

SERONO S A
Form 6-K
February 01, 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 February, 2005

Serono S.A.
(Registrant's Name)

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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-_____)

Media Release

FOR RELEASE FEBRUARY 1, 2005, 4:01 PM EST

SERONO REPORTS STRONG FULL YEAR 2004 RESULTS

- Total revenues grew 21.8% and EPS increased 31.3% -

Rockland, MA, February 1, 2005 - 04:01 pm EST - Serono (virt-x: SEO and NYSE: SRA), the world's third largest biotechnology company, today reported its fourth quarter and full year results for the period ended December 31, 2004.

Key Points for Full Year 2004

- Ø Total revenues up 21.8% to \$2,458.1m (+16.1% in local currencies)
- Ø Product sales up 17.2% to \$2,177.9m (+11.5% in local currencies)
- Ø Rebif® sales up 33.1% to \$1,090.6m (+25.4% in local currencies)
- Ø Reported net income up 26.7% to \$494.2m (+21.7% in local currencies)
- Ø Reported EPS up 31.3% to \$32.35 per bearer share and \$0.81 per ADS
- Ø Raptiva® registered in key markets and now available in 15 countries
- Ø New R&D collaborations with CancerVax and Micromet for novel anti-cancer drug candidates

Ø Significant steps forward in R&D with 6 late-stage clinical development programs on-going (5 Phase III, 1 post-registration head-to-head study)

Ø 2005 outlook for product sales growth between 10% and 15%, total revenues of at least \$2.6 billion and net income between \$520m and \$540m

“We had excellent growth in 2004 and made significant investments for our future,” said Ernesto Bertarelli, Chief Executive Officer of Serono. “Going forward we have a number of exciting late-stage development projects to drive our future growth and we will continue to invest in both internal R&D programs and external collaborations to sustain that growth over the longer-term.”

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Fourth Quarter And Full Year Financial Performance

Total revenues increased by 21.8% (+16.1% in local currencies) to \$2,458.1m in the full year 2004 (2003: \$2,018.6m), and by 20.3% (+15.7% in local currencies) to \$679.7m in the fourth quarter (2003: \$565.1m).

Worldwide product sales were \$2,177.9m in 2004, up 17.2% (2003: \$1,858.0m), and up 16.4% to \$604.5m in the fourth quarter (2003: \$519.3m). Product sales in local currencies grew by 11.5% in 2004 and 11.7% in the fourth quarter.

Royalty and licensing income increased by 74.4% to \$280.1m in 2004, representing 11.4% of total revenues (2003: \$160.6m), and was up 64.4% to \$75.3m (2003: \$45.8m) in the fourth quarter due to Serono's strong intellectual property rights. In the third quarter exceptional license income of \$67m was reported and in the fourth quarter Serono received additional license income totaling \$11m for the grant of technology licenses to third parties.

Gross margin increased to 86.0% of product sales in 2004 (2003: 85.0%), as a result of a more favorable product mix and continuing manufacturing improvements. In the fourth quarter of 2004, gross margin reached 87.9% (2003: 84.5%).

Selling, General and Administrative expenses were \$807.9m or 32.9% of total revenues in 2004 (2003: \$636.8m or 31.5% of total revenues), and \$234.3m or 34.5% of total revenues in the fourth quarter (2003: \$178.9m or 31.7% of revenues). The increase in SG&A as a percentage of revenues in 2004 reflects expenditures related to the launch of Raptiva®, the launch of the Gonal-f® pre-filled pen and the continued investment to drive Rebif® to worldwide market leadership.

Research and Development expenses were \$594.8m or 24.2% of total revenues (2003: \$467.8m or 23.2% of total revenues) for the full year, and \$221.3m or 32.6% of total revenues in the fourth quarter (2003: \$124.2m or 22.0% of total revenues). The increase in R&D as a percentage of revenues in 2004, particularly in the fourth quarter, results from the commencement of several external R&D collaborations (e.g. ZymoGenetics, Micromet and CancerVax), as well as significant progress made in R&D. Six late-stage clinical development programs are currently on-going, involving up to 6,500 patients (five Phase III, one post-registration head-to-head study).

Other operating expenses in 2004 were \$227.1m (2003: \$199.5m), and \$66.4m (2003: \$49.2m) in the fourth quarter. The increase in other operating expenses results from payments made to third parties related to licensing agreements.

Full year 2004 operating income increased by 20.5% to \$524.1m or 21.3% of total revenues (2003: \$434.9m or 21.5% of total revenues). In the fourth quarter, operating income was \$84.8m or 12.5% of total revenues (2003: \$132.4m or 23.4% of total revenues).

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Net financial income was \$63.3m in 2004 (2003: \$44.0m) and \$20.7m in the fourth quarter (2003: \$15.2m) as a result of higher returns on our financial assets and foreign exchange gains.

