

SERONO S A  
Form 20-F  
March 25, 2004

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

**FORM 20-F**

(Mark One)

- .. **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR 12(g) OF THE SECURITIES EXCHANGE ACT OF 1934**  
or
- X **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the fiscal year ended December 31, 2003  
or
- .. **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**Commission File Number: 1-15096**

**SERONO S.A.**

(Exact name of Registrant as specified in its charter)

**Not Applicable**  
(Translation of Registrant's name into English)

**Switzerland**  
(Jurisdiction of incorporation or organization)

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

New York Stock Exchange

\*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

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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, 2003.

Bearer Shares, nominal value CHF 25 per share: 11,406,887 outstanding

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

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, 2003**

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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, as issued by the International Accounting Standards Board, or IASB, and its predecessor organization, the International Accounting Standards Committee. 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 34 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>2003</b>	<b>2002</b>	<b>2001</b>	<b>2000</b>	<b>1999</b>
	(U.S. dollars in thousands, except per share data)				
<b>Income Statement Data:</b>					
Product sales	\$ 1,858,009	\$ 1,423,130	\$ 1,249,405	\$ 1,146,998	\$ 1,054,144
Royalty and license income	160,608	114,705	127,065	92,656	78,400
<b>Total revenues</b>	<b>2,018,617</b>	<b>1,537,835</b>	<b>1,376,470</b>	<b>1,239,654</b>	<b>1,132,544</b>
Operating expenses:					
Cost of product sales	279,619	223,751	213,160	229,907	260,748
Selling, general and administrative	636,823	504,248	446,945	393,716	369,747
Research and development, net	467,779	358,099	308,561	263,152	221,629
Restructuring		16,303			
Other operating expense, net	199,476	85,811	70,152	31,147	58,718
<b>Total operating expenses</b>	<b>1,583,697</b>	<b>1,188,212</b>	<b>1,038,818</b>	<b>917,922</b>	<b>910,842</b>
<b>Operating income</b>	<b>434,920</b>	<b>349,623</b>	<b>337,652</b>	<b>321,732</b>	<b>221,702</b>
Financial income, net	44,018	36,476	51,381	52,277	2,458
Other expense, net	19,743	1,658	2,548	2,411	1,078
<b>Total non-operating income, net</b>	<b>24,275</b>	<b>34,818</b>	<b>48,833</b>	<b>49,866</b>	<b>1,380</b>
<b>Income before taxes and minority interests</b>	<b>459,195</b>	<b>384,441</b>	<b>386,485</b>	<b>371,598</b>	<b>223,082</b>
Taxes	68,905	63,127	69,816	70,384	39,778
<b>Income before minority interests</b>	<b>390,290</b>	<b>321,314</b>	<b>316,669</b>	<b>301,214</b>	<b>183,304</b>
Minority interests	327	536	(52)	174	8

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Net income	\$ 389,963	\$ 320,778	\$ 316,721	\$ 301,040	\$ 183,296
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**Per Share Data:**

Basic income per share (1)(2):					
Bearer shares	\$ 24.63	\$ 20.07	\$ 19.72	\$ 19.50	\$ 12.23
Registered shares	9.85	8.03	7.89	7.80	4.89
American depositary shares (3)	0.62	0.50	0.49	0.49	0.31
Diluted income per share (1)(2):					
Bearer shares	24.59	20.04	19.68	19.46	12.23
Registered shares	9.84	8.02	7.87	7.78	4.89
American depositary shares (3)	0.61	0.50	0.49	0.49	0.31
Cash dividends paid (1)(4):					
Bearer shares	5.42	4.02	3.35	1.15	1.29
Registered shares	2.17	1.61	1.34	0.46	0.52
American depositary shares (3)	0.14	0.10	0.08	0.03	0.03

**Supplemental Per Equivalent Bearer Share Data:**

Net income, basic (1)(5)	\$ 24.63	\$ 20.07	\$ 19.72	\$ 19.50	\$ 12.23
Net income, diluted (1)(5)	24.59	20.04	19.68	19.46	12.23

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**As of December 31,**

<b>2003</b>	<b>2002</b>	<b>2001</b>	<b>2000</b>	<b>1999</b>
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(U.S. dollars in thousands, except per share data)

**Balance Sheet Data:**

Cash, cash equivalents and short-term investments	\$ 1,438,782	\$ 1,064,898	\$ 1,475,504	\$ 1,438,485	\$ 398,812
Working capital (6)	1,543,933	1,139,848	1,527,359	1,505,534	405,721
Property, plant and equipment	701,453	554,509	460,767	462,425	460,712
Total assets	4,571,603	3,484,278	3,018,769	2,794,777	1,591,298
Outstanding share capital(4)	253,895	253,416	253,137	253,072	236,978
Short-term debt	51,224	93,598	173,254	238,585	238,738
Long-term debt	532,022	25,857	37,325	56,626	116,381
Shareholders equity	2,880,190	2,461,198	2,218,914	2,006,416	826,785

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

Net income	398,346	280,176	291,470	304,389	170,952
Basic income per share (1)(7):					
Bearer shares	25.16	17.53	18.15	19.72	11.41
Registered shares	10.06	7.01	7.26	7.89	4.56
Diluted income per share (1)(7):					
Bearer shares	25.12	17.51	18.11	19.68	11.40
Registered shares	10.05	7.00	7.24	7.87	4.56

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Total shareholders equity	2,855,473	2,456,683	2,239,711	2,015,860	862,634
Total assets	4,561,583	3,483,295	3,069,873	2,794,465	1,623,385

**Margins and Other Data:**

Gross margin (8)(9)	85.0%	84.3%	82.9%	80.0%	75.3%
Operating margin (8)(10)	21.5%	22.7%	24.5%	26.0%	19.6%
Net margin (8)(11)	19.3%	20.9%	23.0%	24.3%	16.2%
Cash dividends paid (4)	\$ 85,709	\$ 64,238	\$ 53,759	\$ 17,755	\$ 19,310
Cash flows provided from operating activities	\$ 542,859	\$ 531,982	\$ 404,950	\$ 255,443	\$ 274,632
Depreciation and amortization	\$ 135,607	\$ 100,552	\$ 98,906	\$ 86,266	\$ 71,960
Additions to plant, property and equipment	\$ 185,045	\$ 125,324	\$ 97,131	\$ 67,080	\$ 66,420
Average number of employees	4,597	4,559	4,384	4,117	4,022

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	Year ended December 31,					
	2003		2002		2001	
	Sales	% Total	Sales	% Total	Sales	% Total
	(U.S. dollars in millions)					
<b>Product sales by Region:</b>						
Europe	\$ 813.8	43.8%	\$ 620.4	43.6%	\$ 542.2	43.4%
North America	694.3	37.4	479.6	33.7	390.6	31.2
Latin America	98.8	5.3	109.2	7.7	130.9	10.5
Other regions	251.1	13.5	213.9	15.0	185.7	14.9
Total product sales	\$ 1,858.0	100.0%	\$ 1,423.1	100.0%	\$ 1,249.4	100.0%

	Year ended December 31,					
	2003		2002		2001	
	Sales	% Total	Sales	% Total	Sales	% Total
	(U.S. dollars in millions)					
<b>Product sales by Therapeutic Area:</b>						
Neurology:						
Rebif	\$ 819.3	44.1%	\$ 548.8	38.6%	\$ 379.6	30.4%
Novantrone	30.9	1.7	0.3	0.0	-	-
Total	850.2	45.8	549.1	38.6	379.6	30.4
Reproductive Health:						
Gonal-f	526.1	28.3	450.4	31.6	410.5	32.9
Cetrotide	24.8	1.3	18.4	1.3	10.6	0.9

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Crinone	20.8	1.1	10.9	0.8	2.4	0.2
Ovidrel	12.3	0.7	5.7	0.4	2.7	0.2
Luveris	9.6	0.5	6.6	0.5	0.9	0.0
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Core Infertility Portfolio	593.6	31.9	492.0	34.6	427.1	34.2
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Pergonal	45.8	2.5	46.0	3.2	38.1	3.0
Metrodin HP	24.8	1.3	50.1	3.5	67.1	5.4
Profasi	15.4	0.9	19.8	1.4	23.8	1.9
Other products	13.3	0.7	14.0	1.0	18.2	1.5
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Total Reproductive Health	692.9	37.3	621.9	43.7	574.3	46.0
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Growth and Metabolism:						
Saizen	151.4	8.1	124.0	8.7	107.3	8.6
Serostim	88.8	4.8	95.1	6.7	125.3	10.0
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Total	240.2	12.9	219.1	15.4	232.6	18.6
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Other products	74.7	4.0	33.1	2.3	62.9	5.0
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Total product sales	\$ 1,858.0	100.0%	\$ 1,423.1	100.0%	\$ 1,249.4	100.0%
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>

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

Year ended December 31,

	2003	2002	2001	2000	1999
<b>Basic per share:</b>					
Bearer shares	11,427,194	11,580,611	11,658,108	11,032,835	10,581,187
Registered shares	11,013,040	11,013,040	11,013,040	11,013,040	11,013,040
Equivalent bearer shares	15,832,410	15,985,827	16,063,324	15,438,051	14,986,403
<b>Diluted per share:</b>					
Bearer shares	11,452,890	11,598,155	11,687,609	11,063,889	10,584,790
Registered shares	11,013,040	11,013,040	11,013,040	11,013,040	11,013,040
Equivalent bearer shares	15,858,106	16,003,371	16,092,825	15,469,105	14,990,006

(2) The portion of net income allocated to bearer and registered shares was \$281,459 and \$108,504, respectively for the year ended December 31, 2003, \$232,381 and \$88,397, respectively, for the year ended December 31, 2002, and \$229,863 and \$86,858, respectively, for the year ended December 31, 2001. On a diluted basis, the portion of net income allocated to bearer shares and registered shares was \$281,635 and \$108,328, respectively for the year ended December 31, 2003, \$232,478 and \$88,300, respectively, for the year ended December 31, 2002, and \$230,022 and \$86,699, respectively, for the year ended December 31, 2001.

(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. For fiscal year 1999, the share dividend paid by us in May 2000 and our related payment of Swiss withholding tax totaling \$59.8 million on these new shares, as more fully described in Item 8 under the caption Dividends and Dividend Policy, was accounted for in fiscal year 2000. However, we have complied with Topic 4-C of the SEC Staff Accounting

Bulletins by restating our share capital to reflect the free share dividend distributed effective May 26, 2000 for all periods presented.

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- (5) Supplemental per equivalent bearer share data have been calculated on the basis of that 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 \$287,510 and \$110,836, respectively, for the year ended December 31, 2003, \$202,968 and \$77,208, respectively, for the year ended December 31, 2002, and \$211,537 and \$79,933, respectively, for the year ended December 31, 2001. On a diluted basis, the portion of net income allocated to bearer shares and registered shares was \$287,689 and \$110,657, respectively, for the year ended December 31, 2003, \$203,053 and \$77,123, respectively, for the year ended December 31, 2002, and \$211,684 and \$79,786, respectively, for the year ended December 31, 2001.
- (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 profit means product sales less cost of product sales. Gross margin means gross profit divided by product sales.
- (10) Operating margin means operating income divided by total revenues.
- (11) Net margin means net income divided by total revenues.

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### **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 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 over 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:

- λ development of products may be stopped due to a variety of reasons, such as lack of efficacy, harmful side effects and evolution in the competitive environment. For example, in December 2002, the development of oncept in rheumatoid arthritis was stopped due to inadequate efficacy at the low dose at which we tested the product;
- λ 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;
- λ products may fail to receive necessary regulatory approvals. For example, in April 2003 the Committee for Proprietary Medicinal Products recommended not granting initial marketing authorization for our high-dose recombinant human growth hormone product, Serostim, for the treatment of AIDS wasting in the European Union; and
- λ 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.

**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

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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.

**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.

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, including Owen Mumford, 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 roll-out by Teva Pharmaceuticals in 2002 and 2003 of its product Copaxone in Europe 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.

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**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 2003, \$813.8 million (43.8%) of our 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.

**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. Competitors market a number of generic urine-derived follicle stimulating hormone, or FSH, products in competition with our urine-derived and recombinant FSH products. 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.

#### **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 announced 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**

For example in 2003, Rebif, our recombinant beta interferon, accounted for 44.1% (\$819.4 million) of our total sales. Rebif faces competition from Avonex and Betaseron, other recombinant beta interferon products, as well as from Copaxone (glatiramer acetate), another drug used in multiple sclerosis. 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 2002, Gonal-f, our recombinant follicle stimulating hormone, accounted for 28.3% (\$526.1 million) of our total sales. Gonal-f faces competition from Puregon, 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.

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#### **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 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.

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 U.S. 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 \$160.6 million in 2003 and \$114.7 million in 2002, 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 four 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

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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. Our 2003 net interest income (\$36.9 million) was lower than in 2002 (\$54.0 million) due to the continuing low interest rate environment and the maturity of longer-term bond investments with rates of interest above the current market. We cannot predict how interest rates will move in the future. If interest rates continue to stay low or fall further, our investment 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.

**Foreign exchange fluctuations could significantly impact the US 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 2003 our sales growth was 20.9% in local currencies, but 31.3% 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 2003 our expenses growth was 33.3% as reported in U.S. dollars, but 22.4% in local currencies. Due to this translation effect, the prevailing foreign exchange rate could cause our net income growth rate to not meet expectations.

### **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 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 92 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,

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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.

#### **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.

### **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. 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.

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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. 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 2003, 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 which 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**

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The market price for our shares has been volatile and may continue to be volatile in the future. During 2003, based on prices on the virt-X, our bearer share price ranged from CHF 562 to CHF 958. During the same period, based on prices on the New York Stock Exchange, the price range for our ADSs ranged from \$10.58 to \$17.79. 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:

- λ a revenue shortfall, which, due to fixed near-term expenses, causes a period's results to be below expectations;
- λ a short-term increase in expenses that is not matched by a corresponding increase in revenue;
- λ changes in wholesaler buying patterns;
- λ publicity regarding our collaborations and actual or potential results relating to products and indications under development by us or our competitors;
- λ regulatory developments in the countries in which we operate;
- λ public concern as to the safety of our products;
- λ perceptions as to the prospects of our company;
- λ perceptions as to the prospects of our competitors and the biotechnology industry in general;
- l general market conditions;
- λ changes in the exchange rate of the U.S. dollar against the euro and the Swiss franc; and
- λ 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.

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

As of December 31, 2003, Bertarelli & Cie held 52.51% of our capital and 61.62% 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 7.15% of our capital and 9.92% 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. None of our directors is a resident 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.

**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 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 2003 total revenues of \$2,018.6 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 we expect to move into the dermatology market 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 approximately 4,600 employees.

As a biotechnology company, research and development are central to our efforts to grow our business. We currently employ approximately 1,350 research and development personnel, and in 2003 we spent \$467.8 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 introduce new compounds into development. In 2002, we enhanced our in-house genomics capabilities with the acquisition of Genset. 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 85.0% in 2003 from 67.7% in 1995 and to increase our net margin to 19.3% of revenues in 2003 from 4.2% in 1995.

Our approximately 1,750 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 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 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 six recombinant products Rebif, Gonal-f, Saizen, Serostim, Ovidrel and Luveris, and we will launch a seventh, Zorbitive, in 2004. 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 one 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 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 sometimes be classified as having RMS.

We estimate that the treatment of MS with disease modifying drugs was an approximately \$3.6 billion global market in 2003, based on publicly reported sales data for our product and three 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 have important therapeutic potential in a wide range of 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 2003, Rebif was our largest selling product, accounting for \$819.4 million (44.1%) of total product sales. We began marketing Rebif in the United States in March 2002. At the end of 2003, our estimated market share in terms of total prescriptions was 13.4%.

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 RRMS. In this study, 560 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. In addition brain scans showed that the number of multiple sclerosis lesions is reduced by Rebif.

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 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, marks the largest prospective comparative study of two disease-modifying drugs in MS. The study sought to demonstrate the clinical benefit of Rebif over 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. The results of

this trial, which were positive for Rebif, were submitted to the FDA. 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*.

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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 cohort 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. 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 January 2004, we initiated a post-registration head-to-head study of Rebif versus Copaxone (glatiramer acetate) given at standard 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.

We have registered Rebif for the treatment of MS in 82 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 2003, Novantrone was our fifth largest selling product, accounting for \$77.1 million or 4.1% of total product sales.

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### **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.

#### *Cladribine*

In October 2002, we entered into a worldwide agreement with IVAX to develop and commercialize cladribine, as potentially the first orally effective disease modifying treatment for MS. Cladribine is a purine-analogue that disrupts 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 intravenous cladribine may be effective in certain MS patients. We have worked with IVAX to establish an oral

formulation of cladribine and initiated Phase I clinical trials in the fourth quarter of 2003. We obtained positive results from these trials in March 2004, and expect to initiate Phase II studies in late 2004.

#### *Atexakin Alpha*

Interleukin-6, or IL-6, has shown strong neuroprotective effect in experimental models of neuropathy. Based on preclinical work, we have decided to begin a Phase II study of our recombinant IL-6 (atexakin alpha) to investigate if it is able to modulate the clinical symptoms and progression of disease in patients with peripheral neuropathy.

#### *Breaker Peptide*

In May 1999, we entered into an agreement with Axonyx Inc. to license technology relating to peptides having potential to treat diseases associated with accumulations of abnormal forms of proteins, such as Alzheimer's Disease and prion diseases. A peptide inhibitor of amyloid plaque formation as a potential treatment for Alzheimer's disease entered a Phase I clinical trial in the first quarter of 2003. In view of the latest Phase I data on the beta-sheet breaker peptide, we have decided to put the further development of the lead molecule on hold.

### **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 55% of the approximately \$1.15 billion global gonadotropin market and sales of Gonal-f currently account for about 59% of the approximately \$890 million global recombinant FSH market.

Human infertility is often caused by an insufficiency of gonadotropins, which are hormones that are synthesized and secreted by the pituitary gland and act on the sex organs to produce sex hormones and sperm or ova. 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 luteinizing hormone-releasing hormone, or LHRH, which controls the release of FSH and LH. FSH stimulates the ovaries to produce estrogen, allowing the formation of a mature, egg-containing follicle in the first half of the cycle. The mid-cycle LH surge induces ovulation, resulting in the formation of the corpus luteum, which is the structure responsible for producing progesterone and estrogen, the hormones that, upon the occurrence of pregnancy, support the uterine lining so menstruation does not occur. After conception occurs, hCG is released to ensure that the corpus luteum continues to produce progesterone to maintain the pregnancy. In men, FSH stimulates the production of sperm, and LH stimulates the production of sperm and testosterone.

Traditional urine-based infertility treatments, such as Pergonal, Metrodin HP and Profasi, rely on gonadotropins extracted from human urine. Older gonadotropin preparations typically contain less than 5% of the active hormone, with the majority of the remaining preparation made up of other proteins. Because these treatments contain a limited amount of active hormone and because the production and purity of the product are subject to greater variation than those of recombinant products, these traditional treatments may be less advantageous to patients than recombinant gonadotropins. In addition, some of the urine-derived gonadotropin preparations have to be given by intramuscular injection, which can be painful and limits patients' ability to administer the products themselves.

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Our goal in the reproductive health area is to offer a complete line of fertility products. With Gonal-f, Ovidrel and Luveris, we are implementing our strategy of replacing our urine-derived reproductive health products with recombinant versions. An historical analysis of pregnancy success rates demonstrated that use of recombinant FSH products like Gonal-f leads to successful pregnancies more often than use of urine-derived gonadotropins. At the end of 2002, we decided to proceed with the closure of our production facilities for urine-derived products. We have stopped selling urine-derived products in the European Union and we expect to phase out these products in other countries in the near term.

