

SERONO S A  
Form 20-F  
March 16, 2005

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As filed with the Securities and Exchange Commission on March 16, 2005.

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**FORM 20-F**

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(Mark One)

**REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR 12(g)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

or

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2004

or

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

**Commission File Number: 1-15096**

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**SERONO S.A.**

(Exact name of Registrant as specified in its charter)

**Not Applicable**

**Switzerland**

(Translation of Registrant's name into English)

(Jurisdiction of incorporation or organization)

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15 bis, Chemin des Mines

Case Postale 54

CH-1211 Geneva 20

Switzerland

(Address of principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

**Title of each class:**

Bearer Shares, nominal value CHF25 per share

**Name of each exchange on which registered:**

New York Stock Exchange\*

American Depositary Shares (as evidenced by  
American Depositary Receipts), each representing one  
fortieth of a Bearer Share

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New York Stock Exchange

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\*Not for trading, but only in connection with the registration of American Depositary Shares, pursuant to the requirements of the Securities and Exchange Commission.

\_\_\_\_\_  
Securities registered pursuant to Section 12(g) of the Act:

None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of December 31, 2004.

Bearer Shares, nominal value CHF 25 per 10,126,741 outstanding share:

Registered Shares, nominal value CHF 10 11,013,040 outstanding per share:

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark which financial statement item the registrant has elected to follow.

Item 17  Item 18

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**Serono S.A.**  
**Annual Report on Form 20-F**  
**for the year ended**  
**December 31, 2004**

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## PART I

**Item 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS**

Not applicable.

**Item 2. OFFER STATISTICS AND EXPECTED TIMETABLE**

Not applicable.

**Item 3. KEY INFORMATION****Selected Consolidated Historical Financial Data**

We have derived our selected consolidated historical financial data from our consolidated financial statements. We prepare and present our consolidated financial statements in accordance with International Financial Reporting Standards or IFRS. IFRS differ in significant respects from United States Generally Accepted Accounting Principles, or U.S. GAAP. You can find a reconciliation of our audited consolidated financial statements to U.S. GAAP in Note 35 to our audited consolidated financial statements included in this Annual Report. Since the information we present below is only a summary and does not provide all of the information contained in our consolidated financial statements, you should read our consolidated financial statements and the notes to the consolidated financial statements included in this Annual Report.

	<b>Year ended December 31,</b>				
	<b>2004</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>	<b>2000</b>
	(U.S. dollars in thousands, except per share data)				
<b>Income Statement Data:</b>					
Product sales	\$ 2,177,949	\$ 1,858,009	\$ 1,423,130	\$ 1,249,405	\$ 1,146,998
Royalty and license income	280,101	160,608	114,705	127,065	92,656
Total revenues	2,458,050	2,018,617	1,537,835	1,376,470	1,239,654
Operating expenses:					
Cost of product sales	304,111	279,619	223,751	213,160	229,907
Selling, general and administrative	807,940	636,823	504,248	446,945	393,716
Research and development,	594,802	467,779	358,099	308,561	263,152
Restructuring	—	—	16,303	—	—
Other operating expense, net	227,096	199,476	85,811	70,152	31,147
Total operating expenses	1,933,949	1,583,697	1,188,212	1,038,818	917,922
Operating income	524,101	434,920	349,623	337,652	321,732
Financial income, net	63,281	44,018	36,476	51,381	52,277
Other expense, net	629	19,743	1,658	2,548	2,411
Total non-operating income, net	62,652	24,275	34,818	48,833	49,866
Income before taxes and minority interests	586,753	459,195	384,441	386,485	371,598
Taxes	90,947	68,905	63,127	69,816	70,384
Income before minority interests	495,806	390,290	321,314	316,669	301,214
Minority interests	1,653	327	536	(52)	174
Net income	\$ 494,153	\$ 389,963	\$ 320,778	\$ 316,721	\$ 301,040

**Per Share Data:**

Basic income per share (1)(2):										
Bearer shares	\$	32.35	\$	24.63	\$	20.07	\$	19.72	\$	19.50
Registered shares		12.94		9.85		8.03		7.89		7.80
American depositary shares (3)		0.81		0.62		0.50		0.49		0.49
Diluted income per share (1)(2):										
Bearer shares		32.29		24.59		20.04		19.68		19.46
Registered shares		12.92		9.84		8.02		7.87		7.78
American depositary shares (3)		0.81		0.61		0.50		0.49		0.49
Cash dividends paid (1)(4):										
Bearer shares		6.54		5.42		4.02		3.35		1.15
Registered shares		2.57		2.17		1.61		1.34		0.46
American depositary shares (3)		0.16		0.14		0.10		0.08		0.03

**Supplemental Per Equivalent****Bearer Share Data:**

Net income, basic (1)(5)	\$	32.35	\$	24.63	\$	20.07	\$	19.72	\$	19.50
Net income, diluted (1)(5)		32.29		24.59		20.04		19.68		19.46

## As of December 31,

2004                      2003                      2002                      2001                      2000

(U.S. dollars in thousands, except per share data)

**Balance Sheet Data:**

Cash, cash equivalents and short-term investments	\$ 1,060,978	\$ 1,438,782	\$ 1,064,898	\$ 1,475,504	\$ 1,438,485
Working capital (6)	1,183,852	1,543,933	1,139,848	1,527,359	1,505,534
Tangible fixed assets	799,878	701,453	554,509	460,767	462,425
Total assets	4,404,290	4,571,603	3,484,278	3,018,769	2,794,777
Outstanding share capital(4)	254,420	253,895	253,416	253,137	253,072
Short-term financial debts	34,527	51,224	93,598	173,254	238,585
Long-term financial debts	640,892	532,022	25,857	37,325	56,626
Shareholders' equity	2,447,878	2,880,190	2,461,198	2,218,914	2,006,416

**Amounts in Accordance with****U.S. GAAP:**

Net income	471,024	398,346	280,176	291,470	304,389
Basic income per share (1)(7):					
Bearer shares	30.83	25.16	17.53	18.15	19.72
Registered shares	12.33	10.06	7.01	7.26	7.89
Diluted income per share (1)(7):					
Bearer shares	30.78	25.12	17.51	18.11	19.68
Registered shares	12.31	10.05	7.00	7.24	7.87
Total shareholders' equity	2,398,311	2,855,473	2,456,683	2,239,711	2,015,860
Total assets	4,367,211	4,561,583	3,483,295	3,069,873	2,794,465

**Margins and Other Data:**

Gross margin (8)(9)	86.0%	85.0%	84.3%	82.9%	80.0%
Operating margin (8)(10)	21.3%	21.5%	22.7%	24.5%	26.0%
Net margin (8)(11)	20.1%	19.3%	20.9%	23.0%	24.3%
Cash dividends paid (4)	\$ 99,354	\$ 85,709	\$ 64,238	\$ 53,759	\$ 17,755
Net cash flow from operating activities	\$ 471,709	\$ 542,859	\$ 531,982	\$ 404,950	\$ 255,443
Depreciation and amortization	\$ 145,221	\$ 135,607	\$ 100,552	\$ 98,906	\$ 86,266
Additions to tangible fixed assets	\$ 151,504	\$ 185,045	\$ 125,324	\$ 97,131	\$ 67,080
Average number of employees	4,740	4,597	4,559	4,384	4,117

	Year ended December 31,					
	2004		2003		2002	
	Sales	% Total	Sales	% Total	Sales	% Total
	(U.S. dollars in millions)					
<b>Product sales by Region:</b>						
Europe	\$ 895.2	41.1%	\$ 796.8	42.9%	\$ 620.4	43.6%
North America	837.9	38.5	694.3	37.4	479.6	33.7
Middle East, Africa and Eastern Europe	196.3	9.0	151.2	8.1	107.6	7.6
Asia-Pacific, Oceania and Japan	137.5	6.3	116.9	6.3	106.3	7.4
Latin America	111.0	5.1	98.8	5.3	109.2	7.7
Total product sales	\$ 2,177.9	100.0%	\$ 1,858.0	100.0%	\$ 1,423.1	100.0%

	Year ended December 31,					
	2004		2003		2002	
	Sales	% Total	Sales	% Total	Sales	% Total
	(U.S. dollars in millions)					
<b>Product sales by Therapeutic Area:</b>						
Neurology:						
Rebif	\$ 1,090.6	50.1%	\$ 819.3	44.1%	\$ 548.8	38.6%
Novantrone	32.4	1.5	30.9	1.7	0.3	0.0
Total Neurology	1,123.0	51.6	850.2	45.8	549.1	38.6
Reproductive Health:						
Gonal-f	572.7	26.3	526.1	28.3	450.4	31.6
Cetrotide	24.8	1.1	24.8	1.3	18.4	1.3
Crinone	19.8	0.9	20.8	1.1	10.9	0.8
Ovidrel	17.7	0.8	12.4	0.7	5.7	0.4
Luveris	10.6	0.5	10.0	0.6	6.6	0.5
Core Infertility Portfolio	645.6	29.6	594.9	32.0	492.0	34.6
Metrodin HP	15.9	0.7	24.8	1.3	50.1	3.5
Pergonal	11.5	0.5	45.8	2.5	46.0	3.2
Profasi	6.7	0.3	15.4	0.9	19.8	1.4
Other products	12.6	0.7	12.0	0.6	14.0	1.0
Total Reproductive Health	692.3	31.8	692.9	37.3	621.9	43.7
Growth and Metabolism:						
Saizen	182.1	8.4	151.5	8.1	124.0	8.7
Serostim	86.8	4.0	88.7	4.8	95.1	6.7
Zorbtive	0.9	0.0	0.0	0.0	0.0	0.0
Total Growth and Metabolism	269.8	12.4	240.2	12.9	219.1	15.4
Dermatology						
Raptiva	4.9	0.2	0.0	0.0	0.0	0.0
Total Dermatology	4.9	0.2	0.0	0.0	0.0	0.0
Other products	87.9	4.0	74.7	4.0	33.0	2.3



Total product sales           \$ 2,177.9           100.0%   \$ 1,858.0           100.0%   \$ 1,423.1           100.0%

(1) Basic and diluted per share data have been calculated net of treasury shares held on the following basis:

	Year ended December 31,				
	2004	2003	2002	2001	2000
<b>Basic per share:</b>					
Bearer shares	10,871,187	11,427,194	11,580,611	11,658,108	11,032,835
Registered shares	11,013,040	11,013,040	11,013,040	11,013,040	11,013,040
Equivalent bearer shares	15,276,403	15,832,410	15,985,827	16,063,324	15,438,051
<b>Diluted per share:</b>					
Bearer shares	10,896,618	11,452,890	11,598,155	11,687,609	11,063,889
Registered shares	11,013,040	11,013,040	11,013,040	11,013,040	11,013,040
Equivalent bearer shares	15,301,834	15,858,106	16,003,371	16,092,825	15,469,105

(2) The portion of net income allocated to bearer and registered shares was \$351,655 and \$142,498, respectively, for the year ended December 31, 2004, \$281,459 and \$108,504, respectively for the year ended December 31, 2003, and \$232,381 and \$88,397, respectively, for the year ended December 31, 2002. On a diluted basis, the portion of net income allocated to bearer shares and registered shares was \$351,892 and \$142,261, respectively, for the year ended December 31, 2004, \$281,635 and \$108,328, respectively for the year ended December 31, 2003, and \$232,478 and \$88,300, respectively, for the year ended December 31, 2002.

(3) Per share data for American depositary shares is equal to one-fortieth of the amount shown for bearer shares.

(4) Dividends for any fiscal year are generally declared and paid in the following year, after approval at the annual shareholders' meeting.

- (5) Supplemental per equivalent bearer share data have been calculated on the basis of the number of total equivalent bearer shares outstanding during the applicable period, as set forth in footnote (1) above. Per equivalent bearer share information assumes the conversion of all of our outstanding registered shares into bearer shares. We believe the per equivalent bearer share information may be useful to investors in analyzing our financial results on a per share basis. Because our bearer shares and registered shares have different dividend rights, we believe that per equivalent bearer share information should be considered in conjunction with our other reported per share data in order to obtain a clear understanding of our consolidated historical per share information.
- (6) Working capital means current assets less current liabilities.
- (7) The portion of net income in accordance with U.S. GAAP allocated to bearer shares and registered shares was \$335,196 and \$135,828 respectively, for the year ended December 31, 2004, \$287,510 and \$110,836, respectively, for the year ended December 31, 2003, and \$202,968 and \$77,208, respectively, for the year ended December 31, 2002. On a diluted basis, the portion of net income allocated to bearer shares and registered shares was \$335,422 and \$135,602, respectively, for the year ended December 31, 2004, \$287,689 and \$110,657, respectively, for the year ended December 31, 2003, and \$203,053 and \$77,123, respectively, for the year ended December 31, 2002.
- (8) These measures are not defined in IFRS or U.S. GAAP and should not be considered as an alternative to any IFRS and U.S. GAAP data. The method of calculating these measures may be different from methods used by other companies.
- (9) Gross margin means gross profit divided by product sales. Gross profit means product sales less cost of product sales.
- (10) Operating margin means operating income divided by total revenues.
- (11) Net margin means net income divided by total revenues.

## **Risk Factors**

*We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. You should carefully consider each of the risks and uncertainties we describe below and all of the other information in this Annual Report before deciding to invest in our bearer shares or ADSs. The risks and uncertainties we describe below are not the only ones facing our company. Additional risks and uncertainties that we do not currently know or that we currently believe to be immaterial may also adversely affect our business.*

### **Risks Related to Technological Change and Research and Development**

#### **If technological change makes our products obsolete, we will no longer be able to sell our products and our revenues will decline**

Pharmaceutical and biotechnology development is characterized by significant and rapid technological change. Research and discoveries by others, including possible developments of which we are not currently aware, may make our products and those from which we derive royalty income obsolete. If technological changes make our products obsolete, doctors will be less likely to prescribe our products, and sales of our products will be reduced. If sales of our products are reduced, our results of operations could be adversely affected.

#### **If we are not able to develop and realize the full market potential of our current and new products, we may not be able to maintain our current level of sales growth and our stock price could decline**

Our long-term growth will depend on our ability to realize the full market potential of our current products and to develop and commercialize new products. Successful biotechnology product development is highly uncertain and depends on numerous factors, many of which are beyond our control. We currently have approximately 30 post-discovery projects in preclinical or clinical development. Products that appear promising in the early phases of development may fail to reach the market for numerous reasons, including, but not limited to:

• Development of products may be stopped due to a variety of reasons, such as lack of efficacy, harmful side effects and evolution of the competitive environment. For example, in July 2004, the development of emfilermin in embryo implantation failure was stopped due to inadequate efficacy in a Phase II clinical trial;

• We may not successfully complete clinical trials for our products within any specific time period, or at all, for a variety of reasons, such as our inability to attract a sufficient number of investigators, our inability to enroll and maintain a sufficient number of patients in the clinical trials and suspension of the trials by regulatory authorities;

• Products may fail to receive necessary regulatory approvals. For example, in April 2003 the Committee for Proprietary Medicinal Products recommended not granting marketing authorization for our high-dose recombinant human growth hormone product, Serostim, for the treatment of AIDS Wasting in the European Union;

• Products may turn out to be uneconomical to commercialize because of manufacturing costs or other factors.

These factors are important, not only with respect to new drugs, but also with respect to new indications for existing drugs, because we must obtain regulatory approval for each indication and market acceptance for various indications may vary. These factors may also lead to gaps in the product development pipeline and delays between the approval of one product and approval of the next new product.

### **Risks Related to Our Products and Markets**

**If we encounter problems with any of our key suppliers or service providers, we could experience higher costs of sales, delays in our manufacturing or loss of revenues**

Other companies produce raw materials necessary for the manufacture of some of our products, as well as some of our products themselves. As a result, we are subject to the risk that some of the products we sell may have manufacturing defects that we cannot control. For example, we obtain Crinone exclusively from Columbia Laboratories. In April 2001, we announced a voluntary recall of batches of Crinone due to a manufacturing defect and suspended sales for the remainder of 2001 and the first part of 2002.

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In some cases, we cite our third party sources specifically in our drug applications with regulatory authorities and accordingly we must obtain those materials or products as specified. We also use subcontractors for certain services, and in some cases the subcontracts are with sole- or limited-source suppliers. For example, Owen Mumford is the exclusive provider of the injection device Rebiject for use with Rebif, our largest product. Our subcontractors may also be registered with the regulatory authorities, so we would have to obtain regulatory approval in order to use a different subcontractor. If such services were no longer available at a reasonable cost from those suppliers, we would need to find new subcontractors.

If our suppliers experience manufacturing defects or if we have to find and register alternative raw material, product or service suppliers, we may experience significant delays in our ability to manufacture or sell our products and incur significant expense or fail to realize significant revenues.

**We may encounter unexpected difficulties in the design and construction of production facilities and the scale-up of production to viable commercial levels**

In order to manufacture a product candidate commercially, we require access to large-scale production facilities. We may encounter unexpected difficulties in the design and construction or adaptation of production facilities and the scale-up of production to viable commercial levels. These difficulties could result in substantial additional costs or affect the commercial viability of a product candidate. We are particularly at risk of encountering these difficulties in the manufacture of biological products, which are inherently more difficult to produce than chemical compounds.

**We face growing and new competition that may reduce our likelihood of market success**

We operate in a highly competitive environment. This competition may become more intense as commercial applications for biotechnology products increase. Our principal competitors are pharmaceutical companies, pharmaceutical divisions of chemical companies and biotechnology companies. Some of our competitors have greater clinical, research, regulatory, financial and marketing resources than we do and may be able to market competing products earlier than we do or market products with greater efficacy, fewer side effects or lower cost than ours. For example, the approval and launch of natalizumab (Tysabri) in the United States by Biogen Idec and its partner Elan in November 2004 is an indication of increasing competition in the field of multiple sclerosis.

Small biotechnology companies, academic institutions, governmental agencies and other public and private research organizations conduct a significant amount of research and development in the biotechnology field. These entities may seek patent protection and enter into licensing arrangements to collect royalties for the use of technology they have developed. We face competition in licensing activities from pharmaceutical companies, pharmaceutical divisions of chemical companies and biotechnology companies that also seek to acquire technologies from the same entities. If we are not able to compete effectively with these entities to acquire the technology we need to develop new products, we may not be able to maintain our current level of sales growth and our stock price could decline.

**We may be required to revise the labeling for our products from time to time**

We may be required to change the labeling for our products for a variety of reasons, such as to include new safety or efficacy data from clinical trials or post-marketing surveillance, to reflect experiential use following a period of commercialization, or to be in keeping with evolving regulatory or clinical environments. Prescribers of our products may interpret such changes in various ways that could influence their decisions on initiation, further use or discontinuance of these products. If prescribers interpret changes in the labeling of our products in ways that cause them to decrease or cease prescribing those products, we may not be able to continue our current level of sales growth and our stock price could decline.

**Resale of our biotechnology products within the European Union may cause our sales and gross profit margin to decline**

In an effort to create a single economic sphere and reduce barriers to the mobility of commercial products, the European Union has interpreted its competition and patent laws to permit the resale of various products, including biotechnology products. In 2004, \$895.2 million (41.1%) of our product sales were in Europe. Once we place our products in the stream of commerce in the European Union, we have limited ways of preventing third-party distributors from re-packaging, and then reselling, our products in any other country of the European Union. However, our prices vary across the European Union, principally as a function of different government policies regarding product pricing and reimbursement. Third-party distributors may purchase our products in markets within the European Union where our prices are lower, and then re-sell our products in countries where prices are higher. As a result, we face competition from third-party distributors that resell our products into these latter countries. We do not have the right to be the exclusive seller of our products within the European Union, nor do our patent rights protect us from third-party distributors re-selling our products in this manner. As a result, we cannot prevent a shift in sales to markets in which we realize lower unit sales prices for our products. If we sell a larger percentage of our products into these markets, our sales and gross profit margin will decline. We bear a similar risk to the extent that our products may be imported into the United States from Canada.

### **Competition from non-approved uses and generic drugs could reduce our sales growth**

We face competition from generic products and products sold for non-approved uses. For example, Serostim faces competition from drugs prescribed for non-approved indications. Physicians may prescribe anabolic steroids or competing human growth hormone products to treat AIDS Wasting although, as indicated by their labeling, regulators have not approved these products for this indication. In addition, producers of generic products may receive approval for the sale of their drugs by relying on the registration files of products already granted regulatory approval. Because producers of generic products do not have to incur the costs necessary to go through the full drug development process to prove that their products are safe and effective for these indications, they can afford to sell their products at lower prices than products like ours which have gone through that process. It is possible that our products will lose market share to these alternative therapies and that therefore we may not be able to maintain our current level of sales growth and our stock price could decline.

We may also face competition from the introduction of biosimilar products in Latin America and in Asia. These are not generic versions of Rebif as the exact formulation for Rebif is highly dependent on our well-established manufacturing process. In the United States and in Europe, regulatory agencies have so far recognized the need for clinical testing of biosimilar products to establish both efficacy and safety. However, in Latin America (Mexico and Argentina) licenses for biosimilar products were granted in the fourth quarter of 2004. Although biosimilar products are not proven and supply may be restricted, we expect there will be some impact on Rebif sales in these regions.

### **Sales of counterfeit products may damage our reputation and cause customers to lose faith in our products**

As a manufacturer of biotechnology products, we are subject to the risk that third parties will attempt to create counterfeit versions of our products and sell the counterfeits as our products. For example, in January 2001 and again in May 2002, we discovered that a counterfeit product was being sold as Serostim in the United States. Counterfeit products are not approved by regulatory authorities and may not be safe for use. If any counterfeit products are sold as ours, our reputation could suffer and patients could lose faith in our products. In addition, our products could be subject to recall in the event of counterfeit sales. If patients lose faith in our products or we are forced to recall any of our products as a result of the counterfeiting of those products, our sales could decline.

## **Risks Related to Our Sources of Revenue**

### **If our sales of any of our major products decline, our profitability would be reduced**

In 2004, Rebif, our recombinant beta interferon, accounted for 50.1% (\$1,090.6 million) of our total product sales. Rebif faces competition from Avonex and Betaseron, other recombinant beta interferon products, from Copaxone (glatiramer acetate), another drug used in multiple sclerosis, and from Tysabri (natalizumab). Because our business is highly dependent on Rebif, a reduction in revenue from sales of Rebif would have a significant impact on our overall profitability. Further, in 2004, Gonal-f, our recombinant follicle stimulating hormone, accounted for 26.3% (\$572.7 million) of our total product sales. Gonal-f faces competition from Puregon (marketed in the United States as Follistim), another recombinant product, and a variety of other FSH products. Because our business is highly dependent on Gonal-f, a reduction in revenue from sales of Gonal-f would have a significant impact on our overall profitability.

### **Our revenues are dependent on reimbursement from third-party payers who could reduce their reimbursement rates**

In most of our markets, sales of our products are or may be dependent, in part, on the availability of reimbursement from third-party payers. These payers include state and national governments, such as the health systems in many European Union countries and Medicaid and Medicare programs in the United States, and private insurance plans.

When a new product is approved, the reimbursement status and rate for the product is uncertain and must be negotiated with third-party payers in each European country, a process that can take up to several years. In addition reimbursement policies for existing products may change at any time. Changes in reimbursement rates or our failure to obtain and maintain reimbursement for our products may reduce the demand for, or the price of, our products and result in lower product sales or revenues. For example, in January 2004 the Federal Republic of Germany, Europe's largest pharmaceutical market, announced an across-the-board reduction of 10% in reimbursement rates for all pharmaceuticals, including our products.

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In certain markets, the pricing and reimbursement of our products are subject to government controls. In Europe, some third-party payers link the reimbursement price to maximum quantities of the product sold in a given year. Single payer medical insurance systems, which are predominant in Europe, are under increasing financial strain, which creates an incentive to decrease the amount that such systems will pay to reimburse the cost of drugs. In the United States, there have been, and we expect there will continue to be, a number of state and federal proposals that limit the amount that state or federal governments will pay to reimburse the cost of drugs, and we believe the increasing emphasis on managed care will put pressure on the price and usage of our products, which may impact product sales. For example, in 2001 and 2002 many states in the United States imposed prior authorization requirements for the purchase of certain drugs under Medicaid, including Serostim. Not all jurisdictions recognize the importance of infertility treatment and accordingly do not offer reimbursement coverage for such treatment. In addition, in some countries the extent of reimbursement may be affected by local public policy and ethical concerns about certain therapies, such as in vitro fertilization.

Third-party insurance coverage may not be available to patients for products we discover and develop. If third-party payers do not provide adequate coverage and reimbursement levels for our products, the market acceptance of these products may be significantly reduced.

#### **We may have difficulty successfully integrating acquired businesses with our operations**

From time to time, we may acquire businesses. We may not be able to successfully implement integration plans, dispose of certain non-core businesses, or profitably manage those businesses. We may not realize the expected synergies of acquisitions.

#### **A significant percentage of our net income is dependent on royalty and license payments that are beyond our control**

We derive a significant percentage of our net income from royalty and license income. Our royalty and license income was \$280.1 million in 2004 and \$160.6 million in 2003, relating primarily to royalties received from Biogen Idec on its sales of Avonex, Organon on its sales of Puregon, Amgen (formerly Immunex) on its sales of Enbrel, and Abbott on its sales of Humira. In addition to ongoing royalty payments, we also receive periodic milestone payments and other revenues pursuant to contracts related to our intellectual property. Our receipt of these payments is largely dependent on the successful development and sale of products by other companies over which we have no control or against which we compete. In addition, some of these revenues are dependent on patents that may be invalidated or expire. If these parties are not successful at developing and selling their products or our underlying patents are no longer in force, our net income could decline.

#### **Our investment income is unpredictable and the value of our investments may decline in the future**

Our financial assets include deposits with prime banks, investments in short-term money market funds and rated bonds with a life to maturity of up to three years. The income generated by these assets is sensitive to movements in interest rates and, in the case of the rated bonds, the realizable value of the investment also can be influenced by movements in the market price related to the underlying asset. For example, a decrease in short-term U.S. dollar interest rates would have a direct impact on the revenue generated by our bank deposits and money market funds. An increase in longer-term interest rates would negatively impact the fair value of our longer-term bond investments. Similarly, a rating downgrade or change in the market's perception of risk can lead to a reduction in the fair value of our bond investments. For example, our 2003 net financial income (\$36.9 million) was lower than our 2002 net financial income (\$54.0 million) due to a low interest rate environment and the maturity during the latter period of longer-term bond investments with higher rates of interest. Although our 2004 net financial income (\$44.1 million) was higher than in 2003, we cannot predict how interest rates and other factors that affect net financial income will change in the future. For example, if interest rates continue to stay low or fall further, our net

financial income may be reduced when compared to previous periods.

We have a number of minority participations in listed and unlisted companies that are usually, but not always, related to collaborative agreements with the respective company. The value of the unlisted investments can be difficult to assess, and changes in the market value of the listed investments can have an impact on our income. For example, in the fourth quarter of 2003, we took a non-cash charge of \$16.1 million related to the write-down of our equity investment in Swiss International Air Lines.

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### **Foreign exchange fluctuations could significantly impact the U.S. dollar value of our revenues and expenses**

Our operations are conducted by subsidiaries in many countries, and the results of operations and the financial position of each of those subsidiaries are reported in the relevant currency and then translated into U.S. dollars at the applicable exchange rate for inclusion in our consolidated financial statements. As a result, our reported sales figures may differ substantially from our sales figures as measured in local currencies. For example, in 2004 our sales growth was 11.5% in local currencies, but 17.2% as reported in U.S. dollars. Due to this translation effect, the prevailing foreign exchange rate could cause our sales growth rates to not meet expectations. If our sales figures do not meet market expectations, our stock price could decline.

Conversely, our reported expenses may also differ substantially from our expenses as measured in local currencies. For example, in 2004 our expenses growth was 22.1% as reported in U.S. dollars, but 16.3% in local currencies. Due to this translation effect, the prevailing foreign exchange rate could cause our net income growth rate to not meet expectations. Again, if our sales figures do not meet market expectations, our stock price could decline.

### **Risks Related to Government Regulation**

#### **Governmental regulations may restrict our ability to sell our products, which could result in a loss of revenues and a decrease in our stock price**

Our research, preclinical testing, clinical trials, facilities, manufacturing, labeling, pricing, and sales and marketing are subject to extensive regulation by numerous governmental authorities, including authorities in the European Union (such as the European Medicine Agency or EMEA) and Switzerland, as well as governmental authorities in the United States, such as the Food and Drug Administration, or FDA. Our research and development activities are subject to laws regulating such things as laboratory practices and the use and disposal of potentially hazardous materials including radioactive compounds and infectious disease agents. We are also required to obtain and maintain regulatory approval to market products for approved indications in the European Union, the United States, Japan and other markets. Obtaining regulatory approval is a lengthy and complex process. For example, though we have obtained regulatory approval to sell Gonal-f in 95 countries including the United States and the countries of the European Union, in order to obtain regulatory approval to sell the product in Japan we have been required to conduct additional local clinical studies, which will delay potential registration of Gonal-f in this market. Even if we are able to obtain regulatory approval for our products, both our manufacturing processes and our marketed products are subject to continued review. Later discovery of previously unknown problems with the safety or efficacy of our products or manufacturing processes may result in restrictions on these products or processes, including withdrawal of the products from the market or suspension of our manufacturing operations. For example, in February 2003, the Committee on Safety of Medicines advised that Metrodin HP should no longer be used in the United Kingdom. The Committee based its advice on the precautionary principle that products manufactured from human urine sourced from a country with one or more cases of variant Creutzfeldt-Jakob Disease, or vCJD, should not be used whenever practicable. Metrodin HP was manufactured from urine sourced from Italy, and the withdrawal of Metrodin HP from the United Kingdom market was a precautionary measure following the confirmation of a case of vCJD in Italy. In February 2005, the United States Department of Health and Human Services announced the establishment within the FDA of a new Drug Safety Oversight Board to monitor FDA-approved medicines once they are on the market and update physicians and patients with emerging information on risks and benefits. Any adverse report by this Board with respect to our products could have an effect on our product sales, profits and stock price.

#### **Pharmaceutical usage guidelines may recommend lower use of our products**

If government agencies or other respected groups or organizations recommend reducing the use of one of our products, our sales of that product could drop and our revenues could be reduced. In addition, professional societies, practice management groups, private foundations and organizations involved in various diseases may also publish

guidelines or recommendations to the health care and patient communities. These organizations may make recommendations that affect a patient's usage of certain therapies, drugs or procedures, including our products. Such decisions may also influence prescription guidelines for our products issued in other countries. Recommendations or guidelines that are followed by patients and health care providers could result in, among other things, decreased use of our products. For example the National Institute for Clinical Excellence (NICE) in the U.K. systematically issues guidelines in selected therapeutic areas which may limit prescription of our products.

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**Potential regulation of the use of biological materials could make production of our products more expensive or not possible**

We use biological materials, in particular animal-derived materials, in the development and manufacture of our products. Some interest groups in the European Union and the United States are seeking to ban or regulate the use of animal-derived materials generally, including their use in biotechnology products and for research and development.

Although we are developing manufacturing processes for our major molecules that will be free of animal-derived components, we may not be successful in that development and we cannot be certain that regulatory authorities will approve the new processes. If a government were to ban or regulate our use of animal-derived materials, we would incur additional costs that could make the production of our products less profitable or economically impractical, or we could have to cease production of certain of our products, which could cause our net income and stock price to decline.

**Risks Related to Legal Uncertainty**

**If we are not able to defend our intellectual property rights, we may lose the competitive advantage they give us**

Our long-term success depends largely on our ability to market technologically competitive products. The patents and patent applications relating to our products and the technologies from which we derive license revenue may be challenged, invalidated or circumvented by third parties and might not protect us against competitors with similar products or technology. Any challenge to or invalidation or circumvention of patents related to products produced using licenses we have granted could affect our licensing revenues. If we are unable to prevent unauthorized third parties from using proprietary rights relating to our products, we will not be able to realize the full value of our research investment, and we will lose a source of competitive advantage. Even if our patents are not invalidated or circumvented, each of them will eventually expire.

The competitive position of a number of our products is dependent on various patents. We believe that these patents discourage other companies from entering our markets. Certain of these patents also allow us to realize licensing revenue from competitors whose products would otherwise infringe these patents. If we cannot defend these patents, other companies could sell products that directly compete with our products.

Moreover, the patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual issues. Important legal issues remain to be resolved as to the extent and scope of available patent protection for biotechnology products and processes in the European Union, the United States and other important markets. To date, no consistent policy has emerged regarding the breadth of claims allowed in pharmaceutical and biotechnology patents. As a result, it is difficult for us to assess the amount of protection our patents provide for our competitive position.

We rely on trade secrets and trademarks to protect our technology, especially where we believe patent protection not to be appropriate or obtainable. We protect our proprietary technology and processes, in part, by confidentiality agreements with our key employees, consultants, collaborators and contractors. These agreements may be breached, or we may have inadequate remedies for any breach, or our trade secrets or those of our collaborators or contractors may otherwise become known to or be discovered independently by competitors.

**If we do not have access to the intellectual property we need for our business, our ability to develop and market our products may be limited**

We are aware that others, including various universities and companies working in the biotechnology field, have filed patent applications and have been granted patents in the European Union, the United States and other jurisdictions claiming subject matter potentially useful or necessary to our business. Some of those patents and applications claim only specific products or methods of making such products, while others claim more general processes or techniques useful or now used in the biotechnology industry, either alone or in combination with other products. For example, Berlex Laboratories and Schering AG own three U.S. patents that they have asserted cover the recombinant manufacture of interferon beta. Following the filing by us of a declaratory judgment action against Berlex and Schering AG asserting that we do not infringe their patent rights, we settled with them and agreed to make a one-time payment to Berlex and pay Berlex royalties on our U.S. sales of Rebif in the United States for a limited period of time.

Litigation and administrative proceedings, which could result in substantial costs to us, may be necessary to enforce any patents issued to us or to determine the scope and validity of third-party proprietary rights. We have in the past been, are currently, and may in the future be involved in patent litigation. If we lose one of these proceedings, we may be required to obtain third-party licenses at a material cost or cease using the technology or product in dispute. If others have or obtain patents or proprietary rights with respect to products we currently are developing, we may not be able to continue to research and develop our products profitably. If we are unable to enforce our patents, we may lose competitive advantage or marketing revenue.

**If we are subject to significant legal action or to a government investigation, we may incur substantial costs related to pursuing or settling such litigation or investigation**

We participate in an industry that has been subject to significant product liability, intellectual property and other litigation and to government investigations. Many of these actions involve large claims and significant defense costs. For example, our principal U.S. subsidiary has received subpoenas from the U.S. Attorney's office in Boston, Massachusetts, relating to Serostim. The outcome of this investigation could include the imposition of substantial civil and/or criminal penalties that could be material to us, including exclusion from government reimbursement programs. For a further description of this matter, please see "Item 8—Legal Proceedings."

**Changes in tax laws could adversely affect our earnings**

Changes in the tax laws of Switzerland, the United States or other countries in which we do significant business, as well as changes in our effective tax rate for the fiscal year caused by other factors, could affect our net income. During 2004, no major tax legislation was enacted that would materially impact our net income. It is not possible to predict the impact on our results of any tax legislation that may be enacted in the future.

**Risks Related to Our Share Price and Corporate Control**

**Our share price is likely to be volatile and may decline**

The market price for our shares has been volatile and may continue to be volatile in the future. During 2004, based on prices on the virt-X, our bearer share price ranged from CHF 711 to CHF 974. During the same period, based on prices on the New York Stock Exchange, the price range for our ADSs ranged from \$14.57 to \$19.60. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of the shares and may cause the price to decline:

• A revenue shortfall, which, due to fixed near-term expenses, causes a period's results to be below expectations;

• a short-term increase in expenses that is not matched by a corresponding increase in revenue;

• changes in wholesaler buying patterns;

• publicity regarding our collaborations and actual or potential results relating to products and indications under development by us or our competitors;

• regulatory developments in the countries in which we operate;

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- public concern as to the safety of our products;
- perceptions as to the prospects of our company;
- perceptions as to the prospects of our competitors and the biotechnology industry in general;
- general market conditions;
- changes in the exchange rate of the U.S. dollar against the euro and the Swiss franc; and
- period-to-period fluctuations in our financial results.

**The value of dividends on our ADSs will be affected by exchange rates**

We declare and pay dividends on our bearer shares in Swiss francs. Exchange rate fluctuations between the Swiss franc and the U.S. dollar will affect the U.S. dollar value of dividends that holders of our ADSs will receive.

**Our controlling shareholders may have interests that are adverse to yours**

As of December 31, 2004, Bertarelli & Cie held 51.43% of our capital, including treasury shares, and 65.36% of our voting rights. Ernesto Bertarelli, our Vice Chairman, Managing Director and Chief Executive Officer, controls Bertarelli & Cie. In addition, Maria-Iris Bertarelli, Ernesto Bertarelli and Donata Bertarelli Späth own as individuals in the aggregate 7.00% of our capital, including treasury shares, and 10.53% of our voting rights. The members of the Bertarelli family may in the future, through open market purchases or otherwise, acquire additional shares. Ernesto Bertarelli, through his control of Bertarelli & Cie and his ownership of additional shares, currently controls the management of our company and the outcome of all actions requiring the approval of our shareholders. The interests of Ernesto Bertarelli and the Bertarelli family may conflict with the interests of our other investors, and you may not agree with the actions they take. For example, Mr. Bertarelli and the Bertarelli family have the combined voting power necessary to reject any offer to acquire us, even if the offer would be attractive to our other investors. In addition, Mr. Bertarelli and the Bertarelli family control enough votes that they can cause us to increase our share capital, change our corporate purposes and create shares with privileged voting rights. This could have the effect of diluting the voting rights and ownership of our other investors and of maintaining the control of Mr. Bertarelli and the Bertarelli family.

**Future sales by current shareholders could cause the price of our shares to decline**

If our existing shareholders sell a substantial number of our shares in the public market, the market price of our shares could fall. Subject to applicable Swiss law, United States federal securities laws and other applicable laws, the Bertarelli family may sell or distribute any and all of the shares owned by them. Sales or distributions by the Bertarelli family of substantial amounts of our capital stock, or the perception that such sales or distributions could occur, could adversely affect prevailing market prices for our shares. The Bertarelli family is not subject to any contractual obligation to retain its controlling interest.

**It may not be possible to enforce judgments of United States courts against the members of our board of directors**

We are a Swiss stock corporation. Most of our directors are not residents of the United States. In addition, a substantial portion of our assets and the assets of our board members are located outside the United States. As a result, it may not be possible to effect service of process within the United States on us or on our directors, or to enforce against them judgments obtained in the United States courts based on the civil liability provisions of the securities



laws of the United States. In addition, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in Switzerland.

**U.S. persons may not be able to participate in some of our securities offerings**

United States securities laws may restrict the ability of U.S. persons who hold our ADSs from participating in certain rights offerings, share dividends or other transactions involving our securities that we may undertake in the future. We are not under any obligation to register any such transactions under the U.S. securities laws.

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**Our actual results may differ from forward-looking statements that we make in this annual report**

Many statements made in this Annual Report under Items 3, 4 and 5 and elsewhere are forward-looking statements relating to future events and/or future performance, including, without limitation, statements regarding our expectations, beliefs, intentions or future strategies that are signified by the words “expects,” “anticipates,” “intends,” “believes,” “plans” or similar language. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of, among other factors, the factors set forth in this “Risk Factors” section.

We caution you that these forward-looking statements, which may deal with subjects such as our research and development plans, our marketing strategies, our planned regulatory approvals, our planned relationships with our research collaborators, the development of our business, the markets for our products, our anticipated capital expenditures, the possible impacts of regulatory requirements and other matters that are not historical facts, are only predictions and estimates regarding future events and circumstances. All forward-looking statements included in this document are based on information available to us on the date of this Annual Report, and we undertake no obligation to update these forward-looking statements to reflect events occurring after the date of this Annual Report. You should carefully consider the information set forth in this section in addition to the other information set forth in this Annual Report before deciding whether to invest in our bearer shares or ADSs.

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## **Item 4. INFORMATION ON THE COMPANY**

### **Overview**

We are the third largest biotechnology company in the world based on 2004 total revenues of \$2,458.1 million. Biotechnology companies use human genetic information to discover and manufacture therapeutic products for the treatment of human diseases. We currently focus on the highly specialized markets of reproductive health, neurology, growth and metabolism, where we have established strong positions, and on the dermatology market, which we entered, in 2004. We have a global presence with operations in over 40 countries, five principal production facilities located in four countries, sales in over 90 countries and 4,902 employees.

As a biotechnology company, research and development are central to our efforts to grow our business. We currently employ 1,387 research and development personnel, and in 2004 we spent \$594.8 million on R&D. Our in-house R&D capabilities, which span a variety of disciplines, and our numerous external collaborations enhance our ability to develop new medications. We currently have approximately 30 high priority projects in preclinical or clinical development.

We have integrated operations that allow us to manufacture and market the products we derive from our R&D efforts. The use of biotechnology techniques has allowed us to improve our manufacturing efficiency and helped us to increase our product gross margin to 86.0% in 2004 from 67.7% in 1995 and to increase our net margin to 20.1% of revenues in 2004 from 4.2% in 1995.

Our 2,084 sales and marketing personnel sell our products primarily by calling on prescribing physicians in our highly specialized markets.

We are a Swiss corporation, with our principal executive offices in Geneva. We were incorporated in 1987, and our bearer shares have been listed in Switzerland since that time. Our American depositary shares or ADSs have been listed on the New York Stock Exchange since July 2000.

Our principal offices are operated by our wholly owned subsidiary, Serono International S.A., and are located at 15 bis, Chemin des Mines, Case Postale 54, CH-1211 Geneva 20, Switzerland. Our telephone number is +41-22-739-3000. We have established a Website at [www.serono.com](http://www.serono.com). The information on our Website is not part of this Annual Report.

### **Recombinant Technology**

We currently market eight recombinant products— Rebif, Gonal-f, Saizen, Serostim, Ovidrel, Luveris, Zorbtive and Raptiva. Recombinant DNA technology gives us an efficient, cost-effective and consistent method of producing commercial quantities of proteins.

Proteins are important components of human cells and have various biological functions, and some proteins have been developed as therapeutics. Historically, we obtained proteins relevant to our therapeutic areas by extracting them from natural sources, such as human urine or pituitary tissue, and then purifying them. These processes have presented several challenges in terms of identifying suitable sources and economically collecting a sufficient amount of the raw materials for production.

Using recombinant technology, we now clone, or copy, the human gene containing instructions for the synthesis of a protein product and transfer it to a host cell. We then induce the host cell to produce commercial quantities of that protein. When using recombinant technology to produce pharmaceuticals, the choice of host cell is important. Recombinant DNA technology can be used to transfer genetic information into bacterial, yeast, mammalian or other

cell types. If bacterial, yeast and certain other cells are used for recombinant drug production, certain complex protein molecules may not be able to be produced in their natural forms, rendering the molecules unstable, or biologically less active or even inactive. However, mammalian host cells can produce molecules as they are made in the natural environment. All of our recombinant products are currently produced using mammalian cell technology.

Recombinant technology allows us to solve many of the problems associated with production of complex pharmaceuticals through extraction from natural sources. Because of the nature of recombinant production, we can closely control the quality and purity of the products and more easily achieve batch-to-batch consistency. In addition, we are not as dependent on difficult-to-organize raw material supply chains, so we are able to more quickly respond to changes in market demand for our products.

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## Neurology

Multiple sclerosis, or MS, is a chronic and often progressive debilitating disease of the central nervous system that primarily affects young adults. It is an autoimmune disease in which the body's immune system reacts against its own cells, thereby destroying the myelin sheath that protects the axons in the central nervous system. Damage to the myelin sheath impedes the normal transmission of nervous impulses. These interruptions of transmission cause motor and sensory difficulties. The progress of the disease is highly variable. However, in its most severe forms, MS leads to rapidly progressive disability and death.

Over one-half of the world's estimated 1.2 million people with MS suffer from the relapsing-remitting form of this disease, or RRMS, and nearly 80% of all MS cases start with RRMS.

RRMS patients suffer from relapses or exacerbations, which are unpredictable occurrences of new symptoms or worsening of old symptoms punctuated by remissions. In the majority of cases patients progress from RRMS into secondary progressive MS, or SPMS, as they start to accumulate disability. In the early stages of SPMS patients continue to have relapses and, together with RRMS patients, are sometimes described as having relapsing MS, or RMS. Additionally patients in the early stages of the disease, prior to a diagnosis of RRMS, may also sometimes be classified as having RMS.

We estimate that the treatment of relapsing MS with disease modifying drugs was an approximately \$4.4 billion global market in 2004, based on publicly reported sales data for our product and four competing products.

## Products

### *Rebif*

Rebif is a recombinant interferon beta-1a that helps strengthen the body's immune system. It is identical to the interferon beta that the human body produces in certain circumstances, for example, in response to viral infection. Interferons fight viruses, inhibit cell multiplication and regulate the activity of the immune system. Because of their complex effects on the immune system, interferons may have important therapeutic potential in other indications.

We developed Rebif for the treatment of MS, and we currently manufacture and market it for use in the RRMS and RMS indications. In 2004, Rebif was our largest selling product, accounting for \$1,090.6 million (50.1%) of total product sales. We began marketing Rebif in the United States in March 2002. In 2004, our estimated market share in the United States in terms of total prescriptions was 16.4% and 18.6% in new prescriptions.

In November 1998, we published the results of the Prevention of Relapses and Disability with Interferon beta-1a Subcutaneously in Multiple Sclerosis, or PRISMS, study in the *Lancet*. The study showed that Rebif is the first therapeutic agent to demonstrate efficacy on all major endpoints in MS (disability, relapses, MRI area and activity). In this study, 560 RRMS patients were given one of two doses of Rebif or a placebo. The results of the trial showed that Rebif reduces the number of relapses experienced by patients and delays the rate at which patients become disabled (as measured by a confirmed 1-point Expanded Disability Status Scale, or EDSS, progression). In addition, brain scans showed that the number of multiple sclerosis lesions is reduced by Rebif (as measured by a reduction in the T2 disease burden).

In June 2001, four-year data from the study were published in *Neurology* and showed that the higher of the two doses tested (44 mcg three times per week) was associated with better efficacy than the lower dose (22 mcg three times per week). In the first quarter of 2001, the European Union granted marketing approval for the highest available dose of Rebif as a first line therapy for patients with RRMS.

This research has since been followed by the publication of the Secondary Progressive Efficacy Clinical Trial of Rebif in MS, or SPECTRIMS study, in the June 2001 issue of *Neurology*. This study suggests that the rate of progression of disability in patients is reduced if Rebif is administered in the early stages of secondary progressive multiple sclerosis (in patients who continue to experience relapses) as opposed to later stages of the disease.

During 2001, we completed a study involving 677 patients in a head-to-head trial comparing the high dose of Rebif with the standard dose of our competitor's product, Avonex. The Evidence for Interferon Dose-effect: European-North American Comparative Efficacy Study, or EVIDENCE, was at the time the largest prospective comparative study of two disease-modifying drugs in MS. The objective of the study was to compare the clinical benefit of Rebif and Avonex based on pre-defined FDA-approved endpoints. We conducted the study with the concurrence of the FDA regarding its design, primary and secondary endpoints and the prospectively defined statistical analysis plan. The study showed that 32% fewer patients treated with Rebif had relapses compared to patients treated with Avonex during a six-month treatment period. In March 2002, the FDA approved Rebif on the basis that it had been shown to be clinically superior in the reduction of exacerbations at 24 weeks. 48-week data from the EVIDENCE study showed that 62% of patients who received Rebif did not have a relapse compared to 52% of Avonex-treated patients. Rebif patients had a 19% relative increase in remaining free of relapses over the 48 weeks compared to Avonex patients. Rebif patients also had a 30% reduction in the rate of occurrence of first relapse during 48 weeks relative to Avonex patients. The 12-month data from the EVIDENCE study, which showed the superiority of Rebif 44 mcg three times per week over Avonex 30 mcg once per week in reducing exacerbations, were published in the November 2002 issue of *Neurology*.

In May 2003, we and Pfizer announced that the final 63-week findings from the EVIDENCE study continue to show that Rebif is significantly more effective in reducing frequency of relapses and magnetic resonance imaging, or MRI, activity as compared to Avonex. Final 63-week data from the EVIDENCE study showed that 56% of patients who received Rebif did not have a relapse during this observation period compared to 48% of Avonex patients. Rebif patients had a 17% relative increase in remaining free of relapses over the 63 weeks compared to Avonex patients. These data further support the benefit of increased dose and frequency of interferon administration in the treatment of relapsing forms of MS. The findings are consistent with data comparing Rebif and Avonex at 24 and 48 weeks.

At the conclusion of the comparative phase of the EVIDENCE study, patients randomized to Avonex were offered our MS therapy, Rebif. Approximately 73% of Avonex patients (n=223) chose to convert to Rebif. In June 2003, we reported that patients who converted from Avonex to higher dose, higher frequency Rebif showed a significant reduction in frequency of relapses and MRI lesion activity. Following their change in therapy, these patients experienced a 50% relative reduction in the frequency of relapses ( $p < 0.001$ ) and a 22% relative reduction in MRI lesion activity ( $p = 0.022$ ) compared to the previous six months.

In September 2003, we presented new data from a long-term assessment of a group of patients with RRMS on Rebif therapy. The eight-year extension data come from an open-label follow-up of the PRISMS study, a double-blind, placebo-controlled study that began in 1994 and involved 560 patients at 22 centers in nine countries. Patients were originally randomized to receive Rebif 44 mcg subcutaneously three times per week, Rebif 22 mcg subcutaneously three times per week or placebo. 381 patients (67% of the original cohort) were followed up after eight years. The results support the long-term benefit of Rebif 44 mcg subcutaneously three times weekly in the treatment of RRMS on relapses, disability and MRI outcomes measured, with a favorable risk benefit profile through eight years.

In October 2004, we presented data from a prospective pre-planned crossover analysis of the PRISMS study showing that patients with RRMS who were treated for two years with placebo and then treated for two years with Rebif showed substantial clinical benefits with a 54% relative reduction in relapse rate. The data also showed a significant improvement in MRI results for patients treated with Rebif 44 mcg. There was a highly, statistically significant relative reduction in the mean number of brain lesions of 67%. In addition, 76% of patients treated with Rebif 44 mcg remained free of disease progression during the two years of treatment.

In January 2004, we initiated a post-registration head-to-head study of Rebif versus Copaxone (glatiramer acetate) given at approved doses. The objective of the trial is to compare the safety and efficacy of Rebif and glatiramer acetate in RRMS patients to obtain data that will support an evidence-based approach to rational treatment decisions in MS. The study design is a two-year study with a relapse-related primary endpoint as well as other clinical and MRI secondary endpoints. The doses of study drugs are the standard doses of Rebif (44 mcg three times per week) versus glatiramer acetate (20 mg daily) both given by subcutaneous injection. In January 2005, we announced the completion of patient enrolment into this study with over 700 patients enrolled.

In May 2004, we announced the launch of the Rebiject II auto-injector, a device specifically designed to make self-injection of Rebif more convenient for MS patients on Rebif therapy, in Europe and we launched Rebiject II in the United States at the end of 2004. A study conducted in 115 patients with MS on Rebif therapy showed that 71% of those patients found the Rebiject II was better than their previous autoinjection method of injection, with patients indicating that injections using the Rebiject II were less painful and that the Rebiject II was easier to use than their previous autoinjection method of injection.

