

SERONO S A
Form 6-K
April 22, 2004

**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 April, 2004

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-_____)

Media Release

FOR RELEASE APRIL 22, 2004, 7:00 am CET

**EXCELLENT FIRST QUARTER WITH TOTAL REVENUES UP
25.9% TO \$557.1M
AND STRONG EARNINGS PER SHARE GROWTH OF 77.3%**

- 2004 net income guidance increased to at least 20% growth -

Geneva, Switzerland, April 22, 2004 Serono (virt-x: SEO and NYSE: SRA), the third largest biotechnology company in the world, today reported its first quarter results for the period ended March 31, 2004.

Key Points for First Quarter 2004

- Ø Total revenues up 25.9% to \$557.1m (up 16.4% in local currencies)
- Ø Product sales up 26.7% to \$516.7m (up 16.7% in local currencies)
- Ø Net income up 76.4% to \$106.1m (up 54.7% in local currencies)
- Ø Basic EPS up 77.3% to \$6.73 per bearer share and \$0.17 per ADS
- Ø Increase in 2004 net income growth outlook to at least 20% in local currencies
- Ø R&D milestones achieved: start of Rebit[®] vs Copaxone[®] head-to-head trial and successful completion of Phase I program for oral cladribine
- Ø Swiss approval of Raptiva[®]
- Ø European approval of Gonal-f[®] prefilled pen

Our first quarter performance was very strong with all of our businesses doing well. said Ernesto Bertarelli, Chief Executive Officer of Serono. With such momentum, I am very pleased to increase our guidance for net income growth to at least 20% for the full year.

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First Quarter Financial Performance

Total revenues increased by 25.9% to \$557.1m in the first quarter of 2004 (Q1 2003: \$442.4m), or 16.4% in local currencies, reflecting strong underlying growth. Product sales grew 26.7% to \$516.7m (Q1 2003: \$407.8m), or 16.7% in local currencies, with strong growth from the lead products in each of the therapeutic areas. Royalty and license income increased by 16.6% to \$40.4m (Q1 2003: \$34.6m), indicative of the company's strong intellectual property rights.

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Gross margin increased to 85.4% of product sales (Q1 2003: 84.6%), as a result of continuing manufacturing improvements.

Selling, General and Administrative expenses were \$184.2m or 33.1% of total revenues (Q1 2003: \$140.9m or 31.9% of total revenues). The increase in SG&A as a percentage of revenues reflects the investment in pre-launch activities in our new therapeutic area of psoriasis.

Research and Development expenses were \$126.2m or 22.7% of total revenues (Q1 2003: \$127.9m or 28.9% of total revenues, or 23.2% of total revenues without the Raptiva® milestone payment to Genentech of \$25m in that quarter).

Other operating expenses were \$54.9m (Q1 2003: \$45.8m). Operating income increased by 78.2% to \$116.1m or 20.8% of total revenues (Q1 2003: 65.2m or 14.7% of total revenues) and financial income net was \$9.0m (Q1 2003: \$6.7m).

Total taxes were \$20.0m, representing an overall tax rate of 16.0% of profit before tax (Q1 2003: \$11.5m, or 16.0% of profit before tax).

Reported net income was up 76.4% to \$106.1m (Q1 2003: \$60.2m), or 54.7% in local currencies. Excluding the Raptiva® milestone payment to Genentech made in the first quarter of 2003, net income was up 30.8% or 17.7% in local currencies.

Basic earnings per share (EPS) were up 77.3% to \$6.73 per bearer share (Q1 2003: \$3.80) and \$0.17 per American Depositary Share (ADS) (Q1 2003: \$0.09).

For the first quarter, net cash flow from operating activities was \$102.9m (Q1 2003: \$115.2m). Excluding the one-time payment of \$55m received from OSI Pharmaceuticals in the first quarter of 2003, operating cash flows increased 70.9%.

As part of our ongoing share buy-back plan, in the first quarter we have purchased CHF131.5m of our bearer shares. Since the commencement of this plan in July 2002, we have bought back shares for a total amount of CHF350.6m, representing 70.1% of the CHF500m authorized amount.

As of March 31, 2004, there were 15,679,471 outstanding equivalent bearer shares of Serono S.A.

