

SERONO S A
Form 6-K
October 26, 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 October, 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 IMMEDIATE RELEASE

EXCELLENT THIRD QUARTER WITH STRONG EPS GROWTH OF 54.2%

- Rebif® achieves blockbuster status with sales reaching over \$1 billion a year and grows by 24.3% in the third quarter -

Geneva, Switzerland, October 26, 2004 - Serono S.A. (virt-x: SEO and NYSE: SRA), the world's third largest biotechnology company, today reported its third quarter results for the period ended September 30, 2004.

Highlights

Ø Total revenues of \$633.6m, up 26.0% (+21.0% in local currencies) driven by significant sales growth of leading products in each therapeutic area: Rebif® up 24.3%, Gonal-f® up 13.6% and Saizen® up 19.7%, as well as an additional exceptional royalty and license revenue of \$67m

Ø Net income of \$162.5m, up 47.2% (+43.5% in local currencies), notwithstanding an exceptional charge of \$20.5m for the closure of a manufacturing site

Ø Reported basic EPS up 54.2% to \$10.76 per Bearer Share and \$0.27 per American Depositary Share

Ø US Rebif® market share grew to 16.7% in total prescriptions and 20.0% in new prescriptions

Ø Latest Rebif® 44mcg 4-year data presented at ECTRIMS shows a 54% relative reduction in relapse rate and 76% of MS patients remaining free of disease progression

Ø Launch of Raptiva® following European Commission marketing authorization and FDA approval of Luveris®

Ø Start of patient enrollment into three oncept Phase III studies in psoriasis

Ø Broad strategic R&D and commercialization alliance with ZymoGenetics for protein pipeline

We continue to deliver strong quarterly results with substantial top and bottom line growth and are on track to deliver our full year guidance, said Ernesto Bertarelli, Chief Executive Officer. We are excited to be making Raptiva® available to patients. The product is now being launched in Germany, UK, Denmark, Sweden, Switzerland, Australia, and Latin America.

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Financial Performance

In the third quarter of 2004, total revenues grew by 26.0% to \$633.6m (Q3 2003: \$502.7m), or by 21.0% in local currencies.

Royalty and license income was \$115.5m (Q3 2003: \$39.2m), reflecting the company's strong intellectual property rights. In connection with the grant of a license under a non-core technology, Serono recorded exceptional license revenue of \$67m in the third quarter.

Product sales growth continued to be impacted by recent price and reimbursement issues in Germany. Worldwide product sales rose 11.8% to \$518.1m (Q3 2003: \$463.5m), or 7.5% in local currencies, and excluding Germany, product sales grew by 15.4% or 11.4% in local currencies.

Gross margin was 83.9% (Q3 2003: 85.8%) including an exceptional charge of \$20.5m taken in the third quarter of 2004 related to the closure of one of Serono's oldest manufacturing sites, which has become obsolete. Excluding this charge, gross margin reached 87.9%, primarily driven by a more favorable product mix and sustained productivity improvements.

Selling, general and administrative expenses were \$196.4m or 31.0% of total revenues (Q3 2003: \$158.9m or 31.6% of total revenues), reflecting commercial expenditures related to the launch of Raptiva[®], as well as the continued investment to drive Rebif[®] to worldwide market leadership.

Research and development expenses were \$124.2m or 19.6% of total revenues (Q3 2003: \$107.1m or 21.3% of total revenues). Serono announced a broad partnership agreement in the third quarter which for a \$20m payment provides access to ZymoGenetics' protein pipeline over the next five years. In addition Serono made an initial license payment to ZymoGenetics of \$11.25m to acquire rights to Fibroblast Growth Factor 18, Interleukin 22 Receptor, and Interleukin 31. As US Federal Trade Commission approval of the agreement was only received on October 5th, 2004, both payments will be recorded in the fourth quarter of 2004.

Operating income grew by 51.4% to \$177.7m (Q3 2003: \$117.3m). Net financial income was \$18.2m in the third quarter (Q3 2003: \$9.4m) as a result of higher returns on our financial assets, foreign exchange gains and an unrealized gain of \$5.4m related to the commitment to acquire \$50.0m of ZymoGenetics' common shares.

Reported net income grew 47.2% to \$162.5m (Q3 2003: \$110.5m), or 43.5% in local currencies, taking into account the exceptional license fee of \$67m and the exceptional charge for the closure of a manufacturing facility of \$20.5m.

Reported basic earnings per share (EPS) increased 54.2% to \$10.76 per bearer share (Q3 2003: \$6.98) and \$0.27 per American Depositary Share (ADS) (Q3 2003: \$0.17). The average number of equivalent bearer shares outstanding for the three months ended September 30, 2004 was 15,101,262.

In the third quarter, share repurchases were CHF358.4m (\$284.4m) representing 457,935 bearer shares. The company's liquid financial assets were \$2.2 billion at the end of the third quarter of 2004.

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Neurology

In the third quarter of 2004, total neurology sales increased by 22.3% to \$271.8m (Q3 2003: \$222.2m). Rebif® achieved blockbuster status with 12-month rolling sales reaching over \$1 billion. Rebif® worldwide sales were up 24.3% to \$263.5m, or 18.5% in local currencies (Q3 2003: \$212.0m) and Novantrone® sales in multiple sclerosis (MS) were \$8.3m (Q3 2003: \$10.2m).

In the USA, Rebif® sales increased by 53.3% to \$77.3m (Q3 2003: \$50.4m). Rebif® is the fastest growing MS disease modifying drug and has overtaken Betaseron® in terms of new prescription share since July 2004 in the USA. Rebif® 4-week rolling market share grew to 16.7% in total prescriptions and 20.0% in new prescriptions by the end of the third quarter of 2004.