We have registered Rebif for the treatment of MS in 87 countries, including the United States, Canada, Australia, and all of the countries of the European Union.

*Novantrone*

In December 2002, we completed a license and commercialization agreement with Amgen, pursuant to which we acquired the rights to sell the MS and oncology drug Novantrone in the United States. Novantrone is a topoisomerase II inhibitor, which acts by inhibiting DNA replication in dividing cells. The drug is approved in the United States for secondary progressive, progressive relapsing and worsening relapsing-remitting MS and for certain forms of cancer. Novantrone has orphan drug status in the United States for use in patients with the approved MS indications until October 2007. In March 2003, we entered into an agreement with OSI Pharmaceuticals pursuant to which OSI markets and promotes Novantrone in the United States for its approved oncology indications. Novantrone is strategic for our neurology franchise in the United States as it is complementary to Rebif and allows us to leverage investments made in our neurology infrastructure. In 2004, Novantrone was our fifth largest selling product, accounting for \$83.9 million or 3.9% of total product sales.

***Product Pipeline***

Our product pipeline in the field of neurology includes projects targeted toward improving the delivery of Rebif and discovery projects seeking new approaches to the treatment of MS.

*Mylinax*

In October 2002, we entered into a worldwide agreement with IVAX to develop and commercialize cladribine (now known as Mylinax), as potentially the first orally effective disease modifying treatment for MS. Mylinax is a purine-analogue that interferes with the behavior and the proliferation of certain white blood-cells, including monocytes and lymphocytes, which are involved in the pathological process of MS. Data from earlier trials suggest that injected Mylinax may be effective in certain MS patients. We have worked with IVAX to establish an oral formulation of Mylinax and initiated Phase I clinical trials in the fourth quarter of 2003. We obtained positive results from these trials in March 2004. Following discussions with regulatory authorities, we decided to initiate a Phase III clinical trial in early 2005. Cladribine is currently approved for patients with active hairy cell leukemia.

*MMP-12 inhibitor*

An MMP-12 inhibitor, an orally active matrix metalloprotease inhibitor with potential as a treatment for MS, entered Phase I clinical development in January 2005. Data from preclinical trials shows efficacy in an animal model of relapsing remitting MS.

*JNK inhibitor*

A JNK inhibitor, an orally active small molecule inhibitor of apoptosis, with potential as a treatment for MS, entered Phase I clinical development in 2004. This molecule demonstrated a promising profile in experimental models of progressive MS.

*Osteopontin*

Osteopontin, a naturally occurring protein with potential to remyelinate damaged neurons, entered preclinical development in 2003 and could become a treatment for multiple sclerosis as well as various demyelinating neuropathies of the peripheral nervous system.



**Reproductive Health**

We are the global market leader in the treatment of human infertility and have a broad offering of products in the field. The World Health Organization estimates that eight to 12 percent of all couples experience some form of infertility problem during their reproductive lives. We estimate that sales of our products currently account for more than 46% of the approximately \$1.2 billion global gonadotropin market and sales of Gonal-f currently account for about 62% of the approximately \$900 million global recombinant FSH segment.

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In women, the maturation of ova in the ovary and subsequent maintenance of pregnancy depend on three main gonadotropins: follicle stimulating hormone, or FSH, luteinizing hormone, or LH, and human chorionic gonadotropin, or hCG. In a normal menstrual cycle, the hypothalamus produces gonadotropin releasing hormone or GnRH, which controls the release of FSH and LH. FSH stimulates estrogen production of the ovaries and the maturation and development of follicles. The mid-cycle LH surge induces ovulation, resulting in the formation of the corpus luteum, which, besides other factors, produces progesterone and estrogen. Upon conception, hCG is produced by the trophoblast, stimulating progesterone production of the corpus luteum graviditatis to maintain the pregnancy. In men, FSH stimulates spermatogenesis, and LH stimulates testosterone production of Leydig cells.

Our goal in the reproductive health area is to offer fertility products addressing the major steps in the infertility treatment process. With Gonal-f, Ovidrel and Luveris, we have implemented our strategy of replacing our urine-derived reproductive health products with recombinant versions. At the end of 2002, we decided to proceed with the closure of our production facilities for urine-derived products. We stopped selling urine-derived products in the European Union in 2003, in the United States in the second quarter of 2004, and in the rest of the world (except for Japan, where our recombinant gonadotropins are not yet approved) by the end of 2004.

### Major Steps in the Infertility Treatment Process

- Ø Pituitary down-regulation—Cetrotide
- Ø Ovarian stimulation—Gonal-f, Luveris, Serophene, anastrozole (in development)
- Ø Follicular maturation and ovulation triggering—Ovidrel
- Ø Luteal phase support—Crinone
- Ø Treatment of preterm labor. Prevention of preterm delivery is one of the major challenges in perinatology. We currently have two products in pre-clinical development - an oxytocin receptor antagonist and a prostanoid FP receptor antagonist - which have potential in the treatment of preterm labor.

### **Recombinant Products**

Sales of our recombinant products have grown in recent years and currently stand at approximately 94% of our total gonadotropin sales worldwide. We believe that use of recombinant products has increased due to the greater efficacy of recombinant products and the superior tolerance of the products by patients. These products are administered subcutaneously — just under the skin — using a small needle, which is a significant advantage over some of the urine-derived products that must be given through more painful intramuscular injection. We are continuing to encourage the switch to recombinant products, because we believe them to be superior. With Gonal-f, Ovidrel and Luveris, we are the only company that offers a totally recombinant gonadotropin portfolio.

#### *Gonal-f*

Gonal-f, the first recombinant drug developed for the treatment of infertility to receive marketing approval anywhere in the world, is a human FSH. Gonal-f is the global market leader, having been approved for use in 95 countries, including the entire European Union and the United States. It is indicated for the treatment of patients suffering from ovulation disorders. Gonal-f also stimulates the development of multiple follicles in women being treated with assisted reproductive technologies, such as in vitro fertilization, in which eggs are extracted from a woman's body, fertilized and then inserted in the uterus. A multi-dose presentation of Gonal-f is available in the European Union, the United States and other countries and accounted for 64.7% of Gonal-f sales in 2004. Gonal-f is also approved in the European Union, the United States and other countries for treating a sub-form of male infertility called

hypogonadotropic hypogonadism. In 2004, Gonal-f was our second largest selling product, accounting for \$572.7 million (26.3%) of total product sales.

Several randomized studies designed to compare Gonal-f to the urine-derived gonadotropins we formerly manufactured have shown that Gonal-f is more effective in increasing the number of follicles and embryos obtained during treatment with assisted reproductive technologies. Based on the latter studies, the European Commission permitted the labeling of Gonal-f to be amended to include a statement that it is more effective than urine-derived FSH preparations.

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In order to control product variability, we have developed a highly controlled manufacturing process for Gonal-f. This manufacturing process allows us to produce recombinant human FSH with a highly consistent isoform profile and highly consistent batch-to-batch bioactivity, which is measured by a precise physico-chemical method to determine the potency of the product. As a result, Gonal-f is now filled-by-mass (i.e., protein weight). By doing so, we eliminate the intrinsic variability of the rat bioassay and ensure high batch-to-batch and vial-to-vial consistency of r-hFSH content. In 2004, we received European Union and U.S. FDA approval for our pre-filled liquid pen injector, which is designed to improve the patient-friendliness of Gonal-f injections.

#### *Ovidrel/Ovitrelle*

Our recombinant hCG, which we market as Ovidrel in the United States and Ovitrelle in the European Union, is used to induce final maturation of ovarian follicles and to trigger ovulation. hCG is a hormone produced by the human placenta that acts in a similar manner to LH. A monthly surge in the production of LH is responsible for ovulation. The hCG contained in Ovidrel triggers ovulation in a way similar to the way LH does in a natural monthly menstrual cycle. Ovidrel is registered in 70 countries. Recombinant hCG is better tolerated by patients and can be administered through subcutaneous injection, a significant patient advantage over earlier urine-derived products, which had to be given by intramuscular injection. In October 2003, the Ovidrel/Ovitrelle pre-filled syringe was approved by both the FDA and the European Commission, making it the first liquid, ready-to-use recombinant hCG. In 2004, Ovidrel accounted for \$17.7 million or 0.8% of total product sales. As of November 2004, in the United States Ovidrel was the number one product in the hCG market segment, which includes many generic competitors.

#### *Luveris*

Luveris is the first product ever developed in which LH is available as a stand-alone hormone. Luveris provides a pure source of recombinant LH for the small population of patients that have a deficiency of both LH and FSH (LH <1.2 IU/L) and therefore require treatment with both hormones to achieve pregnancy. We have marketed Luveris in the European Union since mid-2001. In October 2004, the U.S. FDA approved Luveris for concomitant use with Gonal-f for stimulation of follicular development in infertile hypogonadotropic hypogonadal women with profound LH deficiency. We launched Luveris in the United States in the last quarter of 2004. The U.S. FDA has granted Luveris orphan drug status until October 8, 2011. Luveris is registered in 67 countries.

#### ***Urine-Derived Products***

At the end of 2002, we decided to proceed with the closure of our production facilities for urine-derived products. We stopped selling urine-derived products in the European Union in 2003, in the United States in the second quarter of 2004, and in the rest of the world (except for Japan where our recombinant gonadotropins are not yet approved) by the end of 2004. As a result of our decision to phase out these products, sales of our urine-derived gonadotropins were \$38.2 million, down by 57.2%, in 2004.

#### *Pergonal*

Pergonal is a preparation of FSH and LH for intramuscular injection extracted from the urine of post-menopausal women. It is indicated for use in inducing ovarian follicular growth in infertile women with ovulation disorders. In addition, it may be used to stimulate the development of multiple follicles in patients having treatment with assisted reproductive technologies. Pergonal, when administered to men at the same time as hCG, is indicated for the stimulation of sperm formation in patients who have a form of male infertility.

#### *Metrodin HP*

Metrodin HP, which was marketed in the United States as Fertinex, is a highly purified preparation of FSH extracted from the urine of post-menopausal women. Metrodin HP contains 95% FSH, a much higher percentage than first generation gonadotropin preparations. Metrodin HP was used for many of the same indications as Gonal-f, which has largely replaced Metrodin HP. In 2004, Metrodin HP accounted for \$15.9 million or 0.7% of total product sales.

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### *Profasi*

Profasi consists of hCG derived from the urine of pregnant women. Profasi is given to women to induce final follicular maturation and trigger ovulation, once follicular development has been achieved by treatment with products such as Gonal-f, Metrodin HP or Pergonal. Profasi is administered to men with certain types of infertility to enhance the production of testosterone, a hormone essential in the development of sperm. It is also indicated for the support of luteal function in women with certain fertility disorders. Profasi is used for many of the same indications as Ovidrel, which has replaced Profasi.

### ***Other Products***

#### *Crinone*

Crinone is a progesterone product with an advanced delivery technology that permits it to be self-administered as a vaginal gel. Progesterone is a hormone that is required to prepare the lining of the uterus for the implantation of a fertilized egg and for the maintenance of pregnancy. The gel is used in connection with certain assisted reproductive technologies, including in vitro fertilization. Crinone is associated with high clinical pregnancy rates and is convenient for patients, because it is user friendly and does not require painful intramuscular injections. It is the only progesterone product with marketing authorization for infertility treatment in Germany and the United Kingdom. In July 1999, we acquired exclusive worldwide marketing rights to Crinone, which we license from Columbia Laboratories. Pursuant to this license, Columbia Laboratories supplies Crinone to us for resale. The agreement will be in effect for four more years, after which it is renewable for additional five-year terms. In April 2001, we withdrew Crinone from the market due to a manufacturing defect. In March 2002, we relaunched Crinone in the United States and reintroduced Crinone in other worldwide markets later in 2002. As a part of our settlement of litigation with Columbia Laboratories related to the recall, we amended our marketing agreement for Crinone. Under the amended agreement, we will continue to market Crinone outside the United States and to reproductive endocrinologists, obstetricians and gynecologists who prescribe injectable gonadotropins in the United States, and Columbia Laboratories will market a second brand of its product to other obstetricians and gynecologists in the United States in exchange for royalty payments to us. In 2004, Crinone accounted for \$19.8 million or 0.9% of total product sales. Crinone is registered in 50 countries.

#### *Cetrotide*

In ovarian stimulation for assisted reproductive techniques such as IVF (in vitro fertilization) or ICSI (intracytoplasmic sperm injection), the successful prevention of a premature LH surge is crucial. Cetrotide is the first LHRH antagonist in the world to be approved for the prevention of the LH surge. Treatment with Cetrotide is generally more convenient than treatment with LHRH agonists, which involves prolonged therapy to achieve pituitary down-regulation. We market Cetrotide under an agreement with Zentaris (formerly Asta Medica) which gives us the right to market, distribute and sell Cetrotide worldwide, with the exception of Japan. The agreement expires in 2020. Thereafter, we have a perpetual fully paid up license. We currently market Cetrotide in 79 countries. In 2004, sales of Cetrotide accounted for \$24.8 million or 1.1% of total product sales. We provide Cetrotide in two different doses: 0.25 mg for multiple dose application and 3 mg for single dose application. It has been shown and published in peer-reviewed journals that the tolerability of Cetrotide is better when compared to a similar product provided by a competitor. Furthermore, the application of the single-dose Cetrotide protocol results in significantly fewer injections for the patient compared with the competitor's product.

### ***Product Pipeline***

#### *Gonal-f*

We are currently consolidating our worldwide labeling for Gonal-f by seeking to register it in additional jurisdictions or for additional indications in jurisdictions where we already have approval. For example, in 2004 we filed for Gonal-f in Japan and the application is currently under review by the Japanese health authorities.

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### *Onercept*

Onercept, or TBP-1, is a recombinant, soluble type I TNF receptor which acts as an inhibitor of tumor necrosis factor (TNF) alpha. Based on preclinical data suggesting that blocking TNF inhibits the development of endometriotic lesions, we plan to start a proof of concept trial in endometriosis in 2005.

### *Anastrozole*

In July 2002, we entered into an exclusive worldwide agreement with AstraZeneca pursuant to which we have the right to develop, register and market the aromatase inhibitor anastrozole in ovulation induction and improvement of follicular development. Anastrozole is an oral aromatase inhibitor, which acts by blocking the synthesis of estrogen and thereby improving ovulation. Because of its characteristics, we hope it will have benefits over currently available treatments, both in terms of efficacy and having fewer side effects. We commenced a Phase II trial of the drug investigating single doses in this indication in the first quarter of 2003, which showed that monofollicular development with ovulation and pregnancy can be achieved in the target population. Results indicate that the dose regimen could be further optimized before entering Phase III. Therefore, we plan to start a further Phase II multiple-dose dose-finding, comparative trial versus clomiphene citrate in the first half of 2005. Anastrozole is currently sold by AstraZeneca under the trade name Arimidex for the treatment of breast cancer in approximately 100 countries worldwide.

### *Oxytocin Receptor Antagonist*

We are developing a low molecular weight oxytocin receptor antagonist which can be administered orally and has potential as a treatment for premature labor. Results from a Phase I clinical trial with a lead molecule indicated that this was not optimal. A new optimized lead has been identified and preclinical studies are ongoing.

### *Prostanoid FP Receptor Antagonist*

We are developing a low molecular weight prostanoid FP receptor antagonist which can be administered orally and has potential as a treatment for premature labor. This compound is currently in preclinical development.

## **Growth and Metabolism**

Human growth hormone is used in the treatment of growth retardation in children and the treatment of AIDS Wasting, growth hormone deficiency and short bowel syndrome in adults. We estimate that the worldwide human growth hormone market generated approximately \$2.1 billion in sales in 2004, based on publicly reported sales data for Saizen, Serostim and Zorbitive and five competing products.

### ***Growth***

Children may experience growth retardation as a result of a variety of conditions. These include growth hormone deficiency, Turner's syndrome, a genetic disease that affects girls, and chronic renal failure. Growth hormone deficiency is associated with abnormally low levels of pituitary growth hormone.

### *Saizen*

Saizen is recombinant human growth hormone. We introduced Saizen in 1989, and it is now

Ø Approved in 81 countries, including the U.S., for the treatment of growth hormone deficiency in children;



Ø Approved in 18 E.U. countries, the U.S. and 25 other countries for treatment of growth hormone deficiency in adults;

Ø Approved in 72 countries, excluding the U.S., for the treatment of growth failure due to Turner's syndrome; and

Ø Approved in 38 countries, excluding the U.S., for treatment of children with growth failure associated with chronic renal failure.

In May 2004, we filed an application in Europe for use of Saizen in children who were born too small for gestational age. This indication sometimes is known as intra-uterine growth retardation. In 2004, Saizen was our third largest selling product, accounting for \$182.1 million or 8.4% of total product sales.

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Saizen is available worldwide in freeze-dried formulations containing 8.8 mg and 5 mg that is stable at room temperature before reconstitution, and is therefore more easily stored and more convenient for patients than some competing drugs. Because growth retardation primarily affects children and requires long-term treatment with daily injections, delivery systems are a key differentiator among competing products. Saizen is delivered by two innovative delivery devices: one.click (autoinjector) and cool.click (needle-free). One.click enables the needle to be introduced automatically under the skin, significantly reducing the pain of injection. We launched one.click in Europe in 2001 and in the United States in September 2004. Cool.click is a needle-free delivery system and was the first needle-free device to be launched in the United States for use with human growth hormone. We launched cool.click in the United States in September 2000 and in Europe in the third quarter of 2002, and we are currently rolling it out worldwide.

In October 2000, we expanded our agreement with Bioject to give us the right to use Bioject's Vitajet 3 needle-free injection system, which is the basis for cool.click, in all current and future human growth hormone products and indications worldwide. In addition, we obtained exclusive options to use all new technologies developed by Bioject for the delivery of human growth hormone.

### ***Metabolism***

***AIDS Wasting.*** AIDS Wasting is associated with decreased survival in AIDS patients. It is caused by a disturbance in the patient's metabolism that interferes with the body's effective use of nutrients. This metabolic disturbance causes the body to break down vital organ and muscle tissue, known as lean body mass, to generate energy while at the same time conserving fat. AIDS Wasting is a metabolic condition that is independent of the level of the HIV virus. Clinical data have shown that without critical lean body mass, HIV patients get sick more often and may not live as long as those who are not losing lean body mass.

Conventional treatments for AIDS Wasting, such as appetite stimulants, generally do not help patients regain lean body mass, because they do not treat the underlying metabolic cause of AIDS Wasting. Though protease inhibitors, which are used in the treatment of AIDS, can cause patients to gain weight, studies show that a significant percentage of patients on optimal protease inhibitor therapy still suffer from wasting.

### ***Serostim***

Serostim is our recombinant human growth hormone formulation which is approved for the treatment of AIDS Wasting in the U.S., Japan and 11 other countries. In 2004, Serostim was our fourth largest selling product, accounting for \$86.8 million or 4.0% of total product sales.

Serostim reverses the underlying metabolic disturbance that occurs in AIDS Wasting through its protein building and protein sparing activity, which promotes a significant increase in patient lean body mass and weight. It remains the only growth hormone whose safety and efficacy for treating AIDS Wasting has been proven in a double-blind, placebo-controlled setting.

Serostim is also the first and only human growth hormone approved for AIDS Wasting by the FDA. In August 2003, following completion of a 750-patient, multi-center, placebo-controlled study which confirmed that Serostim improved physical performance, and increased lean body mass and decreased truncal fat, the U.S. FDA granted Serostim full approval for treatment of AIDS Wasting, confirming the accelerated approval that had been granted in 1996. During 2001, we received FDA clearance for a needle-free device, SeroJet, to deliver Serostim. SeroJet was developed in partnership with Bioject under the exclusive licensing agreement we entered into in October 2000. We launched SeroJet in the United States in February 2002.

***Short Bowel Syndrome.*** Short bowel syndrome, or SBS, is a rare, serious and potentially life-threatening condition that follows extensive surgical removal of portions of the small intestine as a result of disease or trauma. Removal of a

large portion of the bowel results in impaired absorption of nutrients. Currently the standard treatment for SBS involves careful management of dietary intake and hydration or, where appropriate, a process referred to as parenteral nutrition in which patients are fed through an intravenous tube. On rare occasions, surgical transplant of the intestine may also be performed for this condition. There are an estimated 10,000-20,000 patients in the United States who are receiving intravenous parenteral nutrition for SBS.

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### *Zorbtive*

Zorbtive is our trade name for our recombinant human growth hormone indicated for short bowel syndrome. In a randomized, double-blind, controlled, parallel group Phase III clinical study, Zorbtive administered with specialized nutritional support was shown to significantly reduce patient dependence on total parenteral nutrition as measured by total volume and frequency of infusion. In December 2003, the U.S. FDA approved Zorbtive for use in the treatment of SBS. We launched Zorbtive in the United States in May 2004. The FDA has granted Zorbtive orphan drug exclusivity for use in the treatment of patients with SBS until December 2010.

### ***Product Pipeline***

#### Serostim in HARS

HIV-Associated Adipose Redistribution Syndrome, or HARS, is an abnormal accumulation of truncal adipose tissue (including visceral fat) in people infected with HIV. It is a rare condition and is a subset of abnormal disorders of fat distribution and altered metabolism often called HIV-related lipodystrophy. In March 2004, the FDA granted orphan drug designation for the use of human growth hormone in this indication in the United States. In the second quarter of 2004, we initiated a Phase III clinical trial of Serostim for the treatment of HARS. The trial was fully enrolled by the end of 2004.

#### *PTB1b inhibitor*

A protein tyrosine phosphatase 1b inhibitor with potential as a treatment for diabetes and obesity entered Phase I in the fourth quarter of 2004.

### **Dermatology**

In addition to strengthening our existing core therapeutic areas, our strategy is to expand our product offerings into new highly specialized markets where there are major unmet medical needs. As part of that strategy, in August 2002, we entered into an agreement with Genentech to market the psoriasis drug Raptiva (efalizumab). Under our agreement, we have the exclusive license to market Raptiva worldwide, except in the United States and Japan. We will also collaborate with Genentech and its U.S. partner Xoma on co-developing other indications for Raptiva. As of January 2005, Xoma is no longer involved in the development of Raptiva but receives royalties from Genentech.

Psoriasis is a chronic autoimmune disease with an average prevalence of about 2% in Europe and the United States. Approximately one quarter of these patients have moderate or severe forms of the disease. The disease is characterized by the abnormal growth of new skin cells, resulting in thick, red, scaly, inflamed patches. Psoriasis can be limited to a few spots or involve extensive areas of the body. There is no known cure for the disease. While some current treatments for psoriasis may help control the symptoms of the disease, their benefits are not long-lasting and they may be associated with serious side-effects. It is estimated that the currently available therapies are ineffective or inappropriate in about 20% of moderate-to-severe psoriasis patients.

### ***Product***

#### *Raptiva*

Raptiva (efalizumab) is a humanized monoclonal antibody designed to inhibit three key inflammatory processes in the series of events that are associated with psoriasis. It is administered subcutaneously once per week. In July 2004, we announced preliminary 30-month results from an open-label study evaluating the safety and efficacy of long-term continuous treatment with Raptiva in adults with moderate-to-severe chronic plaque psoriasis. The results of the study

suggest that continuous, weekly dosing of Raptiva provided sustained clinical benefit over 2.5 years. Of the 159 subjects participating in the study who completed 30 months of treatment, a 75% or greater improvement on the Psoriasis Area Sensitivity Index, or PASI, was observed in 75% of patients with weekly Raptiva therapy (as-treated analysis). Ninety-one percent of patients achieved an improvement of 50% on the PASI and 45% of patients achieved a 90% or greater improvement on the PASI (as-treated analysis).

In September 2004, we received authorization to market Raptiva in the 25 countries of the European Union for people with moderate-to-severe chronic plaque psoriasis for whom other systemic treatments or phototherapy have been inadequate or inappropriate. Raptiva is the first biologic treatment for psoriasis to be authorized for marketing in the European Union. Raptiva is registered in the E.U., U.S. and 12 other countries (Argentina, Australia, Brazil, Bulgaria, Hong Kong, Iceland, Korea, Mexico, Norway, Romania, Singapore and Switzerland). We have made Raptiva available in Germany, Austria, Greece, Ireland, Hong Kong, Portugal, Norway, UK, Denmark, Sweden, Switzerland, Australia, Argentina, Mexico and Singapore. We expect that the roll-out of Raptiva will continue throughout 2005 with the launch in major European markets such as France, Spain and Italy and in Canada.

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## ***Product Pipeline***

### *Onercept*

Onercept, or TBP-1, is a recombinant, soluble type I TNF receptor which acts as an inhibitor of tumor necrosis factor (TNF) alpha, a cytokine that can cause irreversible damage to organs when secreted in excessive amounts by people with inflammatory and other diseases. Following the announcement of positive Phase II results for onercept in psoriasis in 2003, we initiated a multicenter, multinational Phase III program in the third quarter of 2004. Onercept has already been shown to have a highly competitive efficacy profile in Phase II, with more than 50% of patients achieving a 75% improvement in PASI score after 12 weeks.

## **Research and Development**

Research and development is vital to our ability to continue to grow our business. We employ 1,387 research and development personnel, and our R&D expenses were 24.2% of our total revenues in 2004. R&D efforts are spearheaded by our scientists at the Serono Pharmaceutical Research Institute in Geneva, Serono Reproductive Biology Institute in Boston, Serono Genetics Institute (formerly Genset S.A.) in Evry, France and Istituto di Ricerca Cesare Serono and Istituto di Ricerche Biomediche “Antoine Marxer” RBM in Italy, with important contributions provided under collaborative arrangements with other biotechnology companies and institutions, particularly the Weizmann Institute of Science in Israel. Our discovery group at the Serono Pharmaceutical Research Institute focuses on drug discovery in neurological diseases like MS, autoimmune diseases and wasting. The Serono Reproductive Biology Institute concentrates on reproductive health and related clinical indications. Serono Genetics Institute focuses on genomics research. During 2002, 2003 and 2004, we spent \$358.1 million, \$467.8 million and \$594.8 million, respectively, on research and development.

As a leader in the field, we are committed to taking full advantage of the opportunities presented by biotechnology. We have concentrated on establishing state-of-the-art skills in those technologies that will significantly enhance our ability to deliver innovative products to specialist markets. Our R&D efforts are focused on:

- pursuing drug discovery efforts that may lead to new products;
- enhancing our discovery capabilities through research partnerships;
- improving drug delivery of our protein therapeutics;
- strengthening our key therapeutic areas through new products and line extensions; and
- developing products in new therapeutic areas, such as oncology.

## ***Pursuing Drug Discovery***

We are actively seeking new therapies for new indications. Our molecular biologists are using DNA sequencing and identification technologies to identify new drug targets in the human genome. We can monitor the genes expressed in a cell at a particular time by integrating data from gene chips and gene filters. Working with clinical groups around the world, we are able to use our data to identify how genes are expressed in connection with different diseases. By understanding how genes are expressed in connection with different diseases, we identify points of intervention at which molecules may alter the progression and development of the diseases. We then determine whether the point of intervention would be best addressed through the use of protein therapeutics or therapies using smaller molecules.

Advances in chemistry, screening technology and robotics allow us to rapidly test a multitude of compounds to see if any one of the compounds may be used to treat a given disease process. We use high throughput screening and combinatorial chemistry techniques to try to identify small molecules that may have beneficial therapeutic effects on targeted disease processes.

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High throughput screening is a technique for quickly screening many possible treatments for a specified condition. The process starts by selecting a type of cell that will react in accordance with a specified disease process. To do this we often genetically modify cells to give them the characteristics we desire. We then select a large number of small, simple molecules that we believe may have a positive therapeutic effect on the disease process. The cells are then exposed to the different molecules, and we select those that, based on their effect on the cells, appear to hold the greatest promise as future therapies. Once we have narrowed the field of potential molecules, using combinatorial chemistry techniques we modify them in different ways to determine whether a slightly different structure of the same basic molecule may have a more powerful effect on the disease process. We then assess whether the molecules we have identified are appropriate for preclinical trials.

In September 2002, we significantly increased our drug discovery capability through our acquisition of Genset S.A. Genset, now the Serono Genetics Institute, provides us with leading expertise in the linkages between genes and diseases, a strong scientific team, an extensive cDNA library of secreted proteins and an integrated technology platform in bioinformatics, genetics, biostatistics and therapeutic genomics.

Our research has helped us to identify several potential new therapeutic compounds that are currently in preclinical development.

#### *Neurology*

- Osteopontin, a molecule with potential to remyelinate damaged neurons, entered preclinical development in 2003 and could become a treatment for various neuropathies, including MS.

#### *Reproductive Health*

- An orally available low molecular weight prostanoid FP receptor antagonist with potential as a treatment for premature labor entered preclinical development in 2003.
- A new lead molecule of an orally available low molecular weight oxytocin receptor antagonist with potential as a treatment for premature labor entered preclinical development in 2004.

#### *Autoimmune/inflammatory diseases*

- The antisense compound Kappaproct is undergoing additional preclinical trials to establish a more solid proof of principle in its use in inflammatory diseases as well as a more adequate dosing regime for ulcerative colitis patients.
- The cytokine tadekinig alpha is undergoing additional preclinical trials to establish whether it has potential in the treatment of autoimmune conditions.

#### ***Entering into Strategic Research Collaborations***

We are also enhancing our discovery capabilities by entering into strategic research collaborations with several leading companies in the field of small molecule drug discovery.

In February 2004, we extended the collaborative research agreement signed in 2001 with Inpharmatica Ltd. Under the expanded agreement, Inpharmatica received an up-front fee for granting us additional rights to novel protein sequences delivered under the collaboration. The up-front fee has been expensed as research and development expense.



In October 2004, we entered into an agreement with Paratek Pharmaceuticals Inc. to discover, develop and commercialize an orally available disease modifying treatment for multiple sclerosis (MS). Under the terms of the agreement, Paratek received an up-front fee and a loan convertible into Paratek stock and will receive research funding and milestone payments related to development progress and regulatory milestones. In addition to the up-front consideration, Paratek would receive \$38.0 million in milestone payments for the first product to be successfully developed and registered in MS. The initial fees have been expensed as research and development expense.

In October 2004, we entered into a broad alliance with ZymoGenetics Inc. to research, develop and commercialize novel protein and antibody therapeutics based on discoveries made by ZymoGenetics. As part of this alliance, we will gain access to a portfolio of ZymoGenetics' genes and proteins, will have rights over the next five years to license up to 12 products, and will have exclusive worldwide rights to develop and commercialize 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). Under the terms of the agreement, we paid ZymoGenetics an up-front fee of \$20.0 million in exchange for the rights to license proteins over the next five years, paid \$11.3 million for entering into three license agreements and purchased \$50.0 million of ZymoGenetics' common stock. We will pay a series of milestone payments, will share all profits from the co-commercialization of products in the United States for which ZymoGenetics has co-funded development, and will pay royalties on eventual sales of the products outside the United States and, to the extent ZymoGenetics elects not to co-develop products, on product sales in the United States. The up-front fee and license fees have been expensed as research and development expense. The purchase of common stock was recorded as an available-for-sale equity investment.

In November 2004, we signed a worldwide agreement with Nautilus Biotech to develop the next-generation of human growth hormone, with improved biological, pharmacological and clinical profiles. Under the terms of the agreement, Nautilus received an up-front fee and will receive potential milestone payments and undisclosed royalties on sales of the improved protein. The up-front fee has been expensed as research and development expense.

In December 2004, we entered into an agreement with Micromet AG to develop and commercialize Micromet's MT201 (adecatumumab), a pan-carcinoma monoclonal antibody directed against the epithelial cell adhesion molecule Ep-CAM for the treatment of cancers of epithelia cell origin. Under the terms of the agreement, Micromet received an initial license fee of \$10.0 million and will receive additional milestone payments of up to \$138.0 million if the product is successfully developed and registered worldwide in three or more indications. In addition, Micromet will receive undisclosed royalties based on net sales of the product. The up-front fee has been expensed as research and development expense.

In December 2004, we entered into a worldwide collaboration with CancerVax Corporation for the development and commercialization of Canvaxin, an investigational specific active immunotherapy product being developed for the treatment of advanced-stage melanoma. Under the terms of the agreement, we paid CancerVax an up-front fee of \$25.0 million and purchased one million shares of CancerVax common stock for \$12.0 million. In addition, CancerVax could receive up to \$253.0 million in milestone payments for the achievement of development, regulatory and commercial milestones. The fee has been expensed as research and development expense. The purchase of common stock was recorded as an available-for-sale equity investment.

### ***Improving Drug Delivery***

An integral part of our research and development programs is the development of more patient-friendly drug delivery systems. Because most of our products must be injected under the skin, we believe easier and less painful drug delivery systems will promote patient compliance and product loyalty.

The value of protein therapeutics can be greatly enhanced by improved delivery systems. These systems may be able to provide alternatives to injection or reduce the frequency of injections. Because many of our products, such as Rebif, Gonal-f, Saizen and Serostim, must be administered frequently and Saizen is used mostly for children, we believe that many of our potential customers would consider the ease of administration to be an important factor when selecting between our products and those of our competitors. As a result, we have set up our own drug delivery laboratory and have established major collaborations with specialist drug delivery companies on projects designed to improve the delivery of all of our major protein and peptide products.

### ***Strengthening Key Therapeutic Areas***

Novel protein therapeutics were the first benefits provided by biotechnology, beginning with the replacement of naturally derived hormones and cytokines with biotechnology-derived proteins. With our production of recombinant fertility hormones, growth hormones and interferon beta, we are at the forefront of these developments.

For information on our R&D projects in the four key therapeutic areas on which we currently focus, consult the respective Product Pipeline sections for each therapeutic area (Neurology, Reproductive Health, Growth and Metabolism, and Dermatology) above.

***Developing Products in New Therapeutic Areas***

In addition to our continuing commitment to our existing therapeutic areas, we are also performing research and developing potential products in new areas like autoimmune diseases, gastroenterology, and oncology. Several molecules are currently in development in new therapeutic areas:

*TACI-Ig.* A TACI (transmembrane activator and CAML-interactor) fusion protein, which interacts with B lymphocytes and represents a novel therapeutic approach to treating autoimmune diseases, such as systemic lupus erythematosus or SLE and rheumatoid arthritis, as well as B-cell malignancies, is being co-developed with ZymoGenetics. Following the successful completion of a Phase I trial in human volunteers with this molecule, during 2004 we initiated Phase Ib clinical trials in SLE, rheumatoid arthritis and multiple myeloma, as well as a Phase I trial in relapsed or refractory B-cell malignancies.

*Canvaxin.* We recently acquired the worldwide rights to develop and commercialize CancerVax's specific active immunotherapy product Canvaxin for the treatment of advanced-stage melanoma, a deadly form of skin cancer. Canvaxin is currently being evaluated in two international, multi-center Phase III clinical trials for the treatment of Stage III and Stage IV melanoma.

*Adecatumumab.* We recently acquired the worldwide rights to develop and commercialize Micromet's antibody product adecatumumab which has potential in the treatment of a broad range of cancers of epithelial origin, including prostate, breast, colon, lung, stomach, pancreatic, head and neck, and ovarian cancer. Adecatumumab, a fully human antibody directed against the epithelial cell adhesion molecule, is currently being evaluated in two Phase II trials for the treatment of metastatic breast cancer and prostate cancer.

*Kappaproct.* We have acquired the worldwide rights to develop and commercialize InDex Pharmaceuticals' antisense compound Kappaproct for the treatment of ulcerative colitis. A Phase II clinical trial did not reach its primary endpoint in terms of clinical remission versus placebo; however there was a dose-response trend. Patients on the two highest dose levels went into clinical remission faster than those treated with the two lowest dose levels or the patients treated with placebo. Overall, the safety profile was good. Serono and InDex are focusing on finding a more solid preclinical proof of principle in the use of Kappaproct in inflammatory diseases and a more adequate dosing regime for ulcerative colitis patients.

*Interferon beta.* We are currently conducting a Phase III trial of interferon beta-1a for the treatment of Asian patients suffering from chronic hepatitis C. Results from a study completed in 2001 suggested that patients of Asian origin with this disease may benefit from r-IFN-beta.

*Tadakinig alpha.* In 2004, we completed Phase IIa trials of tadakinig alpha, our recombinant interleukin-18 binding protein, in psoriasis and rheumatoid arthritis. Results did not show the expected promise based on preclinical data in animal models. Preclinical investigations are ongoing to identify if tadakinig alpha has potential in the treatment of autoimmune conditions.

## Major Products and High Priority R &amp; D Projects

Product Type	Trade Name	Indications	Status as of January 31, 2005
Recombinant human interferon 1a (r-IFN-β1a)	Rebif	Multiple sclerosis	Approved in E.U. (25 countries), U.S. and 61 other countries
	*	Chronic hepatitis C in Asian patients	Phase III clinical trial
Mitoxantrone	Novantrone	Multiple sclerosis, certain cancers	Rights to commercialize approved product in U.S.; Orphan Drug Status in U.S. for MS
Cladribine	Mylinax	Multiple sclerosis	Phase III clinical trial
JNK inhibitor	*	Multiple sclerosis	Phase I clinical trial
MMP-12 inhibitor	*	Multiple sclerosis	Phase I clinical trial
Osteopontin	*	Remyelination	Preclinical
Recombinant human follicle stimulating hormone (r-hFSH)	Gonal-f	Female infertility	Approved in E.U. (25 countries), U.S. and 69 other countries
	Gonal-f	Male infertility - hypogonadotropic hypogonadisma	Approved in E.U. (25 countries), U.S. and 38 other countries
	Gonal-f	Multi-dose formulation	Approved in E.U. (25 countries), U.S. and 40 other countries
	Gonal-f	Fill by mass formulation	Approved in E.U. (25 countries), U.S. and 41 other countries
	Gonal-f	Pre-filled pen injector	Approved in E.U. (25 countries), U.S. and 10 other countries
Recombinant human luteinizing hormone (r-hLH)	Luveris	Severe FSH and LH deficiency	Approved in E.U. (25 countries), U.S. and 41 other countries; received Orphan Drug Status in U.S.
Recombinant human chorionic gonadotropin (r-hCG)	Ovidrel/Ovitrelle	Female infertility/ovulation induction and use in assisted reproductive	Approved in E.U. (25 countries), U.S. and 44 other countries

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Cetrorelix (GnRH antagonist)	Cetrotide	Premature ovulation prevention	Approved in E.U. (25 countries), U.S. and 53 other countries.
Progesterone gel (8%)	Crinone	Luteal phase support	Approved in U.S., 15 E.U. countries and 34 other countries
Anastrozole (aromatase inhibitor)	*	Ovulation induction and improvement of follicular development	Phase II clinical trial
Onercept	*	Endometriosis	Phase I clinical trial
Oxytocin receptor antagonist	*	Pre-term labor	Preclinical
Prostanoid FP receptor antagonist	*	Pre-term labor	Preclinical
Recombinant human growth hormone (r-hGH)	Saizen	Growth hormone deficiency	Approved in 81 countries
	Saizen	Growth hormone deficiency in adults	Approved in 18 E.U. countries, U.S. and 25 other countries
	Saizen	Growth failure due to Turner's syndrome	Approved in 72 countries
	Saizen	Growth failure associated with chronic renal failure	Approved in 38 countries
	Saizen	Small for gestational age babies (IUGR)	Filed in E.U.
Recombinant human growth hormone (r-hGH) high dose	Serostim	AIDS Wasting (cachexia)	Approved in U.S., Japan and 11 other countries
	Serostim	HARS/Lipodystrophy	Phase III clinical trial; received Orphan Drug Designation in U.S.
	Zorbtive	Short bowel syndrome	Approved in U.S.; received Orphan Drug Designation in U.S.
PTP1b inhibitor	*	Diabetes and obesity	Phase I
Efalizumab	Raptiva	Psoriasis	Registered in E.U., U.S. and 12 other countries

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Onercept (r-TBP-1)	*	Psoriasis	Phase III clinical trial
Tadekinig alpha (r-IL-18bp)	*	Autoimmune diseases	Preclinical
TACI-Ig	*	Systemic lupus erythematosus	Phase Ib clinical trial
	*	Rheumatoid arthritis	Phase Ib clinical trial
	*	Multiple myeloma	Phase Ib clinical trial
	*	Relapsed or refractory B-cell malignancies	Phase I clinical trial
p65 inhibitor	Kappaproct	Inflammatory diseases	Preclinical
Adecatumumab	*	Prostate cancer	Phase II clinical trial
	*	Metastatic breast cancer	Phase II clinical trial
	CanVaxin	Stage IV melanoma	Phase III clinical trial

\* Trade name not yet determined

## **Sales and Marketing**

We have marketing, sales and distribution organizations based in Europe and the United States, and we employ a sales and marketing force of 2,084 people worldwide. Because we focus on highly specialized markets with a limited number of prescribing physicians, we believe that our sales force can efficiently penetrate each of our target markets. In general, our products are sold to wholesale distributors or directly to pharmacies or medical centers. We utilize common pharmaceutical company marketing techniques, including physician detailing, advertising, targeting opinion leaders and other methods. We also employ marketing strategies specific to our individual product lines.

### ***Neurology***

In certain markets we focus on neurologists that specialize in MS. In other markets we focus on general neurologists.

In the United States, we promote Rebif directly through our own sales force and, in addition, since October 2002, through a second sales force operated by Pfizer Inc. under a copromotion agreement under which we have agreed to share U.S. marketing and development costs. Pfizer has an established neurology franchise.

Our agreement with Pfizer allows us to contact a much larger proportion of the expanding prescriber base more frequently than we would have been able to contact acting alone. We believe that Pfizer's presence in the neurology therapeutic area helps us more quickly and effectively distribute the message of Rebif's attributes.

Outside the United States, we are committed to continuing medical education programs, which examine the latest developments in MS, including research and treatments. Our programs in the United States focus on the scope of treatment protocols to address all aspects of the disease and helping medical professionals learn more about ways to offer the highest level of patient care. A major initiative in 2004 was the establishment of the MSBase Foundation to run the state-of-the-art MS registry independently of Serono for the benefit of physicians and their patients.

In 2003, we introduced new resources for the MS community in the United States, including the Learning for life empowerment series as well as the newly enhanced MSLifeLines.com website. The Learning for life series offers an array of information to people living with MS and provides a jumping off point for doctors and patients to communicate better about the specific treatment needs of each patient. Specifically, the empowerment series provides in depth information on use of MRI, parameters to consider in evaluating therapy as well as information on the disease and the different treatment options available for people with MS.

Outside the U.S. we have well-established call centers and nurse programs in many countries to provide support and guidance for MS patients generally and specifically to help with the introduction of Rebiject II and the new 29G needle. In addition to this we have provided help with access to MRI facilities to aid diagnosis in some regions. We are active in lobbying for patients to have greater access to therapy and for MS to receive a higher priority on national healthcare agendas. In particular, we provide support to the European MS Platform and to the Multiple Sclerosis International Federation patients associations.

### ***Reproductive Health***

We focus our reproductive health marketing efforts on educating and informing reproductive endocrinologists about treatment options for infertility.

In February 2004, we announced the launch of [www.fertility.com](http://www.fertility.com), a new website for patients outside the United States, which offers a definitive source of information for people who have concerns about their fertility or are seeking or undergoing treatment. This new website provides comprehensive facts and describes therapy throughout each stage of the patient journey, from any initial concerns about infertility to a potential pregnancy. The website provides people

who are concerned about their chances of having a child with information on the physiology of reproduction and causes of possible fertility disorders. For those considering therapy, it outlines the various options available to them. It also provides advice to patients already undergoing treatment. Finally, recommendations are given to couples on the lifestyle choices and medications that may help to support early pregnancy. The website contains a variety of useful links to patient associations as well as references for further reading. For the United States market, we relaunched [www.seronofertility.com](http://www.seronofertility.com), which includes comprehensive infertility information for consumers and patients, as well as interactive tools such as a “find a specialist” service, which allows visitors to find local reproductive endocrinologists. The site also features animated, narrated patient instructions for mixing and injecting Serono products. To drive traffic to [seronofertility.com](http://seronofertility.com), we implemented web advertising programs on popular consumer sites such as [google.com](http://google.com), [WebMD.com](http://WebMD.com) and [babycenter.com](http://babycenter.com).

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We also have a number of ongoing initiatives that are designed to support access to infertility treatment. In the United States, we launched the first ever manufacturer-sponsored direct-to-consumer (DTC) advertising campaign in the infertility market in June 2003, including television, radio, magazine and web advertising. Consumers and patients who call our free educational service, Fertility LifeLines, toll-free at 1-866 LETS TRY receive customized educational materials via mail, including a list of local fertility centers. In several major markets, including Germany, Spain and the UK, we have performed pharmaco-economic study programs to demonstrate the cost benefit of recombinant products versus urine-derived preparations. This activity supports our strategy to help establish and maintain reimbursement for our products. For those patients in the United States who are not eligible for reimbursement, do not have appropriate insurance coverage and are unable to pay for the treatment themselves we have a Compassionate Care program. This program helps provide patients that meet certain criteria with access to our infertility products at no cost.

### ***Growth and Metabolism***

#### *Growth*

We focus our marketing of growth products on capturing new patients, since patient loyalty is particularly strong in this market. To do this we target pediatric endocrinologists and leading pediatricians in clinics and treatment centers. We implement medical clinical programs and set up innovative registries. We are also developing new drug delivery devices for use in this market, where patient convenience is particularly important. In September 2000, we launched cool.click, a needle-free delivery system for Saizen, which is the first needle-free delivery system for human growth hormone in the United States and Canada. We launched cool.click in Europe in the third quarter of 2002 and are currently rolling it out worldwide. In September 2004, we launched our autoinjector pen device for growth hormone, one.click, in the United States. The U.S. FDA also granted approval for Saizen to be promoted in the Adult Growth Hormone Deficiency market. This indication will be launched in early 2005.

#### *Metabolism*

Our sales and marketing efforts for our AIDS Wasting product focus on the education of HIV/AIDS-treating physicians and their staffs and nurses that work with the patients. In addition to focusing on the therapeutic benefits of Serostim, our sales and marketing efforts are directed toward education about AIDS Wasting.

We also engage in patient-advocacy efforts. A large number of Serostim patients have received reimbursement support via our medical reimbursement specialists who work one-on-one with each patient to secure access to and insurance coverage for Serostim once the patient has agreed to receive assistance from our reimbursement specialists. However, during 2004 state-based reimbursers in the United States continued to impose restrictions on the use of Serostim. In some states these restrictions include requiring prescribers to obtain prior authorization before starting a patient on Serostim treatment.

Due to the apparently enlarging gap between demand data and ex-factory sales, we and the relevant authorities initiated investigations to try and discover the cause of this discrepancy. As a result of these investigations, we determined that there were several causes of this discrepancy, including circulation of counterfeit Serostim in the market, potential diversion of the product and an active secondary source for the product in the marketplace. In order to address this issue, we implemented the Serostim Secured Distribution Program, or SSDP, in the United States in October 2002. This program is designed to track and trace Serostim through the distribution process to ensure that patients who require Serostim receive the genuine product on a timely basis. The program restricts distribution of Serostim to a group of contracted network pharmacies that meet predefined criteria and are the exclusive distributors of the product. Through this program we are able to track each individual box of Serostim from Serono to the contracted network pharmacy. We are working closely with individual state and federal agencies to monitor the program's effectiveness. The FDA recognized SSDP as an effective anti-counterfeiting system that assures patients

receive genuine product.

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In 2001, we received FDA approval for a needle-free delivery device for Serostim. This device is called Serojet and was launched in the U.S. market in February 2002.

### ***Gastroenterology***

Zorbtive was launched into the U.S. market in May 2004. We promote Zorbtive to gastroenterologists and specialized surgeons. Our efforts are targeted on educating physicians and other patient care providers on the therapeutic benefits of Zorbtive, which is the first drug therapy approved by the FDA for the treatment of Short Bowel Syndrome. We also focus our efforts on educating patients about the therapeutic benefits of Zorbtive and providing support services to assist patients with their therapy.

Zorbtive is also being distributed through the SSDP. We have partnered with our specialty pharmacies to assist in the education process for providers and their patients.

We also engage in patient-advocacy efforts. Zorbtive patients can receive reimbursement support via our medical reimbursement specialists who work one-on-one with each patient to secure access to and insurance coverage for Zorbtive once the patient has agreed to receive assistance from our reimbursement specialists. Zorbtive is currently not available under Medicare.

### ***Dermatology***

We have developed a dedicated dermatology sales and marketing structure in our affiliates, consistent with the scheduled launch of Raptiva. Since the beginning of our involvement in dermatology, we have developed strong relationships with key opinion leaders and psoriasis patients associations worldwide.

### **Manufacturing**

Our principal commercial manufacturing facilities are located in Aubonne and Corsier-sur-Vevey, Switzerland; Bari, Italy; Tres Cantos, Spain; and Martillac, France. In 2004, we closed our manufacturing facility in Israel, which was one of our oldest manufacturing sites and had become obsolete. For clinical supplies and process development, manufacturing facilities are located in Martillac, France and Rome, Italy. We have created additional manufacturing centers that specialize in different phases of the production process. For certain key products, we have two production facilities and/or large inventories available to ensure a continuity of supply in the event of contamination, catastrophe or other unforeseen events at one of our facilities.

### **Intellectual Property**

Our patents are very important for protecting our proprietary rights in the products we have developed. We have applied for or received patents covering inventions ranging from basic recombinant DNA to processes relating to production of specific products and to the products themselves. We either have been granted patents or have patent applications pending which relate to a number of current and potential products, including products licensed to others. We believe that in the aggregate our patent applications, patents and licenses under patents owned by third parties are of material importance to our operations.

We expect that litigation will be necessary to determine the validity and scope of certain of our proprietary rights. We have in the past been and may in the future be involved in a number of patent lawsuits, as either a plaintiff or defendant, and in administrative proceedings relating to our patents and those of others. These lawsuits and proceedings may result in a significant commitment of our resources in the future.

We cannot be sure that our patents will give us legal protection against competitors or provide significant proprietary protection or competitive advantage. In addition, we cannot be sure that our patents will not be held invalid or unenforceable by a court, infringed or circumvented by others or that others will not obtain patents that we would need to license or avoid. We are aware that others, including various universities and companies working in the biotechnology field, have also filed patent applications and have been granted patents in the European Union, the United States and other jurisdictions claiming subject matter potentially useful or necessary to our business. Some of those patents and applications claim only specific products or methods of making such products, while others claim more general biotechnology processes or techniques. Competitors or potential competitors may have filed patent applications or received patents, and may obtain additional patents and proprietary rights relating to proteins, compounds or processes competitive with our products.

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In general, we have obtained licenses from various parties that we deem to be necessary or desirable for the manufacture, use or sale of our products. These licenses, both exclusive and non-exclusive, generally require us to pay royalties to the parties on product sales.

Trade secret protection for our unpatented confidential and proprietary information is also important to us. To protect our trade secrets, we generally require our employees, material consultants, scientific advisors and parties to collaboration and licensing agreements to execute confidentiality agreements upon the commencement of employment, the consulting relationship or the collaboration or licensing arrangement. However, we cannot be sure that others will not either develop independently the same or similar information or otherwise obtain access to our proprietary information.