### **Infertility Treatment Process**

1. Medical work-up
2. Pituitary down-regulation Cetrotide
3. Ovarian stimulation Gonal-f, Luveris, Metrodin HP, Pergonal, Serophene, anastrozole (in development)
4. Follicular maturation Ovidrel, Profasi
5. Ovum pick-up
6. Embryo Implantation LIF (in development)
7. Luteal phase support Crinone
8. Diagnosis of pregnancy and monitoring oxytocin receptor antagonist, prostanoid FP receptor antagonist (in development to prevent premature labor)

In vitro fertilization and other fertility treatments involve multiple treatment and laboratory steps. We regard each step in a treatment process as an opportunity to provide patients with products to optimize their fertility treatment. Historically, we have sold drugs for ovarian stimulation and follicular maturation. We now have additional products, product candidates and collaborations that we believe will help us contribute therapies throughout the infertility treatment process, as depicted above. As a result, we will be able to assist patients at multiple stages in this process.

#### **Recombinant Products**

Sales of our recombinant products have grown in recent years and currently stand at over 86.0% 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 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. We are also able to produce them at higher margins than urine-derived products. 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 92 countries, including throughout the European Union and in 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 womb. A multi-dose presentation of Gonal-f is available in the European Union, the United States and other countries and accounted for 55% of Gonal-f sales in 2003. Gonal-f is also approved in the European Union, the United States and other countries for treating a form of male infertility. In 2003, Gonal-f was our second largest selling product, accounting for \$526.1 million (28.3%) of total product sales.

A peer-reviewed analysis of historical data has demonstrated that women using recombinant FSH during assisted reproductive technologies more often became pregnant than those using urine-derived gonadotropins, including highly purified FSH. Additionally, several randomized studies designed to compare Gonal-f to our urine-derived gonadotropins have shown that Gonal-f is more effective in increasing the number of follicles and embryos obtained during treatment with assisted reproductive technologies.

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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.

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. Furthermore, we have now identified a new more 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 February 2004, we received European Union approval for our pre-filled pen injector device, 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 provokes ovulation in a way similar to the way LH does in a natural monthly menstrual cycle. By the end of 2003, Ovidrel was registered in 48 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.

### *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 and therefore require treatment with both hormones to achieve pregnancy. We have marketed Luveris in the European Union since mid-2001. We submitted Phase III clinical data from an additional trial to the U.S. FDA in 2001 and in September 2003 an advisory committee of the U.S. FDA issued a favorable recommendation of Luveris in our proposed indication of follicular development in infertile hypogonadotropic hypogonadal women with profound luteinizing hormone deficiency. We anticipate a U.S. FDA decision in the first half of 2004. By the end of 2003, Luveris was registered in 50 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 have stopped selling urine-derived products in the European Union and we expect to phase out these products in other countries in the near term. As a result of our decision to phase out these products, sales of our urine-derived gonadotropins were \$89 million, down by 26%, in 2003.

### *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 who have difficulty ovulating. 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. In 2003, Pergonal accounted for \$45.8 million or 2.5% of total product sales.

### *Metrodin HP*

Metrodin HP, 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 is used for many of the same indications as Gonal-f, which is replacing Metrodin HP. In 2003, Metrodin HP accounted for \$24.8 million or 1.3% of total product sales.

### *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 is replacing Profasi. In 2003, Profasi accounted for \$15.4 million or 0.8% of total product sales.

### **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 six 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 2003, Crinone accounted for \$20.8 million or 1.1% of total product sales. By the end of 2003, Crinone was registered in 42 countries.

#### *Cetrotide*

Cetrotide is the first LHRH antagonist in the world to be approved for the prevention of the LH surge, which is desirable in assisted reproductive technologies. Treatment with Cetrotide is generally more practical 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 78 countries. In 2003, sales of Cetrotide accounted for \$24.8 million or 1.3% of total product sales.

### **Product Pipeline**

Our pipeline of reproductive health products includes improvements in the user-friendliness of Gonal-f, such as microencapsulated r-FSH. In addition, in the second quarter of 2003 we commenced a Phase II trial with emfilermin or recombinant human Leukemia Inhibitory Factor. We also have in development an oxytocin receptor antagonist and a prostanoid FP receptor antagonist, both of which have the potential to treat premature labor.

#### *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, we recently filed for Gonal-f in Japan.

#### *Microencapsulated r-FSH*

We have successfully completed Phase I clinical trials with a microencapsulated FSH using the Alkermes delivery system and we have made the decision to progress to a Phase II program.

#### *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. We commenced a Phase II trial of the drug in this indication in

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the first quarter of 2003. 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 expect to have results from this trial in the second half of 2004. Anastrozole is an oral aromatase inhibitor, which acts by blocking the synthesis of estrogen and thereby improving ovulation. It is currently sold by AstraZeneca under the trade name Arimidex for the treatment of breast cancer in approximately 100 countries worldwide.

#### *Emfilermin*

We are developing the recombinant protein emfilermin or LIF (for Leukemia Inhibitory Factor) to improve embryo implantation during assisted reproduction. In January 2000, we signed an exclusive agreement with Amrad with a view to developing a novel treatment to address implantation failure. Under the terms of the agreement, Amrad has licensed to us certain patent rights and technology pertaining to emfilermin and has agreed to supply us with pharmaceutical grade recombinant human LIF. In 2002, we completed a clinical trial of r-hLIF in 59 patients with a history of recurrent embryo implantation failures. We initiated a multi-center, multinational Phase II clinical trial in 2003. We expect to have results of this trial in the second half of 2004.

#### *Oxytocin Receptor Antagonist*

In the third quarter of 2003, we initiated a Phase I clinical trial with a low molecular weight oxytocin receptor antagonist which can be taken by mouth and has potential as a treatment for premature labor.

#### *Prostanoid FP Receptor Antagonist*

We are developing a prostanoid FP receptor antagonist with 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 \$1.95 billion in sales in 2003, based on publicly reported sales data for Saizen and Serostim 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 registered in over 80 countries for the treatment of growth hormone deficiency in children. It is also registered in over 70 countries for treatment of Turner's syndrome and in over 35 countries for treatment of children with growth failure associated with chronic renal failure. The use of Saizen as a treatment for adult growth hormone deficiency has been approved in over 30 countries including those in the European Union. We expect to file Saizen for use in children who were born too small for gestational age - this indication sometimes is known as intra-uterine growth retardation - in mid-2004 in Europe. In 2003, Saizen was our third largest selling product, accounting for \$151.5 million or 8.2% of total product sales.

Saizen's main presentation, 8 mg click.easy, is available in a freeze-dried formulation 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. 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

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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 defined by the U.S. Centers for Disease Control as involving the loss of 10% or more of the usual body weight of a person with HIV infection. 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 high-dose recombinant human growth hormone formulation which is approved for the treatment of AIDS wasting in the U.S., Japan and 11 other countries. In 2003, Serostim was our fourth largest selling product, accounting for \$88.8 million or 4.8% 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 available product with these effects 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 biotechnology-derived drug 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, 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. The European Union has granted Serostim orphan drug status through September 2010. In June 2001, we filed an application for marketing approval of Serostim in the European Union. In April 2003, the Committee for Proprietary Medicinal Products, or CPMP, recommended not granting initial marketing authorization for Serostim for treatment of AIDS wasting in the European Union. 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 treatment for acute or chronic disorders of the intestine. 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.

*Zorbtive*

Zorbtive is a new trade name for our high-dose 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, total calories and frequency of infusion. In December 2003, the U.S. FDA approved Zorbtive for use in the treatment of SBS. We plan to launch Zorbtive in the United States during 2004. The FDA has granted Zorbtive orphan drug status for use in the treatment of patients with SBS until December 2010.

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**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 a 228-patient, double-blind, placebo-controlled study in HARS, Serostim therapy significantly reduced visceral adipose tissue, truncal fat and dyslipidemia. We received Orphan Drug Status in this indication in the United States in March 2004 and have decided to proceed to a Phase III clinical trial of Serostim for the treatment of HARS in the second 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. As part of that strategy, in August 2002, we entered into an agreement with Genentech to develop and market a psoriasis drug called Raptiva. Under our agreement, we have the exclusive license to develop and market Raptiva worldwide, except in the United States and Japan. We will also collaborate with Genentech and its U.S. partner Xoma (US) on co-developing other indications for Raptiva.

Psoriasis is a chronic autoimmune disease that affects approximately 7.2 million people in Europe and approximately 4.5 million people in the United States. Approximately one third 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. 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. There is no known cure for the disease.

**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. During 2003, we filed applications for approval of Raptiva for moderate to severe psoriasis in Europe and in some of the other countries covered by our agreement, including Switzerland, Canada, Australia, New Zealand, Brazil and Argentina. We received approval in Switzerland in the first quarter of 2004 and expect to launch Raptiva there by mid-2004. Genentech and Xoma filed a Biologics License Application with the U.S. FDA for approval of Raptiva in psoriasis in December 2002 and received U.S. FDA approval in October 2003.

**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 plan to initiate a multicenter, multinational Phase III program in 2004.

#### *Tadakinig Alpha*

In 2003, we completed Phase I studies of tadakinig alpha, or recombinant Interleukin-18 binding protein, a potential treatment for psoriasis. We initiated a Phase IIa study in psoriasis in the third quarter of 2003.

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### **Research and Development**

Research and development is vital to our ability to continue to grow our business. We employ approximately 1,350 research and development personnel, and our R&D expenses were 23.2% of our total revenues in 2003. 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 2001, 2002 and 2003, we spent \$308.6 million, \$358.1 million and \$467.8 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:

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

#### ***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.

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.

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

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#### *Neurology*

- λ An orally active small molecule inhibitor of apoptosis, which is an inhibitor of JNK, is in preclinical development as a potential treatment for MS.
- λ A chemokine inhibitor with promising activity in a MS model entered preclinical development in 2001.
- λ A matrix metalloprotease inhibitor with potential as a treatment for MS entered preclinical development in 2003.
- λ 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*

- λ A prostanoid FP receptor antagonist with potential as a treatment for premature labor entered preclinical development in 2003.

#### *Metabolism*

- λ A protein tyrosine phosphatase 1b inhibitor with potential as a treatment for diabetes and obesity entered preclinical development in 2003.
- λ A new single molecule rationally designed which has both FSH and LH activity is currently in preclinical development. This FSH-LH chimera is an engineered dual active gonadotropin which stimulates ovarian follicle formation *in vivo*.

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.

#### ***Entering into Strategic Research Partnerships***

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

For example, in September 2001, we entered into an exclusive co-development and commercialization agreement with ZymoGenetics. ZymoGenetics scientists identified two molecules, termed TACI and BCMA, as key regulators of the human immune system. Our activities will focus upon the development of one or more products based upon these molecules for the treatment of autoimmune diseases involving the overproduction of autoantibodies. We are currently focused on a modified form of the TACI molecule, TACI-Ig, a fusion protein inhibitor of B-cell activation, which represents a novel therapeutic approach to treating autoimmune diseases such as systemic lupus erythematosus, or SLE, rheumatoid arthritis, and potentially other diseases such as

B-cell lymphomas. This molecule moved into Phase I clinical development in the third quarter of 2003 and we expect to initiate Phase IIa clinical trials in SLE in the first half of 2004 and rheumatoid arthritis in the second half of 2004. Under the terms of the agreement, ZymoGenetics could receive license fees and milestone payments linked to the development and approval of products, as well as royalties on product sales. We will share most costs of research and development with ZymoGenetics and ZymoGenetics will have an option to co-promote any derived products in the United States and Canada. The exclusive right to market products in the remainder of the world will remain with us, and we will manufacture all products for both clinical trials and commercial sale.

### ***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

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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.

For example, in December 1999, we entered into an agreement with Alkermes for development of its ProLease drug delivery system for use with r-FSH, the active principle in Gonal-f. ProLease encapsulates a compound in biodegradable microspheres, thereby creating an extended-release formulation of the compound. We have an exclusive worldwide license for the product under development in return for the payment of royalties and milestones upon the occurrence of specified events. We have successfully completed Phase I clinical trials using the Alkermes delivery system and we are currently preparing for a Phase II study.

### ***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 lymphomas, is being co-developed with ZymoGenetics. TACI-Ig moved into Phase I clinical development in the third quarter of 2003 and we expect to initiate Phase IIa clinical trials in SLE in the first half of 2004 and rheumatoid arthritis in the second half of 2004.

*Kappaproct.* We recently acquired the worldwide rights to develop and commercialize InDex Pharmaceuticals' antisense compound Kappaproct for the treatment of ulcerative colitis. Kappaproct is currently being tested in Phase II clinical trials for active ulcerative colitis. In a proof-of-concept, double-blind, placebo-controlled clinical trial in patients with therapy-resistant inflammatory bowel disease, it was shown that the majority of these patients responded positively to a single dose of Kappaproct. Patients receiving Kappaproct experienced no adverse effects other than mild ones.

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Several of our products such as interferon beta, oncept and tadekinig alpha are natural proteins, which have multiple biological functions. As a consequence, they have the potential for beneficial effects in a variety of disease indications.

*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.

*Tadekinig alpha.* We completed Phase I studies of tadekinig alpha, our recombinant IL-18 binding protein, in 2003 and in late 2003 we initiated a Phase IIa study oftadekinig alpha in rheumatoid arthritis.

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

Product Type	Trade Name	Indications	Status as of December 31, 2003
Recombinant human interferon1a (r-IFN-β1a)	Rebif	Multiple sclerosis	Approved in E.U., U.S. and 66 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.
Atexakin alpha (r-IL-6)	*	Neuropathy	Phase II clinical trial (planned)
Cladribine	*	Multiple sclerosis	Phase I clinical trial
JNK inhibitor	*	Multiple sclerosis	Preclinical
Chemokine inhibitor	*	Multiple sclerosis	Preclinical
MMP-12 inhibitor	*	Multiple sclerosis	Preclinical
Osteopontin	*	Remyelination	Preclinical
Recombinant human follicle stimulating hormone (r-hFSH)	Gonal-f	Female infertility	Approved in E.U., U.S. and 76 other countries
	Gonal-f	Male infertility hypogonadotropic hypogonadisma	Approved in E.U. and U.S. and 41 other countries
	Gonal-f	Multi-dose formulation	Approved in E.U. and U.S. and 42 other countries
	Gonal-f	Fill by mass formulation	Approved in E.U. and 34 other countries
	Gonal-f	Pre-filled pen injector	Approved in E.U. and Australia; filed in U.S.
Microencapsulated r-FSH	*	To reduce the frequency of administration of r-hFSH	Phase II clinical trial (planned)

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Recombinant human luteinizing hormone (r-hLH)	Luveris	Severe FSH and LH deficiency	Approved in E.U. and 35 other countries; filed in U.S.
Recombinant human chorionic gonadotropin (r-hCG)	Ovidrel/Ovitrelle	Female infertility/ovulation induction and use in assisted reproductive technology	Approved in E.U., U.S. and 32 other countries
Cetrorelix (GnRH antagonist)	Cetrotide	Premature ovulation prevention	Approved in E.U., U.S. and 62 other countries
Progesterone gel	Crinone	Luteal phase support	Approved in U.S., 13 European countries and 28 other countries
Anastrozole (aromatase inhibitor)	*	Ovulation induction and improvement of follicular development	Phase II clinical trial
Emfilermin (r-LIF)	*	Embryo implantation failure	Phase II clinical trial
Oxytocin receptor antagonist	*	Pre-term labor	Phase I clinical trial
Prostanoid FP receptor antagonist	*	Pre-term labor	Preclinical
FSH-LH chimera	*	Female infertility	Preclinical
Recombinant human growth hormone (r-hGH)	Saizen	Growth hormone deficiency	Approved in 81 countries
	Saizen	Growth hormone deficiency in adults	Approved in 13 E.U. countries and 18 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)	To be 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 Status in U.S.

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Product Type	Trade Name	Indications	Status as of December 31, 2003
	Zorbtive	Short bowel syndrome	Approved in U.S.; received Orphan Drug Status in U.S.
PTP1b inhibitor	*	Diabetes and obesity	Preclinical
Efalizumab	Raptiva	Psoriasis	Filed in E.U. and 6 other countries
Onercept (r-TBP-1)	*	Psoriasis	Phase III clinical trial (planned)
Tadekinig alpha (r-IL-18bp)	*	Rheumatoid arthritis	Phase IIa clinical trial
	*	Psoriasis	Phase IIa clinical trial
TACI-Ig	*	Systemic lupus erythematosus	Phase I clinical trial

	*	Rheumatoid arthritis	Phase I clinical trial
	*	B-cell lymphoma	Phase I clinical trial
p65 inhibitor	Kappaproct	Ulcerative colitis	Phase II 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 approximately 1,750 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

Our multiple sclerosis marketing efforts vary depending on the key prescribers in each market. In certain markets we focus on leading neurologists that specialize in MS. In other markets we focus on general neurologists.

In the United States, we sell 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 expect Pfizer's presence in the neurology therapeutic area to help us more quickly and effectively distribute the message of Rebif's attributes.

We are committed to continuing medical education programs which examine the latest developments in MS, including research and treatments. Our programs include faculty members striving to broaden 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.

Our online continuing medical education, or CME, curriculum combines timely, insightful content with the convenience of home or workplace study. Courses are available to anyone wishing to participate. Physicians, nurses and pharmacists can earn CME credit by completing the registration form at the beginning of each CME course.

In October 2002, we initiated a direct-to-consumer campaign in the United States, including a celebrity endorsement. Another important initiative directed at MS patients is the [www.ms lifelines.com](http://www.ms lifelines.com) website. Through MS LifeLines, patients can get access to reimbursement support, injection training and ongoing therapy support. MS LifeLines offers patients the option to receive ongoing updates and information about

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MS and Rebif. MS LifeLines can also provide them with a complimentary Rebiject. The Rebiject is a device designed for exclusive use with Rebif and may help ensure proper injection technique. We also organize Living with MS seminars where patients can speak with an experienced physician and hear from MS community ambassadors about positive living strategies. A toll-free number is also available to patients.

In 2003, we introduced new resources for the MS community, including the Learning for life empowerment series as well as the newly enhanced MS LifeLines.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 better communicate around 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.



In December 2003, we announced the launch of Novantrone.com, an online resource for United States-based patients with worsening MS, their caregivers, and healthcare professionals. This new web site provides access to comprehensive information about the disease, treatment with Novantrone, common questions, therapy considerations, as well as resources and tools to help patients and their physicians make important treatment and disease management decisions. Novantrone.com's user-friendly site design allows for easy navigation for both patients and healthcare providers. The site's patient portal offers relevant information for people with worsening MS to better understand their progressing disease so that they can work with their physician to identify when treatment with Novantrone might be the right choice for them. Novantrone.com's professional portal offers healthcare professionals important information on when to use Novantrone, the efficacy and safety of the therapy, dosing and monitoring, as well as information on reimbursement services.

### **Reproductive Health**

We focus our reproductive health marketing efforts on educating and informing reproductive endocrinologists about treatment options for infertility. To supplement our sales efforts, we also work in partnership with leading fertility specialists to coordinate and support clinical trials in order to develop efficacious and convenient new treatment options and further refine current treatment techniques to improve the chances of pregnancy for infertile couples.

For many years, we have supported the development of comprehensive information resources on the Internet. One example is [www.ferti.net](http://www.ferti.net), a worldwide fertility network dedicated to the science and practice of assisted fertilization and human reproduction. This website offers in-depth information to fertility specialists and health care professionals interested in learning more about infertility and its current treatments. Among many other services, [www.ferti.net](http://www.ferti.net) provides registered visitors with free access to Ferti.Magazine, a monthly on-line scientific publication edited by a panel of internationally recognized fertility specialists.

In February 2004, we announced the launch of [www.fertility.com](http://www.fertility.com), a new patient 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).

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 direct-to-consumer (DTC) advertising campaign in the infertility market in June 2003, including television, radio and web advertising. Consumers and

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patients who called our toll-free number (1-866 LETS TRY) received customized educational materials via mail, including a list of local fertility specialists. In several major markets, including the United States, 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.

In June 2002, FertiQoL was officially launched by representatives from the European Society for Human Reproduction and Embryology, the American Society for Reproductive Medicine, and Serono, with endorsement from the International Consumer Support for Infertility, a major worldwide patient support group. FertiQoL is the first global initiative to measure quality of life in patients undergoing infertility treatment. The aim of the FertiQoL initiative is to develop an internationally validated and locally applicable tool to measure quality of life, which will be available to healthcare professionals and patient groups worldwide.