Total taxes in 2004 were \$90.9m, representing an overall tax rate of 15.5% of profit before tax (2003: \$68.9m, or 15.0% of profit before tax). In the fourth quarter, taxes were \$13.9m, or 13.2% of profit before tax (2003: \$19.7m or 15.0% of profit before tax).

Reported net income in the full year 2004 was up 26.7% to \$494.2m (2003: \$390.0m), or 21.7% in local currencies. In the fourth quarter, reported net income decreased 19.6%, or 19.8% in local currencies, to \$89.7m (2003: \$111.6m) as a result of significant R&D expenses resulting from the commencement of three external R&D collaborations and progress in several late-stage programs.

Basic earnings per share (EPS) were up 31.3% to \$32.35 per bearer share (2003: \$24.63) and \$0.81 per American Depositary Share (ADS) (2003: \$0.62). The average number of equivalent bearer shares outstanding for the year ended December 31, 2004 was 15,276,403.

On April 26, 2005, the Board of Directors will propose to the Annual General Meeting a cash dividend of CHF9.0 per bearer share, CHF3.6 per registered share, and CHF0.23 per ADS, representing an increase of 12.5% over the 2003 dividend.

For the full year ended 2004, net cash flow from operating activities was \$471.7m (2003: \$542.9m).

In 2004, share repurchases were CHF1,017.4m (\$833.1m) representing 1,313,644 bearer shares. As of December 31, 2004, there were 14,531,957 outstanding equivalent bearer shares of Serono S.A. The company's liquid financial assets were \$1.8 billion at the end of 2004 providing significant flexibility for non-organic growth.

In 2005, Serono expects product sales to grow between 10% and 15% leading to total revenues of at least \$2.6 billion and net income between \$520m and \$540m based on prevailing currency exchange rates. This outlook does not include expenses related to any new business development transactions or other extraordinary items in 2005.

Neurology

Neurology sales were up 32.1% to \$1,123.0m for the full year 2004, and fourth quarter sales were \$319.1m. Rebif® reached blockbuster status in 2004 with full year sales up 33.1% (25.4% in local currencies) to \$1,090.6m (2003: \$819.4m). In the fourth quarter, worldwide sales of Rebif® increased by 32.9% (26.6% in local currencies) to \$310.0m (2003: \$233.2m). Given the strong performance of Rebif® in 2004, the company is on track to achieve its goal of worldwide market leadership in 2006.

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In 2004, Rebif® was the fastest growing multiple sclerosis (MS) therapy in the US with \$295.6m sales for the full year, representing an increase of 56.8% (2003: \$188.5m). In the fourth quarter, sales of Rebif® in the US were up 54.5% to \$86.0m (2003: \$55.7m).

Rebif® continues its market leadership outside the US with 2004 sales increasing by 26.0% to \$795.0m (2003: \$630.8m). Sales ex-US were up by 26.2% to \$224.0m in the fourth quarter (2003: \$177.5m).

On January 5th 2005, Serono announced that patient enrolment for a head-to-head study comparing Rebif® with Copaxone® in relapsing remitting MS had been completed. This trial will provide comparative data that will support an evidence-based approach for rational treatment decisions in multiple sclerosis, and Serono expects the data to support Rebif® as a foundation therapy for treatment of multiple sclerosis.

On January 11th 2005, Serono announced that it will initiate a large Phase III study with Mylinax® (oral formulation of cladribine) in Q1 2005. Mylinax® could be the first oral disease modifying treatment for MS to reach the market. This multi-center, multi-national study is designed to assess the effectiveness of Mylinax® in patients with relapsing forms of multiple sclerosis. It will be a two-year, double-blind, placebo-controlled study involving over 1,200 patients.

In 2004, Serono introduced Rebiject II, a new auto-injection device, and an ultra-thin needle for the Rebif® pre-filled syringe. A titration pack has also recently been approved by the FDA simplifying initiation of therapy for new patients.

Reproductive Health

In 2004, sales of Gonal-f® increased by 8.7% (3.6% in local currencies) to \$572.7m (2003: \$526.9m) and by 2.2% (-1.7% in local currencies) to \$151.1m (2003: \$147.9m) in the fourth quarter. Excluding Germany which was impacted by government and reimbursement issues, Gonal-f® worldwide sales grew by 17.5% (12.3% in local currencies) in 2004 reflecting the availability of the newly launched Gonal-f® pre-filled pen.

Serono's core reproductive health portfolio consisting of three recombinant hormones (Gonal-F®, Ovidrel®/Ovitrelle®, Luveris®) and two complementary products (Cetrotide®, Crinone®) grew by 8.5% (3.4% in local currencies) to \$645.6m representing 93.3% of total reproductive health sales in 2004. With the approval of Luveris® in the US, the complete portfolio of infertility products is now globally available with the exception of Japan.

New initiatives have been undertaken to raise disease and treatment awareness, such as www.fertility.com and *Fertility Lifelines* (www.fertilitylifelines.com), educational services that offer customized information and support to people with fertility concerns.

