

Edgar Filing: SERONO S A - Form 6-K

SERONO S A
Form 6-K
October 05, 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 October, 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 Omitted] serono

MEDIA RELEASE

Edgar Filing: SERONO S A - Form 6-K

FOR IMMEDIATE RELEASE

SERONO LAUNCHES RAPTIVA(R) AS THE FIRST BIOLOGICAL TREATMENT FOR PSORIASIS LAUNCHED IN THE EUROPEAN UNION

"Germany takes the lead in psoriasis treatment," says leading dermatologist
MUNCHEN, DEUTSCHLAND - OCTOBER 5, 2004 - Serono announced today that it has
launched Raptiva(R) (efalizumab) in Germany, making it the first biological
treatment for moderate-to-severe chronic plaque psoriasis in the European Union.

Raptiva, which can be self-injected by patients just once-weekly, selectively
targets the T-cells; that are now known to be involved in the development of
psoriasis symptoms. Many experts believe this to be a major advance on current
treatments. Many of these current treatments have limiting side effects, can be
inconvenient and difficult for patients to comply with.

According to Prof. Jorg Prinz, Clinic of Dermatology, Venereology and
Allergology at the University of Munich, new treatments will "give people with
psoriasis exciting new hope for the future."

"Based on current knowledge biological treatments such as Raptiva(R) offer
psoriasis patients improved therapies that will be easier to manage and will
provide effective and safe, long-term control of their condition," he added.

This view was supported by Horst von Zitzewitz, President of the Deutscher
Psoriasis Bund, Germany's leading Psoriasis Association* "We have long sought
better treatments which have a favorable safety profile and can easily be
integrated into a patient's life," he said. "Now with biological treatments like
Raptiva we will have a treatment option which will give long-term sufferers,
especially those who cannot be satisfied with current treatments, a chance to
live a more normal life."

Serono has set up a free call number for patients wanting to know more about the
disease and its treatment on 0800 7278482 (0800 RAPTIVA), as well as a website
at www.psoriasis-konkret.de. Serono will launch throughout the European Union

by the end of 2005.

* (For more information you can visit the psoriasis-homepage:
www.psoriasis-bund.de)

1/3

ABOUT RAPTIVA(R)

Raptiva(R) is a humanized therapeutic antibody designed to selectively and
reversibly block the activation, reactivation and trafficking of T-cells that
lead to the development of psoriasis symptoms. Raptiva is designed to be
administered once weekly via subcutaneous injection and can be self-administered
by patients at home after training by a healthcare professional.

Raptiva received EU approval for the 'Treatment of adult patients with moderate
to severe chronic plaque psoriasis who have failed to respond to, or who have a
contraindication to, or are intolerant to other systemic therapies including
cyclosporine, methotrexate and PUVA'.

Serono has already launched Raptiva(R) in Switzerland and Argentina, has

Edgar Filing: SERONO S A - Form 6-K

recently received approval in Mexico, Brazil and Australia. Raptiva(R) has also been available since November 2003 in the U.S., where it is marketed by Genentech for the treatment of moderate to severe chronic plaque psoriasis in adults aged 18 or older who are candidates for systemic therapy or phototherapy.

Serono has the rights to develop and market Raptiva worldwide outside of the United States and Japan. Development and marketing rights in the United States remain with Genentech Inc. (NYSE:DNA) and its U.S. partner XOMA (Nasdaq: XOMA).

More than 3,500 patients in the U.S. and Europe have been included in Raptiva trials to date, creating the largest existing database of patients taking part in studies with a biological therapy for psoriasis, with about 200 of these treated continuously for more than 2-and-a-half years.

Adverse events observed with Raptiva include headache, non-specific infection (e.g., common colds), chills, pain, nausea, asthenia (weakness), and fever, all of which diminished after the first 1-2 doses. Further, there was no evidence of accumulation or cumulative toxicity. At 30-months, the occurrence of serious adverse events was infrequent which is consistent with data from previous Raptiva Phase III studies.

ABOUT PSORIASIS

Psoriasis is a T-cell mediated disease which occurs when skin cells grow abnormally, resulting in thick, red, scaly, inflamed patches. Plaque psoriasis, the most common form of the disease is characterized by inflamed patches of skin ("lesions") topped with silvery white scales. Psoriasis can be limited to a few spots or involve extensive areas of the body, appearing most commonly on the scalp, knees, elbows and trunk. Although it is highly visible, psoriasis is not a contagious disease. While there are a number of medications that may help control the symptoms of psoriasis, there currently is no known cure.

BACKGROUND MATERIAL

For free B-roll, video and other content about Raptiva, psoriasis and Serono, 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(R), Gonal-F(R), Luveris(R), Ovidrel(R)/Ovitrelle(R), Serostim(R), Saizen(R), Zorbtive(TM) and Raptiva(R) (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 and has recently entered the psoriasis area. 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).

2/3

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

Edgar Filing: SERONO S A - Form 6-K

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 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.

###

FOR MORE INFORMATION, PLEASE CONTACT:

| | |
|----------------------------|-------------------------------|
| CORPORATE MEDIA RELATIONS: | CORPORATE INVESTOR RELATIONS: |
| Tel: +41 22 739 36 00 | Tel: +41 22 739 36 01 |
| Fax: +41 22 739 30 85 | Fax: +41 22 739 30 22 |
| www.serono.com | Reuters: SEO.VX / SRA.N |

Bloomberg: SEO VX / SRA US
INVESTOR RELATIONS, USA
Tel: +1 781 681 2552
Fax: +1 781 681 2912

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)

October 5, 2004

By: /s/ Francois Naef

Name: Francois Naef
Title: Secretary