## **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.

### *Metabolism*

Our sales and marketing efforts for our AIDS wasting product focus on HIV/AIDS treating physicians and their staffs and nurses that work with the patients. In addition to focusing on the therapeutic benefits of Serostim, all of our sales and marketing effort is 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 2003 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 manage 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. 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 agencies to monitor the program's effectiveness. These individual states are using SSDP in their efforts to eliminate potential fraud and abuse within their own systems.

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.

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## **Manufacturing**

Our principal commercial manufacturing facilities are located in Aubonne and Corsier-sur-Vevey, Switzerland; Bari, Italy; Tres Cantos, Spain; and Ness-Ziona, Israel. For clinical supplies, manufacturing facilities are located in Martillac, France and Rome, Italy. We have created manufacturing centers that specialize in different phases of the production process. For certain key products, we have two production facilities available to ensure a continuity of supply in the event of contamination, catastrophe or other unforeseen event 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.

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 mark<sup>(SM)</sup>, Cetrotide , click.easy®, cool.click®, Crinone®, EasyJect®, Ferti.net®, Fertinex®, Geref®, Gonaf®, GHMonitor<sup>SM</sup> , Howkidsgrow<sup>SM</sup>, Luveris®, Metrodin HP®, MSLifelines<sup>SM</sup>, Novantrone , one.click®, Ovidrel®, Ovitrelle®, Pergonal®, Profasi®, Raptiva , Rebif®, Rebiject®, Rebiject II®, Reliser®, Saizen®, SeroJet , Serono®, Serophene®, Serostim®, Stilamin® and Zorbitive , 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:

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

We also receive a maintenance fee from Roche pursuant to a license of our endogenous gene activation technology.

### **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 process of phasing out, already face increased competition from generic products.

### **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 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. During 2001, we completed the EVIDENCE study involving 677 patients in a head-to-head trial comparing the high dose of Rebif with the standard dose of Avonex. The positive results of this trial were the basis for FDA approval in March 2002 to sell Rebif in the United States for relapsing forms of the disease ahead of the expiration of Avonex's orphan drug status for the same indication in mid-2003. 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. Rebif also competes with Copaxone in the United States,

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Europe and certain other countries for the treatment of RRMS. In early 2004, we initiated a head-to-head Phase IV trial comparing Rebif with Copaxone. A number of other companies are working to develop products to treat multiple sclerosis that may in the future compete with Rebif.

### **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 and became available in 2001 in certain European countries, but is not yet approved in the U.S. In countries in which it is available it competes with urine-derived human menopausal gonadotropins, which are impure preparations of FSH and LH. 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.

### ***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 substantially chemically identical. 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 protection for Serostim in the United States expired in August 2003. Our competitors may now seek approval of applications for their products in the United States for AIDS wasting indications. The appetite stimulants Megace, which is marketed by Bristol-Myers Squibb, and Marinol, which is marketed by Roxane Laboratories, are the only other drugs approved for the treatment of AIDS wasting in the United States. In addition, Serostim competes with weight-promotion drugs that are used off-label in AIDS wasting, such as other appetite stimulants and anabolic steroids.

We have received orphan drug protection for Zorbtive in the treatment of patients with short bowel syndrome until December 2010. That means that our competitors cannot sell human growth hormone in the United States for that indication until that date.

### **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.

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 Evaluation 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 Proprietary Medicinal Products, or CPMP, has 210 days, or a longer period if further information is required, to give its opinion to the EMEA as to whether a marketing authorization should be granted. The European marketing authorization is granted after the CPMP opinion has been reviewed and accepted. 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 EU countries due to poorly defined public health concerns, and there can be no assurance that this relatively new process will not introduce delays or require additional studies compared to the prior system. 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 other than 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 reporting requirements to the European and U.S. 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

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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.

## Capital Expenditures, Divestitures and Investments

Our capital expenditure on property, plant and equipment for 2003 totaled approximately \$185 million, compared to \$125 million in 2002 and \$97 million in 2001. 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 2003, 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 CHF 350.0 million or \$283.8 million which we will substantially finance by means of a credit facility we have entered into. We started construction in the middle of 2003.

## 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 33 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 Italy. Our principal manufacturing facilities are located in Switzerland, Italy, Spain and Israel. 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.

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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 CHF 350.0 million or \$283.8 million. The total costs capitalized as of December 31, 2003 were CHF 101.8 million or \$82.5 million. We substantially financed this project by way of a CHF 300 million committed unsecured revolving bank facility. As of December 31, 2003, the amount outstanding under this facility was CHF 72.6 million or \$58.9 million. The facility is due for repayment on December 31, 2006.

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

Location	Use	Owned or Leased	Size
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
Ivrea, Italy	Research and Development	Leased-Expires 2010	2,736 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
Ness-Ziona, Israel	Manufacturing	Leased-Expires 2005	9,700 sq. meters
Ness-Ziona, Israel	Manufacturing	Leased-Expires 2007	3,670 sq. meters
Tres Cantos, Spain	Manufacturing	Owned	6,028 sq. meters
Martillac, France	Manufacturing	Leased-Expires 2008	1,107 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 34 to our consolidated financial statements.

### Overview

We are the third largest biotechnology company in the world based on 2003 total revenues of \$2,018.6 million. We use human genetic information to discover, develop and manufacture therapeutic products for the treatment of human diseases. We currently focus on the highly specialized markets of neurology, reproductive health, and growth and metabolism, where we have established strong positions. We are also embarking on a fourth therapeutic area, dermatology, with the expected launch of Raptiva as a treatment for psoriasis. We have a global presence with operations in over 40 countries, production facilities in four countries and sales in over 90 countries. 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 34 of the consolidated financial statements a reconciliation of net income and shareholders' equity from IFRS to US GAAP. The preparation of consolidated financial statements in conformity with IFRS and the reconciliation under US 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 and bad debt and the assessment of impairment of intangible assets and available-for-sale investments, income taxes, and 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 and that 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.

### **Revenue recognition**

We recognize product sales revenue upon transfer to the buyer of the significant risks and rewards of ownership, net of estimated returns, provided that we determine that collection is probable. 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, unsold products in our 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 from period to period and the actual amounts could vary significantly from our estimates.

### **Inventory provision**

We write down our inventory for estimated obsolescence in 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.

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### **Bad debt**

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 regularly whenever indicators of impairment exist. If we determine that such indicators are present, we prepare a discounted future net cash flow projection to determine the value in use of the asset. 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 our calculation of value in use is in excess of the carrying value of the recorded asset, we do not record an impairment. In the event the carrying value of the asset exceeded the value in use, we would estimate the net price at which the asset could be sold (its net selling price), and, where appropriate, we would use the assistance of an external valuation expert. If the carrying value also exceeded 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 manufacturing assets as well as intangible assets.

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

We hold available-for-sale investments at fair value and have elected to take any unrealized gains and losses as fair value reserves, which affects 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, but is not limited to, 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 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 is available in the affiliate that has recognized the deferred tax assets an assessment that requires management judgment.

#### **Pensions**

Substantially all of our employees are covered by defined benefit, insured or state pension plans. The expense we incur 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, and future salary increases as well as future pension increases. Furthermore, our independent actuaries use statistical 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 we recognize in future periods.

#### **Contingencies**

Several of our subsidiaries are parties from time to time to various legal proceedings related to alleged breaches of contract, patent infringements and other matters. In these proceedings, claims could be made against them which might not be covered by existing financial provisions or by insurance. Our management believes that the outcomes of such actions, if any, would not be material to our financial position, but could be material to our results of operations for a given period.

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### **Results of operations Overview**

#### **Total revenues**

#### **Product sales**

In 2003, five products accounted for 89.5% of our total product sales. Rebif, our largest selling product, is a recombinant interferon beta-1a that we sell for the treatment of multiple sclerosis. Gonal-f, our second largest selling product, 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. 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 sales and marketing rights in the U.S. market, was our fifth largest selling product. It is indicated for certain types of worsening MS and also for certain forms of cancer. Sales of Novantrone for the two separate indications are reported under our neurology therapeutic area and as other product sales, respectively.

In addition to the main products highlighted above, we also sell a variety of other products in our three therapeutic areas.

#### **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 receive fees from Roche in connection with a licensing agreement concerning our endogenous gene activation technology. We derive license income from out-licensing certain products to third parties and from time to time we 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 manufacturers finished products that we sell as a result of in-licensing agreements that grant us exclusive rights to sell a given product in a specific territory.

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

Our selling, general and administrative expenses, or SG&A, 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 to sell our products.

**Selling and marketing.** We maintained a marketing and sales force of approximately 1,750 employees in 2003 (1,700 employees in 2002) to sell or manage distribution of our products in over 90 countries. Our selling and marketing expenditures consist primarily of employee-related expenses and costs associated with congresses, exhibitions and advertising. Selling and marketing expense generally correlates with the volume of product sales we achieve due to the variable nature of the expenses. However, when we introduce products into new markets, selling and marketing expenses typically increase because we hire additional sales personnel to undertake product launch. For example, we are responsible for developing and commercializing Raptiva worldwide outside of the United States and Japan. During 2003, we submitted regulatory applications in key markets for the use of Raptiva in moderate-to-severe plaque psoriasis and we expect to commence its launch program for this

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innovative therapy in the second half of 2004. Costs associated with the launch of Raptiva are projected to be between \$30 million and \$50 million in 2004.

**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.

### **Research and development**

Research and development is one of our key functions, and we employed approximately 1,350 R&D personnel in 2003 (1,350 employees in 2002). 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, Istituto di Ricerca Cesare Serono, which merged into Industria Farmaceutica Serono, and Istituto di Ricerche Biomediche Antoine Marxer RBM in Italy and our corporate R&D organization.

In 2003, we completed the acquisition of Genset S.A., a genomics-based biotechnology company. We believe that the acquisition of Genset S.A., which we have renamed the Serono Genetics Institute, enhances our research and discovery capabilities in genomics.

## Restructuring

There were no restructuring expenses incurred during 2003. In 2002, we incurred \$16.3 million related to the withdrawal from the urinary sector of the reproductive health business in Italy and the sale of two companies in Latin America. The restructuring provision of \$6.2 million as of December 31, 2002 has been fully utilized against payments in 2003 as all significant actions associated with the restructuring plan were completed during the year.

## Other operating expense

Royalty and licensing expenses incurred on the sales of certain products are reported under other operating expense. We incur royalty and licensing expenses under agreements that we have with several companies. Our expenses under these agreements vary with the royalties received and the sales of products subject to these agreements. Other operating expense, net also includes increases in litigation provisions, amortization of intangibles and other long-term assets, patent and trademark expenses and other non-recurring payments.

## 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:

1. Overview
2. Sales by Therapeutic Area
3. 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 US 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 our 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

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expenses that reflects the licensing in of Novantrone and royalties paid to third parties as well as higher amortization of intangible expenses.

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 that 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.

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Our outlook for 2004 is an increase in total revenue of at least 12% and an increase in net income of between 15% and 20%, reflecting our underlying growth. We do not take a view on changes in foreign exchange rates in the coming year and therefore our outlook is in constant currency relative to our reported results.

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

Product sales by therapeutic area	Year ended December 31				
	2003 US\$m	Change %	2002 US\$m	Change %	2001 US\$m
<b>Neurology</b>					
Rebif	819.3	49.3	548.8	44.6	379.6
Novantrone	30.9	10166.7	0.3	-	-
<b>Total neurology</b>	<b>850.2</b>	<b>54.9</b>	<b>549.1</b>	<b>44.6</b>	<b>379.6</b>
<b>Reproductive health</b>					
Gonal-f	526.1	16.8	450.4	9.7	410.5
Cetrotide	24.8	35.3	18.4	73.1	10.6
Crinone	20.8	90.2	10.9	347.0	2.4
Ovidrel	12.3	117.2	5.7	112.6	2.7
Luveris	9.6	46.3	6.6	600.1	0.9
<b>Core infertility portfolio</b>	<b>593.6</b>	<b>20.7</b>	<b>492.0</b>	<b>15.4</b>	<b>427.1</b>
Pergonal	45.8	(0.4)	46.0	20.7	38.1
Metrodin HP	24.8	(50.6)	50.1	(25.3)	67.1
Profasi	15.4	(22.4)	19.8	(16.9)	23.8
Other products	13.3	(5.0)	14.0	(23.1)	18.2
<b>Total reproductive health</b>	<b>692.9</b>	<b>11.4</b>	<b>621.9</b>	<b>8.3</b>	<b>574.3</b>
<b>Growth and metabolism</b>					
Saizen	151.4	22.1	124.0	15.6	107.3
Serostim	88.8	(6.6)	95.1	(24.1)	125.3
<b>Total growth and metabolism</b>	<b>240.2</b>	<b>9.6</b>	<b>219.1</b>	<b>(5.8)</b>	<b>232.6</b>

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Other products	74.7	125.7	33.1	(47.4)	62.9
<b>Total product sales</b>	<b>1,858.0</b>	<b>30.6</b>	<b>1,423.1</b>	<b>13.9</b>	<b>1,249.4</b>
Recombinant products	1,608.1	30.5	1,232.0	19.9	1,027.4
Non-recombinant products	249.9	30.8	191.1	(13.9)	222.0

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Product sales by region	Year ended December 31				
	2003 US\$m	Change %	2002 US\$m	Change %	2001 US\$m
Europe	813.8	31.2	620.4	14.4	542.2
North America	694.3	44.8	479.6	22.8	390.6
Latin America	98.8	(9.5)	109.2	(16.5)	130.9
Other regions	251.1	17.3	213.9	15.2	185.7
<b>Total product sales</b>	<b>1,858.0</b>	<b>30.6</b>	<b>1,423.1</b>	<b>13.9</b>	<b>1,249.4</b>

## 2. Sales by Therapeutic Area

### Neurology

In 2003, neurology sales were up 54.9% (39.5% in local currencies) 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 average selling price per equivalent unit was due to the increase 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 estimate 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. In the last quarter of 2003, our sales of Novantrone ran at an annualized rate of \$89.5 million. This level of sales is representative of our expectations going forward.

### 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 core portfolio of infertility products increased by 20.7% (10.7% in local currencies) to \$593.6 million in 2003 from \$492.0 million in 2002. Our sales of Gonal-f increased by 16.8% to \$526.1 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.

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% (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 \$151.4 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 \$88.8 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 Zorbtive for use in the treatment of short bowel syndrome, a serious and potentially life-threatening condition. Additionally the FDA granted

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orphan drug status for the use of Zorbtive in this indication through December 2010. We plan to launch Zorbtive in the U.S. during 2004.

### **Other products**

Our sales of other products increased by 125.7% to \$74.7 million in 2003 from \$33.1 million in 2002. This increase was due to strong first year sales of Novantrone for oncology.

## **3. Sales by Region**

### **Europe**

Our total European product sales increased by 31.2% to \$813.8 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 Novantrone of \$77.1 million; and an increase of sales of Saizen by \$14.5 million.

### **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.

### Other regions

In the Middle East, Africa and Eastern Europe regions, our product sales increased by 24.6% to \$134.1 million in 2003 from \$107.6 million in 2002, due primarily to the continued sales growth of Rebif and Gonal-f in these markets. In the Asia-Pacific region, which excludes Japan, our product sales increased by 10.5% to \$61.0 million in 2003 from \$55.2 million in 2002, due largely to increased demand of Gonal-f and Rebif. 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. 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.

### Royalty and license income

	Year ended December 31				
	2003 US\$m	Change %	2002 US\$m	Change %	2001 US\$m
<b>Royalty and license income</b>	160.6	40.0	114.7	(9.7)	127.1

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 royalties received from Organon on its sales of Puregon.

## 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

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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. However, we expect this ratio to continue to benefit from the economies of scale and continued improvements in our manufacturing processes in the near term.

### Selling, general and administrative

	Year ended December 31				
	2003 US\$m	Change %	2002 US\$m	Change %	2001 US\$m
Selling & marketing	472.9	25.4	377.1	14.3	329.8



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General & administrative	163.9	28.9	127.1	8.6	117.1
<b>Total selling, general and administrative</b>	<b>636.8</b>	<b>26.3</b>	<b>504.2</b>	<b>12.8</b>	<b>446.9</b>

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 US, 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. SG&A expenses represented 31.5% of revenues in 2003, compared to 32.8% in 2002.

Selling, general and administration expenses as a percentage of total revenues are not expected to change significantly in the immediate future.

**Research and development expense, net**

	Year ended December 31		
	2003 US\$m	2002 US\$m	2001 US\$m
<b>R&amp;D expense, net</b>	<b>467.8</b>	<b>358.1</b>	<b>308.6</b>
<b>R&amp;D expense, net as a % of revenues</b>	<b>23.2</b>	<b>23.3</b>	<b>22.4</b>

Our net 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 Tadekinig alpha; and the functional genomic program as well as a full year of operating costs related to the Serono Genetics Institute (formerly Genset), which we acquired in late third quarter 2002.

**Other operating expense, net**

Our net other operating expense 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. Royalty and license expenses increased by \$85.4 million to \$120.1 million, amortization of intangible assets and patent and trademark expenses increased by \$11.2 million to \$38.6 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**

Year ended December 31

	2003 US\$m	2002 US\$m	2001 US\$m
Interest income	49.8	64.6	75.9
Interest expense	(13.0)	(10.6)	(14.7)
Foreign currency gains/(losses)	7.2	(17.5)	(9.8)
<b>Total financial income, net</b>	<b>44.0</b>	<b>36.5</b>	<b>51.4</b>

Net interest 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.

#### 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 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.

#### Year ended December 31, 2002 compared to year ended December 31, 2001

The following compares our results in the year ended December 31, 2002 to those of the year ended December 31, 2001. Our analysis is presented as follows:

1. Overview
2. Sales by Therapeutic Area

3. Sales by Region
4. Operating Expenses to Net Income

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## 1. Overview

Our total revenues increased by 11.7% to \$1,537.8 million compared to \$1,376.5 million in 2001. Our consolidated worldwide product sales increased by 13.9% to \$1,423.1 million in 2002 from \$1,249.4 million in 2001. We experienced a favorable currency effect of \$29.6 million on product sales; however, there was an adverse currency impact of \$35.7 million on operating expenses.

Our sales of recombinant products increased by 19.9% to \$1,232.0 million, or 86.6% of total product sales, in 2002 from \$1,027.4 million, or 82.2% of total product sales, in 2001. Our sales of urine-derived and other non-recombinant products decreased by 13.9% to \$191.1 million, or 13.4% of total product sales, in 2002 from \$222.0 million, or 17.8% of total product sales, in 2001. The changing sales mix reflects our strategy of focusing on biotechnology products, and the transition from urine-derived products to recombinant products.

Royalty and licensing income decreased by 9.7% to \$114.7 million due to lower license income received in 2002.

Operating expenses increased by 14.4% in 2002 to \$1,188.2 million or 77.3% of total revenues. Operating margin declined to 22.7% in 2002 from 24.5% in 2001 due to a \$16.3 million restructuring charge we incurred upon completion of the final stage of the closure of our production facilities for urine-derived reproductive hormone products in Italy, and upon the sale of our generics sector in Latin America, which was not core to our business.

Net income per share increased by 1.8% from \$19.72 to \$20.07 in 2002.

## 2. Sales by Therapeutic Area

### Reproductive health

Our reproductive health product sales increased by 8.3% (6.6% in local currencies) to \$621.9 million in 2002 from \$574.3 million in 2001. Our sales of Gonal-f increased by 9.7% to \$450.4 million in 2002 from \$410.5 million in 2001. As a result of the continued switch to biotechnology products, our sales of Metrodin HP declined by 25.3% to \$50.1 million in 2002 from \$67.1 million in 2001. We expect that we will continue to gradually replace Metrodin HP with Gonal-f. Our sales of Pergonal increased by 20.7% to \$46.0 million in 2002 from \$38.1 million in 2001. Our sales of Cetrotide reached \$18.4 million in 2002 compared to \$10.6 million in 2001.

