SERONO S A
Form 6-K
October 19, 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 October

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 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

Serono Delivers Strong Adjusted* Net Income of $183.5m in Third Quarter 2006

- Excellent performance of Rebif® with sales up 18.7% to $374.8m -

Geneva, Switzerland, October 19, 2006 Serono (virt-x: SEO and NYSE: SRA) today reported its third quarter results for the period ended September 30, 2006.

Key Points for Third Quarter 2006

- Total revenues of $699.1m, up 9.5%
- Product sales up 8.4% to $619.2m
- Rebif® sales up 18.7% to $374.8m worldwide and up 30.1% to $133.3m in USA
- Operating margin of 28.6% of total revenues, up from 25.0% in Q3 2005
- Reported net income of $170.6m, up 19.8%
- Reported basic EPS of $11.64 per bearer share and $0.29 per ADS
- Continued good progress in several R&D programs:
- In-licensing of safinamide in early Phase 3 in Parkinson s Disease
- Fast Track designation for oral cladribine in relapsing forms of multiple sclerosis
- Rebif New Formulation (RNF) 12-month results presented substantially improved tolerability and much lower immunogenicity compared with historical data **
- Aurora kinase inhibitor oncology project moved to Phase 1

We have delivered an excellent quarter with strong performance of our leading product, Rebif®, and our company has again generated strong cash flow, said Ernesto Bertarelli, Chief Executive Officer. Our investment in R&D has yielded good progress in several clinical programs.

During the third quarter of 2006, we sustained the operating leverage we established over the last 18 months resulting in higher operating margin and strong growth on the bottom line, said Stuart Grant, Chief Financial Officer.

* Non-IFRS earnings measure which excludes a $13.0m charge related to the revised carrying value of the convertible bond in Q3 2006.

** The new formulation of Rebif® is currently under regulatory review by the European Medicines Agency, the US Food and Drug Administration and other healthcare authorities.

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Financial Performance

Total revenues increased by 9.5%, or 7.0% in local currencies, to $699.1m in the third quarter of 2006 (Q3 2005: $638.3m). Product sales grew 8.4%, or 5.7% in local currencies, to $619.2m (Q3 2005: $571.5m). Royalty and license income increased by 19.4% to $79.8m (Q3 2005: $66.9m), representing 11.4% of revenues.

Gross margin continues to be strong at 88.6% of product sales (Q3 2005: 88.6%). Selling, General and Administrative expenses were $226.1m (Q3 2005: $201.3m) while Research and Development expenses were $141.3m (Q3 2005: $146.9m). Other operating expenses were down 6.4% to $61.7m (Q3 2005: $65.9m).

Operating income in the third quarter of 2006 was up 25.2% to $199.6m (Q3 2005: $159.4m). Continued operational leverage has delivered an operating margin of 28.6% of total revenues compared to 25.0% of total revenues in the same period last year.

Financial income was $23.2m (Q3 2005: $17.3m) and financial expense was $19.7m (Q3 2005: $5.9m) including a $13.0m charge related to the revised carrying value of the convertible bond as a consequence of the anticipated change of control.

Reported net income in the third quarter of 2006 was $170.6m up 19.8% (Q3 2005: $142.4m), leading to a net margin of 24.4% of total revenues (Q3 2005: 22.3% of total revenues). Basic earnings per share in the third quarter of 2006 were up 19.1% to $11.64 per bearer share (Q3 2005: $9.77) and $0.29 per American Depositary Share (Q3 2005: $0.24).

On an adjusted basis, net income increased 15.5% to $183.5m from $158.9m in the prior year. Adjustments included an $18.3m charge related to the transfer of the Serono Genetics Institute in the third quarter 2005 and a $13.0m charge related to the convertible bond taken in the third quarter 2006.

For the first nine months, net cash flow from operating activities before change in working capital was $750.0m (YTD 2005: $555.0m), or $622.7m after change in working capital (YTD 2005: $439.5m). The company s liquid financial assets were $2.1 billion at the end of the third quarter 2006.

As of September 30, 2006, there were 14,661,190 outstanding equivalent bearer shares of Serono S.A., net of treasury shares. The total weighted average number of equivalent bearer shares of Serono S.A. was 14,654,546 for the three months ending September 30, 2006.

Key Product Sales

In the third quarter of 2006, Rebif® had an excellent performance with worldwide sales of $374.8m, up 18.7%, or 15.4% in local currencies (Q3 2005: $315.6m). Rebif® continues to be the best-selling therapy for multiple sclerosis outside the US, with sales of $241.5m, growing 13.3%, or 8.2% in local currencies (Q3 2005: $213.2m). More than four years after launch in the US, Rebif®

continues to grow strongly and reached US sales of $133.3m, up 30.1% (Q3 2005: $102.5m).

Novantrone® sales in the third quarter of 2006 were $2.8m, down 84.6%, consequent to the introduction of generics of mitoxantrone in the US in April 2006 (Q3 2005: $18.2m).

Sales of Gonal-f® were $122.8m in line with the third quarter of 2005 (Q3 2005: $125.6m). Global sales of supporting products (Ovidrel®, Cetrotide®, Crinone® and Luveris®) were up 11.5%, or 9.5% in local currencies to $21.9m (Q3 2005: $19.6m).

Saizen® sales were $50.5m (Q3 2005: $50.8m), while Serostim® sales grew 9.5% to $19.5m (Q3 2005: $17.8m).

Sales of Raptiva® were up 80.6% to $18.1m in the third quarter 2006 (Q3 2005: $10.0m).

