SERONO S A
Form 6-K
September 12, 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 September

Commission File Number 1-15096

Serono S.A.

(Translation of registrant s name into English)

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(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 x Form 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): 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)(7): o

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 x

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 Data on Phenoptin in PKU to be Presented at the 56th Annual Meeting of the American Society of Human Genetics

Novato, California, and Geneva, Switzerland, September 12, 2006 BioMarin Pharmaceutical Inc. (Nasdaq and SWX: BMRN) and Serono (virt-x: SEO and NYSE: SRA) today announced data from clinical studies of Phenoptin (sapropterin dihydrochloride), an investigational oral small-molecule therapeutic for the treatment of phenylketonuria (PKU), that will presented at the 56th Annual Meeting of the American Society of Human Genetics (ASHG) being held in New Orleans, Louisiana, October 9 to 13, 2006. Data to be presented is summarized below.

ASHG Program # 57: Phase 3 Clinical Study of Phenoptin for PKU

Results from the Phase 3, double-blind, placebo-controlled clinical study of Phenoptin (commonly referred to as 6R-BH4, or BH4) in patients with elevated blood phenylalanine (Phe) levels demonstrated a statistically significant reduction at six weeks in blood Phe levels ($p<0.0001$) in patients receiving 10 mg/kg/day of Phenoptin, compared with those receiving placebo. 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. A summary of the data from this trial was previously announced in a press release issued March 15, 2006. Following the six-week, double-blind study, patients were enrolled into a 22-week, Phase 3 open-label extension study, which is currently ongoing. This study is designed to further evaluate the long-term safety and efficacy of Phenoptin, as well as dose titration.

These data will be presented by Harvey Levy, M.D., of Children s Hospital of Boston, Boston, Massachusetts, in an oral presentation scheduled for October 11, 2006.

ASHG Program # 2332/C : Phase 2 Screening Study of Phenoptin for PKU

Results from the Phase 2 screening study conducted to identify appropriate patients for inclusion in the Phase 3, double-blind, placebo-controlled study of PKU, demonstrate that Phenoptin was well tolerated and rapidly reduced blood Phe levels by varying degrees in PKU patients across the complete spectrum of PKU phenotypes. The majority of adverse events were mild, including headaches and gastrointestinal disorders, and all were resolved without complications and none were assessed as clinically significant.

A total of 490 patients, age 8 or older, with blood Phe levels of at least 450µM were screened to determine eligibility for inclusion into the Phase 3 study. Patients who demonstrated a 30 percent or greater reduction in blood Phe level from baseline following an 8-day course of 10 mg/kg per day of Phenoptin were eligible to enroll into the Phase 3 study. Of the 485 patients who completed the 8-day treatment course, 96 demonstrated at least a 30 percent reduction in blood Phe. The data from the Phase 2 screening study are summarized in the table below:

Baseline Phe Level (µM)	**Number of Patients with 30% Reduction in Blood Phe Following 8 days of Treatment with 10mg/kg/day of Phenoptin(1)**
450 to 600	31 of 57 (54.4%)
600 to 900	38 of 157 (24.2%)
900 to 1200	14 of 135 (10.4%)
>1200	13 of 136 (9.6%)

These data will be presented by Barbara Burton, M.D., of Children s Memorial Hospital, Northwestern University Feinberg School of Medicine, Chicago, Illinois, at a poster session scheduled for October 12, 2006.

These results are consistent with the estimated 30 percent to 50 percent frequency of BH4-responsiveness in the overall PKU population based on the retrospective analysis conducted by Bernegger and Blau (Mol Genet Metab. 2002 Dec;77(4):304-13), given the following considerations: (2)

- The Phase 2 screening study evaluated Phenoptin dosed at 10 mg/kg, half the dose administered to patients included in the retrospective analysis conducted by Bernegger and Blau. Data from a prior study conducted by Matalon, et.al., (Mol Genet Metab. 2005 Dec;86 Suppl 1:S17-21) demonstrate that BH4 dosed at 20mg/kg results in a greater number of BH4 responders than BH4 dosed at 10mg/kg.

- The Phase 2 study, due to minimum blood Phe level requirements, was biased toward individuals with the more severe form of PKU who are less likely to demonstrate a response to BH4.

ASHG Program # 1415/A: Meta-Analysis Evaluating Blood Phe Levels and Clinical Outcomes in PKU

Results from a BioMarin-sponsored meta-analysis conducted to determine if blood Phe levels can be used as a predictive biomarker of clinical outcomes for the development of new PKU treatments confirm findings from previous studies reporting a significant correlation between concurrent and long-term blood Phe levels and intelligence quotient (IQ) in individuals with PKU. Researchers conducted a comprehensive formal protocol-driven analysis that evaluated data (published from 1980 to 2004) that related Phe level to IQ. The key findings of this analysis are as follows:

- each 100µM increase in blood Phe in the range of 423µM to 750µM is correlated with a 1.3 to 3.1 reduction in IQ for people with PKU 0 to 12 years of age;

- each 100 µM increase in Phe in a range of 394µM to 666µM is correlated to a 1.9 to 4.1 point decrease in IQ for lifetime exposure;

- the meta-analysis study also confirmed that the majority of PKU patients do not comply with the recommended low-Phe diet, leading to blood Phe levels that exceed recommended maximum levels.

These data will be presented by Susan Waisbren, Ph.D., of Children s Hospital of Boston, Boston, Massachusetts, at a poster session scheduled for October 10, 2006.

References

(1) The data in this press release reflect information that will be presented in the poster presentation at the ASHG annual meeting being held in October.

(2) The following is a summary of the data published in *Molecular Genetics and Metabolism* (Mol Genet Metab. 2002 Dec;77(4):304-13.) regarding 6R-BH4 responsiveness in 278 newly diagnosed PKU patients:

Baseline Phe Level (µM)	**Percent of Patients with 30% Reduction following 8 days of Treatment with 20mg/kg/day of 6R-BH4**	
400 to 800	74	%
800 to 1200	33	%
1200 to 1600	17	%
1600 to 2200	0	%
>2200	10	%

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.

About BioMarin

BioMarin develops and commercializes innovative biopharmaceuticals for serious diseases and medical conditions. The company s product portfolio is comprised of two 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, and Aldurazyme® (laronidase) for mucopolysaccharidosis I (MPS I), a product which BioMarin developed through a 50/50 joint venture with Genzyme Corporation. Investigational product candidates include Phenoptin (sapropterin dihydrochloride), a Phase 3 product candidate for the treatment of phenylketonuria (PKU), and 6R-BH4 for cardiovascular indications, which is currently in Phase 2 clinical development for the treatment of poorly controlled hypertension. For additional information, please visit www.BMRN.com. Information on BioMarin s website is not incorporated by reference into this press release. The websites indicated in this press release are provided by BioMarin as additional information for interested parties. With the exception of its own websites, BioMarin does not endorse any particular organization or the content contained on their website.

Naglazyme® is a registered trademark of BioMarin Pharmaceutical Inc.

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

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.

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 for 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 expected market for 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; 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 any government investigations and litigation. Serono is providing this information as of the date of this press release, and 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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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 September 12, 2006

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