Given the demonstrated benefits of recombinant products in infertility, our strategy for some time now has been to replace previous-generation urine-derived products with recombinant products that have been registered around the world. Recombinant DNA technology is our preferred method for providing human proteins for therapeutic use as it enables the production of consistent and extremely pure proteins in predictable quantities. In accordance with our strategy, at the end of 2002 we decided to proceed with the final closure of our production facilities for urine-derived products. As a result, we incurred a restructuring charge of \$16.3 million in 2002 for the phase-out of urine-derived products. The restructuring charge includes \$6.1 million of employee-related termination benefits, \$8.9 million of asset-related write-downs and \$1.3 million of other costs, largely associated with contract cancellation fees and legal costs related to the termination of contracts with various suppliers and subcontractors. The restructuring plan included the planned termination of approximately 56 employees. We do not expect to incur any costs relating to these matters in addition to those for which we have provided.

### Neurology

Our sales of Rebig increased by 44.6% (39.9% in local currencies) to \$548.8 million in 2002 from \$379.6 million in 2001. Following the FDA approval on March 7, 2002, Rebig was launched in the United States on March 11, 2002. During 2002, we announced an agreement with Pfizer to co-promote Rebig in the United States with the aim of increasing sales and market penetration. Our total

Rebif sales in the United States were \$71.2 million in 2002. Rebif sales in the rest of the world grew by 25.5% to \$477.6 million in 2002 compared to \$379.6 million in 2001. We estimate that our worldwide market share at the end of 2002 was approximately 19% compared with 16% at the end of 2001. Outside the United States, we estimate that our market share at the end of 2002 and 2001 was approximately 36%. Finally, we estimate that our dollar market share reached 5% in the United States at the end of 2002.

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### **Growth and metabolism**

Our growth and metabolism product sales decreased by 5.8% (6.9% in local currencies) to \$219.1 million in 2002 from \$232.6 million in 2001.

Our sales of Saizen increased by 15.6% to \$124.0 million in 2002 from \$107.3 million in 2001. This increase was due to higher demand in the United States, driven by the continuing good success of the first needle-free device for the delivery of human growth hormone, cool.click, and higher demand in Europe thanks to the roll-out of our auto-injector, one.click. Cool.click was approved in June 2002 in Europe, and launched during the last quarter of 2002.

Our sales of Serostim decreased by 24.1% to \$95.1 million in 2002 from \$125.3 million in 2001. Serostim sales declined as a result of tighter control and usage guidelines in key U.S. states. In October 2002, we announced the implementation of the new Serostim Secured Distribution Program in the United States. This program was designed to track and manage Serostim through the distribution process, and ensure that patients who require Serostim receive genuine products on a timely basis.

### **Other products**

Our sales of other products declined by 47.4% to \$33.1 million in 2002 from \$62.9 million in 2001. This decrease was primarily due to the discontinuation of Curosurf sales following the sale of that product to Chiesi Farmaceutici in 2001, lower sales of generic drugs in Latin America, and lower sales of Stilamin.

## **3. Sales by Region**

### **Europe**

Our total European product sales increased by 14.4% to \$620.4 million in 2002 from \$542.2 million in 2001. The increase was primarily due to the increased sales of Rebif and Saizen.

### **North America**

Our total North American product sales increased by 22.8% to \$479.6 million in 2002 from \$390.6 million in 2001. In North America, the increase was primarily due to the strong performance of Rebif following its successful launch in the United States in 2002, and increased Saizen and Gonal-f sales, that were partially offset by lower Serostim sales. Our total Rebif sales in the United States were \$71.2 million in 2002.

### **Latin America**

Our total Latin American product sales decreased by 16.5% to \$109.2 million in 2002 from \$130.9 million in 2001. Our sales performance in 2002 was adversely impacted by the continued economic difficulties in several countries in Latin America, Argentina in particular.

### **Other regions**

In the Middle East, Africa and Eastern Europe regions, our product sales increased by 28.0% to \$107.6 million in 2002 from \$84.1 million in 2001, due primarily to the continued sales growth of Rebif and Gonal-f in these markets. In the Asia-Pacific region, which

excludes Japan, our product sales increased by 1.4% to \$55.2 million in 2002 from \$54.4 million in 2001, due largely to increased demand of Gonal-f, which was partially offset by lower sales of urine-derived products. In Japan, our product sales decreased by 0.5% to \$29.2 million in 2002 from \$29.3 million in 2001, due primarily to the weakening of the Japanese Yen, which was partially offset by increased demand for Saizen and Metrodin HP. In Oceania, our product sales increased by 22.4% to \$21.9 million in 2002 from \$17.9 million in 2001, due largely to higher Rebif and Gonal-f sales.

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## Royalty and license income

	Year ended December 31				
	2002 US\$m	Change %	2001 US\$m	Change %	2000 US\$m
Royalty income	113.1	14.0	99.2	27.0	78.1
License income	1.6	(94.3)	27.9	91.1	14.6
<b>Royalty and license income</b>	<b>114.7</b>	<b>(9.7)</b>	<b>127.1</b>	<b>37.1</b>	<b>92.7</b>

Our revenues from royalty and license income decreased by 9.7% to \$114.7 million in 2002, compared to \$127.1 million in 2001. Our royalty income reached \$113.1 million in 2002 compared to \$99.2 million in 2001. The increase was due primarily to higher royalty income from Biogen on its sales of Avonex and from Organon on its sales of Puregon.

Our license income decreased to \$1.6 million in 2002 from \$27.9 million in 2001. The decrease of our license income was mainly due to the fact that in 2001 we received an exceptional payment of \$27.6 million from a third party related to the divestiture of a product which was not core to our business.

## 4. Operating Expenses to Net Income

### Cost of product sales

Our cost of product sales increased by 5.0% to \$223.8 million in 2002 from \$213.2 million in 2001. This increase was driven by higher product sales. However, cost of product sales increased less than product sales due to an increasing proportion of our product sales from higher margin recombinant product and due to increased production yields driven by technical improvements in our biotechnology manufacturing processes. As a result, our gross profit on product sales, which is product sales less cost of product sales, increased by 15.7% to \$1,199.4 million, or 84.3% of product sales, in 2002 from \$1,036.2 million, or 82.9% of product sales, in 2001.

### Selling, general and administrative

Our SG&A expenses increased by 12.8% to \$504.2 million in 2002 from \$446.9 million in 2001. SG&A expenses represented 32.8% of revenues in 2002, compared to 32.5% in 2001. This increase was primarily due to:

- Higher overall sales volumes;
- Investment in selling and marketing infrastructure in 2002 for the launch of Rebif in the United States;
- Payment of sales commissions to Pfizer related to the co-promotion agreement for Rebif;

- n Selling & marketing expenses associated with the roll-out of three new recombinant products in the area of reproductive health (Ovidrel, Luveris and Gonal-f multidose); and
- n Roll-out of new devices in the area of growth hormone deficiency (cool.click and one.click).

**Research and development expense, net**

	Year ended December 31		
	2002 US\$m	2001 US\$m	2000 US\$m
<b>R&amp;D expense, net</b>	358.1	308.6	263.2
<b>R&amp;D expense, net as a % of revenues</b>	23.3	22.4	21.2

Our net research and development expense increased by 16.1% to \$358.1 million, or 23.3% of revenues, in 2002 from \$308.6 million, or 22.4% of revenues, in 2001. This increase in our research and development expense was due to several factors:

- n Our investment in strategic external collaborations. In 2002, we made significant progress in the

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area of business development with the achievement of agreements with leading biotechnology partners for late-stage and marketed products;

- n The further development of our functional genomics and discovery activities with the integration of the genetic genomic capabilities of Genset; and
- n The further development of the pipeline inclusive of the manufacturing process.

**Restructuring charge**

In December 2002, we took a one-time \$16.3 million restructuring charge related to:

- n The final stage of the closure of our production facilities for urine-derived reproductive hormone products in Italy. This action reflected our strategy to replace urine-derived fertility products with recombinant products; and
- n The sale of two companies in Latin America, in connection with our withdrawal from the generics sector, which was not core to our business.

**Other operating expense, net**

Our net other operating expense was \$85.8 million in 2002, compared to \$70.2 million in 2001. This 22.3% increase was due to a number of factors including:

- n Our royalty and license expense increased to \$34.8 million in 2002 compared to \$22.9 million in 2001, in line with the increase in royalty and license income. In 2002, we reached an agreement with Berlex Laboratories Inc., the U.S.

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subsidiary of Schering AG, concerning patent No. 5 376 567, which relates to the production of human interferon-beta. Under the terms of the settlement we received a non-exclusive license to import, manufacture and sell Rebif in the United States, that will require us to pay a royalty to Berlex Laboratories Inc., based on U.S. sales of Rebif;

- n Amortization of intangibles and other long-term assets decreased to \$22.8 million in 2002 compared to \$31.6 million in 2001; and
- n Litigation and legal costs increased to \$13.3 million in 2002 compared to \$7.6 million in 2001.

### **Operating income**

Our operating income increased by 3.5% to \$349.6 million in 2002 from \$337.7 million in 2001. As a percentage of revenues, our operating income was 22.7% in 2002 compared to 24.5% in 2001.

### **Financial income, net**

Our net financial income decreased to \$36.5 million in 2002 from \$51.4 million in 2001. This decrease was primarily due to lower interest rates on U.S. dollar deposits, and because we incurred translation losses of \$13.9 million in 2002 compared to \$9.1 million in 2001 arising primarily from various currency devaluations in Latin America.

### **Taxes**

Our total taxes decreased by 9.6% to \$63.1 million in 2002 from \$69.8 million in 2001 due primarily to our manufacturing process improvements which resulted in comparatively higher profit recognition in countries with more favorable tax jurisdictions. Our overall tax rate, including capital taxes, decreased to 16.4% in 2002 from 18.1% in 2001.

### **Net income**

Our net income increased by 1.3% to \$320.8 million in 2002 from \$316.7 million in 2001. Our net income represented 20.9% of revenues, compared to 23.0% in 2001.

### **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 borrowings, public financings and various employee equity compensation plans.

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In 2000, we completed a global public offering of 1,070,670 bearer shares in the form of bearer shares and American depository 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, which are convertible into our bearer shares. At December 31, 2003, we had unused lines of credit for short-term financing of \$366.9 million compared to \$112.7 million at December 31, 2002.

Our total financial assets, which are made up of cash and cash equivalents plus short-term and long-term financial assets, amounted to \$2,490.5 million.

The analysis of our cash flows is divided as follows:

1. Cash flows from operating activities and free cash flows
2. Cash flows from investing activities

3. Cash flows from financing activities
4. Net financial assets

### 1. Cash flows from operating activities and free cash flows

Our cash flows from operating activities are a significant ongoing source of funds to finance operations. Cash flows from operating activities increased by 2.0% to \$542.9 million in 2003 from \$532.0 million in 2002. This increase was primarily due to higher net income and non-cash expenses, the majority of which was offset by an increase in working capital. Income before taxes and minority interest increased by \$74.8 million and depreciation and amortization and write-down of available-for-sale investments increased by \$55.2 million. During 2003, we received \$55.0 million from OSI for the right to co-promote Novantrone in the United States; however, in 2002 we received \$200.0 million from Pfizer related to our co-promotion agreement for Rebif also in the United States. Both payments were initially recognized as deferred income to be amortized over the life of the respective agreements. Excluding the one-time payments related to promotional activities from Pfizer in 2002 and from OSI in 2003, operating cash flows increased by 47.0% compared to 2002. We believe that it is useful to provide a calculation of our cash flows from operating activities that excludes these one-time payments, because it permits our investors to compare the 2003 cash flows from operating activities calculation with our cash flows from operating activities from 2002 in order to better assess our operating performance.

#### Free cash flows

	Year ended December 31		
	2003 US\$m	2002 US\$m	2001 US\$m
Net cash flows from operating activities	542.9	532.0	405.0
Purchase of property, plant and equipment	(162.5)	(99.1)	(78.6)
Purchase of intangible and other long-term assets	(46.5)	(35.5)	(42.7)
Acquisition of Genset	(9.7)	(115.1)	-
Purchases of financial assets	(439.7)	(860.4)	(188.9)
Proceeds from the sale of property, plant and equipment and financial assets	19.1	361.5	882.4
Interest received	67.3	48.0	76.1
<b>Free cash flows</b>	<b>(29.1)</b>	<b>(168.6)</b>	<b>1,053.3</b>

### 2. Cash flows from investing activities

Net cash used in investing activities was \$571.9 million in 2003. Our capital expenditure on property, plant and equipment totaled \$162.5 million. This level of capital expenditure reflects our continuing investment in research and development and manufacturing facilities and our continuing implementation of advanced information technology systems. Our total capital commitments as of December 31, 2003 were \$21.0 million.



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 Switzerland-based research and development activities and to support our anticipated growth. We estimate that the cost of this project to scheduled completion in 2006 will be approximately CHF 350.0 or \$283.8 million. The total costs capitalized as of December 31, 2003 were CHF101.8 million or \$82.5 million. A large portion of the project is being financed with bank debt. In 2004, we expect to increase our level of investment in property, plant and equipment by approximately 10% to 20% compared to 2003. We anticipate that most of our capital expenditure excluding the construction of our new headquarters and research and development center will be funded with resources generated from our operations.

In 2003, we increased our investment in long-term corporate bonds by \$439.7 million and spent \$9.7 million to complete the acquisition of Genset.

### 3. Cash flows from financing activities

Net cash flows used in financing activities was \$338.1 million in 2003. On November 26, 2003, we 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. In the event of conversion, we will obtain the shares we will deliver from a combination of treasury shares and conditional share capital. The bonds are 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. The bond has a conversion price of CHF1,497 based on its redemption value of CHF634.8 million. We issued the bonds to take advantage of the attractive financing opportunities then available in the convertible bond market. The offering provides additional financial resources and flexibility while capitalizing on the current favorable interest rate environment. The proceeds of the issue will be used for general corporate and strategic purposes outside Switzerland.

A CHF300.0 million medium-term bank facility has been made available to one of our group companies for the development of the new headquarters and research center in Geneva. This unsecured facility is guaranteed by Serono S.A. and has a maturity date of December 31, 2006. As of December 31, 2003, the amount drawn under the facility was CHF72.6 million or \$58.9 million.

In 2003, we paid \$85.7 million in dividends to investors and spent \$42.0 million for the acquisition of treasury shares.

### 4. Net financial assets

At December 31, 2003, we had total financial assets (cash and cash equivalents, short-term financial assets and long-term financial assets not including equity investments in non-group companies) in the amount of \$2,490.5 million. Net financial assets (financial assets less short and long-term financial debts) as of December 31, 2003 were \$1,907.2 million, and increased by \$291.3 million during the year.

The following table represents the components and the total amount of net financial assets for the last three years.

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.

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#### Net financial assets

For the year ended	2003 US\$m	2002 US\$m	2001 US\$m
Cash flows from operating activities	542.9	532.0	405.0

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Cash flows from investing activities	(571.9)	(700.6)	648.3
Cash flows from financing activities	338.1	(288.8)	(144.4)
Effect of exchange rate changes on cash and cash equivalents	8.9	12.3	(0.8)
<b>Change in cash and cash equivalents</b>	<b>318.0</b>	<b>(445.1)</b>	<b>908.1</b>
Change in short-term and long-term financial assets	437.1	516.2	(682.2)
Change in short-term and long-term financial debts	(463.8)	91.1	84.6
<b>Change in net financial assets</b>	<b>291.3</b>	<b>162.2</b>	<b>310.5</b>
Net financial assets as of January 1	1,615.9	1,453.7	1,143.2
<b>Net financial assets as of December 31</b>	<b>1,907.2</b>	<b>1,615.9</b>	<b>1,453.7</b>
<b>Consists of</b>			
Cash and cash equivalents	1,004.0	686.0	1,131.1
Short-term financial assets	434.8	378.9	344.4
Long-term financial assets	1,104.4	711.2	241.0
Less: Investment in non-group companies	52.7	40.7	52.2
<b>Total financial assets</b>	<b>2,490.5</b>	<b>1,735.4</b>	<b>1,664.3</b>
<b>Less</b>			
Short-term financial debts	51.3	93.6	173.3
Long-term financial debts	532.0	25.9	37.3
<b>Total financial debts</b>	<b>583.3</b>	<b>119.5</b>	<b>210.6</b>
<b>Net financial assets</b>	<b>1,907.2</b>	<b>1,615.9</b>	<b>1,453.7</b>

**Off-balance sheet arrangements**

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors in our shares.

**Contractual cash obligations**

Our future minimum non-cancelable contractual obligations at December 31, 2003 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
Borrowings	544.2	12.2	66.2	458.3	7.5
Lease operating	130.8	24.7	50.4	14.7	41.0
Lease finance	0.6	0.5	0.1	-	-
Capital commitments	21.0	21.0	-	-	-
<b>Total</b>	<b>696.6</b>	<b>58.4</b>	<b>116.7</b>	<b>473.0</b>	<b>48.5</b>

The capital commitments relate mostly to the construction costs and contractors' compensations for the construction of our new headquarters and research center in Geneva, which is expected to be completed before 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 28 to the consolidated financial statements. As part of these agreements

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we have made commitments to make R&D 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 of our collaborators were to achieve all the contractual milestones, we would be required to pay approximately \$438.3 million. The exact timing of eventual payments is uncertain, but it would be over a period of the next 10 years.

Assets with an original cost of \$65.1 million at December 31, 2003 have been pledged as security against long-term debt and certain unused long-term lines of credit. The amount of such assets at December 31, 2002 was \$67.5 million.

**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 and a discussion of the potential impact of some IFRS exposure drafts published by the International Accounting Standards Boards that could have a material impact on our results in note 35 to our consolidated financial statements.

**Item 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES****Board of Directors**

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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.

Name	Age (1)	Position
Georges Muller	64	Chairman
Ernesto Bertarelli	38	Vice-Chairman and Managing Director
Jacques Theurillat	44	Director
Pierre E. Douaze	63	Director
Bernard Mach	71	Director
Sergio Marchionne	51	Director
Hans Thierstein	72	Director

(1) As of March 15, 2004

*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. 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, Chairman of the board of directors of La Suisse Assurances and Vice-Chairman of Bertarelli & Cie. He is a director of Rentenanstalt-Swiss Life and Schindler Aufzüge AG. He participates on the boards of various foundations and associations, namely Chambre Vaudoise du Commerce et de L Industrie; Fondation pour la création d un musée des Beaux Arts, Lausanne (Chairman); ISREC 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 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

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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.

*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 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. Since then he has held several positions of increasing responsibility relating to tax and financial planning. Mr. Theurillat is a director of 21 Invest Partners S.A. 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 France.

*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. He is Vice-President of the Alumni Association of the Federal

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Polytechnical School in Lausanne. 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.

*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 February 2002, Mr. Marchionne has served as Chief Executive Officer and Managing Director 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 is also a director of Fiat SpA. 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.

*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 passed 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.

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### Executive Officers.

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

Name	Age (1)	Position
Ernesto Bertarelli	38	Chief Executive Officer
Jacques Theurillat	44	Deputy Chief Executive Officer; President of European and International Sales and Marketing
Roland Baumann	58	Senior Executive Vice President, Compliance Officer and Head of Corporate Administration
Leon Bushara	37	Senior Executive Vice President, Business Development
Giampiero De Luca	49	Chief Intellectual Property Counsel
Fereydoun Firouz	40	President, Serono, Inc.
Franck Latrille	47	Senior Executive Vice-President, Global Product Development
François Naef	41	Senior Executive Vice-President, Human Resources, Legal and Corporate Communication

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Allan L. Shaw	40	Chief Financial Officer
Timothy Wells	41	Senior Executive Vice President, Research

(1) As of March 15, 2004

*Roland Baumann* is our Senior Executive Vice President, 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 and Strategic Planning. From March 2000 to March 2003, he was our Senior Vice President, Head of Strategic Business Planning and Corporate Administration. 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 accounting and finance 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. He is a director of Pantarhei Bioscience B.V. and Molecular Acupuncture Pty Ltd. 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. Mr. De Luca is an Italian national and a resident of Switzerland.

*Fereydoun 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.

