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SERONO S A
Form 6-K
April 24, 2003

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, 2003

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

Serono
[GRAPHIC OMITTED]

Media Release

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FOR IMMEDIATE RELEASE

SERONO ANNOUNCES GOOD FIRST QUARTER RESULTS WITH STRONG REVENUE GROWTH

- Rebif(R) sales of \$175.2m and Gonal-F(R) sales of \$122.0m -
- Raptiva(TM) filed for psoriasis in the EU, Switzerland and Canada -

GENEVA, SWITZERLAND, APRIL 24, 2003 - Serono S.A. (virt-x: SEO and NYSE: SRA) today reported its first quarter results for the period ended March 31, 2003.

HIGHLIGHTS

- Total revenues of \$442.4m up 29.4% in dollars and 17.3% in local currencies
- Product sales up 30.1% to \$407.8m
- Strong Rebif(R) growth of 52.0% to \$175.2m
- Gonal-F(R) up 20.5% to \$122.0m
- Solid underlying net income growth of 16.8% excluding a \$25m milestone payment related to the filing of Raptiva(TM) in the EU
- Reported net income of \$60.2m
- On track to meet 2003 outlook of total revenue growth of 15% to 20% and net income growth of 15% to 20% on a reported basis

"Our first quarter performance has been very strong with substantial top-line growth driven by sales in Neurology and Reproductive Health," said Ernesto Bertarelli, Chief Executive Officer of Serono. "Our first-quarter net income is in line with our expectations, which included a milestone payment related to the filing of Raptiva(TM) in Europe."

"We are confident of our ability to meet full-year revenue growth of 15% to 20% and net income growth of 15% to 20% on a reported basis," said Allan Shaw, Chief Financial Officer. "The positive currency effect on sales was offset by a corresponding increase in total operating expenses, which resulted in a small favorable currency impact of \$1.2m on the bottom line reflecting the significant natural hedge provided by our global operations."

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FINANCIAL PERFORMANCE

In the first quarter of 2003 total revenues increased by 29.4% to \$442.4m (Q1 2002: \$341.9m). Worldwide product sales advanced 30.1% to \$407.8m (Q1 2002: \$313.5m). Product sales growth in local currency was 17.6%. There was a favorable currency effect of \$39.1 million on product sales due to the relative weakness of the dollar compared with the first quarter of 2002.

Royalty and licensing income rose 22.1% to \$34.6m (Q1 2002: \$28.4m). This included a license fee from Abbott following the first regulatory approval of Humira(R) as well as the commencement of royalty payments on Humira(R) in

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relation to our intellectual property rights in the area of TNF antagonism.

Our gross margin has increased to 84.6% of product sales (Q1 2002: 83.8%), as a result of the continued rise in the proportion of recombinant product sales, which accounted for 90.2% of total product sales in the first quarter of 2003 (Q1 2002: 85.6%).

Selling, general and administrative expenses were \$140.9m or 31.9% of total revenues (Q1 2002: \$116.3m or 34.0% of total revenues). This increase was primarily driven by investments we made in our neurology infrastructure over the past year in the USA and selling expenses related to the promotion of Rebif(R), as well as the launch of a new presentation of Gonal-F(R) in Europe.

Research and development expenses reached \$127.9m or 28.9% of total revenues (Q1 2002: \$75.6m or 22.1% of total revenues). As anticipated, this temporary increase reflects primarily a \$25m milestone payment to Genentech as a result of the filing of Raptiva(TM) in the EU. In this quarter we also extended the Raptiva(TM) agreement, providing Serono with worldwide rights to develop and market Raptiva(TM) outside of the United States and Japan.

Other operating expenses increased to \$45.8m (Q1 2002: \$19.4m), principally reflecting predetermined quarterly licensing fees to Amgen for the marketing rights of Novantrone(R). Novantrone(R), a commercial product protected by orphan drug status, is strategic for our neurology franchise in the USA as it is complementary to Rebif(R) and allows us to leverage investments made in our neurology infrastructure. The increase in other operating expenses also includes higher amortization of goodwill.

Net financial income was \$8.4m in the first quarter (Q1 2002: \$4.6m) reflecting the continued low interest environment.

Total taxes in the first quarter were \$11.5m, representing an overall tax rate of 16.0% of profit before tax (Q1 2002: \$14.2m, or 17.0% of profit before tax).

