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SERONO S A
Form 6-K
November 13, 2002

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 November, 2002

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

AMGEN

MEDIA RELEASE

FOR IMMEDIATE RELEASE

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SERONO AND AMGEN SIGN LICENSE AGREEMENT FOR MULTIPLE SCLEROSIS PRODUCT

THOUSAND OAKS, CALIFORNIA, USA AND GENEVA, SWITZERLAND - NOVEMBER 13, 2002 - Amgen Inc. (NASDAQ:AMGN) and Serono S.A. (virt-x: SEO and NYSE: SRA). Amgen and Serono announced today that they have signed a license and commercialization agreement by which Serono will sell the marketed drug Novantrone (mitoxantrone for injection concentrate) in the United States. Novantrone is approved by the FDA in the United States for secondary progressive, progressive relapsing and worsening relapsing-remitting multiple sclerosis, as well as for certain forms of cancer in the United States. The terms were undisclosed.

Novantrone was acquired by Amgen in connection with Amgen's acquisition of Immunex Corporation in July 2002. The drug was approved by the FDA for MS indications in October, 2000, and had US sales of \$71 million last year. It has also been approved for certain oncology indications since 1987. Full prescribing information for Novantrone can be obtained by visiting www.novantrone.com.

Closing of the transaction is subject to review and clearance by U.S. regulatory authorities.

Amgen is a global biotechnology company that discovers, develops, manufactures and markets important human therapeutics based on advances in cellular and molecular biology. Serono is a global biotechnology leader with six recombinant products on the market, Gonal-F, Luveris, Ovidrel /Ovitrelle, Rebif, Serostim and Saizen (somatropin). (Luveris is not approved in the USA).

This news release contains forward-looking statements that involve significant risks and uncertainties, including the possibility that the license transaction will not close or that the companies may be required to modify aspects of the transaction to achieve regulatory approval, and other risks and uncertainties including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including its most recent Form 10-Q. Amgen conducts research in the biotechnology/pharmaceutical field where movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. In addition, sales of our products are affected by reimbursement policies imposed by third party payors, including governments, private insurance plans and managed care providers. These government regulations and reimbursement policies may affect the development, usage and pricing of our products.

In addition, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors. Because forward-looking statements involve risks and uncertainties, actual results may differ materially from current results expected by Amgen. Amgen is providing this information as of November 13, 2002 and expressly disclaims any duty to update information contained in this press release.

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

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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 May 21 2002. 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.

CONTACT:

Amgen Inc.
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Serono, Inc.
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Europe: 41-22-739 36 00 (media)
 41-22-739 36 01 (investor relations)
www.serono.com

EDITOR'S NOTE: An electronic version of this news release may be accessed via our web site at www.amgen.com. Visit the Corporate Center and click on Amgen News. Journalists and media representative may sign up to receive all news releases electronically at the time of announcement by filling out a short form in the Amgen News section of the site.

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)

November 13, 2002

By: /s/ Jacques Theurillat

Name: Jacques Theurillat
Title: Deputy Chief Executive Officer