Outside the USA Rebif® sales grew by 15.2% to \$186.2m (Q3 2003: \$161.6m). Rebif® has seen its market leadership reinforced with a widening gap in market share between Rebif® and the second and third competitor products.

At the 20th congress of the European Committee for Treatment and Research In Multiple Sclerosis (ECTRIMS) in Vienna, Austria, a new prospectively defined analysis from the PRISMS study was presented and further demonstrates the sustained efficacy of Rebif®. In patients switching from placebo to Rebif® 44mcg, the four year data shows a 54% relative reduction in relapse rate, and 76% of MS patients remain free of disease progression with Rebif® 44mcg.

Reproductive Health

In the third quarter, sales of Gonal-f® grew by 13.6% (9.3% in local currencies) to \$133.3m (Q3 2003: \$117.4m) driven by the launch of the Gonal-f® pen. Excluding Germany which was impacted by market constraints, Gonal-f® worldwide sales grew strongly by 26.6% (22.4% in local currencies).

The Gonal-f® pen was launched in July 2004 in the USA as the first and only pre-filled and ready-to-use multi-dose pen for FSH (follicle stimulating hormone) administration. It is specifically designed for the treatment of infertility allowing patients easy and accurate delivery of a precise daily dose of recombinant FSH.

Serono's core reproductive health portfolio, consisting of Gonal®[®], Ovidrel®, Luveris®, Cetrotide® and Crinone®, grew by 11.8% to \$149.6m, or 7.6% in local currencies. In accordance with our phase out plan, sales of urine-derived gonadotropins were \$7.8m (Q3 2003: \$21.8m), mainly in Japan and other Asian countries.

In October Serono announced that the Food and Drug Administration has approved Luveris® for concomitant use with Gonal-f® for stimulation of follicular development in infertile hypogonadotropic hypogonadal women with profound luteinizing hormone (LH) deficiency (LH < 1.2 UI/L). Luveris® is the first and only approved recombinant human form of LH, a naturally occurring fertility hormone. The Luveris® approval makes Serono the only company to offer three recombinant fertility hormones, part of its long-term global strategy to develop a 100% recombinant human gonadotropin portfolio.

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Growth and Metabolism

Saizen[®] sales increased by 19.7% (14.7% in local currencies) to \$44.1m (Q3 2003: \$36.8m) in the third quarter. The favorable market acceptance of the Saizen[®] family of devices in the USA and in Europe continue to make Saizen[®] a popular choice with prescribers and patients. Serostim[®] sales remained relatively stable at \$21.2m (Q3 2003: \$23.0m).

Dermatology

In late September, Raptiva[®] was approved by the European Commission for the treatment of patients with moderate-to-severe chronic plaque psoriasis for whom other systemic treatments or phototherapy have been inadequate or inappropriate. Raptiva[®] is the first biological treatment for psoriasis to be authorized for marketing in the 25 countries of the European Union. Raptiva[®] is also approved in Switzerland and Australia, as well as Argentina, Mexico and Brazil. Sales of Raptiva[®] in the third quarter were \$1.0m.

Raptiva[®] is being launched in Germany, UK, Denmark, Sweden, Switzerland, Australia, Argentina, Brazil and Mexico. The roll-out of Raptiva[®] will continue throughout 2005.

In late July, 30-month data from an ongoing 36-month trial was presented at the American Academy of Dermatology. This represents the longest continuous treatment recorded for biologics in psoriasis patients, and the data showed that patients who respond to Raptiva[®] continue to improve over time with no change in the excellent safety profile.

Regional Sales

Sales in North America grew strongly by 18.5% to reach \$213.1m (Q3 2003: \$179.8m). North America became the company's largest region in terms of sales in the third quarter of 2004. In Europe, sales increased by 7.4% to \$201.3m (Q3 2003: \$187.5m) despite tightening of pricing and reimbursement, particularly in Germany. Excluding Germany, European sales grew by 16.6%. In the rest of the world, sales rose by 7.8% to \$103.7m (Q3 2003: \$96.2m).

R&D News

Following the FDA clearance of the oncept Phase III program in the second quarter of 2004, studies in psoriasis were recently initiated. Patient enrollment into each of three Phase III studies has commenced. Oncept, Serono's candidate drug targeted at moderate-to-severe psoriasis, has already been shown to have a competitive efficacy profile in Phase II, with more than 50% of patients achieving a 75% improvement in PASI score at 12 weeks.

Phase Ib clinical trials of TACI-Ig in rheumatoid arthritis, multiple myeloma and non-Hodgkin's lymphomas have recently been initiated. These studies follow the successful completion of a Phase I trial with TACI-Ig in healthy volunteers, as well as the initiation of a Phase Ib clinical trial in systemic lupus erythematosus.

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On September 8th, 2004, Serono and ZymoGenetics announced a broad partnership to research, develop and commercialize novel protein and antibody therapeutics based on discoveries made by ZymoGenetics. As part of this alliance, Serono has exclusive worldwide rights to products based on Fibroblast Growth Factor 18 (FGF-18) and the Interleukin 22 Receptor (IL-22R). In addition, the companies will co-develop Interleukin 31 (IL-31). Serono will also have rights over the next five years to license up to twelve products arising from ZymoGenetics' internal core research projects. Finally, Serono will gain access to a large portfolio of ZymoGenetics' genes and proteins for in-house evaluation and screening, and rights to license such proteins over the next five years.

Investor Meetings

Serono's senior management will be presenting a company update in London and New York on November 8th and 10th, 2004 respectively. The London meeting will be webcast.

