /s/ Allan Shaw

Name: Allan Shaw
Title: Chief Financial Officer

