

SERONO S A
Form 6-K
April 22, 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 April, 2005

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 21, 2005, 10.01 pm CET

SERONO REPORTS Q1 2005 RESULTS

- **Rebif® US market share at all-time high and Raptiva® now reimbursed in 12 countries -**
- **Provision taken for Serostim® investigation resulting in one-time exceptional charge of \$725m -**

Geneva, Switzerland, April 21, 2005 - 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, 2005.

Key Points for First Quarter 2005

- Ø Total revenues up 8.0% to \$601.4m (up 4.4% in local currencies) and product sales up 6.7% to \$551.4m (up 3.1% in local currencies)
- Ø Exceptional charge of \$725.0m related to previously reported US Attorney's Office investigation of Serostin® resulting in reported net loss of \$567.7m
- Ø Excluding exceptional charge net income down 11.7% to \$92.7m (down 12.9% in local currencies) and basic EPS down 4.4% to \$6.37 per bearer share and \$0.16 per ADS*
- Ø Rebif® US market share at all-time high with 18.2% of total prescriptions and 22.4% of new prescriptions at the end of the quarter
 - Ø Raptiva® reimbursement progressing well and now reimbursed in 12 countries
- Ø Initiation of Mylinax® phase III trial, potentially the first oral treatment for people living with multiple sclerosis

“Serono’s strong fundamentals in each of its therapeutic areas give us confidence to deliver our top and bottom-line guidance for the full year, excluding the one-time exceptional charge,” said Ernesto Bertarelli, Chief Executive Officer of Serono, “I am very pleased with the recent market share of Rebif® in the US which is at an all-time high as well as with the reimbursement progress of Raptiva®.”

“Excluding the one-time exceptional charge, our first quarter net income is in line with our expectations for quarterly phasing this year,” said Stuart Grant, Chief Financial Officer of Serono.

* Non-IFRS financial measures included in order to permit assessment of the performance of the company’s underlying business for the quarter

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Investigation of Past Serostim® Marketing Activity

The company has taken a provision of \$725.0m, in connection with the previously reported Serostim® investigation. The group's principal US subsidiary, Serono, Inc., received a subpoena in 2001 from the US Attorney's office in Boston, Massachusetts requesting that it produce documents for the period from 1992 to the present relating to Serostim®. As part of an ongoing, industry-wide investigation by the states and the federal government into the setting of average wholesale prices and commercial practices, other pharmaceutical companies have received similar subpoenas. These investigations seek to determine whether such practices violated any laws, including the Federal False Claims Act or the US Food, Drug and Cosmetic Act or constituted fraud in connection with Medicare and/or Medicaid reimbursement to third parties.

Serono has cooperated fully with the investigation and continues to do so. Although no final agreement has been reached, the company's discussions with the US Attorney's office have advanced to a point where it is now appropriate to take a provision that management believes will be sufficient to cover resolution of the investigation related to Serostim®.

Serono is committed to meet the highest standards of ethical behaviour. The company participated in the setting of industry-wide codes of conduct, and has in place a rigorous compliance program.

Financial Performance

Total revenues increased by 8.0% to \$601.4m in the first quarter of 2005 (Q1 2004: \$557.1m), or 4.4% in local currencies. Product sales grew 6.7% to \$551.4m (Q1 2004: \$516.7m), or 3.1% in local currencies, reflecting the strength of the first quarter 2004 and recent developments in the competitive environment in the United States. Royalty and license income increased by 23.8% to \$50.0m (Q1 2004: \$40.4m).

Excluding the one-time exceptional charge of \$725.0m, total operating expenses increased by 11.8% to \$494.2m* in the first quarter of 2005 (Q1 2004: \$442.0m), or 7.6% in local currencies, reflecting tight control on costs, particularly in view of a low base in the first quarter of 2004.

Gross margin increased to 89.2% of product sales (Q1 2004: 85.4%), as a result of continuing manufacturing improvements, an increased proportion of recombinant products sold, as well as a benefit following the closure of an obsolete manufacturing plant last year.

Selling, General and Administrative expenses were \$214.6m (Q1 2004: \$184.2m), an increase of 16.5%. This increase is related to the Rebif® share of voice expansion program and the on-going launch of Raptiva®.

* Non-IFRS financial measures included in order to permit assessment of the performance of the company's underlying business for the quarter

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Research and Development expenses of \$156.3m (Q1 2004: \$126.2m) were in line with the previous quarter's underlying level. R&D expenses increased by 23.8% from the first quarter of 2004, reflecting a strong increase in the number of patients enrolled in late-stage projects during the first quarter of 2005.

Other operating expenses were \$63.8m (Q1 2004: \$56.0m) incorporating for the first time expenses of \$4.0m related to stock options according to the IFRS 2 accounting change.

Including the one-time exceptional charge of \$725.0m, Serono reported an operating loss of \$617.8m in the first quarter of 2005. Excluding the one-time exceptional charge, operating income decreased by 6.9% to \$107.2m or 17.8% of total revenues* (Q1 2004: \$115.1m or 20.7% of total revenues).

Net financial income was \$6.9m (Q1 2004: \$9.0m). Additionally a charge of \$4.7m was taken in the first quarter, in accordance with IAS 38 revised to reflect the impairment in value of our equity stake in CancerVax.

Including the one-time exceptional charge of \$725.0m, Serono reported a net loss of \$567.7m in the first quarter of 2005. Excluding the one-time exceptional charge, net income was down 11.7% to \$92.7m* (Q1 2004: \$105.0m), or 12.9% in local currencies.

