SERONO S A
Form 6-K
March 23, 2006

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of March

Commission File Number 1-15096

Serono S.A.

(Translation of registrant s name into English)

15 bis, Chemin des Mines
Case Postale 54
CH-1211 Geneva 20
Switzerland

(Address of principal executive office)

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 ýForm 40-F o

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 o No ý

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

Media Release

FOR IMMEDIATE RELEASE

BIOMARIN AND SERONO ANNOUNCE POSITIVE RESULTS FROM PHASE 3 CLINICAL STUDY OF PHENOPTIN FOR PKU

All Primary and Secondary Endpoints Met

BioMarin to Hold Conference Call and Webcast Today at 4:30 p.m. ET (22:30 CET)

Novato, California, and Geneva, Switzerland, March 15, 2006 BioMarin Pharmaceutical Inc. (Nasdaq and SWX: BMRN) and Serono (virt-x: SEO and NYSE: SRA) announced today positive results of a Phase 3, double-blind, placebo-controlled clinical study of Phenoptin (sapropterin dihydrochloride), an investigational oral small molecule for the treatment of phenylketonuria (PKU). Results confirm that all pre-specified primary and secondary endpoints were met and data from the Phase 3 study demonstrate a statistically significant reduction at six weeks in blood phenylalanine (Phe) levels ($p<0.0001$) in patients receiving Phenoptin, compared with those receiving placebo.

Emil Kakkis, M.D., Ph.D., Chief Medical Officer of BioMarin stated, This is an exciting day for PKU patients worldwide as a simple oral treatment that could potentially help them reach their treatment goals is now one step closer to becoming a reality. For many patients with genetic diseases, not enough has been done to push forward important new treatments, and we are particularly happy to be able to collaborate with the numerous clinicians and investigators worldwide who have worked on tetrahydrobiopterin and transform their hard work into what could become the first approved drug therapy for this disease.

Susan Herbert, Ph.D., Corporate Vice President, Head of Reproductive Health and Metabolic Endocrinology Global Product Development at Serono commented, These encouraging results represent an important milestone in Serono s strategy to bring to market novel treatments for serious metabolic diseases. PKU is a rare condition that can be severely debilitating. Phenoptin has the potential to offer patients hope for the successful, long-term management of this disease.

The study enrolled 89 patients with elevated blood Phe levels aged eight years and above at 29 sites in the United States, Europe and Canada. All patients had demonstrated a reduction in blood Phe levels (approximately 30 percent or more) following treatment with Phenoptin in a Phase 2 screening study.

The patients were randomly assigned to receive placebo or 10 mg/kg of Phenoptin daily for six weeks. Patients were evaluated every two weeks for changes in blood Phe levels and adverse events. The primary endpoint of the study was the difference in mean blood Phe levels between the placebo and Phenoptin groups at Week 6, adjusted for baseline levels. A total of 87 patients completed six weeks of treatment.

Following the six-week double-blind study, patients were eligible to enroll into an on-going 22 week Phase 3 open-label extension study designed to further evaluate the long-term safety and efficacy of Phenoptin, as well as dose titration. BioMarin and Serono expect to file marketing authorization applications for Phenoptin for PKU in the United States and European Union in 2007. BioMarin has licensed to Serono exclusive rights for Phenoptin outside of the United States and Japan.

Results from the Phase 3 double-blind study are summarized below:

Primary Endpoint

Patients treated with Phenoptin for six weeks had a mean decrease in blood Phe level of 236 µM (29 percent) compared to a mean increase of 3 µM (3 percent) in the placebo group ($p<0.0001$). Prior to treatment, patients in the Phenoptin group and placebo group had mean blood Phe levels of 843 µM and 888 µM, respectively.

Secondary Endpoints

At Week 6, the percentage of patients in the Phenoptin group with blood Phe levels less than or equal to 600 µM was 54 percent compared to 23 percent in the placebo group ($p=0.004$). At baseline the proportions were 17 percent and 19 percent for the Phenoptin and placebo groups, respectively.

The mean blood Phe level at each visit among patients receiving Phenoptin showed a consistent reduction compared to the blood Phe levels in patients receiving placebo ($p<0.001$) throughout the six-week period.

The type and incidence of adverse events was similar in the Phenoptin and placebo groups. Phenoptin was well tolerated and investigators reported that no serious adverse event occurred.