*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

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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 is a member of the Board of the Swiss Society of Chemical Industries as well as a member of the Pharma working group of this Society. 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.

*Allan L. Shaw* has been our Chief Financial Officer since November 2002. From 1996 until June 2002, Mr. Shaw was a member of the board of directors of Viatel Inc., an international telecommunications company for which he also served as Chief Financial

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Officer from 1996 until May 2001 and as corporate controller from 1994 until 1996. Mr. Shaw received a BS degree from the State University of New York (Oswego College). He is a certified public accountant in the State of New York. He is a United States national and a resident of Switzerland.

*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, 2003, we paid our directors and executive officers as a group, for services in all capacities, \$17,937,136. Of this amount, we paid \$4,337,712 pursuant to a bonus plan, which provides for payments to executive officers based on their performance and the performance of our company. In addition, during the year ended December 31, 2003, we set aside or accrued \$521,709 to provide pension, retirement or similar benefits for our executive officers. During the year ended December 31, 2003, we granted to our directors and executive officers options to purchase 20,000 bearer shares at an exercise price of CHF 649, expiring on March 31, 2013 and options to purchase 4,600 bearer shares at an exercise price of CHF 692, expiring on May 12, 2013. 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 2003, we allotted a total of 791 bearer shares to our directors and executive officers. During the year ended December 31, 2003, we paid our most highly compensated director a total of \$4,517,218, 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.

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

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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:

- I 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);
- I Assure that the independence of the independent auditors is maintained;
- I 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;

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- | 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, for approval by the Board of Directors;
- | Set the compensation of the independent auditors and pre-approve all audit and non-audit related engagements performed by the independent auditors; and
- | Resolve issues related to conflicts of interests.

### **Compensation Committee**

In 2001, the Board of Directors also established a Compensation Committee, which consisted as of December 31, 2003, 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

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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



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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:

- I Approving our stock option plans and any modification thereof;
- I Approving the number of options which are granted to the Chief Executive Officer; and
- I 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.

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.

### Employees

As of December 31, 2003, 2002 and 2001, respectively, we had 4,577, 4,617 and 4,501 employees, of whom approximately 1,350, 1,350, and 1,300, respectively, were engaged in research and development, approximately 1,750, 1,690, and 1,300, respectively, were engaged in sales and marketing, approximately 1,090, 1,200 and 1,200, respectively, were engaged in manufacturing and approximately 400, 380 and 700 were engaged in other areas such as finance, information technology and human resources. As of December 31, 2003, 2002 and 2001, respectively, we had approximately 3,115, 2,900, and 2,900 employees in Europe, approximately 725, 655 and 600 employees in North America, approximately 180, 300 and 300 employees in Latin America and approximately 555, 840 and 700 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.

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### Share Ownership

As of December 31, 2003, Bertarelli & Cie, a partnership limited by shares with its principal offices at Chésereux (Vaud), Switzerland, held 52.51% of our capital and 61.62% of our voting rights. Ernesto Bertarelli, our Chief Executive Officer, Vice-Chairman and Managing Director, controls Bertarelli & Cie.

As of December 31, 2003, there were 11,406,887 bearer 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:

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	4,748,700	41.6	65.5
Roland Baumann	0	0	*	*	*
Leon Bushara	0	0	*	*	*
Giampiero De Luca	0	0	*	*	*
Pierre E. Douaze	0	0	*	*	*
Fereydoun Firouz	0	0	*	*	*
Franck Latrille	0	0	*	*	*
Bernard Mach	0	0	*	*	*
Sergio Marchionne	0	0	*	*	*
Georges Muller	0	0	*	*	*
François Naef	0	0	*	*	*
Allan L. Shaw	0	0	*	*	*
Jacques Theurillat	0	0	*	*	*
Hans Thierstein	0	0	*	*	*
Timothy Wells	0	0	*	*	*
All directors and executive officers as a group (15 persons) (1)(2)	9,973,200	90.6	4,760,825	41.6	65.5

\* Less than one percent.

- (1) Includes all registered shares and bearer shares reported by Bertarelli & Cie. Ernesto Bertarelli controls Bertarelli & Cie. Includes 5,250 bearer shares that we may issue to Mr. Bertarelli upon the exercise of stock options.
- (2) Includes 15,219 bearer shares that we may issue if our directors and current executive officers exercise stock options. As of December 31, 2003, our directors and current executive officers held a total of 58,945 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

### 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 22,276 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 meeting held on May 16, 2000, our shareholders approved an increase in our conditional capital for our stock option plans so that as of December 31, 2003, the total nominal capital authorized for the grant of options to employees and directors under our option plans, as adjusted for the exercise of 2,741 options under our Stock Option Plan and purchase of 23,229 shares under our Employee Share

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Purchase Plan from January 1, 2003 to and including December 31, 2003, consisted of CHF 8,824,900, corresponding to 352,996 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 92,630 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. Of these options, options for 22,276 bearer shares have been exercised, options for 49,582 bearer shares have been cancelled and are available for re-grant under the plan, and options for 277,782 bearer shares remain outstanding.

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.

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 61,014 bearer shares.

A compensation charge in the amount of \$1.4 million has been recognized for stock options granted in 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**

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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)

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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.

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.

### **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, for every three shares purchased in the Employee Share Purchase Plan on January 5, 2004 that are still held by an employee on December 31, 2004, 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, 2003, Bertarelli & Cie, a partnership limited by shares with its principal offices at Chéserey (Vaud), Switzerland, held 52.51% of our capital and 61.62% 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 7.15% of our capital and 9.92% of our voting rights. Our registered shares and our bearer shares are each entitled to one vote per share.

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As of December 31, 2003, there were 11,406,887 bearer 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:

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Name of Owner	Registered Shares Owned	Percent of Registered Shares	Bearer Shares Owned	Percent of Bearer Shares	Aggregate Voting Percent
Bertarelli & Cie (1)	9,189,300	83.4	4,626,930	40.6	61.6
Ernesto Bertarelli (2)	9,973,200	90.6	4,748,700	41.6	65.6
Maria-Iris Bertarelli (3)	255,940	2.3	154,000	1.4	1.8
Donata Bertarelli Späth (3)	783,900	7.1	130,520	1.1	4.1

- (1) Bertarelli & Cie is a partnership limited by shares with its principal offices in Chéserey (Vaud), Switzerland.
- (2) Includes all registered shares and bearer shares reported by Bertarelli & Cie. Ernesto Bertarelli controls Bertarelli & Cie. Includes 5,250 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 60 holders of record of our ADSs in the United States as of February 26, 2004. 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 facilities. The lease provides for a rent of approximately \$1.0 million per year. Subsequent to the negotiation of the lease, Mr. Bertarelli acquired a controlling interest in the company that owns the building. During 2003, we subleased a portion of the building to another company controlled by Mr. Bertarelli for a rent of approximately \$0.2 million per year. In 2003, 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 2003, we paid market-rate rental fees for the jet totaling approximately \$1.6 million.

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, 2003 is CHF 1.1 million (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, 2003 were \$2.4 million (2002:\$2.0 million). As of December 31, 2003, we had \$10,000 (2002:\$186,000) 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.

## 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-53.

## 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

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early to mid-1980s. The trial of the ownership and contractual issues started in 2002 and is expected to continue through 2004. In 2002, 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 court granted Yeda's motion for summary judgment declaring that Yeda was the rightful owner of the 701 patent.

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 in 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 have filed a counterclaim alleging Italfarmaco's default in the execution of the agreement and claiming monetary damages. We expect the proceedings to last at least through 2004.

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.

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 other practices. These investigations seek to determine whether such practices violated any laws, including the Federal False Claims Act or constituted fraud in connection with Medicare and/or Medicaid reimbursement to third parties. Our subsidiary is providing documents in response to the subpoena and is cooperating with the investigation.

## 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.

	<u>2003<sup>(1)</sup></u>	<u>2002</u>	<u>2001</u>	<u>2000</u>	<u>1999<sup>(2)</sup></u>
Declared dividend per bearer share (CHF)	8.00	7.00	6.25	6.00	2.00
Declared dividend per bearer share (US\$)	5.99	4.52	3.69	3.55	1.32

Declared dividend per ADS (US\$)(3)	0.15	0.11	0.09	0.09	
Declared dividend per registered share (CHF)	3.20	2.80	2.50	2.40	0.80
Declared dividend per registered share (US\$)	2.40	1.81	1.48	1.42	0.53

- (1) Our dividend for the 2003 fiscal year will not be declared and paid until our annual general meeting on May 25, 2004.
- (2) For the fiscal year 1999, we also declared a special dividend of one bearer share for each existing bearer share and one registered share for each existing registered share, thus doubling our share capital from CHF 187,367,100 to CHF 374,734,200. In addition to an aggregate cash dividend of approximately CHF 30 million, we also paid the Swiss withholding tax totaling approximately CHF 101 million on these new shares. Some of our shareholders may be able to receive a refund of the withholding tax as described in Item 10. Additional Information - Taxation.
- (3) 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 Depository in converting dividends from Swiss francs to U.S. dollars and on the expenses of the Depository.

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

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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 depository, in Swiss francs. The agreement with the depository provides that the depository will then convert the cash dividends to U.S. dollars and make payment to the holders of the American depository 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 depository 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.

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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 Per Bearer Share		NYSE Per ADS	
	High	Low	High	Low
	(CHF)		(US\$)	
<b>1999</b>	875	483		
<b>2000(1)</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
First Quarter	1,537	1,200	23.19	17.75
Second Quarter	1,490	915	22.58	15.37
Third Quarter	995	605	16.77	10.25
Fourth Quarter	894	627	15.00	10.65
<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
September	958	855	17.48	16.03
Fourth Quarter	950	840	17.79	16.13
October	935	840	17.65	16.13
November	950	875	17.37	16.50
December	905	840	17.79	16.72
<b>2004</b>				
January	974	875	19.60	17.58
February	973	826	19.27	16.58

(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 18, 2004. 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. 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:

- 1 changes in our purpose;
- 1 the creation of shares with privileged voting rights;
- 1 the restriction of the transferability of registered shares;
- 1 an authorized or conditional increase in share capital;

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- 1 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;
- 1 the restriction or elimination of preemptive rights of shareholders;
- 1 a transfer of our registered office; or
- 1 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.

### Repurchase of Shares

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

- 1 we have sufficient free reserves to pay the purchase price; and

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- 1 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:

- 1 an absolute majority of the shares represented at the meeting in the case of dissolution by way of liquidation; or
- 1 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, 2003, the Bertarelli family controlled approximately 71.5% 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:

- I 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;
- I if the preemptive rights of our shareholders are limited or excluded; or
- I 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

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an increase of share capital in a specified aggregate nominal amount up to 50% of share capital in the form of:

- I 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
- I 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

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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.

### 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 Depositary, as depositary under our ADS program, and the assumption that each obligation in the deposit agreement between us and the Depositary and any related agreement will be performed in accordance with its terms.

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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:

- 1 an individual citizen or resident of the United States;
- 1 a 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;
- 1 an estate the income of which is subject to U.S. federal income tax without regard to its source; or
- 1 a 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:

- 1 is a resident of the United States for purposes of the Treaty;
- 1 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

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- 1 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 Depository, 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

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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 group treasury 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.

### 1. Foreign exchange exposure

We use the U.S. dollar as our functional currency. 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

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anticipated net revenues in currencies other than the U.S. dollar. Net investments in Serono affiliates with a functional currency other than the U.S. dollar are of 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 in the 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		
	2003 %	2002 %	2001 %
<b>Product sales</b>			
In U.S. dollar	47	46	46
In EUR	36	37	35
In other currencies	17	17	19
<b>Total</b>	<b>100</b>	<b>100</b>	<b>100</b>

**Operating expenses (SG&A and R&D)**

In U.S. dollar	37	34	38
In Swiss franc	29	30	32
In EUR	23	27	19
In other currencies	11	9	11
<b>Total</b>	<b>100</b>	<b>100</b>	<b>100</b>

During 2003, the U.S. dollar weakened against most major currencies, including the Swiss franc and the EUR, which are the most important non-U.S. dollar currencies. This weakening resulted in a total positive currency effect on product sales of 7.7%, which was largely offset by a negative currency effect on operating expenses of 7.6%. The net impact on net income was a positive 6.0% in 2003 (negative net impact of less than 1.0% in 2002). This was primarily due to the strengthening of the EUR, 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 (approximately two months), 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 eight months.

**2. Interest rate exposure**

We manage our exposure to interest rate risk through the proportion 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 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. The group's financial assets include deposits with prime banks, investments in short-term money market funds, and investments in rated bonds with a life to maturity of up to four years.

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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 that 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

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purchased as part of our normal day-to-day management of financial assets managed by the group treasury department, with the exception of treasury shares that are acquired under our CHF500.0 million Share Buy Back Plan.

### 5. Commodities

The Serono 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 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 the group's earnings.

### 6. Sensitivity analysis

The table below presents the changes in fair values of our financial instruments to hypothetical changes in exchange or interest rates. The analysis shows forward-looking projections of changes in fair value assuming certain adverse market conditions to occur. 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 1% increase or decrease in the yield curves from their levels as of December 31, 2003, with all other variables remaining constant. For those financial instruments that are sensitive to changes in foreign currency exchange rates, we have calculated the potential change in the fair value resulting from an immediate hypothetical 10% weakening or rising in the U.S. dollar against all other currencies from their levels as of December 31, 2003, 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 10% decrease in the quoted market prices from their levels as of December 31, 2003, with all other variables remaining constant. The fair values of financial instruments are quoted market prices or, if not available, values estimated by discounted future cash flows to net present values.

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.

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	Fair value changes arising from					
	Fair value as of December 31, 2003	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	860,241	(334)		(1,263)		
Held-to-maturity and available-for-sale debt securities	1,495,000	(26,000)				
Available-for-sale equity securities	52,657			(732)		(5,213)
Financial debts, excluding convertible	(128,008)		(745)		(12,958)	

bond			
Convertible bond	(486,156)	(12,161)	(54,000)
Forward foreign exchange contracts	(3,914)		(2,300)
Foreign currency options	5,985		(1,800)
Interest rate swaps - fair value hedges	(2,346)	(600)	
Interest rate swaps - cash flow hedges	(467)	(1,700)	
Interest rate swaps	(321)	(53)	(36)

Our exposure to interest rate risk primarily results from our investments in debt securities. The majority of our debt securities consists of fixed-rate investments in rated Eurobonds denominated in U.S. dollars with maturities up to four years and short-term money market funds. A sensitivity analysis indicates that a one percent increase in interest rates at December 31, 2003 would unfavorably impact the net aggregated fair value of those securities by \$26.0 million, while a one percent decrease in interest rates would unfavorably impact the fair value of our convertible bond by \$12.2 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 and borrowings denominated in currencies other than U.S. dollars. The value of our financial debts, including our convertible bond, would increase by \$67.0 million if the U.S. dollar devalued by ten percent.

The group has investments in available-for-sale equity securities. We classify all such investments as long-term financial assets. The fair value of these investments is \$52.7 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 \$5.2 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

#### Use of Proceeds

1. Registration Statement on Form F-1  
Commission File No. 333-12192

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Effective Date: July 26, 2000

- 4.g. As of December 31, 2003, 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

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.

There were no significant changes in our internal controls or in other factors that could significantly affect those controls subsequent to the date of the evaluation described above.

## 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 that is applicable to our principal executive officer, principal financial officer, principal accounting officer or controller and persons performing similar functions. 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, 2003 and 2002, we paid the following fees for professional services to PricewaterhouseCoopers:

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	2003	2002
	(U.S.\$ in thousands)	
Audit Services	2,369	1,559
Audit-Related Services	206	134
Tax Services	591	949
Other Services	270	1,742 <sup>1</sup>
Total	3,436	4,384

- (1) Other services reported in 2002 include \$1.3 million related to services provided by the consulting arm of PricewaterhouseCoopers that was sold to IBM on September 30, 2002.

*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 can 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.

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### **PART III**

#### **Item 17. FINANCIAL STATEMENTS**

Not applicable.

#### **Item 18. FINANCIAL STATEMENTS**

See pages F-1 through F-53.

#### **Item 19. EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
1.1	<u>Articles of Association, dated March 18, 2004</u>
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

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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.)
- 2.8 Guarantee, dated as of November 26, 2003, of Serono S.A. in respect of the Convertible Bonds
- 8.1 List of Subsidiaries of the Registrant
- 11.1 Code of Ethics for Principal Executive Officer and Senior Financial Officers
- 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)
- 14.1 Consent of PricewaterhouseCoopers S.A.

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### 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.

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Serono S.A.  
(Registrant)

/s/ Ernesto Bertarelli

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

Date: March 25, 2004

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**FINANCIAL STATEMENTS AND AUDITORS REPORTS**

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Case postale 2895  
1211 Genève 2  
Telephone 22 748 51 11  
Fax 22 748 51 15



**Report of Independent Accountants**

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, 2003 and 2002 and for each of the three years in the period ended December 31, 2003.

These consolidated financial statements are the responsibility of the board of directors. 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 auditing standards generally accepted in the United States of America, 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 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, 2003 and 2002, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2003, 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 and as allowed by Item 18 to Form 20-F. The application of the latter would have affected the determination of consolidated net income for each of the three years in the period ended December 31, 2003 and the determination of consolidated shareholders' equity at December 31, 2003 and 2002 to the extent summarized in Note 34 to the consolidated financial statements.