Basic loss per share was \$38.99 per bearer share (Q1 2004 EPS: \$6.66) and \$0.97 per American Depositary Share (ADS) (Q1 2004 EPS: \$0.17). Excluding the one-time exceptional charge, basic earnings per share were down 4.4% to \$6.37 per bearer share and \$0.16 per ADS*.

For the first quarter, net cash flow from operating activities before change in working capital was \$146.4m (Q1 2004: \$157.1m), or \$53.3m after change in working capital (Q1 2004: \$102.9m), reflecting milestone payments made in the first quarter of 2005 relating to agreements signed in 2004 with CancerVax and Micromet.

As of March 31, 2005, there were 14,563,008 outstanding equivalent bearer shares of Serono SA, net of treasury shares.

Therapeutic Areas Review

In the first quarter of 2005, sales of Rebif® were up 12.8% (8.4% in local currencies) to \$292.8m (Q1 2004: \$259.6m). Rebif® continues its market leadership outside the US with sales increasing by 9.7% to \$216.1m (Q1 2004: \$196.9m), or 4.1% in local currencies. Sales in the US were up 22.4% to \$76.8m in the first quarter. Rebif® ended the quarter with an all-time high US market share of 18.2% of total prescriptions and 22.4% of new prescriptions.

* Non-IFRS financial measures included in order to permit assessment of the performance of the company's underlying business for the quarter

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Sales of Raptiva[®], the first biological treatment for psoriasis to be authorized for marketing in the European Union, were \$4.5m in the first quarter 2005 (Q1 2004: \$0.1m). The pricing and reimbursement process progresses well and we recently achieved reimbursement in the Netherlands, Spain, Italy and Norway. Raptiva[®] is now reimbursed in 12 countries and the roll-out will continue throughout 2005.

Sales of Gonal-f[®] increased by 0.5% (-2.7% in local currencies) to \$138.0m (Q1 2004: \$137.4m). Gonal-f[®] performed well outside of the US but was impacted in the US by significant discount programs offered by a competitor. In keeping with the phase out plan, urine-derived gonadotropin sales were \$5.1m in the first quarter (Q1 2004: \$12.9m).

Saizen[®] sales increased by 17.6% (13.1% in local currencies) to \$47.8m (Q1 2004: \$40.7m). Serostim[®] sales decreased by 15.2% (15.3% in local currencies) to \$18.3m (Q1 2004: \$21.5m). In April, Saizen[®] successfully completed the EU mutual recognition procedure leading to marketing approval for the treatment of short children born small for gestational age. National approvals in 15 European countries based on this procedure will follow shortly.

Regional Sales

European sales increased by 10.8% (4.4% in local currencies) to \$264.9m (Q1 2004: \$239.1m). North American sales grew by 0.8% to \$184.9m (Q1 2004: \$183.3m). In the rest of the world, sales grew by 7.8% (5.6% in local currencies) to \$101.7m (Q1 2004: \$94.3m).

R&D News

In the first quarter Serono initiated a Phase III trial with Mylinax[®] in relapsing forms of multiple sclerosis (MS). This is a two-year, double-blind, placebo-controlled study. Endpoints include assessment of clinical relapses, disability and MRI (magnetic resonance imaging) brain scans.

Serono's commitment to the field of MS is further underlined by its in-house research programs and in-licensing activities. Recently Serono achieved a major milestone in the identification of 80 genes involved in the inflammatory and neuro-degenerative pathways of MS thereby providing potential new drug targets. On March 31 Serono concluded an agreement with Syntonix to develop and commercialize interferon-beta:Fc products. Syntonix' technologies may enable the development of an interferon-beta therapy for MS that can be administered by inhalation.

On April 6 Serono announced the discontinuation of two clinical trial programs; oncept (recombinant tumor necrosis factor binding protein) in moderate to severe psoriasis and Canvaxin[™] in stage IV melanoma. The decision to discontinue these clinical programs is based on the recommendations of two separate independent Data and Safety Monitoring Boards.

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Conference Call and Webcast

Serono will hold a conference call on April 22nd, 2005, starting at 15:00 Central European Time (9:00 am US Eastern Time) during which Serono Management will present the Company's First Quarter 2005 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.

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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 US Securities and Exchange Commission on March 16, 2005. 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 government investigations and litigation 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[®], Zorbitive[™] 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 months ended March 31, 2005 and 2004.
- Consolidated statements of income for the 3 months ended March 31, 2005 and 2004; the consolidated balance sheets as of March 31, 2005 and December 31, 2004; the consolidated statements of equity as of March 31, 2005 and 2004; the consolidated statements of cash flows for the 3 months ended March 31, 2005 and 2004; and the selected explanatory notes to the consolidated financial statements. 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, 2005 | | | Three Months Ended March 31, 2004 | |
|----------------------------|--------------------------------------|------------|-------------|--------------------------------------|------------|
| | \$ million | % of sales | % change \$ | \$ million | % of sales |
| Neurology | 298.0 | 54.1% | 12.3% | 265.5 | 51.4% |
| Reproductive Health | 165.5 | 30.0% | (2.8%) | 170.2 | 32.9% |
| Growth & Metabolism | 66.4 | 12.0% | 6.8% | 62.2 | 12.0% |
| Dermatology | 4.5 | 0.8% | 3478.5% | 0.1 | 0.0% |
| Others | 17.0 | 3.1% | (9.0%) | 18.7 | 3.6% |
| Total sales (US\$ million) | \$ 551.4 | | | | |

| | | | | | |
|---|--|--|--|--|-----------------|
| | | | | | 100 |
| % | | | | | |
| | | | | | 6.7 |
| % | | | | | |
| | | | | | \$ 516.7 |
| | | | | | 100 |
| % | | | | | |

