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SERONO S A
Form 6-K
February 02, 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 February, 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
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(Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101 (b) (1).)

(Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101 (b) (7).)

(Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.)

Yes No
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(If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-_____)

SERONO

MEDIA RELEASE

FOR RELEASE FEBRUARY 2, 2004, 4:01 PM EST

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RECORD YEAR FOR SERONO WITH OVER \$2 BILLION IN REVENUES

- Net income up 21.6% to \$390.0 million in 2003 -

ROCKLAND, MA, FEBRUARY 2, 2004 - 04:01 PM EST - Serono (virt-x: SEO and NYSE: SRA), the third largest biotechnology company in the world, today reported its fourth quarter and full year results for the period ended December 31, 2003.

KEY POINTS FOR FULL YEAR 2003

- Total revenues up 31.3% to \$2,018.6m (up 20.9% in local currencies)
- Neurology now Serono's largest therapeutic area with sales up 54.9% to \$850.2m
- Reproductive Health core portfolio growing at 20.7% to \$593.7m
- Reported net income up 21.6% to \$390.0m (up 14.2% in local currencies) and up 26.9% (or 18.9% in local currencies) excluding non-recurring non-operational charges
- Reported EPS up 22.7% to \$24.63 per bearer share and \$0.62 per ADS
- Proposed dividend of CHF8.0 per bearer share and of CHF0.2 per ADS*
- 2004 growth outlook in local currencies of 12% or more for total revenues and 15% to 20% for net income

"2003 was a record year for Serono with total revenues breaking through the \$2 billion mark," said Ernesto Bertarelli, Chief Executive Officer of Serono. "Going forward we are very well positioned to take advantage of the many opportunities which exist in the biotech sector."

"We forecast another strong financial performance in 2004," said Allan Shaw, Chief Financial Officer. "This year, we expect our net income growth to be between 15% and 20%, inclusive of launch costs for Raptiva(TM)."

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FOURTH QUARTER AND FULL YEAR FINANCIAL PERFORMANCE

Total revenues increased by 31.3% to \$2,018.6m in the full year 2003 (2002: \$1,537.8m), and by 29.1% to \$565.1m in the fourth quarter (2002: \$437.7m).

Worldwide product sales were \$1,858.0m in 2003, up 30.6% (2002: \$1,423.1m), and up 26.8% to \$519.3m in the fourth quarter (2002: \$409.4m). Notwithstanding weakness in the US dollar, product sales in local currencies grew by 19.9% in 2003 and 16.5% in the fourth quarter.

Royalty and licensing income increased by 40.0% to \$160.6m in 2003 (2002: \$114.7m), and was up 61.8% to \$45.8m (2002: \$28.3m) in the fourth quarter, reflecting the company's strong intellectual property rights.

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Gross margin increased to 85.0% of product sales in 2003 (2002: 84.3%), as a result of continuing manufacturing improvements leading to higher production yields. In the fourth quarter of 2003 gross margin was 84.5% (2002: 84.1%).

Selling, General and Administrative expenses were \$636.8m or 31.5% of total revenues in 2003 (2002: \$504.2m or 32.8% of total revenues), and 31.7% of revenues at \$178.9m in the fourth quarter (2002: \$144.5m or 33.0% of revenues). The decrease in SG&A as a percentage of revenues reflects an improvement in the company's operating leverage in 2003.

Research and Development expenses were \$467.8m or 23.2% of total revenues (2002: \$358.1m or 23.3% of total revenues) for the full year, and \$124.2m or 22.0% of total revenues in the fourth quarter (2002: \$95.4m or 21.8% of total revenues).

Other operating expenses in 2003 were \$199.5m (2002: \$85.8m), and \$49.2m (2002: \$27.7m) in the fourth quarter. The increase in other operating expenses reflects payments related to licensing agreements for new products and higher royalties paid to third parties.

Full year 2003 operating income increased by 24.4% to \$434.9m or 21.5% of total revenues (2002: \$349.6m or 22.7% of total revenues), and was up 49.5% to \$132.4m in the fourth quarter or 23.4% of total revenues (2002: \$88.6m or 20.2% of total revenues).

Net financial income was \$44.0m in 2003 (2002: \$36.5m) and \$15.2m in the fourth quarter (2002: \$9.2m).

Other expense was \$19.7m in 2003 (2002: \$1.7m) and \$16.1m in the fourth quarter (2002: income of \$0.2m), reflecting non-recurring non-operational charges. In the fourth quarter, the company took a non-cash charge of \$16.1m related to the write-down of an equity investment made in Swiss International Air Lines.