PricewaterhouseCoopers SA

/s/ M. Aked     /s/ H-J. Hofer

M. Aked     H-J. Hofer  
Geneva, March 1, 2004

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## Consolidated income statements

Year ended December 31

	Notes	2003 US\$000	2002 US\$000	2001 US\$000
Revenues				
Product sales	3	1,858,009	1,423,130	1,249,405
Royalty and license income	3	160,608	114,705	127,065
<b>Total revenues</b>	3	<b>2,018,617</b>	<b>1,537,835</b>	<b>1,376,470</b>

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<b>Operating expenses</b>				
Cost of product sales		<b>279,619</b>	223,751	213,160
Selling, general and administrative		<b>636,823</b>	504,248	446,945
Research and development, net	4	<b>467,779</b>	358,099	308,561
Restructuring			16,303	
Other operating expense, net	5	<b>199,476</b>	85,811	70,152
<b>Total operating expenses</b>		<b>1,583,697</b>	1,188,212	1,038,818
<b>Operating income</b>		<b>434,920</b>	349,623	337,652
<b>Non-operating income, net</b>				
Financial income, net	6	<b>44,018</b>	36,476	51,381
Other expense, net	7	<b>19,743</b>	1,658	2,548
<b>Total non-operating income, net</b>		<b>24,275</b>	34,818	48,833
<b>Income before taxes and minority interests</b>		<b>459,195</b>	384,441	386,485
Taxes	9	<b>68,905</b>	63,127	69,816
<b>Income before minority interests</b>		<b>390,290</b>	321,314	316,669
Minority interests		<b>327</b>	536	(52)
<b>Net income</b>		<b>389,963</b>	320,778	316,721
		<b>US\$</b>	US\$	US\$
<b>Basic earnings per share</b>				
Bearer shares	10	<b>24.63</b>	20.07	19.72
Registered shares	10	<b>9.85</b>	8.03	7.89
American depositary shares	10	<b>0.62</b>	0.50	0.49
<b>Diluted earnings per share</b>				
Bearer shares	10	<b>24.59</b>	20.04	19.68
Registered shares	10	<b>9.84</b>	8.02	7.87
American depositary shares	10	<b>0.61</b>	0.50	0.49

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

# Consolidated balance sheets

As of December 31

	Notes	2003 US\$000	2002 US\$000
<b>ASSETS</b>			
<b>Current assets</b>			
Cash and cash equivalents	11	1,003,972	686,033
Short-term financial assets	16	434,810	378,865
Trade accounts receivable	12	318,388	257,313
Inventories	13	319,820	259,477
Prepaid expenses and other current assets	14	220,334	234,709
<b>Total current assets</b>		<b>2,297,324</b>	<b>1,816,397</b>
<b>Non-current assets</b>			
Property, plant and equipment	15	701,453	554,509
Long-term financial assets	16	1,104,333	711,201
Intangible assets	17	259,626	230,117
Deferred tax assets	18	169,693	126,291
Other long-term assets		39,174	45,763
<b>Total non-current assets</b>		<b>2,274,279</b>	<b>1,667,881</b>
<b>Total assets</b>		<b>4,571,603</b>	<b>3,484,278</b>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Trade and other payables	19	338,862	268,089
Short-term financial debts	20	51,224	93,598
Income taxes		146,086	173,656
Deferred income current		47,200	18,221
Other current liabilities	21	170,019	122,985
<b>Total current liabilities</b>		<b>753,391</b>	<b>676,549</b>
<b>Total non-current liabilities</b>			
Long-term financial debts	20	532,022	25,857
Deferred tax liabilities	18	15,919	12,080
Deferred income non-current		174,911	176,507
Provisions and other long-term liabilities	22	213,556	130,922
<b>Total non-current liabilities</b>		<b>936,408</b>	<b>345,366</b>
<b>Total liabilities</b>		<b>1,689,799</b>	<b>1,021,915</b>
<b>Minority interests</b>		<b>1,614</b>	<b>1,165</b>

<b>SHAREHOLDERS EQUITY</b>			
Share capital	24	<b>253,895</b>	253,416
Share premium		<b>1,002,991</b>	989,141
Treasury shares	24	<b>(157,642)</b>	(126,460)
Retained earnings	25	<b>1,669,700</b>	1,364,626
Fair value and other reserves		<b>22,711</b>	(44,807)
Cumulative foreign currency translation adjustments		<b>88,535</b>	25,282
<b>Total shareholders equity</b>		<b>2,880,190</b>	2,461,198
<b>Total liabilities, minority interests and shareholders equity</b>		<b>4,571,603</b>	3,484,278

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

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## Consolidated statements of changes in equity

Notes	Share capital US\$000	Share premium US\$000	Treasury shares US\$000	Retained earnings US\$000	Fair value and other reserves US\$000	Cumulative foreign currency translation adjustments US\$000	Total US\$000
Balance as of January 1, 2001 As previously reported	253,072	973,251	(4,750)	845,124		(60,281)	2,006,416
Effect of adopting IAS 39					(21,519)		(21,519)
<b>Balance as of January 1, 2001 as restated</b>	<b>253,072</b>	<b>973,251</b>	<b>(4,750)</b>	<b>845,124</b>	<b>(21,519)</b>	<b>(60,281)</b>	<b>1,984,897</b>
Issue of share capital	65	2,084	1,106				3,255
Net income for 2001				316,721			316,721
Purchase of treasury shares			(5,578)				(5,578)
Dividend for 2000 bearer shares				(39,017)			(39,017)
Dividend for 2000 registered shares				(14,742)			(14,742)
Revaluation adjustments					(3,616)		(3,616)
Foreign currency translation						(23,006)	(23,006)

adjustments

<b>Balance as of December 31, 2001</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>
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<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>
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Issue of share capital	26/27	279	13,806	184			14,269
Net income for 2002					320,778		320,778
Purchase of treasury shares	24			(117,422)			(117,422)
Dividend for 2001 bearer shares	25				(46,637)		(46,637)
Dividend for 2001 registered shares	25				(17,601)		(17,601)
Revaluation adjustments						(19,672)	(19,672)
Foreign currency translation adjustments							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>
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<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>
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Issue of share capital	26/27	479	15,129				15,608
Issuance of convertible debt	20					24,605	24,605
Issue of treasury shares	27		(1,404)	10,844			9,440
Written calls			125		820		945
Net income for 2003					389,963		389,963
Purchase of treasury shares	24			(42,026)			(42,026)
Dividend for 2002 bearer shares	25				(61,849)		(61,849)
Dividend for 2002 registered shares	25				(23,860)		(23,860)
Revaluation adjustments						25,903	25,903
Recognition of unrealized loss on available-for-sale investment	7					11,265	11,265
Sale of available-for-sale investment	7					5,745	5,745
Foreign currency translation adjustments							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>
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The accompanying notes form an integral part of these financial statements.

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## Consolidated statements of cash flows

Year ended December 31

	Notes	2003 US\$000	2002 US\$000	2001 US\$000
<b>Cash flows from operating activities</b>				
Income before taxes and minority interests		459,195	384,441	386,485
Depreciation and amortization	3	135,607	100,552	98,906
Financial income	6	(49,815)	(64,645)	(75,858)
Financial expense	6	12,963	10,643	14,709
Loss on available-for-sale investments	7	20,149		
Other non-cash items		17,846	17,233	25,595
<b>Cash flows from operating activities before working capital changes</b>		<b>595,945</b>	<b>448,224</b>	<b>449,837</b>
<b>Working capital changes</b>				
Trade and other payables, other current liabilities and deferred income		104,497	208,341	20,530
Trade accounts receivable		(34,245)	(3,968)	(22,231)
Inventories		(41,757)	(32,620)	(37,335)
Prepaid expenses and other current assets		8,066	(25,482)	34,879
Taxes paid		(89,647)	(62,513)	(40,730)
<b>Net cash flows from operating activities</b>		<b>542,859</b>	<b>531,982</b>	<b>404,950</b>
<b>Cash flows from investing activities</b>				
Acquisition of subsidiary, net of cash acquired	2	(9,651)	(115,092)	
Purchase of property, plant and equipment		(162,527)	(99,144)	(78,565)
Purchase of intangible and other long-term assets		(30,813)	(25,194)	(44,352)
Purchase of financial assets		(439,669)	(860,407)	(188,853)
Other non-current liabilities		(15,717)	(10,257)	1,653
Proceeds from sale of financial assets	7	8,058	344,362	871,343
			6,628	

Disposal of subsidiary, net of cash disposed				
Proceeds from sale of property, plant and equipment		11,081	10,488	11,033
Interest received		67,324	48,005	76,076
<b>Net cash flows from investing activities</b>		<b>(571,914)</b>	<b>(700,611)</b>	<b>648,335</b>
<b>Cash flows from financing activities</b>				
Proceeds from issuance of share capital		13,105	11,610	
Proceeds from exercises of stock options	26	7,536	1,454	1,825
Premiums received on written calls		945		
Purchase of treasury shares	24	(42,026)	(117,422)	(5,578)
Repayment on short-term financial debts		(27,096)	(94,490)	
Repayments on long-term financial debts		(23,086)	(17,642)	(73,062)
Issuance of long-term financial debts		53,948		
Issuance of convertible bond		444,820		
Interest paid		(4,361)	(8,121)	(13,810)
Dividends paid	25	(85,709)	(64,238)	(53,759)
<b>Net cash flows from financing activities</b>		<b>338,076</b>	<b>(288,849)</b>	<b>(144,384)</b>
Effect of exchange rate changes on cash and cash equivalents		8,918	12,420	(819)
<b>Net increase/(decrease) in cash and cash equivalents</b>		<b>317,939</b>	<b>(445,058)</b>	<b>908,082</b>
<b>Cash and cash equivalents</b>				
At beginning of year	11	686,033	1,131,091	223,009
At end of year	11	1,003,972	686,033	1,131,091

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

## Notes to the consolidated financial statements

### 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) as issued by the International Accounting Standards Board (IASB) and its predecessor organization, the International Accounting Standards Committee. The consolidated financial statements have been prepared under the historical cost convention as modified by available-for-sale and held-to-maturity investments and financial liabilities. 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 US dollars than in any other single currency, the consolidated financial statements are reported in that currency.

The preparation of the consolidated financial statements in conformity with generally accepted accounting principles 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 reserves for fiscal and legal claims, sales returns, and inventory obsolescence. Actual results could differ from those estimates.

There were no revised or new standards or interpretations that became effective from January 1, 2003 that had a significant effect on the group's consolidated financial statements.

### **1.1 Group accounting**

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 up, shares issued or liabilities undertaken 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 1.14). The proportion of the net assets and income attributable to minority shareholders are shown separately in the balance sheet and income statement, respectively. All 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 according to the equity method.

### **1.2 Foreign currencies**

Assets and liabilities of the holding company, its subsidiaries and equity investments are translated into US 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 foreign entity, 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. Local currency financial statements of foreign entities operating in highly inflationary economies are restated using appropriate indices to current values at the balance sheet date before translation into the company's reporting currency in accordance with IAS 29, Financial Reporting in Hyperinflationary Economies.

### **1.3 Revenue recognition**

Revenue from the sale of products is recognized upon transfer to the buyer of significant risks and rewards and is disclosed net of sales taxes and rebates and after eliminating sales within the group. Revenue from the rendering of services is recognized when the service is rendered or on a percentage of completion basis over the contract period. 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. Provisions for product returns are made based on historical trends and specific knowledge of any customer's intent to return products.

### **1.4 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 1.14). 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.

### **1.5 Government grants**



Government grants received are deferred and recognized in the income statement over the period necessary to match them with the costs they are intended to compensate, except for those amounts received for the purchase of property, plant and equipment, which are recorded as deferred income in the balance sheet, in other current liabilities and other long-term liabilities as appropriate, and amortized over the useful life of the asset. Government grants become non-refundable upon the achievement of designated milestones.

#### **1.6 Employee benefits**

The group operates Share Purchase Plans for employees and members of the Board of Directors. Contributions received from employees 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 the fair market value of the share on date of purchase and expensed as incurred.

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.

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.

#### **1.7 Stock options**

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

#### **1.8 Taxation**

Taxes reported in the income statement 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 property, plant and equipment, 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. Irrecoverable withholding taxes paid on dividends received are included in the income tax charge of the year.

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

Cash and cash equivalents consist of cash in hand and deposits with banks that have maturity of three months or less from the date of acquisition. Cash and cash equivalents are carried in the consolidated balance sheet at cost. Bank overdrafts are included in bank advances within short-term financial debts. Bank deposits that have maturities greater than three months but less than twelve months from the date of acquisition are included in short-term financial assets.

#### **1.10 Trade accounts receivable**

Trade accounts receivable are carried at invoiced amounts less adjustment for doubtful receivables. An estimate is made for doubtful receivables based on a review of all outstanding amounts at the year-end. Bad debts are written off, through selling expense, in the year they are identified. Trade accounts receivable factored out to financial institutions for a single non-returnable fixed sum with no recourse to the group are treated as being fully settled. The corresponding payment from the financial institution is recorded as a cash receipt from customers and no liability is recognized. Fees incurred to effect the factoring are recognized as a financial expense in the period in which the factoring takes place.

#### **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 materials, direct labor and an appropriate proportion of variable and fixed production overhead expenditure, the latter being allocated on the basis of normal operating capacity. Net realizable value is the estimated selling price in the ordinary course of business less the costs of completion and selling expenses.

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### 1.12 Property, plant and equipment

Property, plant and equipment are carried at cost, including interest and operating expenses directly related to projects that are capitalized during construction. Subsequent expenditure on an item of property, plant and equipment is capitalized at cost provided that increased economic benefits will be earned from the asset. Depreciation is recorded as a charge against income computed on a straight-line basis, at rates considered adequate to depreciate the cost of such assets over their useful lives. Land is not depreciated. Estimated useful lives are as follows:

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

Gains and losses on disposal or retirement of property, plant and equipment are determined by reference to their carrying amount and are taken into account in determining operating income. Repairs and maintenance costs are expensed as incurred.

### 1.13 Leases

Leases of assets under which the group assumes substantially all the benefits and risks 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 property, plant and equipment and depreciated over the shorter of the useful life of the asset and the lease term, according to the rates listed in note 1.12. The corresponding liabilities are included in the current and long-term portion of financial debt. The interest element of the finance cost is charged to the income statement over the lease period. Leases of assets under which the lessor effectively retains all the risks and benefits of ownership are classified as operating leases. Payments under operating leases are charged to income on a straight-line basis over the period of the lease.

### 1.14 Intangible assets

#### Goodwill

Goodwill represents the excess of the acquisition cost over the company's share of the fair value of the net assets acquired, at the date of acquisition. Goodwill on acquisitions occurring on or after January 1, 1995 is capitalized 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. Management determines the estimated useful life of goodwill 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 and fair value adjustments are treated as assets and liabilities of the group. Goodwill on acquisitions that occurred prior to January 1, 1995, was charged in full to retained earnings; such goodwill has not been retroactively capitalized and amortized.

#### Research and development

Research and development costs are generally expensed as incurred. In the opinion of management, due to the regulatory and other uncertainties inherent in the development of the group's new products, the criteria for development costs to be recognized as an asset, as prescribed by IAS 38, *Intangible Assets*, are not met until the product has received regulatory approval and when it is probable that future economic benefits will flow to the group. Capitalized development costs are amortized on a straight-line basis over the period of the expected benefit not exceeding five years. Property, plant and equipment used for research and development purposes are capitalized and depreciated in accordance with the group's depreciation policy (note 1.12).

#### Computer software

Generally, costs associated with developing computer software are expensed as incurred. However, costs that are clearly associated with an identifiable and unique asset, which will be controlled by the group and has a probable benefit exceeding the cost beyond one year, are capitalized and amortized on a straight-line basis over their useful lives, not exceeding a period of three years. Associated costs include staff costs of the development team and an appropriate portion of relevant overheads.

### **Technology rights and patents**

Expenditure on acquired patents, trademarks and licenses and technology rights are recognized when it is probable that future economic benefits will flow to the group and the cost can be measured reliably. Patents and technology rights are amortized by a charge against income computed on a straight-line basis over their useful lives.

#### **1.15 Impairment of long-lived assets**

Property, plant and equipment 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. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows.

#### **1.16 Financial assets**

Investments in debt and equity securities are classified into held-to-maturity and available-for-sale categories, as they are not acquired to generate profit from short-term fluctuations in price. Investments with fixed maturity that management has the intent and

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ability to hold to maturity are classified as held-to-maturity and are included in long-term financial assets, except for maturities within twelve months from the balance sheet date, which are classified as current assets. Investments intended to be held for an indefinite period of time are classified as available-for-sale and are also included within long-term financial assets.

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. Cost of purchase includes transaction costs. Available-for-sale investments are subsequently carried at fair value, whilst held-to-maturity investments are carried at amortized cost. Unrealized gains and losses arising from changes in the fair value of available-for-sale investments are recognized directly in equity until the financial asset is sold, collected or otherwise disposed of, or until the financial asset is determined to be impaired, at which time the cumulative gain or loss previously recognized in equity is included in net income for the period. Available-for-sale securities comprising marketable equity securities that are traded in active markets are carried at their fair value as of each balance sheet date. For these investments, fair value is determined by reference to stock exchange quoted bid prices.

#### **1.17 Financial instruments**

Financial instruments include cash and cash equivalents, long-term and short-term investments, trade accounts receivable, corporate debt securities, bank advances, trade accounts payable and long-term debt. The particular recognition methods adopted are disclosed in the individual policy statements associated with each item. Derivative financial instruments, including foreign exchange forward contracts, options and interest rate swaps, are initially recognized in the balance sheet at cost and are subsequently remeasured at their fair value.

The group uses foreign exchange forward contracts and currency options to hedge the risk of movements in foreign currency exchange rates which are not naturally hedged from our operations. Gains and losses on forward exchange contracts and currency options taken out to cover short-term receivable and payable exposures are offset against the corresponding gains and losses recognized in the balance sheet and income statement. Certain derivatives transactions, while providing effective economic hedges under the group's risk management policy, do not qualify for hedge accounting under the specific rules of IAS 39. Changes in the fair value of any derivative instruments that do not qualify for hedge accounting under IAS 39 are recognized immediately in the income statement as part of the financial result.

The group designated certain interest rate swaps as 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 hedges). 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. 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. 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.

The fair value of publicly traded derivatives and available-for-sale securities 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. 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.

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#### **1.20 Share capital**

The authorized and the conditional share capital have been translated into US 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 group's shareholders.

#### **1.21 Segment reporting**

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.

#### **1.22 Comparatives**

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

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## **2. Acquisitions and disposals**

### **Acquisitions and disposals 2003**

During 2003 the group acquired additional shares in Genset S.A. and, following the purchase of all remaining minority interests, increased its ownership of the share capital and voting rights in Genset S.A. from 92.47% to 100%. The acquisition was accounted for under the purchase method for aggregated considerations paid of \$9.7 million plus the assumption of \$2.3 million in financial debts. Goodwill arising on the acquisition of Genset S.A. was adjusted to \$83.2 million. There were no disposals during 2003.

### **Acquisitions and disposals 2002**

On September 12, 2002, the group acquired Genset S.A., a genomics-based biotechnology company, through a cash tender offer. The tender offer expired on October 31, 2002 resulting in an ownership of 91.8%. The group continued to buy shares on the market

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and, as of December 31, 2002, the group held 92.47% of the share capital and voting rights of Genset S.A. The acquisition was accounted for under the purchase method. Genset S.A. was acquired for \$140.1 million in cash and the assumption of \$4.1 million in financial debts. The related goodwill of \$111.5 million was capitalized as an intangible asset and amortized on a straight-line basis over 20 years.

On December 30, 2002, the group sold its generics business in Latin America through a disposal of its investments in Filaxis International S.A. and Laboratorios Filaxis S.A. for a total of \$7.3 million in cash. The disposal resulted in a recognized loss of \$2.4 million and was reported as restructuring expense.

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### 3. Segment information

Primary reporting format   geographic segment

Year ended December 31, 2003

Notes	Europe US\$000	North America US\$000	Latin America US\$000	Other US\$000	Total US\$000	
Product sales	813,826	694,257	98,841	251,085	<b>1,858,009</b>	
Royalty and license income	86,906	1,283		72,419	<b>160,608</b>	
<b>Total revenues</b>	<b>900,732</b>	<b>695,540</b>	<b>98,841</b>	<b>323,504</b>	<b>2,018,617</b>	
Allocable operating income	456,647	361,194	45,055	77,962	<b>940,858</b>	
Corporate research and development expenses					<b>(376,798)</b>	
Unallocated expenses					<b>(129,140)</b>	
<b>Operating income</b>					<b>434,920</b>	
Segment assets	1,691,985	153,287	51,988	274,958	<b>2,172,218</b>	
Unallocated assets					<b>2,399,385</b>	
<b>Total assets</b>					<b>4,571,603</b>	
Segment liabilities	785,112	102,206	12,366	203,091	<b>1,102,775</b>	
Unallocated liabilities					<b>587,024</b>	
<b>Total liabilities</b>					<b>1,689,799</b>	
<b>Other segment items</b>						
Additions to property, plant and equipment	15	170,610	7,957	317	6,161	<b>185,045</b>
Additions to intangible assets	17	(716)			55,698	<b>54,982</b>

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Depreciation	15	82,363	6,617	924	13,525	<b>103,429</b>
Amortization	5	23,866	794		7,518	<b>32,178</b>
Interest income	6	2,445	378	73	46,919	<b>49,815</b>
Interest expense	6	(7,048)	(154)	(3,303)	(2,458)	<b>(12,963)</b>

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Year ended December 31, 2002

	Notes	Europe US\$000	North America US\$000	Latin America US\$000	Other US\$000	Total US\$000
Product sales		620,366	479,553	109,281	213,930	1,423,130
Royalty and license income		54,093	868		59,744	114,705
<b>Total revenues</b>		<b>674,459</b>	<b>480,421</b>	<b>109,281</b>	<b>273,674</b>	<b>1,537,835</b>
Allocable operating income		263,404	345,398	62,769	119,561	791,132
Corporate research and development expenses						(324,874)
Unallocated expenses						(116,635)
<b>Operating income</b>						<b>349,623</b>
Segment assets		1,400,887	171,968	52,152	175,215	1,800,222
Unallocated assets						1,684,056
<b>Total assets</b>						<b>3,484,278</b>
Segment liabilities		657,602	91,705	22,114	129,447	900,868
Unallocated liabilities						121,047
<b>Total liabilities</b>						<b>1,021,915</b>
<b>Other segment items</b>						
Additions to property, plant and equipment	15	102,219	12,011	2,911	8,183	125,324
Additions to intangible assets	17	132,038	5,000		1,793	138,831
Depreciation	15	61,212	8,223	1,872	6,454	77,761
Amortization	5	20,526	409	202	1,654	22,791
Restructuring		12,420		3,883		16,303
Interest income	6	14,208	258	146	50,033	64,645
Interest expense	6	(6,033)	(163)	(3,341)	(1,106)	(10,643)

Year ended December 31, 2001

	Notes	Europe US\$000	North America US\$000	Latin America US\$000	Other US\$000	Total US\$000
Product sales		542,246	390,563	130,889	185,707	1,249,405
Royalty and license income		74,759			52,306	127,065
<b>Total revenues</b>		<b>617,005</b>	<b>390,563</b>	<b>130,889</b>	<b>238,013</b>	<b>1,376,470</b>
Allocable operating income		338,486	247,265	50,513	96,101	732,365
Corporate research and development expenses						(282,914)
Unallocated expenses						(111,799)
<b>Operating income</b>						<b>337,652</b>
Segment assets		958,579	165,401	94,296	120,124	1,338,400
Unallocated assets						1,680,369
<b>Total assets</b>						<b>3,018,769</b>
Segment liabilities		482,396	57,793	53,729	103,247	697,165
Unallocated liabilities						102,103
<b>Total liabilities</b>						<b>799,268</b>
<b>Other segment items</b>						
Additions to property, plant and equipment		62,916	24,819	1,590	7,806	97,131
Additions to intangible assets		1,784			1,291	3,075
Depreciation		52,433	3,439	5,656	5,781	67,309
Amortization		26,504	79	202	4,812	31,597
Interest income	6	12,597	981	163	62,117	75,858
Interest expense	6	(8,381)	(1,803)	(2,967)	(1,558)	(14,709)

Product sales are based on the country in which the customer is located, while royalty and license income is based on the country that receives the royalty. Segment assets and additions to property, plant and equipment and intangible assets are shown by the geographical area in which the assets are located. Segment assets consist primarily of current and long-term assets excluding short-term and long-term financial assets and short-term bank deposits. Segment liabilities comprise current and long-term

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liabilities and exclude items such as taxation and the convertible bond. Unallocated expenses represent corporate expenses.