Sales by geographic region

| | Three Months Ended March 31, 2005 | | | Three Months Ended March 31, 2004 | |
|----------------------------|--------------------------------------|------------|-------------|--------------------------------------|------------|
| | \$ million | % of sales | % change \$ | \$ million | % of sales |
| Europe | 264.9 | 48.0% | 10.8% | 239.1 | 46.3% |
| North America | 184.9 | 33.5% | 0.8% | 183.3 | 35.5% |
| Latin America | 29.5 | 5.4% | 11.9% | 26.4 | 5.1% |
| Others | 72.2 | 13.1% | 6.2% | 67.9 | 13.1% |
| Total sales (US\$ million) | \$ 551.4 | | | | |

| | | | | | |
|---|--|--|--|--|-----------------|
| | | | | | 100 |
| % | | | | | |
| | | | | | 6.7 |
| % | | | | | |
| | | | | | \$ 516.7 |
| | | | | | 100 |
| % | | | | | |

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TOP TEN PRODUCTS

| | *TA | Three Months Ended March, 2005 | | | Three Months Ended March, 2004 | |
|-------------|-------------|-----------------------------------|------------|----------------|-----------------------------------|------------|
| | | \$ million | % of sales | % change \$ | \$ million | % of sales |
| Rebif® | MS | 292.8 | 53.1% | 12.8% | 259.6 | 50.2% |
| Gonal-f® | RH | 138.0 | 25.0% | 0.5% | 137.4 | 26.6% |
| Saizen® | Growth | 47.8 | 8.7% | 17.6% | 40.7 | 7.9% |
| Serostim® | Wasting | 18.3 | 3.3% | (15.2%) | 21.5 | 4.2% |
| Novantrone® | MS/Oncology | 16.0 | 2.9% | 4.5% | 15.3 | 3.0% |
| Cetrotide® | RH | 6.2 | 1.1% | (1.0%) | 6.3 | 1.2% |
| Ovidrel® | RH | 5.7 | 1.0% | 46.2% | 3.9 | 0.8% |
| Crinone® | RH | 5.6 | 1.0% | 24.7% | 4.5 | 0.9% |
| Raptiva® | Dermatology | 4.5 | 0.8% | 3478.5% | 0.1 | 0.0% |
| Stilamin® | Other | 3.5 | 0.6% | (14.1%) | 4.1 | 0.8% |

*** Therapeutic Areas**

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

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CONSOLIDATED INCOME STATEMENTS

| Three months ended March 31 | 2005* US\$'000 | % of Revenues | % change | 2004* US\$'000 | % of Revenues |
|---|-------------------|------------------|----------|-------------------|------------------|
| Revenues | | | | | |
| Product sales | 551,413 | | 6.7% | 516,713 | |
| Royalty and license income | 49,969 | | 23.8% | 40,378 | |
| Total Revenues | 601,382 | 100.0 | 8.0% | 557,091 | 100.0% |
| Operating Expenses | | | | | |
| Cost of product sales | 59,470 | | | 75,669 | |
| % of Sales | 10.8% | | | 14.6% | |
| Selling, general and administrative | 214,650 | 35.7% | 16.5% | 184,203 | 33.1% |
| Research and development | 156,273 | 26.0% | 23.8% | 126,199 | 22.7% |
| Exceptional litigation expense and related costs | 725,000 | 120.6% | -- | -- | -- |
| Other operating expense, net | 63,824 | 10.6% | 14.1% | 55,954 | 10.0% |
| Total Operating Expenses | 1,219,217 | 202.7% | 175.8% | 442,025 | 79.3% |
| Operating (Loss) / Income | (617,835) | (102.7%) | (636.9%) | 115,066 | 20.7% |
| Financial income, net | 6,887 | | (23.8%) | 9,034 | |
| Other (expense) / income, net | (4,289) | | | 4 | |
| Total Non Operating Income, net | 2,598 | | | 9,038 | |
| (Loss) / Income Before Taxes and Minority Interests | (615,237) | (102.3%) | (595.7%) | 124,104 | 22.3% |
| Taxes | (48,061) | | | 20,031 | |
| (Loss) / Income Before Minority Interests | (567,176) | | | 104,073 | |
| Minority interests | 573 | | | (974) | |
| Net (Loss) / Income | (567,749) | (94.4%) | (640.5%) | 105,047 | 18.9% |

The accompanying selected explanatory notes form an integral part of these financial statements.

* Unaudited

Proforma net income excluding exceptional litigation expense and related costs * *:

| | | | | | |
|--|------------------|-------|---------|---------|-------|
| Net (Loss) / Income | (567,749) | | | 105,047 | 18.9% |
| Exceptional litigation expense and related costs | 725,000 | | | -- | |
| Tax impact | (64,525) | | | -- | |
| Net Income without exceptional litigation expense and related costs | 92,726 | 15.4% | (11.7%) | 105,047 | 18.9% |

* * Non-IFRS financial measure included in order to permit assessment of the performance of the company's underlying business for the quarter.