Reported net income was 13.4% less than last year at \$60.2m (Q1 2002: \$69.5m) reflecting the temporary increase in R&D expenses in the first quarter. Excluding the \$25m milestone payment, our underlying net income was \$81.2m representing growth of 16.8%.

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Foreign exchange fluctuations have increased the reported US dollar value of our revenues and also raised our expenses in terms of US dollars. The net impact of translation of currency on our operating results was only \$1.2m, or a 2.0% positive effect on reported net income. The company's currency exposures principally continue to be hedged by the broad geographic nature of our global operations.

Basic earnings per share (EPS) for the first quarter were \$3.80 per bearer share (Q1 2002: \$4.32) and \$0.09 per American Depositary Share (ADS) (Q1 2002: \$0.11). Excluding the \$25m milestone payment to Genentech in the first quarter, EPS were \$5.12 per bearer share and \$0.13 per ADS.

For the first quarter, net cash flow from operating activities was up 156.4% to \$115.2m, compared to \$44.9m for Q1 2002. This includes a \$55m payment received from OSI Pharmaceuticals, following the agreement by which OSI will market and promote Novantrone(R) for the approved oncology indications in the United States.

As of March 31, 2003, we have bought back 281,995 of our bearer shares on the open market, representing 41.2% of the CHF500m authorized amount.

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The weighted average amount of equivalent bearer shares outstanding for the three months ended March 31, 2003 was 15,849,191.

NEUROLOGY

Rebif(R) performed very strongly with worldwide sales up 52.0% to \$175.2m in the first quarter (Q1 2002: \$115.3m). Rebif(R) continues its market leadership outside the US. In Europe, sales grew by 37.6% to \$98.3m (Q1 2002: \$71.4m).

Since launch in the United States in March 2002, Rebif(R) sales have broken through the \$100m mark, and at the end of March 2003, our US market share in dollar terms is estimated to be 11%. US sales were \$40.3m in the first quarter of 2003 (Q1 2002: \$6.2m). Underlying demand was strong with prescriptions growing at 25.4% between the fourth quarter of 2002 and the first quarter of 2003.

Quarterly sales of Novantrone(R) were \$12.8m in the USA for both MS and oncology. In the first quarter, we took over the marketing of Novantrone(R) in MS and we recently commenced our own promotional activities. During the quarter, we signed an agreement with OSI Pharmaceuticals by which they will market and promote Novantrone(R) in oncology allowing us to focus on the marketing of this product in MS.

REPRODUCTIVE HEALTH

In the first quarter, we strengthened our market leadership in reproductive health with product sales increasing by 13.7% to \$160.6m (Q1 2002: \$141.3m) while continuing the phase-out of our urine-derived products. In Europe, we introduced a new multidose presentation of Gonal-F(R) providing physicians with more dosing flexibility and optimal product consistency. Sales of Gonal-F(R) increased by 20.5% to \$122.0m (Q1 2002: \$101.2m). Recombinant product sales in this franchise grew by 22.2%, and accounted for 85.3% of Serono's gonadotropin sales.

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GROWTH AND METABOLISM

In the first quarter, sales of Serono's recombinant growth hormone products rose by 7.4% to \$53.0m (Q1 2002: \$49.4m). Saizen(R) sales increased by 12.3% to \$33.1m (Q1 2002: \$29.5m). The launch of our needle-free device, cool.click(TM), across Europe contributed to this growth. Serostim(R) sales were flat at \$19.9m reflecting the rollout of the Serostim(R) Secured Distribution Program across the USA allowing us to stabilize reimbursement in the major states.

REGIONAL SALES

Sales in North America were very strong, growing at 56.6% to reach \$149.2m (Q1 2002: \$95.3m). European sales were also strong, increasing by 31.2% to \$185.6m (Q1 2002: \$141.5m), and sales in the Middle East, Africa and Eastern Europe were up 30.4% to \$33.0m (Q1 2002: \$25.3m). Sales in Japan and Oceania were stable at \$11.5m (Q1 2002: \$10.8m), as were sales in Asia Pacific at \$13.0m (Q1 2002: \$13.8m). Economic and market conditions in Latin America were reflected in first quarter sales which declined to \$15.5m (Q1 2002: \$26.9m); notwithstanding these conditions, we maintained our leadership position in MS and reproductive health in this region.