Conference Call and Webcast

Serono will hold a conference call today, October 26, 2004, starting at 3.00 pm Central European Time (9.00 am U.S. Eastern Time) during which Serono management will present the Company's third quarter 2004 results. To join the telephone conference please dial 091 610 5600 (from Switzerland), 0207 107 0611 (from the UK), 1 866 291 4166 (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 6.00 pm CET on October 29th, 2004. 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 215# 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 November 15, 2004.

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Some of the statements in this press release are forward looking. Such statements are inherently subject to known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements of Serono S.A. and affiliates to be materially different from those expected or anticipated in the forward-looking statements. Forward-looking statements are based on Serono's current expectations and assumptions, which may be affected by a number of factors, including those discussed in this press release and more fully described in Serono's Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission on March 25, 2004. These factors include any failure or delay in Serono's ability to develop new products, any failure to receive anticipated regulatory approvals, any problems in commercializing current products as a result of competition or other factors, our ability to obtain reimbursement coverage for our products, and government regulations limiting our ability to sell our products. Serono has no responsibility to update the forward-looking statements contained in this press release to reflect events or circumstances occurring after the date of this press release.

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About Serono

Serono is a global biotechnology leader. The Company has eight biotechnology products, Rebif[®], Gonal-F[®], Luveris[®], Ovidrel[®]/Ovitrelle[®], Serostim[®], Saizen[®], Zorbtive and Raptiva[®]. In addition to being the world leader in reproductive health, Serono has strong market positions in neurology, metabolism and growth and has recently entered the psoriasis area. The Company's research programs are focused on growing these businesses and on establishing new therapeutic areas. 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).

For more information, please contact:

Serono in Geneva, Switzerland:

| | |
|---|-------------------------------|
| Media Relations: | Investor Relations: |
| Tel: +41-22-739 36 00 | Tel: +41-22-739 36 01 |
| Fax: +41-22-739 30 85 | Fax: +41-22-739 30 22 |
| http://www.serono.com | Reuters: SEOZ.VX / SRA.N |
| | Bloomberg: SEO VX / SRA US |

Serono, Inc., Rockland, MA

| | |
|---|----------------------------|
| Media Relations: | Investor Relations: |
| Tel. +1 781 681 2340 | Tel. +1 781 681 2552 |
| Fax: +1 781 681 2935 | Fax: +1 781 681 2912 |
| http://www.seronusa.com | |

On the following pages, there are:

- Tables detailing sales in dollars by therapeutic area, geographic region and the top 10 products for the 3 and 9 months ended September 30, 2004 and 2003.
- Consolidated statements of income for the 3 and 9 months ended September 30, 2004 and 2003, the consolidated balance sheets as of September 30, 2004 and December 31, 2003, the consolidated statements of equity as of September 30, 2004 and 2003, the consolidated statements of cash flows for the 9 months ended September 30, 2004 and 2003, as well as the selected explanatory notes to the interim 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 September 30, 2004 | | | Three Months Ended September 30, 2003 | | |
|-----------------------------------|--|------------|----------------|--|------------|--|
| | \$ million | % of sales | % change \$ | \$ million | % of sales | |
| Neurology | 271.8 | 52.5% | 22.3% | 222.2 | 47.9% | |
| Reproductive Health | 159.4 | 30.8% | 1.0% | 157.9 | 34.1% | |
| Growth & Metabolism | 65.4 | 12.6% | 9.2% | 59.9 | 12.9% | |
| Others | 21.5 | 4.1% | (8.5%) | 23.5 | 5.1% | |
| Total sales (US\$ million) | \$518.1 | | | | | |

% **100**

% **11.8**

\$463.5

% **100**

Sales by geographic region

| | Three Months Ended September 30, 2004 | | | Three Months Ended September 30, 2003 | | |
|-----------------------------------|--|------------|----------------|--|------------|--|
| | \$ million | % of sales | % change \$ | \$ million | % of sales | |
| Europe | 201.3 | 38.8% | 7.4% | 187.5 | 40.4% | |
| North America | 213.1 | 41.1% | 18.5% | 179.8 | 38.8% | |
| Latin America | 25.4 | 4.9% | (10.7%) | 28.5 | 6.1% | |
| Others | 78.3 | 15.2% | 15.6% | 67.7 | 14.7% | |
| Total sales (US\$ million) | \$518.1 | | | | | |

% **100**

% **11.8**

\$463.5

100

%

Sales by therapeutic area

| | Nine Months Ended September 30, 2004 | | | Nine Months Ended September 30, 2003 | |
|-----------------------------------|---|------------|----------------|---|------------|
| | \$ million | % of sales | % change \$ | \$ million | % of sales |
| Neurology | 803.9 | 51.1% | 32.2% | 608.1 | 45.4% |
| Reproductive Health | 510.4 | 32.4% | 1.7% | 501.9 | 37.5% |
| Growth & Metabolism | 193.4 | 12.3% | 10.4% | 175.1 | 13.1% |
| Others | 65.8 | 4.2% | 22.7% | 53.6 | 4.0% |
| Total sales (US\$ million) | \$1,573.5 | | | | |

100

%

17.5

%

\$1,338.7

100

%

Sales by geographic region

| | Nine Months Ended September 30, 2004 | | | Nine Months Ended September 30, 2003 | |
|-----------------------------------|---|------------|----------------|---|------------|
| | \$ million | % of sales | % change \$ | \$ million | % of sales |
| Europe | 647.4 | 41.1% | 14.0% | 567.8 | 42.4% |
| North America | 605.2 | 38.5% | 20.7% | 501.6 | 37.5% |
| Latin America | 80.5 | 5.1% | 15.9% | 69.4 | 5.2% |
| Others | 240.4 | 15.3% | 20.2% | 200.0 | 14.9% |
| Total sales (US\$ million) | \$1,573.5 | | | | |