We consider the registered (®) and the filed (™) trademarks and the filed service marks<sup>(SM)</sup> Canvaxin™, Cetrotide®, click.easy®, cool.click®, Crinone®, EasyJect®, Fertility LifeLines™, Ferti.net®, Fertinex®, Geref®, Gonal-f®, GHMonitor<sup>SM</sup>, Howkidsgrow<sup>SM</sup>, Learning for life™, Luveris®, Metrodin HP®, MSLifelines<sup>SM</sup>, Mylinax®, Novantrone®, one.click®, Ovidrel®, Ovitrelle®, Pergogreen®, Pergonal®, Profasi®, Raptiva®, Rebif®, Rebiject®, Rebiject II®, Rebiject mini®, Reliser®, Saizen®, SeroJet™, Serono®, Serophene®, Serostim®, Stilamin® and Zorbtive™, as well as the filed trademarks (™) for the “S” symbol, used alone or with the words “Serono” or “Serono biotech and beyond,” in the aggregate to be materially important. We have generally registered or are seeking to register these trademarks throughout Europe, in the United States and in other countries throughout the world.

### ***Out-Licensing***

Our strength of innovation is evidenced by our strong patent position and our ability to license certain of our technology and rights to third parties. We receive royalties and license fees from a number of companies with respect to their products. Among these are:

- Biogen Idec on its sales of Avonex;
- Organon on its sales of Puregon and Antagon;
- Amgen on its sales of Enbrel; and
- Abbott Laboratories on its sales of Humira.

### **Competition**

We face competition, and believe significant long-term competition can be expected, from pharmaceutical companies and pharmaceutical divisions of chemical companies as well as biotechnology companies. We expect this competition to become more intense as commercial applications for biotechnology products increase.

The introduction of new products or the development of new processes by competitors or new information about existing products may result in price reductions or product replacements, even for products protected by patents. In certain markets, such as Latin America, there is limited patent protection available for our products as a result of the historical weakness of the patent law systems. However, we believe our competitive position is enhanced by our commitment to research leading to the discovery and development of new products and manufacturing methods. Other factors which should help us address competition include ancillary services provided to support our products, customer service and dissemination of technical information to prescribers of our products and to the health care community, including payers.

Over the longer term, our and our collaborators' ability to successfully market current products, expand their usage and bring new products to the marketplace will depend on many factors, including but not limited to the effectiveness and safety of the products, regulatory agencies' approvals for new products and indications, the degree of patent protection afforded to particular products, and the effect of the managed care industry as an important purchaser of pharmaceutical products.

***Generic Drugs***

Generic products are typically sold at a lower price than our products, because producers of generic drugs do not have to incur research and development costs. Therefore, there is increasing pressure on the applicable regulatory entities in both the European Union and the United States to make it easier for pharmaceutical producers to gain approval for generic drugs, including generic recombinant drugs. Our urine-derived reproductive health products, which we are in the final stages of phasing out, already face increased competition from generic products.

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### ***Drug Delivery Systems***

A growing area of competition in the biotechnology industry results from developments in drug delivery systems - the manner in which drugs are delivered into the human body and the processes by which drugs are time-released into the blood stream once they have been delivered into the human body. Easier and less painful drug delivery systems promote patient compliance and usage and are, therefore, more marketable. Several of our competitors sell autoinjection devices that facilitate self-administration of their treatments. We will face increased competition from drugs that have drug delivery systems that may be more patient-friendly than our own.

### ***Neurology***

Rebif and Novantrone are increasingly used in a highly competitive MS marketplace worldwide. In 2004, Rebif was the fastest growing MS treatment in the U.S. and retained market leadership outside the U.S. In the U.S., Rebif and its three competitors faced an additional new competitor, natalizumab (Tysabri), in the last month of 2004. Currently the prescribing label for Rebif is more comprehensive than that of natalizumab as it includes an effect on disability and long-term efficacy data.

Rebif also competes with interferon beta-1b, which is sold by Schering AG or its affiliate Berlex in Europe under the brand name Betaferon and is sold by these companies in the United States and Canada under the name Betaseron. In addition, Rebif competes with Avonex, an interferon beta-1a product sold by Biogen Idec, and with Copaxone, sold by Teva Pharmaceuticals, in the U.S., Europe and other countries. In early 2004, we initiated a head-to-head Phase IV trial comparing Rebif with Copaxone. We announced in January 2005 that recruitment was completed with over 700 patients enrolled. A number of other companies are working to develop products to treat multiple sclerosis that may in the future compete with Rebif.

Another source of competition is the introduction of biosimilar products in Latin America and in Asia. These are not generic versions of Rebif as the exact formulation for Rebif is highly dependent on our well-established manufacturing process. In the U.S. and in Europe the regulatory agencies have so far recognized the need for clinical testing of biosimilar products to establish both efficacy and safety. However, in Latin America (Mexico and Argentina), licenses for biosimilar products were granted in the fourth quarter of 2004. Although the products are not proven and supply may be restricted, we expect there will be some impact on Rebif sales in these regions. Similar developments are not expected in the European Union or U.S. in the near future.

We have exclusive rights to market Novantrone in the United States for advanced forms of MS and have received orphan drug status for Novantrone in these indications. We believe this provides us with a marketing advantage in the United States.

### ***Reproductive Health***

Our reproductive health products compete with Organon's recombinant FSH, Puregon, which is marketed as Follistim in the United States. Our products also compete with urine-derived products, including Ferring Pharmaceutical's Menopur, Menogon, which is marketed as Repronex in the United States, and Bravelle as well as with Institut Biochimique's Fostimon and Merional. Ovidrel is currently the only recombinant source of hCG available. However, Ovidrel competes with urine-derived sources of hCG. Luveris is currently the only recombinant source of LH available. In certain markets, Luveris competes with urine-derived human menopausal gonadotropins, which are less pure preparations of FSH and LH. In the United States, Luveris competes with urine-derived human menopausal gonadotropins within its approved indication of hypogonadotropic hypogonadal women with profound LH deficiency. We have received orphan drug protection for Luveris in the United States through October 8, 2011. Crinone competes with other progesterone products; however it is the only preparation available as a non-injectable formulation that is labeled for assisted reproductive technologies, except in the United States where Columbia Laboratories markets

Prochieve to certain obstetricians and gynecologists.

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## ***Growth and Metabolism***

### **Growth**

Saizen competes with human growth hormone products produced by companies such as Eli Lilly, BioTechnology General, Novo Nordisk, Pfizer and Genentech. The competition in this market is intense because different human growth hormone products are chemically and biologically similar. As a result, it is difficult for one product to differentiate itself. One way that we differentiate our product is through drug delivery systems. However, many of our competitors now also offer patient-friendly delivery systems for their products. Other companies are working to bring to market comparable growth hormone products that may compete with Saizen in the future.

In addition to the presence of competing products in the growth retardation market, we believe that competition in this market is enhanced by the fact that parents show considerable brand loyalty once they have selected a product for treatment of their child. As a result, much of the competition between pharmaceutical companies in this market must focus on the relatively small number of new patients beginning treatment each year.

### ***Metabolism***

Orphan drug exclusivity for Serostim in the United States expired in August 2003. Our competitors may now seek approval of applications for their growth hormone products in the United States for AIDS Wasting indications. The appetite stimulants Megace, which is marketed by Par and Roxane, and Marinol, which is marketed by Unimed, and the anabolic steroid Oxandrin, marketed by Savient, are other drugs approved for the treatment of weight loss associated with AIDS or chronic infection in the United States.

### ***Gastroenterology***

We have been granted orphan drug exclusivity for Zorbitive in the treatment of patients with short bowel syndrome until December 2010. That means that our competitors cannot receive FDA approval to promote human growth hormone in the United States for that indication until that date.

### ***Dermatology***

In psoriasis we currently compete with Enbrel, commercialized by Wyeth, which received regulatory approval in the European Union about one month after Raptiva. In the other markets outside the European Union we currently compete with Amevive from Biogen Idec. Consistent with the product label, traditional systemic therapies or phototherapy are not considered competitors in the European Union markets.

## **Government Regulation**

Our research, preclinical testing, clinical trials, facilities, manufacturing, labeling, pricing and sales and marketing are subject to extensive regulation by numerous governmental authorities in the European Union, the United States, Switzerland and other jurisdictions. The levels of expenditure and the laboratory and clinical information required for regulatory approval are substantial, and obtaining such approval can require a number of years. The results generated through laboratory and clinical studies conducted worldwide may be used in most countries for the registration of products. However, country-specific regulations, such as in Japan, and possible genetic differences among populations may force us to tailor some studies to specific countries, causing additional delays and expense in the registration process. We cannot sell our products in a given jurisdiction without first obtaining regulatory approval to do so. The success of our current and future products will depend in part upon obtaining and maintaining regulatory approval to market them for approved indications in the European Union, the United States and other markets. The regulatory approval process is lengthy and complex in the European Union, the United States and other jurisdictions. We cannot

be sure that we will obtain the required regulatory approvals on a timely basis, if at all, for any of the products we are developing. Even if we obtain regulatory approval, both our manufacturing processes and our marketed products are subject to continued review. Later discovery of previously unknown issues with our products or manufacturing processes may result in restrictions on these processes, and may ultimately lead to withdrawal of the products from the market. Also, new government requirements may be established that could delay or prevent regulatory approval of the products we have in development.

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The European Union requires anyone seeking to market a medicinal product for human use to obtain approval of a Marketing Authorization Application, or MAA. Currently, two main regulatory authorization processes coexist in the European Union. Medicinal products of significant therapeutic interest or constituting a significant innovation undergo a centralized assessment procedure for marketing authorizations valid in all European Union member states, which is administered by the European Medicines Agency, or EMEA. This procedure is applicable to drugs that fall within the definition of “high technology medicines,” and includes all new biotechnology products. Under this procedure, the Committee for Human Products, or CHMP, has 210 days, or a longer period if further information is required, to give its opinion as to whether a marketing authorization should be granted. The European marketing authorization is granted after the CHMP opinion has been reviewed and accepted, and the Decision (i.e., the licence) is granted by the European Commission. The single license is valid for the entire European Union. Products that do not qualify for registration under the centralized procedure, or which were registered under a prior system, are still registered nationally, although by a mutual recognition procedure. The regulatory process is complex and involves extensive consultation with the regulatory authorities of the various European Union member states. Issues still exist regarding the right of member states not to mutually recognize licenses granted in other European Union countries due to poorly defined public health concerns, and there can be no assurance that this European process will not introduce delays. Similarly, prior to commercial sale in the United States, all new drugs and new indications for existing drugs must be approved by the FDA. As in the case of the European Union, securing FDA marketing approvals requires the submission of extensive preclinical and clinical data, chemistry, manufacturing and controls information and other relevant supporting information to the FDA. The submitted data should provide sufficient risk and benefit information for the authorities to determine the approvability of the product and indication in terms of its quality, safety and efficacy.

Regulatory approval of pricing and reimbursement is required in most countries outside the United States. For example, regulators in certain European countries condition their reimbursement of a pharmaceutical product on the agreement of the seller not to sell the product for more than a certain price or in more than certain quantities per year in their respective countries. In some cases, the price established in any of these countries may serve as a benchmark in the other countries. As such, the price approved in connection with the first approval obtained in any of these European countries may serve as the maximum price that may be approved in the other European countries. Also, a price approved in one of these European countries that is lower than the price previously approved in the other European countries may require a reduction in the prices in those other European countries. In that event, the resulting prices may be insufficient to generate an acceptable return on our investment in the products.

Manufacturers of drugs also are required to comply with current Good Manufacturing Practice regulations and similar regulations in the countries in which they operate. These include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Manufacturing facilities are subject to inspection by government regulators, including unannounced inspection in their own and other jurisdictions. Most material manufacturing changes to approved drugs also are subject to regulatory review and approval.

We or our suppliers may fail to comply with applicable regulatory requirements such as adverse event reporting, which could lead to product withdrawal or other regulatory action. Serious, unexpected and unlabeled events observed post-marketing worldwide are subject to expedited reporting requirements to the European, U.S. and other health authorities and could result in changes in the “Warnings” and “Precautions” section of the product labeling.

Various laws, regulations and recommendations relating to safe working conditions, Good Laboratory Practices, Good Clinical Practices, the experimental use of animals and the purchase, storage, movement, import and export and use and disposal of hazardous or potentially hazardous materials, including radioactive compounds and infectious disease agents, used in connection with our research work are or may be applicable to our activities. Although we believe that our safety procedures for handling and disposing of hazardous materials comply with the standards prescribed by applicable laws, regulations and recommendations, the risk of accidental contamination or injury from these materials cannot be completely eliminated.

**Environmental Regulation**

We seek to comply with all applicable statutory and administrative requirements concerning environmental quality. We have made, and will continue to make, expenditures for environmental compliance and protection. Expenditures for compliance with environmental laws have not had, and we do not expect them to have, a material effect on our capital expenditures, results of operation, financial condition or competitive position.

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## **Capital Expenditures, Divestitures and Investments**

Our capital expenditure on tangible fixed assets for 2004 totaled approximately \$151.5 million, compared to \$185.0 million in 2003 and \$125.3 million in 2002. This level of capital expenditure reflects our continuing investment in research and development and manufacturing facilities, our investment in our new corporate headquarters and our continuing implementation of advanced information technology systems.

In the fourth quarter of 2003, we took a non-cash charge of CHF 20.8 million or \$16.1 million related to the write-down of our 2001 CHF 25.0 million investment in Swiss International Air Lines Ltd. At the end of 2004, the market value of our investment was CHF 4.2 million or \$3.4 million and the significant decline in the market value of the investment was considered to be other than temporary.

In the second half of 2002, our subsidiary, Serono France Holding S.A. conducted a tender offer for the outstanding shares of Genset S.A., a French public company. As a result of this tender offer and subsequent open market purchases, as of March 26, 2003, Serono France Holding S.A. had acquired 7,670,863 shares (representing 92.9% of the outstanding shares), 520,431 bonds convertible into new shares (representing 99.7% of such bonds outstanding) and all of the company's outstanding warrants for an aggregate purchase price of \$140.1 million. In addition, following the launch by Genset S.A. of a capital increase in March 2003, Serono France Holding S.A. acquired in the market 354,336 subscription rights. The purchase of these rights increased Serono France Holding S.A.'s stake in Genset S.A. to more than 95% of the share capital of Genset S.A., which permitted Serono France Holding S.A. to launch a squeeze-out merger that enabled it to gain control of all of the outstanding equity securities of Genset S.A. in June 2003. As of June 15, 2003, Serono France Holdings S.A. owned 100% of the Genset share capital.

In the first quarter of 2003, we exercised an option to purchase land adjacent to our current headquarters in Geneva in order to construct a facility to support our future growth. This facility will bring together our corporate management and administration and our Switzerland-based research and development in a single location. We estimate that the cost of this project to scheduled completion in 2006 will be approximately CHF371.1 million or \$327.7 million which we will substantially finance by means of a credit facility we have entered into. We started construction in the middle of 2003 and this construction is ongoing.

## **Organizational Structure**

We are a holding company for the companies of the Serono group. A listing of our principal operating companies, their country of incorporation and the proportion of our ownership of each can be found in Note 34 of the Notes to Consolidated Financial Statements elsewhere in this Annual Report.

## **Facilities**

We occupy owned or leased facilities in over 40 countries. Our headquarters are located in Geneva, Switzerland. We maintain research and development facilities in Geneva, the Boston area, Evry, France, and Ardea, Italy. Our principal manufacturing facilities are located in Switzerland, Italy, Spain and France. In 2004, we closed our manufacturing facility in Israel, which was one of our oldest manufacturing sites and had become obsolete. We also have leases for additional office facilities in several locations in Europe, North America, Latin America and Asia. We have made and continue to make improvements to our properties to accommodate our growth. We believe our facilities are in good operating condition and that the real property we own or lease is adequate for all present and near-term future uses. We believe that any additional facilities could be obtained or constructed with our existing capital resources.

In 2003, we exercised an option to purchase a 40,000 square meter section of land near our current headquarters in Geneva for the purpose of bringing together on a single site our headquarters and Switzerland-based research and development activities and supporting our anticipated growth. We estimate that the cost of this project to scheduled

completion in 2006 will be approximately CHF371.1 million or \$327.7 million. The total costs capitalized as of December 31, 2004 were CHF 161.3 million or \$130.4 million. We substantially financed this project by way of a CHF 300 million committed unsecured revolving bank facility. As of December 31, 2004, the amount outstanding under this facility was CHF131.5 million or \$116.1 million. The facility is due for repayment on December 31, 2006. In addition, we purchased approximately 31,000 square meters of land in Martillac, France, at a purchase price of \$0.1 million, and thereby added to our existing land holdings in Martillac, France. The additional land may be used at a future date to expand our manufacturing production in Martillac.

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The following table lists our principal office, research and development and manufacturing facilities:

<u>Location</u>	<u>Use</u>	<u>Owned or Leased</u>	<u>Size</u>
Geneva, Switzerland	Headquarters	Leased-Expires 2006	14,578 sq. meters
Geneva, Switzerland	Research and Development	Leased-Expires 2011	12,698 sq. meters
Rockland, Massachusetts, U.S.A.	U.S. Headquarters	Leased-Expires 2016	200,000 sq. feet
Rome, Italy	Italian Headquarters	Owned	10,212 sq. meters
Ardea, Italy	Research and Development	Owned	46,838 sq. meters
Evry, France	Research and Development	Leased-Expires 2005	13,696 sq. meters
Corsier-sur-Vevey, Switzerland	Manufacturing	Owned	36,395 sq. meters
Aubonne, Switzerland	Manufacturing	Owned	43,800 sq. meters
Coinsins, Switzerland	Manufacturing	Owned	19,800 sq. meters
Rome, Italy	Manufacturing, Research and Development	Owned	51,015 sq. meters
Bari, Italy	Manufacturing	Owned	122,150 sq. meters
Tres Cantos, Spain	Manufacturing	Owned	6,028 sq. meters
Martillac, France	Manufacturing	Leased-Expires 2008	1,107 sq. meters
Martillac, France	Manufacturing	Owned	47,683 sq. meters

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## **Item 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

**You should read the following operating and financial review and prospects in conjunction with the consolidated financial statements and the notes to the consolidated financial statements appearing elsewhere in this Annual Report. We have prepared our consolidated financial statements in accordance with International Financial Reporting Standards (IFRS), which differ in significant respects from United States Generally Accepted Accounting Principles (U.S. GAAP). You can find a reconciliation of the significant differences between IFRS and U.S. GAAP in note 35 to our consolidated financial statements.**

### **Overview**

We are a global biotechnology leader with 4,902 employees, worldwide revenues of \$2,458.1 million and a net income of \$494.2 million in the year 2004. We have eight biotechnology products on the market and a strong pipeline with approximately 30 ongoing development projects, based both on proteins and small molecules.

We use human genetic information to discover, develop and manufacture therapeutic products for the treatment of human diseases. We currently focus on the specialized markets of neurology, reproductive health, growth and metabolism, and dermatology, our newest therapeutic human genetic area.

We are committed to bringing hope to people suffering from multiple sclerosis or MS. Rebif is a treatment for relapsing MS. Several studies support the concept of maximal benefit with higher and more frequent doses of beta-interferon. Rebif 44 mcg, three times per week, has been shown to achieve maximum treatment effect in terms of disease progression and reducing the frequency and severity of relapses.

We are the world leader in the treatment of infertility. Our vision is to develop and market innovative products to help infertile couples at every stage of the reproductive cycle, from follicular development to early pregnancy, in making their dream of having a child come true. We are the only company that uses recombinant technology to produce all three gonadotropin hormones for treatment of infertility and, with a complete portfolio of highly effective fertility drugs that cover every aspect of the reproductive cycle, we offer clinicians the ability to tailor treatment to individual patient needs.

Our goal is to improve and maintain the quality of life of people with metabolic disorders. To meet this goal, we were one of the first to make recombinant growth hormone available for the treatment of Growth Hormone Deficiency in children and adults (Saizen) and for the treatment of patients suffering from AIDS Wasting (Serostim). We continue our commitment to patients with these disorders through these treatments delivered by easy-to-use devices.

We have a global presence with operations in more than 40 countries, production facilities in four countries and sales in over 90 countries. We have spent 24.2% of total revenues on research and development in 2004. We have integrated operations that allow us to manufacture and market the products we derive from our research and development efforts. Our global sales and marketing infrastructure has made us a global partner of choice in the biotechnology industry.

### **Critical accounting policies and estimates**

Our operating and financial review and prospects are based upon our consolidated financial statements, which we prepared in accordance with IFRS. We have provided in note 35 of the consolidated financial statements a reconciliation of net income and shareholders' equity from IFRS to U.S. GAAP. The preparation of financial statements in conformity with IFRS and the reconciliation under U.S. GAAP require us to make estimates and assumptions that affect the amounts we report in the financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates, including those related to reserves for fiscal and legal claims, sales returns, inventory



obsolescence, bad debt reserves and the assessment of impairment of intangible assets and available-for-sale investments, income taxes, pensions and retirement benefit plans. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe the following critical accounting policies affect the more significant judgments and estimates that we use in the preparation of our consolidated financial statements.

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## **Revenue recognition**

We recognize revenue from product sales when there is evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collectibility is reasonably assured. Allowances are established for estimated uncollectible amounts, product returns and discounts. We adjust the estimates for returns periodically based upon historical rates of returns, inventory shipment history, estimated levels of product in the distribution channel, and other related factors. While we believe that we can make reliable estimates for these matters, nevertheless unsold products in the distribution channels can be exposed to rapid changes in market conditions or obsolescence due to new competitive environments, product updates or competing products. Accordingly, it is possible that these estimates will change in the near future or that the actual amounts could vary significantly from our estimates.

## **Assessment of returns**

Provisions for sales returns are based on actual historical returns as we feel that this is the best means to estimate future returns of products sold in the current period. The amount of returns we receive varies by region and is dependent upon the return policy within a given country. We perform periodic quantitative analysis by product for each reserve category to assess whether the current assumptions used to calculate the sales return provisions are valid. We calculate a twelve-month rolling return rate based on actual product returns. We then apply this rate against all future outstanding products that could be subject to expiration. The result is the reserve needed for future returns. The reserves that are generated based on the historical rate of actual returns are compared to a qualitative analysis of sales reserves to ensure that the amount of the reserves recorded in our financial statements reflect all of the facts and circumstances that could potentially impact the amount of future returns that we will receive. The qualitative factors that are incorporated into our sales return analysis would include the potential impact on future product returns, for example, of the introduction of a competing product or changes in reimbursement practices.

## **Assessment of inventory levels in the distribution channel**

Our distribution channel includes wholesaler distributors, pharmacies, hospitals and other medical facilities that distribute and/or administer our products. In the U.S. market for example, which accounts for 35.1% of our total product sales, we receive monthly inventory reports from the wholesalers we sell to summarizing by product the amount of inventory held at the end the month. Inventory levels maintained at the wholesalers in the U.S. are approximately 30 days of sales. In Europe, our single largest region, representing 41.1% of our total product sales, we generally maintain inventory levels of less than 30 days. We assess inventory levels maintained in the Europe region based on a comparison of sale volumes to wholesalers against their reported sales to pharmacies, hospitals and other medical facilities.

Throughout all of our regions, wholesalers typically sell to pharmacies, hospitals and other medical facilities. Therefore, there is an additional level of inventory in our distribution channel. However, given the relatively high inventory value of our products and the fact that wholesalers can deliver our products to a healthcare facility on the same day, pharmacies, hospitals and other medical facilities are reluctant to carry significant amounts of our products. Thus we believe that the inventory held at the wholesaler represents the substantial part of the inventory held within the entire distribution channel at any given time.

## **Assessment of the average age of inventory in the distribution channel**

At present time we do not have the ability to track the expiration date of inventory held in the distribution channel on a global basis. Movements in sales reserves during the past three years are summarized in the following table:

	Product returns U.S.\$m	Discounts, chargebacks and rebates U.S.\$m	Total sales reserves U.S.\$m
Balance as of January 1, 2002	21.4	23.0	<b>44.4</b>
Add: New reserves recorded in 2002	20.0	103.5	<b>123.5</b>
Less: Reserves applied during 2002	(20.5 )	(94.1 )	<b>(114.6 )</b>
Balance as of December 31, 2002	20.9	32.4	<b>53.3</b>
Add: New reserves recorded in 2003	31.1	153.7	<b>184.8</b>
Less: Reserves applied during 2003	(15.6 )	(132.0 )	<b>(147.6 )</b>
Balance as of December 31, 2003	36.4	54.1	<b>90.5</b>
Add: New reserves recorded in 2004	8.8	187.6	<b>196.4</b>
Less: Reserves applied during 2004	(15.3 )	(187.7 )	<b>(203.0 )</b>
<b>Balance as of December 31, 2004</b>	<b>29.9</b>	<b>54.0</b>	<b>83.9</b>

Gross product sales recorded in 2004, 2003 and 2002 before sales reserves were \$2,374.4 million, \$2,042.8 million and \$1,546.7 million, respectively. New reserves recorded in 2004, 2003, and 2002 as a percentage of gross product sales were 8.3%, 9.0%, and 8.0%, respectively. Reserves for product returns recorded in 2004 were lower when compared to 2003; this was the result of the application of lower product return rates in the U.S. for sales of Rebif and Novantrone. The initial forecasted rates of return that were established upon the launch of these products in the first and fourth quarters of 2002 were estimated without the benefit of historical return data. Return rates for these products were reduced during 2004 based on the volume of actual returns received. In addition, product returns of existing Gonal-f product related to the 2004 U.S. launch of Gonal-f fill-by-mass formulation and the Gonal-f pre-filled pen were less than expected.

### Inventory provisions

We write down our inventory by an amount equal to the difference between the cost of inventory and the net realizable value of the inventory, based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those we project, we may need to take additional inventory write-downs.

### Bad debts

We maintain allowances for estimated losses resulting from the inability of our customers to make required payments. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, we might need to make additional allowances.

### Impairment testing

We evaluate the carrying value of our tangible and intangible assets for impairment on an annual basis, and also whenever indicators of impairment exist. If we determine that such indicators are present, we prepare a discounted future net cash flow projection for the asset (“value in use”). In preparing this projection, we must make a number of assumptions and estimates concerning such things as future sales performance of our various products and the rates of increase in operating expenses over the remaining useful life of the asset. If the calculation of value in use is in excess of the carrying value of the recorded asset, no impairment is recorded. In the event the carrying value of the asset exceeded the value in use, we would estimate the net selling price of the asset and, where appropriate, we would use the assistance of an external valuation expert. If the carrying value also exceeded the net selling price, we would take

an impairment charge to bring the carrying value down to the higher of net selling price and value in use. The discount rate we use in the calculation represents our best estimate of the risk-adjusted pre-tax rate. Should the sales performance of one or more products be significantly below our estimates, we might have to take an impairment charge on certain tangible assets or intangible assets.

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### **Accounting for available-for-sale investments**

We hold available-for-sale investments at fair value and have elected to treat any unrealized gains and losses as increases or decreases in fair value reserves, which affect shareholders' equity. We have a policy in place to review each individual holding of available-for-sale investments at each balance sheet date to evaluate whether or not each investment is permanently impaired. Our policy includes reviewing all publicly available information provided by the company in which we have invested and analysts' reports for evidence of significant financial difficulty, recognition of impairment losses, possibility of bankruptcy, severe operational setbacks and other impairment indicators. If we believe that a permanent impairment has been incurred and the eventual recoverable amount will not exceed the original cost, it is our policy to recognize an impairment loss in the income statement.

### **Deferred income taxes**

We account for deferred income taxes based upon differences between the financial reporting and income tax bases of our assets and liabilities. We record deferred tax assets only to the extent that it is probable that taxable profit will be available in the affiliate that has recognized the deferred tax assets, which is an assessment that is based on management judgment.

### **Pensions**

Substantially all of our employees are covered by defined benefit, defined contribution, insured or state pension plans. The expense incurred under the defined benefit retirement plans is based upon statistical and actuarial calculations, and is impacted by assumptions on discount rates used to arrive at the present value of future pension liabilities, expected returns that will be made on existing pension assets, future salary increases as well as future pension increases. Furthermore, our independent actuaries use statistical based assumptions covering future withdrawals of participants from the plan and estimates on life expectancy. The actuarial assumptions used may differ materially from actual results due to changes in market and economic conditions, higher or lower withdrawal rates or longer or shorter life spans of participants. These differences could impact significantly the amount of pension income or expense recognized in future periods.

### **Contingencies**

Several of our subsidiaries are parties to various legal proceedings including possible breach of contract, patent infringement cases and other matters. As a result, claims could be made against them which might not be covered by existing provisions or by insurance. There can be no assurance that there will not be an increase in the scope of these matters or that any future lawsuits, claims, proceedings or investigations will not be material. Management believes that during the next few years, the aggregate impact, beyond current reserves, of these and other legal matters affecting the company is reasonably likely to be material to the company's results of operations and cash flows, and may be material to its financial condition and liquidity.

### **Results of operations – Overview**

We are active in the research, development, production and marketing of products that address our four current therapeutic areas of neurology, reproductive health, growth and metabolism and dermatology.

### **Total revenues**

### **Product sales**

In 2004, five products accounted for 92.6% of our total product sales. Rebif, our largest selling product accounted for 50.1% of our sales, is a recombinant interferon beta-1a that we sell for the treatment of multiple sclerosis. Gonal-f, our second largest selling product accounted for 26.3% of our product sales, is a recombinant human follicle stimulating hormone that we sell for the treatment of infertility. Saizen and Serostim are different formulations of recombinant human growth hormone, and are our third and fourth largest selling products, respectively and on a combined basis, accounted for 12.3% of our product sales. Saizen is used in the treatment of growth retardation due to a variety of causes. Serostim is used to treat AIDS Wasting. Novantrone, for which we purchased the marketing rights to sell in the U.S. market, is indicated for certain types of worsening MS and also for certain forms of cancer. Product sales of Novantrone for the two separate indications are reported under our neurology therapeutic area and as other product sales, respectively and accounted for 3.9% of our total product sales. In addition to the main products highlighted above, we also sell a variety of other products.

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### **Royalty and license income**

We currently receive ongoing royalties under licensing agreements with Biogen Idec for its sales of Avonex, Organon for its sales of Puregon, Amgen for its sales of Enbrel and Abbott Laboratories for its sales of Humira. Our revenues from these agreements increase or decrease in proportion to our licensees' sales of their products. We derive license income from licensing our intellectual property to third parties. In addition, we also receive non-recurring amounts through patent settlements with third parties.

### **Operating expenses**

Our operating expenses are composed of cost of product sales, selling, general and administrative expenses, research and development expenses, and other operating expenses.

### **Cost of product sales**

Cost of product sales includes all costs we incur to manufacture the products we sell in a given year. Our largest components of cost of product sales are employee-related expenses, depreciation of manufacturing plant, property and equipment, materials and supplies, utilities and other manufacturing-related facility expenses. We also purchase directly from outside manufacturers finished products including Raptiva, Crinone and Cetrotide, that we sell as part of in-licensing agreements that grant us exclusive rights to sell these products in specific territories. The payments that we make to our in-licensing partners are capitalized as intangible assets and amortized over the shorter of the term of the license and the period in which we expect to sell the in-licensed product. Amortization expense is reported under other operating expense.

### **Selling, general and administrative**

Our selling, general and administrative expenses are composed of distribution, selling and marketing and general and administrative expenses:

**Distribution.** In general, we sell our products to wholesale distributors or directly to hospitals, medical centers and pharmacies. Distribution expenses are primarily freight expenses, employee-related expenses and expenses incurred by third-party distributors in distributing our products.

**Selling and marketing.** We maintained a marketing and sales force of 2,084 employees in 2004 to sell or manage the distribution of our products in almost 100 countries. Our selling and marketing expenditures consist primarily of employee-related expenses and costs associated with congresses, exhibitions and advertising as well as commissions paid to our two co-promotion partners: Pfizer, which co-promotes Rebif in the U.S. market, and OSI Pharmaceuticals, which co-promotes Novantrone in the U.S. as a treatment for certain forms of cancer.

Selling and marketing expense generally maintains a positive correlation with the volume of products that we sell. However, we may incur additional selling and marketing expense upon the introduction of a new product or when we introduce existing products into new markets, as we hire additional sales personnel to undertake product launches. For example, we received European Commission Marketing Authorization for Raptiva (efalizumab) for the treatment of adult patients with moderate to severe chronic plaque psoriasis who failed to respond to, or who have a contraindication to, or are intolerant of other systemic therapies including cyclosporine, methotrexate and PUVA. Raptiva is the first new biological treatment for psoriasis to be authorized for marketing in the European Union. Raptiva was available in 15 countries including Germany and UK by the end of 2004 and will launch throughout the rest of the Serono territories during 2005. The cost of the launch of Raptiva contributed to the increase in reported selling and marketing expense expressed as a percentage of product sales.

**General and administrative.** We incur general and administrative expenses in maintaining our headquarters in Geneva and our operations in more than 40 countries. We centralize certain functions, such as finance, information technology, treasury, tax and legal, to the extent possible, to achieve economies of scale in operations.

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## Research and development

Research and development or R&D is one of our key functions, and we employed 1,387 R&D employees in 2004. We incur our primary R&D expenses in connection with the operation of the Serono Pharmaceutical Research Institute in Geneva, the Serono Reproductive Biology Institute in Boston, the Istituto di Ricerca Cesare Serono, which merged into the Industria Farmaceutica Serono, the Istituto di Ricerche Biomediche “Antoine Marxer” RBM in Italy, the Serono Genetics Institute in France, Bourn Hall in UK and our corporate R&D organization.

We also invest significantly in collaborations with other biotechnology companies that can require material up-front payments, future ongoing milestone payments, and eventually future royalty payments that are normally based on a percentage of sales we generate from a product that we have in-licensed. In most cases, up-front and milestone payments, payable under research and development agreements, are charged directly to research and development expense, unless there is significant evidence that all of the criteria for capitalization, as prescribed by IAS 38, “Intangible Assets”, are met. Acquired projects which have achieved technical feasibility, usually signified by regulatory body approval, are capitalized, as it is probable that the costs will give rise to future economic benefits. During 2004, we incurred \$83.7 million in collaborative payments that have been recognized as research and development expense, as they did not meet the criteria for capitalization.

On January 1, 2005, we will adopt IAS 38 (revised 2004), “Intangible Assets”, which will have a material impact on the accounting for our collaborative arrangements. This standard recognizes that the price that we pay to acquire an intangible asset as part of an in-licensing agreement reflects expectations about the probability that the expected future economic benefits from the asset will flow to us. The effect of probability is reflected in the cost of the asset. The probability recognition criterion is always considered to be satisfied for separately acquired intangible assets. We expect that the adoption of this standard in 2005 will result in an increase in the amount of capitalized intangible assets. This revised standard is to be applied prospectively. Therefore, the accounting for the transactions made prior to January 1, 2005, will not be amended by this revised standard.

The adoption of IAS 38 (revised 2004), “Intangible Assets”, in fiscal year 2005 will result in a significant difference between IFRS and U.S. GAAP as intangible assets acquired as part of a separate transaction will continue to be expensed under U.S. GAAP until the asset has achieved technical feasibility which is usually signified by regulatory approval. The difference that will be included in our reconciliation from IFRS to U.S. GAAP will be equal to the amount of payments that we make to acquire intangible assets that are part of separate transactions, that have been capitalized as intangible assets and that have not achieved technical feasibility at the time of the transaction. This difference will be deducted from our reported net income in accordance with IFRS to arrive at net income reported under U.S. GAAP. Had IAS 38 (revised 2004), “Intangible Assets”, been effective on January 1, 2004, reported research and development expense for the year ended December 31, 2004, would have been lower by \$83.7 million.

## Other operating expense

Other operating expense includes royalty and license expense, amortization of intangibles and other long-term assets, litigations and legal costs, patent and trademark expenses, and equity compensation expenses related to our Employee Share Purchase Plan.

We incur the majority of our royalty and licensing expenses under agreements that we have with Amgen and Wyeth on sales of Novantrone; Genentech on sales of Raptiva; Yeda, the commercial arm of the Weizmann Institute in Israel, on royalties received from Biogen, Amgen and Abbott Laboratories and also on sales of Rebif; Columbia University on sales of Gonal-f; Roche on sales of Rebif; and Berlex Laboratories Inc., the U.S. subsidiary of the Schering Group, on sales of Rebif. Our expenses under these licenses vary with the royalties received and the sales of the applicable products.

On January 1, 2005, we will adopt IFRS 2, “Share-Based Payments”, which will require us to expense the fair value of stock options granted to employees and directors. The application of this new standard requires that all stock options that were granted after November 7, 2002 and had not vested before January 1, 2005 must be expensed over their vesting period. Therefore, in 2005, being the first period that we will expense the fair value of stock options, we will adjust our 2004 reported results to reflect additional operating expense in the amount of \$12.2 million before tax.

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**Year ended December 31, 2004 compared to year ended December 31, 2003**

The following compares our results in the year ended December 31, 2004 to those of the year ended December 31, 2003. Our analysis is presented as follows:

- |    |                                   |
|----|-----------------------------------|
| 1. | Overview                          |
| 2. | Product sales by therapeutic area |
| 3. | Product sales by region           |
| 4. | Operating expenses to net income  |

**1. Overview**

Our total revenues increased by 21.8% to \$2,458.1 million during 2004. Our total revenue growth in local currencies was approximately 16.1%, reflecting our strong underlying growth. Worldwide product sales were \$2,177.9 million in 2004, representing an increase for the year of 17.2%. Product sales growth in local currencies was 11.5% in 2004. The total currency impact on reported product sales and total revenues was \$100.1 million or 4.6% and \$107.4 or 4.4%, respectively.

Royalty and licensing income increased by 74.4% to \$280.1 million for the year and was impacted by a new license agreement under a non-core technology that was granted during the year and for which we recognized \$67.0 million in license income. The license fee is payable in equal annual installments over the next three years. However, the full amount of the license fee was recognized as royalty and license income in 2004 as no further performance obligation exists on our behalf.

Our royalty income increased by 19.8% to \$188.7 million during the year and reflects our strong intellectual property rights. The increase was due to higher royalty income received from Abbott Laboratories on its sales of Humira; from Amgen on its sales of Enbrel and from Biogen Idec on its sales of Avonex.

Operating expenses increased by 22.1% to \$1,933.9 million or 78.7% of total revenues. Our operating expenses were unfavorably impacted by the weakening of the U.S. dollar against most major currencies and in particular the Swiss franc and Euro. The total estimated currency impact on reported operating expenses was \$85.7 million or 4.4%. Our operating margin was 21.3% compared to 21.5% in 2003. Our operating margin, after removing the currency impact, was 21.4%.

Net income increased by \$104.2 million or 26.7% and represents 20.1% of total revenues. Our reported net income benefited from a net favorable currency impact of \$17.2 million or 3.5%. Basic earnings per bearer shares increased by 31.3% from \$24.63 in 2003 to \$32.35 in 2004.

Our outlook for 2005 includes sales growth of between 10% and 15%, total 2005 revenues of at least \$2.6 billion and net income of between \$520 million and \$540 million all based on prevailing currency exchange rates.

**2. Product sales by therapeutic area**

The following tables summarize, for the periods indicated, our product sales by therapeutic area:



	Year ended December 31,				
	2004 U.S. \$m	Change in %	2003 U.S. \$m	Change in %	2002 U.S.\$m
<b>Neurology</b>					
Rebif	1,090.6	33.1	819.3	49.3	548.8
Novantrone	32.4	5.0	30.9	10,166.7	0.3
<b>Total neurology</b>	<b>1,123.0</b>	<b>32.1</b>	<b>850.2</b>	<b>54.9</b>	<b>549.1</b>
<b>Reproductive health</b>					
Gonal-f	572.7	8.7	526.9	17.0	450.4
Cetrotide	24.8	(0.2 )	24.8	35.3	18.4
Crinone	19.8	(4.6 )	20.8	90.2	10.9
Ovidrel	17.7	43.3	12.4	117.2	5.7
Luveris	10.6	6.0	10.0	52.4	6.6
<b>Core infertility portfolio</b>	<b>645.6</b>	<b>8.5</b>	<b>594.9</b>	<b>20.9</b>	<b>492.0</b>
Metrodin HP	15.9	(36.0 )	24.8	(50.6 )	50.1
Pergonal	11.5	(74.9 )	45.8	(0.4 )	46.0
Profasi	6.7	(56.2 )	15.4	(22.4 )	19.8
Other products	12.6	4.9	12.0	(13.4 )	14.0
<b>Total reproductive health</b>	<b>692.3</b>	<b>(0.1 )</b>	<b>692.9</b>	<b>11.4</b>	<b>621.9</b>
<b>Growth and metabolism</b>					
Saizen	182.1	20.2	151.5	22.1	124.0
Serostim	86.8	(2.2 )	88.7	(6.6 )	95.1
Zorbtive	0.9	-	-	-	-
<b>Total growth and metabolism</b>	<b>269.8</b>	<b>12.3</b>	<b>240.2</b>	<b>9.6</b>	<b>219.1</b>
<b>Dermatology</b>					
Raptiva	4.9	-	-	-	-
<b>Total dermatology</b>	<b>4.9</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
Other products	87.9	17.8	74.7	125.5	33.0
<b>Total product sales</b>	<b>2,177.9</b>	<b>17.2</b>	<b>1,858.0</b>	<b>30.6</b>	<b>1,423.1</b>
Recombinant products	1,961.7	21.9	1,609.4	30.7	1,231.3
Non-recombinant products	216.2	(13.0 )	248.6	29.7	191.8

## Neurology

In 2004, neurology sales were up 32.1% to \$1,123.0 million, reflecting the continued strong demand for Rebif, with a significant market share increase. Rebif achieved blockbuster status reaching over one billion U.S. dollars in annual worldwide sales in 2004. Worldwide sales of Rebif increased by 33.1% to \$1,090.6 million in 2004, compared to \$819.3 million last year. In local currencies, Rebif sales increased by 25.4%. Sales growth was driven by a

combination of a volume increase of 29.0% and a 3.2% increase in average selling price on account of sales denominated in currencies other than U.S. dollar. When holding exchange rates constant, our average selling price decreased by 2.8%, mostly due to pressure on prices, particularly in the European Union.

Rebif sales in the U.S. increased by 56.8% in 2004 to reach \$295.6 million, compared to \$188.5 million in 2003 reflecting the continued strong demand.

Rebif sales in Europe grew by 25.6% to \$531.7 million compared to \$423.2 million in 2003. In local currencies, sales increased by 13.7%. This was primarily driven by increased patient market share in Italy, Spain, and France and a growing patient base in the UK following an increase in the funding from health authorities.

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Rebif sales in Latin America increased by 23.8% to \$75.9 million in 2004 compared to \$61.3 million in 2003, primarily due to higher sales in Brazil, Venezuela and Argentina.

Rebif sales in the rest of the world grew by 28.0% (or 21.2% in local currencies) to \$187.4 million compared to \$146.3 million in 2003 driven by strong sales in the Middle East, Central Europe and Switzerland as well as the emerging markets of Bulgaria and Romania.

For the twelve months ended September 2004, our worldwide dollar market share reached 24.1%, up 1.7% compared to the same period last year. Excluding sales in the U.S., our dollar market share was 35.5%, down 0.3% compared to the same period in 2003. In the U.S., our dollar market share reached 12.6% as of September 30, 2004 compared to 9.7% one year earlier.

### **Reproductive health**

Reproductive health or RH product sales were \$692.3 million during 2004 compared to \$692.9 million in 2003. In local currencies, RH product sales decreased by 4.7%. Our RH core infertility portfolio made up of three recombinant hormones (Gonal-f, Ovidrel, Luveris) and two supporting products (Cetrotide, Crinone) grew by 8.5% (or 3.4% in local currencies) from \$594.9 million in 2003 to \$645.6 million in 2004.

In 2004, difficult market conditions, primarily in Europe, impacted our RH franchise performance. The implementation of healthcare reforms in Germany at the beginning of the year reduced pricing and reimbursement levels. However, we have seen a good performance in other regions beginning with the U.S., where recombinant market share increased, though this was partially offset by the phase-out of Pergonal as of March 2004. We had market share gains in Spain and a successful launch of the Gonal-f pen in Oceania and strong sales growth in Middle East, Africa and Eastern Europe.

Our sales of Gonal-f increased by 8.7% to \$572.7 million in 2004 from \$526.9 million in 2003 or by 3.6% in local currencies. Sales growth of Gonal-f was driven by a volume increase of 5.2% and an increase in the average selling price of 3.4% due to both currency and regional sales mix. After removing the favorable impact of foreign currency, the average selling price decreased by 1.5% during 2004. The growth in volumes was largely due to the increasing penetration of our multidose presentation and the launch of our fill-by-mass formulation and Gonal-f pre-filled pen.

The sales growth of Gonal-f was achieved despite the adverse impact of the German healthcare reform that took effect on January 1, 2004. Gonal-f sales in Germany have decreased during the year by \$36.2 million.

Ovidrel sales increased by 43.3% to \$17.7 million compared to \$12.4 million in 2003. In the same period, Luveris sales increased by 6.0% to \$10.6 million. Recombinant gonadotropin sales as a percentage of total gonadotropin sales increased from 86.0% in 2003 to 94.0% this year. Urine-derived gonadotropins sales decreased by 57.2% from \$89.3 million in 2003 to \$38.2 million in 2004. Metrodin HP sales declined by 36.0% from \$24.8 million in 2003 to \$15.9 million this year. In line with our strategy to phase out Pergonal in 2004, its sales continued to decrease from \$45.8 million in 2003 to \$11.5 million this year.

Sales of Crinone decreased by 4.6% (or 7.8% in local currencies) to \$19.8 million compared to \$20.8 million in 2003. Sales of Cetrotide were slightly below last year, down 0.2% (or 5.4% in local currencies), at \$24.8 million in 2004.

### **Growth and metabolism**

Our growth and metabolism product sales increased by 12.3% to \$269.8 million in 2004 from \$240.2 million in 2003. In local currencies, product sales increased by 8.2%. Sales of Saizen increased by 20.2% to \$182.1 million in 2004 from \$151.5 million in 2003 or by 13.6% in local currencies. Sales growth resulted from strong demand in the U.S.

market and also in Asia Pacific, mostly in Korea and Taiwan, as well as in Middle East, Africa and Eastern Europe. Volumes and average selling price increased by 16.7% and 3.0%, respectively during the year. After removing the favorable impact of foreign currency, the average selling price decreased by 2.6%.

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Serostim sales in AIDS Wasting were \$86.8 million in 2004, down 2.2% compared to 2003, reflecting the slight decrease in Serostim demand in the U.S.

### Dermatology

We received European Commission Marketing Authorization for Raptiva (efalizumab) for the treatment of adult patients with moderate to severe chronic plaque psoriasis who failed to respond to, or who have a contraindication to, or are intolerant of other systemic therapies including cyclosporine, methotrexate and PUVA. Raptiva is the first new biological treatment for psoriasis to be authorized for marketing in the European Union. We launched Raptiva in 15 countries including Germany and UK during the 2004 and will launch throughout the rest of the Serono territories during 2005. Product sales of Raptiva in 2004 were \$4.9 million.

### 3. Product sales by region

The following tables summarize, for the periods indicated, our product sales by region:

	Year ended December 31,				
	2004 U.S.\$m	Change in %	2003 U.S.\$m	Change in %	2002 U.S.\$m
Europe	<b>895.2</b>	12.3	796.8	28.4	620.4
North America	<b>837.9</b>	20.7	694.3	44.8	479.6
Middle East, Africa and Eastern Europe	<b>196.3</b>	29.8	151.2	40.5	107.6
Asia-Pacific, Oceania and Japan	<b>137.5</b>	17.6	116.9	10.1	106.3
Latin America	<b>111.0</b>	12.4	98.8	(9.5 )	109.2
<b>Total product sales</b>	<b>2,177.9</b>	17.2	1,858.0	30.6	1,423.1

#### Europe

Sales in Europe for the year 2004 increased by 12.3% to \$895.2 million compared to \$796.8 million in 2003. In local currencies, sales increased by 1.7%. This result was primarily due to increased sales of Rebif in almost all European countries, up 13.7% in local currencies. Our RH core infertility portfolio was down 14.5% primarily from the decrease in sales of Gonal-f in Germany as a result of healthcare reform that was enacted on January 1, 2004. Gonal-f sales in Germany decreased by \$36.2 million during the year.

#### North America

Sales in North America increased by 20.7% in 2004 to \$837.9 million. Sales growth in this region was primarily within the U.S. due to the strong performance of Rebif (up 56.8%), Gonal-f (up 13.2%), Saizen (up 24.0%), and Novantrone (up 8.8%). This was partially offset by lower sales of Pergonal as it was phased-out of the U.S. market as of March 2004, down 79.9%.

**Middle East, Africa and Eastern Europe**

In the Middle East, Africa and Eastern Europe, sales increased by 29.8% to \$196.3 million due to the strong performance of Rebif, the RH core infertility portfolio and Saizen, partially offset by decreased sales of Pergonal, Profasi and Metrodin HP.

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### Asia-Pacific, Oceania and Japan

Sales in Asia-Pacific were \$65.1 million, up 6.8% (or 5.5% in local currencies) primarily driven by increased sales of Gonal-f and Saizen up 15.2% and 59.2%, respectively, partially offset by decreased sales of Metrodin HP, Pergonal and Profasi. Sales in Oceania increased by 39.2% (or 22.5% in local currencies) to \$40.2 million, primarily attributable to higher sales of the RH core infertility portfolio products. In Japan, sales increased by 18.7% (or 10.4% in local currencies) to reach \$32.1 million mainly attributable to higher sales of Saizen, Pergogreen and Serostim.

### Latin America

Sales in Latin America increased by 12.4% to \$111.0 million primarily driven by strong Rebif sales performance, up 23.8% and the RH core infertility portfolio, up 16.2%. This was partially offset by lower Pergonal sales down 98.3%.

### Royalty and license income

	Year ended December 31,				
	2004	Change	2003	Change	2002
	U.S.\$m	in %	U.S.\$m	in %	U.S.\$m
<b>Royalty and license income</b>	<b>280.1</b>	74.4	160.6	40.0	114.7

Our royalty and license income increased by 74.4% (or 69.5% in local currencies) to \$280.1 million in 2004 compared to \$160.6 million in 2003. They were impacted by a new license agreement for a non-core technology that was granted during the year for which we recognized \$67.0 million in license income. The license fee is payable in equal annual installments over the next three years. However, the full amount of the license fee was recognized as royalty and license income in 2004 as no further performance obligation exists on our behalf.

Our royalty income increased by 19.8% to \$188.7 million during the year compared to \$157.5 million in 2003 and reflects our strong intellectual property rights. This increase was due to higher royalty income received from Abbott on its sales of Humira, Amgen on its sales of Enbrel, and Biogen Idec on its sales of Avonex. This was partially offset by a decrease in royalty income earned from Organon on its sales of Puregon, and a number of other products.

## 4. Operating expenses to net income

### Cost of product sales

Cost of product sales in 2004 increased by 8.8% to \$304.1 million from \$279.6 million in 2003. Cost of product sales as a percentage of product sales decreased to 14.0% from 15.0% in the prior year. The corresponding gross margin percentage was 86.0% in 2004, compared to 85.0% last year. Our gross margin in 2004 includes the impact of closing our manufacturing operation in Israel that resulted in a one-time charge of \$20.5 million related to people costs and the write-down of tangible fixed assets. Our gross margin percentage without the impact of these closure costs would have been 87.0%.

The increase in gross margin was primarily the result of favorable changes in product mix and continuing manufacturing productivity gains leading to higher production yields. However, this was partially offset by the strength of the Swiss franc and Euro against the U.S. dollar during 2004, as our costs of manufacturing are incurred in Swiss franc and Euro. Our reported product sales benefited from sales denominated in non-U.S. dollar currencies resulting in a favorable currency impact in 2004 of \$100.1 million while cost of product sales was adversely impacted by an unfavorable currency impact of \$14.3 million.