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Total taxes in 2003 were \$68.9m, representing an overall tax rate of 15.0% of profit before tax (2002: \$63.1m, or 16.4% of profit before tax). In the fourth quarter, taxes were \$19.7m, or 15.0% of profit before tax (2002: \$15.8m or 16.2% of profit before tax).

Reported net income in the full year 2003 was up 21.6% to \$390.0m (2002: \$320.8m), or 14.2% in local currencies. Excluding non-recurring non-operational charges, net income growth was 26.9%, or 18.9% in local currencies in 2003. In the fourth quarter, reported net income grew 36.8%, or 25.8% in local currencies, to \$111.6m (2002: \$81.6m).

Basic earnings per share (EPS) were up 22.7% to \$24.63 per bearer share (2002: \$20.07) and \$0.62 per American Depositary Share (ADS) (2002: \$0.50).

On May 25, 2004, the Board of Directors will propose to the Annual General Meeting a cash dividend of CHF8.0 per bearer share, CHF3.2 per registered share or CHF0.2 per ADS*, representing an increase of 14.3% over the 2002 dividend.

For the full year ended 2003, net cash flow from operating activities was \$542.9m (2002: \$532.0). When excluding one-time payments received from third parties in connection with the signing of collaborative agreements (Pfizer in 2002 and OSI Pharmaceuticals in 2003), operating cash flows increased 47.0% compared to 2002.

As of December 31, 2003, there were 15.812 million outstanding equivalent bearer shares of Serono SA.

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NEUROLOGY

Neurology sales were up 54.9% to \$850.2m for the full year 2003, and fourth quarter sales were \$242.2m. Full year sales of Rebif(R) were up 49.3% (34.1% in local currencies) to \$819.4m (2002: \$548.8m). In the fourth quarter, worldwide sales of Rebif(R) increased by 35.9% (22.7% in local currencies) to \$233.2m (2002: \$171.5m).

Sales of Rebif(R) in the US were up 60.0% to \$55.7m in the fourth quarter (2002: \$34.8m). In 2003, with \$188.5m sales for the full year, representing an increase of 164.8% (2002: \$71.2m), Rebif(R) was clearly the fastest growing multiple sclerosis (MS) therapy in the US, more than doubling its market share during the year.

Rebif(R) continues its market leadership outside the US with 2003 sales increasing by 32.1% to \$630.8m (2002: \$477.6m). European sales increased by 39.0% (16.9% in local currencies) to \$436.8m (2002: \$314.1m). Sales outside the US were \$177.5m in the fourth quarter (2002: \$136.7m).

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In 2003, the performance of Rebif(R) was supported by the release of a series of positive study results. These included the final 63-week EVIDENCE study results, data showing greater efficacy with Rebif(R) in patients who converted from Avonex(R) to Rebif(R) at the end of the comparative phase of the study, as well as the safety and efficacy results from the eight-year long-term follow-up of the PRISMS study.

Given the strong performance of Rebif(R) in 2003, the company is on track to achieving its goal of worldwide market leadership by the end of 2006.

Novantrone(R) sales in MS were \$30.9m in 2003 and \$9.0m the fourth quarter (total Novantrone(R) sales were \$77.1m in 2003 and \$22.4m the fourth quarter).

REPRODUCTIVE HEALTH

In 2003, worldwide reproductive health sales grew 11.4% to \$692.9m (2002: \$621.9m), and by 15.2% to \$191.0m in the fourth quarter (2002: \$165.8m). Sales of Gonal-f(R) increased by 16.8% (7.3% in local currencies) to \$526.1m (2002: \$450.4m) in the full year, and by 21.6% (11.2% in local currencies) to \$147.5m (2002: \$121.3m) in the fourth quarter.

Serono's core reproductive health portfolio consisting of three recombinant hormones (Gonal-f(R), Ovidrel(R)/Ovitrelle(R), Luveris(R)) and two complementary products (Cetrotide(R), Crinone(R)) grew by 20.7% (10.7% in local currencies) to \$593.7m representing 85.7% of total reproductive health sales in 2003. In the fourth quarter this core portfolio grew by 25.6% (14.7% in local currencies) to \$168.1m (2002: \$133.8m).

In October, the Ovidrel(R)/Ovitrelle(R) pre-filled syringe was approved by both the FDA and the European Commission making it the first liquid, ready-to-use recombinant hCG..