The following countries contributed to more than 5% of total revenues, capital expenditures (additions to property, plant and equipment and intangible assets) or segment assets:

	Total revenues Year ended December 31			Capital expenditures Year ended December 31			Segment assets As of December 31	
	2003 US\$000	2002 US\$000	2001 US\$000	2003 US\$000	2002 US\$000	2001 US\$000	2003 US\$000	2002 US\$000
Switzerland	115,269	87,039	93,573	155,757	96,352	46,256	947,153	748,551
United States	630,477	426,188	343,032	7,921	16,715	24,177	153,200	163,973
Germany	228,579	161,095	129,878	1,213	1,403	673	49,329	34,180
Italy	160,526	117,999	101,895	32,066	10,420	12,087	237,602	209,878
France	118,228	97,951	80,697	6,941	122,915	564	90,898	178,217
Other	765,538	647,563	627,395	36,129	16,350	16,449	694,036	465,423
<b>Total</b>	<b>2,018,617</b>	<b>1,537,835</b>	<b>1,376,470</b>	<b>240,027</b>	<b>264,155</b>	<b>100,206</b>	<b>2,172,218</b>	<b>1,800,222</b>

No other individual country contributed more than 5% of total revenues, capital expenditures or segment assets. No single customer accounts for 10% or more of total revenues.

**Secondary reporting format business segment**

The group operates in one business segment, namely human therapeutics. The human therapeutics business comprises over 95% of the revenues and the shareholders' equity of the group. Therefore, results of operations, segment assets and liabilities, capital expenditures, depreciation and amortization are reported on a consolidated basis for purposes of segment reporting.

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Revenues including product sales by therapeutic areas consist of the following:

	Year ended December 31		
	2003 US\$000	2002 US\$000	2001 US\$000
Rebif ®	819,376	548,806	379,628
Novantrone ®	30,867	258	
<b>Total neurology</b>	<b>850,243</b>	<b>549,064</b>	<b>379,628</b>
Gonal-f ®	526,099	450,440	410,462
Cetrotide ®	24,840	18,362	10,607
Crinone ®	20,790	10,932	2,446
Ovidrel ®	12,330	5,676	2,670
Luvertis ®	9,614	6,570	938



<b>Core infertility portfolio</b>	<b>593,673</b>	491,980	427,123
Pergonal ®	45,804	46,001	38,106
Metrodin HP ®	24,760	50,146	67,120
Profasi ®	15,376	19,803	23,839
Other products	13,294	13,942	18,138
<b>Total reproductive health</b>	<b>692,907</b>	621,872	574,326
Saizen ®	151,459	124,048	107,262
Serostim ®	88,759	95,067	125,301
<b>Total growth and metabolism</b>	<b>240,218</b>	219,115	232,563
<b>Other product sales</b>	<b>74,641</b>	33,079	62,888
<b>Total product sales</b>	<b>1,858,009</b>	1,423,130	1,249,405
Royalty and license income	160,608	114,705	127,065
<b>Total revenues</b>	<b>2,018,617</b>	1,537,835	1,376,470

#### 4. Research and development, net

	Year ended December 31		
	2003 US\$000	2002 US\$000	2001 US\$000
Research and development expense, gross	467,875	358,267	308,720
Less government grants	(96)	(168)	(159)
<b>Total research and development, net</b>	<b>467,779</b>	358,099	308,561

#### 5. Other operating expense, net

	Year ended December 31		
	2003 US\$000	2002 US\$000	2001 US\$000
Royalty and license expense	120,112	34,750	22,868
Amortization of intangible and other long-term assets	30,425	22,791	31,597

Litigation and legal costs	25,690	13,314	7,595
Other	23,249	14,956	8,092
<b>Total other operating expense, net</b>	<b>199,476</b>	<b>85,811</b>	<b>70,152</b>

Amortization of intangible assets not included in other operating expense amounted to \$1.7 million in 2003 (none in 2002) and was mainly reported as selling, general and administrative expense.

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## 6. Financial income, net

	Year ended December 31		
	2003 US\$000	2002 US\$000	2001 US\$000
Interest income	49,815	64,645	75,858
Interest expense	(12,963)	(10,643)	(14,709)
Foreign currency gains/(losses)	7,166	(17,526)	(9,768)
<b>Total financial income, net</b>	<b>44,018</b>	<b>36,476</b>	<b>51,381</b>

## 7. Other expense, net

Other expense 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. During 2003, a \$16.1 million unrealized loss on an available-for-sale equity investment was considered to be other than temporary. The unrealized loss was calculated based on the quoted market price as of December 31, 2003. In addition, an available-for-sale equity security with an original cost of \$12.1 million was sold in 2003 for proceeds of \$8.1 million, resulting in a realized loss on disposal of \$4.0 million.

## 8. Personnel costs

	Year ended December 31		
	2003 US\$000	2002 US\$000	2001 US\$000
Salaries and wages	340,807	297,745	244,256
Social benefits and other	163,911	133,082	112,944
<b>Total personnel costs</b>	<b>504,718</b>	<b>430,827</b>	<b>357,200</b>

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As of December 31, 2003, there were 4,577 employees (2002: 4,616 employees and 2001: 4,501 employees) within the group.

## 9. Taxes

Income before taxes and minority interests, reduced by capital and other taxes, consists of the following:

	Year ended December 31		
	2003 US\$000	2002 US\$000	2001 US\$000
Switzerland	326,405	204,377	201,122
Foreign	116,959	170,543	178,610
<b>Total income before taxes and minority interests, reduced by capital and other taxes</b>	<b>443,364</b>	<b>374,920</b>	<b>379,732</b>

Total tax expense consists of the following:

	Year ended December 31		
	2003 US\$000	2002 US\$000	2001 US\$000
Switzerland	40,050	19,001	33,772
Foreign	10,513	56,554	43,858
<b>Total current income taxes</b>	<b>50,563</b>	<b>75,555</b>	<b>77,630</b>
Switzerland	7,403	(4,337)	2,851
Foreign	(4,892)	(17,613)	(17,418)
<b>Total deferred income taxes</b>	<b>2,511</b>	<b>(21,950)</b>	<b>(14,567)</b>
<b>Total income taxes</b>	<b>53,074</b>	<b>53,605</b>	<b>63,063</b>
Capital and other taxes	15,831	9,522	6,753
<b>Total tax expense</b>	<b>68,905</b>	<b>63,127</b>	<b>69,816</b>

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The change in the proportion of tax expense 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:

	Year ended December 31		
	2003	2002	2001
	%	%	%
Corporate tax rate	30.0	30.0	30.0
Effect of tax rates different from 30%	(15.9)	(13.3)	(12.9)
Effect of utilizing prior periods tax losses not previously recognized		(0.1)	(1.0)
Effect of current year s losses not yet recognized	1.4	0.4	1.7
Effect of adjustments recognized in the period for current tax of prior periods	(6.2)	(3.6)	(1.7)
Other, net	2.7	0.9	0.5
<b>Effective tax rate</b>	<b>12.0</b>	<b>14.3</b>	<b>16.6</b>

The decrease in the effective tax rate in 2003 is mainly due to the favorable close of prior fiscal years in various countries, which permitted a non-recurring reduction in certain tax provisions during 2003.

The tax loss carried forward for income tax purposes by expiring date is as follows:

	US\$000
2004	4,281
2005	5,894
2006	11,549
2007	10,435
2008	28,318
Thereafter	106,519
<b>Total</b>	<b>166,996</b>

As of December 31, 2003, tax losses available for carry-forward which have not been recognized due to uncertainty of their recoverability amount to \$61.6 million (2002: \$248.6 million).

### 10. Earnings per share

Basic earnings per share is calculated in accordance with IAS 33, Earnings Per Share, by dividing the net income of the group by the weighted average number of shares in issue during the year.

	Year ended December 31		
	2003	2002	2001
	US\$000	US\$000	US\$000

Net income attributable to bearer shareholders	281,459	232,381	229,863
Net income attributable to registered shareholders	108,504	88,397	86,858
<b>Total net income</b>	<b>389,963</b>	<b>320,778</b>	<b>316,721</b>
Weighted average number of bearer shares in issue	11,427,194	11,580,611	11,658,108
Weighted average number of registered shares in issue	11,013,040	11,013,040	11,013,040

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	Year ended December 31		
	2003 US\$	2002 US\$	2001 US\$
<b>Basic earnings per share</b>			
Bearer shares	24.63	20.07	19.72
Registered shares	9.85	8.03	7.89
American depositary shares	0.62	0.50	0.49

For diluted earnings per share, the weighted average number of bearer shares is adjusted to assume conversion of all potential dilutive shares arising from outstanding stock options and the convertible bond. For stock options a calculation is done to determine the number of shares that could have been acquired at fair value with proceeds from the exercise of stock options and compared with the number of shares that would have been issued assuming the exercise of the stock options. The difference is added to the denominator as an issue of shares for no consideration. No adjustment is made to the numerator. In 2003, share equivalents of 25,696 bearer shares arising from stock options granted to employees and directors were included in calculating diluted earnings per share (2002: 17,544 and 2001: 29,501). For the convertible bond, a calculation is done to assume conversion into bearer shares and the net income is adjusted to eliminate the interest expense less the tax effect. In 2003, the effect of the convertible bond was excluded from the calculation of diluted earnings per share, as it was anti-dilutive. Diluted earnings per share for bearer, registered and American depositary shares were:

	Year ended December 31		
	2003 US\$	2002 US\$	2001 US\$
<b>Diluted earnings per share</b>			
Bearer shares	24.59	20.04	19.68
Registered shares	9.84	8.02	7.87
American depositary shares	0.61	0.50	0.49

**11. Cash and cash equivalents**

	As of December 31	
	2003 US\$000	2002 US\$000
Cash in hand and at bank	143,731	92,043
Short-term bank deposits	860,241	593,990
<b>Total cash and cash equivalents</b>	<b>1,003,972</b>	<b>686,033</b>

Short-term bank deposits are mainly denominated in US dollars with 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 effective interest rate on short-term bank deposits was 1.05% (2002: 1.47%) and these deposits have an average maturity of fourteen days (2002: eight days) as of December 31, 2003.

**12. Trade accounts receivable**

	As of December 31	
	2003 US\$000	2002 US\$000
Trade accounts receivable, gross	324,898	268,507
Provision for doubtful accounts	(6,510)	(11,194)
<b>Total trade accounts receivable</b>	<b>318,388</b>	<b>257,313</b>

The group sells its products worldwide through major wholesale distributors and direct to clinics and hospitals. No individual customer accounts for more than 10% of trade accounts receivable at the year-end or of product sales during the year.

**13. Inventories**

	As of December 31	
	2003 US\$000	2002 US\$000

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Raw materials	56,687	38,259
Work-in-progress	191,461	152,594
Finished goods	71,672	68,624
<b>Total inventories</b>	<b>319,820</b>	<b>259,477</b>

Included in inventories as of December 31, 2003 are \$20.8 million in inventory provisions (2002: \$14.5 million).

#### 14. Prepaid expenses and other current assets

	As of December 31	
	2003 US\$000	2002 US\$000
Prepaid expenses	24,757	26,609
VAT receivable	71,598	93,392
Accrued royalty revenue	49,176	27,528
Accrued interest income	41,175	36,292
Other receivables	15,351	30,266
Advances	4,701	8,161
Other	13,576	12,461
<b>Total prepaid expenses and other current assets</b>	<b>220,334</b>	<b>234,709</b>

#### 15. Property, plant and equipment

	Land and buildings US\$000	Machinery and equipment US\$000	Furniture and fixtures US\$000	Leasehold improvements US\$000	Construction in progress US\$000	<b>Total 2003 US\$000</b>	Total 2002 US\$000
<b>Cost</b>							
As of January 1	372,171	520,717	32,668	73,071	56,592	1,055,219	879,492
Additions (note 3)	35,226	39,084	1,961	4,753	104,021	185,045	125,324
Disposals	(12,209)	(42,667)	(2,189)	(5,330)	(124)	(62,519)	(90,347)
Impairment							(533)
Currency adjustments	52,510	68,075	4,180	8,470	17,007	150,242	141,283
<b>As of December 31</b>	<b>447,698</b>	<b>585,209</b>	<b>36,620</b>	<b>80,964</b>	<b>177,496</b>	<b>1,327,987</b>	<b>1,055,219</b>
<b>Accumulated depreciation</b>							
As of January 1	115,793	310,226	18,934	55,757		500,710	418,725

Disposals	(6,574)	(38,735)	(1,951)	(3,580)		<b>(50,840)</b>	(61,572)
Depreciation (note 3)	19,613	70,171	3,535	10,110		<b>103,429</b>	77,761
Currency adjustments	16,900	48,561	3,020	4,754		<b>73,235</b>	65,796
<b>As of December 31</b>	<b>145,732</b>	<b>390,223</b>	<b>23,538</b>	<b>67,041</b>		<b>626,534</b>	500,710
<b>Net book value as of December 31</b>	<b>301,966</b>	<b>194,986</b>	<b>13,082</b>	<b>13,923</b>	<b>177,496</b>	<b>701,453</b>	554,509
Net book value under finance lease contracts						<b>814</b>	1,113

As of December 31, 2003, the group plans to dispose of property, plant and equipment with an original cost of \$23.4 million (2002: \$20.0 million) and accumulated depreciation of \$20.5 million (2002: \$11.4 million). Assets with an original cost of \$65.1 million as of December 31, 2003 (2002: \$67.5 million), have been pledged as security against long-term financial debt and certain unused long-term lines of credit. The group has other capital commitments totaling \$21.0 million (2002: \$51.8 million). Borrowing costs of \$0.5 million, arising on financing specifically entered into for the construction of the new headquarters and research centre in Geneva, were capitalized during 2003 and included in additions to construction in progress. A capitalization rate of 0.76% was used, representing the borrowing cost of the loan used to finance the project. No interest has been capitalized during 2002.

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## 16. Investments

	Cost 2003 US\$000	Gross unrealized gains 2003 US\$000	Gross unrealized losses 2003 US\$000	Carrying and estimated fair values 2003 US\$000	Carrying and estimated fair values 2002 US\$000
Held-to-maturity securities	368,488			<b>368,488</b>	403,860
Available-for-sale securities					
Equity securities	58,886	7,347	(13,576)	<b>52,657</b>	40,745
Debt securities	1,112,701	6,878	(1,581)	<b>1,117,998</b>	645,461
<b>Net book value as of December 31</b>	<b>1,540,075</b>	<b>14,225</b>	<b>(15,157)</b>	<b>1,539,143</b>	1,090,066

Classification in the consolidated balance sheets

<b>Short-term financial assets</b>	<b>434,810</b>	378,865
<b>Long-term financial assets</b>	<b>1,104,333</b>	711,201



The group's financial assets primarily include deposits with prime banks, investments in short-term money market funds, and rated Eurobonds denominated in US dollar with maturities up to four years. Financial assets are actively managed by the Serono group treasury in accordance with a written policy approved by the Board of Directors and subject to internal controls. Equity security investments are typically related to collaboration agreements with other biotechnology and research companies. Equity security investments are not purchased as part of the normal day-to-day management of financial assets, with the exception of treasury shares that are acquired under the approved Share Buy Back Plan.

Held-to-maturity securities include corporate debt securities with fixed interest rates ranging from 3.40% to 4.81% (2002: 3.14% to 4.72%), which mature between one month and two years (2002: four months and three years). Included in available-for-sale securities are securities transferred to banks in connection with security lending transactions for a total amount \$34.1 million in 2003 and \$50.8 million in 2002, respectively.

The fair value and other reserves as of December 31, 2003 of \$22.7 million include fair value adjustments of \$0.5 million related to cash flow hedges (none in 2002).

## 17. Intangible assets

	Technology rights and patents US\$000	Goodwill US\$000	Software development US\$000	Other Intangible US\$000	Total 2003 US\$000	Total 2002 US\$000
<b>Cost</b>						
As of January 1	219,082	132,793	26,489	3,855	<b>382,219</b>	238,500
Transfers	(1,377)			3,834	<b>2,457</b>	
Additions	63,252	(28,292)	19,726	296	<b>54,982</b>	138,831
Disposals			(137)		<b>(137)</b>	(4,046)
Currency adjustments	6,438		5,059	955	<b>12,452</b>	8,934
<b>As of December 31</b>	<b>287,395</b>	<b>104,501</b>	<b>51,137</b>	<b>8,940</b>	<b>451,973</b>	382,219
<b>Accumulated amortization</b>						
As of January 1	126,729	8,775	12,743	3,855	<b>152,102</b>	124,653
Transfers	(620)			3,077	<b>2,457</b>	
Amortization	21,487	6,358	2,981	636	<b>31,462</b>	22,757
Disposals			(137)		<b>(137)</b>	(1,814)
Currency adjustments	3,595	151	1,816	901	<b>6,463</b>	6,506
<b>As of December 31</b>	<b>151,191</b>	<b>15,284</b>	<b>17,403</b>	<b>8,469</b>	<b>192,347</b>	152,102
<b>Net book value as of December 31</b>	<b>136,204</b>	<b>89,217</b>	<b>33,734</b>	<b>471</b>	<b>259,626</b>	230,117

The 2003 movement in goodwill was the result of the acquisition of the remaining 7.53% interest in Genset S.A. that was completed in June 2003. Goodwill initially increased by \$12.0 million and was equal to the additional purchase consideration paid by the group

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for the remaining shares of Genset S.A. of \$9.7 million plus the assumption of \$2.3 million in financial debts. However, goodwill subsequently decreased by \$40.3 million upon the recognition of a deferred tax asset that was related to the utilization of Genset's non-operating loss carry forwards that was possible upon the 100% acquisition of Genset S.A.

## 18. Deferred taxes

	Deferred tax assets 2003 US\$000	Deferred tax liabilities 2003 US\$000	Deferred tax assets 2002 US\$000	Deferred tax liabilities 2002 US\$000
Tax losses carried forward	29,626		3,526	
Various research and development tax credits carried forward	19,827		20,361	
Depreciation and amortization	29,384	8,232	15,036	3,841
Inventories	61,186	13,915	53,984	12,643
Other	29,670	(6,228)	33,384	(4,404)
<b>Total deferred taxes</b>	<b>169,693</b>	<b>15,919</b>	<b>126,291</b>	<b>12,080</b>

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.