The proportion of recombinant products sales reached an all time high in 2004 of 90.1%. This proportion is expected to level off upon the completion of our final phase out of our urinary products combined with our launch of Raptiva outside the U.S. and Japan. Gross margin is expected to continue to benefit in the near term from continued economies of scale and the expected utilization of some of our spare manufacturing capacity. We expect that gross margin will reach 88% within the next two years.

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**Selling, general and administrative**

	Year ended December 31,				
	2004 U.S.\$m	Change in %	2003 U.S.\$m	Change in %	2002 U.S.\$m
Selling and marketing	612.5	29.5	472.9	25.4	377.1
General and administrative	195.4	19.3	163.9	28.9	127.1
<b>Total selling, general and administrative</b>	<b>807.9</b>	<b>26.9</b>	<b>636.8</b>	<b>26.3</b>	<b>504.2</b>

Selling and marketing expenses were \$612.5 million, or 24.9% of total revenues in 2004 compared to \$472.9 million for last year, corresponding to an increase of 29.5%. This increase in reported selling and marketing expenses was mainly driven by higher sales commissions incurred on sales of Rebif and Novantrone in the U.S., sales and marketing costs associated with the launch of Raptiva, and marketing activities to support our product sales growth including Gonal-f filled-by-mass and Gonal-f pre-filled pen.

General and administrative expenses were \$195.4 million or 8.0% of revenues in 2004 compared to \$163.9 million in 2003, which represents an increase of 19.3%. This increase was primarily due to increased personnel related costs and facility expenses.

Our reported selling, general and administrative expenses include an unfavorable currency impact of \$36.6 million or 4.5% primarily due to the strength of the Euro and Swiss franc compared to the U.S. dollar.

**Research and development**

	Year ended December 31,				
	2004 U.S.\$m	Change in %	2003 U.S.\$m	Change in %	2002 U.S.\$m
<b>Research and development</b>	<b>594.8</b>	<b>27.1</b>	<b>467.8</b>	<b>30.6</b>	<b>358.1</b>
<b>Research and development as a % of revenues</b>	<b>24.2</b>		<b>23.2</b>		<b>23.3</b>

Research and development expenses in 2004 reached \$594.8 million, or 24.2% of total revenues, compared to \$467.8 million, or 23.2% of total revenues, in 2003. Research and development expenses include the costs of several key new collaborative and license agreements that were signed with ZymoGenetics Inc., CancerVax Corporation and Micromet AG. We also continued to invest substantially in the pharmaceutical development of new molecules, most notably oncept and TACI-Ig. There were also significant investments in clinical development projects aimed at the development of oncept in psoriasis, Serostim for HARS in the U.S., the Raptiva study supporting the New Drug Application in Europe, which was granted in the third quarter of 2004, and the Rebif vs. Copaxone head-to-head study. Finally there were significant additional investments made in the discovery area, mainly in functional genomics aimed at identifying novel therapeutics proteins from the human genome, and the genetics work in the field of autoimmune diseases at the SeroGenetics Institute.

**Other operating expense, net**

Other operating expenses, net were \$227.1 million in 2004 compared to \$199.5 million in 2003, corresponding to an increase of 13.8% or 13.2% in local currencies. This increase was due to higher ongoing royalty expenses that were driven by higher sales of Rebif and additional royalty expenses related to royalty income received for Humira, Enbrel and Avonex.

**Operating income**

Our operating income increased by 20.5% to \$524.1 million in 2004 from \$434.9 million in 2003. As a percentage of total revenues, our operating income was 21.3% in 2004 compared to 21.5% in 2003.

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**Financial income, net**

	Year ended December 31,				
	2004 U.S.\$m	Change in %	2003 U.S.\$m	Change in %	2002 U.S.\$m
Financial income	68.2	36.8	49.8	(22.9 )	64.6
Financial expense	(24.0 )	85.4	(13.0 )	21.7	(10.6 )
Foreign currency gains/(losses)	19.1	167.1	7.2	140.8	(17.5 )
<b>Total financial income, net</b>	<b>63.3</b>	<b>43.7</b>	<b>44.0</b>	<b>20.6</b>	<b>36.5</b>

Financial income increased by \$18.4 million to \$68.2 million in 2004. The increase is due to a one-time gain on the forward purchase of shares in ZymoGenetics Inc. as part of a research and development collaboration that was entered into during the year. Financial income earned on the investment in corporate bonds also increased during 2004 by \$9.1 million which reflects the fact that the group held more financial assets during 2004 compared to 2003 despite the impact of the Share Buy Back Plans.

Financial expense increased during 2004 by \$11.0 million and reflects the impact of the convertible bond. We are paying annual coupon interest at the rate of 0.5%. In addition, financial expense also includes the non-cash amortization of the conversion feature as well as the redemption premium on the convertible bond if the bond is not converted which amounted to \$11.4 million.

Foreign currency gains increased by \$11.9 million and were a result of the gains on derivative instruments taken out to hedge the foreign currency exposure that we incur because of the disproportionate amount of our expenses that are incurred in currencies other than the U.S. dollar.

**Other expenses, net**

Other expenses decreased significantly in 2004. In 2003, we took a non-operating, non-recurring, non-cash charge of \$16.1 million related to the write-down of an equity investment as well as a \$4.0 million realized loss upon our sale of another equity investment.

**Taxes**

Our total taxes incurred as a percentage of income before taxes and minority interests increased slightly to a final rate of 15.5% compared to 15.0% in 2003.

**Net income**

Our net income increased by 26.7% to \$494.2 million in 2004 from \$390.0 million in 2003. Our net income represented 20.1% of total revenues, compared to 19.3% in 2003.

Exchange rate movements favorably impacted net income by \$17.2 million or 3.5%.

Our basic earnings per share grew by 31.3% from \$24.63 to \$32.35 per share. Our percentage increase in basic earnings per share outpaced our increase in net income due to the impact of treasury shares that were acquired during 2004 as a result of two Share Buy Back Plans. The weighted average number of shares outstanding used to calculate basic earnings per share decreased during 2004 by 556,007 shares resulting in an increase in our basic earnings per share of \$1.14 per share.

The first Share Buy Back Plan, authorized to repurchase CHF500.0 million worth of Serono bearer shares, was fully utilized by the end of May 2004. The second Share Buy Back Plan was authorized to repurchase CHF750.0 million worth of Serono bearer shares, of which CHF13.5 million remains unspent. Unlike the first Share Buy Back Plan, whereby shares acquired will be held until granted at some time in the future, shares acquired under the second Share Buy Back Plan will be cancelled subject to approval by shareholders at the Annual General Meeting of Shareholders.

**Year ended December 31, 2003 compared to year ended December 31, 2002**

The following compares our results in the year ended December 31, 2003 to those of the year ended December 31, 2002. Our analysis is presented as follows:

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1.	Overview
2.	Product sales by therapeutic area
3.	Product sales by region
4.	Operating expenses to net income

## 1. Overview

Our total revenues increased by 31.3% to \$2,018.6 million for the full year of 2003. Our total revenue growth in local currencies was approximately 20.9%, reflecting our strong underlying growth. Worldwide product sales were \$1,858.0 million in 2003, representing an increase for the year of 30.6%. Notwithstanding weakness in the U.S. dollar, product sales growth in local currencies was 19.9% in 2003. Sales growth was driven by an increase of 24.7% in the volume of the products sold that was partially offset by a decrease in the average selling price of our products due to changes in regional sales mix and decreases in sales prices.

Royalty and licensing income increased by 40.0% to \$160.6 million for the full year, reflecting the company's strong intellectual property rights.

In 2003, operating expenses increased by 33.3% to \$1,583.7 million or 78.5% of total revenues. Operating margin declined to 21.5% in 2003 from 22.7% in 2002 due to an increase in other operating expenses that reflects the in-licensing in of Novantrone and royalties paid to third parties as well as higher expenses from the amortization of intangible assets.

Net income increased by \$69.2 million or 21.6% and represented 19.3% of total revenues. Excluding the non-recurring, non-operating charges related to a \$16.1 million write-down of our investment in Swiss International Air Lines and a \$4.0 million loss on the sale of our investment in PowderJect Pharmaceuticals, net income increased by 26.9% or 19.4% in local currencies. We believe that it is useful to provide a calculation of our net income that excludes these non-recurring, non-operating charges, because it permits our investors to compare 2003 net income calculation with our net income from 2002 in order to better assess our operating performance. Net income per share increased by 22.7% from \$20.07 in 2002 to \$24.63 in 2003.

## 2. Product sales by therapeutic area

### Neurology

In 2003, neurology sales were up 54.9% (39.5% in local currency) to \$850.2 million. Rebif is the fastest growing MS product in the world, with full year sales growing by 49.3% or 34.1% in local currencies. Sales growth was driven by a volume increase of 43.3% in equivalent units; however, average selling price per equivalent unit in local currencies decreased by 6.4% during the year. The majority of the decrease in the proportion of Rebif sales derived from our 44 mcg dosage, which has a lower average selling price per equivalent unit compared to our 22 mcg dosage. Rebif is the market leader outside the U.S., where 2003 sales increased by 32.1% to \$630.8 million. Total Rebif sales in the U.S., our fastest growing region, were \$188.5 million in 2003, representing an increase in full year sales of 164.8%. Market share more than doubled during the year and, at the end of the year, the rolling 4-week share of total prescriptions was 13.4%. Rebif was the fastest growing disease modifying drug in multiple sclerosis in the U.S. in 2003. At the end of 2003, we estimated that our worldwide market share was approximately 24.4% compared to 19% at the end of 2002. Our target is to become U.S. and worldwide market leader in 2006.

We started promoting Novantrone for MS in 2003 in conjunction with OSI Pharmaceuticals, which is only responsible for marketing Novantrone for oncology. Sales of Novantrone were \$88.8 million in 2003.

**Reproductive health**

2003 was a very good year for our reproductive health franchise due to the success of our portfolio strategy and our focus on recombinant products. Our sales of our RH core infertility portfolio increased by 20.9% (or 10.7% in local currencies) to \$594.9 million in 2003 from \$492.0 million in 2002. Our sales of Gonal-f increased by 17.0% to \$526.9 million in 2003 from \$450.4 million in 2002. Sales growth of Gonal-f was driven by a volume increase of 9.7%; however, average selling price in local currencies decreased by 2.2% during the year. The growth in volumes was largely due to the increasing penetration of our multidose presentation and the launch of our fill-by-mass formulation.

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As a result of the continued switch to biotechnology products, our sales of Metrodin HP declined by 50.6% to \$24.8 million in 2003 from \$50.1 million in 2002. We expect that we will continue to gradually replace Metrodin HP with Gonal-f. Our sales of Pergonal decreased by 0.4% to \$45.8 million in 2003 from \$46.0 million in 2002.

### **Growth and metabolism**

Our growth and metabolism product sales increased by 9.6% (or 3.4% in local currencies) to \$240.2 million in 2003 from \$219.1 million in 2002. Our sales of Saizen increased by 22.1% to \$151.5 million in 2003 from \$124.0 million in 2002. Sales growth was driven by a volume increase of 8.5% and an increase in average selling price in local currencies of 2.3% during the year. Saizen's growth is largely due to our portfolio of innovative drug delivery devices, which greatly simplify administration of the drug for our patients. Our sales of Serostim decreased by 6.6% to \$88.7 million in 2003 from \$95.1 million in 2002, which corresponds to a decrease in sales volume of 10.1%. Serostim sales declined as a result of tighter control and usage guidelines in key U.S. states.

In December 2003, the Food and Drug Administration approved Zorbitive for use in the treatment of short bowel syndrome, a serious and potentially life-threatening condition. Additionally the FDA granted orphan drug status for the use of Zorbitive in this indication through December 2010.

### **3. Product sales by region**

#### **Europe**

Our total European product sales increased by 28.4% to \$796.8 million in 2003 from \$620.4 million in 2002. In local currencies, product sales increased by 10.1% from 2002. The increase was primarily due to the increased sales of Rebif and Gonal-f, which increased by \$122.7 million and \$57.7 million, respectively, and in local currencies by 16.9% and 9.8%, respectively. Sales of Metrodin HP decreased by \$15.7 million or 80.6% in 2003 and by 83.7% in local currencies.

#### **North America**

Our total North American product sales increased by 44.8% to \$694.3 million in 2003 from \$479.6 million in 2002. In North America, the increase was primarily due to the strong performance of Rebif which experienced a \$126.5 million increase in sales; strong first year U.S. sales of Novatrone of \$77.1 million; and an increase of sales of Saizen by \$14.5 million.

#### **Middle East, Africa and Eastern Europe**

In the Middle East, Africa and Eastern Europe regions, our product sales increased by 40.5% to \$151.2 million in 2003 from \$107.6 million in 2002, due primarily to the continued sales growth of Rebif and Gonal-f in these markets.

#### **Asia-Pacific, Oceania and Japan**

In the Asia-Pacific region, our product sales increased by 10.5% to \$61.0 million in 2003 from \$55.2 million in 2002, due largely to increased demand for Gonal-f and Rebif. In Oceania, our product sales increased by 31.6% to \$28.9 million in 2003 from \$21.9 million in 2002, due largely to higher Rebif and Gonal-f sales. In Japan, our product sales decreased by 6.3% to \$27.1 million in 2003 from \$29.2 million in 2002, due primarily to weakening demand for Saizen that was partially offset by higher sales of Metrodin HP.

#### **Latin America**

Our total Latin American product sales decreased by 9.5% to \$98.8 million in 2003 from \$109.2 million in 2002, which was principally the result of our sale of two companies in Latin America in connection with our withdrawal from the generics sector, which was not core to our business.

**Royalty and license income**

Our revenues from royalty and license income increased by 40.0% to \$160.6 million in 2003, compared to \$114.7 million in 2002. The increase was due primarily to higher royalty income from Amgen on its sales of Enbrel and new royalties from Abbott Laboratories on its sales of Humira that began at the end of the second quarter of 2003. The remaining increase in royalty income stems from higher maintenance fees received from Roche on its sales of Recormon and NeoRecormon, and from royalties received from Organon on its sales of Puregon.

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#### **4. Operating expenses to net income**

##### **Cost of product sales**

For the year ended December 31, 2003, cost of product sales as a percentage of product sales decreased to 15.0% from 15.7% in the prior year. The decrease was primarily the result of favorable changes in product mix and continuing manufacturing productivity gains and improvements leading to higher production yields. However, the effect of these factors was partially offset by stronger European currencies against the U.S. dollar during 2003. Product sales benefited from a favorable currency impact in 2003 of \$143.6 million while cost of product sales was adversely impacted by an unfavorable currency impact of \$22.1 million. As the proportion of recombinant products sales levels off upon the completion of our final phase-out of our urine-derived products, the rate at which our cost of product sales decreases, as a percentage of product sales, will decline.

##### **Selling, general and administrative**

Selling, general and administrative expenses increased to \$636.8 million in 2003 from \$504.2 million in 2002, which represents an increase of 26.3%, or 15.7% in local currencies. This increase was primarily in marketing and medical activities to support the growth of our sales and to support the promotion of Rebif in the U.S., as well as the launch of Gonal-f FbM in Europe. The increase was also the result of sales commissions related to co-promotion agreements signed in 2002 and 2003. Selling, general and administrative expenses represented 31.5% of revenues in 2003, compared to 32.8% in 2002.

##### **Research and development**

Our research and development expenses increased to \$467.8 million in 2003, which represents an increase of 30.6% or 17.8% in local currencies. This increase in our research and development expenses was due to the clinical development of Raptiva for launch in Europe including milestone payments to Genentech upon filing the application, and for the license extension to Asia; the pharmaceutical development of oncept and IL-18bp; and the functional genomic program as well as a full year of operating costs related to the Serono Genetics Institute (formerly Genset S.A.), which we acquired in late third quarter 2002.

##### **Other operating expense, net**

Our other operating expense, net was \$199.5 million in 2003, compared to \$85.8 million in 2002. The increase was due to higher ongoing royalty and licensing expenses driven by Novantrone and Rebif sales, and royalty expenses related to Humira, plus higher amortization of intangibles in the form of license payments that are amortized over the life of the license agreement, and higher amortization of goodwill from the acquisition of Genset S.A. Royalty and license expenses increased by \$85.4 million to \$120.1 million, amortization of intangible assets increased by \$7.6 million to \$30.4 million, and litigation and legal costs increased by \$12.4 million to \$25.7 million.

##### **Operating income**

Our operating income increased by 24.4% to \$434.9 million in 2003 from \$349.6 million in 2002. As a percentage of revenues, our operating income was 21.5% in 2003 compared to 22.7% in 2002.

##### **Financial income, net**

Financial income was lower in 2003 compared to the previous year due to generally lower interest rates. However, 2002 was adversely impacted by translation losses arising from various currency devaluations in Latin America such that our financial income net increased by \$7.5 million to \$44.0 million in 2003 compared to \$36.5 million in 2002.

**Other expense, net**

Other expense, net was \$19.7 million in 2003 compared to \$1.7 in 2002. We took a non-operating, non-recurring, non-cash charge of \$16.1 million related to the write-down of an equity investment in Swiss International Air Lines. Other expense, net also includes a \$4.0 million realized loss upon our sale of our investment in PowderJect Pharmaceuticals following Chiron's cash acquisition of 100% of the outstanding shares of PowderJect.

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## Taxes

Our total taxes increased by 9.2% to \$68.9 million in 2003 from \$63.1 million in 2002. Our tax rate (as a percentage of profit before taxes) decreased from 16.4% in 2002 to 15.0% in 2003 primarily due to the favorable close of prior fiscal years in various countries, which permitted a non-recurring reduction in certain tax provisions during 2003.

## Net income

Our net income increased by 21.6% to \$390.0 million in 2003 from \$320.8 million in 2002. Our net income represented 19.3% of total revenues, compared to 20.9% in 2002. Excluding the non-recurring, non-operating charges related to the \$16.1 million write-down of our investment in Swiss International Air Lines and the \$4.0 million loss on the sale of our investment in PowderJect Pharmaceuticals, net income represented 20.2% of our 2003 revenues. Exchange rate movements favorably impacted 2003 net income by \$23.5 million or 1.2% of total revenues, which represents \$1.48 per share.

Our basic earnings per share grew by 22.7% from \$20.07 to \$24.63 per share. Our percentage increase in basic earnings per share outpaced our increase in net income due to the impact of treasury shares that were acquired during 2002 and 2003 as a result of our Share Buy Back Plan that was initiated in July 2002. The weighted average number of shares outstanding used to calculate basic earnings per share decreased during 2003 by 153,416 shares resulting in an increase in our basic earnings per share of \$0.24 per share. The Share Buy Back Plan was authorized to repurchase CHF500.0 million worth of Serono bearer shares, of which CHF218.7 million has been spent. Using the share price of CHF882 as of December 31, 2003, we could repurchase 318,900 additional bearer shares, which would increase materially our earnings per share.

## Liquidity and capital resources

Our sources of liquidity have been a combination of cash generated from operations and investing activities, short-term and long-term financial debts, as well as two significant public financings. In 2000, we completed a global public offering of 1,070,670 bearer shares in the form of bearer shares and American depositary shares for net proceeds of \$951.8 million. In 2003, we issued CHF600.0 million (approximately \$444.8 million) of senior unsubordinated convertible bonds due November 2008, convertible into our bearer shares. As of December 31, 2004, we had unused lines of credit for short-term financing of \$365.3 million (2003: \$366.9 million). Our total financial assets, which are made up of cash and cash equivalents plus short-term and long-term financial assets, amounted to \$1,839.4 million.

The analysis of our cash flow is divided as follows:

1. Free cash flow and net cash flow from operating activities
2. Net cash flow used for investing activities
3. Net cash flow used for financing activities
4. Net financial assets

### 1. Free cash flow and net cash flow from operating activities

	Year ended December 31,		
	2004	2003	2002

	U.S.\$m	U.S.\$m	U.S.\$m
<b>Net cash flow from operating activities</b>	<b>471.7</b>	542.9	532.0
Purchase of tangible fixed assets	(178.9)	(162.5)	(99.1)
Purchases of intangible and other long-term assets	(55.0)	(30.8)	(25.2)
Interest paid	(4.2)	(4.3)	(8.1)
<b>Free cash flow</b>	<b>233.6</b>	345.3	399.6

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We present free cash flow as additional information as it is a useful indicator of our ability to operate without reliance on additional borrowing or use of existing cash. In addition, we feel that free cash flow is relevant to investors as it is a measure of the cash that is generated over and above what is required to sustain our current competitive position. It is our ability to generate free cash flow that funds our research and development activities, business development activities including the in-licensing of new products, the repayment of financial debts and the payment of dividends. We also use free cash flow to evaluate the performance of our businesses.

Our commercial operations generated cash flow from operating activities in the amount of \$471.7 million, which is a decrease of \$71.2 million compared to 2003. Cash flow from operating activities before working capital changes increased in 2004 by \$51.2 million to \$589.9 million in 2004. Income before taxes and minority interests increased in 2004 by \$127.6 million due to higher product sales and royalty and license income. Depreciation and amortization was higher in 2004 because of the additional depreciation recognized during the year from the closure of our manufacturing operations in Israel.

Financial income and unrealized foreign currency gains, that are deducted from net income to arrive at operating cash flow, were higher in 2004 by \$42.8 million, due to an unrealized gain on the forward purchase of shares in ZymoGenetics Inc. of \$8.6 million; an increase in interest income earned on bond investments of \$9.1 million; and an increase in unrealized foreign exchange gains of \$24.5 million.

Other non-cash items, that are deducted from net income to arrive at operating cash flow amounted to \$52.2 million, relating mostly to the release of deferred income from up-front payments received from our co-promotion partners, Pfizer Inc. and OSI Pharmaceuticals Inc.

The amount of operating cash flow that was lost due to increases in working capital in 2004 was \$118.2 million compared to a decrease of \$4.2 million in working capital during 2003.

The increase in trade and other payables, other current liabilities and deferred income provided \$127.9 million in operating cash flow, which represents an increase of \$23.4 million compared to 2003. Increases in these current liabilities were related to an increase in accrued research and development expenses incurred as part of new collaborative agreements that were signed in the fourth quarter of 2004.

The increase in trade accounts receivable and other receivables erased \$141.2 million of operating cash flow compared to only \$34.2 million in 2003. This increase in 2004 reflects the sales-driven increase in trade accounts receivable during 2004 versus 2003, as well as a new receivable related to the licensing agreement of a non-core technology signed in the third quarter of 2004 (\$60.0 million).

Taxes paid during 2004, that are recognized as a reduction of operating cash flow, increased during 2004, reaching \$100.9 million compared to \$89.6 million in 2003. The increase in 2004 was due mostly to higher income taxes paid in Switzerland.

Inventory levels were reduced during 2004 and thus provided \$24.2 million of operating cash flow despite the fact that inventory as reported within the balance sheet, increased during 2004, by \$7.1 million. The increase in reported inventories included a currency impact, which is eliminated when calculating operating cash flow. After removing the currency impact, inventory decreased during 2004 by \$24.2 million.

## **2. Net cash flow used for investing activities**

Net cash used for investing activities was \$322.1 million in 2004. Our cash paid for investment in tangible fixed assets totaled \$178.9 million. This includes \$52.7 million spent on our new headquarters and Swiss-based research and development activities. In 2003, we exercised an option to purchase a 40,000 square meter section of land that is near

our current headquarters in Geneva for the purpose of bringing together on a single site our headquarters and Swiss-based research and development activities and to support our anticipated growth. We expect to complete the work on the first phase of this facility by the end of 2006. The estimated cost of the facility, including land and construction costs, is \$278.9 million (CHF315.8 million) and a further \$48.8 million (CHF 55.3 million) for completion of the laboratories and offices. The total capital commitments related to this project as of December 31, 2004 are CHF200.8 million or \$177.3 million. The entire project is being financed with bank debt.

We acquired 3.2 million newly issued shares in ZymoGenetics Inc. as part of a research and development collaboration. We paid a fixed price of \$15.74 per share for a total amount of \$50.0 million. We also acquired \$787.9 million in financial assets consisting of fixed-rate investments in rated Eurobonds denominated in U.S. dollars with maturities up to three years and short-term money market funds. We received a combined amount of \$654.6 million from the maturity of a portion of the bond portfolio as well as from the sale of bonds, some of which included bonds that were previously classified as held-to-maturity. The sale of held-to-maturity bonds required us to reclassify the remaining held-to-maturity portfolio as available-for-sale, whereby changes in fair values are recognized as fair value reserves within shareholders' equity, and prevents us from classifying any current or future bond investment as held-to-maturity for the next two years regardless of our intention or ability to hold such bonds to their maturities.

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In 2005, we expect to increase our level of investment in tangible fixed assets by approximately 10% to 20% compared to 2004. All capital expenditure excluding the construction of our new headquarters and research and development center will be funded with resources generated from our operations.

### **3. Net cash flow used for financing activities**

Net cash flow used for financing activities was \$878.3 million, of which \$811.7 million was spent as part of two Share Buy Back Plans. The first plan, which was initiated in July 2002, was authorized to acquire CHF500.0 million worth of bearer shares. The shares acquired during the year under this Share Buy Back Plan, 351,209 bearer shares for a total cost of CHF280.9 million or \$221.8 million, will eventually be re-issued. This first Share Buy Back Plan was fully utilized at the end of May 2004.

Subsequent to the completion of the first Share Buy Back Plan, we obtained authorization from the Board of Directors of Serono S.A. to launch a second Share Buy Back Plan for the total amount of CHF750.0 million. The shares acquired under this plan will be eventually cancelled, subject to the approval of the Annual General Meeting of Shareholders. During 2004, 962,435 bearer shares were acquired under this plan for a total value of CHF736.5 million or \$611.3 million. The actual cash paid to acquire shares under the second Share Buy Back Plan was \$21.4 million less, which represents that amount of withholding taxes that will eventually be remitted to the Swiss tax authority.

We paid \$99.4 million in dividends to investors in 2004, an increase of \$13.6 million compared to 2003. The dividend per share declared and paid in 2004 was CHF8.00, compared to the prior year dividend of CHF7.00.

We increased the amount of financial debts during the year by CHF58.9 million or \$48.7 million. In 2003, we obtained a CHF300.0 million medium term bank facility for the development of our new headquarters and research center in Geneva, Switzerland. This unsecured facility is guaranteed by Serono S.A. and has a maturity date of December 31, 2006. As of December 31, 2004, the amount drawn under the facility was CHF131.5 million or \$116.1 million.

### **4. Net financial assets**

We had total financial assets (cash and cash equivalents, short-term financial assets and long-term financial assets not including long-term equity investments in non-group companies) of \$1,839.4 million. Net financial assets (total financial assets less short and long-term financial debts) as of December 31, 2004 were \$1,164.0 million, and decreased by \$743.2 million during the year. The following table sets out the components and the total amount of net financial assets for the last three years.

	For the year ended		
	2004 U.S.\$m	2003 U.S.\$m	2002 U.S.\$m
Net cash flow from operating activities	471.7	542.9	532.0
Net cash flow used for investing activities	(322.1)	(556.2)	(690.4)
Net cash flow used for financing activities	(878.3)	322.4	(299.1)
Effect of exchange rate changes on cash and cash equivalents	0.7	8.8	12.4
Change in cash and cash equivalents	(728.0)	317.9	(445.1)
Change in short-term and long-term financial assets	77.0	437.2	516.1
Change in short-term and long-term financial debts	(92.2)	(463.8)	91.1
Change in net financial assets	(743.2)	291.3	162.1
Net financial assets as of January 1	1,907.2	1,615.9	1,453.8
<b>Net financial assets as of December 31</b>	<b>1,164.0</b>	<b>1,907.2</b>	<b>1,615.9</b>
Consists of			
Cash and cash equivalents	275.9	1,004.0	686.0
Short-term financial assets	785.0	434.8	378.9
Long-term financial assets	929.0	1,104.3	711.2
Less: Investments in non-group companies	(150.5)	(52.7)	(40.7)
<b>Total financial assets</b>	<b>1,839.4</b>	<b>2,490.4</b>	<b>1,735.4</b>
Short-term financial debts	(34.5)	(51.2)	(93.6)
Long-term financial debts	(640.9)	(532.0)	(25.9)
<b>Total financial debts</b>	<b>(675.4)</b>	<b>(583.2)</b>	<b>(119.5)</b>
<b>Net financial assets</b>	<b>1,164.0</b>	<b>1,907.2</b>	<b>1,615.9</b>

We believe that our existing net financial assets, cash generated from operations, and unused sources of debt financing will be adequate to satisfy our working capital and capital expenditure requirements during the next several years. However, we may raise additional capital from time to time for other strategic purposes.

### Contractual cash obligations

Our future minimum non-cancelable contractual obligations as of December 31, 2004 are described below:

Contractual obligation	Total	Payments due by year (in U.S.\$m)			
		Less Than 1 year	1-3 years	4-5 years	After 5 years
Financial debts	647.9	7.0	630.8	3.7	6.4
Operating lease	141.9	33.5	55.6	20.5	32.3
Capital lease	0.1	0.1	-	-	-
Capital commitments	180.9	92.3	88.6	-	-
Total	970.8	132.9	775.0	24.2	38.7

The capital commitments relate mostly to the construction costs and contractors' compensations for the construction of the new headquarters and research center in Geneva, which is expected to be completed by the end of 2006. Given our ability to generate consistent and significant operating cash flow, we do not anticipate difficulty in renegotiating our borrowings should this be necessary.

In addition to the amounts disclosed above, we have a number of commitments under collaborative agreements as described in note 32 to the consolidated financial statements. As part of these agreements we have made commitments to make research and development payments to the collaborators, usually once milestones have been achieved, but in

some cases on a regular basis. We do not consider any single collaborative agreement to be a sufficiently large commitment that it could impair significantly our financial condition. In the unlikely event that all the collaborators were to achieve all the contractual milestones, we would be required to pay approximately \$726.3 million. The exact timing of eventual payments is uncertain, but it would be over a period of 10 years.

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Assets with an original cost of \$30.7 million as of December 31, 2004 (2003: \$65.1 million) have been pledged as security against long-term financial debts and certain unused long-term line of credits.

### **Inflation**

Our results in recent years have not been significantly affected by inflation or changes in prices related to inflation.

### **Recent accounting pronouncements**

You can find a discussion of recent accounting pronouncements related to IFRS and U.S. GAAP applicable to our company in note 36 to our consolidated financial statements. In addition, you can find a discussion of the potential impact of some IFRS exposure drafts published by the International Accounting Standards Board that could have a material impact on our results.

## **Item 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

### **Board of Directors**

Directors are elected each year at our Annual General Meeting and serve until the following Annual General Meeting, which must be held within six months after the end of each financial year.

<u>Name</u>	<u>Age (1)</u>	<u>Position</u>
Georges Muller	65	Chairman
Ernesto Bertarelli	39	Vice-Chairman and Managing Director
Jacques Theurillat	45	Director
Pierre E. Douaze	64	Director
L. Patrick Gage	63	Director
Bernard Mach	71	Director
Sergio Marchionne	52	Director
Hans Thierstein	73	Director

(1) As of February 15, 2005

*Georges Muller* has been the Chairman of our board since 1999 and a board member since 1992. He has practiced law with the firm of Bourgeois, Muller, Pidoux & Partners in Lausanne, Switzerland for over 25 years and has been of counsel with that firm since 1987. He retired as professor of commercial law at the University of Lausanne School of Law in June 2000 and currently holds the title of Honorary Professor. He is Chairman of the board of directors of SGS SA and The 2000 Management Corporation, and Vice-Chairman of Bertarelli & Cie. He is a director of S.I. Château de Bonmont S.A., Schweizerische Lebensversicherung und Rentenanstalt, Swiss Life Holding, Schindler Aufzüge AG, Actafinance S.A., Animan Publications S.A., Lavotel S.A., Kedge Capital Partners Ltd. and Kedge Capital Services Ltd. He participates on the boards of various foundations and associations, namely Fondation pour la création d'un musée des Beaux Arts, Lausanne (Chairman); Institut Suisse de Recherche Expérimentale sur le Cancer (Chairman); and World Arts Forum. He has worked at the Federal Tax Administration, Division of International Tax Law, in Berne, Switzerland and at Union Bank of Switzerland in Lausanne, Switzerland. Mr. Muller received a PhD in law and degree in business administration (HEC) at the University of Lausanne. He also has received an LLM from Harvard University. Mr. Muller is a Swiss national and resident.

*Ernesto Bertarelli* is our Chief Executive Officer. He is also Vice-Chairman and the Managing Director of our board. Prior to his appointment as Chief Executive Officer in January 1996, Mr. Bertarelli served for five years as Deputy

Chief Executive Officer and Vice-Chairman of the board, where he was responsible for finance and operations. Mr. Bertarelli began his career with us in 1985, since which time he has held several positions of increasing responsibility in sales and marketing. Mr. Bertarelli is the Chairman of Bertarelli & Cie, Kedge Capital Partners Ltd, Alinghi Holdings Ltd and Team Alinghi SA. He is a director of UBS AG, PHRMA, BIO, European Federation of Pharmaceutical Industries and Associations and the Bertarelli Foundation. He is also a member of the Harvard Medical School Biological Chemistry and Molecular Pharmacology Advisory Council. He received a BS degree from Babson College in Boston, Massachusetts, and an MBA from Harvard Business School. Mr. Bertarelli is a Swiss national and resident.

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Jacques Theurillat has been our Deputy Chief Executive Officer since May 2002 and has been a director since May 2000. Mr. Theurillat also serves as our President of European and International Sales & Marketing and served as our Acting Chief Financial Officer during 2004, until the appointment of Stuart Grant. He previously served as our Chief Financial Officer from 1996 until October 2002. Prior to that, Mr. Theurillat was Managing Director of our operations in Italy. He began his career with us in 1987. Mr. Theurillat has law degrees from Madrid University and Geneva University and holds a Swiss Federal Diploma (Tax Expert). He also received an MBA from the Madrid School of Finance. Mr. Theurillat is a Swiss national and a resident of Switzerland.

*Pierre E. Douaze* has been a director since 1998. Until 1998, he was a member of the executive committee and former chief executive officer of the healthcare division of Novartis, the company that resulted from the merger of Sandoz and Ciba Geigy. Before that merger in 1997, Mr. Douaze worked at Ciba Geigy, where he served in various capacities beginning in 1970. In 1991, he became a member of Ciba Geigy's executive committee, with responsibility for healthcare. He currently serves as a board member of the Galenica Group, Switzerland and Chiron Corporation. Mr. Douaze received a MS degree from the Federal Polytechnical School and an MBA from INSEAD Fontainebleau. Mr. Douaze is a French national and a resident of Switzerland.

*L. Patrick Gage* has been a director since May 2004. Dr. Gage is a partner in Flagship Ventures, an entrepreneurship and venture capital firm formed to create and finance companies in the life sciences, information technology and communications sectors. From 1997 until 2002, Dr. Gage held various positions at Wyeth. From March 1998 through June 2002, he served as President of Wyeth Research, a division of Wyeth, and from 2000 through June 2002, Dr. Gage also served as Senior Vice President, Science and Technology of Wyeth. From 1989 through March 1998, Dr. Gage served as the head of Research and Development, then Chief Operating Officer and finally, after that company had been acquired by Wyeth, as President of Genetics Institute. Prior to 1989, Dr. Gage held various positions in research management at Hoffmann-La Roche Inc. over an 18-year period. Dr. Gage is also a director of Neose Technologies, Inc. and Protein Design Labs, Inc., serves as Chair of the Life Sciences Advisory Board (SAB) for Perkin Elmer Inc., is a member of the SAB of Functional Genetics, a private biotech company, and serves on the Scientific Advisory Board for Warburg Pincus, a private equity investment company. In addition, Dr. Gage is a director of two non-profit organizations, the Biotechnology Institute and the Philadelphia Orchestra Association. Dr. Gage has a BS in physics from the Massachusetts Institute of Technology and a PhD from The University of Chicago. Dr. Gage performed postdoctoral research at the Carnegie Institution of Washington. Dr. Gage is a United States national and resident.

*Bernard Mach* has been a director since 1997. He retired from the University of Geneva Medical School in 1998. Until then, Dr. Mach was the chairman of the department of genetics and microbiology and of the graduate program in molecular and cellular biology, and he was the Louis Jeantet Professor of Molecular Genetics. Dr. Mach is a former member of the Swiss Science Council, the scientific advisory board to the Swiss government, and a former president of the Union of Swiss Societies for Experimental Biology. He is also a founder and former board and SAB member of Biogen, founder and chairman of the scientific board of Lombard Odier Immunology Fund, and founder and chairman of NovImmune S.A. Dr. Mach is the Vice-Chairman of Lonza Group AG. Dr. Mach received an MD degree from the University of Geneva and a PhD degree from Rockefeller University in New York and did his internship and residency at the Massachusetts General Hospital/Harvard Medical School. Dr. Mach is a member of the French Academy of Science. He is a Swiss national and resident.

*Sergio Marchionne* has been a director since May 2000. Since June 2004, Mr. Marchionne has been Chief Executive Officer of Fiat SpA, whose board of directors he joined in May 2003. From February 2002 to June 2004, Mr. Marchionne served as Chief Executive Officer and Managing Director of SGS SA. Mr. Marchionne continues to serve as Vice Chairman of SGS SA. From October 1999 until February 2002, Mr. Marchionne served as Chief Executive Officer of Lonza Group AG, which was spun-off from Alusuisse-Lonza Group in October 1999. Mr. Marchionne still serves as Chairman of Lonza Group AG. Prior to that he worked at Alusuisse-Lonza Group in various capacities, including Chief Financial Officer, and from 1997 as Chief Executive Officer. Mr. Marchionne received an LLB from



Osgoode Hall Law School in Toronto, Canada and an MBA from the University of Windsor, Canada. He is a barrister and solicitor and a Chartered Accountant. Mr. Marchionne holds dual Canadian and Italian nationalities and is a resident of Switzerland.

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*Hans Thierstein* was the Chairman of our board from 1992 until 1999 and has been a board member since 1987. He served as our Chief Financial Officer from 1980 until 1996. Before joining us, Mr. Thierstein was associated with ICN Pharmaceuticals from 1971 to 1980 where he served as treasurer and controller Europe, as vice president and corporate controller in the United States, as general manager of the Swiss and Italian operation, and as vice president of corporate development Europe. Prior to that, he was treasurer and area financial manager and a director of Chesebrough-Pond's, Europe for nine years. In addition, his professional experience includes five years in public accounting, of which four years was with Price Waterhouse, Zurich. From 1996 to 2000, Mr. Thierstein served as a member of the board of the Swiss Society of Chemical Industries. He received a diploma in Commerce and Administration from the Commercial School Meiringen, Switzerland (with an Apprenticeship in district court of justice/debtors and bankruptcy court) and obtained a certificate of the preliminary examination of the Swiss Certified Public Accountants Chamber. Mr. Thierstein is a director of Temtrade S.A. Mr. Thierstein is a Swiss national and resident.

## Executive Officers

The current members of our Executive Management Board, who constitute our executive officers, are:

<b><u>Name</u></b>	<b><u>Age (1)</u></b>	<b><u>Position</u></b>
Ernesto Bertarelli	39	Chief Executive Officer
Jacques Theurillat	45	Deputy Chief Executive Officer; President of European and International Sales and Marketing
Roland Baumann	59	Senior Executive Vice-President, Group Compliance Officer and Head of Corporate Administration
Leon Bushara	38	Senior Executive Vice-President, Business Development
Giampiero De Luca	50	Chief Intellectual Property Counsel
Fereydoun Firouz	41	President, Serono, Inc.
Stuart Grant	49	Chief Financial Officer
Franck Latrille	47	Senior Executive Vice-President, Global Product Development
François Naef	42	Senior Executive Vice-President, Human Resources, Legal and Corporate Communication
Timothy Wells	42	Senior Executive Vice-President, Research

(1)

As of February 15, 2005

*Roland Baumann* is our Senior Executive Vice-President, Group Compliance Officer and Head of Corporate Administration. Prior to his appointment to this position in February 2004, he was our Senior Executive Vice-President, Head of the CEO Office, Corporate Strategic Planning & Corporate Administration and Head of Group Internal Audit. From March 2000 to March 2003, he was our Senior Vice President, Strategic Business Planning and Corporate Administration, Head of Internal Audit. Before his appointment to that position, Mr. Baumann worked for us in positions of increasing responsibility related to finance, information systems, internal audit and strategic business planning from 1991. Before joining us, Mr. Baumann was a senior vice president with La Suisse Assurances, where he was the head of business process engineering and finance and accounting services. Mr. Baumann holds a degree in economics and business administration from the Ecole Supérieure des Cadres pour l'Economie et l'Administration in Basel. He is a Swiss national and resident.

*Leon Bushara* is our Senior Executive Vice-President, Business Development. Before his appointment to that position in 1996, Mr. Bushara worked in positions of increasing responsibility in our Business Development department since 1993. Prior to joining us, Mr. Bushara founded and managed a chain of cafés and restaurants in New York City from 1988 until 1993. Mr. Bushara holds a BA degree from Brown University. He is a United States national and a resident of Switzerland.

*Giampiero De Luca* is our Chief Intellectual Property Counsel. Prior to his appointment to this position in November 1999, Mr. De Luca worked for us in positions of increasing responsibility related to intellectual property and product development from 1988. Prior to joining us, Mr. De Luca worked as a patent examiner at the European Patent Office, where he focused on patents related to genetic engineering. Mr. De Luca holds a doctoral degree in industrial chemistry from the University of Milan and a diploma from the Institut Pasteur in general microbiology. He is a chartered European patent attorney, chartered Italian patent attorney, and chartered attorney before the Office for Harmonization in the Internal Market. Mr. De Luca is an Italian national and a resident of Switzerland.

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*Fereydown Firouz* is President of Serono, Inc., our U.S. operating subsidiary. From 2001 until March 2003, he was Executive Vice President, Reproductive Health, of Serono, Inc. Prior to his appointment to that position in 2001, Mr. Firouz worked in positions of increasing responsibility in our sales and marketing operation from 1991 and in our government affairs office in Washington, D.C. from 1989 to 1991. Mr. Firouz holds a BS degree in political science from George Washington University in Washington, D.C. He has participated in the Executive Program on General Management at the F.W. Olin Graduate School of Business at Babson College in Massachusetts. He is a Swiss national and a resident of the United States.

*Stuart Grant* is our Chief Financial Officer. Prior to this appointment in November 2004, Mr. Grant served for almost three years as Chief Financial Officer of Serono, Inc., our U.S. operating subsidiary. Mr. Grant joined us from Digital Equipment Corporation in 1995, and has held various senior financial and general management positions of increasing responsibility since that time. Mr. Grant has over 25 years of financial and business management experience in the high technology sector, in both the corporate and field environments. Mr. Grant received a Bachelor of Accountancy from the University of Glasgow, and is a Chartered Accountant. He is a British national.

*Franck Latrille* is our Senior Executive Vice-President, Global Product Development. Prior to his appointment to this position in March 2003, Mr. Latrille was our Senior Executive Vice-President, Manufacturing Operations and Process Development. Before that, he served for three years as our General Manager, Italian manufacturing operations. From 1994 to 1997, he served as general manager of Sorebio, which he co-founded in 1987. Mr. Latrille joined us in 1994, following our acquisition of Sorebio. Mr. Latrille holds a PhD degree in animal physiology and biochemistry and an MS degree from the University of Bordeaux. He is a French national and resident.

*François Naef* is our Senior Executive Vice-President, Human Resources, Legal and Corporate Communication. Prior to his appointment to this position in February 2004, he was our Senior Executive Vice-President, Human Resources. From November 1999 to February 2001, Mr. Naef served as our General Counsel. He had previously worked in positions of increasing responsibility in our legal department from 1988. Mr. Naef also serves as Company Secretary. Prior to joining us, Mr. Naef was an attorney at the Geneva law firms of Combe & de Senarclens and Me Rossetti. Mr. Naef also serves as General Manager of Serono International SA, one of our principal subsidiaries. He is also a member of the Board and Executive Committee of the Geneva Chamber of Commerce as well as a member of the Economic Council of the State of Vaud. Mr. Naef holds a law degree and a master's degree in European law from the University of Geneva. Mr. Naef was admitted to the Geneva Bar in 1986. He is a Swiss national and resident.

*Timothy Wells* is our Senior Executive Vice-President, Research. Prior to his appointment to this position in March 2003, he served as our Vice-President Research, Head of Discovery, where he was responsible for integrating the discovery research in our global organization. Mr. Wells joined us from Glaxo Wellcome in 1998, where he had held a number of positions of increasing responsibility. Mr. Wells holds a PhD degree in protein engineering from Imperial College, London, and a MA degree in natural sciences from the University of Cambridge and is a fellow of the Royal Society of Chemistry. He is a British national and a resident of France.

## **Compensation**

During the year ended December 31, 2004, we paid our directors and executive officers as a group, for services in all capacities, \$24,991,571. Of this amount, we paid \$6,637,849 pursuant to a bonus plan, which provides for payments to executive officers based on their performance and the performance of our company. During the year ended December 31, 2004, we set aside or accrued \$797,840 to provide pension, retirement or similar benefits for our executive officers. During the year ended December 31, 2004, we granted to our directors and executive officers options to purchase 38,010 bearer shares at an exercise price of CHF 782, expiring on March 31, 2014, and options to purchase 5,200 bearer shares at an exercise price of CHF 772, expiring on June 1, 2014. The amount we show above as paid to our directors and executive officers as a group includes the tax value of these stock options calculated based on the Black-Scholes option pricing model. In 2004, we allotted a total of 2,661 bearer shares to our directors and executive

officers. During the year ended December 31, 2004, we paid our most highly compensated director a total of \$5,864,353, inclusive of fees, salaries, credits, bonuses and benefits of every kind valued according to market value at the time they were conferred. This amount also includes the tax value of stock options granted during the year calculated based on the Black-Scholes option pricing model.

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None of our directors has a service contract with us or any of our subsidiaries that provides for benefits upon termination of their mandate.

## **Board Committees**

### *Audit Committee*

In 2001, the Board of Directors established an Audit Committee consisting of Sergio Marchionne (Chairman), Pierre E. Douaze and Hans Thierstein, all non-executive directors. While these directors all have sufficient financial and compliance experience and ability to enable them to discharge their responsibilities as members of the Audit Committee, Sergio Marchionne is our designated Financial Expert on the Audit Committee. In discharging its oversight role, the Audit Committee is empowered to investigate any matter relating to our accounting, auditing, internal control, or financial reporting practices brought to its attention, with full access to all of our books, records, facilities and personnel.

The Audit Committee has the following responsibilities:

- Review with the selected independent auditors for the company the scope of the prospective audit, the estimated fees thereof and such other matters pertaining to such audit as the Committee may deem appropriate and receive copies of the annual comments from the independent auditors on accounting procedures and systems of control (Management Letter);
- Ensure that the independence of the independent auditors is maintained;
- Review with the independent auditors any questions, comments or suggestions they may have regarding the internal control, accounting practices and procedures of the company and its subsidiaries;
- Review and oversee the internal audit activities, including discussing with management and the internal auditors the internal audit function's organization, objectivity, responsibilities, plans, results, budgets and staffing;
- Discuss with management, the internal auditors and the independent auditors the quality and adequacy of the compliance with the company's internal controls;
- Receive summaries of the audit reports issued by the internal audit department;
- Review with management and the independent auditors the annual audited financial statements of the company and the quarterly financial statements and any material changes in the accounting principles or practices used in preparing the statements prior to publication and the filing of reports with the SWX Swiss Exchange and the filing of the report on Form 20-F with the U.S. Securities and Exchange Commission;
- Discuss with management and the company's General Counsel any legal matters (including the status of pending litigation) that may have a material impact on the company's financial statements and any material reports or inquiries from regulatory or governmental agencies which could materially impact the company's contingent liabilities and risks;
- Make or cause to be made, from time to time, such other examinations or reviews as the Committee may deem advisable with respect to the adequacy of the systems of internal control and accounting practices of the company and its subsidiaries and with respect to accounting trends and developments and take such action with respect thereto as may be deemed appropriate;

·Subject to approval by the shareholders, recommend annually the public accounting firm to be the independent auditors for the company;

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- Set the compensation of the independent auditors and pre-approve all audit and non-audit related engagements performed by the independent auditors;
- Resolve issues related to conflicts of interests involving members of the Board of Directors or the Executive Management Board; and
- Engage independent counsels and other advisors as it deems necessary to carry out its duties.

The Audit Committee maintains free and open communication throughout the year with the independent auditors, the internal auditors and our management, in particular the Chief Executive Officer and Managing Director, the Chief Financial Officer and the Senior Executive Vice-President, Human Resources, Legal and Corporate Communication. Its Chairman is responsible for the leadership of the Audit Committee, including scheduling and presiding over meetings, preparing agendas and making regular reports to the Board of Directors. The Audit Committee meets at least four times a year or more, if required. In 2004, the Audit Committee held six sessions. The external auditors attended all of these sessions.

### ***Compensation Committee***

In 2001, the Board of Directors also established a Compensation Committee, which consisted as of December 31, 2004, of Pierre E. Douaze (Chairman), Sergio Marchionne and Hans Thierstein, all non-executive directors. The Compensation Committee ensures that our senior executives are compensated in a manner consistent with our stated compensation strategy, internal equity considerations, competitive practice, and applicable legal requirements.

The Compensation Committee submits to the Board of Directors for approval the principles to be applied for the remuneration of the members of the Board of Directors and of our executives.

The Compensation Committee reviews as often as necessary, but no less than one time per year, the compensation plans for our executives to ensure that such plans are designed to effectively attract, retain and reward our executives, to motivate their performance in the achievement of our business objectives and to align their interest with the long-term interest of the shareholders. In particular, the Compensation Committee ensures that:

- The company's annual incentive plans for executives are properly administered as to participation in these plans, alignment of awards with the company's financial goals, actual awards paid to executive officers and total funds reserved for payments under these plans; and
- The company's long-term plans for executives are properly administered as to participation in these plans, alignment of awards to the achievement of the company's long-term goals, key personnel retention objectives and shareholders' decisions concerning the use of capital for management incentive plans.

The Compensation Committee reviews annually and determines the individual elements of the compensation of the Chief Executive Officer.

The Compensation Committee reviews annually the individual elements of the compensation of our senior officers who report to the Chief Executive Officer, ensuring that the objectives defined in the Compensation Committee Charter are met.

The Compensation Committee reviews and recommends to the Board of Directors for approval the remuneration of the members of the Board.

The Compensation Committee is also responsible for:



- Approving our stock option plans and any modification thereof;
- Approving the number of options which are granted to the Chief Executive Officer; and
- Approving the global number of options that the Chief Executive Officer is authorized to distribute to senior management during the year.

In addition, the Compensation Committee makes a recommendation to the Board on all reports that the company is required to make to shareholders pursuant to legal or regulatory requirements in the area of executive compensation.

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The Compensation Committee also makes a recommendation to the Board on all proposals for incentive plans that require shareholders' approval, including proposals to create share capital for compensation plans.

The Compensation Committee reports to the Board on its activities at least once in each calendar year. Its Chairman is responsible for summoning meetings, preparing the agenda and ensuring that members of the Compensation Committee receive proper documentation prior to meetings. The Managing Director and Chief Executive Officer is invited to attend meetings of the Compensation Committee, except when discussions are held on his remuneration. In 2004, the Compensation Committee met once and adopted two circulating board resolutions. Its Chairman regularly and openly communicated throughout the year with our management, in particular the Chief Executive Officer and Managing Director, the Chief Financial Officer and the Senior Executive Vice-President, Human Resources, Legal and Corporate Communication.

