

Edgar Filing: SERONO S A - Form 6-K

SERONO S A  
Form 6-K  
January 10, 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 January, 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 X  
    ---    -----

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

SERONO

MEDIA RELEASE

FOR IMMEDIATE RELEASE

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

-----  
SERONO ANNOUNCES THE AVAILABILITY OF SAIZEN(R) FOR ADULT GROWTH HORMONE  
DEFICIENCY (AGHD) IN THE UNITED STATES

NEEDLE-FREE DELIVERY OPTION EXCLUSIVE TO SAIZEN(R) AVAILABLE FOR PATIENTS

GENEVA, SWITZERLAND AND ROCKLAND, MA, JANUARY 10, 2005 - Serono Inc., the US affiliate of Serono (virt-x: SEO and NYSE: SRA), announced today the availability of Saizen(R) [somatropin (rDNA origin) for injection] for use in the treatment of patients with adult growth hormone deficiency (AGHD), following its FDA approval.

"This new indication for Saizen(R) represents the evolution of our growth hormone portfolio and further demonstrates our commitment to the metabolic franchise," said James Sapirstein, executive vice president of Metabolic Endocrinology at Serono, Inc. "Patients with AGHD who are treated with Saizen(R) therapy can use our easy-to-use drug delivery devices such as cool.click(R), a needle-free device that is preferred by pediatric patients and is now available for use by adults taking Saizen(R)."

Adult Growth Hormone Deficiency (AGHD) can be effectively treated with Saizen(R). With the U.S. approval, patients who were growth hormone deficient during childhood and have growth hormone deficiency as an adult, may continue to use Saizen(R). In addition, adult patients who have adult onset growth hormone deficiency either alone, or associated with multiple hormone deficiencies, now have access to Saizen(R) and its line of devices.

Saizen(R) can be administered using a needle-free device, cool.click(R), the only FDA approved needle-free device for the administration of growth hormone. It can also be administered with a recently launched autoinjector pen device, one.click(R), or by traditional needle and syringe. Serono's portfolio of innovative devices gives patients the choice they want in growth hormone delivery.

Patients can learn more about Saizen(R) and Serono's growth hormone delivery devices by talking with their physician, or by calling Serono Connections for Growth(R) toll-free at 1-800-582-7989. The full prescribing information for Saizen(R) can be found online at [www.seronusa.com](http://www.seronusa.com).

-----  
**About Adult Growth Hormone Deficiency (AGHD)**

Growth hormone deficiency can be a significant problem for adults even though they no longer get taller. AGHD is recognized as a specific clinical syndrome with numerous physiological consequences, with effects on:

- Changes in body composition, including central obesity;
- Lipids in the blood;
- Muscle strength;
- Bone composition;
- Exercise capacity and energy;
- Cardiovascular risk; and
- Psychological well-being (social isolation and depression).

There are also studies indicating that patients with AGHD have an increased risk of mortality from cardiovascular disease, possibly attributable to their growth hormone (GH) deficiency.

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

GH deficiency in adults can result from a pituitary or peri-pituitary tumor or as a direct result of the surgery/radiation used to manage these conditions. Less commonly, GH deficiency in adults arises from a deficiency acquired in childhood.

### ABOUT SAIZEN(R)

Saizen(R) [somatropin (rDNA origin) for injection] is a human growth hormone produced by recombinant DNA technology. The recommended dose for adults at the start of therapy is .005 mg/kg daily. The dosage may be increased to not more than .01 mg/kg daily after four weeks depending upon the patient's tolerance of treatment.

Saizen(R) is indicated for the long-term treatment of children with growth failure due to inadequate secretion of endogenous growth hormone. It is indicated for replacement of endogenous growth hormone in adults with growth hormone deficiency that meets the criteria of adult onset or childhood onset.

In patients with AGHD, the most common adverse events with associated growth hormone therapy are joint and muscle pain, edema, carpal tunnel syndrome, and tingling.

Growth hormone should be used with caution in patients with insulin resistance, glucose intolerance, diabetes, hypothyroidism, intracranial hypertension, and in women who are pregnant or nursing. GH should not be used in patients with Prader-Willi syndrome who are severely obese or have severe respiratory impairment; in the presence of active neoplasia; and in patients with proliferative or preproliferative diabetic retinopathy; or in patients hospitalized with acute critical illnesses.

Full prescribing information for Saizen(R), including important safety information, is available at [www.seronusa.com](http://www.seronusa.com).

-----

### ABOUT SERONO CONNECTIONS FOR GROWTH(R)

Connections for Growth(R) provides reimbursement support and educational materials for practitioners and families. They offer educational materials, reconstitution and dosage information, reimbursement support, access to cool.click(R) supplies, and contact information for local nurses in the Serono Nurse Network.

###

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 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

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

update the forward-looking statements contained in this press release to reflect events or circumstances occurring after the date of this press release.

###

### 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), Zorbitive(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. 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).

FOR MORE INFORMATION, PLEASE CONTACT:

### SERONO, GENEVA, SWITZERLAND:

#### MEDIA RELATIONS:

Tel: +41-22-739 36 00

Fax: +41-22-739 3085

<http://www.serono.com>

-----

#### INVESTOR RELATIONS:

Tel: +41-22-739 36 01

Fax: +41-22-739 30 22

Reuters: SEO.VS/SRA.N

Bloomberg: SEO VX/SRA US

### SERONO, INC., ROCKLAND, MA

#### MEDIA RELATIONS:

Stacie Madden

Tel: +1 781 681 2496

[stacie.madden@serono.com](mailto:stacie.madden@serono.com)

-----

#### INVESTOR RELATIONS:

Tel: +1 781 681 2552

Fax: +1 781 681 2912

### 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)

January 10, 2005

By: /s/ Stuart Grant

-----  
Name: Stuart Grant

Title: Chief Financial Officer