About Phenoptin

Phenoptin is an investigational oral small molecule therapeutic for the treatment of PKU. The active ingredient in Phenoptin, sapropterin dihydrochloride, is the synthetic form of 6R-BH4 (tetrahydrobiopterin), a naturally occurring enzyme cofactor that works in conjunction with phenylalanine hydroxylase (PAH) to metabolize Phe. Preliminary clinical data have suggested that Phenoptin has a potential to produce significant reductions in blood Phe levels in the subset of patients who are BH4-responsive. BioMarin and Serono estimate that Phenoptin could be a potential treatment option for approximately 30 percent to 50 percent of the estimated 50,000 individuals in the developed world who have been diagnosed with PKU.

Phenoptin received orphan drug designation to treat PKU from both the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMEA). If Phenoptin becomes the first drug therapy approved for the treatment of PKU, Phenoptin would receive seven years of market exclusivity in the United States and 10 years in the European Union for this indication. Additionally, the FDA has granted Phenoptin Fast Track designation, which is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs.

About PKU

PKU, a genetic disorder affecting approximately 50,000 diagnosed patients in the developed world, is caused by a deficiency of the enzyme phenylalanine hydroxylase (PAH). PAH is required for the metabolism of phenylalanine (Phe), an essential amino acid found in most protein-containing foods. If the active enzyme is not present in sufficient quantities, Phe accumulates to abnormally high levels in the blood and brain, resulting in a variety of complications including severe mental retardation and brain damage, mental illness, seizures and tremors, and cognitive problems. As a result of global newborn screening efforts implemented in the 1960s and early 1970s, virtually all PKU patients in developed countries have been diagnosed at birth. The only treatment currently available for PKU patients is a highly restrictive and expensive medical food diet that most patients fail to adhere to the extent needed for achieving adequate control of blood Phe levels. To learn more about PKU, please visit www.PKU.com. Information on this website is not incorporated by reference into this press release.

Conference Call and Webcast Scheduled for Today, March 15 at 4:30 p.m. ET (22:30 CET)

BioMarin will host a conference call and webcast to discuss today s announcement. This event can be accessed on the investor section of the BioMarin website at www.BMRN.com.

Date: March 15, 2006

Time: 4:30 p.m. ET (22:30 CET)

U.S. & Canada Toll-free Dial in #: 800.299.0148

International Dial in #: 617.801.9711

Participant Code: 44460826

Replay Toll-free Dial in #: 888.286.8010

Replay International Dial in #: 617.801.6888

Replay Code: 56350669

About BioMarin

BioMarin develops and commercializes innovative biopharmaceuticals for serious diseases and medical conditions. The company s product portfolio is comprised of three approved products and multiple clinical and preclinical product candidates. Approved products include Naglazyme (galsulfase) for mucopolysaccharidosis VI (MPS VI), a product wholly developed and commercialized by BioMarin, Aldurazyme® (laronidase) for mucopolysaccharidosis I (MPS I), and Orapred® (prednisolone sodium phosphate oral solution) for inflammatory conditions. Investigational product candidates include Phenoptin (sapropterin dihydrochloride), 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.

Aldurazyme® is a registered trademark of BioMarin/Genzyme LLC.

Orapred® is a registered trademark of Medicis Pediatrics, Inc., and is used under license.

About Serono

Serono is a global biotechnology leader. The Company has eight biotechnology products, Rebif®, Gonal-f®, Luveris®, Ovidrel®/Ovitrelle®, Serostim®, Saizen®, Zorbtive and Raptiva®. 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 and autoimmune diseases. Currently, there are more than 25 on-going development projects.

In 2005, Serono, whose products are sold in over 90 countries, achieved worldwide revenues of US$2,586.4 million. Reported net loss in 2005 was US$106.1 million, reflecting a charge of US$725 million taken relating to the settlement of the US Attorney s Office investigation of Serostim. Excluding this charge as well as other non-recurring items, adjusted net income grew 28.4% to US$565.3 million in 2005. 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).

Background Material

For free B-roll, video and other content Serono and its products, 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.

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 candidate Phenoptin; the final results of the data from the Phase 3 trial of Phenoptin; and expectations regarding filings with regulatory agencies. 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; 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; the conclusion of the final data analysis of the Phase 3 trial of Phenoptin; and those factors detailed in BioMarin s filings with the Securities and Exchange Commission, including, without limitation, the factors contained under the caption Risk Factors in BioMarin s 2005 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-looking statements.

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 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 February 28, 2006. 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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Contacts:

For BioMarin:

Investors ***Media***

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SIGNATURE

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)

Date March 22, 2006

By: /s/ Stuart Grant
Name: Stuart Grant
Title: Chief Financial Officer