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Neurology

Neurology sales were \$265.5m (Q1 2003: \$180.4m) in the first quarter, up 47.2% or 33.7% in local currencies. Sales of Rebif® were up 48.2% (34.2% in local currencies) to \$259.6m (Q1 2003: \$175.2m).

Rebif® continues its market leadership outside the US with sales increasing by 45.9% to \$196.9m (Q1 2003: \$134.9m), or 28.3% in local currencies. The Rebif® ready-to-use prefilled syringe is now available with a new ultra-fine needle (29 gauge) in all European countries.

Sales of Rebif® in the US were up 55.7% to \$62.7m in the first quarter. Rebif®, the fastest growing MS therapy in the US, continues to gain market share and reached 15.6% of total prescriptions at the end of the first quarter, compared with 13.4% at the end of 2003.

Novantrone® sales in MS in the first quarter were \$5.9m (Q1 2003: \$5.1m). Total Novantrone® sales were up 19.0% to \$15.3m (Q1 2003: \$12.8m).

Reproductive Health

In the first quarter, reproductive health sales grew 5.9% to \$170.2m (Q1 2003: \$160.6m). Sales of Gonal-f® increased by 12.6% (3.8% in local currencies) to \$137.4m (Q1 2003: \$122.0m).

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Serono's core reproductive health portfolio consisting of three recombinant hormones (Gonal-f[®], Ovidrel[®]/Ovitrelle[®], Luveris[®]) and two complementary products (Cetrotide[®], Crinone[®]) grew by 13.4% (4.5% in local currencies) to \$154.8m.

In keeping with the plan of phasing out urinary products, urine-derived gonadotropins sales were \$12.9m in the first quarter or 7.6% of reproductive health sales (Q1 2003: \$21.8m or 13.6% of reproductive health sales).

In February, the European Commission approved the Gonal-f[®] prefilled pen, the first ready-to-use pen for the treatment of infertility. The Gonal-f[®] prefilled pen, which combines the efficacy of the most consistent FSH with enhanced accuracy of dosing, will be available in 3 multidose strengths.

Metabolic Endocrinology

In the first quarter, sales of Serono's recombinant growth hormone products rose by 17.2% to \$62.2m (Q1 2003: \$53.0m). Saizen[®] sales increased by 22.8% (11.5% in local currencies) to \$40.7m (Q1 2003: \$33.1m). Serostim[®] sales increased by 8.0% (7.9% in local currencies) to \$21.5m (Q1 2003: \$19.9m).

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Psoriasis

In March, Raptiva[®] (efalizumab) was approved by Swissmedic, the Swiss regulatory authority, for the treatment of adult patients with moderate-to-severe plaque psoriasis. Raptiva[®]'s Swiss approval is the first approval of a biological therapy for psoriasis in Europe and ex-US. In the European Union, the opinion of the Committee for Proprietary Medicinal Products is expected by the end of June 2004.

Raptiva[®] provides effective and safe long-term control of the disease and can be self-administered by patients as a single, once-weekly, subcutaneous injection.

Regional Sales

North American sales grew by 22.9% to \$183.3m (Q1 2003: \$149.2m). European sales increased by 27.0% (8.8% in local currencies) to \$230.6m (Q1 2003: \$181.5m). In the rest of the world, sales grew by 33.5% (27.8% in local currencies) to \$102.8m (Q1 2003: \$77.0m).

R&D News

In February, Serono and InDex announced an agreement under which Serono receives exclusive worldwide rights to develop and commercialize InDex's product Kappaproct[®] for the treatment of ulcerative colitis and potentially other inflammatory diseases. Kappaproct[®] is an antisense inhibitor of the p65 protein, a key activator of the pro-inflammatory NF-kappa B pathway. Kappaproct[®] is currently in Phase II for ulcerative colitis.

Given the positive results from two Phase I clinical trials of a new proprietary oral formulation of cladribine announced in March, and the clinical data already available, Serono intends to meet with the US Food and Drug Administration, and the European Agency for the Evaluation of Medicinal Products, to discuss the next steps of clinical development.