R&D NEWS

In February, we submitted a Marketing Authorization Application to the EMEA for

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Raptiva(TM) (efalizumab) in moderate-to-severe psoriasis and we also filed applications with Swiss and Canadian authorities. During the quarter, we announced the extension of Serono's exclusive license to develop and market Raptiva(TM) in Asia. As a result of the new agreement, Serono will now develop and market Raptiva(TM) worldwide outside of the United States and Japan.

At the recent American Association of Dermatology (AAD) meeting in San Francisco, results were presented from the latest Phase 3 study of Raptiva(TM) that showed consistent, strong efficacy and safety data. The preliminary long-term data from another study demonstrated that approximately 65% of the patients who continued treatment with Raptiva(TM) through 60 weeks, achieved a 75% or greater improvement in PASI scores (PASI 75). These data also demonstrated persistent efficacy of Raptiva(TM) when administered continuously on a weekly basis.

These efficacy results together with Raptiva(TM)'s rapid onset of action, its subcutaneous administration and its safety profile, mean that Raptiva(TM) has significant potential as a once-weekly continuous treatment for moderate-to-severe psoriasis. The on-going Phase 2 study of Raptiva(TM) in Rheumatoid Arthritis has completed enrollment and the Phase 2 study in Psoriatic Arthritis has recently begun enrollment.

We initiated a Phase 2 trial with anastrozole for follicular development and ovulation in infertile women with ovulatory dysfunction. A phase 1 study with our B-sheet breaker peptide, a potential treatment of Alzheimer's disease, has also been initiated in healthy volunteers.

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CONFERENCE CALL AND WEBCAST

Serono will hold a conference call today, April 24, 2003, starting at 3.00 pm Central European Time (9.00 am U.S. Eastern Time) during which Serono Management will present the Company's First Quarter 2003 Results. To join the telephone conference please dial 091 610 5600 (from Switzerland), 0207 866 4111 (from the UK), +1 412 858 4600 (from the USA) 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 CET on April 30, 2003. To access this playback please dial the following numbers: 091 612 4330 (from Switzerland), 0207 866 4300 (from the UK), +1 412 858 1440 (from the USA) and +41 91 612 4330 (from elsewhere) and enter the PIN code 519# from a touch tone telephone.

The event will also be relayed by live audio webcast that 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 accompanying slides will be made available for download approximately 1 hour before the beginning of the webcast. Additionally, the webcast will be available for replay until close of business on May 16, 2003.

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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 April 17, 2003. 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

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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 six recombinant products on the market, Gonal-F(R), Luveris(R), Ovidrel(R)/Ovitrelle(R), Rebif(R), Serostim(R) and Saizen(R) (Luveris(R) 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 over 30 projects in development.

Serono was awarded the International James D. Watson Helix 2003 Award from the Biotechnology Industry Organization (BIO) in recognition of the Company's outstanding leadership and highest standards of scientific and product achievement.

In 2002, Serono achieved worldwide revenues of US\$1.546 billion, and a net income of US\$321 million, making it the third largest biotech company in the world. The Company operates in 45 countries, and its products are sold in over 100 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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FOR MORE INFORMATION, PLEASE CONTACT:

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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, 2003.
- The unaudited consolidated financial statements for the 3 months ended March 31, 2003, including income statements, balance sheets and statements of cash flows, prepared in accordance with International Financial Reporting Standards (IFRS).

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SALES BY THERAPEUTIC AREA

	THREE MONTHS ENDED MARCH 31, 2003			THREE MONTHS ENDED MARCH 31, 2002	
	\$MILLION	% OF SALES	% CHANGE \$	\$MILLION	% OF SALES
Multiple Sclerosis (Rebif)	175.2	43.00%	52.00%	115.3	36.80%
Reproductive Health	160.6	39.40%	13.70%	141.3	45.10%
Growth	33.1	8.10%	12.30%	29.5	9.40%
AIDS Wasting	19.9	4.90%	0.30%	19.9	6.30%
MS/Oncology (Novantrone)	12.8	3.10%	100.00%	--	--
Others	6.2	1.50%	-20.00%	7.5	2.40%
Total sales (US\$million)	\$ 407.8	100%	30.10%	\$ 313.5	100%