100

%

17.5

9

%

\$1,338.7

%

100

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TOP TEN PRODUCTS

| | * TA | Three Months Ended September 30, 2004 | | | Three Months Ended September 30, 2003 | |
|--------------|-------------|--|------------|----------------|--|------------|
| | | \$ million | % of sales | % change \$ | \$ million | % of sales |
| Rebif® | MS | 263.5 | 50.9% | 24.3% | 212.0 | 45.7% |
| Gonal-f® | RH | 133.3 | 25.7% | 13.6% | 117.4 | 25.3% |
| Saizen® | Growth | 44.1 | 8.5% | 19.7% | 36.8 | 7.9% |
| Novantrone® | MS/Oncology | 21.5 | 4.1% | (18.3%) | 26.3 | 5.7% |
| Serostim® | Wasting | 21.2 | 4.1% | (8.2%) | 23.0 | 5.0% |
| Cetrotide® | RH | 5.4 | 1.0% | (4.6%) | 5.6 | 1.2% |
| Crinone® | RH | 4.6 | 0.9% | (10.3%) | 5.2 | 1.1% |
| Metrodin-HP® | RH | 4.1 | 0.8% | (22.0%) | 5.2 | 1.1% |
| Ovidrel® | RH | 3.9 | 0.8% | 30.5% | 3.0 | 0.7% |
| Stilamin® | Other | 3.4 | 0.7% | (9.7%) | 3.8 | 0.8% |

| | * TA | Nine Months Ended September 30, 2004 | | | Nine Months Ended September 30, 2003 | |
|--------------|-------------|---|------------|----------------|---|------------|
| | | \$ million | % of sales | % change \$ | \$ million | % of sales |
| Rebif® | MS | 780.6 | 49.6% | 33.2% | 586.2 | 43.8% |
| Gonal-f® | RH | 421.6 | 26.8% | 11.2% | 379.0 | 28.3% |
| Saizen® | Growth | 129.0 | 8.2% | 18.1% | 109.2 | 8.2% |
| Novantrone® | MS/Oncology | 60.4 | 3.8% | 10.4% | 54.7 | 4.1% |
| Serostim® | Wasting | 64.1 | 4.1% | (2.7%) | 65.9 | 4.9% |
| Cetrotide® | RH | 18.1 | 1.2% | 5.8% | 17.1 | 1.3% |
| Crinone® | RH | 13.7 | 0.9% | (5.2%) | 14.4 | 1.1% |
| Metrodin-HP® | RH | 11.5 | 0.7% | (41.2%) | 19.5 | 1.5% |
| Ovidrel® | RH | 12.2 | 0.8% | 40.3% | 8.7 | 0.7% |
| Stilamin® | Other | 11.6 | 0.7% | 1.6% | 11.4 | 0.9% |

* Therapeutic Areas

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

Consolidated Income Statements

| Three months ended September 30 | 2004 * | % of | | 2003 * | % of |
|---|----------------|---------------|--------------|----------------|---------------|
| | US\$'000 | Revenues | % change | US\$'000 | Revenues |
| Revenues | | | | | |
| Product sales | 518,147 | | 11.8% | 463,533 | |
| Royalty and license income | 115,483 | | 194.7% | 39,187 | |
| Total Revenues | 633,630 | 100.0% | 26.0% | 502,720 | 100.0% |
| Operating Expenses | | | | | |
| Cost of product sales | 83,244 | | 26.6% | 65,753 | |
| % of Sales | 16.1% | | | 14.2% | |
| Selling, general and administrative | 196,385 | 31.0% | 23.6% | 158,919 | 31.6% |
| Research and development | 124,158 | 19.6% | 15.9% | 107,102 | 21.3% |
| Other operating expense, net | 52,170 | 8.2% | (2.7%) | 53,621 | 10.7% |
| Total Operating Expenses | 455,957 | 72.0% | 18.3% | 385,395 | 76.7% |
| Operating Income | 177,673 | 28.0% | 51.4% | 117,325 | 23.3% |
| Financial income, net | 18,235 | | 93.2% | 9,436 | |
| Other (expense) / income, net | (708) | | | 38 | |
| Total Non Operating Income, net | 17,527 | | | 9,474 | |
| Income Before Taxes and Minority Interests | 195,200 | 30.8% | 53.9% | 126,799 | 25.2% |
| Taxes | 31,231 | | | 17,011 | |
| Income Before Minority Interests | 163,969 | | | 109,788 | |
| Minority interests | 1,431 | | | (666) | |
| Net Income | 162,538 | 25.7% | 47.2% | 110,454 | 22.0% |

* Unaudited

| | 2004 | % Change | 2003 |
|---|-------|-------------|------|
| Basic Earnings per Share (in U.S. dollars) | | | |
| - Bearer shares | 10.76 | 54.2% | 6.98 |
| - Registered shares | 4.31 | 54.2% | 2.79 |
| - American depositary shares | 0.27 | 54.2% | 0.17 |

| Diluted Earnings per Share (in U.S. dollars) | | | |
|--|--------------|--------------|-------------|
| - Bearer shares | 10.67 | 53.3% | 6.96 |
| - Registered shares | 4.27 | 53.3% | 2.78 |
| - American depositary shares | 0.27 | 53.3% | 0.17 |

Basic earnings per share are calculated in accordance with IAS 33 (Earnings per Share) by dividing the net income of the group, US\$162.5 million (2003 US\$110.5 million), by an appropriate number of shares. This is 10,696,046 bearer shares (2003 11,423,825) and 11,013,040 registered shares (2003 11,013,040). The total weighted average equivalent number of bearer shares is 15,101,262 (2003 15,829,041) for the nine months ended September 30, 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 as well as the impact of the convertible bond, which is also dilutive. The number of bearer shares used to calculate diluted earnings per share is 11,143,231 (2003 11,459,401).

