

Edgar Filing: SERONO S A - Form 6-K

SERONO S A  
Form 6-K  
March 31, 2005

-----  
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, 2005

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-\_\_\_\_\_) \_\_\_\_\_

[GRAPHIC OMITTED]

Syntonix  
Pharmaceuticals

[GRAPHIC OMITTED]

Serono

MEDIA RELEASE

## Edgar Filing: SERONO S A - Form 6-K

FOR IMMEDIATE RELEASE  
-----

### SERONO AND SYNTONIX SIGN WORLDWIDE AGREEMENT TO DEVELOP AND COMMERCIALIZE AN INHALEABLE INTERFERON-BETA THERAPY FOR MULTIPLE SCLEROSIS

GENEVA, SWITZERLAND AND WALTHAM, MASS. - MARCH 31, 2005 Serono (virt-x: SEO and NYSE: SRA) and Syntonix Pharmaceuticals Inc. announced today that they have entered into an agreement under which Serono has licensed worldwide exclusive rights to Syntonix' Transceptor(TM) and Synfusion(TM) technologies for the development and commercialization of interferon-beta:Fc products.

Syntonix' technologies may enable the development of an interferon-beta therapy for multiple sclerosis (MS) that can be administered by inhalation. It has been demonstrated that certain Fc constructs can facilitate transport of therapeutic proteins across the lung epithelium through neonatal Fc receptor-mediated uptake. In in vivo experiments conducted by Syntonix and Serono, a proprietary interferon-beta:Fc molecule produced by Syntonix exhibited pharmacokinetic and pharmacodynamic properties that justify further development.

Serono currently markets Rebif(R), a high-dose, high-frequency interferon beta-1a therapy for relapsing forms of MS, which is administered three times weekly via subcutaneous injection. Rebif(R) is the leading treatment for MS outside the US and the fastest growing treatment for MS in the US.

"Serono has a long-term commitment to people living with multiple sclerosis, as demonstrated by our continual product enhancements and educational support services, and we are constantly investigating new therapies and improvements to current options," said Tim Wells, Head of Research of Serono. "We believe that interferon-beta:Fc represents a promising approach to enable delivery of interferon beta-1a by inhalation, and has the potential to provide an easier way to administer therapy in the future."

"Serono's commitment to multiple sclerosis combined with its global leadership in biotechnology make them an important partner for Syntonix," stated Garen Bohlin, President and CEO of Syntonix. "We are pleased that our Transceptor(TM) and SynFusion(TM) technologies have provided Serono with an opportunity to extend its already highly successful product franchise in the multiple sclerosis field."

Under the terms of the agreement, Serono will be responsible for all further development and commercialization of the product. Syntonix will receive an upfront license fee and will be eligible for development milestones and royalties upon commercialization. Additional financial terms were not disclosed.

1/3

### ABOUT SYNTONIX' SYNFISSION(TM) AND TRANCEPTOR(TM) TECHNOLOGIES

Syntonix' SynFusion technology links the Fc region of an antibody to a drug in a novel manner, resulting in active receptor-dependent uptake of these drugs. Specifically, this enables the development of longer-acting protein therapeutics by facilitating the recirculation of proteins through the FcRn pathway, delaying catabolism (the natural processes through which the body breaks down proteins) and extending their circulating half-life.

Syntonix' Transceptor technology uses the FcRn transport pathway to enable the pulmonary delivery of its novel Fc-fusion drugs. Syntonix' pulmonary drug

## Edgar Filing: SERONO S A - Form 6-K

formulations work with existing marketed inhaler devices and do not require changes to Fc fusions that are longer acting injectable drugs.

### ABOUT REBIF(R)

Rebif(R) (interferon beta-1a) is a disease-modifying drug used to treat relapsing forms of multiple sclerosis and is similar to the interferon beta protein produced by the human body. Interferon helps modulate the body's immune system, fight disease and reduce inflammation.

Rebif(R) , which was approved in Europe in 1998 and in the US in 2002, is registered in more than 80 countries worldwide. In the United States, Rebif(R) is co-marketed by Serono, Inc. and Pfizer Inc. In 2004, Rebif(R) sales amounted to US\$1.1 billion.

Rebif(R) has been proven to reduce MRI lesion activity and area(1), reduce the frequency of relapses, and delay the progression of disability. Rebif(R) is available in a 22 mcg and 44 mcg ready-to-use pre-filled syringe and can be stored at room temperature for up to 30 days if a refrigerator is not available.

Most commonly reported side effects are injection site disorders, flu-like symptoms, elevation of liver enzymes and blood cell abnormalities. Patients, especially those with depression, seizure disorders, or liver problems, should discuss treatment with Rebif(R) with their doctors.

### 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 may affect 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.

###

### 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 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 March 16, 2005. 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.

###

---

(1) The exact relationship between MRI findings and the clinical status of patients is unknown

## ABOUT SERONO

Serono is a global biotechnology leader. The Company has eight biotechnology products, Rebif(R) , Gonal-f(R) , Luveris(R) , Ovidrel(R) /Ovitrelle(R) , Serostim(R) , Saizen(R) , Zorbtive(TM) and Raptiva(R) . 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. Currently, there are approximately 30 ongoing development projects.

In 2004, Serono achieved worldwide revenues of US\$2,458.1 million, and a net income of US\$494.2 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 SYNTONIX

Syntonix is developing next generation biopharmaceuticals that enable better treatment options for patients with devastating chronic diseases such as hemophilia, anemia and autoimmune disorders. The company applies its core expertise around a critical biological pathway to enhance important existing drugs and to discover novel therapeutics. The resulting proteins, peptides and antibodies are being commercialized through internal development programs and collaborations with biotechnology and pharmaceutical partners. More information is available at [www.syntnx.com](http://www.syntnx.com).

FOR MORE INFORMATION, PLEASE CONTACT:

## SERONO

CORPORATE MEDIA RELATIONS:  
Tel: +41 22 739 36 00  
Fax: +41 22 739 30 85  
<http://www.serono.com>  
-----

CORPORATE INVESTOR RELATIONS:  
Tel: +41 22 739 36 01  
Fax: +41 22 739 30 22  
Reuters: SEO.VX / SRA.N  
Bloomberg: SEO VX / SRA US

MEDIA RELATIONS, USA:  
Tel: +1 781 681 2340  
Fax: +1 781 681 2935  
<http://www.seronusa.com>  
-----

INVESTOR RELATIONS, USA:  
Tel: +1 781 681 2552  
Fax: +1 781 681 2912

## SYNTONIX

MEDIA RELATIONS:  
Kari Lampka  
MacDougall Biomedical  
Communications  
Tel: +1 508 647 0209  
[klampka@macbiocom.com](mailto:klampka@macbiocom.com)

CORPORATE AND INVESTOR RELATIONS:  
Garen Bohlin  
Chief Executive Officer  
Tel: +1 781 547 5248  
<http://www.syntnx.com>  
-----

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 31, 2005

By: /s/ Stuart Grant

-----  
Name: Stuart Grant

Title: Chief Financial Officer