A multicentre multinational head-to-head trial comparing Rebit[®] vs. Copaxone[®] was initiated in January 2004 to investigate the relative efficacy of the two drugs. This is a 2-year study involving more than 600 patients with relapsing remitting MS. The primary endpoint is the time to first relapse during 96 weeks of therapy.

Outlook for 2004

Given the strong first quarter performance, Serono raises its 2004 guidance for net income growth to at least 20%. This guidance is in local currencies relative to 2003 reported net income of \$390.0m.

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Conference Call and Webcast

Serono will hold a conference call on April 22nd, 2004, starting at 15:00 Central European Time (9:00 am Eastern Time) during which Serono Management will present the Company's First Quarter 2004 Results. To join the telephone conference please dial 412 858 4600 (from the US), 091 610 5600 (from Switzerland), 0207 866 4111 (from the UK) and +41 91 610 5600 (from elsewhere). Telephone playback will be available one hour after the conference call and until close of business 5.00 pm ET on April 29th, 2004. To access this playback please dial the following numbers: 412 858 1440 (from the US), 091 612 4330 (from Switzerland), 0207 866 4300 (from the UK) and +41 91 612 4330 (from elsewhere) and enter the PIN code 247# from a touch tone telephone.

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.

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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 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 seven recombinant products, Rebif[®], Gonal-F[®], Luveris[®], Ovidrel[®]/Ovitrelle[®], Serostim[®], Saizen[®] and Zorbtive (Luveris[®] is not approved in the USA). In addition to being the world leader in reproductive health, Serono has strong market positions in neurology, metabolism and growth. The Company's research programs are focused on growing these businesses and on establishing new therapeutic areas. Currently, there are approximately 30 ongoing development projects.

In 2003, Serono achieved worldwide revenues of US\$2,018.6 million, and a net income of US\$390.0 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 months ended March 31, 2004 and 2003.
- Consolidated statements of income for the 3 months ended March 31, 2004 and 2003, the consolidated statements of cash flows for the 3 months ended March 31, 2004 and 2003, the consolidated balance sheets as of March 31, 2004 and December 31, 2003, as well as consolidated statements of equity as of March 31, 2004 and 2003. These consolidated financial statements have been prepared on the basis of International Financial Reporting Standards.

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Sales by therapeutic area

	Three Months Ended March 31, 2004			Three Months Ended March 31, 2003	
	\$ million	% of sales	% change \$	\$ million	% of sales
Neurology	265.5	51.4%	47.2%	180.4	44.2%
Reproductive Health	170.2	32.9%	5.9%	160.6	39.4%
Growth & Metabolism	62.2	12.0%	17.2%	53.0	13.0%
Others	18.8	3.7%	37.1%	13.7	3.4%
Total sales (US\$ million)	\$ 516.7	100%	26.7%	\$ 407.8	100%

Sales by geographic region

	Three Months Ended March 31, 2004			Three Months Ended March 31, 2003	
	\$ million	% of sales	% change \$	\$ million	% of sales
Europe	230.6	44.6%	27.0%	181.5	44.5%
North America	183.3	35.5%	22.9%	149.2	36.6%
Latin America	26.4	5.1%	70.6%	15.5	3.8%
Others	76.5	14.8%	24.1%	61.6	15.1%
Total sales (US\$ million)	\$ 516.7	100%	26.7%	\$ 407.8	100%

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TOP TEN PRODUCTS

	* TA	Three Months Ended March 31, 2004			Three Months Ended March 31, 2003	
		\$ million	% of sales	% change \$	\$ million	% of sales
Rebif®	MS	259.6	50.2%	48.2%	175.2	43.0%
Gonal-f®	RH	137.4	26.6%	12.6%	122.0	29.9%
Saizen®	Growth	40.7	7.9%	22.8%	33.1	8.1%
Serostim®	Wasting	21.5	4.2%	8.0%	19.9	4.9%
Novantrone®	MS/Oncology	15.3	3.0%	19.0%	12.8	3.1%
Pergonal®	RH	7.4	1.4%	(28.0%)	10.3	2.5%
Cetrotide®	RH	6.3	1.2%	12.4%	5.6	1.4%
Crinone®	RH	4.5	0.9%	(0.1%)	4.5	1.1%
Stilamin®	Other	4.1	0.8%	25.0%	3.3	0.8%
Ovidrel®	RH	3.9	0.8%	67.3%	2.3	0.6%