Consolidated Income Statements

| Nine months ended September 30 | 2004 * | % of | % change | 2003 * | % of |
|---|------------------|---------------|----------|------------------|----------|
| | US\$'000 | Revenues | | US\$'000 | Revenues |
| Revenues | | | | | |
| Product sales | 1,573,482 | | 17.5% | 1,338,733 | |
| Royalty and license income | 204,842 | | 78.4% | 114,820 | |
| Total Revenues | 1,778,324 | 100.0% | 22.3% | 1,453,553 | 100.0% |
| Operating Expenses | | | | | |
| Cost of product sales | 231,095 | | 16.0% | 199,201 | |
| % of Sales | 14.7% | | | 14.9% | |
| Selling, general and administrative | 573,638 | 32.3% | 25.3% | 457,959 | 31.5% |
| Research and development | 373,538 | 21.0% | 8.7% | 343,571 | 23.6% |
| Other operating expense, net | 160,745 | 9.0% | 6.9% | 150,320 | 10.3% |
| Total Operating Expenses | 1,339,016 | 75.3% | 16.3% | 1,151,051 | 79.2% |
| Operating Income | 439,308 | 24.7% | 45.2% | 302,502 | 20.8% |
| Financial income, net | 42,615 | | 47.6% | 28,864 | |
| Other expense, net | 644 | | | 3,619 | |
| Total Non Operating Income, net | 41,971 | | | 25,245 | |
| Income Before Taxes and Minority Interests | 481,279 | 27.1% | 46.8% | 327,747 | 22.5% |
| Taxes | 77,004 | | | 49,162 | |
| Income Before Minority Interests | 404,275 | | | 278,585 | |
| Minority interests | (180) | | | 235 | |
| Net Income | 404,455 | 22.7% | 45.3% | 278,350 | 19.1% |

* Unaudited

| | 2004 | 2003 | % Change |
|---|-------|-------|-------------|
| Basic Earnings per Share (in U.S. dollars) | | | |
| - Bearer shares | 26.15 | 17.58 | 48.8% |
| - Registered shares | 10.46 | 7.03 | 48.8% |
| - American depositary shares | 0.65 | 0.44 | 48.8% |

| Diluted Earnings per Share (in U.S. dollars) | | | |
|---|--------------|--------------|--------------|
| - Bearer shares | 26.05 | 17.55 | 48.4% |
| - Registered shares | 10.42 | 7.02 | 48.4% |
| - American depositary shares | 0.65 | 0.44 | 48.4% |

Basic earnings per share are calculated in accordance with IAS 33 (Earnings per Share) by dividing the net income of the group, US\$404.5 million (2003 US\$278.4 million), by an appropriate number of shares. This is 11,059,040 bearer shares (2003 11,429,052) and 11,013,040 registered shares (2003 11,013,040). The total weighted average equivalent number of bearer shares is 15,464,256 (2003 15,834,268) for the nine months ended September 30, 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 as well as the impact of the convertible bond, which is also dilutive. The number of bearer shares used to calculate diluted earnings per share is 11,509,808 (2003 11,450,658).

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Consolidated Balance Sheets

| As of | September 30, 2004 * | December 31, 2003 |
|---|-------------------------|----------------------|
| | US\$'000 | US\$'000 |
| Assets | | |
| Current Assets | | |
| Cash and cash equivalents | 444,415 | 1,003,972 |
| Short-term financial assets | 760,816 | 434,810 |
| Trade accounts receivable | 374,685 | 318,388 |
| Inventories | 289,471 | 319,820 |
| Prepaid expenses and other current assets | 250,074 | 220,334 |
| Total Current Assets | 2,119,461 | 2,297,324 |
| Non-Current Assets | | |
| Property, plant and equipment | 705,250 | 701,453 |
| Long-term financial assets | 1,048,057 | 1,104,333 |
| Intangible assets | 286,401 | 259,626 |
| Deferred tax assets | 172,235 | 169,693 |
| Other long-term assets | 79,525 | 39,174 |
| Total Non-Current Assets | 2,291,468 | 2,274,279 |
| Total Assets | 4,410,929 | 4,571,603 |
| Liabilities | | |
| Current Liabilities | | |
| Trade and other payables | 331,011 | 338,862 |
| Short-term financial debts | 56,445 | 51,224 |
| Income taxes | 157,416 | 146,086 |
| Deferred income - current | 46,687 | 47,200 |
| Other current liabilities | 227,442 | 170,019 |
| Total Current Liabilities | 819,001 | 753,391 |
| Non-Current Liabilities | | |
| Long-term financial debts | 556,543 | 532,022 |
| Deferred tax liabilities | 13,507 | 15,919 |
| Deferred income - non current | 154,045 | 174,911 |
| Provisions and other long-term liabilities | 225,605 | 213,556 |
| Total Non-Current Liabilities | 949,700 | 936,408 |
| Total Liabilities | 1,768,701 | 1,689,799 |
| Minority Interests | 1,422 | 1,614 |
| Shareholders' Equity | | |
| Share capital | 254,417 | 253,895 |
| Share premium | 1,022,742 | 1,002,991 |
| Treasury shares | (695,357) | (157,642) |
| Retained earnings | 1,974,801 | 1,669,700 |
| Fair value and other reserves | 14,867 | 22,711 |
| Cumulative foreign currency translation adjustments | 69,336 | 88,535 |

| | | |
|--|------------------|------------------|
| Total Shareholders' Equity | 2,640,806 | 2,880,190 |
| Total Liabilities, Minority Interests and Shareholders' Equity | 4,410,929 | 4,571,603 |