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CONSOLIDATED BALANCE SHEETS

| As of | March 31, 2005 * | December 31, |
|---|-------------------------|------------------|
| | US\$'000 | 2004 |
| | | US\$'000 |
| Assets | | |
| Current Assets | | |
| Cash and cash equivalents | 486,187 | 275,979 |
| Short-term financial assets | 715,836 | 784,999 |
| Trade accounts receivable | 415,595 | 427,935 |
| Inventories | 314,556 | 326,937 |
| Prepaid expenses and other current assets | 243,680 | 237,205 |
| Total Current Assets | 2,175,854 | 2,053,055 |
| Non-Current Assets | | |
| Tangible fixed assets | 764,905 | 799,878 |
| Intangible assets | 283,317 | 290,558 |
| Deferred tax assets | 264,722 | 201,021 |
| Long-term financial assets | 818,589 | 929,030 |
| Other long-term assets | 128,988 | 133,302 |
| Total Non-Current Assets | 2,260,521 | 2,353,789 |
| Total Assets | 4,436,375 | 4,406,844 |
| Liabilities | | |
| Current Liabilities | | |
| Trade and other payables | 389,773 | 426,616 |
| Short-term financial debts | 38,791 | 34,527 |
| Income taxes | 156,361 | 166,861 |
| Deferred income - current | 32,948 | 33,128 |
| Other current liabilities | 915,255 | 208,071 |
| Total Current Liabilities | 1,533,128 | 869,203 |
| Non-Current Liabilities | | |
| Long-term financial debts | 625,136 | 640,892 |
| Deferred tax liabilities | 20,347 | 24,242 |
| Deferred income - non current | 149,367 | 157,004 |
| Provisions and other long-term liabilities | 275,625 | 276,610 |
| Total Non-Current Liabilities | 1,070,475 | 1,098,748 |
| Total Liabilities | 2,603,603 | 1,967,951 |
| Minority Interests | 3,869 | 3,343 |
| Shareholders' Equity | | |
| Share capital | 254,951 | 254,420 |
| Share premium | 1,039,557 | 1,023,332 |
| Treasury shares | (984,874) | (987,489) |
| Retained earnings | 1,453,114 | 2,020,863 |
| Fair value and other reserves | 19,940 | 56,829 |
| Cumulative foreign currency translation adjustments | 46,215 | 667,595 |

| | | |
|--|------------------|-----------|
| Total Shareholder's Equity | 1,828,903 | 2,435,550 |
| Total Liabilities, Minority Interests and Shareholders' Equity | 4,436,375 | 4,406,844 |

The accompanying selected explanatory notes form an integral part of these financial statements.

* Unaudited

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CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

| | Share capital US\$'000 | Share premium US\$'000 | Treasury shares US\$'000 | Retained earnings US\$'000 | Fair value and other reserves US\$'000 | Cumulative foreign currency translation adjustments US\$'000 | Total US\$'000 |
|--|------------------------------|------------------------------|--------------------------------|----------------------------------|---|---|-------------------|
| Balance as of January 1, 2004: | | | | | | | |
| As previously reported | 253,895 | 1,002,991 | (157,642) | 1,669,700 | 22,711 | 88,535 | 2,880,190 |
| Effect of revisions to IAS 39 Financial Instruments: | | | | | | | |
| Recognition and Measurement | | | | (26,649) | 33,137 | (2,035) | 4,453 |
| Effect of IFRS 2 Share Based Payments | | | | (2,945) | | | (2,945) |
| As restated | 253,895 | 1,002,991 | (157,642) | 1,640,106 | 55,848 | 86,500 | 2,881,698 |
| Acquisition of treasury shares | | | (103,125) | | | | (103,125) |
| Issue of share capital | 419 | 16,690 | 3,189 | | | | 20,298 |
| Net income | | | | 105,047 | | | 105,047 |
| Fair value adjustments on available-for sales investments | | | | | 9,962 | | 9,962 |
| Translation effects | | | | | | (23,540) | (23,540) |
| Balance as of March 31, 2004 * | 254,314 | 1,019,681 | (257,578) | 1,745,153 | 65,810 | 62,960 | 2,890,340 |
| Balance as of January 1, 2005: | | | | | | | |
| As previously reported | 254,420 | 1,023,125 | (987,489) | 2,064,499 | 23,482 | 69,841 | 2,447,878 |
| Effect of revisions to IAS 39 Financial Instruments: | | | | | | | |
| Recognition and Measurement | | | | (28,546) | 33,347 | (2,246) | 2,555 |
| Effect of IFRS 2 Share Based Payments | | 207 | | (15,090) | | | (14,883) |
| As restated | 254,420 | 1,023,332 | (987,489) | 2,020,863 | 56,829 | 67,595 | 2,435,550 |
| Issue of share capital | 531 | 16,206 | 2,615 | | | | 19,352 |
| Fair value of stock options on Serono shares that have vested | | 19 | | | | | 19 |
| Net loss | | | | (567,749) | | | (567,749) |
| Recognition of unrealized loss on available-for-sale investment | | | | | 4,700 | | 4,700 |
| Fair value adjustments on available-for sales investments | | | | | (40,111) | | (40,111) |

| | | | | | | | | |
|--|----------------|------------------|------------------|------------------|---------------|-----------------|--|------------------|
| Fair value adjustments on financial instruments | | | | | | (1,478) | | (1,478) |
| Translation effects | | | | | | (21,380) | | (21,380) |
| Balance as of March 31, 2005 * | 254,951 | 1,039,557 | (984,874) | 1,453,114 | 19,940 | 46,215 | | 1,828,903 |

The accompanying selected explanatory notes form an integral part of these financial statements.