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Growth and Metabolism

Total growth hormone sales increased by 12.3% (8.2% in local currencies) to \$269.8m (2003: \$240.2m) in 2004 and by 17.3% (13.8% in local currencies) to \$76.4m (2003: \$65.1m) in the fourth quarter driven by a strong performance of Saizen®.

Saizen® sales increased by 20.2% (13.6% in local currencies) to \$182.1m (2003: \$151.5m) in 2004, and were up 25.8% (20.4% in local currencies) to \$53.2m (2003: \$42.3m) during the fourth quarter. Our investment in innovative devices and support tools to improve the management of growth disorders contributed to making Saizen® a popular choice with patients. Saizen® was recently approved by the FDA in Adult Growth Hormone Deficiency (AGHD).

Serostim® sales were \$86.8m for the full year (2003: \$88.8m), and \$22.6m (2003: \$22.8m) in the fourth quarter. A Phase III trial of Serostim in HIV-associated adipose redistribution syndrome (HARS) completed recruitment at the end of 2004.

Dermatology

In late September 2004, Raptiva® was approved by the European Commission for the treatment of patients with moderate-to-severe chronic plaque psoriasis for whom other systemic treatments or phototherapy have been inadequate or are inappropriate. Raptiva® was the first biological treatment for psoriasis to be authorized for marketing in the 25 countries of the European Union.

Raptiva® is also approved in Switzerland and Australia, as well as Argentina, Mexico and Brazil and is now available in 15 countries. Sales of Raptiva® were \$4.9m for the full year, and \$3.7m in the fourth quarter. The roll-out of Raptiva® will continue throughout 2005.

Regional Sales

North American sales grew by 20.7% to \$837.9m in 2004 (2003: \$694.3m). European sales increased by 12.3% to \$895.2m (2003: \$796.8m). In the rest of the world, sales grew by 21.2% to \$444.9m (2003: \$367.0m).

In the fourth quarter, North American sales were up 20.8% to \$232.7m (Q4 2003: \$192.7m) while European sales grew by 8.2% to \$247.8m (Q4 2003: \$229.0m) and sales in the rest of the world increased by 27.1% to \$124.0m (Q4 2003: \$97.5m).

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R&D News

Significant steps forward in R&D were made in the last twelve months. Serono now has six late-stage clinical development programs on-going, consisting of five Phase III programs (onercept in psoriasis; interferon-beta in chronic hepatitis C in Asian patients; Serostim® in HIV-associated adipose redistribution syndrome; Canvaxin™ in stage III and IV melanoma and Mylinax® in relapsing forms of MS) and one post-registration head-to-head study comparing Rebif® with Copaxone® in relapsing remitting MS.

In December 2004, Serono announced two significant agreements strengthening its R&D presence in oncology. One collaboration is with CancerVax for the global development and commercialization of Canvaxin™, currently in two Phase III trials for respectively stage III and IV melanoma involving over 1,800 patients. The second collaboration is a partnership with Micromet for the global development and commercialization of adecatumumab (MT201). This monoclonal antibody is currently in Phase II trials for the treatment of metastatic breast cancer and prostate cancer.

Conference Call and Webcast

Serono will hold a conference call on February 2nd, 2005, starting at 11:00 am Eastern Time (5:00 pm Central European Time) during which Serono Management will present the Company's Fourth Quarter and Full Year 2004 Results.

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. Additionally, the webcast will be available for replay until close of business on February 20th, 2005.

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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 25, 2004. 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, 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 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. 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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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 12 months ended December 31, 2004 and 2003.
- Consolidated income statements for the 3 and 12 months ended December 31, 2004 and 2003, the consolidated balance sheets as of December 31, 2004 and 2003, the consolidated statement of changes in equity as of December 31, 2004 and 2003, as well as the consolidated cash flow statements for the 12 months ended December 31, 2004 and 2003. These consolidated financial statements have been prepared on the basis of International Financial Reporting Standards. The accompanying notes to these 2004 full-year consolidated financial statements will be

available upon the release of Serono's 2004 Annual Report.

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Sales by therapeutic area**Three Months Ended
December 31, 2004****Three Months Ended
December 31, 2003**

	\$ million	% of sales	% change \$	\$ million	% of sales
Neurology	319.1	52.8%	31.9%	241.9	46.6%
Reproductive Health	181.9	30.1%	(4.8%)	191.0	36.8%
Growth & Metabolism	76.4	12.6%	17.3%	65.1	12.5%
Dermatology	3.7	0.6%	n/a		
Others	23.4	3.9%	10.1%	21.3	4.1%
Total sales (US\$ million)	\$ 604.5	100%	16.4%	\$ 519.3	100%

Sales by geographic region**Three Months Ended
December 31, 2004****Three Months Ended
December 31, 2003**

	\$ million	% of sales	% change \$	\$ million	% of sales
Europe	247.8	41.0%	8.2%	229.0	44.1%