* Unaudited

-more-

Consolidated Statements of 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, 2003 | 253,416 | 989,141 | (126,460) | 1,364,626 | (44,807) | 25,282 | 2,461,198 |
| Issue of share capital to employees | 466 | 13,611 | 10,844 | | | | 24,921 |
| Purchase of treasury shares | | | (24,637) | | | | (24,637) |
| Written calls | | | | 723 | | | 723 |
| Net income for 2003 | | | | 278,350 | | | 278,350 |
| Dividend for 2002 - bearer shares | | | | (61,849) | | | (61,849) |
| Dividend for 2002 - registered shares | | | | (23,860) | | | (23,860) |
| Revaluation adjustments | | | | | 18,614 | | 18,614 |
| Foreign currency translation adjustments | | | | | | 47,162 | 47,162 |
| Balance as of September 30, 2003 * | 253,882 | 1,002,752 | (140,253) | 1,557,990 | (26,193) | 72,444 | 2,720,622 |
| 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 | 522 | 19,751 | 3,301 | | | | 23,574 |
| Net income for 2004 | | | | 404,455 | | | 404,455 |
| Purchase of treasury shares | | | (541,016) | | | | (541,016) |
| Dividend for 2003 - bearer shares | | | | (71,096) | | | (71,096) |
| Dividend for 2003 - registered shares | | | | (28,258) | | | (28,258) |
| Revaluation adjustments | | | | | 313 | | 313 |
| Cash flow hedge reserve | | | | | (8,157) | | (8,157) |
| Foreign currency translation adjustments | | | | | | (19,199) | (19,199) |
| Balance as of September 30, 2004 * | 254,417 | 1,022,742 | (695,357) | 1,974,801 | 14,867 | 69,336 | 2,640,806 |

* Unaudited

Consolidated Statements of Cash Flows

| Nine months ended September 30 | 2004 * US\$'000 | 2003 * US\$'000 |
|--|----------------------------------|----------------------------------|
| Cash Flows From Operating Activities | | |
| Income before taxes and minority interests | 481,279 | 327,747 |
| Depreciation and amortization | 108,603 | 100,849 |
| Financial income | (51,304) | (37,077) |
| Financial expense | 17,704 | 13,720 |
| Other non-cash items | 5,458 | 23,503 |
| Cash Flows From Operating Activities Before Working Capital Changes | 561,740 | 428,742 |
| Working Capital Changes | | |
| Trade accounts payable, other current liabilities and deferred income | 55,933 | 72,346 |
| Trade accounts receivable and other receivables | (102,815) | (45,036) |
| Inventories | (570) | (48,785) |
| Prepaid expenses and other current assets | (22,301) | 12,596 |
| Taxes paid | (67,914) | (67,697) |
| Net Cash Flows From Operating Activities | 424,073 | 352,166 |
| Cash Flows From Investing Activities | | |
| Purchase of property, plant and equipment | (130,774) | (125,323) |
| Purchase of intangible and other long-term assets | (21,773) | (6,842) |
| Purchase of financial assets | (838,059) | (505,423) |
| Proceeds from sale of financial assets | 536,611 | 296,980 |
| Proceeds from sale of property, plant and equipment | 3,867 | 8,804 |
| Interest received | 75,095 | 53,988 |
| Net Cash Flows From Investing Activities | (375,033) | (277,816) |
| Cash Flows From Financing Activities | | |
| Proceeds from issuance of share capital | 10,333 | 13,105 |
| Proceeds from exercises of stock options | 2,095 | 7,651 |
| Premiums received on written calls | -- | 1,249 |
| Issuance of long-term financial debt | 24,488 | 44,208 |
| Purchase of treasury shares | (541,016) | (24,637) |
| Repayment of bank advances | -- | (30,812) |
| Receipt of bank advances | 11,704 | -- |
| Repayment of long-term debt | (5,504) | (13,965) |
| Other non-current liabilities | (7,013) | (10,204) |
| Interest paid | (3,249) | (3,361) |
| Dividends paid | (99,354) | (85,709) |
| Net Cash Flows From Financing Activities | (607,516) | (102,475) |
| Effect of Exchange Rate Changes on Cash and Cash Equivalents | (1,081) | 4,022 |
| Net Decrease in Cash and Cash Equivalents | (559,557) | (24,103) |
| Cash and Cash Equivalents | | |

| | | |
|-----------------------|------------------|----------------|
| - Beginning of period | 1,003,972 | 686,033 |
| - End of period | 444,415 | 661,930 |

* Unaudited

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 IAS 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, 2003. These interim consolidated financial statements should be read in conjunction with the 2003 annual consolidated financial statements. These consolidated financial statements were approved for issuance on October 25th, 2004 by Serono S.A.'s board of directors.

2. Adoption of International Accounting Standards

There were no new standards adopted in the first 9 months of the year.

3. Segment information - geographic segment

| | Europe | North America | Latin America | Other | Group |
|---|----------------|----------------|----------------|----------------|------------------|
| Nine months ended September 30, 2004 | US\$000 | US\$000 | US\$000 | US\$000 | US\$000 |
| Product sales | 647,425 | 605,191 | 80,500 | 240,366 | 1,573,482 |
| Royalty and license income | 128,004 | 626 | - | 76,212 | 204,842 |
| Total revenues | 775,429 | 605,817 | 80,500 | 316,578 | 1,778,324 |
| Allocable operating income | 373,652 | 295,411 | 38,427 | 85,717 | 793,207 |
| Corporate R&D expenses | | | | | (284,951) |
| Unallocated expenses | | | | | (68,948) |
| Operating income | | | | | 439,308 |
| Nine months ended September 30, 2003 | US\$000 | US\$000 | US\$000 | US\$000 | US\$000 |
| Product sales | 567,755 | 501,564 | 69,444 | 199,970 | 1,338,733 |
| Royalty and license income | 62,276 | 740 | - | 51,804 | 114,820 |
| Total revenues | 630,031 | 502,304 | 69,444 | 251,774 | 1,453,553 |
| Allocable operating income | 319,738 | 263,241 | 28,662 | 59,773 | 671,414 |
| Corporate R&D expenses | | | | | (280,261) |
| Unallocated expenses | | | | | (88,651) |
| Operating income | | | | | 302,502 |

Unallocated expenses represent corporate expenses. 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. Taxes

The effective tax rate for the nine months ended September 30, 2004 amounts to 16.0% (2003: 15.0%).