### **Employees**

As of December 31, 2004, 2003 and, 2002, respectively, we had 4,902, 4,577 and 4,617 employees, of whom 1,387, 1,346 and 1,348, respectively, were engaged in research and development, 2,084, 1,746 and 1,673, respectively, were engaged in sales and marketing, 1,005, 1,082 and 1,215, respectively, were engaged in manufacturing and 426, 403 and 380, respectively, were engaged in other areas such as finance, information technology and human resources. As of December 31, 2004, 2003 and 2002, respectively, we had 3,235, 3,115 and 2,900 employees in Europe, approximately 727, 725 and 655 employees in North America, approximately 205, 180 and 300 employees in Latin America and approximately 735, 555 and 840 employees in the rest of the world. In addition, we maintain consulting arrangements with a number of scientists at various universities and other research institutions in Europe, Israel and the United States. In Europe, our employees are covered by customary collective bargaining agreements. In the United States, none of our employees is covered by a collective bargaining agreement. We have experienced no work stoppages, and we consider our employee relations to be good.

### **Share Ownership**

As of December 31, 2004, Bertarelli & Cie, a partnership limited by shares with its principal offices at Chésereux (Vaud), Switzerland, held 51.43% of our capital, including treasury shares, and 65.36% of our voting rights. Ernesto Bertarelli, our Chief Executive Officer, Vice-Chairman and Managing Director, controls Bertarelli & Cie.

As of December 31, 2004, there were 11,738,175 bearer shares, including 1,611,434 treasury shares, and 11,013,040 registered shares outstanding. The following table sets forth the ownership of our voting securities by all of our directors and current executive officers as individuals and as a group. For the purposes of calculating percentages shown in the table, the 1,611,434 treasury shares are deemed not to be outstanding.

Name of Owner	Registered Shares Owned	Percent of Registered Shares	Bearer Shares Owned	Percent Of Bearer Shares	Aggregate Voting Percent
Ernesto Bertarelli (1)	9,973,200	90.6	4,753,289	46.9	69.6
Roland Baumann	0	0	*	*	*
Leon Bushara	0	0	*	*	*
Giampiero De Luca	0	0	*	*	*
Pierre E. Douaze	0	0	*	*	*
Fereydoun Firouz	0	0	*	*	*
L. Patrick Gage	0	0	*	*	*
Stuart Grant	0	0	*	*	*
Franck Latrille	0	0	*	*	*
Bernard Mach	0	0	*	*	*
Sergio Marchionne	0	0	*	*	*
Georges Muller	0	0	*	*	*
François Naef	0	0	*	*	*
Jacques Theurillat	0	0	*	*	*
Hans Thierstein	0	0	*	*	*
Timothy Wells	0	0	*	*	*
All directors and executive officers as a group (16 persons) (1)(2)	9,973,200	90.6	4,780,223	47.1	69.7

\*

Less than one percent.

(1)Includes all registered shares and bearer shares reported by Bertarelli & Cie. Ernesto Bertarelli controls Bertarelli & Cie. Includes 9,800 bearer shares that we may issue to Mr. Bertarelli upon the exercise of stock options.

(2)Includes 31,709 bearer shares that we may issue if our directors and current executive officers exercise stock options. As of December 31, 2004, our directors and current executive officers held a total of 102,155 stock options, which have the following exercise prices and expiration dates:

Number of Outstanding Options Held By Our Directors and Current Executive Officers	Exercise Price in CHF	Expiration Date
1,320	522.50	June 17, 2005
2,290	546.25	April 1, 2008
2,755	546.00	April 1, 2009
6,400	512.50	June 10, 2009
3,530	1,520.50	April 1, 2010
3,200	1,397.50	May 16, 2010
7,650	1,346.00	April 1, 2011
8,100	1,434.00	April 1, 2012
1,500	810.00	November 11, 2012
17,600	649.00	March 31, 2013
4,600	692.00	May 12, 2013

38,010	782.00	March 31, 2014
5,200	772.00	June 1, 2014

## Stock Options

In 1997, our shareholders first approved the creation of conditional capital for use in stock option plans for our employees. Since that time, our employees have exercised options for 26,806 bearer shares under our Stock Option Plan, and our issued and fully paid share capital reflects the issuance of those bearer shares. We have adjusted the number of options outstanding and their exercise price to reflect the two-for-one stock split that our shareholders approved at the annual meeting of shareholders held on May 16, 2000 and the grant to our option holders of one additional option for each option held as of April 15, 2000 to compensate them for the effect of the 100% stock dividend and the corresponding increase in share capital that our shareholders approved at the annual meeting.

At our annual meetings held on May 16, 2000 and May 25, 2004, our shareholders approved increases in our conditional capital for our stock option plans so that as of December 31, 2004, the total nominal capital authorized for the grant of options to employees and directors under our option plans, as adjusted for the exercise of 4,530 options under our Stock Option Plan and purchase of 21,819 shares under our Employee and Director Share Purchase Plan from January 1, 2004 to and including December 31, 2004, consisted of CHF 18,166,275, corresponding to 726,651 bearer shares with a par value of CHF 25 each.

We generally grant stock options to our employees under our Stock Option Plan every plan year. Each option gives the holder the right to purchase one bearer share or one ADS. Employee options vest ratably over four years. Each employee option has a 10-year duration. The exercise price for employee options is the fair market value of our bearer shares on the virt-X at the date of grant. Until 2002, the option price for our ADSs was set based on the price of the underlying bearer share at the date of grant. Since 2003, the option price for our ADSs has been set based on the fair market value of our ADSs on the New York Stock Exchange at the date of grant. In 1998, we granted 26,200 options to a total of 190 employees, at an exercise price of CHF 546.25 per bearer share. In 1999, we granted 29,160 options to a total of 218 employees, at an exercise price of CHF 546 per bearer share. In 2000, we granted 32,676 options to a total of 302 employees at an exercise price of CHF 1,520.50 per bearer share. In 2001, we granted 77,934 options to a total of 532 employees at an exercise price of CHF 1,346 per bearer share. In 2002, we granted 90,540 options to a total of 625 employees at a weighted average exercise price of CHF 1,350 per bearer share. In 2003, we granted 93,230 options for bearer shares to a total of 558 employees at a weighted average exercise price of CHF 650 per bearer share and 20,000 options for ADSs to one employee at an exercise price of \$16.51 per ADS. In 2004, we granted 95,700 options for bearer shares to a total of 1,761 employees at a weighted average exercise price of CHF 791 per bearer share and 1,102,000 options for ADSs to 778 employees at an exercise price of \$15.53 per ADS. Of the options for bearer shares, options for 26,806 bearer shares have been exercised and options for 75,293 bearer shares have been cancelled and are available for re-grant under the plan. Of the options for ADSs, no options for ADSs have been exercised and options for 55,200 ADSs have been cancelled and the corresponding bearer shares are available for re-grant under the plan. Total options for 336,808 bearer shares (some of which are in the form of options for ADSs) remain outstanding as of December 31, 2004.

In addition to the options we have granted to employees under our stock option plan, we made a single grant of options to each of our directors when they first took office between 1998 and 2001. Director options vest on December 31 of each year over a period of five years (four years for one director), but directors may not exercise their options for a period of five years (four years in the case of one director) from the date of grant. After the options become exercisable, directors may exercise their options for a period of five years (four years for one director). The exercise price for director options is the price of our bearer shares on the virt-X on the date of the annual meeting of shareholders following which the options were granted.

In 2003, we set up a new stock option plan for directors. Grants of options for bearer shares are made each year following the annual meeting. Options vest beginning one year after the date of grant and vest ratably over four years, expiring 10 years from the date of grant. The exercise price is the fair market value of the bearer share on the date of grant. The Compensation Committee is responsible for selecting the beneficiaries for each of the plan's cycles and determining the number of shares granted. In 2003, we granted 4,600 options for our bearer shares to a total of seven directors at an exercise price of CHF 692 per bearer share. In 2004, we granted 5,200 options for our bearer shares to a total of eight directors at an exercise price of CHF 772 per bearer share.

Our conditional capital covers the grants of options we made to our directors that vested or will vest in 2001 and thereafter, and will cover future grants to directors, but did not cover the grants of options to our directors that vested prior to 2001. After deducting the number of employee options that remain outstanding under our stock option plan and the options we granted to our directors that will vest in 2001 and thereafter, our conditional capital allows us to grant options for approximately an additional 336,808 bearer shares.

A compensation charge in the amount of \$1.2 million (compared to \$1.4 million in 2003) has been recognized for stock options granted in the plan years 2002, 2001 and 2000. The compensation charge related to the stock options granted is being expensed over the four-year vesting period of the options. In addition, we have taken the stock options granted to employees and directors into consideration in the calculation of diluted earnings per share.

### **Employee Share Purchase Plan**

Our Employee Share Purchase Plan became effective on January 1, 2001 in Switzerland and the United States and was implemented for our affiliates in the rest of the world throughout the 2001 year. The plan is designed to allow our eligible employees to purchase our bearer shares or ADSs through periodic payroll deductions.

A participant may contribute up to 15% of his or her salary through payroll deductions, and the accumulated payroll deductions are applied to the purchase of bearer shares or ADSs on the participant's behalf at the end of the year. The purchase price per share is 85% of the lower of (i) the average closing price of our bearer shares on the virt-X in the 10 business days prior to January 1 of the plan's year and (ii) the average closing price of our bearer shares on the virt-X in the 10 business days prior to December 31 of the plan's year.

On January 3, 2002, January 18, 2002 and November 19, 2002, we issued 14,500, 10 and 1 bearer shares, respectively, under this plan. On January 3, 2003, January 27, 2003 and May 5, 2003, we issued 23,181, 18 and 30 bearer shares, respectively, under this plan. On January 5, 2004, we issued 20,301 bearer shares under this plan. On January 4, 2005 we issued 20,940 bearer shares under this plan.

The shares available for issuance under the plan were authorized by our shareholders through the creation of the conditional capital for stock options discussed above under "Stock Options." We reserve the right to change, amend or discontinue the plan at any time.

### **Director Share Purchase Plan**

In 2003, we set up a share purchase plan for the Board of Directors. The plan allows directors to purchase our bearer shares through allocation of 50% or 100% of their gross yearly directors' fees to the plan. The sum of fee deductions accumulated is applied to the purchase of shares on the participant's behalf at the end of each plan cycle. Each cycle commences on the first business day following our annual meeting of shareholders and terminates on the date of the next annual meeting. Each director may become a participant by notifying us during the 10 business days after the annual meeting. The purchase price per bearer share is 85% of the fair market value of the share on the fifth business day following the annual meeting. The shares available for issuance under the plan were authorized by our shareholders through the creation of the conditional capital for stock options discussed above under "Stock Options." We reserve the right to change, amend or discontinue the plan at any time. On June 1, 2004, we issued 1,518 bearer shares under this plan.

### **Share Match Plan**

If an employee completes one year of service with us after purchasing shares through the Employee Share Purchase Plan and retains any of the purchased shares at the end of that year of service, then the employee is eligible for our Share Match Plan. Under the Share Match Plan, we will grant additional shares to each eligible employee in an amount to be determined by our Board. For the first plan year, which ended on December 31, 2001, we granted 4,208 additional shares from our treasury shares pursuant to the plan. For the second plan year, which ended on December 31, 2002, we granted 6,648 additional shares from our treasury shares pursuant to the plan. For the third plan year, which ended on December 31, 2003, we granted 5,766 additional shares from our treasury shares pursuant to the plan. For the fourth plan year, which ended on December 31, 2004, for every three shares purchased in the Employee Share Purchase Plan on January 4, 2005 that are still held by an employee on December 31, 2005, we will grant to the employee one additional share. All share grants under the Share Match Plan are at the discretion of our Board. In jurisdictions other than the United States, the matching feature is a part of the Employee Share Purchase Plan.

## **Item 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS**

### **Major Shareholders**

As of December 31, 2004, Bertarelli & Cie, a partnership limited by shares with its principal offices at Chésereux (Vaud), Switzerland, held 51.43% of our capital, including treasury shares, and 65.36% of our voting rights. Ernesto Bertarelli, our Chief Executive Officer, Vice-Chairman and Managing Director, controls Bertarelli & Cie. On the same date, Maria-Iris Bertarelli, Ernesto Bertarelli and Donata Bertarelli Späth owned in the aggregate 7.00% of our capital, including treasury shares, and 10.53% of our voting rights. Our registered shares and our bearer shares are each entitled to one vote per share.

As of December 31, 2004, there were 11,738,175 bearer shares, including 1,611,434 treasury shares, and 11,013,040 registered shares outstanding. The following table sets forth the ownership of our voting securities by all persons known to us to own more than 5% of our registered shares and bearer shares. For the purposes of calculating

percentages shown in the table, the 1,611,434 treasury shares are deemed not to be outstanding.

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<b>Name of Owner</b>	<b>Registered Shares Owned</b>	<b>Percent of Registered Shares</b>	<b>Bearer Shares Owned</b>	<b>Percent of Bearer Shares</b>	<b>Aggregate Voting Percent</b>
Bertarelli & Cie (1)	9,189,300	83.4	4,626,930	45.7	65.4
Ernesto Bertarelli (2)	9,973,200	90.6	4,753,289	46.9	69.6
Maria-Iris Bertarelli (3)	255,940	2.3	154,000	1.5	1.9
Donata Bertarelli Späth (3)	783,900	7.1	130,520	1.3	4.3

- (1) Bertarelli & Cie is a partnership limited by shares with its principal offices in Chésereux (Vaud), Switzerland.
- (2) Includes all registered shares and bearer shares reported by Bertarelli & Cie. Ernesto Bertarelli controls Bertarelli & Cie. Includes 9,800 bearer shares that we may issue upon the exercise by Mr. Bertarelli of stock options.
- (3) Does not include the registered shares and bearer shares reported by Bertarelli & Cie. Ernesto Bertarelli controls Bertarelli & Cie.

All of our registered shares are held by Bertarelli & Cie and members of the Bertarelli family, all of whom are residents of Switzerland. Because our publicly traded shares are in bearer form, there are no holders of record of our bearer shares. Our American depositary shares, or ADSs, each of which represents one fortieth of a bearer share, are issued in registered form. Based on information provided by The Bank of New York, the depositary for the ADS program, there were 50 holders of record of our ADSs in the United States as of February 7, 2005. We believe that approximately 4.5% of our bearer shares (including bearer shares held in the form of ADSs) are beneficially owned by residents of the United States.

### **Related Party Transactions**

In 2000, we leased from an unaffiliated company, under a lease that expires in 2006, a building then under construction adjacent to our headquarters building that we have used to expand our headquarters. The lease provides for a rent of approximately \$1.1 million (2003: \$1.0 million) per year. Subsequent to the negotiation of the lease, Ernesto Bertarelli acquired a controlling interest in the company that owns the building. We have subleased a portion of the building to another company controlled by Mr. Bertarelli. The lease payments to us in 2004 were approximately \$0.3 million (2003: \$0.2 million).

We have sub-leased a portion of the Serono Biotech Center located in Switzerland to an unaffiliated company that is indirectly controlled by Mr. Bertarelli. The lease expires in 2005. The lease payments to us in 2004 amounted to approximately \$0.1 million (2003: \$0.1 million). In 2004, from time to time we made use of a private jet for business-related travel. The jet is owned by a company that is indirectly controlled by Mr. Bertarelli. During 2004, we paid market-rate rental fees for the jet totaling approximately \$2.3 million (2003: \$1.6 million). In 2004, a company that is indirectly controlled by Mr. Bertarelli provided certain media production services to us for events such as our Annual General Meeting of Shareholders and employee sessions. Services totaling \$0.2 million were provided to us by this company for the year ended December 31, 2004. In 2004, we paid a one-time consulting fee of \$0.1 million to Bertarelli & Cie, a company controlled by Mr. Bertarelli that is our principal shareholder, for consulting services related to certain business development activities.

There are three loans outstanding to members of the Executive Management Board. The most recent loan was granted on June 12, 2002 for the amount of CHF 300,000 (approximately \$224,000). All loans to executives accrue fixed interest at 3% per year. The total amount outstanding as of December 31, 2004 is CHF 0.7 million or approximately \$0.6 million (2003: CHF1.1 million or approximately \$0.9 million). Two of the loans are repayable in three equal installments and will be fully repaid April 30, 2005, while for the remaining loan, accrued interest is paid on the anniversary of the loan grant date, with the principal payable on December 31, 2005.



We continue to hold an equity investment in Cansera International, Inc., or Cansera, a Canadian company specializing in sterile animal sera and cell culture products from which we purchase products. We purchase products from Cansera on commercial terms and conditions and at market prices. Our total purchases from Cansera for the year ended December 31, 2004 were \$1.5 million (2003: \$2.4 million). As of December 31, 2004, there was an amount of \$0.1 million (2003: \$0.1 million) payable to Cansera.

We have obtained in the past, and may in the future obtain, commercial and investment banking services from, and have had other commercial dealings with, UBS AG and its affiliates. Ernesto Bertarelli, our Chief Executive Officer, is a director of UBS AG.

In 2004, we acquired an equity investment in Integrated Solutions S.A., an information systems consulting company located in Switzerland. We entered into a master service agreement with Integrated Solutions S.A. for the provision of information technology services. In 2004, Integrated Solutions S.A. provided us services in the amount of \$4.3 million, of which \$0.6 million remained payable as of December 31, 2004.

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## **Item 8. FINANCIAL INFORMATION**

### **Consolidated Financial Statements**

Our consolidated financial statements specified by this standard are included in Item 18 and set forth on pages F-1 through F-54.

### **Legal Proceedings**

We are a party to various legal proceedings, including breach of contract and patent infringement cases and other matters.

Interpharm Laboratories and others of our subsidiaries are defendants in a lawsuit, filed by the Israel Bio-Engineering Project Limited Partnership, or IBEP, in 1993 in the District Court of Tel Aviv-Jaffa, Israel, concerning certain proprietary rights and royalty rights and other claims of IBEP arising out of funding provided for the development of recombinant human interferon beta as well as certain other products in the early to mid-1980s. The trial of the ownership and contractual preliminary issues started in 2002 and is expected to continue through 2005. In 2003, IBEP sued Amgen Inc., Immunex Corporation, and Wyeth in United States District Court in Los Angeles, California, alleging that the product Enbrel infringes IBEP's asserted rights under a patent known as the "701 patent" issued to Yeda Research and Development Co. Ltd., or Yeda, and exclusively licensed to us. Yeda joined as a defendant and on February 18, 2004, the United States District Court granted Yeda's motion for summary judgment declaring that Yeda was the rightful owner of the 701 patent. IBEP has appealed the summary judgment decision to the United States Court of Appeals for the Federal Circuit, which heard argument on January 11, 2005.

In 1996, one of our Italian subsidiaries entered into an agreement with an Italian company, Italfarmaco, for the co-marketing of recombinant interferon beta-1a in Italy. Italfarmaco terminated the contract at the end of 1999, alleging breach by our subsidiary of its obligations, and initiated proceedings before the International Chamber of Commerce International Court of Arbitration in Milan, Italy, asking for the payment of damages, including loss of profit and business opportunities. We filed a counterclaim alleging Italfarmaco's default in the execution of the agreement and claiming monetary damages. The Arbitration Panel has appointed an expert for the evaluation of the potential damages. We expect the proceedings to last at least through 2005.

In 1999, Institut Biochimique S.A., or IBSA, initiated proceedings before the Tribunale Civile in Rome, Italy, the Tribunal de Grande Instance in Paris, France, and the Cour de Justice of the Canton of Geneva, Switzerland asserting that either our patents relating to highly purified (urinary) FSH are invalid or that the processes used by IBSA do not infringe them. The proceedings filed in Switzerland and France have been stayed, pending the outcome of the proceedings in Italy. The Italian court decided in October 2003 that the patent is valid in its entirety and that the fact that an FSH product is made by a third party using a process different from the one described in the patent is not sufficient to rule out infringement of the product claims. The decision is open to appeal by IBSA. IBSA has not appealed the decision of the court of first instance and the parties entered into a settlement agreement on May 10, 2004.

Our 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. Other pharmaceutical companies have received similar subpoenas as part of an ongoing, industry-wide investigation by the states and the federal government into the setting of average wholesale prices and marketing and other practices. 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. We are cooperating

with the investigation. The outcome of this investigation could include the commencement of civil and/or criminal proceedings involving the imposition of substantial fines, penalties and injunctive or administrative penalties, including exclusion from government reimbursement programs, or a resolution of civil and/or criminal allegations resulting in a substantial monetary settlement. The final settlement or adjudication of this matter could have a material adverse effect on our operations or financial condition. We cannot predict the timing of the resolution of this matter or its ultimate outcome.

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## Dividends and Dividend Policy

The following table sets forth the amount of dividends that we have declared with respect to the past five years. We calculated the U.S. dollar amounts based on the average exchange rate for the year.

	2004 <sup>(1)</sup>	2003	2002	2001	2000
Declared dividend per bearer share (CHF)	9.00	8.00	7.00	6.25	6.00
Declared dividend per bearer share (U.S.\$)	7.27	5.99	4.52	3.69	3.55
Declared dividend per ADS (U.S.\$)(2)	0.20	0.15	0.11	0.09	0.09
Declared dividend per registered share (CHF)	3.60	3.20	2.80	2.50	2.40
Declared dividend per registered share (U.S.\$)	3.18	2.40	1.81	1.48	1.42

(1) Our dividend for the 2004 fiscal year will not be declared and paid until our annual general meeting on April 26, 2005.

(2) Amount is equal to one fortieth of the amount declared per bearer share in U.S. dollars. Actual amounts paid to holders of ADSs may vary depending on the actual exchange rate obtained by the Depositary in converting dividends from Swiss francs to U.S. dollars and on the expenses of the Depositary.

Our current dividend policy is to pay between 20% and 30% of net income as dividends to our shareholders. The pay-out ratio is adjusted to take into account special events such as the investment for the launch of Rebif in the U.S. We cannot assure you that in the future we will pay dividends in this target range, in another amount or at all. We will review our dividend policy periodically depending on our financial position, capital requirements and general business conditions. We pay cash dividends in Swiss francs net of applicable Swiss withholding tax.

Our bearer shares and our registered shares participate in dividends in proportion to their nominal value, which is CHF 25 for the bearer shares and CHF 10 for the registered shares. Accordingly, the dividends per share on the bearer shares are 2.5 times the dividends per share on the registered shares.

Our shareholders are required to approve in a general shareholders' meeting any distribution of dividends proposed by our Board of Directors. In addition, our statutory auditors are required to declare that the dividend proposal of the Board of Directors is in accordance with Swiss law. We expect to hold the shareholders' meeting to approve any dividends in the second quarter of each year. We will pay any dividends approved at the shareholders' meeting shortly after the meeting.

Under Swiss corporate law, in most circumstances, general reserves exceeding 20% of the nominal share capital of a company are at the disposal of the shareholders' meeting for distribution as dividends if the company is a holding company, as we are.

Owners of ADSs will be entitled to receive any dividends paid on the underlying bearer shares. We will pay cash dividends to The Bank of New York, our depositary, in Swiss francs. The agreement with the depositary provides that the depositary will then convert the cash dividends to U.S. dollars and make payment to the holders of the American depositary receipts, or ADRs, which represent our ADSs, in U.S. dollars. Fluctuations in the exchange rate between

the Swiss franc and the U.S. dollar will affect the U.S. dollar amounts of cash dividends received by holders of ADRs. The depositary may withhold a portion of any dividend if, because of conversion from Swiss francs into U.S. dollars, that portion cannot be divided among the holders of ADRs to the nearest cent.

**Significant Changes**

Except as otherwise disclosed in this Annual Report, there has been no significant change in our financial position since December 31, 2004, the date of our last audited financial statements.

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**Item 9. THE OFFER AND LISTING****Market Prices of Bearer Shares and ADSs**

Our bearer shares have been traded on the virt-X pan-European Exchange since June 2001, under the symbol “SEO”. All Swiss company shares included in the Swiss Market Index (SMI) are now traded on virt-X, which was created to increase pan-European trading liquidity. Our bearer shares had previously traded on the SWX Swiss Exchange and predecessor Swiss exchanges since 1987. Our bearer shares have been traded in the form of ADSs, each of which represents one fortieth of a bearer share, on the New York Stock Exchange under the symbol “SRA” since July 27, 2000. The following table sets forth, for the periods indicated, the high and low sales prices of our bearer shares in Swiss francs on the virt-X or SWX Swiss Exchange, and our ADSs in U.S. dollars on the New York Stock Exchange.

Period	SWX Swiss Exchange or virt-X		NYSE Per ADS	
	Per Bearer Share		High	Low
	High (CHF)	Low	High (U.S.\$)	Low
<b>2000<sup>(1)</sup></b>	2,160	801	31.94	20.81
<b>2001</b>	1,820	1,100	25.50	16.85
<b>2002</b>	1,537	605	23.19	10.25
<b>2003</b>	958	562	17.79	10.58
First Quarter	800	562	14.35	10.58
Second Quarter	855	633	16.24	11.88
Third Quarter	958	759	17.48	14.30
Fourth Quarter	950	840	17.79	16.13
<b>2004</b>	974	711	19.60	14.57
First Quarter	974	776	19.60	15.21
Second Quarter	833	751	16.32	14.57
Third Quarter	824	728	16.33	14.68
September	824	761	16.33	15.10
Fourth Quarter	784	711	16.52	14.62
October	784	723	15.73	14.62
November	766	724	16.28	15.26
December	755	711	16.52	15.31
<b>2005</b>				
January	768	725	16.40	15.30
February	915	708	18.92	14.75

(1) Trading prices per ADS for 2000 are for the period from July 27, 2000 (the first day of trading of our ADSs on the New York Stock Exchange) through December 31, 2000.

**Item 10. ADDITIONAL INFORMATION****Articles of Association**

We were formed in 1987 as a *société anonyme* or limited stock corporation under Swiss law. Our registered office is located at 1267 Coinsins (Vaud), Switzerland, and our Articles of Association are entered in the commercial register in the canton of Vaud (Ref. No. L996/00173). Our current Articles of Association are dated March 9, 2005. Article 3 states our corporate purpose as follows: “The principal object of the company is to act as a holding company (for the

acquisition and management of shareholdings in Switzerland and abroad) in the pharmaceutical and related fields. The company may establish enterprises or companies, carry out any financial, commercial, industrial and real estate transactions, and conclude any contracts which further or are directly or indirectly connected with its object.”

## **Transfer of Shares**

### ***Bearer Shares***

The transfer of our bearer shares is effected by a corresponding entry in the books of a bank or depositary institution that holds the definitive certificates representing the bearer shares in custody or by transfer of possession of the certificate representing the bearer share.

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### ***Registered Shares***

The transfer of registered shares is subject to approval by the executive committee of our board of directors which acts upon a delegation from our board of directors. The executive committee of the board will not approve the transfer if the prospective acquiror of the registered shares does not certify that the registered shares will be acquired in its own name and for its own account. The executive committee of the board may retroactively cancel any transfer of registered shares that it approved in reliance on a false certification by the potential acquiror of the registered shares that the shares would be acquired in its own name and for its own account. The executive committee of the board may refuse to approve a transfer if it identifies adequate grounds for such refusal, in particular if it concludes that our economic independence may be threatened by the prospective transfer, or that the prospective acquiror of the registered shares is one of our competitors or a competitor of a company in which we hold a participating interest. The executive committee of the board also may refuse to approve the transfer by offering to purchase the registered shares for our own account, for the accounts of other shareholders or for the accounts of third parties. If we offer to purchase the registered shares for the accounts of other shareholders, we will follow the principle of equal treatment of all holders of registered shares.

If the registered shares are transferred by succession, we will automatically enter the name of the acquiror in the share register unless we conclude that there are adequate grounds for refusal, as we describe above. If we refuse to allow such a transfer of registered shares by succession, we will offer to purchase the shares for our own account, for the accounts of other shareholders or for the accounts of third parties. If we offer to purchase the registered shares for the accounts of other shareholders, we will follow the principle of equal treatment of all holders of registered shares.

A holder of registered shares must have the approval of the executive committee of our board in order to use such shares as a pledge, guarantee or security.

A resolution of a qualified majority of at least two-thirds of the number of shares represented and an absolute majority of the nominal value of shares represented at a general meeting of shareholders is required to amend these restrictions on the transfer of registered shares.

### **Shareholders' Meetings**

Under Swiss law, a general annual shareholders' meeting must be held within six months after the end of each financial year. Shareholders' meetings may be convened by the board of directors or, if necessary, by the statutory auditors. The board of directors is required to convene an extraordinary shareholders' meeting if so resolved by a shareholders' meeting or if so requested by shareholders holding in aggregate at least 10% of the company's nominal share capital. Shareholders holding shares with a nominal value of at least CHF 1 million have the right to request that a specific proposal be discussed and voted upon at the next shareholders' meeting. The request must be submitted in writing to the Board of Directors at least 45 days before the date of the Annual General Meeting. A shareholders' meeting is convened by publishing a notice in the Swiss Official Gazette of Commerce and sending a notice to each holder of registered shares at the address indicated in the share register at least 20 days prior to the meeting.

There are no provisions in our Articles of Association that require a quorum for shareholders' meetings.

Resolutions generally require the approval of an absolute majority of the shares represented at the shareholders' meeting. Shareholders' resolutions requiring a vote by absolute majority include, among others, amendments to the Articles of Association other than those indicated below, elections of directors and statutory auditors, approval of the annual report and the annual group accounts, the setting of the annual dividend and decisions to discharge the directors and management from liability for matters disclosed to the shareholders' meeting.



A resolution passed at a shareholders' meeting with a qualified majority of at least two-thirds of the number of shares represented and an absolute majority of the nominal value of shares represented at the meeting is required for:

- changes in our purpose;
- the creation of shares with privileged voting rights;
- the restriction of the transferability of registered shares;

• an authorized or conditional increase in share capital;

• an increase in share capital by way of transformation of reserves, against contribution in kind, for the acquisition of assets or involving the grant of special benefits;

• the restriction or elimination of preemptive rights of shareholders;

• a transfer of our registered office; or

• dissolution other than by liquidation, such as a merger in which we are not the surviving entity.

In addition, under Swiss law, the introduction and abolition of any provision in the Articles of Association providing for a qualified majority must be adopted with such qualified majority.

At shareholders' meetings, shareholders can be represented by proxy. Voting takes place openly unless the shareholders' meeting resolves to vote by ballot or a ballot vote is ordered by the chairman of the meeting.

### **Net Profits and Dividends**

Swiss law requires that at least 5% of the annual net profits of a corporation must be retained by the corporation as general reserves for so long as general reserves amount to less than 20% of the company's nominal share capital.

Under Swiss law, a corporation may pay dividends only if it has sufficient distributable profits from previous business years or if the reserves of the corporation for dividend distribution are sufficient to allow the distribution of a dividend. In either event, dividends may be paid out only after they have been approved by the shareholders' meeting. The board of directors may propose that a dividend be paid out, but cannot itself set the dividend. The statutory auditors must confirm that the dividend proposal of the board conforms to Swiss law. In practice, the shareholders' meeting usually approves the dividend proposal of the board of directors.

Under Swiss law, unless a corporation's articles of association provide for a dividend preference, when a corporation has shares with different nominal values it must pay dividends in proportion to the relative nominal values of the shares. Our articles of association do not provide for a dividend preference. Because our bearer shares have a nominal value of CHF 25 and our registered shares have a nominal value of CHF 10, dividends per share on our bearer shares are 2.5 times the dividends per share on our registered shares.

Dividends are usually due and payable a few business days after the shareholders' resolution relating to the allocation of profits has been passed. The statute of limitations in respect of dividend payments is five years. Dividends for which no payment has been requested within five years after the due date accrue to us and are allocated to our general reserves.

### **Preemptive Rights**

Under Swiss law, any share issue, whether for cash or non-cash consideration, is subject to the prior approval of the shareholders' meeting. Shareholders of a corporation have certain preemptive rights to subscribe, in proportion to the nominal amount of shares held, for new issues of shares, bonds with warrants or convertible bonds. Shareholders may only subscribe for their class of shares if the different classes are increased simultaneously and in the same proportion. A resolution adopted at a shareholders' meeting with a qualified majority, however, may limit or suspend preemptive rights in certain limited circumstances.

U.S. securities laws may restrict the ability of U.S. persons, as that term is defined in Regulation S promulgated under the U.S. Securities Act of 1933, as amended, who hold shares to participate in certain rights offerings or share or warrant dividend alternatives which we may undertake in the future in the event we are unable or choose not to register the securities under the U.S. securities laws and are unable to rely on an exemption from registration under those laws.

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## Repurchase of Shares

Swiss law limits the amount of shares that we may hold or repurchase. We may repurchase shares only if:

- we have sufficient free reserves to pay the purchase price; and
- the aggregate nominal value of the shares does not exceed 10% of our nominal share capital.

Furthermore, we must create a reserve on our balance sheet in the amount of the purchase price of the repurchased shares. Repurchased shares that we or our subsidiaries hold do not carry any rights to vote at a shareholders' meeting but are entitled to the economic benefits applicable to shares generally.

## Notices

We publish notices to shareholders in the Swiss Official Gazette of Commerce. In addition, we usually publish our official notices, such as invitations to shareholders' meetings and payment of dividends, in the following Swiss newspapers: AGEFI, Le Temps and Finanz und Wirtschaft. Our board of directors, however, reserves the right to change any of these media, other than the Swiss Official Gazette of Commerce, or to add additional ones at its sole discretion.

## Duration and Liquidation

Our Articles of Association do not limit our duration.

We may be dissolved at any time by a shareholders' resolution which must be passed by:

- an absolute majority of the shares represented at the meeting in the case of dissolution by way of liquidation; or
- a qualified majority of at least two-thirds of the votes represented and an absolute majority of the nominal value of the shares represented at the meeting in other events, such as a merger in which we are not the surviving entity.

Under Swiss law, any surplus arising out of a liquidation, after the settlement of all claims of all creditors, is distributed to shareholders in proportion to the paid-up nominal value of shares held.

## Notification of Share Interests

Under the Swiss Stock Exchange Act, shareholders, or shareholder groups acting in concert, who acquire or dispose of shares and thereby reach, exceed or fall below the respective threshold of 5%, 10%, 20%, 33 1/3%, 50% or 66 1/2% of the voting rights of a Swiss listed corporation must notify the corporation and the stock exchange on which such shares are listed of the acquisition or disposition in writing within four business days, whether or not the voting rights can be exercised. Following receipt of such notification, a corporation must inform the public.

In addition, under Swiss company law we must disclose the identity of all shareholders who we are aware hold more than 5% of our voting rights. Such disclosure must be made once a year in the notes to the financial statements as published in our annual report.

## Mandatory Bid Rules

According to the Swiss Stock Exchange Act, shareholders and groups of shareholders acting in concert who acquire more than 33 1/3% of the voting rights of a listed Swiss corporation will have to submit a takeover bid to all the

remaining shareholders. This mandatory bid obligation may be waived under certain circumstances, in particular if another shareholder owns a higher percentage of voting rights than the acquiror. The Swiss Takeover Board or the Swiss Federal Banking Commission may grant such a waiver from the mandatory bid rules. If no waiver is granted, the mandatory takeover bid must be made pursuant to the procedural rules set forth in the Swiss Stock Exchange Act and the implementing ordinances enacted thereunder.

**Anti-takeover Effects**

Each of our bearer shares and registered shares entitles the holder to one vote. Since the nominal value of the bearer shares is two and one-half times greater than the nominal value of the registered shares, the registered shares effectively have super voting rights. Generally, super voting shares are viewed as having anti-takeover implications. As of December 31, 2004, the Bertarelli family controlled approximately 75.89% of the outstanding voting power. As a result, no third party can take over our company without the approval of the Bertarelli family.

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### **Conversion of Registered Shares into Bearer Shares**

According to our Articles of Association, at a general meeting of shareholders, our shareholders may vote to convert some or all of our registered shares into bearer shares, and some or all of the bearer shares into registered shares, at any time. If part or all of our registered shares are converted into bearer shares of a nominal value of CHF 10, the privileged voting rights of such converted shares will lapse as a matter of law and one converted share will have 0.4 votes as compared to one vote of a bearer share of CHF 25 nominal value. If at the same time we split our bearer shares into bearer shares of CHF 10, then the present rule of one vote per share may be maintained. The bearer shares into which the registered shares are converted would not be subject to any transfer restrictions.

### **Conversion of Bearer Shares into Registered Shares**

Under current Swiss law and pursuant to our Articles of Association, all or part of our bearer shares may be converted into registered shares. Such conversion has to respect the proportional ownership of each shareholder. The conversion of bearer shares into registered shares as such would not change the rule that one share carries one vote. The transfer restrictions currently in effect for registered shares would not be valid for such converted shares. Under current Swiss law, the only permissible transfer restriction for listed registered shares is that voting rights may not be granted to a shareholder or a group of shareholders acting in concert in excess of a percentage limit that may be expressed in the Articles of Association. Our Articles of Association do not contain any such restriction.

### **Share Capital Increases and Decreases**

Our shareholders may increase our share capital by passing a resolution at a general meeting of shareholders by an absolute majority of the shares represented at the meeting in person or by proxy. A majority of two-thirds of the shares represented in person or by proxy and the absolute majority of the nominal value of the shares represented is required:

- to increase our share capital if the capital increase is made in consideration of contributions in kind, for the purpose of acquiring assets or for the grant of special benefits;
- if the preemptive rights of our shareholders are limited or excluded; or
- in the event of a transformation of reserves into share capital.

In addition, under the Swiss Federal Code of Obligations, the general meeting of shareholders may, with a majority of two-thirds of the shares represented in person or by proxy and an absolute majority of the nominal value of the shares represented, decide on an increase of share capital in a specified aggregate nominal amount up to 50% of share capital in the form of:

- conditional capital for the purposes of issuing shares (i) to grant conversion rights or warrants to holders of convertible bonds or (ii) to grant rights to employees of the corporation to subscribe to new shares; and
- authorized capital to be utilized by the board of directors within a period not to exceed two years.

Pursuant to Swiss law, any decrease in share capital following a special procedure requires the approval of a general meeting of shareholders by an absolute majority of the shares represented in person or by proxy at the meeting.

### **Convertible Bonds**

In November 2003, our subsidiary, Ares International Finance 92 Ltd (now known as Serono 92 Limited), issued CHF 600,000,000 aggregate principal amount of unsubordinated convertible bonds due in 2008. The bonds, which we have

guaranteed, bear interest at a rate of 0.50% per annum. Unless the bonds have previously been redeemed or converted, they will be redeemed on November 26, 2008 at 105.8108% of their principal amount, which would provide a yield to maturity of 1.625% per annum. The bonds were issued in bearer form in denominations of CHF 5,000 nominal amount or integral multiples thereof, and are convertible into our bearer shares at a rate of 3.5333 bearer shares per CHF 5,000 bond, subject to adjustment. The initial conversion price is CHF 1,415.11 per bearer share, and the bonds are convertible in the aggregate into 423,996 bearer shares, which may be treasury shares or shares issued from our conditional capital. Under certain circumstances, which are specified in the Terms of the Bonds which are filed as part of Exhibit 2.7 to this annual report and incorporated by reference into this description, the conversion price may be adjusted or we may elect to redeem, or be required to redeem, the bonds. The bonds are listed on the SWX Swiss Exchange.

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## Exchange Controls and Other Limitations Affecting Shareholders

There are currently no limitations, either under the laws of Switzerland or in our Articles of Association, on the rights of non-residents of Switzerland to hold or vote our shares or ADSs. In addition, there are currently no Swiss foreign exchange control restrictions on the conduct of our operations or affecting the remittance of dividends on unrestricted shareholders' equity.

## Taxation

The following is a discussion of the material Swiss tax and United States federal income tax consequences of the acquisition, ownership and disposition of bearer shares or ADSs by U.S. Holders, as defined below.

This summary does not purport to address all tax consequences of the ownership of bearer shares or ADSs and does not take into account the specific circumstances of any particular investors. In particular, the description of U.S. tax consequences deals only with U.S. Holders that will hold bearer shares or ADSs as capital assets and who do not at any time own individually, nor are treated as owning, 10% or more of the shares of the company. In addition, this description of U.S. tax consequences does not address the tax treatment of special classes of U.S. Holders, such as banks, tax-exempt entities, insurance companies, persons holding bearer shares or ADSs as part of a hedging or conversion transaction or as part of a "straddle," U.S. expatriates, persons subject to the alternative minimum tax, dealers or traders in securities or currencies and holders whose functional currency is not the U.S. dollar.

This summary is based on the tax laws of Switzerland and the United States (including the Internal Revenue Code of 1986, as amended, or the "Code", its legislative history, existing and proposed regulations thereunder, published rulings and court decisions) and on the Convention Between the United States of America and the Swiss Confederation for the Avoidance of Double Taxation with Respect to Taxes on Income, or the Treaty, all as in effect on the date hereof and all of which are subject to change (or changes in interpretation), possibly with retroactive effect. In addition, the summary is based in part upon the representations of The Bank of New York, or the Depository, as depository under our ADS program, and the assumption that each obligation in the deposit agreement between us and the Depository and any related agreement will be performed in accordance with its terms.

For purposes of this discussion, a U.S. Holder is any beneficial owner of bearer shares or ADSs that is for U.S. federal income tax purposes:

• an individual citizen or resident of the United States;

• corporation, or other entity that is taxable as a corporation, organized under the laws of the United States or any State thereof, including the District of Columbia;

• an estate the income of which is subject to U.S. federal income tax without regard to its source; or

• trust the administration of which is subject to the primary supervision of a court in the United States and for which one or more U.S. persons have the authority to control all substantial decisions, or which elects under U.S. Treasury regulations to be treated as a U.S. person.

If a partnership holds bearer shares or ADSs, the U.S. federal income tax treatment of a partner will generally depend upon the status of the partner and the activities of the partnership. Persons holding bearer shares or ADSs through a partnership should consult their tax advisers as to their status.

A Non-U.S. Holder is any beneficial owner of bearer shares or ADSs that is not a U.S. Holder. An Eligible U.S. Holder is a U.S. Holder that:



Ÿ is a resident of the United States for purposes of the Treaty;

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Does not maintain a permanent establishment or fixed base in Switzerland to which bearer shares or ADSs are attributable and through which the beneficial owner carries on or has carried on business (or, in the case of an individual, performs or has performed independent personal services); and

Who is not otherwise ineligible for benefits under the Treaty with respect to income and gain derived in connection with the bearer shares or ADSs.

This discussion does not address any aspects of U.S. taxation other than federal income taxation or any aspects of Swiss taxation other than income and capital taxation, withholding tax and stamp duties. You are urged to consult your tax advisors regarding the U.S. federal, state and local and the Swiss and other tax consequences of owning and disposing of bearer shares or ADSs. In particular, you are urged to confirm your status as Eligible U.S. Holders with your advisors and to discuss with your advisors any possible consequences of your failure to qualify as Eligible U.S. Holders. Also, Non-U.S. Holders should consult their own tax advisors, particularly as to the applicability of any tax treaty.

In general, and taking into account the earlier assumptions, for Swiss tax and U.S. federal income tax purposes, holders of ADRs evidencing ADSs will be treated as the owners of the shares represented by those ADSs, and exchanges of shares for ADRs, and ADRs for shares, will not be subject to Swiss tax or to U.S. federal income tax.

## **Swiss Taxation**

***Withholding Tax on Dividends and Distributions.*** Dividends paid and similar cash or in-kind distributions made by us to a holder of bearer shares or ADSs, including liquidation proceeds in excess of the nominal value of the shares and stock dividends, are subject to a Swiss federal withholding tax, or the Withholding Tax, at a rate of 35%. We must withhold the Withholding Tax from the gross distribution and pay it to the Swiss Federal Tax Administration.

A recipient of one of our distributions who is not a resident of Switzerland for tax purposes and does not hold the bearer shares or ADSs in connection with the conduct of a trade or business in Switzerland through a permanent establishment or a fixed place of business, which is called a non-resident holder, is subject to the Withholding Tax described above. The non-resident holder may be entitled to a full or partial refund of the Withholding Tax if the country in which he resides has entered into a bilateral treaty for the avoidance of double taxation with Switzerland. The United States has entered into such a bilateral treaty with Switzerland, which we call the Treaty.

***Capital Gains upon Disposal of Bearer Shares or ADSs.*** Under current Swiss law, a U.S. holder of bearer shares or ADSs, who is not a resident of Switzerland, will be exempted from any Swiss federal, cantonal or municipal income tax during the year on the sale of bearer shares or ADSs.

A non-resident holder of Swiss shares will not be liable for any Swiss taxes other than the Withholding Tax described above and the Stamp Duties upon Transfer of Securities (described below) if the transfer occurs through or with a Swiss bank or other Swiss securities dealer. If, however, the bearer shares or ADSs can be attributed to a permanent establishment or fixed place of business maintained by such person within Switzerland during the relevant tax year, then this person may be subject to Swiss taxes generally in relation to its holding of the shares.

## ***Obtaining a Refund of Swiss Withholding Tax***

The Treaty provides for a mechanism whereby an Eligible U.S. Holder can seek a refund of the Withholding Tax paid on dividends in respect of our shares, to the extent such withholding exceeds 15%. The Depository intends to make use of informal procedures under which it will submit a certificate to the Swiss tax authorities in respect of all U.S. Holders who have provided certifications of their entitlement to Treaty benefits. So long as these procedures remain available it generally should be possible for Eligible U.S. Holders to recover on a timely basis Withholding Tax in

excess of the 15% rate as provided in the Treaty. There can be no assurance that these informal procedures will remain available.

Alternatively, an Eligible U.S. Holder may apply for a refund of the Withholding Tax withheld in excess of the 15% Treaty rate. The claim for refund must be filed with the Swiss Federal Tax Administration, Eigerstrasse 65, 3003 Berne, Switzerland. The form used for obtaining a refund is Swiss Tax Form 82 (82C for companies; 82E for other entities; 82I for individuals), which may be obtained from any Swiss Consulate General in the United States or from the Swiss Federal Tax Administration at the address above. The form must be filled out in triplicate with each copy duly completed and signed before a notary public in the United States. The form must be accompanied by evidence of the deduction of Withholding Tax withheld at the source. We will provide this information on request.

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### ***Stamp Duties upon Transfers of Securities (Umsatzabgabe)***

The sale of bearer shares or ADSs, whether by Swiss resident or non-resident holders, may be subject to a Swiss securities transfer stamp duty of up to 0.15% calculated on the sale proceeds if it occurs through or with a Swiss bank or other Swiss securities dealer as defined in the Swiss Federal Stamp Tax Act. In addition to the stamp duty, the sale of bearer shares by or through a member of the Swiss Exchange may be subject to a stock exchange levy.

### **United States Federal Income Taxation**

***Taxation of Dividends.*** Under the U.S. federal income tax laws, and subject to the passive foreign investment company rules discussed below, U.S. Holders will include in gross income the gross amount of any dividend paid by us (before reduction for Swiss withholding taxes) out of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes) as ordinary income when the dividend is actually or constructively received by the U.S. Holder, in the case of bearer shares, or by the Depositary, in the case of ADSs. Dividends received by a U.S. Holder will not be eligible for the dividends-received deduction generally allowed to U.S. corporations in respect of dividends received from other U.S. corporations. The amount of the dividend distribution includable in income of a U.S. Holder will be the U.S. dollar value of the Swiss franc payments made, determined at the spot Swiss franc/U.S. dollar rate on the date such dividend distribution is includable in the income of the U.S. Holder, regardless of whether the payment is in fact converted into U.S. dollars. Generally, any gain or loss resulting from currency exchange fluctuations during the period from the date the dividend payment is includable in income to the date such payment is converted into U.S. dollars will be treated as ordinary income or loss. Such gain will generally be income from sources within the United States and such losses will generally be used to offset U.S. source income for foreign tax credit limitation purposes. Distributions in excess of current and accumulated earnings and profits, as determined for U.S. federal income tax purposes, will be treated as a return of capital to the extent of the U.S. Holder's basis in the bearer shares or ADSs and thereafter as capital gain. We do not maintain calculations of our earnings and profits for U.S. federal income tax purposes.

Subject to certain limitations, the Swiss tax withheld in accordance with the Treaty and paid over to Switzerland will be creditable against the U.S. Holder's U.S. federal income tax liability. To the extent a refund of the tax withheld is available to a U.S. Holder under the laws of Switzerland or under the Treaty, the amount of tax withheld that is refundable will not be eligible for credit against the U.S. Holder's U.S. federal income tax liability. See “—Swiss Taxation—Obtaining a Refund of Swiss Withholding Tax,” above, for the procedures for obtaining a refund of tax.

For foreign tax credit limitation purposes, the dividend will be income from sources without the United States, but generally will be treated separately, together with other items of “passive income” (or, in the case of certain holders, “financial services income”).

Distributions of additional shares to U.S. Holders with respect to their bearer shares or ADSs that are made as part of a pro rata distribution to all of our shareholders generally will not be subject to U.S. federal income tax.

***Taxation of Capital Gains.*** Subject to the passive foreign investment company rules discussed below, upon a sale or other disposition of bearer shares or ADSs, a U.S. Holder will recognize gain or loss for U.S. federal income tax purposes in an amount equal to the difference between the U.S. dollar value of the amount realized and the U.S. Holder's tax basis (determined in U.S. dollars) in such bearer shares or ADSs. Generally, such gain or loss will be a capital gain or loss. Capital gains realized by a U.S. Holder that is an individual, estate or trust are generally subject to federal income tax at a reduced rate, if the U.S. Holder's holding period for the bearer shares or ADSs exceeds one year. Limitations apply to the deductibility of capital losses by corporate and non-corporate U.S. Holders. Any gain recognized by a U.S. Holder on the sale or other disposition of the bearer shares or ADSs generally will be treated as U.S. source gain and any loss generally will be used to offset U.S. source income for purposes of the U.S. foreign tax credit limitations.



### ***Additional Tax Considerations***

#### ***Passive Foreign Investment Company Rules***

We believe that our bearer shares or ADSs should not be treated as stock of a passive foreign investment company, or PFIC, for U.S. federal income tax purposes, but this conclusion is based on our interpretation of the law and it is a factual determination made annually and thus may be subject to change. In general, we would be a PFIC with respect to a U.S. Holder if, for any taxable year in which the U.S. Holder held its bearer shares or ADRs, either (1) at least 75% of our gross income for the taxable year were “passive income” or (2) at least 50% of the value (determined on the basis of a quarterly average) of our assets were attributable to assets that produce or are held for the production of passive income. If we were to be treated as a PFIC, unless a U.S. Holder made a “QEF election” or a mark-to-market election, gain realized on the sale or other disposition of bearer shares or ADSs would in general not be treated as capital gain, and a U.S. Holder would be treated as if such holder had realized such gains and certain “excess distributions” ratably over the holder’s holding period for the bearer shares or ADSs and would be taxed at the highest tax rate on ordinary income in effect for each such year to which the gain was allocated, together with an interest charge in respect of the tax attributable to each such year.

#### ***Backup Withholding and Information Reporting***

In general, reporting requirements will apply to dividends in respect of bearer shares and ADSs and the proceeds received on the disposition of bearer shares or ADSs paid within the United States or through certain U.S. related financial intermediaries to U.S. Holders other than certain exempt recipients (such as corporations), and backup withholding may apply, from time to time at rates established under the Code, to such amounts if the U.S. Holder fails to provide an accurate taxpayer identification number and other information or fails to comply with certain other requirements. The current backup withholding rate is 28%. The amounts of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the U.S. Holder’s U.S. federal income tax liability.

