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SERONO S A
Form 6-K
August 18, 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 August, 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
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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-)

GENMAB

SERONO

MEDIA RELEASE

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FOR IMMEDIATE RELEASE

SERONO AND GENMAB ANNOUNCE GLOBAL DEVELOPMENT AND COMMERCIALIZATION AGREEMENT FOR HUMAX-CD4

HuMax-CD4 currently in Phase III Clinical Trial for Cutaneous T-Cell Lymphoma
and Phase II Clinical Trial for Non-Cutaneous T-Cell Lymphoma

GENEVA, SWITZERLAND AND COPENHAGEN, DENMARK - AUGUST 18, 2005 -
Serono (virt-x: SEO and NYSE: SRA) and Genmab A/S (CSE: GEN) announced today an agreement under which Genmab has granted Serono exclusive worldwide rights to develop and commercialize Genmab's HuMax-CD4. HuMax-CD4 is a fully human monoclonal antibody in development for the treatment of cutaneous and non-cutaneous T-cell lymphomas. It is currently being evaluated in a pivotal Phase III clinical trial for cutaneous T-cell lymphoma (CTCL) under the US Food and Drug Administration's Special Protocol Assessment process and has Fast Track designation from the FDA. HuMax-CD4 is also being studied in a Phase II trial for non-cutaneous T-cell lymphoma (NCTCL). HuMax-CD4 is directed against the CD4 antigen and causes depletion of certain T-cells through antibody-dependent cellular cytotoxicity.

Under the terms of the agreement, Genmab will receive a license fee of USD 20 million, and Serono will make a USD 50 million investment in Genmab common stock, at a premium to the market price. Genmab may receive up to USD 215 million in total payments, including the initial license fee and equity purchase, milestone payments for regulatory submissions and approvals of HuMax-CD4 in CTCL and NCTCL in the US, Europe and Japan, and payments based on the achievement of certain sales milestones. Genmab will be entitled to receive royalties on global sales of HuMax-CD4. Serono will be responsible for all future development costs for HuMax-CD4 and for future manufacturing of the product. Genmab will continue to conduct the ongoing clinical trials as described above.

"Serono's proficiency in bringing biotechnology products to market as well as their established presence in highly specialized dermatology clinics, which play a significant role in the diagnosis and treatment of CTCL, makes the company an excellent strategic partner," said Lisa N. Drakeman, Ph.D., Chief Executive Officer of Genmab.

"We are committed to building a strong oncology pipeline through partnerships with leading companies such as Genmab, and through our own internal research," said Ernesto Bertarelli, Chief Executive Officer of Serono. "HuMax-CD4 is an important addition to Serono's oncology portfolio, which now consists of four different clinical-stage products being investigated across a broad range of indications."

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Simultaneously with this release, Genmab will publish a separate stock exchange release containing more information regarding the placement of Genmab shares to Serono, which is made in direct connection with the Global Development and Commercialization Agreement regarding HuMax-CD4.

ABOUT CTCL AND NCTCL -----

Cutaneous T-cell lymphomas (CTCL) are a group of lymphomas characterized by

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abnormal accumulation of malignant T-cells in the skin, potentially resulting in the development of rashes, plaques and tumors. The most common types of CTCL include mycosis fungoides (MF) and Sezary syndrome (SS). CTCL result from errors in the production of T-lymphocytes or transformation of T-lymphocytes into malignant cells. Abnormal, uncontrolled growth and multiplication of malignant T-lymphocytes result in accumulation of these lymphocytes in the skin and may in some cases spread and affect the lymph nodes and other body tissues and organs, resulting in life-threatening complications.

Non-cutaneous T-cell lymphomas (NCTCL) are defined by highly malignant disease, which has localized to the lymph nodes even at the earliest stage of presentation, and include angioimmunoblastic T-cell lymphoma, anaplastic large cell lymphoma (ALCL) and unspecified peripheral T-cell lymphoma. NCTCL is characterized by aggressive progression with average survival time of approximately two years.

ABOUT HUMAX-CD4 (ZANOLIMUMAB)

HuMax-CD4 is a human monoclonal antibody currently in Phase III development for cutaneous T-cell lymphoma (CTCL) and in Phase II for non-cutaneous T-cell lymphoma. These types of lymphomas express the CD4 receptor, which is the target of HuMax-CD4. In April 2005, Genmab and the United States Food and Drug Administration (FDA) reached an agreement on the design of its pivotal study protocol for HuMax-CD4 to treat CTCL under the Special Protocol Assessment process (SPA). The pivotal study will include patients with mycosis fungoides (MF) who are refractory to or intolerant of Targretin(R) and one other standard therapy, and will treat a total of 88 patients.

In March 2004, Genmab announced that HuMax-CD4 had been designated a Fast Track Product by the US Food and Drug Administration (FDA). This designation covers patients with CTCL for whom no available therapy exists, i.e. have failed at least two systemic treatment regimens. HuMax-CD4 for the treatment of MF has also been granted Orphan Drug status in the US and Europe.

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GENMAB FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements. The words "believe", "expect", "anticipate", "intend" and "plan" and similar expressions identify forward looking statements. Actual results or performance may differ materially from any future results or performance expressed or implied by such statements. The important factors that could cause our actual results or performance to differ materially include, among others, risks associated with product discovery and development, uncertainties related to the outcome and conduct of clinical trials including unforeseen safety issues, uncertainties related to product manufacturing, the lack of market acceptance of our products, our inability to manage growth, the competitive environment in relation to our business area and markets, our inability to attract and retain suitably qualified personnel, the unenforceability or lack of protection of our patents and proprietary rights, our relationships with affiliated entities, changes and developments in technology which may render our products obsolete, and other factors. Genmab is not under an obligation to up-date statements regarding the future following the publication of this release; nor to confirm such statements in relation to actual results, unless this is required by law.

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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, the outcome of government investigations and litigation 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.

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ABOUT GENMAB A/S

Genmab A/S is a biotechnology company that creates and develops human antibodies for the treatment of life-threatening and debilitating diseases. Genmab has numerous products in development to treat cancer, infectious disease, rheumatoid arthritis and other inflammatory conditions, and intends to continue assembling a broad portfolio of new therapeutic products. At present, Genmab has multiple partnerships to gain access to disease targets and develop novel human antibodies including agreements with Roche and Amgen. A broad alliance provides Genmab with access to Medarex, Inc.'s array of proprietary technologies, including the UltiMab(R) platform for the rapid creation and development of human antibodies to virtually any disease target. Genmab has operations in Copenhagen, Denmark, Utrecht, the Netherlands, and Princeton, New Jersey in the US. For more information about Genmab, visit www.genmab.com.

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).

FOR MORE INFORMATION, PLEASE CONTACT:
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GENMAB

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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)

August 18, 2005

By: /s/ Stuart Grant

Name: Stuart Grant
Title: Chief Financial Officer