* Therapeutic Areas

RH	= Reproductive Health	Wasting	= AIDS Wasting
MS	= Multiple Sclerosis	Growth	= Growth Retardation
Oncology	= Oncology		

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Consolidated Income Statements

Three months ended March 31	2004 *	% of		2003 *	% of
	US\$'000	Revenues	% change	US\$'000	Revenues
Revenues					
Product sales	516,713		26.7%	407,786	
Royalty and license income	40,378		16.6%	34,620	
Total Revenues	557,091	100.0%	25.9%	442,406	100.0%
Operating Expenses					
Cost of product sales	75,669		20.8%	62,631	

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% of Sales	14.6%			15.4%	
Selling, general and administrative	184,203	33.1%	30.7%	140,916	31.9%
Research and development	126,199	22.7%	(1.4%)	127,937	28.9%
Other operating expense, net	54,871	9.8%	19.9%	45,751	10.3%
Total Operating Expenses	440,942	79.2%	16.9%	377,235	85.3%
Operating Income	116,149	20.8%	78.2%	65,171	14.7%
Financial income, net	9,034		35.7%	6,656	
Other income, net	4			226	
Total Non Operating Income, Net	9,038			6,883	
Income Before Taxes and Minority Interests	125,187	22.5%	73.7%	72,054	16.3%
Taxes	20,031			11,529	
Income Before Minority Interests	105,156			60,525	
Minority interests	(974)			365	
Net Income	106,130	19.1%	76.4%	60,160	13.6%

* Unaudited

	2004	2003	% Change
Basic Earnings per Share (in U.S. dollars)			
- Bearer shares	6.73	3.80	77.3%
- Registered shares	2.69	1.52	77.3%
- American depositary shares	0.17	0.09	77.3%
Diluted Earnings per Share (in U.S. dollars)			
- Bearer shares	6.71	3.79	77.0%
- Registered shares	2.69	1.52	77.0%
- American depositary shares	0.17	0.09	77.0%

Basic earnings per share are calculated in accordance with IAS 33 (Earnings per Share) by dividing the net income of the group, US\$106.1 million (2003 US\$60.2 million), by an appropriate number of shares. This is 11,368,535 bearer shares (2003 11,443,975) and 11,013,040 registered shares (2003 11,013,040). The total weighted average equivalent number of bearer shares is 15,773,751 (2003 15,849,191) for the

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three months ended March 31, 2004. As each American depositary share represents ownership interest in one fortieth of a bearer share, basic and diluted earnings per American depositary share is calculated as one fortieth of the earnings per bearer share.

For diluted earnings per share, the total number of bearer shares is adjusted to assume conversion of all in the money share options granted to employees and directors and does not take into consideration the impact of the convertible bond because it is anti-dilutive. The number of bearer shares used to calculate diluted earnings per share is 11,403,634 (2003 11,451,180).

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Consolidated Statements of Cash Flows

Three months ended March 31	2004 *	2003 *
	US\$'000	US\$'000
Cash Flows From Operating Activities		
Income before taxes and minority interests	125,187	72,054
Depreciation and amortization	33,204	34,498
Financial income	(16,864)	(12,087)
Financial expense	6,896	2,161
Other non-cash items	8,647	13,686
Cash Flows From Operating Activities Before Working Capital Changes	157,070	110,312
Working Capital Changes		
Trade accounts payable, other current liabilities and deferred income	19,332	74,800
Trade accounts receivable	(16,154)	(9,982)
Inventories	1,148	(22,638)
Prepaid expenses and other current assets	(20,817)	(6,200)
Taxes paid	(37,704)	(31,081)
Net Cash Flows From Operating Activities	102,875	115,211
Cash Flows From Investing Activities		
Purchase of property, plant and equipment	(39,492)	(57,468)
Purchase of intangible and other long-term assets	(3,510)	(7,257)
Purchase of financial assets	(415,231)	(130,926)
Proceeds from sale of property, plant and equipment	2,954	2,220
Interest received	26,931	21,330
Net Cash Flows From Investing Activities	(428,348)	(172,101)
Cash Flows From Financing Activities		
Proceeds from issuance of share capital	10,333	13,090
Proceeds from exercises of stock options	318	159
Premiums received on written calls	--	384