#### ***Available Information***

We are subject to the reporting requirements of the U.S. Securities Exchange Act of 1934, as amended, applicable to a foreign private issuer, and in accordance with the Exchange Act we file annual reports on Form 20-F with and provide other information to the Commission. You can inspect our annual reports, including exhibits thereto, and other information filed with or provided to the Commission without charge and copy those documents, upon payment of prescribed rates, at the public reference facility maintained by the Commission at Room 1024, 450 Fifth Street, N.W., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the Commission at 1-800-732-0330. You can obtain copies of our filings by mail from the Public Reference Section of the Commission at 450 Fifth Street, N.W., Washington, D.C. 20549, at prescribed rates. In addition, you can inspect and copy these materials at the offices of the New York Stock Exchange, Inc., 20 Broad Street, New York, New York 10005. Our filings and other Commission submissions made on or after October 23, 2002 are also available to the public on the Commission’s website at <http://www.sec.gov>.

### **Item 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are exposed to market risk, primarily related to foreign currency exchange rates, interest rates and the market value of our investments in financial assets and equity securities. These exposures are actively managed by the Serono treasury group in accordance with a written policy approved by the Board of Directors and subject to internal controls. Our objective is to minimize, where we deem appropriate, fluctuations in earnings and cash flows associated with changes in foreign currency exchange rates, interest rates and the market value of our investments in financial assets and equity securities. It is our policy to use a variety of derivative financial instruments to manage the volatility relating to these exposures, and to enhance the yield on our investment in financial assets. We do not use financial

derivatives for trading or speculative reasons, or for purposes unrelated to the normal business activities of the group. Any loss in value on a financial derivative would normally be offset by an increase in the value of the underlying transaction.

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## 1. Foreign exchange exposure

We present our consolidated financial statements in U.S. dollars. As a consequence of the global nature of our business, we are exposed to foreign currency exchange rate movements, primarily in European, Asian and Latin American countries. We enter into various contracts that change in value as foreign currency exchange rates change, to preserve the value of assets, commitments and anticipated transactions. Typically we use foreign currency options and forward foreign exchange contracts to hedge certain anticipated net revenues in currencies other than the U.S. dollar. Net investments in our affiliates with a functional currency other than the U.S. dollar are of a long-term nature and we do not hedge such foreign currency translation exposures, other than in circumstances where the currencies are particularly volatile and could lead to unforeseen impacts on earnings and cash flows of the Serono group.

Our product sales and operating expenses (comprising selling, general and administrative and research and development) by currencies are as follows:

	Year ended December 31,		
	2004	2003	2002
	%	%	%
<b>Product sales</b>			
In U.S. dollar	49	47	46
In Euro	34	36	37
In other currencies	17	17	17
Total	100	100	100
<b>Operating expenses (SG&amp;A and R&amp;D)</b>			
In U.S. dollar	39	37	34
In Swiss franc	28	29	30
In Euro	23	23	27
In other currencies	10	11	9
Total	100	100	100

During 2004, the U.S. dollar weakened against most major currencies, including the Swiss franc and the Euro, which are our most important non-U.S. dollar currencies. This weakening resulted in a total positive currency effect on product sales of 4.6%, which was largely offset by a negative currency effect on operating expenses of 4.4%. The net impact on net income was a positive 3.5% in 2004 (positive 6.0% in 2003). This was primarily due to the strength of the Euro, the currency in which we have the largest proportion of non-U.S. dollar revenues, against the Swiss franc, the currency in which we have the largest proportion of non-U.S. dollar costs.

The primary purpose of our currency exchange risk management is to achieve stable and predictable cash flows. Consequently, our current policy is to enter into foreign currency options and forward foreign currency exchange contracts to cover the currency risk associated with existing assets, liabilities and other contractually agreed transactions (typically up to two months forward), as well as a portion of the currency risk associated with transactions that we anticipate conducting within the following six months. We use foreign currency options and forward foreign currency exchange contracts that are contracted with banks, which in most cases have credit ratings of A or higher, and that have a maximum maturity of 12 months.



## **2. Interest rate exposure**

We manage our exposure to interest rate risk through the relative proportions of fixed rate debt and floating rate debt, as well as the maturity profile of our fixed rate financial assets. Net financial income earned on the group's net financial assets is generally affected by changes in the level of interest rates, principally the U.S. dollar interest rate. We manage our exposure to fluctuations in net financial income by making investments in high quality financial assets that pay a fixed interest rate until maturity. Interest rate swaps are also used to limit the impact of fluctuating interest rates on both financial income and financial expense.

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### **3. Counterparty risk**

Counterparty risk includes issuer risk on debt securities, settlement risk on derivative and money market transactions, and credit risk on cash and fixed term deposits. We limit our issuer risk by buying debt securities which are at least A rated. We reduce our settlement and credit risk by entering into transactions with counterparties that are usually at least A rated banks or financial institutions. Exposure to these risks and compliance with the risk parameters approved by the Board of Directors is closely monitored. We do not expect any losses due to non-performance by these counterparties, and our diverse portfolio of investments limits our exposure to any single counterparty or sector.

### **4. Equity price risk**

We are exposed to equity price risks on the marketable portion of the available-for-sale equity securities. Our equity investments are typically related to collaboration agreements with other biotechnology and research companies. Equity securities are not purchased as part of our normal day-to-day management of financial assets managed by the group treasury department, with the exception of shares that are acquired under our Share Buy Back Plans.

### **5. Commodities**

We have very limited exposures to price risk related to anticipated purchases of certain commodities used as raw materials in our business. A change in commodities prices may alter our gross margin but, due to our limited exposure to any single raw material, a price change is unlikely to have a material unforeseen impact on our earnings.

### **6. Sensitivity analysis**

The table below presents the changes in fair values of our financial instruments in response to hypothetical changes in exchange or interest rates. The analysis shows forward-looking projections of changes in fair value assuming certain adverse market conditions. This is a method used to assess and mitigate risk and should not be considered as a projection of likely future events and losses. Actual results and market conditions in the future may be materially different from those projected and could cause losses to exceed the amounts projected.

For those financial instruments which are sensitive to changes in interest rates, we have calculated the potential change in the fair value resulting from an immediate hypothetical one percent increase or decrease in the yield curves from their levels as of December 31, 2004, with all other variables remaining constant. For those financial instruments which are sensitive to changes in foreign currency exchange rates, we have calculated the potential change in the fair value resulting from an immediate hypothetical ten percent weakening or rising in the U.S. dollar against all other currencies from their levels as of December 31, 2004, with all other variables remaining constant. For those financial instruments that are sensitive to changes in equity prices as they are listed on stock exchanges, we have estimated the potential change in the fair value resulting from an immediate hypothetical ten percent decrease in the quoted market prices from their levels as of December 31, 2004, with all other variables remaining constant. The fair values of financial instruments are quoted market prices or, if not available, net present values estimated by discounting future cash flows.

For illustrative purposes, only unfavorable variances are shown in the sensitivity analysis below, although movements in interest rates, foreign currency exchange rates or equity prices can also result in favorable variances.

(U.S. dollar equivalents in thousands)	Fair value as of December 31, 2004	Fair value changes arising from				
		1% increase in interest rates (unfavorable)	1% decrease in interest rates (unfavorable)	10% rising in U.S. dollar against other currencies (unfavorable)	10% weakening in U.S. dollar against other currencies (unfavorable)	10% decrease in equity price (unfavorable)
Short-term bank deposits included in cash and cash equivalents	212,746	(32)	-	(1,537)	-	-
Available-for-sale debt securities	1,563,196	(15,249)	-	-	-	-
Available-for-sale equity securities	150,833	-	-	(719)	-	(14,692)
Financial debts, excluding convertible bond	(166,815)	-	(276)	-	(15,123)	-
Convertible bond	(523,179)	-	(20,491)	-	(58,131)	-
Forward foreign exchange contracts	7,230	-	-	-	(18,285)	-
Foreign currency options	1,065	-	-	(3,151)	-	-
Interest rate swaps - fair value hedges	(1,728)	-	(93)	-	-	-
Interest rate swaps - cash flow hedges	(13,717)	-	(22,629)	-	-	-

Our exposure to interest rate risk is primarily related to our investments in debt securities, the convertible bond, and the financing related to the construction of the new headquarters and research center in Geneva. The majority of our debt securities consist of fixed-rate investments in rated Eurobonds denominated in U.S. dollars with maturities up to three years and short-term money market funds. A sensitivity analysis indicates that a one percent increase in interest rates as of December 31, 2004 would unfavorably impact the net aggregated fair value of those securities by \$15.2 million, while a one percent decrease in interest rates would unfavorably impact the fair value of our convertible bond by \$20.5 million. We have entered into interest rate swaps to fix the cost of the anticipated post completion financing linked to the new headquarters and research project. The current fair value of this swap is negative \$13.7 million and the adverse impact of a one percent decrease in interest rates would unfavorably impact the value of the swap by \$22.7 million.

Our financial assets are primarily denominated in U.S. dollars, the market values of which are not significantly impacted by changes in foreign exchange rates. However, changes in foreign exchange rates would have a more significant impact on the fair value of our Swiss franc denominated convertible bond, the Swiss franc borrowings related to the Geneva headquarters and research center project and other borrowings denominated in currencies other than U.S. dollars. The value of our financial debts, including our convertible bond, would increase by \$73.3 million if

the U.S. dollar devalued by ten percent.

We have investments in available-for-sale equity securities. We classify all such investments as long-term financial assets. The fair value of these investments is \$150.8 million. The majority of these investments are listed on stock exchanges. If the market price of the traded equity securities were to decrease by ten percent, the fair value would decrease by \$14.7 million.

**Item 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES**

Not applicable.

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**PART II**

**Item 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES**

Not applicable.

**Item 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS**

A-D. Not applicable.

**E. Use of Proceeds**

1. Registration Statement on Form F-1  
Commission File No. 333-12192  
Effective Date: July 26, 2000

4.g. As of December 31, 2004, we have invested the net offering proceeds primarily in a combination of short-term (original maturities less than one year) and long-term (with maturities ranging between 12 months and four years) corporate debt securities. These financial assets were mainly denominated in U.S. dollars.

**Item 15. CONTROLS AND PROCEDURES**

**Disclosure Controls and Procedures**

Our principal executive officer and principal financial officer have conducted an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this annual report. Based on that evaluation, the principal executive officer and principal financial officer concluded that such controls and procedures were satisfactory to ensure that material information regarding our company, including our consolidated subsidiaries, was made known to such officers by others within those entities, particularly during the period in which this annual report was being prepared.

**Changes in Internal Controls Over Financial Reporting**

There were no significant changes in our internal controls over financial reporting during the period covered by this annual report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 16A. AUDIT COMMITTEE FINANCIAL EXPERT**

Our board of directors has determined that Sergio Marchionne, a member of our Audit Committee, is an audit committee financial expert.

**Item 16B. CODE OF ETHICS**

We have adopted a code of ethics applicable to our principal executive officer, principal financial officer, principal accounting officer or controller and persons performing similar functions. Our board of directors has revised the code of ethics to extend its applicability to our directors, members of our Executive Management Board, Regional Vice-Presidents and General Managers. The code of ethics is filed as an exhibit to this Annual Report.

**Item 16C.**

**PRINCIPAL ACCOUNTANT FEES AND SERVICES**

Our principal independent auditor is PricewaterhouseCoopers S.A., Geneva, Switzerland.

**Fees and Services**

During the years ended December 31, 2004 and 2003, we paid the following fees for professional services to PricewaterhouseCoopers:

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	2004	2003
	(U.S.\$ in thousands)	
Audit Fees	2,450	2,369
Audit-Related Fees	243	206
Tax Fees	608	591
All Other Fees	155	270
Total	3,456	3,436

*Audit Services* are defined as the standard audit work that needs to be performed each year in order to issue an opinion on our consolidated financial statements and to issue reports on our statutory financial statements. It also includes services that can only be provided by the auditor signing the audit report such as auditing of non-recurring transactions and application of new accounting policies, audits of significant and newly implemented system controls, pre-issuance reviews of quarterly financial results, consents and comfort letters and any other audit services required for U.S. Securities and Exchange Commission or other regulatory filings.

*Audit-Related Services* include those other assurance services provided by auditors but not restricted to those that can only be provided by the auditor signing the audit report. They include amounts for services such as acquisition due diligence, audits of pension and benefit plans, contractual audits of third party arrangements, assurance services on corporate citizenship reporting, and consultation regarding new accounting pronouncements.

*Tax Services* represent tax compliance and other services and expatriate and executive tax return services.

*Other Services* consist of actuarial services for pension and employee benefit plans. As required by the Sarbanes-Oxley Act of 2002, PricewaterhouseCoopers could no longer provide certain of these services to us after May 2004.

#### **Policy on Pre-Approval of Audit and Non-Audit Services of Independent Auditors**

Our Audit Committee is responsible for the oversight of our independent auditor's work. Our Audit Committee's policy is to pre-approve all audit and non-audit services provided by PricewaterhouseCoopers. These services may include audit services, audit-related services, tax services and other services, as described above. In such an event, the Audit Committee sets forth its pre-approval in detail, listing the particular services or categories of services which are pre-approved, and setting forth a specific budget for such services. In urgent circumstances, the Audit Committee's Chair, Sergio Marchionne, or Hans Thierstein, a member of the Audit Committee, may issue such a pre-approval. Additional services may be pre-approved on an individual basis. PricewaterhouseCoopers and our management then report to the Audit Committee on a quarterly basis regarding the extent of services actually provided in accordance with the applicable pre-approval, and regarding the fees for the services performed.

All of the services provided by PricewaterhouseCoopers since Rule 2-01(c)(7) of Regulation S-X became effective were approved by our Audit Committee pursuant to the approval policies described above. None of such services were approved pursuant to the procedures described in Rule 2-01(c)(7)(i)(C) of Regulation S-X, which waives the general requirement for pre-approval of non-audit services in certain circumstances.

#### **ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES**

Not applicable.

**Item 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS**

	<b>Total Number of Bearer Shares Purchased</b>	<b>Average Price Paid per Bearer Share (U.S. \$)</b>	<b>Total Number of Bearer Shares Purchased as Part of Publicly Announced Plans or Programs</b>	<b>Approximate Value of Bearer Shares that May Yet Be Purchased Under the Plans or Programs (U.S. \$)</b>
January 1-31, 2004	--	--	--	223,610,232
February 1-29, 2004	37,500	673.54	37,500	195,592,279
March 1-31, 2004	123,100	632.56	123,100	117,035,066
April 1-30, 2004	47,259	616.72	47,259	86,297,602
May 1-31, 2004	143,350	624.61	143,350	--
June 1-30, 2004	59,050	629.38	59,050	561,064,199
July 1-31, 2004	138,000	604.67	138,000	469,504,540
August 1-31, 2004	262,500	617.13	262,500	306,623,156
September 1-30, 2004	57,435	637.24	57,435	275,932,990
October 1-31, 2004	--	--	--	287,954,107
November 1-30, 2004	348,100	656.74	348,100	75,296,796
December 1-31, 2004	97,350	652.51	97,350	11,961,579
<b>Total</b>	<b>1,313,644</b>		<b>1,313,644</b>	

- (1) On July 15, 2002, we announced a share repurchase program pursuant to which we purchased CHF 500 million (approximately \$380 million) of our bearer shares on the virt-X. This share repurchase program was completed on May 25, 2004.
- (2) On May 25, 2004, we announced a new share repurchase program under which our Board of Directors authorized the expenditure of up to CHF 750 million (approximately \$623 million) for the purchase of our bearer shares on the virt-X. This share repurchase program will expire not later than May 25, 2009. The approximate dollar value of bearer shares that may yet be purchased under the this plan is \$12 million.



**PART III****Item 17. FINANCIAL STATEMENTS**

Not applicable.

**Item 18. FINANCIAL STATEMENTS**

The financial statements filed as part of this report may be found on pages F-1 through F- 54.

**Item 19 EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
1.1	Articles of Association, dated March 9, 2005
2.1	Deposit Agreement among the Registrant, The Bank of New York, as Depositary, and all Owners and Beneficial Owners from time to time of ADRs issued thereunder, including the form of ADRs (incorporated by reference to Exhibit 4.6 to Registrant's Registration Statement on Form S-8 (Registration No. 333-12480), as filed with the Commission on September 6, 2000)
2.2	Form of Certificate for One Bearer Share (incorporated by reference to Exhibit 4.2 to Amendment No. 1 to Registrant's Registration Statement on Form F-1 (Registration No. 333-12192), as filed with the Commission on July 10, 2000)
2.3	Form of Certificate for Ten Bearer Shares (incorporated by reference to Exhibit 4.3 to Amendment No. 1 to Registrant's Registration Statement on Form F-1 (Registration No. 333-12192), as filed with the Commission on July 10, 2000)
2.4	Form of Certificate for One Hundred Bearer Shares (incorporated by reference to Exhibit 4.4 to Amendment No. 1 to Registrant's Registration Statement on Form F-1 (Registration No. 333-12192), as filed with the Commission on July 10, 2000)
2.5	Form of Certificate for One Thousand Bearer Shares (incorporated by reference to Exhibit 4.5 to Amendment No. 1 to Registrant's Registration Statement on Form F-1 (Registration No. 333-12192), as filed with the Commission on July 10, 2000)
2.6	Form of American Depositary Receipt (included in Exhibit 2.1 hereto)
2.7	Paying and Conversion Agency Agreement, dated November 17, 2003, by and among Ares International Finance 92 Ltd (the "Issuer"), Serono S.A. and UBS AG relating to the issuance by the Issuer of CHF 600,000,000 aggregate principal amount of 0.50% Convertible Unsubordinated Bonds due 2008 (the "Convertible Bonds") (incorporated by reference to Exhibit 2.7 to Registrant's Annual Report on Form 20-F for the year ended December 31, 2003)
2.8	Guarantee, dated as of November 26, 2003, of Serono S.A. in respect of the Convertible Bonds (incorporated by reference to Exhibit 2.8 to Registrant's Annual Report on Form 20-F for the year ended December 31, 2003)

- 8.1 List of Subsidiaries of the Registrant
- 11.1 Code of Ethics
- 12.1 Certification of Chief Executive Officer pursuant to SEC Rule 13a-14(a)
- 12.2 Certification of Chief Financial Officer pursuant to SEC Rule 13a-14(a)
- 13.1 Certification of Chief Executive Officer pursuant to SEC Rule 13a-14(b)
- 13.2 Certification of Chief Financial Officer pursuant to SEC Rule 13a-14(b)
- 15.1 Consent of PricewaterhouseCoopers S.A.

**SIGNATURES**

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Serono S.A.  
(Registrant)

/s/ Ernesto Bertarelli

Ernesto Bertarelli  
Vice-Chairman of the Board,  
Managing Director and Chief  
Executive Officer

Date: March 16, 2005

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**FINANCIAL STATEMENTS AND AUDITORS' REPORTS**

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**PricewaterhouseCoopers SA**

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**Report of Independent Registered Public Accounting Firm**

To the Shareholders and Board of Directors  
Of Serono SA, Coinsins (Vaud), Switzerland

As auditors of the group, we have audited the consolidated financial statements (balance sheet, income statement, statement of cash flows, statement of changes in equity and notes) of Serono SA as of December 31, 2004 and 2003 and for each of the three years in the period ended December 31, 2004.

These consolidated financial statements are the responsibility of the board of directors and management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We confirm that we meet the legal requirements concerning professional qualification and independence.

Our audits were conducted in accordance with auditing standards promulgated by the Swiss profession and with the International Standards on Auditing and with the standards of the Public Company Accounting Oversight Board (United States), which require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement. We have examined on a test basis evidence supporting the amounts and disclosures in the consolidated financial statements. We have also assessed the accounting principles used, significant estimates made by management and the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of Serono SA and its subsidiaries at December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004, in conformity with the International Financial Reporting Standards (IFRS) and comply with Swiss law.

International Financial Reporting Standards (IFRS) vary in certain important respects from the accounting principles generally accepted in the United States of America. Information relating to the nature and effect of such differences is presented in Note 35 to the consolidated financial statements.

PricewaterhouseCoopers SA

/s/ M. Aked     /s/ H-J. Hofer

M. Aked H-J. Hofer  
Geneva, January 31, 2005

**Consolidated income statements**

	Notes	Year ended December 31,		
		2004 U.S.\$000	2003 U.S.\$000	2002 U.S.\$000
<b>Revenues</b>				
Product sales	3	2,177,949	1,858,009	1,423,130
Royalty and license income	3	280,101	160,608	114,705
<b>Total revenues</b>	3	<b>2,458,050</b>	2,018,617	1,537,835
<b>Operating expenses</b>				
Cost of product sales		304,111	279,619	223,751
Selling, general and administrative		807,940	636,823	504,248
Research and development		594,802	467,779	358,099
Restructuring		-	-	16,303
Other operating expense, net	4	227,096	199,476	85,811
<b>Total operating expenses</b>		<b>1,933,949</b>	1,583,697	1,188,212
<b>Operating income</b>		<b>524,101</b>	434,920	349,623
Financial income, net	5	63,281	44,018	36,476
Other expense, net	6	629	19,743	1,658
<b>Total non-operating income, net</b>		<b>62,652</b>	24,275	34,818
<b>Income before taxes and minority interests</b>		<b>586,753</b>	459,195	384,441
Taxes	8	90,947	68,905	63,127
<b>Income before minority interests</b>		<b>495,806</b>	390,290	321,314
Minority interests		1,653	327	536
<b>Net income</b>		<b>494,153</b>	389,963	320,778
		U.S.\$	U.S.\$	U.S.\$
<b>Basic earnings per share</b>				
Bearer shares	9	32.35	24.63	20.07
Registered shares	9	12.94	9.85	8.03
American depositary shares	9	0.81	0.62	0.50
<b>Diluted earnings per share</b>				
Bearer shares	9	32.29	24.59	20.04
Registered shares	9	12.92	9.84	8.02
American depositary shares	9	0.81	0.61	0.50

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

**Consolidated balance sheets**

		As of December 31,	
	Notes	2004 U.S.\$000	2003 U.S.\$000
<b>ASSETS</b>			
<b>Current assets</b>			
Cash and cash equivalents	10	275,979	1,003,972
Short-term financial assets	17	784,999	434,810
Trade accounts receivable	11	427,935	318,388
Inventories	12	326,937	319,820
Prepaid expenses and other current assets	13	237,205	220,334
<b>Total current assets</b>		<b>2,053,055</b>	<b>2,297,324</b>
<b>Non-current assets</b>			
Tangible fixed assets	14	799,878	701,453
Intangible assets	15	290,558	259,626
Deferred tax assets	16	198,467	169,693
Long-term financial assets	17	929,030	1,104,333
Other long-term assets		133,302	39,174
<b>Total non-current assets</b>		<b>2,351,235</b>	<b>2,274,279</b>
<b>Total assets</b>		<b>4,404,290</b>	<b>4,571,603</b>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Trade and other payables	18	426,616	338,862
Short-term financial debts	19	34,527	51,224
Income taxes		166,861	146,086
Deferred income - current		33,128	47,200
Other current liabilities	21	208,071	170,019
<b>Total current liabilities</b>		<b>869,203</b>	<b>753,391</b>
<b>Total non-current liabilities</b>			
Long-term financial debts	19/20	640,892	532,022
Deferred tax liabilities	16	24,242	15,919
Deferred income - non-current		157,004	174,911
Provisions and other long-term liabilities	22/23	261,728	213,556
<b>Total non-current liabilities</b>		<b>1,083,866</b>	<b>936,408</b>
<b>Total liabilities</b>		<b>1,953,069</b>	<b>1,689,799</b>
<b>Minority interests</b>		<b>3,343</b>	<b>1,614</b>
<b>SHAREHOLDERS' EQUITY</b>			
Share capital	24	254,420	253,895
Share premium		1,023,125	1,002,991
Treasury shares	25	(987,489)	(157,642)
Retained earnings	26	2,064,499	1,669,700
Fair value and other reserves		23,482	22,711
Cumulative foreign currency translation adjustments		69,841	88,535
<b>Total shareholders' equity</b>		<b>2,447,878</b>	<b>2,880,190</b>
<b>Total liabilities, minority interests and shareholders' equity</b>		<b>4,404,290</b>	<b>4,571,603</b>

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





## Consolidated statements of changes in equity

	Notes	Share capital U.S.\$000	Share premium U.S.\$000	Treasury shares U.S.\$000	Retained earnings U.S.\$000	Fair value and other reserves U.S.\$000	Cumulative foreign currency translation adjustments U.S.\$000	Total U.S.\$000
<b>Balance as of January 1, 2002</b>		<b>253,137</b>	<b>975,335</b>	<b>(9,222)</b>	<b>1,108,086</b>	<b>(25,135)</b>	<b>(83,287)</b>	<b>2,218,914</b>
Purchase of treasury shares		-	-	(117,422)	-	-	-	(117,422)
Issue of share capital		279	13,806	184	-	-	-	14,269
Net income		-	-	-	320,778	-	-	320,778
Dividend - bearer shares		-	-	-	(46,637)	-	-	(46,637)
Dividend - registered shares		-	-	-	(17,601)	-	-	(17,601)
Fair value adjustments on available-for-sale investments		-	-	-	-	(19,672)	-	(19,672)
Translation effects		-	-	-	-	-	108,569	108,569
<b>Balance as of December 31, 2002</b>		<b>253,416</b>	<b>989,141</b>	<b>(126,460)</b>	<b>1,364,626</b>	<b>(44,807)</b>	<b>25,282</b>	<b>2,461,198</b>
<b>Balance as of January 1, 2003</b>		<b>253,416</b>	<b>989,141</b>	<b>(126,460)</b>	<b>1,364,626</b>	<b>(44,807)</b>	<b>25,282</b>	<b>2,461,198</b>
Purchase of treasury shares	25	-	-	(42,026)	-	-	-	(42,026)
Issue of share capital	27/28	479	13,725	10,844	-	-	-	25,048
Issue of call options on Serono shares		-	125	-	820	-	-	945
Issue of convertible debt	20	-	-	-	-	24,605	-	24,605
Net income		-	-	-	389,963	-	-	389,963
Dividend - bearer shares	26	-	-	-	(61,849)	-	-	(61,849)
Dividend - registered shares	26	-	-	-	(23,860)	-	-	(23,860)
Fair value adjustments on available-for-sale investments		-	-	-	-	25,903	-	25,903
Recognition of unrealized loss on available-for-sale investments		-	-	-	-	11,265	-	11,265
Sale of available-for-sale		-	-	-	-	5,745	-	5,745

investments								
Translation effects		-	-	-	-	-	63,253	63,253
<b>Balance as of December 31, 2003</b>		<b>253,895</b>	<b>1,002,991</b>	<b>(157,642)</b>	<b>1,669,700</b>	<b>22,711</b>	<b>88,535</b>	<b>2,880,190</b>
<b>Balance as of January 1, 2004</b>		<b>253,895</b>	<b>1,002,991</b>	<b>(157,642)</b>	<b>1,669,700</b>	<b>22,711</b>	<b>88,535</b>	<b>2,880,190</b>
Purchase of treasury shares	25	-	-	(833,148)	-	-	-	(833,148)
Issue of share capital	27/28	525	20,134	3,301	-	-	-	23,960
Net income		-	-	-	494,153	-	-	494,153
Dividend - bearer shares	26	-	-	-	(71,096)	-	-	(71,096)
Dividend - registered shares	26	-	-	-	(28,258)	-	-	(28,258)
Fair value adjustments on available-for-sale investments		-	-	-	-	14,488	-	14,488
Fair value adjustments on financial instruments	30	-	-	-	-	(13,717)	-	(13,717)
Translation effects		-	-	-	-	-	(18,694)	(18,694)
<b>Balance as of December 31, 2004</b>		<b>254,420</b>	<b>1,023,125</b>	<b>(987,489)</b>	<b>2,064,499</b>	<b>23,482</b>	<b>69,841</b>	<b>2,447,878</b>

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

**Consolidated statements of cash flows**

	Notes	Year ended December 31		
		2004 U.S.\$000	2003 U.S.\$000	2002 U.S.\$000
<b>Income before taxes and minority interests</b>		<b>586,753</b>	459,195	384,441
<b>Reversal of non-cash items</b>				
Depreciation and amortization	3	145,221	135,607	100,552
Financial income	5	(68,174)	(49,815)	(64,645)
Unrealized foreign exchange result		(39,137)	(14,671)	(15,868)
Financial expense		17,440	4,884	10,643
Loss on available-for-sale investments	6	-	20,149	-
Other non-cash items		(52,248)	(16,647)	17,233
<b>Cash flow from operating activities before working capital changes</b>		<b>589,855</b>	538,702	432,356
<b>Working capital changes</b>				
Trade and other payables, other current liabilities and deferred income		127,946	104,497	208,341
Trade accounts receivable and other receivables		(141,160)	(34,245)	(3,968)
Inventories		24,216	(7,265)	(16,752)
Prepaid expenses and other current assets		(28,253)	30,818	(25,482)
Taxes paid		(100,895)	(89,648)	(62,513)
<b>Net cash flow from operating activities</b>		<b>471,709</b>	542,859	531,982
Purchase of subsidiary, net of cash acquired	2	-	(9,651)	(115,092)
Proceeds from disposal of subsidiary, net of cash disposed	2	-	-	6,628
Purchase of tangible fixed assets		(178,919)	(162,527)	(99,144)
Proceeds from disposal of tangible fixed assets		5,569	11,081	10,488
Purchase of intangible and other long-term assets		(54,932)	(30,813)	(25,194)
Purchase of financial assets		(849,066)	(439,669)	(860,407)
Proceeds from sale of financial assets		654,628	8,058	344,362
Interest received		100,596	67,324	48,005
<b>Net cash flow used for investing activities</b>		<b>(322,124)</b>	(556,197)	(690,354)
Purchase of treasury shares	25	(811,677)	(42,026)	(117,422)
Proceeds from issue of share capital		10,333	13,105	11,610
Proceeds from exercise of stock options	27	2,163	7,536	1,454
Proceeds from issue of call options on Serono shares		-	945	-
Proceeds from issue of convertible bond	20	-	444,820	-
Proceeds from issue of financial debts		48,661	53,948	-

Repayments of financial debts		<b>(17,526)</b>	(50,182)	(112,132)
Other non-current liabilities		<b>(6,699)</b>	(15,717)	(10,257)
Interest paid		<b>(4,215)</b>	(4,361)	(8,121)
Dividends paid	26	<b>(99,354)</b>	(85,709)	(64,238)
<b>Net cash flow used for financing activities</b>		<b>(878,314)</b>	322,359	(299,106)
Effect of exchange rate changes on cash and cash equivalents		<b>736</b>	8,918	12,420
<b>Change in cash and cash equivalents</b>		<b>(727,993)</b>	317,939	(445,058)
<b>Cash and cash equivalents</b>				
At beginning of year	10	<b>1,003,972</b>	686,033	1,131,091
At end of year	10	<b>275,979</b>	1,003,972	686,033

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

## **Notes to the consolidated financial statements**

### **1. Summary of significant accounting policies**

#### **1.1 Basis of preparation**

The consolidated financial statements of the Serono group (“group” or “Serono”) have been prepared in accordance with International Financial Reporting Standards (IFRS). The consolidated financial statements have been prepared under the historical cost convention as modified by available-for-sale financial assets and certain financial assets and liabilities (including derivative instruments) at fair value. In view of the international nature of the group’s activities and due to the fact that more of the group’s revenues are denominated in U.S. dollars than in any other single currency, the consolidated financial statements are presented in that currency.

The preparation of the consolidated financial statements in conformity with IFRS requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Examples of the more significant estimates include accruals and provisions for fiscal and legal claims, sales provisions and returns, and inventory obsolescence. Actual results could differ from those estimates.

There were no new or revised standards or interpretations that became effective during 2004 and have been adopted by the group.

#### **1.2 Consolidation**

The consolidated financial statements include all companies in which the group, directly or indirectly, has more than 50% of the voting rights or over which it exercises control, unless they are held on a temporary basis. Companies are included in the consolidation as from the date on which control is transferred to the group, while companies sold are excluded from the consolidation as from the date that control ceases. The purchase method is used to account for acquisitions. The cost of an acquisition is measured as the fair value of the assets given, shares issued and liabilities incurred or assumed at the date of acquisition plus costs directly attributable to the acquisition. The excess of the cost of acquisition over the fair value of the net assets of the company acquired is recorded as goodwill (note 1.15). The proportion of the net assets and income attributable to minority shareholders are shown separately in the balance sheet and income statement, respectively. Intercompany transactions, balances and unrealized gains and losses on transactions between group companies are eliminated. Investments in companies over which the group is able to exercise significant influence, generally participations of 20% or more of the voting power, but over which it does not exercise management control, are accounted for by using the equity method. Such investments are initially recognized at cost and subsequently adjusted for the group’s share of net income and equity.

#### **1.3 Foreign currencies**

Assets and liabilities of group companies are translated into U.S. dollars at year-end exchange rates. Income and expense items are translated at average rates of exchange prevailing during the year. The translation adjustments resulting from exchange rate movements are accumulated in shareholders’ equity. On disposal of the group company, such translation differences are recognized in the income statement as part of the gain or loss on sale. Foreign currency transactions are translated using the exchange rate prevailing at the dates of the transactions. Foreign currency transaction gains and losses are included in the income statement, except for those related to intercompany transactions of a long-term investment nature which represent in substance part of the reporting entity’s net investment in a foreign entity; such gains and losses are included in the cumulative foreign currency translation adjustments component of shareholders’ equity.



#### **1.4 Revenue recognition**

Revenue from the sale of products is recognized upon transfer of significant risks and rewards of ownership to the customer. Revenue from the sales of products is reported net of sales and value added taxes, rebates and discounts and after eliminating sales within the group. Provisions for rebates and discounts are recognized in the same period that the related sales are recorded, based on the contract terms and historical experience. Provisions for product returns are made based on historical trends and specific knowledge of any customer's intent to return products. Royalty and licensing incomes are recognized on an accrual basis in accordance with the economic substance of the agreement. Interest income is recognized as earned unless collectibility is in doubt. Revenue from the rendering of services is recognized as the service is rendered over the contract period and reported as part of revenue from the sale of products.

#### **1.5 Research and development**

Research and development costs are expensed as incurred. The group considers that regulatory and other uncertainties inherent in the development of its new products preclude it from capitalizing development costs. Tangible fixed assets used for research and development purposes are capitalized and depreciated in accordance with the group's depreciation policy (note 1.12).

#### **1.6 Collaborative agreements**

Milestone and signing payments, payable under collaborative research and development or marketing agreements, are charged directly to research and development expense, unless there is significant evidence that all of the criteria for capitalization, as prescribed by IAS 38, "Intangible Assets", are met. Acquired projects which have achieved technical feasibility, usually signified by regulatory body approval, are capitalized, as it is probable that the costs will give rise to future economic benefits. In this case, the costs are capitalized and amortized as technology rights included in intangible assets (note 1.15). Receipts of upfront payments and other similar non-refundable payments relating to the sale or licensing of products or technology are initially reported as deferred income and recognized as income over the period of the collaboration on a straight-line basis.

#### **1.7 Employee benefits**

##### **Pension obligations**

The group operates a number of defined benefit and defined contribution plans, the assets of which are generally held in separate trustee-administered funds. The pension plans are generally funded by payments from employees and by the relevant group companies, taking into consideration the recommendations of independent qualified actuaries. For defined benefit plans, the group companies provide for benefits payable to their employees on retirement by charging current service costs to income. The liability in respect of defined benefit pension plans is the present value of the defined benefit obligation at the balance sheet date minus the fair value of plan assets, together with adjustments for actuarial gains/losses and past service costs. Defined benefit obligation is calculated annually by independent actuaries using the projected unit credit method, which reflects services rendered by employees to the date of valuation, incorporates assumptions concerning employees' projected salaries and uses interest rates of highly liquid corporate bonds which have terms to maturity approximating the terms of the related liability. Significant actuarial gains or losses arising from experience adjustments, changes in actuarial assumptions and amendments to pension plans are charged or credited to income over the average service life of the related employees. The group's contributions to the defined contribution pension plans are charged to the income statement in the year to which they relate.

##### **Stock option plan**

Stock options are granted to senior management and members of the Board of Directors. A compensation charge, being the difference between the market price of the bearer shares and American depository shares of Serono S.A. stock and the exercise price of the stock options, is calculated at the date the options are granted. This charge is recognized over the stock option's vesting period. When the option is exercised, the proceeds received net of any transaction costs are credited to share capital and share premium.

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## **Share purchase plans**

The group operates share purchase plans for employees and members of the Board of Directors. Contributions received from employees and directors are recorded as other current liabilities. Compensation cost related to the plans is calculated based on the difference between the price paid by employees and directors and the market value of the share on date of purchase which is recognized as expense.

## **Other employee benefits**

Salaries, wages, social contributions and other benefits are recognized on an accrual basis in the personnel expenses in the year in which the employees render the associated services.

### **1.8 Taxation**

Taxes reported in the consolidated income statements include current and deferred income taxes, as well as other taxes, principally those to be paid on capital and property. Deferred income tax is provided, using the liability method, for all temporary differences arising between the tax bases of assets and liabilities and their carrying values for financial reporting purposes. Currently enacted tax rates are used to determine deferred income tax. The principal temporary differences arise from depreciation on tangible fixed assets, provision for inventory, elimination of unrealized intercompany profits, tax losses carried forward and research and development tax credits carried forward. Deferred tax assets are recognized to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilized.

### **1.9 Cash and cash equivalents**

Cash and cash equivalents consist of cash on hand and deposits with banks that have a maturity of three months or less from the date of acquisition and which are readily convertible to known amounts of cash. This definition is also used for the consolidated statements of cash flows. Bank overdrafts are included in bank advances within short-term financial debts.

### **1.10 Trade accounts receivable**

Trade accounts receivable are carried at the original invoice amount less provisions made for doubtful accounts. Provisions for doubtful accounts are established when there is objective evidence that the group will not be able to collect all amounts due and are estimated based on a review of all outstanding invoice amounts. Bad debts are written off, through selling expense, in the year they are identified.

### **1.11 Inventories**

Inventories are carried at the lower of cost and net realizable value. Cost is calculated on a FIFO basis. The cost of work-in-progress and finished goods inventories includes raw materials, direct labor and production overhead expenditure based upon normal operating capacity. Net realizable value is the estimated selling price in the ordinary course of business less the costs of completion and distribution expenses. Provisions are established for slow-moving and obsolete inventory.

### **1.12 Tangible fixed assets**

Tangible fixed assets are initially recorded at cost of acquisition or construction cost and are depreciated on a straight-line basis over the following estimated useful lives:



Buildings	20-40 years
Machinery and equipment	3-10 years
Furniture and Fixtures	6-10 years
Leasehold improvement	over life of lease

Land is not depreciated. Construction costs include borrowing costs and operating expenses that are directly attributable to items of tangible fixed assets capitalized during construction. Borrowing costs incurred for the construction of any qualifying asset are capitalized during the period of time that is required to complete and prepare the asset for its intended use. Subsequent expenditure on an item of tangible fixed assets is capitalized at cost only when it is probable that future economic benefits associated with the item will flow to the group and the cost of the item can be measured reliably. Repair and maintenance costs are expensed as incurred. Gains and losses on disposal or retirement of tangible fixed assets are determined by comparing the proceeds received with the carrying amounts and are included in the consolidated income statements.

### 1.13 Leases

Leases of tangible fixed assets under which the group assumes substantially all the risks and rewards of ownership are classified as finance leases. Finance leases are capitalized at the inception of the lease at the lower of the fair value of the leased property and the present value of the minimum lease payments as tangible fixed assets. The tangible fixed assets acquired under finance leases are depreciated over the shorter of the useful life of the asset in accordance with the group's depreciation policy (note 1.12) and the lease term. The corresponding liabilities, net of financing charges, are included in the current and long-term portions of financial debts. The interest element of the financing cost is charged to the income statement over the lease period. Leases under which the lessor effectively retains a significant portion of the risks and rewards of ownership are classified as operating leases. Payments made under operating leases are charged to the income statement on a straight-line basis over the period of the lease.

### 1.14 Financial assets

The group has classified all its investments in debt and equity securities as available-for-sale securities, as they are not acquired to generate profit from short-term fluctuations in price. Available-for-sale securities are reported as short-term and long-term financial assets, depending on their remaining maturities. Purchases and sales of investments are recognized on the trade date, which is the date that the group commits to purchase or sell an asset. Investments are initially recognized at purchase cost including transaction costs and subsequently carried at fair value. Unrealized gains and losses arising from changes in the fair value of available-for-sale investments are recognized in equity. When the available-for-sale investments are sold, impaired or otherwise disposed of, the cumulative gains and losses previously recognized in equity are included in the income statement for the period. The fair values of marketable investments that are traded in active markets are determined by reference to stock exchange quoted bid prices.

### 1.15 Intangible assets

#### Technology rights and patents

Expenditure on acquired technology rights, patents, trademarks and licenses are capitalized as intangible assets when it is probable that future economic benefits will flow to the group and the cost can be measured reliably. Technology rights and patents are amortized on a straight-line basis over their estimated useful lives.



**Goodwill**

Goodwill represents the excess of the acquisition cost over the group's share of the fair value of the net assets acquired, at the date of acquisition. Goodwill and fair value adjustments are treated as assets and liabilities of the group. Goodwill on acquisitions is capitalized as an intangible asset at the date of acquisition and amortized on a straight-line basis over its estimated useful life, which, in the case of a biotechnology business, may exceed five years but which does not exceed 20 years. The estimated useful life of goodwill is determined based on its evaluation of the respective company at the time of acquisition, considering factors such as existing market share, potential growth and other factors inherent in the acquired company. Goodwill related to acquisitions occurring prior to January 1, 1995 has been fully charged to retained earnings and has not been retroactively capitalized and amortized.

**Software development**

Costs associated with developing or maintaining computer software are expensed as incurred. However, costs that are directly associated with an identifiable and unique asset controlled by the group, and that will probably generate economic benefits exceeding costs beyond one year, are capitalized as intangible assets and amortized on a straight-line basis over their useful lives, not exceeding a period of three years. Direct costs include the salaries and wages of the development team and an appropriate portion of relevant overheads.

**1.16 Impairment of long-lived assets**

Tangible fixed assets and other non-current assets, including goodwill and intangible assets, are reviewed at least annually for impairment losses, and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the carrying amount of the asset exceeds its recoverable amount, which is the higher of an asset's net selling price and value in use. Value in use is calculated based on estimated future cash flows expected to result from the use of the asset and its eventual disposition, discounted using an appropriate long-term pre-tax interest rate. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows.

**1.17 Derivative financial instruments and hedging activities**

Derivative financial instruments are initially recognized in the balance sheet at cost and are subsequently remeasured at their fair value. The method of recognizing the resulting gain or loss is dependent on whether the derivative is designated to hedge a specific risk and qualifies for hedge accounting. The group designates certain derivatives which qualify as hedges for accounting purposes as either a hedge of the fair value of recognized assets or liabilities (fair value hedge) or as a hedge of a forecasted transaction or a firm commitment (cash flow hedge).

The group documents at the inception of the transaction the relationship between hedging instruments and hedged items, as well as its risk management objective and strategy for undertaking various hedge transactions. This process includes linking all derivatives designated as hedges to specific assets. The group also documents its assessment, both at the hedge inception and on an ongoing basis, of whether the derivatives that are used in hedging transactions are highly effective in offsetting changes in fair values of hedged items.

**Fair value hedge**

Changes in the fair value of derivatives that are designated and qualify as fair value hedges and that are highly effective are recorded in the income statement, along with any changes in the fair value of the hedged asset or liability that is attributable to the hedged risk.



### **Cash flow hedge**

Changes in the fair value of derivatives that are designated and qualify as cash flow hedges and that are highly effective are recognized in equity. Where the forecasted transaction or firm commitment results in the recognition of an asset or of a liability, the gains and losses previously included in equity are included in the initial measurement of the asset or liability. Otherwise, amounts recorded in equity are transferred to the income statement and classified as revenue or expense in the same period in which the forecasted transaction affects the income statement.

When a hedging instrument no longer meets the criteria for hedge accounting, any cumulative gain or loss existing in equity at that time is recognized in the income statement. When a forecast transaction is no longer expected to occur, the cumulative gain or loss that was reported in equity is immediately transferred to the income statement.

### **Derivatives that do not qualify for hedge accounting**

Certain derivatives transactions do not qualify for hedge accounting. Changes in the fair value of any derivative instruments that do not qualify for hedge accounting are recognized immediately in the income statement as part of the financial result. The fair value of publicly traded derivatives is based on quoted market prices at the balance sheet date. The fair value of interest rate swaps is calculated as the present value of the estimated future cash flows. The fair value of forward foreign exchange contracts is determined using forward exchange market rates at the balance sheet date.

### **1.18 Provisions**

Provisions are recognized by the group when a present legal or constructive obligation exists as a result of past events, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate of the amount of the obligation can be made. Restructuring provisions are recorded in the period in which management has committed to a plan and it becomes probable that a liability will be incurred and the amount can be reasonably estimated. Restructuring provisions comprise lease termination penalties, other penalties and employee termination payments.

### **1.19 Financial debts**

Financial debts are recognized initially at the proceeds received, net of transaction costs incurred. In subsequent periods, financial debts are stated at amortized cost using the effective yield method; any difference between the proceeds and the redemption value is recognized in the income statement in the period of the borrowings. Financial debts are classified as current liabilities unless the group has an unconditional right to defer settlement of the liability for at least 12 months after the balance sheet date. When convertible bonds are issued, the fair value of the liability portion is determined using a market interest rate for an equivalent non-convertible bond; this amount is recorded as a non-current liability on the amortized cost basis until extinguished on conversion or maturity of the bonds. The remainder of the proceeds is allocated to the conversion option, which is recognized and included in shareholders' equity; the value of the conversion option is not changed in subsequent periods.

### **1.20 Share capital**

The authorized and the conditional share capital have been translated into U.S. dollars, for information purposes only, at the appropriate year-end exchange rates. Issued and fully paid share capital has been translated at the prevailing exchange rate on the date of issuance. Treasury shares are presented as a deduction from equity at cost and are presented as separate items within shareholders' equity. Differences between this amount and the eventual amount received upon reissue are recorded in share premium. Dividends are recorded in the group's financial statements in the period in which they are approved by the company's shareholders.





**1.21****Segment reporting**

The group's primary reporting format for segment reporting is geographical segments and the secondary reporting format is business segment. Geographical segments provide products or services within a particular economic environment that is subject to risks and returns that are different from those of components operating in other economic environments. The risk and return of the group's operations are primarily determined by the geographical location of the operations. This is reflected by the group's organizational structure and internal financial reporting system.

**1.22****Comparatives**

Where necessary, comparative figures have been adjusted to conform with changes in presentation in the current year.

**2.****Acquisitions and disposals****Acquisitions and disposals 2004**

There were no acquisitions or disposals during 2004.

**Acquisitions and disposals 2003**

During 2003 the group completed the acquisition of Genset S.A., a genomic-based biotechnology company. The acquisition was accounted for under the purchase method. Genset S.A. was acquired for aggregated cash considerations paid of \$149.7 million and the assumption of \$6.4 million in financial debts. The related goodwill arising on the acquisition of Genset S.A. was \$83.2 million, which is amortized over 20 years. The carrying amount of the goodwill arising on the acquisition of Genset S.A. as of December 31, 2004 was \$72.2 million (2003: \$76.3 million). There were no disposals during 2003.

**3.****Segment information****Primary reporting format - geographical segments**

	Notes	Year ended December 31, 2004					Unallocated <sup>(1)</sup> U.S.\$000	Total U.S.\$000
		Europe U.S.\$000	North America U.S.\$000	Middle East, Africa and Eastern Europe U.S.\$000	Asia-Pacific, Oceania and Japan U.S.\$000	Latin America U.S.\$000		
Product sales <sup>(2)</sup>		895,184	837,903	196,284	137,453	111,125	-	2,177,969
Royalty and license income <sup>(3)</sup>		243,673	6,755	29,673	-	-	-	280,101

<b>Total revenues</b>		<b>1,138,857</b>	<b>844,658</b>	<b>225,957</b>	<b>137,453</b>	<b>111,125</b>	<b>-</b>	<b>2,458,000</b>
Operating income <sup>(4)</sup>		568,650	403,370	41,888	43,543	52,955	(115,782)	994,600
Corporate research and development expenses		-	-	-	-	-	(470,523)	(470,523)
<b>Operating income</b>								<b>524,100</b>
<b>Total assets</b> <sup>(5)</sup>		<b>1,902,936</b>	<b>274,235</b>	<b>97,021</b>	<b>68,588</b>	<b>66,506</b>	<b>1,995,004</b>	<b>4,404,200</b>
<b>Total liabilities</b> <sup>(6)</sup>		<b>974,614</b>	<b>131,384</b>	<b>80,596</b>	<b>30,574</b>	<b>15,605</b>	<b>720,296</b>	<b>1,953,000</b>
<b>Other segment items</b>								
Additions to tangible fixed assets <sup>(7)</sup>	14	137,405	10,421	1,572	1,365	741	-	151,504
Additions to intangible assets <sup>(7)</sup>	15	67,407	-	-	-	-	-	67,407
Depreciation	14	84,645	9,341	9,976	1,560	882	18	106,412
Amortization	4	37,088	794	917	-	-	-	38,809
Financial income	5	13,607	363	449	73	42	53,640	68,133
Financial expense	5	(7,128)	(225)	(279)	(553)	(1,732)	(14,118)	(24,035)

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	<b>161,131</b>
	<b>116,926</b>
	<b>98,841</b>
	-
	<b>2,018,617</b>
Operating income <sup>(4)</sup>	
	494,455
	361,194
	38,398
	25,314
	45,055
)	(152,698)
	<b>811,718</b>
Corporate research and development expenses	
	-
	-
	-
	-
	-
)	(376,798)
	<b>(376,798)</b>
)	
<b>Operating income</b>	
	<b>434,920</b>
Total assets <sup>(5)</sup>	

	<b>1,691,985</b>
	<b>153,287</b>
	<b>113,650</b>
	<b>57,693</b>
	<b>51,988</b>
	<b>2,503,000</b>
	<b>4,571,603</b>
Total liabilities <sup>(6)</sup>	
	<b>797,144</b>
	<b>102,206</b>
	<b>27,133</b>
	<b>45,984</b>
	<b>12,366</b>
	<b>704,966</b>
	<b>1,689,799</b>
<b>Other segment items</b>	
Additions to tangible fixed assets	
	14
	170,610
	7,957
	4,201
	1,922
	317
	38
	<b>185,045</b>
Additions to intangible assets <sup>(7)</sup>	
	189

	15
	54,982
	-
	-
	-
	-
	-
	<b>54,982</b>
Depreciation	
	14
	82,363
	6,617
	4,898
	8,618
	924
	9
	<b>103,429</b>
Amortization	
	4
	30,467
	794
	917
	-
	-
	-
	190

									<b>32,178</b>
Financial income									5
									2,445
									378
									674
									61
									73
									46,184
									<b>49,815</b>
Financial expense									5
)									(7,062)
)									(154)
)									(404)
)									(560)
)									(3,303)
)									(1,480)
)									<b>(12,963)</b>

	Year ended December 31, 2002						
Notes	Europe	North	Middle	Asia-Pacific,	Latin	Unallocated <sup>(1)</sup>	<b>Total</b>
	U.S.\$000	America	East,	Oceania	America	U.S.\$000	<b>U.S.\$000</b>
		U.S.\$000	Africa	and Japan	U.S.\$000		
			and	U.S.\$000			

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Eastern  
Europe  
U.S.\$000

Product sales (2)		620,366	479,553	107,585	106,345	109,281	-	<b>1,423,130</b>
Royalty and license income (3)		113,332	868	500	5	-	-	<b>114,705</b>
<b>Total revenues</b>		<b>733,698</b>	<b>480,421</b>	<b>108,085</b>	<b>106,350</b>	<b>109,281</b>	-	<b>1,537,835</b>
Operating income (4)		308,621	345,398	53,459	31,495	62,769	(127,245 )	<b>674,497</b>
Corporate research and development expenses		-	-	-	-	-	(324,874 )	<b>(324,874 )</b>
<b>Operating income</b>								<b>349,623</b>
Total assets (5)		<b>1,400,887</b>	<b>171,968</b>	<b>80,993</b>	<b>55,308</b>	<b>52,152</b>	<b>1,722,970</b>	<b>3,484,278</b>
Total liabilities (6)		<b>665,222</b>	<b>91,705</b>	<b>34,137</b>	<b>60,241</b>	<b>22,114</b>	<b>148,496</b>	<b>1,021,915</b>
<b>Other segment items</b>								
Additions to tangible fixed assets (7)		102,219	12,011	7,028	1,155	2,911	-	<b>125,324</b>
Additions to intangible assets (7)		133,831	5,000	-	-	-	-	<b>138,831</b>
Depreciation		61,212	8,223	4,471	1,983	1,872	-	<b>77,761</b>
Amortization	4	21,263	409	917	-	202	-	<b>22,791</b>
Restructuring		12,420	-	-	-	3,883	-	<b>16,303</b>
Financial income	5	14,224	258	677	27	146	49,313	<b>64,645</b>
Financial expense	5	(6,039 )	(163 )	(324 )	(730 )	(3,341 )	(46 )	<b>(10,643 )</b>

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The following countries contributed to more than 5% of total revenues, capital expenditures or allocated assets:

	Total revenues <sup>(2) (3)</sup>			Capital expenditures <sup>(7)</sup>			Allocated assets <sup>(5)</sup>	
	Year ended December 31			Year ended December 31			As of December 31	
	<b>2004</b> U.S.\$000	2003 U.S.\$000	2002 U.S.\$000	<b>2004</b> U.S.\$000	2003 U.S.\$000	2002 U.S.\$000	<b>2004</b> U.S.\$000	2003 U.S.\$000
Switzerland	<b>205,997</b>	115,269	87,039	<b>149,564</b>	155,757	96,352	<b>1,197,631</b>	947,153
U.S.	<b>764,580</b>	630,477	426,188	<b>10,303</b>	7,921	16,715	<b>257,942</b>	153,200
Germany	<b>216,454</b>	228,579	161,095	<b>40</b>	1,213	1,403	<b>14,813</b>	49,329
Italy	<b>181,553</b>	160,526	117,999	<b>42,344</b>	32,066	10,420	<b>293,267</b>	237,602
France	<b>143,416</b>	118,228	97,951	<b>6,200</b>	6,941	122,915	<b>94,771</b>	90,898
Other	<b>946,050</b>	765,538	647,563	<b>10,460</b>	36,129	16,350	<b>550,862</b>	590,421
<b>Total</b>	<b>2,458,050</b>	2,018,617	1,537,835	<b>218,911</b>	240,027	264,155	<b>2,409,286</b>	2,068,603

(1) Unallocated items represent income, expenses, assets and liabilities of corporate coordination functions which are not directly attributable to specific geographical segments.