METABOLIC ENDOCRINOLOGY

Saizen(R) sales increased by 22.1% (11.0% in local currencies) to \$151.5m (2002: \$124.0m) in 2003, and were up 17.4% (7.1% in local currencies) to \$42.3m (2002: \$36.0m) during the fourth quarter.

Serostim(R) sales were \$88.8m for the full year (2002: \$95.1m), and \$22.8m (2002: \$26.5m) in the fourth quarter.

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In December 2003, the FDA approved Zorbtive(TM) [somatropin (rDNA origin) for injection], Serono's recombinant human growth hormone, for use in the treatment of short bowel syndrome, a serious and potentially life-threatening condition. Zorbtive(TM) was granted orphan drug status for use in the treatment of patients with short bowel syndrome by the FDA Office of Orphan Products Development.

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PSORIASIS

Serono is committed to developing and commercializing new biotherapeutics for psoriasis, a chronic skin disease.

On October 27, 2003, our partners Genentech and XOMA announced that Raptiva(TM) (efalizumab) was approved by the FDA for the treatment of chronic moderate-to-severe plaque psoriasis. Raptiva(TM) is the first biologic therapy designed to provide continuous control of chronic moderate-to-severe plaque psoriasis and can be self-administered by patients as a single, once-weekly, subcutaneous injection. Long-term data on Raptiva(TM) was presented at the American Academy of Dermatology in July 2003.

Serono is responsible for developing and commercializing Raptiva(TM) worldwide outside of the United States and Japan. During 2003, Serono submitted regulatory applications in key markets for the use of Raptiva(TM) in moderate-to-severe plaque psoriasis and currently expects to commence its launch program for this innovative therapy in the second half of 2004. Costs associated with the launch of Raptiva(TM) are projected to be between \$30m and \$50m in 2004.

REGIONAL SALES

North American sales grew by 44.8% to \$694.3m in 2003 (2002: \$479.6m). European sales increased by 31.2% to \$813.8m (2002: \$620.4m). In the rest of the world, sales grew by 8.3% to \$349.9m (2002: \$323.2m). In the fourth quarter, North American sales were up 32.2% to \$192.7m (Q4 2002: \$145.8m) while European sales grew by 31.0% to \$233.0m (Q4 2002: \$177.8m) and sales in the rest of the world increased by 9.1% to \$93.6m (Q4 2002: \$85.8m).

R&D NEWS

A multicentre multinational head-to-head trial comparing Rebif(R) vs. Copaxone(R) was recently initiated. This is a 2-year study with a relapse-related primary endpoint, as well as other clinical and MRI secondary endpoints.

During the last twelve months, key R&D highlights were:

- In June, positive Phase 2 results for onercept (r-hTBP-1) in psoriasis were presented at the 9th International Psoriasis Symposium. A Phase 3 program is scheduled to start in due course following completion of discussions with the FDA.
- Phase 2a studies with IL-18 binding protein were started in rheumatoid arthritis and psoriasis.
- A Phase 2 trial with anastrozole for follicular development and ovulation induction in infertile women with ovulatory dysfunction was initiated in the first quarter. The study outcome is expected by mid-2004.
- In June, positive results from a proof of concept study of emfilermin

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(r-hLIF) for improving embryo implantation in women with recurrent implantation

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failure were presented at ESHRE. A Phase 2 study aiming to enhance embryo implantation in patients who have a history of previous IVF failures was initiated during the second quarter. The outcome of this study is anticipated in the second half of 2004.

During the last twelve months, significant regulatory milestones were also achieved including:

- Positive European CPMP opinion for Gonal-f(R) pre-filled pen injector,
- Favorable FDA advisory committee recommendation for Luveris(R) in treatment of profoundly LH-deficient women,
- EMEA and FDA approvals of Ovidrel(R)/Ovitrelle(R) pre-filled syringe for infertility,
- FDA approval of Zorbitive(TM) for use in patients with short bowel syndrome.

CONFERENCE CALL AND WEBCAST

Serono will hold a conference call on February 3rd, 2004, starting at 11:00 am Eastern Time (5:00 pm Central European Time) during which Serono Management will present the Company's Fourth Quarter and Full Year 2003 Results. To join the telephone conference please dial 412 858 4600 (from the US), 091 610 5600 (from Switzerland), 0207 866 4111 (from the UK) and +41 91 610 5600 (from elsewhere). Telephone playback will be available one hour after the conference call and until close of business 5.00 pm ET on February 6th, 2004. To access this playback please dial the following numbers: 412 858 1440 (from the US), 091 612 4330 (from Switzerland), 0207 866 4300 (from the UK) and +41 91 612 4330 (from elsewhere) and enter the PIN code 247# from a touch tone telephone.