* Unaudited

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CONSOLIDATED CASH FLOW STATEMENTS

| Three months ended March 31 | 2005 * US\$'000 | 2004 * US\$'000 |
|--|--------------------|--------------------|
| (Loss) / Income before taxes and minority interests | (615,237) | 124,104 |
| Reversal of non-cash items | | |
| Depreciation and amortization | 34,493 | 33,204 |
| Financial income | (13,716) | (16,864) |
| Financial expense | 4,550 | 6,896 |
| Legal provision | 725,000 | -- |
| Other non-cash items | 11,302 | 9,730 |
| Cash Flows From Operating Activities Before Working Capital Changes | 146,392 | 157,070 |
| Working Capital Changes | | |
| Trade accounts payable, other current liabilities and deferred income | (40,892) | 19,332 |
| Trade accounts receivable and other receivables | (5,671) | (16,154) |
| Inventories | (3,254) | 1,148 |
| Prepaid expenses and other current assets | (19,866) | (20,817) |
| Taxes paid | (23,434) | (37,704) |
| Total working capital changes | (93,117) | (54,195) |
| Net Cash Flows From Operating Activities | 53,275 | 102,875 |
| Investment in tangible fixed assets | (36,554) | (39,492) |
| Proceeds from disposal of tangible fixed assets | 74 | 2,954 |
| Purchase of intangible and other long-term assets | (5,427) | (3,510) |
| Purchase of available-for-sale investments | (193,331) | (574,439) |
| Proceeds from sale of available-for-sale investments | 334,820 | 159,208 |
| Interest received | 29,138 | 26,931 |
| Net Cash Flows From Investing Activities | 128,720 | (428,348) |
| Acquisition of treasury shares | -- | (103,125) |
| Proceeds from issue of Serono shares | 11,055 | 10,333 |
| Proceeds from exercise of options on Serono shares | 2,220 | 318 |
| Proceeds from issue of options on Serono shares | 283 | -- |
| Increase in long-term financial debts | 14,125 | 8,784 |
| Change in short-term financial debts | 5,071 | (5,582) |
| Other non-current liabilities | (2,883) | 1,985 |
| Interest paid | (953) | (1,894) |
| Net Cash Flows From Financing Activities | 28,918 | (89,181) |
| Effect of Exchange Rate Changes on Cash and Cash Equivalents | (705) | (1,489) |
| Net Increase/(Decrease) in Cash and Cash Equivalents | 210,208 | (416,143) |
| Cash and cash equivalents at the beginning of period | 275,979 | 1,003,972 |
| Cash and cash equivalents at the end of period | 486,187 | 587,829 |

The accompanying selected explanatory notes form an integral part of these financial statements.

*Unaudited

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Selected explanatory notes to the interim consolidated financial statements (unaudited)**1. Accounting principles**

The accompanying condensed unaudited interim consolidated financial statements have been prepared in accordance with International Accounting Standard 34 (Interim Financial Reporting). The accounting policies used in the preparation of the interim consolidated financial statements are consistent with those used by Serono in its annual consolidated financial statements for the year ended December 31, 2004. These interim consolidated financial statements should be read in conjunction with the 2004 annual consolidated financial statements. These consolidated financial statements were approved for issuance on April 19th, 2005 by Serono S.A.'s board of directors.

2. Adoption of International Accounting Standards

On January 1, 2005, the group adopted revisions that were made to International Accounting Standard 39 Financial Instruments: Recognition and Measurement ("IAS 39"). Under the revised version of IAS 39, the definition of objective evidence related to the impairment of available-for-sale investments has been expanded such that any significant or prolonged decline in the fair value of an available-for-sale investment below its cost is objective evidence of impairment. The management of the Serono considers "significant" to mean at least 25% of the cost of an investment and "prolonged" to mean more than six months. Accordingly, several of the group's equity investments were technically impaired in prior years under the revised definition of objective evidence.

The revisions to IAS 39 must be applied retrospectively, and as a result, opening retained earnings as of January 1, 2004 and 2005 have been adjusted as if this standard had always been in use. Reported other expense for the twelve months ended December 31, 2000, 2001 and 2002 has been increased by \$19.3 million, \$7.2 million and \$14.8 million respectively, while other expense for the twelve months ended December 31, 2003 has been decreased by \$10.2 million. Net income for the twelve months ended December 31, 2000, 2001 and 2002 has been decreased by \$18.5 million, \$5.3 million and \$12.8 million, respectively, while net income for the twelve months ended December 31, 2003 has been increased by \$10.0 million.

Shareholders equity as of January 1, 2004 and 2005 has been updated to incorporate the impact of the revisions made to IAS 39. Retained earnings as of January 1, 2004 and 2005 have been reduced by \$26.6 million and \$28.5 million, which is net of income taxes in the amounts of \$4.5 million and \$2.6 million, respectively. Fair value and other reserves as of January 1, 2004 and 2005 have been increased by \$33.1 million and \$33.3 million, respectively.

The group also adopted International Financial Reporting Standard 2 Shares-Based Payment starting January 1, 2005, which must be applied to all grants of shares, stock option or other equity instruments that were granted after November 7, 2002 and had not yet vested at January 1, 2005. As a result, other operating expense reported for the twelve months ended December 31, 2003 and 2004 has been increased by \$2.9 million and \$12.1 million, respectively. Other operating expense for the three months ended March 31, 2004 has been increased by \$1.0 million. Net income for the above periods has been decreased by the same amounts respectively.