(2) Product sales are allocated to the geographical segments based on the country in which the customer is located.

(3) Royalty and license income is allocated to the geographical segments based on the country that receives the royalty.

(4) Operating income is allocated to the geographical segments as recorded by the legal entities in the respective regions.

(5) Assets are allocated to the geographical segments in which the assets are located. Unallocated assets represent primarily short-term and long-term financial assets and short-term bank deposits.

(6) Unallocated liabilities include liabilities related to taxation and a convertible bond.

(7) Additions to tangible fixed assets are allocated to the geographical segments in which the assets are located. Additions to intangible assets are allocated to the geographical segments in which the intangibles are held.

No other individual country contributed more than 5% of total revenues, capital expenditures or allocated assets.

### Secondary reporting format - business segment

The group operates in one business segment, namely human therapeutics. The human therapeutics business comprises over 95% of total revenues and shareholders' equity of the group. Therefore, results of operations, assets and liabilities, capital expenditures, depreciation and amortization, financial income and expense are reported on a consolidated basis for purposes of business segment reporting.

Product sales by therapeutic area consist of the following:

	Year ended December 31		
	<b>2004</b>	2003	2002
	U.S.\$000	U.S.\$000	U.S.\$000

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Rebif	<b>1,090,583</b>	819,376	548,806
Novantrone	<b>32,371</b>	30,867	258
<b>Total neurology</b>	<b>1,122,954</b>	850,243	549,064
Gonal-f	<b>572,710</b>	526,923	450,440
Cetrotide	<b>24,784</b>	24,840	18,362
Crinone	<b>19,824</b>	20,790	10,932
Ovidrel	<b>17,673</b>	12,330	5,676
Luveris	<b>10,615</b>	10,015	6,570
<b>Core infertility portfolio</b>	<b>645,606</b>	594,898	491,980
Metrodin HP	<b>15,855</b>	24,760	50,146
Pergonal	<b>11,476</b>	45,804	46,001
Profasi	<b>6,733</b>	15,376	19,803
Other products	<b>12,654</b>	12,069	13,942
<b>Total reproductive health</b>	<b>692,324</b>	692,907	621,872

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	Year ended December 31		
	2004 U.S.\$000	2003 U.S.\$000	2002 U.S.\$000
Saizen	182,130	151,459	124,048
Serostim	86,787	88,759	95,067
Zorbtive	835	-	-
<b>Total growth and metabolism</b>	<b>269,752</b>	<b>240,218</b>	<b>219,115</b>
Raptiva	4,906	-	-
<b>Total dermatology</b>	<b>4,906</b>	<b>-</b>	<b>-</b>
Other product sales <sup>(8)</sup>	88,013	74,641	33,079
<b>Total product sales</b>	<b>2,177,949</b>	<b>1,858,009</b>	<b>1,423,130</b>

(8) Other product sales include service revenues. Total service revenues earned in 2004 were \$12.1 million (2003: \$10.9 million and 2002: \$8.6 million).

#### 4. Other operating expense, net

	Year ended December 31		
	2004 U.S.\$000	2003 U.S.\$000	2002 U.S.\$000
Royalty and license expense	157,422	120,112	34,750
Amortization of intangible and other long-term assets <sup>(1)</sup>	30,921	30,425	22,791
Litigation and legal costs	20,646	25,690	13,314
Other	18,107	23,249	14,956
<b>Total other operating expense, net</b>	<b>227,096</b>	<b>199,476</b>	<b>85,811</b>

(1) Amortization of intangible assets not included in other operating expense, net amounted to \$7.9 million in 2004 (\$1.7 million in 2003 and none in 2002) and was mainly reported as selling, general and administrative expense.

#### 5. Financial income, net

	Year ended December 31		
	2004 U.S.\$000	2003 U.S.\$000	2002 U.S.\$000
Financial income	68,174	49,815	64,645
Financial expense	(24,035 )	(12,963 )	(10,643 )
Foreign currency gains/(losses)	19,142	7,166	(17,526 )
<b>Total financial income, net</b>	<b>63,281</b>	<b>44,018</b>	<b>36,476</b>

#### 6. Other expense, net

Other expense, net includes transactions that are outside the core group business such as non-operating unrealized losses and losses on disposal of available-for-sale equity investments, donations to charitable and other foundations, rental income and expense earned and paid on certain leases. An unrealized loss on an available-for-sale equity

investment of \$16.1 million, that was considered to be other than temporary, and a realized loss on disposal of an available-for-sale equity security of \$4.0 million were included in the other expense, net reported in 2003.

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## 7. Personnel costs

	Year ended December 31		
	2004	2003	2002
	U.S.\$000	U.S.\$000	U.S.\$000
Salaries and wages	407,541	340,807	297,745
Social benefits and other	190,133	163,911	133,082
<b>Total personnel costs</b>	<b>597,674</b>	<b>504,718</b>	<b>430,827</b>

As of December 31, 2004, there were 4,902 employees (2003: 4,577 employees and 2002: 4,616 employees) within the group.

## 8. Taxes

Income before taxes and minority interests, reduced by capital and other taxes, consists of the following:

	Year ended December 31		
	2004	2003	2002
	U.S.\$000	U.S.\$000	U.S.\$000
Switzerland	84,551	326,405	204,377
Foreign	488,622	116,959	170,543
<b>Total income before taxes and minority interests, reduced by capital and other taxes</b>	<b>573,173</b>	<b>443,364</b>	<b>374,920</b>

Total tax expense consists of the following:

	Year ended December 31		
	2004	2003	2002
	U.S.\$000	U.S.\$000	U.S.\$000
Switzerland	30,315	40,050	19,001
Foreign	61,074	10,513	56,554
Total current income taxes <sup>(1)</sup>	91,389	50,563	75,555
Switzerland	(16,250 )	7,403	(4,337 )
Foreign	2,228	(4,892 )	(17,613 )
Total deferred income taxes <sup>(1)</sup>	(14,022 )	2,511	(21,950 )
<b>Total income taxes</b>	<b>77,367</b>	<b>53,074</b>	<b>53,605</b>
Capital and other taxes	13,580	15,831	9,522
<b>Total tax expense</b>	<b>90,947</b>	<b>68,905</b>	<b>63,127</b>

(1) The change in the proportion of tax expense in 2003 between Switzerland and foreign countries was mainly due to the favorable close of outstanding fiscal years in foreign countries.

The group has operations in various countries that have differing tax laws and rates. Consequently, the effective tax rate on consolidated income may vary from year to year, according to the source of earnings. The effective income tax rate is calculated by dividing the income tax expense by the income before taxes and minority interests reduced by capital and other taxes. Reconciliation between the reported income tax expense and the amount computed using a basic Swiss statutory corporate tax rate of 30% is as follows:

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	Year ended December 31		
	2004	2003	2002
	%	%	%
Corporate tax rate	30.0	30.0	30.0
Effect of tax rates different from 30%	(11.5)	(15.9)	(13.3)
Effect of utilizing prior periods' tax losses not previously recognized	(0.7)	-	(0.1)
Effect of current year's losses not yet recognized	0.5	1.4	0.4
Effect of adjustments recognized in the period for current tax of prior periods	(4.9)	(6.2)	(3.6)
Other, net	0.1	2.7	0.9
<b>Effective tax rate</b>	<b>13.5</b>	<b>12.0</b>	<b>14.3</b>

The increase in the effective tax rate in 2004 is mainly due to the fact that the effective tax rate reported in 2003 was impacted by a non-recurring reduction in certain tax provisions in 2003 for the favorable close of prior fiscal years in various countries. Tax losses carried forward for income tax purposes by expiring date are as follows:

	U.S.\$000
2005	-
2006	11,369
2007	9,597
2008	14,290
2009	-
Thereafter	96,755
<b>Total</b>	<b>132,011</b>

As of December 31, 2004, tax losses available for carry-forward which have not been recognized due to uncertainty of their recoverability amount to \$49.3 million (2003: \$61.6 million).

## 9. Earnings per share

### Basic earnings per share

Basic earnings per share is calculated by dividing the net income attributable to shareholders by the weighted average number of shares outstanding during the year. 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:

	Year ended December 31		
	2004	2003	2002
	U.S.\$000	U.S.\$000	U.S.\$000
Net income attributable to bearer shareholders	351,655	281,459	232,381
Net income attributable to registered shareholders	142,498	108,504	88,397

<b>Total net income</b>	<b>494,153</b>	389,963	320,778
Weighted average number of bearer shares outstanding	<b>10,871,187</b>	11,427,194	11,580,611
Weighted average number of registered shares outstanding	<b>11,013,040</b>	11,013,040	11,013,040

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	Year ended December 31		
	2004 U.S.\$	2003 U.S.\$	2002 U.S.\$
<b>Basic earnings per share</b>			
Bearer shares	32.35	24.63	20.07
Registered shares	12.94	9.85	8.03
American depositary shares	0.81	0.62	0.50

**Diluted earnings per share**

For diluted earnings 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. In 2004, share equivalents of 25,431 bearer shares (2003: 25,696 and 2002: 17,544 bearer shares) arising from stock options granted to employees and directors were included in calculating diluted earnings per share. 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 income, is increased by eliminating the interest expense, net of tax, that would not be incurred if the bond were converted. In 2004 and 2003, the effect of the convertible bond was excluded from the calculation of diluted earnings per share as it was anti-dilutive.

	Year ended December 31		
	2004 U.S.\$000	2003 U.S.\$000	2002 U.S.\$000
Net income attributable to bearer shareholders	351,892	281,635	232,478
Net income attributable to registered shareholders	142,261	108,328	88,300
<b>Total net income</b>	<b>494,153</b>	<b>389,963</b>	<b>320,778</b>
Weighted average number of bearer shares outstanding	10,896,618	11,452,890	11,598,155
Weighted average number of registered shares outstanding	11,013,040	11,013,040	11,013,040

	Year ended December 31		
	2004 U.S.\$	2003 U.S.\$	2002 U.S.\$
<b>Diluted earnings per share</b>			
Bearer shares	32.29	24.59	20.04
Registered shares	12.92	9.84	8.02
American depositary shares	0.81	0.61	0.50



**10. Cash and cash equivalents**

	As of December 31	
	2004	2003
	U.S.\$000	U.S.\$000
Cash at bank and on hand	63,233	143,731
Short-term bank deposits	212,746	860,241
<b>Total cash and cash equivalents</b>	<b>275,979</b>	<b>1,003,972</b>

Short-term bank deposits are mainly denominated in U.S. dollars with an original maturity of three months or less from the date of acquisition. All funds are placed with banks with a high credit rating (minimum rating A). The average effective interest rate on short-term bank deposits was 2.04% (2003: 1.05%) and these deposits have an average maturity of three days (2003: 14 days) as of December 31, 2004.

**11. Trade accounts receivable**

	As of December 31	
	2004	2003
	U.S.\$000	U.S.\$000
Trade accounts receivable, gross	434,072	324,898
Provision for doubtful accounts	(6,137)	(6,510)
<b>Total trade accounts receivable</b>	<b>427,935</b>	<b>318,388</b>

The group sells its products worldwide through major wholesale distributors and direct to clinics and hospitals. There is no concentration of credit risk with respect to trade accounts receivable as the group has a large number of internationally dispersed customers.

**12. Inventories**

	As of December 31	
	2004	2003
	U.S.\$000	U.S.\$000
Raw materials	57,463	56,687
Work-in-progress	180,039	191,461
Finished goods	89,435	71,672
<b>Total inventories</b>	<b>326,937</b>	<b>319,820</b>

Included in inventories as of December 31, 2004 are \$26.6 million (2003: \$20.8 million) of inventory provisions. Inventory write-downs recognized as cost of product sales in 2004 amounted to \$8.3 million (2003: \$7.9 million).



**13. Prepaid expenses and other current assets**

	As of December 31	
	2004	2003
	U.S.\$000	U.S.\$000
Prepaid expenses	31,508	24,757
Accrued royalty income	75,296	49,176
VAT receivable	50,640	71,598
Accrued interest income	41,483	41,175
Fair value of derivative instruments (note 30)	17,245	10,205
Other	21,033	23,423
<b>Total prepaid expenses and other current assets</b>	<b>237,205</b>	<b>220,334</b>

**14. Tangible fixed assets**

	Land and buildings	Machinery and equipment	Furniture and fixtures	Leasehold improvements	Construction in progress	Total 2004	Total 2003
	U.S.\$000	U.S.\$000	U.S.\$000	U.S.\$000	U.S.\$000	U.S.\$000	U.S.\$000
<b>Cost</b>							
As of January 1	447,698	585,209	36,620	80,964	177,496	1,327,987	1,055,219
Additions (note 3)	52,592	80,589	1,313	8,628	8,382	151,504	185,045
Disposals <sup>(1)</sup>	(27,054 )	(80,178 )	(7,028 )	(18,807 )	(32 )	(133,099 )	(62,519 )
Currency adjustments	44,421	48,426	1,784	4,453	10,125	109,209	150,242
<b>As of December 31</b>	<b>517,657</b>	<b>634,046</b>	<b>32,689</b>	<b>75,238</b>	<b>195,971</b>	<b>1,455,601</b>	<b>1,327,987</b>
<b>Accumulated depreciation</b>							
As of January 1	145,732	390,223	23,538	67,041	-	626,534	500,710
Depreciation (note 3)	16,551	76,650	4,717	8,504	-	106,422	103,429
Disposals <sup>(1)</sup>	(22,663 )	(79,169 )	(6,891 )	(17,823 )	-	(126,546 )	(50,840 )
Currency adjustments	11,517	33,157	1,392	3,247	-	49,313	73,235
<b>As of December 31</b>	<b>151,137</b>	<b>420,861</b>	<b>22,756</b>	<b>60,969</b>	<b>-</b>	<b>655,723</b>	<b>626,534</b>
<b>Net book value as of December 31</b>	<b>366,520</b>	<b>213,185</b>	<b>9,933</b>	<b>14,269</b>	<b>195,971</b>	<b>799,878</b>	<b>701,453</b>
Net book value under finance lease contracts						502	814

Net book value of assets held for disposals	<b>6,051</b>	2,976
Capitalized borrowing costs (capitalization rate of 0.95% and 0.76%, respectively)	<b>1,389</b>	508
Tangible fixed assets pledged as security against long-term financial debts and certain unused line of credits	<b>30,718</b>	65,080
Capital commitments	<b>180,937</b>	21,044

(1) Disposals include fully depreciated tangible fixed assets of \$70.3 million in 2004 (\$10.8 million in 2003), which have been retired from active use.

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**15. Intangible assets**

	Technology rights and patents U.S.\$000	Goodwill U.S.\$000	Software development U.S.\$000	Other intangible U.S.\$000	<b>Total 2004</b> <b>U.S.\$000</b>	Total 2003 U.S.\$000
<b>Cost</b>						
As of January 1	287,395	104,501	51,137	8,940	<b>451,973</b>	382,219
Transfers	115	-	-	(115 )	-	2,457
Additions (note 3)	48,987	332	17,830	258	<b>67,407</b>	54,982
Disposals	(47 )	-	-	-	<b>(47 )</b>	(137 )
Currency adjustments	1,057	19	6,127	851	<b>8,054</b>	12,452
<b>As of December 31</b>	<b>337,507</b>	<b>104,852</b>	<b>75,094</b>	<b>9,934</b>	<b>527,387</b>	451,973
<b>Accumulated amortization</b>						
As of January 1	151,191	15,284	17,403	8,469	<b>192,347</b>	152,102
Transfers	115	-	-	(115 )	-	2,457
Amortization	24,964	5,092	7,877	838	<b>38,771</b>	31,462
Disposals	-	-	-	-	-	(137 )
Currency adjustments	2,650	-	2,319	742	<b>5,711</b>	6,463
<b>As of December 31</b>	<b>178,920</b>	<b>20,376</b>	<b>27,599</b>	<b>9,934</b>	<b>236,829</b>	192,347
<b>Net book value as of December 31</b>	<b>158,587</b>	<b>84,476</b>	<b>47,495</b>	<b>-</b>	<b>290,558</b>	259,626

**16. Deferred taxes**

	As of December 31				
	Deferred tax assets 2004 U.S.\$000	Deferred tax liabilities 2004 U.S.\$000	Deferred tax assets 2003 U.S.\$000	Deferred tax liabilities 2003 U.S.\$000	
	Tax losses carried forward	<b>28,343</b>	-	29,626	-
	Various research and development tax credits carried forward	<b>25,767</b>	-	19,827	-
Depreciation and amortization	<b>36,817</b>	<b>4,723</b>	29,384	8,232	
Inventories	<b>95,556</b>	<b>29,745</b>	61,186	13,915	
Other	<b>11,984</b>	<b>(10,226 )</b>	29,670	(6,228 )	
<b>Total deferred taxes</b>	<b>198,467</b>	<b>24,242</b>	169,693	15,919	

The gross movement in the deferred tax assets and liabilities during 2004 and 2003 are as follows:





	2004 U.S.\$000	2003 U.S.\$000
<b>Deferred tax liabilities</b>		
As of January 1	15,919	12,080
Charged to the income statement	7,685	3,070
Currency adjustments	638	769
<b>As of December 31</b>	<b>24,242</b>	<b>15,919</b>
<b>Deferred tax assets</b>		
As of January 1	169,693	126,291
Charged to the income statement	27,068	41,165
Currency adjustments	1,706	2,237
<b>As of December 31</b>	<b>198,467</b>	<b>169,693</b>

No deferred taxes have been charged or credited to shareholders' equity in 2004 and 2003.

Deferred tax assets and deferred tax liabilities are offset when there is a legally enforceable right to offset current tax assets against current tax liabilities and when the deferred taxes relate to the same tax jurisdiction.

Deferred tax assets relating to unused tax losses and deductible temporary differences have been recognized to the extent that it is probable that future taxable profits will be available to utilize such losses and temporary differences.

Deferred tax liabilities have not been recognized for undistributed earnings if such undistributed earnings are deemed to be permanently reinvested. As of December 31, 2004, unremitted earnings of subsidiaries considered permanently invested, for which deferred income taxes estimated at \$0.1 million (2003: \$2.9 million) have not been provided, were approximately \$0.7 million (2003: \$7.7 million).

17.	<b>Investments</b>				
	As of December 31				
	Cost	Gross unrealized gains	Gross unrealized losses	Total	Total
	2004	2004	2004	2004	2003
	U.S.\$000	U.S.\$000	U.S.\$000	U.S.\$000	U.S.\$000
Available-for-sale equity securities	128,680	32,731	(10,578 )	<b>150,833</b>	52,657
Available-for-sale debt securities	1,572,754	699	(10,257 )	<b>1,563,196</b>	1,117,998
Held-to-maturity securities <sup>(1)</sup>	-	-	-	-	368,488
<b>Total investments</b>	<b>1,701,434</b>	<b>33,430</b>	<b>(20,835 )</b>	<b>1,714,029</b>	1,539,143

Classification in the consolidated balance sheets

<b>Short-term financial assets</b>	<b>784,999</b>	434,810
<b>Long-term financial assets</b>	<b>929,030</b>	1,104,333

(1)Held-to-maturity securities with a carrying value of \$50.1 million have been sold in 2004 for proceeds of \$51.4 million, resulting in a realized gain on disposal of \$1.3 million. The remaining held-to-maturity securities have been reclassified as available-for-sale debt securities.

The group's investments primarily include deposits with prime banks, investments in short-term money market funds, and rated Eurobonds denominated in U.S. dollar with maturities up to three years. Equity security investments are typically related to collaborative agreements with other biotechnology and research companies. Included in available-for-sale securities are securities transferred to banks in connection with security lending transactions for a total amount \$49.3 million in 2004 and \$34.1 million in 2003, respectively.

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**18. Trade and other payables**

	As of December 31	
	2004	2003
	U.S.\$000	U.S.\$000
Trade accounts payable	94,140	72,207
Payroll related	122,651	103,439
Accrued expenses	209,825	163,216
<b>Total trade and other payables</b>	<b>426,616</b>	<b>338,862</b>

**19. Financial debts**

	Weighted average interest rate		As of December 31	
	2004	2003	2004	2003
	%	%	U.S.\$000	U.S.\$000
Mortgage notes	1.45	3.84	16,925	22,446
Bank loans	1.30	0.86	123,041	66,407
CHF600.0 million 0.5% senior unsubordinated convertible bond 2003/2008 (note 20)	3.03	3.03	507,790	454,764
Capital lease obligation	-	-	138	620
Total debts, long-term and current portion	-	-	647,894	544,237
Less current portion of long-term debts	-	-	(7,002)	(12,215)
<b>Total long-term financial debts</b>	<b>-</b>	<b>-</b>	<b>640,892</b>	<b>532,022</b>
Bank advances	5.84	3.03	27,525	39,009
Current portion of long-term debts	-	-	7,002	12,215
<b>Total short-term financial debts</b>	<b>-</b>	<b>-</b>	<b>34,527</b>	<b>51,224</b>
<b>Breakdown by maturities</b>				
2004			-	12,215
2005			7,002	2,763
2006			119,086	61,605
2007			1,983	1,832
2008			509,779	456,599
2009			1,864	1,712
Thereafter			8,180	7,511
<b>Total debts, long-term and current portion</b>			<b>647,894</b>	<b>544,237</b>

Total amount of secured financial debts	<b>18,977</b>	22,667
Unused lines of credit for short-term financing	<b>365,325</b>	366,863

The fair value of long-term financial debts, excluding the convertible bond, was \$132.3 million and \$76.8 million as of December 31, 2004 and 2003, respectively. The carrying amounts of short-term financial debts approximate their fair values. The fair values are based on future cash flows using market rate of interests for borrowings with similar credit status and maturities.

The percentage of fixed rate financial debts to total financial debts, excluding the convertible bond, was 17.1% and 28.3% as of December 31, 2004 and 2003, respectively.

Financial debts include only general default covenants. The group is in compliance with these covenants. Future minimum lease payments under capital leases are as follows:

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	U.S.\$000
2005	127
2006	27
2007	8
2008	3
2009 and thereafter	-
<b>Total minimum lease payments</b>	<b>165</b>
Less amount representing interest	(27)
<b>Present value of net minimum lease payments</b>	<b>138</b>

**20. Convertible bond**

	2004 U.S.\$000	2003 U.S.\$000
Face value of convertible bond issued on November 26, 2003	465,261	465,261
Transactions costs	(6,611)	(6,611)
<b>Equity conversion component</b>	<b>(24,605)</b>	<b>(24,605)</b>
Liability component on initial recognition on November 26, 2003	434,045	434,045
Interest expense	13,784	1,094
Cumulative translation adjustment	59,961	19,625
<b>Liability component as of December 31</b>	<b>507,790</b>	<b>454,764</b>

In 2003 the group issued 120,000 0.50% senior unsubordinated convertible bonds at a nominal value of CHF600.0 million. Each bond has a nominal value of CHF5,000 and is convertible into Serono S.A. bearer shares at the rate of 3.533 bearer shares per bond or at an initial conversion price of CHF1,415 per share and will mature in 2008. The bond has a conversion price of CHF1,497 based on its redemption value of CHF634.8 million. The source of the shares is a combination of treasury shares and conditional share capital. The bond is callable after November 30, 2006 subject to a 115% provisional call hurdle of the accreted principal amounts. If not converted prior to the date of maturity, the bonds will be redeemed at 105.8% of their face amount.

Interest expense on the bond is calculated on the effective yield basis using an effective interest rate of 3.03%.

The fair value of the convertible bond as of December 31, 2004 based on quoted market prices was \$523.2 million (2003: \$486.2 million).

**21. Other current liabilities**

	As of December 31	
	2004	2003
	U.S.\$000	U.S.\$000
Royalty payables	56,254	42,332
Taxes other than income taxes	42,596	16,301
Short-term collaboration payables	38,655	32,902
Short-term provisions (note 22)	23,448	31,691
Employee Share Purchase Plan	17,604	19,115
Fair value of derivative instruments (note 30)	10,678	11,268
Other	18,836	16,410
<b>Total other current liabilities</b>	<b>208,071</b>	<b>170,019</b>

**22. Provisions and other long-term liabilities**

	As of December 31	
	2004	2003
	U.S.\$000	U.S.\$000
Long-term legal provisions	100,244	63,022
Long-term collaboration payables	66,744	72,447
Pension liabilities (note 23)	59,805	55,263
Staff leaving indemnities <sup>(1)</sup>	16,397	15,249
Fair value of derivative instruments (note 30)	13,717	-
Other	4,821	7,575
<b>Total provisions and other long-term liabilities</b>	<b>261,728</b>	<b>213,556</b>

(1)The liability for staff leaving indemnities represents amounts payable to employees upon their termination of employment under provisions of the Italian and Israeli civil codes and collective labor contracts.

Balances as of December 31, 2004 and movements in provisions were as follows:

	Short-term legal provisions U.S.\$000	Other short-term provisions U.S.\$000	Total short-term provisions U.S.\$000	Long-term legal provisions U.S.\$000	Total provisions 2004 U.S.\$000
As of January 1	19,169	12,522	31,691	63,022	94,713
Additions	94	24,963	25,057	41,222	66,279
Releases	(16,450)	(2,735)	(19,185)	(4,000)	(23,185)
Cash payments	(155)	(15,020)	(15,175)	-	(15,175)
Currency adjustments	89	971	1,060	-	1,060
<b>As of December 31</b>	<b>2,747</b>	<b>20,701</b>	<b>23,448</b>	<b>100,244</b>	<b>123,692</b>

## Legal provisions

A number of group companies are the subject of litigation arising from the normal conduct of their operations, as a result of which legal proceedings, including breach of contract and patent infringement cases claims, could be made against them. Management believes that during the next few years, the aggregate impact, beyond current reserves, of these and other legal matters affecting the company is reasonably likely to be material to the company's results of operations and cash flows, and may be material to its financial condition and liquidity.

Interpharm Laboratories Ltd. and other group affiliates are defendants in a lawsuit, filed by the Israel Bio-Engineering Project Limited Partnership ("IBEP") in 1993 in the District Court of Tel Aviv-Jaffa, Israel, concerning certain proprietary rights and royalty rights and other claims of IBEP arising out of funding provided for the development of recombinant human interferon beta as well as certain other products in the early to mid-1980s. The trial of the ownership and contractual preliminary issues started in 2002 and is expected to continue through 2005. In 2003 IBEP had sued Amgen Inc., Immunex Corporation, and Wyeth in U.S. District Court in Los Angeles, California, alleging that the product Enbrel infringes IBEP's asserted rights under a patent known as the "701 patent" issued to Yeda Research and Development Co. Ltd. ("Yeda"), and exclusively licensed to the group. Yeda joined as a defendant and on February 18, 2004, the District Court of California granted Yeda's motion for summary judgment declaring that Yeda was the rightful owner of the 701 patent. IBEP has appealed the summary judgment decision to the Federal Circuit Court of Appeals, which heard argument on January 11, 2005.

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In 1996, one of Serono's Italian subsidiaries entered into an agreement with an Italian company, Italfarmaco S.p.A., for the co-marketing of recombinant interferon beta-1a in Italy. Italfarmaco terminated the contract at the end of 1999, alleging breach by Serono's subsidiary of its obligations, and initiated proceedings before the International Chamber of Commerce International Court of Arbitration in Milan, Italy, asking for the payment of damages, including loss of profit and business opportunities. Serono filed a counterclaim alleging Italfarmaco's default in the execution of the agreement and claiming monetary damages. The Arbitration Panel has appointed an expert for the evaluation for the potential damages. Serono expects the proceedings to last at least through 2005.

In 1999, Institut Biochimique S.A. ("IBSA"), initiated proceedings before the Tribunale Civile in Rome, Italy, the Tribunal de Grande Instance in Paris, France, and the Cour de Justice of the Canton of Geneva, Switzerland asserting that either Serono's patents relating to highly purified (urinary) FSH are invalid or the processes used by IBSA do not infringe them. The proceedings filed in Switzerland and France have been stayed, pending the outcome of the proceedings in Italy. The Italian court decided in October 2003 that the patent is valid in its entirety and that the fact that an FSH product is made by a third party using a process different from the one described in the patent is not sufficient to rule out infringement of the product claims. IBSA has not appealed the decision of the court of first instance and the parties have entered into a settlement agreement.

Serono'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. Other pharmaceutical companies have received similar subpoenas as part of an ongoing, industry-wide investigation by the states and the federal government into the setting of average wholesale prices and sales and marketing and other practices. 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 is cooperating with the investigation. The outcome of this investigation could include the commencement of civil and/or criminal proceedings involving the imposition of substantial fines, penalties and injunctive or administrative penalties, including exclusion from government reimbursement programs, or a resolution of civil and/or criminal allegations resulting in a substantial monetary settlement. The final settlement or adjudication of this matter could have a material adverse effect on the operations or financial condition of the group. Serono cannot predict the timing of the resolution of this matter or ultimate outcome.

### **Restructuring provisions**

The restructuring provisions related to the withdrawal from the urinary sector of the reproductive health business in Italy and the sales of two companies in Latin America have been fully utilized for payments in 2003. All significant actions associated with the restructuring plan were completed during 2003. There were no restructurings during 2004.

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## **23.**

### **Retirement pension plans**

Substantially all employees of the group are covered by defined benefit, defined contribution, insured or state pension plans. Pension costs in 2004 amounted to \$24.7 million (2003: \$19.1 million and 2002: \$17.3 million). Included in pension cost is the amount of \$9.3 million (2003: \$6.3 million and 2002: \$2.9 million) which represents contributions to defined contribution plans. The group funds these plans in amounts consistent with the local funding requirements, laws and regulations.



The status and the amounts recognized in the consolidated balance sheets and consolidated income statements for the defined benefit plans are as follows:

	As of December 31	
	2004 U.S.\$000	2003 U.S.\$000
Present value of funded obligations	205,090	168,544
Fair value of plan assets	186,774	145,687
Funded status	18,316	22,857
Unrecognized actuarial gain	41,489	32,406
<b>Total pension liabilities</b>	<b>59,805</b>	<b>55,263</b>

	Year ended December 31		
	2004 U.S.\$000	2003 U.S.\$000	2002 U.S.\$000
Current service cost	17,529	14,960	13,995
Interest cost	7,913	6,014	6,206
Expected return on plan assets	(8,609 )	(6,762 )	(5,960 )
Amortization of unrecognized actuarial (gain)/loss	(1,453 )	(1,342 )	113
<b>Total pension costs</b>	<b>15,380</b>	<b>12,870</b>	<b>14,354</b>

Defined benefit obligations and related costs for defined benefit plans are based upon valuations performed annually by independent actuaries. Plan assets are recorded at fair values.

The actual return on plan assets in 2004 was a gain of \$11.2 million (2003: gain of \$12.9 million and 2002: loss of \$10.1 million).

The movements in the pension liabilities recognized in the consolidated balance sheets are as follows:

	2004	2003
	U.S.\$000	U.S.\$000
As of January 1	55,263	50,047
Pension costs	15,380	12,870
Contributions paid	(15,351 )	(13,563 )
Currency adjustments	4,513	5,909
<b>As of December 31</b>	<b>59,805</b>	<b>55,263</b>

Principal weighted average actuarial assumptions used for accounting purposes are:

	Year ended December 31	
	2004 %	2003 %
Discount rate	4.03	4.24
Expected return on plan assets	5.19	5.65
Future salary increases	2.69	2.67

Future pension increases

**3.76**

4.03

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**24. Share capital**

As of December 31, 2004

Class of shares	Number of shares	Nominal value	CHF000	U.S. \$000
<b>Issued and fully paid share capital</b>				
<b>Registered</b>	<b>11,013,040</b>	<b>CHF10</b>	<b>110,130</b>	<b>68,785</b>
<b>Bearer</b>	<b>11,738,175</b>	<b>CHF25</b>	<b>293,455</b>	<b>185,635</b>
<b>Total share capital</b>			<b>403,585</b>	<b>254,420</b>
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

As of December 31, 2003

Class of shares	Number of shares	Nominal value	CHF000	U.S. \$000
<b>Issued and fully paid share capital</b>				
<b>Registered</b>	<b>11,013,040</b>	<b>CHF10</b>	<b>110,130</b>	<b>68,785</b>
<b>Bearer</b>	<b>11,711,826</b>	<b>CHF25</b>	<b>292,796</b>	<b>185,110</b>
<b>Total share capital</b>			<b>402,926</b>	<b>253,895</b>
Authorized share capital - bearer	1,400,000	CHF25	35,000	28,377
Conditional share capital - bearer for option and/or convertible bonds	152,000	CHF25	3,800	3,081
Conditional share capital - bearer for stock options	352,996	CHF25	8,825	7,155

At the Annual General Meeting of Shareholders held on May 25, 2004, the shareholders approved increasing the maximum amount of the conditional share capital to CHF36.3 million (1,452,000 bearer shares with a par value of CHF25 each) for option and/or convertible bonds and to CHF18.8 million (753,000 bearer shares with a par value of CHF25 each) for stock options. In addition, shareholders approved the renewal of the authorization to increase the share capital by a maximum of CHF35.0 million (1,400,000 bearer shares with a par value of CHF25 each) for a period of two years. 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.

25.

**Treasury shares**

There were 304,939 treasury shares held by a group company as of January 1, 2004. In 2004, an additional 1,313,644 treasury shares were acquired (2003: 80,157 treasury shares) for a total consideration of CHF1,017.4 million or \$833.1 million (2003: CHF55.0 million or \$42.0 million). During 2004, 7,149 treasury shares were granted to employees (4,630 shares in 2003), 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. No treasury shares (2003: 10,000 treasury shares) were reissued during 2004 upon the exercise of call options.

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. 962,435 treasury shares were acquired during 2004 under the second Share Buy Back Plan for a total consideration of CHF736.5 million or \$611.3 million.

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The total number of treasury shares held as of December 31, 2004 is 1,611,434, of which 962,435 treasury shares will eventually be cancelled.

## 26. 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 CHF130.8 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.

## 27. 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:

	2004		2003	
	Bearer options	Weighted average exercise price CHF	Bearer options	Weighted average exercise price CHF
Options outstanding				
As of January 1	277,782	1,068	209,380	1,272
Granted	95,700	791	93,230	650
Exercised	(4,530)	599	(2,741)	546
Cancelled	(24,231)	1,090	(22,087)	1,301
<b>As of December 31</b>	<b>344,721</b>	<b>996</b>	<b>277,782</b>	<b>1,068</b>
Options exercisable	140,193	1,161	92,095	1,182
Options available for grant based on the conditional share capital	336,808	-	61,462	-
Weighted average fair value of options granted (CHF)	-	269	-	191

The table below summarizes employee bearer stock options outstanding and exercisable as of December 31, 2004:

Range of exercise price CHF	Outstanding			Exercisable	
	Bearer Options	Average remaining contractual life years	Weighted average exercise price CHF	Bearer Options	Weighted average exercise price CHF
500 - 700	99,883	7.31	628	40,355	598
700 - 900	105,840	9.09	798	4,285	849
1,300 - 1,500	118,904	6.55	1,392	75,459	1,383
1,500 - 1,700	20,094	5.05	1,521	20,094	1,521
<b>Total</b>	<b>344,721</b>	<b>7.46</b>	<b>996</b>	<b>140,193</b>	<b>1,161</b>

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

	2004		2003	
	ADS Options	Weighted average exercise price U.S.\$	ADS Options	Weighted average exercise price U.S.\$
Options outstanding				
As of January 1	20,000	16.51	-	-
Granted	1,102,000	15.53	20,000	16.51
Exercised	-	-	-	-
Cancelled	(55,200 )	15.55	-	-
<b>As of December 31</b>	<b>1,066,800</b>	<b>15.54</b>	<b>20,000</b>	<b>16.51</b>
Options exercisable	5,000	16.51	-	-
Weighted average fair value of options granted (U.S.\$)	-	6.51	-	7.19

The table below summarizes employee ADS stock options outstanding and exercisable as of December 31, 2004:

Range of exercise price U.S.\$	Outstanding			Exercisable	
	ADS Options	Average remaining contractual life years	Weighted average exercise price U.S.\$	ADS Options	Weighted average exercise price U.S.\$
12 - 16	1,017,200	9.27	15.49	-	-
16 - 20	49,600	9.15	16.57	5,000	16.51
<b>Total</b>	<b>1,066,800</b>	<b>9.27</b>	<b>15.54</b>	<b>5,000</b>	<b>16.51</b>

During 2004, 4,530 bearer stock options (2003: 2,741 bearer stock options) were exercised yielding proceeds of CHF2.7 million or \$2.4 million (2003: CHF1.5 million or \$1.2 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 December 31, 2004 is 336,808 options (2003: 61,462 options).

A compensation charge of \$1.2 million (2003: \$1.4 million and 2002: \$1.0 million) has been recognized for stock options granted in the plan years 2002, 2001 and 2000. The compensation charge related to stock options granted is being expensed over the four-year vesting period.

**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 2004, 5,200 stock options (2003: 4,600 options) were granted to directors at a predetermined exercise price of CHF772 (2003: CHF692). No director stock options were cancelled or exercised in 2004 and 2003. There are 20,720 director stock options outstanding as of December 31, 2004 (2003: 15,520 director stock options) with a weighted average exercise price of CHF755 (2003: CHF749).

**28. 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 depository 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. In 2004, 20,301 bearer shares (2003: 23,229 bearer shares) were granted to employees at a price of CHF654 per share (2003: CHF654 per share). As of December 31, 2004, a total of \$11.5 million (2003: \$10.5 million) in contributions was held by the group to be used to purchase 20,940 bearer and American depository shares on behalf of employees in January 2005. The accrued compensation cost from the discount to be offered to employees based on the contributions held as of December 31, 2004 was \$2.1 million (2003: \$4.0 million and 2002: \$1.6 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 2004, 6,648 bearer shares (2003: 4,208 bearer shares) were distributed to employees. The accrued compensation cost related to the matching shares that will be distributed in January 2005 is \$3.5 million (2003: \$4.8 million and 2002: \$2.2 million) and is calculated based on the number of matching shares multiplied by the year-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 2004, 1,518 bearer shares (none in 2003) were granted to the directors that participate in the plan.

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**29. Commitments and contingencies**

**Collaborative agreements commitments**

The group entered into a number of commitments under collaborative agreements as described in note 32 to the consolidated financial statements. As part of these agreements the group has made commitments to make research and development and in-licensing payments to the collaborators, usually once milestones have been achieved, but in some cases on a regular basis. In the unlikely event that all the collaborators were to achieve all the contractual milestones, the group would be required to pay approximately \$726.3 million. The estimated timing of the eventual payments is presented as follows:



	U.S.\$000
2005	132,022
2006	78,517
2007	104,908
2008	66,406
2009	73,250
Thereafter	271,175
<b>Total</b>	<b>726,278</b>

The group does not consider any single collaborative agreement to be sufficiently large a commitment that it could impair significantly the group's financial condition.

### Operating lease commitments

Payments made during 2004 on operating leases amounted to \$31.0 million (2003: \$23.6 million). Future minimum payments under non-cancelable operating leases, which totaled \$141.9 million (2003: \$130.8 million), are as follows:

	U.S.\$000
2005	33,537
2006	29,330
2007	15,154
2008	11,122
2009	10,255
Thereafter	42,486
<b>Total</b>	<b>141,884</b>

### Other commitments

The group entered into various purchase commitments for services and materials as part of the ordinary business. These commitments are not in excess of current market prices and reflect normal business operations.

### Contingencies

As part of the ordinary course of the business, the group is subject to contingent liabilities in respect of certain litigation in various countries around the world. In the opinion of management and general counsel of the group, none of the outstanding litigation will have a significant adverse effect on the group's financial position.

## 30. Derivative financial instruments

### Market risk

The group is exposed to market risk primarily related to foreign currency exchange rates, interest rates and the market value of investments in financial assets and equity securities. These exposures are actively managed by the Serono treasury group in accordance with a written policy approved by the Board of Directors and subject to internal controls.

The objective is to minimize, where deemed to be appropriate, fluctuations in earnings and cash flows associated with changes in foreign currency exchange rates, interest rates and the market value of investments in financial assets and equity securities. To manage the volatility relating to these exposures and to enhance the yield on the investment in financial assets, the group uses derivative financial instruments. The group does not use financial derivatives for trading or speculative reasons, or for purposes unrelated to the normal business activities. Any loss in value on a financial derivative would normally be offset by an increase in the value of the underlying transaction.

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### **Foreign currency exchange rates**

The group presents its consolidated financial statements in U.S. dollar. As a consequence of the global nature of Serono's business, the group is exposed to foreign currency exchange rate movements, primarily in European, Asian and Latin American countries. The group uses foreign currency options and forward foreign exchange contracts to hedge certain anticipated cash flows in currencies other than the U.S. dollar to achieve relatively stable and predictable cash flows. Net investments in Serono affiliates with a functional currency other than the U.S. dollar are of long-term nature and the group does not hedge such foreign currency translation exposures.

### **Interest rates**

The group manages the exposure to interest rate risk through the proportion of fixed rate debt and floating rate debt, as well as the maturity profile of fixed rate financial assets. Net financial income earned on the group's net financial assets is generally affected by changes in the level of interest rates, principally the U.S. dollar interest rate. The group's exposure to fluctuations in net financial income is managed by making investments in high quality financial assets which pay a fixed interest rate until maturity and to a lesser extent through the use of interest rate swaps that are sensitive to interest movements. To limit the group's exposure to future fluctuations in interest rates, the group has also entered into delayed start swaps that fix the interest rate on the anticipated post-completion financing related to the new headquarter and research centre.

### **Counterparty risk**

Counterparty risk includes issuer risk on debt securities, settlement risk on derivative and money market transactions, and credit risk on cash and fixed term deposits. Issuer risk is limited by buying debt securities which are at least A rated. Settlement and credit risk is reduced by entering into transactions with counterparties that are usually at least A rated banks or financial institutions. Exposure to these risks and compliance with the risk parameters approved by the Board of Directors is closely monitored. The group does not expect any losses due to non-performance by these counterparties, and the diverse portfolio of investments limits the exposure to any single counterparty or sector.

### **Equity prices**

The group is exposed to equity price risks on the marketable portion of the available-for-sale equity securities. Equity securities typically relate to collaborative agreements with other biotechnology and research companies. Equity securities are not purchased as part of the normal day-to-day management of financial assets authorized by the Board of Directors and managed by the group treasury department, with the exception of treasury shares that are acquired under the approved Share Buy Back Plans.

### **Commodities**

The group has very limited exposures to price risk related to anticipated purchases of certain commodities used as raw materials in its business. A change in commodity prices may alter the gross margin, but due to the limited exposure to any single raw material, a price change is unlikely to have a material unforeseen impact on the group's earnings.

### **Derivative financial instruments**

The fair values of derivative financial instruments, if all the instruments were closed out at the year-end, are as follows as of December 31, 2004 and 2003:

	As of December 31, 2004		As of December 31, 2003	
	Positive fair values	Negative fair values	Positive fair values	Negative fair values
	U.S.\$000	U.S.\$000	U.S.\$000	U.S.\$000
Foreign currency derivatives				
Currency options	1,065	-	7,854	(1,869)
Forward foreign exchange contracts	16,180	(8,950)	2,267	(6,181)
Interest rate derivatives				
Interest rate swaps	-	-	-	(321)
Interest rate swaps - fair value hedges	-	(1,728)	-	(2,346)
Interest rate swaps - cash flow hedges	-	(13,717)	84	(551)
<b>Total</b>	<b>17,245</b>	<b>(24,395)</b>	<b>10,205</b>	<b>(11,268)</b>

The positive and negative fair values represent the market values if the instruments were closed out at the year-end, based on available market prices, and are the same as the carrying values in the consolidated balance sheets. Foreign currency derivatives mature in 2005, interest rate swaps that qualify as fair value hedges mature in 2005 and interest rate swaps that qualify as cash flow hedges mature in 2017. As of December 31, 2004 the fixed interest rates varied from 2.56% to 3.79% (2003: 2.40% to 7.38%) and the main floating rates were U.S. dollar and Swiss franc LIBOR. The contract or underlying principal amounts of the outstanding interest rate swaps as of December 31, 2004 were \$315.0 million (2003: \$138.0 million).

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### 31. Principal shareholders

As of December 31, 2004, Bertarelli & Cie, a partnership limited by shares with its principal offices at Chésereux (Vaud), Switzerland, held 51.43% of the capital and 65.36% 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 7.00% of the capital and 10.53% of the voting rights of Serono S.A.

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### 32. Collaborative agreements

Financial terms for certain collaborative agreements described below have not been disclosed, in accordance with confidentiality requirements within the agreements.

Up-front fees related to collaborative agreements totaled \$71.1 million in 2004, \$4.0 million in 2003 and \$24.8 million in 2002. Under the same agreements, milestone payments totaled \$40.1 million in 2004, \$32.5 million in 2003 and \$0.3 million in 2002 and research and development payments totaled \$6.2 million, \$17.2 million and \$11.9 million in 2004, 2003 and 2002, respectively. The amortization charges in respect of the amounts capitalized for collaborative agreements totaled \$22.1 million, \$19.2 million and \$15.8 million in 2004, 2003 and 2002, respectively.

#### Collaborative agreements for 2004

Serono and CancerVax Corporation entered into a worldwide collaboration for the development and commercialization of Canvaxin, an investigational specific active immunotherapy product being developed for the treatment of advanced-stage melanoma. Under the terms of the agreement, Serono paid CancerVax an up-front fee of \$25.0 million and purchased one million shares of CancerVax common stock for \$12.0 million. In addition, CancerVax could receive up to \$253.0 million in milestone payments for the achievement of development, regulatory

and commercial milestones. The fee has been expensed as research and development expense. The purchase of common stock was recorded as an available-for-sale equity investment.

Serono entered into an agreement with Micromet AG to develop and commercialize Micromet's MT201 (adecatumumab), a pan-carcinoma monoclonal antibody directed against the epithelial cell adhesion molecule Ep-CAM for the treatment of cancers of epithelia cell origin. Under the terms of the agreement, Micromet received an initial license fee of \$10.0 million and will receive additional milestone payments of up to \$138.0 million if the product is successfully developed and registered worldwide in three or more indications. In addition, Micromet will receive undisclosed royalties based on net sales of the product. The up-front fee has been expensed as research and development expense.

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Serono and Inpharmatica Ltd extended the collaborative research agreement signed in 2001. Under the expanded agreement, Inpharmatica received an up-front fee for granting Serono additional rights to novel protein sequences delivered under the collaboration. The up-front fee has been expensed as research and development expense.

Serono has amended its agreement with Regeneron Pharmaceuticals Inc. signed in 2002. Under the amended agreement, Serono will pay Regeneron up to \$4.0 million annually for up to five years, which will be expensed as research and development expense.

Serono and Nautilus Biotech signed a worldwide agreement to develop the next-generation of human growth hormone, with improved biological, pharmacological and clinical profiles. Under the terms of the agreement, Nautilus received an up-front fee and will receive potential milestone payments and undisclosed royalties on sales of the improved protein. The up-front fee has been expensed as research and development expense.

Serono entered into an agreement with Paratek Pharmaceuticals Inc. to discover, develop and commercialize an orally available disease-modifying treatment for multiple sclerosis (MS). Under the terms of the agreement, Paratek received an up-front fee and a loan convertible into Paratek stock and will receive research funding and milestone payments related to development progress and regulatory milestones. In addition to up-front consideration, Paratek would receive \$38.0 million in milestone payments for the first product to be successfully developed and registered in MS. The initial fees have been expensed as research and development expense.

Serono and ZymoGenetics Inc. entered into a broad alliance to research, develop and commercialize novel protein and antibody therapeutics based on discoveries made by ZymoGenetics. As part of this alliance, Serono will gain access to a portfolio of Zymogenetics' genes and proteins, will have rights over the next five years to license up to twelve products, and will have exclusive worldwide rights to develop and commercialize 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). Under the terms of the partnership, Serono paid ZymoGenetics an up-front fee of \$20.0 million in exchange for the rights to license proteins over the next five years, paid \$11.3 million for entering into three license agreements and purchased \$50.0 million of ZymoGenetics' common stock. Serono will pay a series of milestone payments, will share all profits from the co-commercialization of products in the United States for which ZymoGenetics has co-funded development, and will pay royalties on eventual sales of the products outside the United States and, to the extent ZymoGenetics elects not to co-develop products, on product sales in the United States. The up-front fee and license fees have been expensed as research and development expense. The purchase of common stock was recorded as an available-for-sale equity investment.