The event will also be relayed by live audio webcast which interested parties may access via Serono's Corporate home page, www.serono.com. A link to the webcast will be provided immediately prior to the event. Additionally, the webcast will be available for replay until close of business on February 20th, 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 and affiliates to be materially different from those expected or anticipated in the forward-looking statements. Forward-looking statements are based on Serono's current expectations and assumptions, which may be affected by a number of factors, including those discussed in this press release and more fully described in Serono's Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission on April 17, 2003. These factors include any failure or delay in Serono's ability to develop new products, any failure to receive anticipated regulatory approvals, any problems in commercializing current products as a result of competition or other factors, our ability to obtain reimbursement coverage for our products, and government regulations

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limiting our ability to sell our products. Serono has no responsibility to update the forward-looking statements contained in this press release to reflect events or circumstances occurring after the date of this press release.

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ABOUT SERONO

Serono is a global biotechnology leader. The Company has seven recombinant products, Rebif(R), Gonal-F(R), Luveris(R), Ovidrel(R)/Ovitrelle(R), Serostim(R), Saizen(R) and Zorbtive(TM) (Luveris(R) is not approved in the USA). In addition to being the world leader in reproductive health, Serono has strong market positions in neurology, metabolism and growth. The Company's research programs are focused on growing these businesses and on establishing new therapeutic areas. Currently, there are 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, the holding company, are traded on the virt-x (SEO) and its American Depositary Shares are traded on the New York Stock Exchange (SRA).

*i.e. \$0.16 based on an exchange rate of \$1=CHF1.2562, as of January 30, 2004. The actual dividend will be based on the exchange rate in effect on the date the dividend is converted into \$ by the depositary for the ADS.

FOR MORE INFORMATION, PLEASE CONTACT:

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On the following pages, there are:

- Tables detailing sales in dollars by therapeutic area, geographic region and the top 10 products for the 3 and 12 months ended December 31, 2003 and 2002.
- Consolidated statements of income for the 3 and 12 months ended December 31, 2003 and 2002, the consolidated statements of cash flows for the 12 months ended December 31, 2003 and 2002, as well as the consolidated balance sheets and consolidated statements of equity as of December 31, 2003 and 2002. These consolidated financial statements have been prepared on the basis of International Financial Reporting Standards. The accompanying notes to these consolidated financial statements will be available upon the release of Serono's 2003 Annual Report.

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SALES BY THERAPEUTIC AREA

| | THREE MONTHS ENDED DECEMBER 31, 2003 | | | THREE MONTHS ENDED DECEMBER 31, 2002 | | |
|---------------------------|---|------------|-------------|---|------------|--|
| | \$ MILLION | % OF SALES | % CHANGE \$ | \$ MILLION | % OF SALES | |
| Neurology | 242.2 | 46.6% | 41.0% | 171.8 | 42.0% | |
| Reproductive Health | 191.0 | 36.8% | 15.2% | 165.8 | 40.5% | |
| Growth & Metabolism | 65.1 | 12.5% | 4.2% | 62.5 | 15.3% | |
| Others | 21.0 | 4.1% | 123.4% | 9.3 | 2.2% | |
| Total sales(US\$ million) | \$ 519.3 | 100% | 26.8% | \$ 409.4 | 100% | |

SALES BY GEOGRAPHIC REGION

| | THREE MONTHS ENDED DECEMBER 31, 2003 | | | THREE MONTHS ENDED DECEMBER 31, 2002 | | |
|---------------------------|---|------------|-------------|---|------------|--|
| | \$ MILLION | % OF SALES | % CHANGE \$ | \$ MILLION | % OF SALES | |
| Europe | 233.0 | 44.9% | 31.0% | 177.8 | 43.4% | |
| North America | 192.7 | 37.1% | 32.2% | 145.8 | 35.6% | |
| Latin America | 29.4 | 5.7% | 14.0% | 25.8 | 6.3% | |
| Others | 64.2 | 12.3% | 7.0% | 60.0 | 14.7% | |
| Total sales(US \$million) | \$ 519.3 | 100% | 26.8% | \$ 409.4 | 100% | |