Retained earnings as of January 1, 2004 and 2005 have been reduced by \$2.9 million and \$15.1 million, respectively.

3. Segment information - geographical segment

| | | | Middle East, Africa and Asia-Pacific, | | | | |
|--------------------------------------|---------|------------------|---|-------------------------|------------------|-------------|---------|
| | Europe | North America | Eastern Europe | Oceania and Japan | Latin America | Unallocated | Total |
| Three months ended March 31, 2005 | US\$000 | US\$000 | US\$000 | US\$000 | US\$000 | US\$000 | US\$000 |

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| | | | | | | | |
|---|----------------|----------------|---------------|---------------|---------------|-----------|------------------|
| Product sales | 264,876 | 184,858 | 42,777 | 29,396 | 29,506 | - | 551,413 |
| Royalty and license income | 42,949 | 428 | 6,592 | - | - | - | 49,969 |
| Total revenues | 307,825 | 185,286 | 49,369 | 29,396 | 29,506 | - | 601,382 |
| Operating loss before unallocated expenses | (589,495) | 88,067 | 14,391 | 8,382 | 15,271 | (28,413) | (491,797) |
| Corporate research and development expenses | - | - | - | - | - | (126,038) | (126,038) |
| Operating loss | | | | | | | (617,835) |

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| | |
|--|---------|
| | 25,708 |
| | 26,362 |
| | - |
| | 516,713 |
| Royalty and license income | |
| | 35,101 |
| | 871 |
| | 4,406 |
| | - |
| | - |
| | - |
| | 40,378 |
| Total revenues | |
| | 274,178 |
| | 184,189 |
| | 46,654 |
| | 25,708 |
| | 26,362 |
| | - |
| | 557,091 |
| Operating income before unallocated expenses | |
| | 107,103 |
| | 96,168 |
| | 12,984 |
| | 6,550 |
| | 23 |

| | |
|---|---------|
| | 13,659 |
|) | (23,427 |
| | 213,037 |
| Corporate research and development expenses | - |
| | - |
| | - |
| | - |
| | - |
|) | (97,971 |
| | (97,971 |
|) | (97,971 |
| Operating income | 115,066 |

Unallocated items represent income, expenses or corporate coordination functions which are not directly attributable to specific geographical segments. Product sales are based on the country in which the customer is located, while royalty and license income is based on the country that receives the royalty. There are no sales or other transactions between the business segments.

4. Available-for-sale investments

During the first quarter of 2005, the group recognized an unrealized loss within other expense of \$4.7 million that resulted from the decline in the fair value of one of its available-for-sales investments as required under International Accounting Standard 39 Financial Instruments: Recognition and Measurement.

5. Taxes

Tax income recognized for the three months ended March 31, 2005 includes \$64.5million in deferred tax income from the recognition of exceptional litigation expense and related costs that was recorded during the quarter as disclosed in note 13 legal proceedings.

6. Loss per share

Basic loss per share

Basic loss per share is calculated by dividing the net loss attributable to shareholders by the weighted average number of shares outstanding during the period presented. The number of outstanding shares is calculated by deducting the average number of shares purchased and held as treasury shares from the total of all issued shares:

| | Three months ended March 31 | |
|---|-----------------------------|----------------|
| | 2005 | 2004 |
| | US \$000 | US \$000 |
| Net (loss) / income attributable to bearer shareholders | (395,977) | 75,710 |
| Net (loss) / income attributable to registered shareholders | (171,772) | 29,337 |
| Total net (loss) / income | (567,749) | 105,047 |
| Weighted average number of bearer shares outstanding | 10,155,130 | 11,368,535 |
| Weighted average number of registered shares outstanding | 11,013,040 | 11,013,040 |

| | Three months ended March 31 | |
|--|-----------------------------|------|
| | 2005 | 2004 |
| | US\$ | US\$ |
| Basic (loss) / earnings per share | | |
| Bearer shares | (38.99) | 6.66 |
| Registered shares | (15.60) | 2.66 |
| American depositary shares | (0.97) | 0.17 |

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Selected explanatory notes to the interim consolidated financial statements (unaudited)

Net income without exceptional litigation expense and related costs was \$92.7 million and basic earnings per share without exceptional litigation expense and related costs was \$6.37 per bearer share, \$2.55 per registered share and \$0.16 per American depositary share. Diluted earnings per share without exceptional litigation expense and related costs was \$6.36 per bearer share, \$2.54 per registered share, and \$0.16 per American depositary share.

Diluted loss per share

For diluted loss per share, the weighted average number of bearer shares outstanding is adjusted to assume conversion of all potential dilutive shares arising from outstanding stock options and the convertible bond. For stock options, a calculation is done to determine the number of shares that could have been acquired at fair value based on proceeds from the exercise of stock options. The number of shares calculated as above is compared with the number of shares that would have been issued assuming the exercise of the stock options. The difference is added to the denominator as additional shares for no consideration. There is no adjustment made to the numerator. The weighted average number of bearer shares outstanding would be increased by 23,807 shares (2004: 35,641 shares); however, the impact of stock options granted to employees and directors was not included in the calculated diluted loss per shares as they were anti-dilutive.