Selected explanatory notes - continued

Page 2

5. Earnings per share

Basic earnings per share is calculated in accordance with IAS 33 (Earnings per Share) by dividing the net income of the company by the weighted average number of shares outstanding during the period presented.

| | 2004 | 2003 |
|---|-------------------|-------------|
| Nine months ended September 30 (unaudited) | US\$000 | US\$000 |
| Net income attributable to bearer shareholders | 289,439 | 200,911 |
| Net income attributable to registered shareholders | 115,016 | 77,439 |
| Total net income | 404,455 | 278,350 |
| Weighted average number of bearer shares in issue | 11,059,040 | 11,429,052 |
| Weighted average number of registered shares in issue | 11,013,040 | 11,013,040 |
| | US\$ | US\$ |
| Basic earnings per bearer share | 26.15 | 17.58 |
| Basic earnings per registered share | 10.46 | 7.03 |
| Basic earnings per American depositary share | 0.65 | 0.44 |

Each American depositary share represents an ownership interest that is equivalent to one-fortieth of a bearer share, and therefore, earnings per American depositary share is calculated as one-fortieth of earnings per bearer share.

For diluted earnings per share, the weighted average number of bearer shares 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 with proceeds from the exercise of stock options and 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 issued for no consideration. There is no adjustment made to the numerator.

During the first nine months ended September 30, 2004, share equivalents of 26,772 bearer shares arising from stock options granted to employees and directors were included in calculating diluted earnings per share (2003: 21,606). For the convertible bond, the weighted average number of bearer shares is increased by 423,996 bearer shares, which is the number of bearer shares that will be issued upon conversion of the bond. Net income attributable to bearer and registered shares holders is increased by the amount of interest expense, net of tax, that would not be incurred if the convertible bond was converted. The impact of the convertible bond was anti-dilutive in 2003.

| | 2004 | 2003 |
|---|-------------------|-------------|
| Nine months ended September 30 (unaudited) | US\$000 | US\$000 |
| Net income attributable to bearer shareholders | 299,846 | 201,016 |
| Net income attributable to registered shareholders | 114,762 | 77,334 |
| Total net income | 414,608 | 278,350 |
| Weighted average number of bearer shares in issue | 11,509,808 | 11,450,658 |
| Weighted average number of registered shares in issue | 11,013,040 | 11,013,040 |
| | US\$ | US\$ |
| Diluted earnings per bearer share | 26.05 | 17.55 |
| Diluted earnings per registered share | 10.42 | 7.02 |

| | | |
|--|-------------|------|
| Diluted earnings per American depositary share | 0.65 | 0.44 |
|--|-------------|------|

Selected explanatory notes - continued

Page 3

| 6. Share capital | | | | |
|--|-------------------------|----------------------|----------------|----------------|
| Class of shares | Number of shares | Nominal value | CHF000 | US\$000 |
| As of September 30, 2004 | | | | |
| Issued and fully paid share capital | | | | |
| Registered | 11,013,040 | CHF10 | 110,130 | 68,785 |
| Bearer | 11,738,050 | CHF25 | 293,452 | 185,632 |
| Total | | | 403,582 | 254,417 |
| Authorized share capital - bearer | 1,400,000 | CHF25 | 35,000 | 27,991 |
| Conditional share capital - bearer for option and/or convertible debt | 1,452,000 | CHF25 | 36,300 | 29,031 |
| Conditional share capital - bearer for stock options | 726,776 | CHF25 | 18,169 | 14,531 |
| As of December 31, 2003 | | | | |
| Issued and fully paid share capital | | | | |
| Registered | 11,013,040 | CHF10 | 110,130 | 68,785 |
| Bearer | 11,711,826 | CHF25 | 292,796 | 185,110 |
| Total | | | 402,926 | 253,895 |
| Authorized share capital - bearer | 1,400,000 | CHF25 | 35,000 | 28,377 |
| Conditional share capital - bearer for option and/or convertible debt | 152,000 | CHF25 | 3,800 | 3,081 |
| Conditional share capital - bearer for stock options | 352,996 | CHF25 | 8,825 | 7,155 |

During the Annual General Meeting held on May 25th, 2004, shareholders approved increasing the conditional capital to CHF 36,300,000 (1,452,000 bearer shares of a par value of CHF 25) for options and/or convertible loans and to CHF 18,825,000 (753,000 bearer shares of a par value of CHF 25) for stock options. In addition, shareholders have approved the authorization to increase capital by CHF 35,000,000 (1,400,000 bearer shares of a par value of CHF 25) for a period of two years.

7. Treasury shares

There were 304,939 treasury shares held by a group company as of January 1, 2004. During the first five months ended May 31, 2004, 351,209 bearer shares were purchased for a total consideration of CHF280.9 million or \$221.8 million, which resulted in the complete utilization of the CHF500 million share buy back plan that was initiated in July 2002. During the first nine months of the year, 7,149 treasury shares were distributed to employees mostly as part of an 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.