SALES BY THERAPEUTIC AREA

| | TWELVE MONTHS ENDED DECEMBER 31, 2003 | | | TWELVE MONTHS ENDED DECEMBER 31, 2002 | | |
|---------------------------|--|------------|-------------|--|------------|--|
| | \$ MILLION | % OF SALES | % CHANGE \$ | \$ MILLION | % OF SALES | |
| Neurology | 850.2 | 45.8% | 54.9% | 549.1 | 38.6% | |
| Reproductive Health | 692.9 | 37.3% | 11.4% | 621.9 | 43.7% | |
| Growth & Metabolism | 240.2 | 12.9% | 9.6% | 219.1 | 15.4% | |
| Others | 74.7 | 4.0% | 125.6% | 33.0 | 2.3% | |
| Total sales(US \$million) | \$ 1,858.0 | 100% | 30.6% | \$ 1,423.1 | 100% | |

SALES BY GEOGRAPHIC REGION

| | TWELVE MONTHS ENDED DECEMBER 31, 2003 | | | TWELVE MONTHS ENDED DECEMBER 31, 2002 | | |
|--------|--|------------|-------------|--|------------|--|
| | \$ MILLION | % OF SALES | % CHANGE \$ | \$ MILLION | % OF SALES | |
| Europe | 813.8 | 43.8% | 31.2% | 620.4 | 43.6% | |

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| | | | | | |
|---------------|-------|-------|--------|-------|-------|
| North America | 694.3 | 37.4% | 44.8% | 479.6 | 33.7% |
| Latin America | 98.8 | 5.3% | (9.5%) | 109.2 | 7.7% |
| Others | 251.1 | 13.5% | 17.3% | 213.9 | 15.0% |

| | | | | | |
|---------------------------|------------|------|-------|------------|------|
| Total sales(US \$million) | \$ 1,858.0 | 100% | 30.6% | \$ 1,423.1 | 100% |
|---------------------------|------------|------|-------|------------|------|

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TOP TEN PRODUCTS

| | | THREE MONTHS ENDED DECEMBER 31, 2003 | | | THREE MONTHS ENDED DECEMBER 31, 2002 | |
|-----------------|-------------|---|------------|-------------|---|------------|
| | * TA | \$MILLION | % OF SALES | % CHANGE \$ | \$MILLION | % OF SALES |
| Rebif (R) | MS | 233.2 | 44.9% | 35.9% | 171.5 | 41.9% |
| Gonal-f (R) | RH | 147.5 | 28.4% | 21.6% | 121.3 | 29.6% |
| Saizen (R) | Growth | 42.3 | 8.1% | 17.4% | 36.0 | 8.8% |
| Serostim (R) | Wasting | 22.8 | 4.4% | (13.9%) | 26.5 | 6.5% |
| Novantrone (R) | MS/Oncology | 22.4 | 4.3% | 3372.7% | 0.6 | 0.2% |
| Pergonal (R) | RH | 11.9 | 2.3% | (10.6%) | 13.3 | 3.2% |
| Cetrotide (R) | RH | 7.7 | 1.5% | 42.3% | 5.4 | 1.3% |
| Crinone (R) | RH | 6.4 | 1.2% | 105.5% | 3.1 | 0.8% |
| Metrodin HP (R) | RH | 5.3 | 1.0% | (49.6%) | 10.4 | 2.5% |
| Stilamin (R) | Other | 3.9 | 0.7% | 5.8% | 3.7 | 0.9% |

| | | THREE MONTHS ENDED DECEMBER 31, 2003 | | | THREE MONTHS ENDED DECEMBER 31, 2002 | |
|-----------------|-------------|---|------------|-------------|---|------------|
| | * TA | \$MILLION | % OF SALES | % CHANGE \$ | \$MILLION | % OF SALES |
| Rebif (R) | MS | 819.4 | 44.1% | 49.3% | 548.8 | 38.6% |
| Gonal-f (R) | RH | 526.1 | 28.3% | 16.8% | 450.4 | 31.7% |
| Saizen (R) | Growth | 151.5 | 8.2% | 22.1% | 124.0 | 8.7% |
| Serostim (R) | Wasting | 88.8 | 4.8% | (6.6%) | 95.1 | 6.7% |
| Novantrone (R) | MS/Oncology | 77.1 | 4.1% | 11866.3% | 0.6 | 0.0% |
| Pergonal (R) | RH | 45.8 | 2.5% | (0.4%) | 46.0 | 3.2% |
| Cetrotide (R) | RH | 24.8 | 1.3% | 35.3% | 18.4 | 1.3% |
| Metrodin HP (R) | RH | 24.8 | 1.3% | (50.6%) | 50.1 | 3.5% |
| Crinone (R) | RH | 20.8 | 1.1% | 90.2% | 10.9 | 0.8% |
| Profasi (R) | RH | 15.4 | 0.8% | (22.4%) | 19.8 | 1.4% |