For the convertible bond, the number of shares into which the bond is assumed to be fully convertible is added to the denominator. The numerator, net loss, is decreased by eliminating the interest expense, net of tax, that would not be incurred if the bond were converted. For the first quarter 2005 and 2004, the effect of the convertible bond was excluded from the calculation of diluted loss and earnings per share as it was anti-dilutive.

7. Share capital

| Class of shares | Number of shares | Nominal value | As of March 31, 2005 | |
|---|-------------------|---------------|----------------------|----------------|
| | | | CHF000 | US\$000 |
| Issued and fully paid share capital | | | | |
| Registered | 11,013,040 | CHF10 | 110,130 | 68,785 |
| Bearer | 11,763,460 | CHF25 | 294,087 | 186,167 |
| Total | | | 404,217 | 254,952 |
| Authorized share capital - bearer | 1,400,000 | CHF25 | 35,000 | 29,276 |
| Conditional share capital - bearer for options and/or convertible bonds | 1,452,000 | CHF25 | 36,300 | 30,364 |
| Conditional share capital - bearer for stock options | 701,366 | CHF25 | 17,534 | 14,667 |
| As of December 31, 2004 | | | | |
| Class of shares | Number of shares | Nominal value | CHF000 | US\$000 |
| Issued and fully paid share capital | | | | |
| Registered | 11,013,040 | CHF10 | 110,130 | 68,785 |
| Bearer | 11,738,175 | CHF25 | 293,455 | 185,635 |
| Total | | | 403,585 | 254,420 |
| Authorized share capital - bearer | 1,400,000 | CHF25 | 35,000 | 30,905 |
| Conditional share capital - bearer for option and/or convertible bonds | 1,452,000 | CHF25 | 36,300 | 32,053 |
| Conditional share capital - bearer for stock options | 726,651 | CHF25 | 18,166 | 16,041 |

The authorized share capital may be used by Serono S.A. or its affiliates to finance research and development projects and acquire interests in other companies.

8. Treasury shares

There were 1,611,434 treasury shares held by the group as of January 1, 2005. During the first three months ended March 31, 2005 no additional treasury shares were acquired (2004: 160,600 treasury shares for a total consideration of CHF131.5 million or \$103.1 million). During the first quarter 2005, 5,766 treasury shares were granted to employees (6,648 shares in 2004), mostly as part of our employee share purchase plan whereby shares purchased under the plan that are held for one year after the purchase date entitle each participant to receive, on a one-time basis, one matching share for every three shares purchased and held.

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Selected explanatory notes to the interim consolidated financial statements (unaudited)

The CHF500.0 million Share Buy Back Plan, that was initiated in July 2002, has been fully utilized resulting in a total of 647,853 treasury shares acquired. In May 2004, a second Share Buy Back Plan was initiated that is authorized to acquire CHF750.0 million in bearer shares over a maximum period of five years. The bearer shares acquired under the second Share Buy Back Plan will be subsequently cancelled subject to the approval of the Annual General Meeting of shareholders that will be held on April 26th 2005.

The total number of treasury shares held as of March 31, 2005 is 1,605,668, of which 962,435 treasury shares will eventually be cancelled.

9. Distribution of earnings

At the Annual General Meeting of Shareholders on April 26, 2005, the Board of Directors will propose a cash dividend in respect of 2004 of CHF3.60 gross (2003: CHF3.20) per registered share, CHF9.00 gross (2003: CHF8.00) per bearer share or CHF0.23 per American depositary share, amounting to a total of CHF131.1 million. The amount available for dividend distribution is based on the available distributable retained earnings of Serono S.A., the holding company of the group, determined in accordance with the legal provisions of the Swiss Code of Obligations. These financial statements do not reflect the dividends payable, which will be accounted for in shareholders' equity as an appropriation of retained earnings in the year ending December 31, 2005.

10. Stock option plan**Employee stock option plan**

Stock options are granted to senior management members of Serono S.A. and its affiliates. Each stock option gives the holder the right to purchase one bearer share or one American depositary share ("ADS") of Serono S.A. stock, depending on which affiliate employs the holder. Stock options are granted every plan year and vest as follows: 25% one year after date of grant, 50% after two years, 75% after three years and 100% after four years. Options expire six years after the fourth and final vesting date such that each option has a 10-year duration. The exercise price is equal to the fair market value of the underlying Serono S.A. bearer share or American depositary shares on the date of grant.

Movements in the number of employee bearer stock options outstanding are as follows:

| | 2005 | | 2004 | |
|-----------------------------------|-----------------------|--|-----------------------|--|
| | Bearer options | Weighted average exercise price CHF | Bearer options | Weighted average exercise price CHF |
| Outstanding as of January 1 | 346,446 | 995 | 277,782 | 1,068 |
| Granted | - | - | 500 | 852 |
| Exercised | (4,345) | 609 | (740) | 546 |
| Cancelled | (4,133) | 1,070 | (6,257) | 1,151 |
| Outstanding as of March 31 | 337,968 | 999 | 271,285 | 1,067 |

Movements in the number of employee ADS stock options outstanding are as follows:

| | 2005 | | 2004 | |
|--|--------------------|---|--------------------|---|
| | ADS options | Weighted average exercise price US\$ | ADS options | Weighted average exercise price US\$ |

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| | | | | |
|-----------------------------------|------------------|--------------|--------|-------|
| Outstanding as of January 1 | 1,066,800 | 15.54 | 20,000 | 16.51 |
| Granted | - | - | 14,000 | 17.21 |
| Exercised | - | - | - | - |
| Cancelled | (59,800) | 15.70 | - | - |
| Outstanding as of March 31 | 1,007,000 | 15.54 | 34,000 | 16.80 |

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Selected explanatory notes to the interim consolidated financial statements (unaudited)

During the first three months ended March 31, 2005, 4,345 bearer stock options (2004: 740 bearer stock options) were exercised yielding proceeds of CHF2.6 million or \$2.2 million (2004: CHF0.4 million or \$0.3 million). Bearer and ADS stock options cancelled in all years since inception of the plan are the result of options forfeited by participants upon their departure from the group. The total number of bearer and ADS stock options available for grant as of March 31, 2005 is 319,771 options (2004: 46,568 options).

