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SERONO S A
Form 6-K
May 16, 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 May, 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]
SERONO

BIOMARIN

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MEDIA RELEASE

FOR IMMEDIATE RELEASE

BIOMARIN AND SERONO FORM STRATEGIC ALLIANCE FOR
THE DEVELOPMENT AND COMMERCIALIZATION OF PHENOPTIN(TM) AND PHENYLASE(TM)

PHENOPTIN CURRENTLY IN PHASE 3 TRIALS

NOVATO, CALIFORNIA, AND GENEVA, SWITZERLAND, MAY 16, 2005 - BioMarin Pharmaceutical Inc. (Nasdaq and SWX: BMRN) and Serono (virt-x: SEO and NYSE: SRA) announced today that they have formed a strategic alliance for the further development and commercialization of two BioMarin product candidates, Phenoptin (sapropterin hydrochloride) and Phenylase (phenylalanine ammonia lyase). Both products have shown potential in the treatment of phenylketonuria (PKU), and there is preliminary clinical evidence that suggests that the active ingredient in Phenoptin, a synthetic form of the naturally occurring enzyme cofactor 6R-BH4, may also be useful in the treatment of other serious diseases, including diabetes and cardiovascular diseases.

By the terms of their agreement, Serono acquires exclusive rights to market the products in all territories outside the United States and Japan. BioMarin retains exclusive rights to market the products in the United States. Serono will make an upfront payment of \$25 million to BioMarin, and will make additional milestone payments of up to \$232 million based on the successful development and registration of both products in multiple indications, of which \$45 million are associated specifically with Phenoptin in PKU. Serono will also pay BioMarin undisclosed royalties on its net sales of the products. The companies will share equally all development costs following successful completion of Phase 2 trials for each product candidate in each indication.

BioMarin is currently investigating Phenoptin, an orally administered product, in a Phase 3 clinical trial for the treatment of PKU. PKU is an inherited metabolic disease caused by a deficiency of the enzyme phenylalanine hydroxylase, resulting in elevated levels of phenylalanine in the blood, which can result in serious neurological damage. There is currently no approved drug to treat PKU, which affects at least 50,000 diagnosed patients under the age of 40 worldwide. Phenylase, an enzyme substitution therapy for the treatment of severe forms of PKU, is currently in preclinical development.

Emil Kakkis MD, PhD, Senior Vice President of Business Operations at BioMarin commented, "We are very pleased to enter into this partnership with Serono, a top-tier biotechnology company with strong global development capabilities and commercial operations. Serono's expertise in developing and marketing novel products for metabolic and genetic diseases will be an invaluable asset for this partnership."

"We are delighted to partner with BioMarin for the further development and commercialization of Phenoptin and Phenylase, products that fit very nicely into our metabolic endocrinology franchise," said Franck Latrille, Senior Executive Vice President Global Product Development at Serono. "PKU is a severely debilitating condition afflicting patients from birth and throughout their lives. Serono's strategy is to invest in bringing to market innovative products like Phenoptin and Phenylase that address significant unmet medical needs."

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ABOUT BIOMARIN

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BioMarin develops and commercializes innovative biopharmaceuticals for serious diseases and medical conditions. The company's product portfolio is comprised of two approved products, Aldurazyme(R) (laronidase) for mucopolysaccharidosis I (MPS I), and Orapred(R) (prednisolone sodium phosphate oral solution) for severe asthma, and multiple product candidates including rhASB (galsulfase), a BLA/MAA-stage product candidate for the treatment of mucopolysaccharidosis VI (MPS VI), and Phenoptin(TM) (sapropterin hydrochloride), a Phase 3 product candidate for the treatment of phenylketonuria (PKU). For additional information, please visit www.BMRN.com. Information on BioMarin's website is

not incorporated by reference into 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), 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).

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FORWARD-LOOKING STATEMENTS

FOR BIOMARIN

This press release contains forward-looking statements about the business prospects of BioMarin Pharmaceutical Inc., including, without limitation, statements about: the development of its product candidates Phenoptin and Phenylase; expectations related to the possible use of Phenoptin for the treatment of indications other than PKU; and the possible milestone revenue from development of these product candidates. These forward-looking statements are predictions and involve risks and uncertainties such that actual results may differ materially from these statements. These risks and uncertainties include, among others: the results of preclinical and clinical trials related to Phenoptin and Phenylase, both for the treatment of PKU and for indications other than PKU; results and timing of current and planned clinical trials of Phenoptin for the treatment of PKU; the content and timing of decisions by the U.S. Food and Drug Administration, the European Medicines Agency and other regulatory authorities concerning Phenoptin and Phenylase; the ability to develop suitable formulations of Phenylase; the ability to develop commercial scale manufacturing for Phenoptin and Phenylase; and those factors detailed in BioMarin's filings with the Securities and Exchange Commission, including, without limitation, the factors contained under the caption "Factors That May Affect Future Results" in BioMarin's 2004 Annual Report on Form 10-K and the factors contained in BioMarin's reports on Forms 10-Q and 8-K. Stockholders are urged not to place undue reliance on forward-looking statements, which speak only as of the date hereof. BioMarin is under no obligation, and expressly disclaims any obligation, to update or alter any forward

FOR SERONO

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

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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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Aldurazyme(R) is a registered trademark of BioMarin/Genzyme LLC. Orapred(R) is a registered trademark of Medicis Pediatrics, Inc., and is used under license.

CONTACTS:

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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)

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May 16, 2005

By: /s/ Stuart Grant

Name: Stuart Grant

Title: Chief Financial Officer