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Issuance of long-term financial debt	8,784	--
Purchase of treasury shares	(103,125)	(24,637)
Repayment of bank advances	(5,582)	(9,260)
Repayment of long-term debt	--	(1,517)
Other non-current liabilities	1,985	(4,308)
Interest paid	(1,894)	(1,102)
Net Cash Flows From Financing Activities	(89,181)	(27,191)
Effect of Exchange Rate Changes on Cash and Cash Equivalents	(1,489)	1,371
Net Decrease in Cash and Cash Equivalents	(416,143)	(82,710)
Cash and Cash Equivalents		
- Beginning of period	1,003,972	686,033
- End of period	587,829	603,323

* Unaudited

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Consolidated Balance Sheets

As of	March 31, 2004 *	December 31, 2003
	US\$'000	US\$'000
Assets		
Current Assets		
Cash and cash equivalents	587,829	1,003,972
Short-term financial assets	572,149	434,810
Trade accounts receivable	325,742	318,388
Inventories	288,779	319,820
Prepaid expenses and other current assets	237,007	220,334
Total Current Assets	2,011,506	2,297,324
Non-Current Assets		
Property, plant and equipment	682,277	701,453
Long-term financial assets	1,382,371	1,104,333
Intangible assets	253,035	259,626
Deferred tax assets	168,264	169,693
Other long-term assets	38,562	39,174
Total Non-Current Assets	2,524,509	2,274,279
Total Assets	4,536,015	4,571,603

Liabilities

Current Liabilities

Trade and other payables	348,586	338,862
Short-term financial debts	44,925	51,224
Income taxes	123,556	146,086
Deferred income - current	47,300	47,200
Other current liabilities	155,460	170,019

Total Current Liabilities	719,827	753,391
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Non-Current Liabilities

Long-term financial debts	525,598	532,022
Deferred tax liabilities	15,935	15,919
Deferred income - non current	167,996	174,911
Provisions and other long-term liabilities	216,129	213,556

Total Non-Current Liabilities	925,658	936,408
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Total Liabilities	1,645,485	1,689,799
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Minority Interests	614	1,614
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Shareholders' Equity

Share capital	254,314	253,895
Share premium	1,019,681	1,002,991
Treasury shares	(257,578)	(157,642)
Retained earnings	1,775,830	1,669,700
Fair value and other reserves	32,751	22,711
Cumulative foreign currency translation adjustments	64,918	88,535

Total Shareholders' Equity	2,889,916	2,880,190
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Total Liabilities, Minority Interests and Shareholders' Equity	4,536,015	4,571,603
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* Unaudited

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Consolidated Statements of Equity

Cumulative
foreign
currency

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	Share capital US\$'000	Share premium US\$'000	Treasury shares US\$'000	Retained earnings US\$'000	Fair value and other reserves US\$'000	translation adjustments US\$'000	Total US\$'000
Balance as of January 1, 2003	253,416	989,141	(126,460)	1,364,626	(44,807)	25,282	2,461,198
Issue of share capital to employees	435	12,480	3,571				16,486
Net income for 2003				60,162			60,162
Purchase of treasury shares			(24,637)				(24,637)
Revaluation adjustments					(6,705)		(6,705)
Foreign currency translation adjustments						13,381	13,381
Balance as of March 31, 2003 *	253,851	1,001,621	(147,526)	1,424,788	(51,512)	38,663	2,519,885
Balance as of January 1, 2004	253,895	1,002,991	(157,642)	1,669,700	22,711	88,535	2,880,190
Issue of share capital to employees	419	16,690	3,189				20,298
Net income for 2004				106,130			106,130
Purchase of treasury shares			(103,125)				(103,125)
Revaluation adjustments					10,040		10,040
Foreign currency translation adjustments						(23,617)	(23,617)
Balance as of March 31 2004 *	254,314	1,019,681	(257,578)	1,775,830	32,751	64,918	2,889,916

* Unaudited

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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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April 22, 2004

By: /s/ Allan Shaw

Name: Allan Shaw
Title: Chief Financial Officer