R&D News

Serono has reported notable progress in its Neurology R&D pipeline during the last three months:

- Serono has recently announced an agreement with Newron Pharmaceuticals SpA under which Serono is granted exclusive worldwide rights for the development of safinamide in Parkinson s disease, Alzheimer s disease, and other cognitive disorders. Positive results from a Phase 3 study of safinamide in Parkinson s disease were reported in June 2006.

- In September 2006, oral cladribine was designated a Fast Track product for patients with relapsing forms of multiple sclerosis by the US Food and Drug Administration. Under Fast Track designation oral cladribine is eligible for Priority Review. Patient enrollment into the ongoing Phase 3 pivotal trial is planned to be completed by the end of 2006.

- Data on a new formulation of Rebif® demonstrating a substantial improvement in tolerability and reduction in antibody formation at one year, compared with historical data from patients, were recently presented at the 22nd ECTRIMS congress.

In the third quarter of 2006, Serono further advanced its R&D initiatives in oncology:

- Serono began enrolling patients in a Phase 1 study evaluating the safety and tolerability of R763, a highly potent, orally available multi-Aurora kinase inhibitor, for the treatment of patients with refractory solid tumors in September 2006.

- With respect to adecatumumab, final data from two Phase 2 clinical trials showed activity in both metastatic breast cancer and prostate cancer. While neither study reached its primary endpoint, good tolerability and encouraging trends towards higher activity for patients with high levels of EpCAM overexpression and treated at higher doses were observed. Serono and Micromet continue to investigate opportunities for further development.

In September 2006, Serono and Syntonix Pharmaceuticals Inc. entered into an agreement to pursue the development of a long-acting FSH therapy for the treatment of infertility that can be inhaled and dosed less frequently, instead of injected daily.

Conference Call and Webcast

Serono will hold a conference call on October 19, 2006, starting at 3.00 pm Central European Time (9.00 am U.S. Eastern Time) during which Serono Management will present the Company s Third Quarter 2006 results. To join the telephone conference please dial 1 866 291 4166 (from the US), 091 610 5600 (from Switzerland), 0207 107 0611 (from the UK) and +41 91 610 5600 (from elsewhere). The event will also be relayed by live audio webcast, which interested parties may access via Serono s Corporate home page, www.serono.com. A link to the webcast will be provided immediately prior to the event and will be available for replay following the event. Additionally, the webcast will be available for replay until close of business on November 24, 2006.

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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 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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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).

For more information, please contact:

Serono in Geneva, Switzerland:

Media Relations:
Tel: +41-22-739 36 00
Fax: +41-22-739 30 85
http://www.serono.com

Investor Relations:
Tel: +41-22-739 36 01
Fax: +41-22-739 30 22
Reuters: SEO.VX / SRA
Bloomberg: SEO VX / SRA US

Serono, Inc., Rockland, MA

Media Relations:
Tel: +1 781 681 2340
Fax: +1 781 681 2935
http://www.seronousa.com

Investor Relations:
Tel: +1 781 681 2552
Fax: +1 781 681 2912

On the following pages, there are:

- Tables detailing sales in dollars by therapeutic area, geographic region and the top 10 products for the 3 and 9 months ended September 30, 2006 and 2005.

- Consolidated income statements for the 3 and 9 months ended September 30, 2006 and 2005; adjusted net income and adjusted earnings per share for the 3 and 9 months ended September 30, 2006 and 2005; the consolidated balance sheets as of September 30, 2006 and December 31, 2005; the consolidated statements of changes in equity as of September 30, 2006 and 2005; the consolidated statements of cash flows for the 9 months ended September 30, 2006 and 2005; the selected explanatory notes to the consolidated financial statements. These consolidated financial statements have been prepared on the basis of International Financial Reporting Standards.

Sales by therapeutic area

	Three Months Ended September 30, 2006 $ million	% of sales	% change $	Three Months Ended September 30, 2005 $ million	% of sales
Neurology	375.7	60.7 %	16.7 %	321.9	56.3 %
Reproductive Health	150.6	24.3 %	(1.4)%	152.8	26.7 %
Growth & Metabolism	70.2	11.3 %	1.8 %	69.0	12.1 %
Dermatology	18.1	2.9 %	80.6 %	10.0	1.8 %
Others	4.5	0.8 %	(74.6)%	17.8	3.1 %
Total sales (US$ million)	**$ 619.2**	**100 %**	**8.4 %**	**$ 571.5**	**100 %**

Sales by geographic region

	Three Months Ended September 30, 2006 $ million	% of sales	% change $	Three Months Ended September 30, 2005 $ million	% of sales
Western Europe	265.9	42.9 %	10.4 %	241.0	42.2 %
North America	232.1	37.5 %	7.5 %	215.9	37.8 %
Latin America	35.3	5.7 %	13.1 %	31.2	5.5 %
Others	85.8	13.9 %	3.0 %	83.3	14.5 %
Total sales (US$ million)	**$ 619.2**	**100 %**	**8.4 %**	**$ 571.5**	**100 %**

Sales by therapeutic area

	Nine Months Ended September 30, 2006 $ million	% of sales	% change $	Nine Months Ended September 30, 2005 $ million	% of sales
Neurology	1 071.9	58.2 %	12.6 %	951.5	54.9 %
Reproductive Health	488.1	26.5 %	(2.0)%	498.1	28.7 %
Growth & Metabolism	207.6	11.3 %	0.5 %	206.5	11.9 %
Dermatology	48.7	2.6 %	123.0 %	21.8	1.3 %
Others	26.5	1.4 %	(53.1)%	56.4	3.2 %
Total sales (US$ million)	**$ 1 842.7**	**100 %**	**6.2 %**	**$ 1 734.4**	**100 %**

Sales by geographic region

	Nine Months Ended September 30, 2006