In June 2004, a second share buy back plan was initiated that was authorized to acquire CHF750 million worth of bearer shares; however, the shares acquired under this second plan will be cancelled and thus will not be available for re-issue. The total cost of the shares acquired under the second share buy back plan as of September 30, 2004, was CHF405.0 million or \$319.2 million. The total number of treasury shares held as of September 30, 2004 is 1,165,984 of which 516,985 will eventually be cancelled.

8.

Distribution of earnings

At the Annual Shareholders Meeting on May 25, 2004, a proposed gross dividend in respect of 2003 of CHF3.20 (2002: CHF2.80) per registered share and CHF8.00 (2002: CHF7.00) per bearer share, amounting to a total of CHF123.9 million (2002: CHF110.8 million), was ratified. This dividend, equivalent to \$99.4 million, was subsequently paid in May 2004 and has been accounted for in shareholders equity as an appropriation of retained earnings in the nine months ended September 30, 2004.

9. Stock option plans

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 of Serono S.A. stock. 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 determined as the closing share price of the share (bearer share and American depositary share) on the date of grant. Movements in the number of stock options outstanding, for both bearer shares and American depositary shares, are as follows:

| | Bearer Options | | American depositary share Options | |
|---------------------------------|---------------------|-------------------------------------|-----------------------------------|--------------------------------------|
| | Options outstanding | Weighted average exercise price CHF | Options outstanding | Weighted average exercise price US\$ |
| As of January 1, 2003 | 220,300 | 1,272 | - | - |
| Granted | 97,830 | 652 | 20,000 | 16.51 |
| Cancelled | (22,087) | 1,301 | - | - |
| Exercised | (2,741) | 546 | - | - |
| As of December 31, 2003 | 293,302 | 1,070 | 20,000 | 16.51 |
| Granted | 100,160 | 788 | 1,092,000 | 15.52 |
| Cancelled | (22,556) | 1,091 | (55,200) | 15.55 |
| Exercised | (4,405) | 598 | - | - |
| As of September 30, 2004 | 367,101 | CHF 961 | 1,056,800 | \$ 15.54 |

10. Share purchase plans**Employee Share Purchase Plan**

The group has an Employee Share Purchase Plan ("the ESPP") covering substantially all of its employees. The plan is designed to allow employees to purchase bearer shares or American depositary shares at 85% of the lower of the fair market value at either the date of the beginning of the plan period or the purchase date. Purchases under the plan are subject to certain restrictions and may not exceed 15% of the employee's annual salary. In January 2004, 20,301 bearer shares (2003: 23,229 bearer shares) were issued to employees at a price of CHF654 per share (2003: CHF654 per share). As of September 30, 2004, a total of \$8.2 million (2003: \$7.4 million) in contributions was held by the company and will be used to purchase bearer and American depositary shares on behalf of its employees in January 2005. The accrued compensation cost from the discount to be offered to employees based on the contributions held as at September 30, 2004 is \$1.4 million (2003: \$3.8 million).

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. In January 2004, 6,648 bearer shares (2003: 4,208) were distributed to employees. The accrued compensation cost for the nine months ended September 30, 2004, related to the matching shares that will be distributed in January 2005, is \$2.8 million (2003: \$3.5 million) and is calculated based on the estimated number of matching shares that will be issued multiplied by the current month-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 company s Annual General Meeting (the AGM) and concludes on the day of the next AGM. The purchase price per share is eighty-five percent of the fair market value of the share on the fifth business day following the AGM. In June, 1,518 bearer shares were issued to Directors that participated in the plan.

11. Principal shareholder

At September 30, 2004, Bertarelli & Cie, a partnership limited by shares with its principal offices at Chésereux (Vaud), Switzerland, held 55.43% of the capital and 64.01% 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 7.55% of the capital and 10.31% of the voting rights of Serono S.A.

12. Events after the balance sheet date

On September 7th, 2004, the company entered into a binding contractual agreement with ZymoGenetics, Inc to research, develop and commercialize novel protein and antibody therapeutics based on discoveries made by ZymoGenetics. The actual payment commitments to ZymoGenetics as of September 30, 2004 include \$31.25 million in exchange for the rights to license proteins over the next five years and the purchase of \$50.0 million of ZymoGenetics common stock.

As disclosed in the press release issued on September 8th, 2004, the terms of this agreement were subject to review by the United States Federal Trade Commission and Department of Justice, under the provisions of Section 7A of the Clayton Act, 15 U.S.C. § 18a, as added by the Hart-Scott-Rodino Antitrust Improvements Act of 1976. As U.S. regulatory approval was not received until October 5th, 2004, the \$31.25 million liability and corresponding research and development expense have not been reflected in the balance sheet as of September 30, 2004 or the statement of income for the three and nine months ended September 30, 2004, following strict interpretation of International Financial Reporting Standards. Had U.S. regulatory approval been received prior to September 30, 2004, research and development expense for the three and nine months ended would have increased by \$31.25 million; tax expense and taxes payable would have decreased by \$5.0 million; and net income for the three and nine months ended would have decreased by \$26.3 million, compared to actual reported results.

On October 12th, 2004, the company purchased 3,176,620 common shares of ZymoGenetics, Inc. at price of \$15.74 per share. The closing price of ZymoGenetics shares on October 6, the date at which the price to be paid was finalized as per the terms of the agreement, was \$18.45 per share, resulting in financial income of \$8.6 million. Reported net income for the three and nine months ended September 30, 2004, included an unrealized gain of \$5.4 million as the commitment to acquire \$50.0 million of ZymoGenetics common shares at a fixed price of \$15.74 qualified as a forward contract for which changes in fair value are reflected in the statement of income in accordance with IAS 39 Financial Instruments.

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)

October 26, 2004

| | |
|--------|-------------------|
| By: | /s/ François Naef |
| Name: | François Naef |
| Title: | Secretary |