SALES BY GEOGRAPHIC REGION

	THREE MONTHS ENDED MARCH 31, 2003			THREE MONTHS ENDED MARCH 31, 2002	
	\$MILLION	% OF SALES	% CHANGE \$	\$MILLION	% OF SALES
Europe	185.6	45.50%	31.20%	141.5	45.10%
North America	149.2	36.60%	56.60%	95.3	30.40%
Latin America	15.5	3.80%	-42.50%	26.9	8.60%
Others	57.5	14.10%	15.20%	49.8	15.90%
Total sales (US\$ million)	\$ 407.8	100%	30.10%	\$ 313.5	100%

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TOP TEN PRODUCTS

		THREE MONTHS ENDED MARCH 31, 2003			THREE MONTHS ENDED MARCH 31, 2002	
		\$MILLION	% OF SALES	% CHANGE \$	\$MILLION	% OF SALES
Rebif (R)	MS	175.2	43.0%	52.0%	115.3	36.8%
Gonal-F (R)	RH	122.0	29.9%	20.5%	101.2	32.3%
Saizen (R)	Growth	33.1	8.1%	12.3%	29.5	9.4%
Serostim (R)	Wasting	19.9	4.9%	0.3%	19.9	6.3%
Novantrone (R)	MS/Oncology	12.8	3.1%	100.0%	--	--
Pergonal (R)	RH	10.3	2.5%	17.2%	8.8	2.8%
Metrodin HP (R)	RH	7.1	1.7%	(49.2%)	14.0	4.5%

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Cetrotide (R)	RH	5.6	1.4%	52.9%	3.7	1.2%
Crinone (R)	RH	4.5	1.1%	41.5%	3.2	1.0%
Profasi (R)	RH	3.7	0.9%	(25.8%)	5.0	1.6%

* 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	2003 *	% OF	% change	2002 *	% of
	US\$ '000	REVENUES		US\$ '000	Revenues
Revenues					
Product sales	407,786		30.1%	313,532	
Royalty and license income	34,620		22.1%	28,359	
TOTAL REVENUES	442,406	100.0%	29.4%	341,891	100.0%
Operating Expenses					
Cost of product sales	62,631		23.4%	50,760	
% of Sales	15.4%			16.2%	
Selling, general and administrative	140,916	31.9%	21.1%	116,340	34.0%
Research and development	127,937	28.9%	69.1%	75,636	22.1%
Other operating expense, net	45,751	10.3%	135.5%	19,430	5.7%
Total Operating Expenses	377,235	85.3%	43.9%	262,166	76.7%
OPERATING INCOME	65,171	14.7%	(18.3%)	79,725	23.3%
Financial income, net	8,382		81.7%	4,613	
Other expense, net	1,499			543	
Total Non Operating Income, Net	6,883			4,070	
Income Before Taxes and Minority Interests	72,054	16.3%	(14.0%)	83,795	24.5%
Taxes	11,529			14,245	
Income Before Minority Interests	60,525			69,550	
Minority interests	367			73	
NET INCOME	60,158	13.6%	(13.4%)	69,477	20.3%
Milestone payment for Raptiva 1)	25,000			0	
Tax impact	(4,000)			0	
NET INCOME W/O RAPTIVA MILESTONE PAYMENT	81,158	18.3%	16.8%	69,477	20.3%

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* Unaudited

1) Payment made to Genentech for filing of Raptiva in Europe

	2003	2002	% CHANGE	2003 W/O RAPTIVA MILESTONE PAYMENT 1)	2002	% CHANGE
Basic Earnings per Share (in U.S. dollars)						
- Bearer shares	3.80	4.32	(12.2%)	5.12	4.32	18.5
- Registered shares	1.52	1.73	(12.2%)	2.05	1.73	18.5
- American depositary shares	0.09	0.11	(12.2%)	0.13	0.11	18.5
Diluted Earnings per Share (in U.S. dollars)						
- Bearer shares	3.79	4.32	(12.1%)	5.12	4.32	18.6
- Registered shares	1.52	1.73	(12.1%)	2.05	1.73	18.6
- American depositary shares	0.09	0.11	(12.1%)	0.13	0.11	18.6