Serono entered into an agreement with an undisclosed party under which Serono granted a license under a non-core technology. Under the terms of the agreement, Serono is to receive a license fee, payable in annual installments over the next three years. The license fee is non-refundable and non-cancelable, received instead of future ongoing royalties, and was recorded as license income of \$67.0 million in 2004.

### **Collaborative agreements for 2003**

Serono and OSI Pharmaceuticals Inc. entered into an agreement under which OSI Pharmaceuticals will market and promote Novantrone for its approved oncology indications in the U.S. Serono will continue to market and promote Novantrone in the U.S. for its approved multiple sclerosis indication and will record all sales of Novantrone in the U.S. for all indications. Under the terms of the agreement, Serono received initial fees totaling \$55.0 million plus ongoing maintenance fees in return for commissions paid to OSI on net sales of the product in oncology. The initial fees have been recorded as deferred income and will be offset against commissions paid to OSI on a straight-line basis over the patent life of Novantrone.

Serono and Genentech Inc. extended the international license agreement for Raptiva signed in 2002 to include an additional fifteen Asian countries. Serono will now develop and market Raptiva worldwide outside the U.S. and Japan. All payments under the extension of the international license agreement have been expensed as research and development expense.

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### **Collaborative agreements for 2002**

Serono entered into an agreement with Regeneron Pharmaceuticals Inc. under which Regeneron will use its proprietary Velocigene technology platform to provide Serono with knockout and transgenic models of gene function.

Serono signed a license and commercialization agreement with Amgen Inc. under which Serono will sell Amgen's Novantrone in the U.S. Novantrone is indicated for the treatment of certain forms of multiple sclerosis and certain types of cancer. An up-front fee paid to Amgen Inc. was capitalized as an intangible asset and will be amortized over the life of the agreement.

Serono and IVAX Corporation entered into a worldwide agreement to develop and commercialize IVAX's product, cladribine, as potentially the first oral disease-modifying treatment for multiple sclerosis. Under the terms of the agreement, IVAX received an up-front fee and will receive a series of undisclosed milestone payments and royalties on eventual sales of the product. The initial payment was expensed as research and development expense.

Serono and Cellular Genomics Inc. signed a collaborative research agreement under the terms of which Cellular Genomics will apply its chemical genetics technologies to four undisclosed kinase targets selected by Serono. Under the terms of the agreement, Cellular Genomics received an up-front fee and a series of milestone payments over a period of two years. The collaborative research agreement has been amended in 2003 for an additional kinase target. Under the terms of this amendment, Cellular Genomics received an additional up-front fee. All payments under the agreements have been expensed as research and development expense.

Serono signed an international license agreement with Genentech Inc. under which Serono obtained exclusive rights to develop and market Genentech's humanized anti-CD11a monoclonal antibody Raptiva outside the U.S., Japan and certain other Asian countries. Under the terms of the agreement, Serono and Genentech may collaborate on developing future indications for Raptiva and will share global development costs. All payments under the agreement have been expensed as research and development expense.

Serono and AstraZeneca signed a worldwide license and development agreement under which Serono obtained the exclusive rights to develop and market AstraZeneca's aromatase inhibitor, anastrozole, as a treatment of ovulation induction and improvement of follicular development. AstraZeneca will manufacture and supply anastrozole to Serono. All payments under the agreement have been expensed as research and development expense.

Serono and Pfizer Inc. entered into a co-promotion agreement for Serono's multiple sclerosis treatment Rebif in the U.S. Under the terms of the agreement, Pfizer paid Serono an up-front fee of \$200.0 million, will share all commercialization and development costs in the U.S., and will receive payments based on Rebif sales in the U.S. Serono will record all sales and continue to distribute the product in the U.S. Serono will continue to be sole marketer for Rebif in the rest of the world. The up-front fee of \$200.0 million has been recorded as deferred income and is being offset against payments made to Pfizer based on Rebif sales in the United States on a straight-line basis over the term of the agreement.

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### **33. Related parties**

In 2004, Serono continued to lease from an unaffiliated company, under a lease that expires in 2006, a building that is used as its headquarters facilities. The lease provides for a rent of approximately \$1.1 million (2003: \$1.0 million) per year. In addition, Serono has sub-leased a portion of the same building mentioned above to a company which is controlled by Ernesto Bertarelli. The lease payments to Serono in 2004 amounted to approximately \$0.3 million (2003: \$0.2 million).



The group sub-leased a portion of the Serono Biotech Center located in Switzerland to an unaffiliated company, which is indirectly controlled by Ernesto Bertarelli. The lease expires in 2005. The lease payments to Serono in 2004 amounted to approximately \$0.1 million (2003: \$0.1 million).

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In 2004, from time to time the company made use of a private jet for business-related travel. The jet is owned by a company that is indirectly controlled by Ernesto Bertarelli. During 2004, the group paid fees for the jet totaling approximately \$2.3 million (2003: \$1.6 million).

In 2004, a company which is indirectly controlled by Ernesto Bertarelli, provided certain media production services to the group for Serono events such as the Annual General Meeting of Shareholders and employee sessions. Services of \$0.2 million have been provided for the year ended December 31, 2004.

In 2004, the group paid a one-time consulting fee of \$0.1 million to Bertarelli & Cie, a company controlled by Ernesto Bertarelli, for consulting services related to certain business development activities.

There are three loans outstanding to members of the Executive Management Board. The most recent loan was issued on June 12, 2002. All loans to executives accrue fixed interest at 3.0% per year. The total amount outstanding as of December 31, 2004 is CHF0.7 million or approximately \$0.6 million (2003: CHF1.1 million or approximately \$0.9 million). Two of the loans are repayable in three equal installments and will be fully repaid by April 2005. The remaining loan accrues interest that is paid on the anniversary of the loan grant date, with the principal repayable on December 31, 2005.

The group continues to hold an investment in the equity of Cansera International Inc. (“Cansera”), a Canadian company specializing in sterile animal sera and cell culture products. Purchases from Cansera are carried out on commercial terms and conditions and at market prices. Total company purchases from Cansera for the year-ended December 31, 2004 were \$1.5 million (2003: \$2.4 million). As of December 31, 2004, there was an amount of \$0.1 million (2003: \$0.1 million) payable to Cansera.

In 2004, the group acquired an investment in the equity of Integrated Solutions S.A., an information systems consulting company located in Switzerland. The group entered into a master service agreement with Integrated Solutions S.A. for information technology services to be provided. In 2004, Integrated Solutions S.A. provided services in the amount of \$4.3 million to the group, of which \$0.6 million remained outstanding as of December 31, 2004.

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### 34. Principal operating companies

Company	Segment	Currency	As of December 31, 2004			Activity
			Capital	Ownership	Location	
Serono International S.A.	Europe	CHF	5,500,000	100%	Switzerland	
Serono Pharma Schweiz, branch of Serono International S.A.	Europe	CHF	-	100%	Switzerland	
Serono Pharmaceutical Research Institute, division of Serono International S.A.	Europe	CHF	-	100%	Switzerland	
Ares Trading S.A.	Europe	CHF	500,000	100%	Switzerland	
Laboratoires Serono S.A.	Europe	CHF	11,009,000	100%	Switzerland	
Laboratoires Serono S.A., branch in Corsier-sur-Vevey	Europe	CHF	-	100%	Switzerland	

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Serono Austria GmbH	Europe	EURO	108,065	100%	Austria
Serono Benelux B.V.	Europe	EURO	613,808	100%	Netherlands
Serono Benelux B.V., Belgian Branch	Europe	EURO	-	100%	Belgium
Serono France S.A.	Europe	EURO	1,456,560	100%	France
Serono Genetics Institute S.A. <sup>(1)</sup>	Europe	EURO	60,160,692	100%	France
Serono GmbH	Europe	EURO	512,000	100%	Germany
Serono Hellas A.E.	Europe	EURO	1,529,062	100%	Greece
Industria Farmaceutica Serono S.p.A.	Europe	EURO	656,250	96.67% <sup>(2)</sup>	Italy
Istituto di Ricerche Biomediche 'Antoine Marxer' RBM S.p.A.	Europe	EURO	5,046,000	96.82%	Italy
Serono España S.A.	Europe	EURO	2,400,000	100%	Spain
Serono Portugal Lda <sup>(3)</sup>	Europe	EURO	523,739	100%	Portugal
Serono Nordic AB	Europe	SEK	250,000	100%	Sweden

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As of December 31, 2004

Company	Segment	Currency	Capital	Ownership	Location	Activity
Serono Pharma Services S.r.o.	Europe	CZK	1,400,000	100%	Czech Republic	
Serono Ltd	Europe	GBP	800,000	100%	UK	
Bourn Hall Ltd <sup>(4)</sup>	Europe	GBP	3,963,404	100%	UK	
Serono (Europe) Ltd	Europe	GBP	50,001	100%	UK	
Serono Inc.	North America	USD	40,867,094	100%	US	
Serono Reproductive Biology Institute Inc.	North America	USD	4,000,100	100%	US	
Serono Canada, Inc.	North America	CAD	1	100%	Canada	
Serono Argentina S.A.	Latin America	ARS	1,100,000	100%	Argentina	
Serono Produtos Farmaceuticos Ltda	Latin America	BRL	8,882,288	100%	Brazil	
Serono de Colombia S.A.	Latin America	COP	52,200,000	100%	Colombia	
Serono de Mexico S.A. de C.V.	Latin America	MXN	25,653,492	100%	Mexico	
Ares Trading Uruguay S.A.	Latin America	UYP	570,000	100%	Uruguay	
Serono de Venezuela S.A.	Latin America	VEB	117,900,000	100%	Venezuela	
Serono Korea Co Ltd	Asia-Pacific	KRW	4,376,800,000	100%	Korea	
Serono Singapore Pte Ltd	Asia-Pacific	SGD	630,000	100%	Singapore	
Serono Singapore Pte Ltd, Taiwan Branch	Asia-Pacific	TWD	-	100%	Taiwan	
Serono (Thailand) Co Ltd	Asia-Pacific	THB	1,250,000	100%	Thailand	
Serono Hong Kong Ltd	Asia-Pacific	HKD	1,000,020	100%	Hong Kong	
Serono Japan Co Ltd	Japan	JPY	4,300,000,000	100%	Japan	
Serono Australia Ltd	Oceania	AUD	60,000	100%	Australia	
Serono Israel Ltd	Middle East	ILS	7,000	100%	Israel	
Inter-Lab Ltd	Middle East	ILS	61,478	100%	Israel	
InterPharm Industries (1991) Ltd	Middle East	ILS	6,750	100%	Israel	
Serono İlaç Pazarlama ve Ticaret A.S.	Middle East	TRL	153,835,000,000	100%	Turkey	

Serono South Africa (Pty) Ltd	Africa	SAR	1,000	100%	South Africa
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**Production:** This company performs manufacturing and/or production activities for the group.

**Research and Development:** This company performs research and development activities for the group.

**Sales:** This company performs marketing, export and trading activities for the group.

**Headquarters:** This company serves as headquarter of the group.

- (1) Genset S.A. became Serono Genetics Institute S.A. on April 30, 2004.
- (2) Industria Farmaceutica Serono S.p.A. holds 3.03% of its own shares (treasury shares).
- (3) Serono Produtos Farmaceuticos Lda became Serono Portugal Lda on January 9, 2004.
- (4) Bourn Hall Clinic is a clinic specializing in the treatment of infertility disorders. Bourn Hall Clinic became Bourn Hall Ltd on December 23, 2004.

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### 35. Significant differences between IFRS and United States Generally Accepted Accounting Principles (U.S. GAAP)

The group's consolidated financial statements have been prepared in accordance with IFRS, which, as applied by the group, differ in certain significant respects from U.S. GAAP. The effects of the application of U.S. GAAP to net income and shareholders' equity are set out in the tables below:

	Year ended December 31		
	2004 U.S.\$000	2003 U.S.\$000	2002 U.S.\$000
<b>Net income reported under IFRS</b>	<b>494,153</b>	389,963	320,778
U.S. GAAP adjustments			
a. Purchase Accounting: Genset S.A.	-	(8,916 )	(26,829 )
b. Purchase accounting: Business combinations	-	(3,303 )	(5,662 )
c. Purchase accounting: IFRS goodwill amortization	<b>5,092</b>	6,358	2,957
d. Pension provisions	<b>(779 )</b>	(374 )	(147 )
e. Available-for-sale securities	-	6,190	(17,789 )
f. Deferred taxes	<b>(30,437 )</b>	903	(822 )
g. Employee Share Purchase Plan	-	3,855	389
h. Convertible bond	<b>4,660</b>	366	-
Deferred tax effect of U.S. GAAP adjustments	<b>(1,665 )</b>	3,304	7,301
<b>Net income reported under U.S. GAAP</b>	<b>471,024</b>	398,346	280,176
	<b>U.S.\$</b>	<b>U.S.\$</b>	<b>U.S.\$</b>
Basic earnings per bearer share reported under U.S. GAAP	<b>30.83</b>	25.16	17.53
Basic earnings per registered share reported under U.S. GAAP	<b>12.33</b>	10.06	7.01
Diluted earnings per bearer share reported under U.S. GAAP	<b>30.78</b>	25.12	17.51
Diluted earnings per registered share reported under U.S. GAAP	<b>12.31</b>	10.05	7.00

	As of December 31	
	2004 U.S.\$000	2003 U.S.\$000
<b>Shareholders' equity reported under IFRS</b>	<b>2,447,878</b>	2,880,190
U.S. GAAP adjustments		
a. Purchase accounting: Genset S.A.	<b>(35,745 )</b>	(35,745 )
b. Purchase accounting: Business combinations	<b>12,158</b>	12,158
c. Purchase accounting: IFRS goodwill amortization	<b>14,407</b>	9,315
d. Pension provisions	<b>9,990</b>	10,773
d. Minimum pension liability	-	(128 )
e. Available-for-sale securities	-	-
f. Deferred taxes	<b>(32,045 )</b>	(1,608 )
g. Employee Share Purchase Plan	-	-
h. Convertible bond	<b>(22,478 )</b>	(25,344 )

Deferred tax effect of U.S. GAAP adjustments	<b>4,146</b>	5,862
<b>Shareholders' equity reported under U.S. GAAP</b>	<b>2,398,311</b>	2,855,473

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Components of shareholders' equity in accordance with U.S. GAAP are as follows:

	As of December 31	
	2004	2003
	U.S.\$000	U.S.\$000
Share capital	254,420	253,895
Share premium	1,023,125	1,002,991
Treasury shares	(987,489 )	(157,642 )
Retained earnings	2,006,617	1,634,947
Accumulated other comprehensive income		
Currency translation adjustment	68,391	88,883
Unrealized market value adjustment on available-for-sale securities (net of taxes of \$1,693 and \$1,693)	47,431	32,943
Unrealized market value adjustment on cash flow hedges (net of tax of \$0 and \$0)	(14,184 )	(467 )
Minimum pension liability adjustment (net of taxes of \$0 and \$51)	-	(77 )
<b>Shareholders' equity reported under U.S. GAAP</b>	<b>2,398,311</b>	<b>2,855,473</b>

The changes of shareholders' equity in accordance with U.S. GAAP are as follows:

	2004	2003
	U.S.\$000	U.S.\$000
<b>Balance as of January 1 reported under U.S. GAAP</b>	<b>2,855,473</b>	<b>2,456,683</b>
Purchase of treasury shares	(833,148)	(42,026)
Issue of share capital	23,960	25,048
Issue of call options on Serono shares	-	945
Net income reported under U.S. GAAP	471,024	398,346
Dividend - bearer shares	(71,096)	(61,849)
Dividend - registered shares	(28,258)	(23,860)
Currency translation adjustment	(20,492)	62,497
Net unrealized market value adjustment on available-for-sale securities	14,488	37,636
Net unrealized market value adjustment on cash flow hedges	(13,717)	(467)
Minimum pension liability adjustment	77	2,520
<b>Balance as of December 31 reported under U.S. GAAP</b>	<b>2,398,311</b>	<b>2,855,473</b>

a) The accounting treatment for the 2002 acquisition of Genset S.A. under IFRS is different from the accounting treatment under U.S. GAAP. In accordance with SFAS No. 141, "Business Combinations" the fair value of acquired in-process research and development ("IPR&D") projects is considered to be a separate asset that must be expensed immediately following the acquisition, unless there is an alternative future use. Under IFRS, acquired IPR&D projects are included as a part of goodwill, unless they meet the criteria for recognition as intangible assets under IAS 38, "Intangible Assets", in which case they should be capitalized as intangible assets as part of the purchase price allocation.

b) Prior to January 1, 1995, all goodwill, being the difference between the purchase price and the aggregated fair value of tangible and intangible assets and liabilities acquired in a business combination, was written off directly to equity in accordance with IFRS existing at that time. Under U.S. GAAP, the difference between the purchase price and the fair value of net assets acquired as part of a pre-1995 business combination would have been capitalized as goodwill and, until December 31, 2001, amortized through the income statement over the estimated useful life. Effective January 1,



2002, the group adopted SFAS No. 142, "Goodwill and Other Intangible Assets". According to SFAS No. 142, all recognized goodwill that exists as of January 1, 2002, after reclassifications between intangible assets and goodwill, is no longer amortized, but rather tested at least annually for impairment. Therefore, there was no amortization charge in 2004 and 2003 under U.S. GAAP. There was no impairment loss recognized in 2004 in accordance with SFAS No. 142. In 2003, non-cash charges of \$3.3 million were recorded for impairment of goodwill and divestments, which related primarily to the write-off of pre-1995 goodwill.

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- c) In accordance with SFAS No. 142, goodwill is no longer amortized but is only subject to impairment testing under U.S. GAAP as of January 1, 2002. The goodwill amortization that was recognized in accordance with IFRS in 2004 was \$5.1 million (2003: \$6.4 million) and has been added to arrive at net income reported under U.S. GAAP.
- d) For purposes of U.S. GAAP, pension costs for defined benefit plans are accounted for in accordance with SFAS No. 87 ‘‘Employers’ Accounting for Pensions’’ and the disclosure is presented in accordance with SFAS No. 132 (revised 2003), ‘‘Employers’ Disclosures about Pensions and Other Post-retirement Benefits’’. IAS 19 (revised 1993), in force up to December 31, 1998, required that the discount rate used in the calculation of benefit plan obligations be of an average long-term nature, whereas U.S. GAAP requires that the discount rate be based on a rate at which the obligations could be currently settled. From January 1, 1999, IFRS and U.S. GAAP accounting rules in this area are essentially the same. However, adjustments arise when reconciling from IFRS to U.S. GAAP due to the pre-1999 accounting rule differences. In addition, U.S. GAAP requires an additional minimum pension liability equal to the excess of the accumulated benefit obligation over the fair value of the plan assets to be recognized as an intangible asset, up to the amount of unrecognized prior service costs. Any amount exceeding the unrecognized prior service costs is reported in other comprehensive income net of tax.
- e) For U.S. GAAP purposes, and in accordance with IAS 39, ‘‘Financial Instruments: Recognition and Measurement’’, marketable securities with readily determinable fair values are classified as available-for-sale with any unrealized gain or loss resulting from changes in their fair values recorded as a separate component of shareholders’ equity. The group considers impairment under U.S. GAAP to be other than temporary if the impairment exceeds 25% over a continual period of six months, and there is no indication of a significant increase in fair value in the short-term. Such unrealized losses are expensed in the income statement. This definition of impairment under U.S. GAAP differs from the definition of impairment under IFRS and, therefore, the amount of unrealized gains and losses recognized under the two standards will be different. During 2003, the group recognized a realized gain under U.S. GAAP upon the disposal of an investment of \$2.2 million, while under IFRS the disposal resulted in a realized loss of \$4.0 million.
- f) Under IAS 12 (revised 2000), ‘‘Income Taxes’’, and U.S. GAAP, unrealized profits resulting from intercompany transactions are eliminated from the carrying amount of assets, such as inventory. In accordance with IAS 12 and effective from January 1, 1998, the group changed its accounting policy relating to the calculation of the deferred tax effect on the elimination of unrealized intercompany profits. Prior to this date, the tax effect was calculated with reference to the local tax rate of the selling or manufacturing company where the intercompany profit was generated. Since January 1, 1998, the group calculates the tax effect with reference to the local tax rate of the company that holds the inventory (the buyer) at year-end. However, U.S. GAAP requires the tax effect to be calculated with reference to the local tax rate in the seller or manufacturer’s jurisdiction.
- g) For U.S. GAAP purposes, the Employee Share Purchase Plan (the ‘‘ESPP’’) as described in note 28 has been accounted for in accordance with Accounting Principles Board Opinion No. 25, ‘‘Accounting for Stock Issued to Employees’’, which is the same as Serono’s current policy in accordance with IAS 19, ‘‘Employee Benefits’’. The accumulated compensation cost associated with the matching share under U.S. GAAP as of December 31, 2002 has been added back as income in the U.S. GAAP reconciliation.
- h) In accordance with SFAS No. 133, ‘‘Accounting for Derivative Instruments and Hedging Activities’’ and SFAS No. 149, ‘‘Amendment of Statement 133 on Derivative Instruments and Hedging Activities’’, all proceeds received from the issuance of the convertible bond should be allocated to long-term debt. Under IFRS, the proceeds of the bond were bifurcated and recognized as separate liability and equity components. The amount of financial expense recognized under IFRS exceeds the amount of financial expense recognized under U.S. GAAP due to the differences in the amounts initially recognized under IFRS and U.S. GAAP. In 2004, \$4.7 million (2003: \$0.4 million) has been added back to arrive at net income under U.S. GAAP. The equity component initially recognized under IFRS of \$24.6 million was reported as a reserve within shareholders’ equity. However, under U.S. GAAP, this reserve is removed from shareholders’ equity and recorded as long-term debt on the consolidated balance sheet.



**Additional U.S. GAAP Disclosures****A. Purchase accounting: Genset S.A.**

On September 12, 2002, the group acquired 92.47% of the share capital of Genset S.A., a genomics-based biotechnology company, in a transaction accounted for as a business combination in accordance with SFAS 141, "Business Combinations". During 2003, the group increased its ownership to 100% by acquiring the remaining outstanding shares of Genset S.A. The final purchase price allocation under U.S. GAAP resulted in acquired IPR&D of \$35.7 million and goodwill of \$47.5 million. The components of shareholders' equity and net income adjustments related to the U.S. GAAP purchase accounting adjustments are as follows:

	As of December 31, 2004	
	Shareholders' equity	Net income
	U.S.\$000	U.S.\$000
IPR&D	(35,745 )	-
IFRS Goodwill amortization	10,960	4,104
<b>Total</b>	<b>(24,785 )</b>	<b>4,104</b>

	As of December 31, 2003	
	Shareholders' equity	Net income
	U.S.\$000	U.S.\$000
IPR&D	(35,745 )	(8,916 )
IFRS Goodwill amortization	6,856	5,184
<b>Total</b>	<b>(28,889 )</b>	<b>(3,732 )</b>

**B. Purchase accounting: Goodwill and other intangibles**

Changes in the carrying amount of goodwill under U.S. GAAP for the years ended December 31, 2004 and 2003 are as follows:

	2004 U.S.\$000	2003 U.S.\$000
As of January 1	74,945	115,380
Goodwill acquired	332	(37,208 )
Impairment losses	-	(3,303 )
Currency adjustments	19	76
<b>As of December 31</b>	<b>75,296</b>	<b>74,945</b>

All goodwill components were tested for impairment during 2004 and 2003. The fair value of the business was determined using the expected present value of future cash flows.

The following table sets out, in accordance with SFAS No. 131, "Disclosures about Segments of an Enterprise and Related information", the carrying amount of goodwill under U.S. GAAP by the geographical segment in which the reporting unit is located:

	As of December 31	
	2004	2003
	U.S.\$000	U.S.\$000
Europe	52,914	52,563
Middle East, Africa and Eastern Europe	22,382	22,382
<b>Total</b>	<b>75,296</b>	<b>74,945</b>

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In accordance with SFAS 142, "Goodwill and Other Intangible Assets", intangible assets with indefinite lives and goodwill are no longer amortized, but tested annually for impairment. Goodwill is the only intangible asset with an indefinite life.

The remaining weighted average amortization period of intangible assets with definite lives as of December 31, 2004 was 5.8 years (2003: 6.9 years). The aggregated amortization expense for intangible assets with definite lives was \$33.7 million and \$25.1 million for the year ended December 31, 2004 and 2003, respectively. The estimated amortization expense for intangible assets for the next five years is as follows:

	U.S. \$000
2005	42,238
2006	41,067
2007	39,429
2008	23,597
2009	23,597

### C. Pension provisions

The following tables provide a reconciliation of the changes in the benefit obligation and fair value of the plan assets and a statement of the funded status for the group's defined benefit pension plans as of December 31, 2004 and 2003, respectively:

	As of December 31	
	2004	2003
	U.S.\$000	U.S.\$000
<b>Benefit obligation</b>		
As of January 1	168,544	185,519
Service cost	24,630	21,077
Interest cost	7,913	6,014
Actuarial gain	(3,716)	(52,638)
Benefit payments	(6,925)	(8,839)
Settlements	-	(451)
Currency adjustments	14,644	17,862
<b>As of December 31</b>	<b>205,090</b>	<b>168,544</b>
<b>Plan assets at fair value</b>		
As of January 1	145,687	108,288
Actual return on plan assets	11,240	12,934
Employer contributions	15,198	12,825
Employee contributions	7,101	6,117
Benefit payments	(6,925)	(8,839)
Currency adjustments	14,473	14,362
<b>As of December 31</b>	<b>186,774</b>	<b>145,687</b>
<b>Funded status</b>		
As of December 31	(18,316)	(22,857)
Unrecognized actuarial gain	(31,499)	(21,637)
Minimum pension liability	-	(128)
<b>Net amount recognized</b>	<b>(49,815)</b>	<b>(44,622)</b>

Accrued benefit liability	(49,815)	(44,494)
Accumulated other		
Comprehensive income, gross	-	(128)
<b>Net amount recognized</b>	<b>(49,815)</b>	<b>(44,622)</b>

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The accumulated benefit obligation for the group's defined benefit pension plans was \$195.3 million as of December 31, 2004 (\$159.0 million as of December 31, 2003).

	Year ended December 31		
	2004	2003	2002
	U.S.\$000	U.S.\$000	U.S.\$000
Current service cost	17,529	14,960	13,995
Interest cost	7,913	6,014	6,206
Expected return on plan assets	(8,609 )	(6,762 )	(5,960 )
Amortization of transition obligation	-	374	147
Amortization of unrecognized actuarial (gain)/loss	(674 )	(1,342 )	113
<b>Net periodic benefit cost</b>	<b>16,159</b>	<b>13,244</b>	<b>14,501</b>
(Decrease)/increase in minimum pension liability included in other comprehensive income, gross	(128 )	(2,758 )	2,886

Unrecognized actuarial gain and loss in excess of 10% of the greater of the benefit obligation or the fair value of plan assets is amortized over the average remaining service period of active participants. The principal weighted average actuarial assumptions used for accounting purposes are as follows:

	Net period benefit costs		Benefit obligation	
	2004	2003	2004	2003
	%	%	%	%
Discount rate	-	-	4.03	4.24
Expected return on plan assets	5.19	5.65	-	-
Future salary increases	2.69	2.67	2.69	2.67
Future pension increases	-	-	3.76	4.03

The expected return on plan assets was determined based on historical benchmarks for returns in the plan asset portfolio as a whole and internal capital market forecasts for each plan asset category based on the targeted asset allocation. Actuarial dates to determine pension benefit measurements for the group's defined benefit pension plans fell within three months from the year ended December 31, 2004.

SFAS No. 132 (revised 2003), "Employer's Disclosures about Pensions and Other Post-Retirement Benefits, an amendment of FASB Statements No. 87, 88 and 106, and a revision of FASB Statement No. 132", requires the following additional information:

The weighted average pension plan asset allocation for the group's defined benefit pension plans as of December 31, 2004 and 2003, by asset category, are as follows:

	As of December 31	
	2004	2003
	%	%
Equity securities	29	27
Debt securities	50	53
Real estate	6	7



Other	15	13
<b>Total</b>	<b>100</b>	<b>100</b>

Investment policies and strategies are determined separately for each of the defined benefit pension plans. The group's main defined benefit pension plan, the Swiss plan, contributes approximately 85% of the total benefit obligation in 2004. For the Swiss defined benefit pension plan, the Foundation Board sets the investment policy, including the relevant investment requirements and investment and risk limits. The objective of the investment policy is to maximize return while limiting risks through a balanced portfolio of investments. Within each plan asset category, a diversified mix of individual equity and debt securities, real estate and investments in funds is selected. Equity securities are targeted at a maximum of 35% of the portfolio. Real estate investments are limited to domestic real estate at a maximum of 50% of the portfolio. Direct investments in Serono shares or derivatives on Serono shares are not allowed.

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The expected employer contributions to the group's defined benefit pension plan amount to \$15.4 million in 2005. The following benefit payments, which represent future service are expected to be paid:

	U.S.\$000
2005	6,834
2006	7,173
2007	7,448
2008	7,988
Thereafter	62,201

The group's U.S. subsidiary, Serono Holding, Inc., maintains a savings plan for eligible employees. This 401(k) plan is designed to supplement the existing pension retirement program of eligible employees and to assist them in strengthening their financial security by providing an incentive to save and invest regularly. The plan provides for a matching contribution by Serono Holding, Inc., which amounted to approximately \$1.4 million, \$1.2 million and \$1.2 million for the three years ended December 31, 2004, 2003 and 2002, respectively.

#### **D. Financial assets**

The U.S. GAAP carrying values of financial assets equal the IFRS carrying values. The components of short-term and long-term financial assets are provided in note 17. Proceeds from the sale of available-for-sale securities in 2004 were \$654.6 million (2003: \$8.1 million). Gross realized gains in 2004 were \$1.8 million (2003: \$2.1 million). Gross realized losses in 2004 were \$1.4 million (2003: \$0.2 million). The net unrealized gain from available-for-sale securities included as a separate component of shareholders' equity under U.S. GAAP was \$12.6 million as of December 31, 2004 (2003: net unrealized gain of \$25.9 million).

The maturities of the available-for-sale debt securities as of December 31, 2004 and 2003, respectively, are as follows:

	2004 U.S.\$000	2003 U.S.\$000
2005	784,714	294,002
2006	560,703	218,957
2007	217,779	363,707
2008	-	241,332
<b>Total</b>	<b>1,563,196</b>	<b>1,117,998</b>

#### **E. Derivative financial instruments**

There were no gains or losses recognized in 2004 on options settled in Serono bearer shares that require a net cash settlement (2003: loss of \$1.7 million).

#### **F. Non-derivative financial instruments**

Non-derivative financial assets consist of cash and cash equivalents, short-term and long-term investments and unconsolidated investments. Non-derivative liabilities consist of bank advances and short-term and long-term financial debts, including the convertible bond. The convertible bond is recognized in the consolidated balance sheets as of December 31, 2004 and 2003 for U.S. GAAP purposes as follows:



	2004	2003
	U.S.\$000	U.S.\$000
Face value of convertible bond issued	465,261	465,261
Transaction costs	(6,611 )	(6,611 )
Liability on initial recognition	458,650	458,650
Interest expense	9,124	729
Cumulative translation adjustment	62,494	20,931
<b>Liability as of December 31</b>	<b>530,268</b>	<b>480,310</b>

The U.S. GAAP carrying values are equivalent to the IFRS carrying values for all non-derivative financial assets and liabilities. The carrying amount of cash and cash equivalents, short-term investments and bank advances approximates their estimated fair values, due to the short-term nature of these instruments. The fair values for the marketable securities are estimated based on listed market prices or broker or dealer price quotes. The fair value of long-term financial debt is estimated based on the current quoted market rates available for debt with similar terms and maturities. The fair value of the convertible bond is determined based on quoted market price as of December 31, 2004 and 2003. The estimated fair values and maturities of the long-term financial debts are provided in note 19 and 20.

#### G. Current and deferred taxes

Deferred tax assets and liabilities under U.S. GAAP consist of the following:

	As of December 31	
	2004	2003
	U.S.\$000	U.S.\$000
<b>Deferred tax assets</b>		
Tax losses carried forward	47,764	60,800
Various research and development tax credits carried forward	30,448	32,943
Depreciation and amortization	37,045	49,797
Inventories	63,617	59,966
Accrued expenses	20,090	21,234
Return provisions	11,487	12,353
Other	6,990	(4,327 )
Total deferred tax assets	217,441	232,766
Less valuation allowance	(46,873 )	(58,819 )
<b>Total net deferred tax assets</b>	<b>170,568</b>	<b>173,947</b>

	As of December 31	
	2004	2003
	U.S.\$000	U.S.\$000
<b>Deferred tax liabilities</b>		
Depreciation and amortization	4,723	8,232

Inventories	<b>29,745</b>	13,915
Other	<b>(10,226 )</b>	(6,228 )
<b>Total deferred tax liabilities</b>	<b>24,242</b>	15,919
<b>Net deferred taxes</b>	<b>146,326</b>	158,028

Other deferred tax assets and liabilities are stated net of any deferred tax assets and liabilities that have been offset against each other and the amount may therefore become negative. The potential for offsetting deferred tax assets and liabilities is limited to those arising within the same tax jurisdiction.

Valuation allowances have been established for certain deferred tax assets related primarily to net operating losses carried forward and portions of other deferred tax assets for which the group determined that it was more likely than not that these benefits would not be realized. During 2004, the valuation allowance decreased by \$11.9 million (2003: decrease of \$57.0 million). The decrease in the valuation allowance in 2003 is mainly related to the recognition of a deferred tax asset that arises from the utilization of the net operating losses carried forward for Genset S.A. A reversal of the valuation allowance could occur when circumstances result in the realization of deferred tax assets becoming probable, which would result in a decrease in the group's effective tax rate.

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Deferred tax assets and liabilities under U.S. GAAP, broken out into current and non-current, are as follows:

	As of December 31	
	2004	2003
	U.S.\$000	U.S.\$000
Current deferred tax assets	101,199	99,258
Non-current deferred tax assets	69,369	74,689
<b>Total net deferred tax assets</b>	<b>170,568</b>	<b>173,947</b>
Current deferred tax liabilities	1,829	2,133
Non-current deferred tax liabilities	22,413	13,786
<b>Total deferred tax liabilities</b>	<b>24,242</b>	<b>15,919</b>

## H. Pro forma earnings per share

As permitted by Statement of SFAS No. 123, "Accounting for Stock Based Compensation" and its amendment in SFAS No. 148, "Accounting for Stock Based Compensation - Transition and Disclosure", the group applies APB No. 25, "Accounting for Stock Issued to Employees", and related interpretations in accounting for the stock option plan for U.S. GAAP purposes. Had the group accounted for stock options in accordance with SFAS 123, net income under U.S. GAAP and earnings per bearer and registered share under U.S. GAAP would have decreased to the pro forma amounts indicated as follows:

	Year ended December 31		
	2004	2003	2002
	U.S.\$000	U.S.\$000	U.S.\$000
Net income as reported	471,024	398,346	280,176
Compensation expense recognized in net income	1,219	1,375	1,045
Compensation expense that would have been included in the determination of net income if SFAS No. 123 had been adopted	(22,028 )	(18,982 )	(14,385 )
<b>Pro forma net income</b>	<b>450,215</b>	<b>380,739</b>	<b>266,836</b>
	U.S.\$	U.S.\$	U.S.\$
<b>As reported</b>			
Basic earnings per bearer share	30.83	25.16	17.53
Basic earnings per registered share	12.33	10.06	7.01
Diluted earnings per bearer share	30.78	25.12	17.51
Diluted earnings per registered share	12.31	10.05	7.00
<b>Pro forma</b>			
Basic earnings per bearer share	29.47	24.05	16.69
Basic earnings per registered share	11.79	9.62	6.68
Diluted earnings per bearer share	29.42	24.01	16.67
Diluted earnings per registered share	11.77	9.61	6.67

The average fair values of stock options granted to employees in 2004, 2003 and 2002 were \$210, \$142 and \$317, respectively. The fair value of stock options granted to directors in 2004 and 2003 was \$195 and \$170, respectively. There were no stock options granted to directors in 2002. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing method with the following weighted average assumptions used for grants for the years ended December 31, 2004, 2003 and 2002, respectively:

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	2004	2003	2002
	%	%	%
Dividend gross rate	1.01	1.07	0.47
Expected stock price volatility	38.2	34.6	33.6
Risk-free interest rate	3.5	3.5	3.5
Expected lives, in years	7.8	7.9	7.5

### I. Advertising costs

The group expenses production costs of print and display advertisements as of the first day the advertisement takes place. Advertising expenses included in selling and marketing expenses were \$100.4 million, \$77.0 million and \$77.2 million for the three years ended December 31, 2004, 2003 and 2002, respectively.

### J. Shipping and handling costs

The group includes shipping and handling costs incurred in connection with the distribution of therapeutic products in the selling, general and administrative line on the income statement. These amounts were \$31.3 million, \$25.7 million and \$18.6 million for the three years ended December 31, 2004, 2003 and 2002, respectively.

### K. Shares issued and outstanding

Regulation S-X, Rule 5-02.30, would require the number of shares issued or outstanding, for each class of shares, to be disclosed on the face of the balance sheet. The group discloses this information in note 24 to the consolidated financial statements.

### L. Consolidated Statements of Cash Flows

Consolidated statements of cash flows of the group are prepared in accordance with IAS 7, "Cash Flow Statements". As permitted by the U.S. Securities and Exchange Commission in Regulation S-X, no reconciliation to U.S. GAAP has been performed.

### M. Comprehensive income

SFAS No. 130, "Reporting Comprehensive Income", established standards for the reporting and display of comprehensive income and its components. Comprehensive income includes net income and all changes in shareholders' equity during a period that arises from non-owner sources, such as currency translation items, unrealized gains and losses on available-for-sale securities, cash flow hedges and minimum pension liabilities. The additional disclosures required under U.S. GAAP are as follows:

	Year ended December 31		
	2004	2003	2002
	U.S.\$000	U.S.\$000	U.S.\$000
<b>Net income reported under U.S. GAAP</b>	<b>471,024</b>	398,346	280,176
<b>Other comprehensive income</b>			
Currency translation adjustment	(20,492 )	62,497	108,668
Unrealized market value adjustment on available-for-sale securities	14,488	37,636	(1,884 )



(net of taxes of \$0, \$0 and \$2,147, respectively)

Unrealized market value adjustment on cash flow hedges

(net of taxes of \$0 and \$0, respectively)	(13,717 )	(467 )	-
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Minimum pension liability adjustment (net of taxes of \$51, \$238 and \$289, respectively)	77	2,520	(2,597 )
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**Comprehensive income reported under U.S.**

<b>GAAP</b>	<b>451,380</b>	500,532	384,363
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### 36. Effect of new accounting pronouncements

#### IFRS

In December 2003, the International Accounting Standards Board (IASB) released revisions to the following standards: IAS 1, “Presentation of Financial Statements”; IAS 2, “Inventories”; IAS 8, “Accounting Policies, Changes in Accounting Estimates and Errors”; IAS 10, “Events after Balance Sheet Date”; IAS 16, “Tangible fixed assets”; IAS 17, “Leases”; IAS 21, “The Effects of Changes in Foreign Exchange Rates”; IAS 24, “Related Parties Disclosures”; IAS 27, “Consolidated and Separate Financial Statements”; IAS 28, “Investment in Associates”; IAS 31, “Interests in Joint Ventures”; IAS 32, “Financial Instruments: Disclosure and Presentation”; IAS 33, “Earnings per Share”; IAS 39, “Financial Instruments: Recognition and Measurement”; and IAS 40, “Investment Property”. The revised standards should be applied for financial statements covering periods beginning on or after January 1, 2005. IAS 1, “Presentation of Financial Statements”, requires that minority interests are included in shareholders’ equity in the consolidated balance sheet and they are no longer deducted in arriving at net income in the consolidated income statement. The adoption of IAS 1 will increase shareholders’ equity as of January 1, 2005 by \$3.3 million. Basic and diluted earnings per share will continue to be calculated based on the net income attributable to shareholders of Serono S.A. only. The other amendments as described above are not expected to have a material impact on the group’s consolidated financial statements.

In February 2004, the IASB published IFRS 2, “Share-Based Payments”, which requires fair-value recognition of equity-based compensation in the group’s consolidated financial statements. IFRS 2 will become effective for annual periods beginning on or after January 1, 2005 and will require retrospective application for all equity-based compensation instruments granted after November 7, 2002 and not vested as of January 1, 2005. As permitted by IFRS 2, the group will restate in 2005 prior year audited historical consolidated financial statements to reflect the expense of stock options granted since the effective date of IFRS 2. Management estimates that the adoption of IFRS 2 will result in:

	2004	2003
(Estimates) (Earnings per share in U.S.\$)	U.S.\$000	U.S.\$000
Increase in share capital and share premium	12,936	2,611
Decrease in retained earnings	12,936	2,611
Increase in compensation expense, net of tax	10,325	2,611
Decrease in basic earnings per bearer share	0.68	0.16
Decrease in basic earnings per registered share	0.27	0.07
Decrease in diluted earnings per bearer share	0.67	0.16
Decrease in diluted earnings per registered share	0.27	0.07

In March 2004, the IASB published IFRS 3, “Business Combinations”; IFRS 4, “Insurance Contracts”; IFRS 5, “Non-Current Assets Held for Sale and Discontinued Operations”; and revised versions of IAS 36, “Impairment of Assets”; IAS 38, “Intangible Assets”; and further amendments to IAS 39. These standards will become effective for annual periods beginning on or after January 1, 2005. IFRS 3 became effective prospectively for all business combinations that take place after March 31, 2004. As there were no acquisitions during 2004, the adoption of IFRS 3 does not impact the amounts presented in the 2004 consolidated financial statements. The adoption of IFRS 3 will cease amortization of goodwill as of January 1, 2005 and will require goodwill to be tested at least annually for impairment, which is identical to the current accounting policy for goodwill under U.S. GAAP. For business combinations with a date of acquisition after March 31, 2004, the adoption of IAS 38 will require that the purchase price be allocated to any IPR&D separately from goodwill. In addition, acquired intangible assets as part of in-licensing agreements after January 1, 2005 will be capitalized even if they have not achieved technical feasibility,

which is usually signified by regulatory approval. The adoption of IFRS 4 and IFRS 5 is not expected to have a material impact on the group's consolidated financial statements.

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## U.S. GAAP

In December 2003, the Financial Accounting Standards Board (“FASB”) issued a revised FASB Interpretation No. 46 (FIN 46R), “Consolidation of Variable Interest Entities, an interpretation of Accounting Research Bulletin No. 51 (ARB 51)”. The FASB published the revision to clarify and amend some of the original provisions of FIN 46, which was issued in January 2003, and to exempt certain entities from its requirements. The provisions of FIN 46R became effective as of March 31, 2004. The group completed its evaluation of the provisions of FIN 46R on the equity investments it holds, none of which would be considered as variable interest entities. Accordingly, the adoption of this standard did not have a material impact on the reconciliation.

In December 2003, the Securities and Exchange Commission (SEC) issued SAB 104, “Revenue Recognition”, which supersedes SAB 101, “Revenue Recognition in Financial Statements”. SAB 104’s primary purpose is to rescind accounting guidance contained in SAB 101 related to multiple element revenue arrangements, superseded as a result of the issuance of EITF 00-21. Additionally, SAB 104 rescinds the SEC’s Revenue Recognition in Financial Statements Frequently Asked Questions and Answers (the FAQ) issued with SAB 101 that had been codified in SEC Topic 13, “Revenue Recognition”. Selected portions of the FAQ have been incorporated into SAB 104. While the wording of SAB 104 has changed to reflect the issuance of EITF 00-21, the revenue recognition principles of SAB 101 remain largely unchanged by the issuance of SAB 104. The adoption of SAB 104 in 2004 did not have a material impact on the reconciliation.

In February 2004, EITF 03-01, “The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments” was issued. EITF 03-01 stipulates disclosure requirements for investments with unrealized losses that have not been recognized as other-than-temporary impairments. The provisions of EITF 03-01 became effective for annual periods beginning after June 15, 2004. On September 30, 2004, the FASB issued FSP 03-01-1, “Effective Date of Paragraphs 10-20 of EITF 03-01”, delaying the effective date for the recognition and measurement guidance in EITF 03-01. The disclosure requirements in EITF 03-01 remain effective. The group complied with the disclosure provisions of EITF 03-01.

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs - An Amendment of ARB No. 43, Chapter 4". This statement requires that certain abnormal costs associated with the manufacturing, freight, and handling costs associated with inventory be charged to current operations in the period in which they are incurred and will be effective for annual periods beginning after June 15, 2005. The group is currently evaluating the impact of this standard on the reconciliation.

In December 2004, the FASB issued SFAS No. 153, "Exchanges of Nonmonetary Assets - Amendment of APB No. 29". This standard eliminates the exception for exchanges of similar productive assets at fair value as stated in APB No. 29 and replaces it with a general exception for exchange transactions that do not have commercial substance, defined as transactions that are not expected to result in significant changes in the cash flows of the reporting entity. This statement is effective for exchanges of nonmonetary assets occurring after June 15, 2005 and is not expected to have a material impact on the reconciliation.

In December 2004, the FASB issued SFAS No. 123R (revised 2004), "Share-Based Payment". SFAS No. 123R is a revision of SFAS No. 123, "Accounting for Stock Based Compensation" and supersedes APB No. 25, "Accounting for Stock Issued to Employees". This standard eliminates the ability to account for share-based compensation transactions using APB No. 25 and requires such transactions to be accounted for using a fair-value-based valuation method and the resulting cost to be recognized in the financial statements. This standard is effective for awards that are granted, modified or settled in cash for annual periods beginning after June 15, 2005 and the accounting policy would be essentially the same as IFRS 2, “Share-Based Payment”. The group is currently evaluating the two methods of adoption allowed by SFAS No. 123R, the modified-prospective transition method and the modified-retrospective transition method and their impact on the reconciliation and disclosure.

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**37. Subsequent events**

On January 25, 2005, the consolidated financial statements were approved by the Board of Directors for presentation to the Annual General Meeting of Shareholders. The proposed dividends are detailed in note 26.

**38. Principal currency translation rate**

Year-end exchange rates used for the consolidated balance sheets.

	<b>2004</b>	2003	2002
	<b>U.S.\$</b>	U.S.\$	U.S.\$
1 CHF	<b>1.1325</b>	1.2334	1.3871
1 EURO	<b>0.7335</b>	0.7915	0.9557

Average exchange rates used for the consolidated income statements and cash flow statements.

	<b>2004</b>	2003	2002
	<b>U.S.\$</b>	U.S.\$	U.S.\$
1 CHF	<b>1.1353</b>	1.2896	1.4852
1 EURO	<b>0.7520</b>	0.8331	1.0075

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**Report of Independent Registered Public Accounting Firm**

To the Shareholders and Board of Directors  
Of Serono SA, Coinsins (Vaud), Switzerland

Our audits of the consolidated financial statements referred to in our report dated January 31, 2005, appearing on page F-2 of this Form 20-F, also included an audit of the financial statement schedule listed in Item 18 of this Form 20-F. In our opinion, this financial statement schedule presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements.

PricewaterhouseCoopers S.A.

/s/ M. Aked    /s/ H-J. Hofer

M. Aked H-J. Hofer  
Geneva, January 31, 2005

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**Schedule II-Valuation and qualifying accounts**

<b>For the years ended December 31, 2004, 2003 and 2002</b>	Balance at the beginning of the period US\$000	Additions US\$000	Deductions <sup>(1)</sup> US\$000	Balance at the end of the period US\$000
<b>Year ended December 31, 2004</b>				
Provisions for doubtful accounts	6,510	1,335	(1,708)	6,137
Provision for inventories	20,756	14,508	(8,701)	26,563
Allowance for deferred taxes	58,819	29,293	(41,239)	46,873
<b>Total</b>	<b>86,085</b>	<b>45,136</b>	<b>(51,648)</b>	<b>79,573</b>
<b>Year ended December 31, 2003</b>				
Provisions for doubtful accounts	11,193	1,080	(5,763)	6,510
Provision for inventories	14,531	8,379	(2,154)	20,756
Allowance for deferred taxes	115,854	26,749	(83,784)	58,819
<b>Total</b>	<b>141,578</b>	<b>36,208</b>	<b>(91,701)</b>	<b>86,085</b>
<b>Year ended December 31, 2002</b>				
Provisions for doubtful accounts	12,702	3,359	(4,868)	11,193
Provision for inventories	17,847	4,450	(7,766)	14,531
Allowance for deferred taxes	35,305	98,888	(18,339)	115,854
<b>Total</b>	<b>65,854</b>	<b>106,697</b>	<b>(30,973)</b>	<b>141,578</b>

(1) Represents amounts used for the purposes for which the accounts were created and reversal of amounts no longer required.



**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
1.1	Articles of Association, dated March 9, 2005
2.1	Deposit Agreement among the Registrant, The Bank of New York, as Depositary, and all Owners and Beneficial Owners from time to time of ADRs issued thereunder, including the form of ADRs (incorporated by reference to Exhibit 4.6 to Registrant's Registration Statement on Form S-8 (Registration No. 333-12480), as filed with the Commission on September 6, 2000)
2.2	Form of Certificate for One Bearer Share (incorporated by reference to Exhibit 4.2 to Amendment No. 1 to Registrant's Registration Statement on Form F-1 (Registration No. 333-12192), as filed with the Commission on July 10, 2000)
2.3	Form of Certificate for Ten Bearer Shares (incorporated by reference to Exhibit 4.3 to Amendment No. 1 to Registrant's Registration Statement on Form F-1 (Registration No. 333-12192), as filed with the Commission on July 10, 2000)
2.4	Form of Certificate for One Hundred Bearer Shares (incorporated by reference to Exhibit 4.4 to Amendment No. 1 to Registrant's Registration Statement on Form F-1 (Registration No. 333-12192), as filed with the Commission on July 10, 2000)
2.5	Form of Certificate for One Thousand Bearer Shares (incorporated by reference to Exhibit 4.5 to Amendment No. 1 to Registrant's Registration Statement on Form F-1 (Registration No. 333-12192), as filed with the Commission on July 10, 2000)
2.6	Form of American Depositary Receipt (included in Exhibit 2.1 hereto)
2.7	Paying and Conversion Agency Agreement, dated November 17, 2003, by and among Ares International Finance 92 Ltd (the "Issuer"), Serono S.A. and UBS AG relating to the issuance by the Issuer of CHF 600,000,000 aggregate principal amount of 0.50% Convertible Unsubordinated Bonds due 2008 (the "Convertible Bonds") (incorporated by reference to Exhibit 2.7 to Registrant's Annual Report on Form 20-F for the year ended December 31, 2003)
2.8	Guarantee, dated as of November 26, 2003, of Serono S.A. in respect of the Convertible Bonds (incorporated by reference to Exhibit 2.8 to Registrant's Annual Report on Form 20-F for the year ended December 31, 2003)
8.1	List of Subsidiaries of the Registrant
11.1	Code of Ethics
12.1	Certification of Chief Executive Officer pursuant to SEC Rule 13a-14(a)
12.2	Certification of Chief Financial Officer pursuant to SEC Rule 13a-14(a)
13.1	Certification of Chief Executive Officer pursuant to SEC Rule 13a-14(b)

- 13.2 Certification of Chief Financial Officer pursuant to SEC Rule 13a-14(b)
- 15.1 Consent of PricewaterhouseCoopers S.A.