Director stock option plan

Stock options are granted to members of the Board of Directors of Serono S.A. Each stock option gives the holder the right to purchase one bearer share of Serono S.A. stock. Stock options are granted every plan year and vest beginning one year after their grant ratably over four years. Each option has a 10-year duration. The exercise price is equal to the fair market value of the underlying Serono S.A. bearer share on the date of grant. During the first three months ended March 31, 2005, no stock options (2004: nil) were granted to directors. No director stock options were cancelled or exercised during the first quarter 2005 and 2004. There are 20,720 director stock options outstanding as of March 31, 2005 (2004: 15,520 director stock options) with a weighted average exercise price of CHF755 (2004: CHF749).

During the first quarter of 2005, the group recognized a compensation expense related to the fair value of stock options granted to employees and directors in the amount of \$4.0 million (2004: \$1.0 million) as required under International Financial Reporting Standard 2 Share-Based Payment. The expense recognized from stock options is based on the binomial option-pricing model. A separate valuation is carried out for each grant. There were no options granted during the first three months of 2005.

11. Share purchase plans

Employee share purchase plan

The group has an employee share purchase plan (the "ESPP") covering substantially all of its employees. The ESPP is designed to allow employees to purchase bearer shares or American depositary shares at 85% of the lower of the fair market value at the date of the beginning of the plan period and the purchase date. Purchases under the ESPP are subject to certain restrictions and may not exceed 15% of the employee's annual salary. During the first quarter 2005, 20,940 bearer shares (2004: 20,301 bearer shares) were issued to employees at a price of CHF630 per share (2004: CHF654 per share). As of March 31, 2005, a total of \$3.2 million (2004: \$2.8 million) in contributions was held by the group to be used to purchase bearer and American depositary shares on behalf of employees in January 2006. The accrued compensation cost from the discount to be offered to employees based on the contributions held as of March 31, 2005 was \$1.1 million (2004: \$0.2 million).

Shares purchased under the ESPP that are held for one year after the purchase date entitle each participant to receive, on a one-time basis, one matching share for every three shares purchased and held. In January 2005, 5,766 bearer shares (2004: 6,648 bearer shares) were distributed to employees. The accrued compensation cost for the three months ended March 31, 2005 related to the matching shares that will be distributed in January 2006 is \$1.1 million (2004: \$1.1 million) and is calculated based on the number of matching shares multiplied by the quarter-end share price.

Director share purchase plan

During 2003, the group initiated a share purchase plan reserved for its Board of Directors (the "DSPP"). The DSPP allows board members to purchase Serono S.A. bearer shares through allocation of 50% or 100% of their gross yearly fees. Each cycle commences on the first business day following the Annual General Meeting of Shareholders (the "AGM") and concludes on the day of the next AGM. Directors must elect to participate in the DSPP at the beginning of each cycle. The purchase price per share is 85% of the fair market value of the share on the fifth business day following the AGM. Shares are purchased at the end of each cycle. During the first three months ended March 31, 2005, no bearer shares (none in 2004) were issued to the directors that participate in the plan.

12.

Principal shareholders

As of March 31, 2005, Bertarelli & Cie, a partnership limited by shares with its principal offices at Chésereux (Vaud), Switzerland, held 51.35% of the capital and 65.26% of the voting rights in Serono S.A. Ernesto Bertarelli controls Bertarelli & Cie. On the same date, Maria-Iris Bertarelli, Ernesto Bertarelli and Donata Bertarelli Späth owned in the aggregate 7.0% of the capital and 10.51% of the voting rights of Serono S.A.

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Selected explanatory notes to the interim consolidated financial statements (unaudited)

13. Legal proceedings

The group's principal U.S. subsidiary, Serono, Inc., received a subpoena in 2001 from the U.S. Attorney's office in Boston, Massachusetts requesting that it produce documents for the period from 1992 to the present relating to Serostim. During 2002, Serono, Inc. also received subpoenas from the states of California, Florida, Maryland and New York, which mirror the requests in the U.S. Attorney's subpoena. As part of an ongoing, industry-wide investigation by the states and the federal government into the setting of average wholesale prices and commercial practices, other pharmaceutical companies have received similar subpoenas. These investigations seek to determine whether such practices violated any laws, including the Federal False Claims Act or the U.S. Food, Drug and Cosmetic Act or constituted fraud in connection with Medicare and/or Medicaid reimbursement to third parties. Serono has cooperated fully with the investigation and continues to do so. Although no final agreement has been reached, the company's discussions with the US Attorney's office have advanced to a point where it is now appropriate to take a provision that management believes will be sufficient to cover resolution of the investigation related to Serostim. A provision in the amount of \$725.0 million (\$660.5 million after-tax) in connection with these investigations has been charged against the first quarter 2005 earnings. The company believes that the provision will be fully utilized before the end of the year.

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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)

April 22, 2005

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