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 as such undistributed earnings are deemed to be permanently reinvested. As of December 31, 2003, unremitted earnings of subsidiaries considered permanently invested, for which deferred income taxes estimated at \$2.9 million (2002: \$0.1 million) have not been provided, were approximately \$7.7 million (2002: \$0.4 million). No deferred taxes have been charged or credited to shareholders' equity in 2003 or 2002.

## 19. Trade and other payables

	As of December 31	
	2003 US\$000	2002 US\$000
Trade accounts payable	72,207	60,591
Payroll related	103,439	85,196
Accrued expenses	163,216	122,302
<b>Total trade and other payables</b>	<b>338,862</b>	<b>268,089</b>

Accrued expenses mainly include accrued rebates and promotions expenses of \$59.0 million (2002: \$49.1 million), accrued research and development expenses of \$16.6 million (2002: \$21.2 million) and accrued construction expenses of \$33.2 million (2002: \$12.9 million).

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**20. Financial debts**

	As of December 31			
	2003 US\$000	2002 US\$000	2003 Weighted average Interest rate	2002 Weighted average Interest rate
Mortgage notes	22,446	30,997	3.84	3.72
Unsecured bank loans	66,407	17,361	0.86	1.64
Convertible bond	454,764		3.03	
Capital lease obligation	620	1,004		
<b>Total debts, long-term and current portion</b>	<b>544,237</b>	<b>49,362</b>		
Less current portion of long-term debts	(12,215)	(23,505)		
<b>Total long-term financial debts</b>	<b>532,022</b>	<b>25,857</b>		
Bank advances	39,009	70,093	3.03	5.52
Current portion of long-term debts	12,215	23,505		
<b>Total short-term financial debts</b>	<b>51,224</b>	<b>93,598</b>		

A CHF300.0 million medium-term bank facility has been made available to the group for the development of the new headquarters and research centre in Geneva. This unsecured bank loan that is guaranteed by Serono S.A. has a maturity date of December 31, 2006, and can be converted into a term loan at the discretion of the group. As of December 31, 2003, the amount drawn under the facility as unsecured bank loan was CHF72.6 million or \$58.9 million. In November 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 CHF 1,497 based on its redemption value of CHF 634.8 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. The convertible bond is recognized in the consolidated balance sheet as of December 31, 2003 as follows:

	2003 US\$000
Face value of convertible bond issued	465,261
Transactions costs	(6,611)
<b>Equity conversion component</b>	<b>(24,605)</b>

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Liability component on initial recognition	434,045
Interest expense	1,094
Cumulative translation adjustment	19,625
<hr/>	
<b>Liability component as of December 31</b>	<b>454,764</b>

Transaction fees of \$6.6 million have been deducted from the carrying value of the liability and equity components upon initial recognition. The transaction fees that were allocated against the liability component will be amortized over the life of the convertible bond with the amortization charge recognized as interest expense. 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, 2003 based on quoted market prices was \$486.2 million and approximated the carrying amount of the liability and equity component plus the transaction fees.

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The maturities of financial debts are as follows:

	US\$000
<hr/>	
2004	12,215
2005	2,763
2006	61,605
2007	1,832
2008	456,599
Thereafter	9,223
<hr/>	
<b>Total debts, long-term and current portion</b>	<b>544,237</b>

Long-term financial debts include secured liabilities totaling \$5.7 million (2002: \$20.8 million) for certain land and buildings of the group (note 15). Unused lines of credit for short-term financing are \$366.9 million (2002: \$112.7 million). As part of the short-term financing, the group has \$225.0 million (2002: \$219.5 million) available under revolving multicurrency operating facilities not including the financing for our new headquarters and research facility in Geneva, of which \$188.3 million (2002: \$157.8 million) was unused as of December 31, 2003. During 2003, the group commitment fees for bank advances were in the range of 0.06% to 0.13% (2002: 0.06% to 0.13%) on the total credit facilities available. Financial debts include only general default covenants. The group is in compliance with these covenants.

Fair values of the financial debts, excluding the convertible bond, as of December 31, 2003 and 2002, respectively are as follows:

	<b>As of December 31, 2003</b>	
	<b>Carrying values US\$000</b>	<b>Fair values US\$000</b>
<hr/>		
Long-term financial debts	77,258	76,784
Short-term financial debts	51,224	51,224
<hr/>		
<b>Total</b>	<b>128,482</b>	<b>128,008</b>

	As of December 31, 2002	
	Carrying values US\$000	Fair values US\$000
Long-term financial debts	25,857	26,347
Short-term financial debts	93,598	93,598
<b>Total</b>	<b>119,455</b>	<b>119,945</b>

Future minimum lease payments under capital leases are as follows:

	US\$000
2004	502
2005	124
2006	25
2007	13
2008	7
Thereafter	
<b>Total minimum lease payments</b>	<b>671</b>
Less amount representing interest	(51)
<b>Present value of net minimum lease payments</b>	<b>620</b>

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## 21. Other current liabilities

	As of December 31	
	2003 US\$000	2002 US\$000
Royalty payables	42,332	19,374
Marketing rights	32,902	8,661
Short-term provisions	31,691	40,927
Employee Share Purchase Plan	19,115	14,650
Taxes other than income	16,301	16,202

Other	27,678	23,171
<b>Total other current liabilities</b>	<b>170,019</b>	<b>122,985</b>

Balances as of December 31, 2003 and 2002 and movements in 2003 of the short-term provisions were as follows:

#### Short-term legal provisions

Short-term legal provisions decreased from \$20.1 million as of December 31, 2002 to \$19.2 million as of December 31, 2003 due to cash payments of \$0.9 million. There were no short-term legal provisions released to income or added in 2003.

#### Restructuring provisions

Restructuring provisions of \$6.2 million as of December 31, 2002 were made for charges of \$16.3 million related to the withdrawal from the urinary sector of the reproductive health business in Italy and the sale of two companies in Latin America. The charge comprised employee related costs of \$6.1 million, asset related costs of \$8.9 million and other costs of \$1.3 million. The restructuring impacted 56 employees; all left the group during 2003. All significant actions associated with the restructuring plan were completed during 2003. The restructuring provision as of December 31, 2002 has been fully utilized for payments in 2003.

#### Other short-term provisions

Other short-term provisions, mainly for severance and non-income taxes, were \$14.6 million as of December 31, 2002 and \$12.5 million as of December 31, 2003. The group increased the other short-term provisions by \$22.8 million in 2003 and made cash payments of \$26.8 million. The currency impact on other short-term provisions was \$1.9 million.

## 22. Provisions and other long-term liabilities

	As of December 31	
	2003 US\$000	2002 US\$000
Long-term legal provisions	63,022	37,238
Pension liabilities	55,263	50,047
Marketing rights	72,447	23,378
Staff leaving indemnities	15,249	13,436
Other	7,575	6,823
<b>Total provisions and other long-term liabilities</b>	<b>213,556</b>	<b>130,922</b>

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.

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. In the opinion of management, however, the outcome of the actions, if any, would not be material to the group's financial condition but could be material to the group's result of operations in a given period. Additional legal provisions of \$5.7 million (2002: \$14.2 million) were recorded during 2003 for legal claims. There were no legal provisions released to income during 2003 and 2002.

Interpharm Laboratories and other group affiliates 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 has started in 2002 and is expected to continue through 2004. In 2003

IBEP had 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 the group. Yeda joined as a

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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.

In 1996, one of Serono's 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 Serono's subsidiary of its obligations, and initiated proceedings in 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. Serono expects the proceedings to last at least through 2004.

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 Serono's 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.

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 other practices. These investigations seek to determine whether such practices violated any laws, including the Federal False Claims Act or constituted fraud in connection with Medicare and/or Medicaid reimbursement to third parties. Serono's subsidiary is providing documents in response to the subpoena and is cooperating with the investigation.

### 23. Retirement pension plans

Substantially all employees of the group are covered by defined benefit, insured or state pension plans. Pension costs in 2003 amounted to \$19.1 million (2002: \$17.3 million and 2001: \$12.8 million). Included in pension cost is the amount of \$6.3 million (2002: \$2.9 million and 2001: \$2.3 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 costs of the defined benefit retirement plans are based upon actuarial valuations of the plans made during 2003. The unrecognized actuarial gain recorded in 2003 reflects a change in the assumptions used by the independent actuary.

The amounts recognized in the consolidated balance sheets and consolidated income statements are as follows:

	As of December 31	
	2003 US\$000	2002 US\$000
Present value of funded obligations	168,544	185,519
Fair value of plan assets	145,687	108,288

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Funded status	<b>22,857</b>	77,231
Unrecognized actuarial gain/(loss)	<b>32,406</b>	(27,184)
<b>Total pension liabilities</b>	<b>55,263</b>	50,047

	Year ended December 31		
	<b>2003</b> US\$000	2002 US\$000	2001 US\$000
Current service cost	<b>14,960</b>	13,995	10,902
Interest cost	<b>6,014</b>	6,206	4,810
Expected return on plan assets	<b>(6,762)</b>	(5,960)	(5,226)
Amortization of unrecognized actuarial (gain)/loss	<b>(1,342)</b>	113	
<b>Total pension costs</b>	<b>12,870</b>	14,354	10,486

The actual return on plan assets was \$12.9 million in 2003 (2002: loss of \$10.1 million and 2001: loss of \$11.6 million).

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The movements in the consolidated balance sheets are as follows:

	As of December 31	
	<b>2003</b> US\$000	2002 US\$000
As of January 1	<b>50,047</b>	40,951
Exchange differences	<b>5,909</b>	6,306
Pension costs	<b>12,870</b>	14,354
Contributions paid	<b>(13,563)</b>	(11,564)
<b>As of December 31</b>	<b>55,263</b>	50,047

Principal weighted average actuarial assumptions used for accounting purposes are:

	Year ended December 31	
	<b>2003</b> %	2002 %
Discount rate	<b>4.24</b>	4.23



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Expected return on plan assets	5.65	6.11
Future salary increases	2.67	3.12
Future pension increases		0.90

## 24. Share capital

As of December 31, 2003

Class of shares	Number of shares	Nominal value	CHF000	US\$000
<b>Issued and fully paid share capital</b>				
Registered	11,013,040	CHF10	110,130	68,785
Bearer	11,711,826	CHF25	292,796	185,110
<b>Total</b>			<b>402,926</b>	<b>253,895</b>
Authorized share capital	1,400,000	CHF25	35,000	28,377
Conditional share capital for convertible bonds	152,000	CHF25	3,800	3,081
Conditional share capital for stock options	352,996	CHF25	8,825	7,155

As of December 31, 2002

Class of shares	Number of shares	Nominal value	CHF000	US\$000
<b>Issued and fully paid share capital</b>				
Registered	11,013,040	CHF10	110,130	68,785
Bearer	11,685,856	CHF25	292,147	184,631
<b>Total</b>			<b>402,277</b>	<b>253,416</b>
Authorized share capital	1,400,000	CHF25	35,000	25,232
Conditional share capital for convertible bonds	152,000	CHF25	3,800	2,740
Conditional share capital for stock options	378,966	CHF25	9,474	6,830

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.

There were 239,412 treasury shares held by a group company as of January 1, 2003. 80,157 additional treasury shares were acquired during 2003 (2002: 227,907 treasury shares) for total consideration of CHF55.0 million or \$42.0 million (2002: CHF174.7 million or \$117.4 million). 4,630 treasury shares were issued to employees during 2003 (200 shares in 2002) 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. 10,000 treasury

shares were issued upon the exercise of 10,000 call options that were written during the year. Premiums received on written calls that expire unexercised are credited to retained earnings. The total number of treasury shares held as of December 31, 2003 is 304,939.

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Treasury shares were acquired through the Share Buy Back Plan that was initiated in July 2002, which authorized the purchase of up to CHF500.0 million in bearer shares. The total amount spent as of December 31, 2003 is CHF218.7 million and the average price paid for the treasury shares is CHF737 per share.

## 25. Distribution of earnings

At the Annual General Meeting of shareholders on May 25, 2004, the Board of Directors will propose a cash dividend in respect of 2003 of CHF3.20 gross (2002: CHF 2.80) per registered share, CHF8.00 gross (2002: CHF7.00) per bearer share or CHF0.20 per American depositary share, amounting to a total of CHF126.5 million (2002: CHF111.0 million). 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, 2004. In accordance with Swiss law, \$50.8 million (2002: \$50.7 million) out of the share premium balance is non-distributable as of December 31, 2003. Distribution of retained earnings on a consolidated basis is subject to local restrictions applicable for all companies within the group. As of December 31, 2003, non-distributable retained earnings were \$539.0 million (2002: \$506.6 million).

## 26. 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 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 determined based on the fair market value on the date of grant. Movements in the number of stock options outstanding are as follows:

	2003			2002		
	Available for grant	Options outstanding	Weighted average exercise price CHF	Available for grant	Options outstanding	Weighted average exercise price CHF
As of January 1	261,010	209,455	1,272	339,583	135,041	1,204
Cancelled	22,062	(22,062)	1,301	11,967	(11,967)	1,355
Granted	(93,130)	93,130	655	(90,540)	90,540	1,350
Exercised		(2,741)	546		(4,159)	546
<b>As of December 31</b>	<b>189,942</b>	<b>277,782</b>	<b>1,070</b>	<b>261,010</b>	<b>209,455</b>	<b>1,272</b>
Exercisable as of December 31		92,095	1,182		50,001	1,065
Weighted average fair value of options granted during the			192			534

year (CHF)

During 2003, 93,130 options (2002: 90,540 options) were granted to a total of 567 employees (2002: 537 employees), at a predetermined weighted average exercise price of CHF655 (2002: CHF1,350). There were 2,741 options (2002: 4,159 options) exercised during the year yielding proceeds of CHF1.5 million or \$1.2 million (2002: CHF2.3 million or \$1.5 million). 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.

A compensation charge of \$1.4 million (2002: \$1.0 million and 2001: \$0.5 million) 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. In February 2004, the IASB published IFRS 2, Share Based Payment, which requires fair-value recognition of equity-based compensation in the group's consolidated financial statements (note 35). Management estimates that the adoption of this statement will result in additional compensation expense that is similar to the amount of compensation expense disclosed under the current US GAAP treatment in note 34.

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The table below summarizes options outstanding and exercisable as of December 31, 2003:

Weighted average exercise price	Options outstanding	Remaining contractual life (years)	Options exercisable
CHF 546	8,615	4.25	8,615
CHF 546	13,678	5.25	13,678
CHF 1,521	21,965	6.25	16,665
CHF 1,346	62,094	7.25	31,920
CHF 1,350	81,360	8.09	20,857
CHF 655	90,070	9.26	360
<b>Total</b>	<b>227,782</b>		<b>92,095</b>

## 27. 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 2003, 20,301 bearer shares (2002: 23,229 bearer shares) were granted to employees at a price of CHF654 per share (2002: CHF654 per share). As of December 31, 2003, a total of \$10.5 million (2002: \$10.9 million) in contributions were held by the group to be used to issue bearer and American depository shares on behalf of employees in January 2004. The accrued compensation cost from the discount to be offered to employees based on the contributions held as of December 31, 2003 was \$4.0 million (2002: \$1.6 million and 2001: \$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 2003, for the first time, 4,208 bearer shares were given to employees. The accrued compensation cost related to the matching shares that will be given in January 2004, based on shares purchased by employees from the 2002 ESPP, is \$4.8 million (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 company's Annual General Meeting (the AGM) and concludes on the day of the next AGM. The purchase price per share is eighty-five percent of the fair market value of the share on the fifth business day following the AGM. The accrued compensation cost from the discount to be offered to members of the board recognized in 2003 was \$0.1 million.

**28. Commitments and contingencies****Operating leasing commitments**

Payments made during 2003 on operating leases amounted to \$23.6 million (2002: \$24.5 million). Future minimum payments under non-cancelable operating leases, which totaled \$130.8 million (2002: \$130.3 million), are as follows:

	US\$000
2004	24,736
2005	22,717
2006	18,842
2007	8,864
2008	7,369
Thereafter	48,236
<b>Total</b>	<b>130,764</b>

**Collaborative agreements commitments**

The group entered into a number of commitments under collaborative agreements as described in note 31 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

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unlikely event that all the collaborators were to achieve all the contractual milestones, the group would be required to pay approximately \$438.3 million. The estimated timing of the eventual payments is presented as follows:

	US\$000
2004	144,996
2005	95,210
2006	41,236
2007	8,750
2008	50,290
Thereafter	97,859
<b>Total</b>	<b>438,341</b>

The group does not consider any single collaborative agreement to be sufficiently large a commitment that it could impair significantly its financial condition.

### **Contingencies**

As part of the normal activities of the business, the group is subject to 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.

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## **29. 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 group treasury 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.

### **Foreign currency exchange rates**

The group uses the US dollar as functional currency. 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 US dollar to achieve relatively stable and predictable cash flows. Net investments in Serono affiliates with a functional currency other than the US 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 US 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.

### **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 Plan.

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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 nominal values and fair values of derivative financial instruments, if all the instruments were closed out at the year-end, are as follows as of December 31, 2003 and 2002:

	As of December 31, 2003			
	Nominal values	Positive fair values	Negative fair values	Net fair values
	US\$000	US\$000	US\$000	US\$000
<b>Foreign currency derivatives</b>				
Currency options	1,127,906	7,854	(1,869)	<b>5,985</b>
Forward foreign exchange contracts	511,300	2,267	(6,181)	<b>(3,914)</b>
<b>Interest rate derivatives</b>				
Interest rate swaps	22,041		(321)	<b>(321)</b>
Interest rate swaps fair value hedges	51,000		(2,346)	<b>(2,346)</b>
Interest rate swaps cash flow hedges	65,000	84	(551)	<b>(467)</b>
<b>Total</b>		<b>10,205</b>	<b>(11,268)</b>	<b>(1,063)</b>

	As of December 31, 2002			
	Nominal values	Positive fair values	Negative fair values	Net fair values
	US\$000	US\$000	US\$000	US\$000
<b>Foreign currency derivatives</b>				
Currency options	564,375	5,235	(1,316)	3,919
Forward foreign exchange contracts	623,656	3,353	(9,095)	(5,742)
<b>Interest rate derivatives</b>				
Interest rate swaps	29,704		(885)	(885)
Interest rate swaps fair value hedges	51,000		(525)	(525)
<b>Other derivatives</b>				
Options	1,298		(4)	(4)
<b>Total</b>		<b>8,588</b>	<b>(11,825)</b>	<b>(3,237)</b>

The nominal values represent the total gross amounts outstanding. The 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 group's consolidated balance sheets (included in other current assets and liabilities). Foreign currency derivatives and interest rate swaps mature in 2004, interest rate swaps that qualify as fair value hedges mature in 2005 and interest rate swaps that qualify as cash flow hedges mature in 2007. As of December 31, 2003 the fixed interest rates varied from 2.40% to 7.38% (2002: 3.50% to 7.38%) and the average floating rates were 1.48% plus a margin ranking up to 4.82% (2002: average of 1.55% plus a margin ranking from 1.70% to 4.82%).

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The nominal values of derivative instruments as of December 31, 2003 and 2002 by currency are as follows:

Nominal values as of December 31				
	Denominated in CHF US\$000	Denominated in US\$ US\$000	Total 2003 US\$000	Total 2002 US\$000
Foreign currency derivatives				
Currency options	995,106	132,800	1,127,906	564,375
Forward foreign exchange contracts	45,069	466,231	511,300	623,656
Interest rate derivatives				
Interest rate swaps	22,041		22,041	29,704
Interest rate swaps fair value hedges		51,000	51,000	51,000
Interest rate swaps cash flow hedges		65,000	65,000	
Other derivatives options				1,298

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### 30. Principal shareholders

As of December 31, 2003, Bertarelli & Cie, a partnership limited by shares with its principal offices at Chésereux (Vaud), Switzerland, held 52.51% of the capital and 61.62% 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 7.15% of the capital and 9.92% of the voting rights of Serono S.A.

### 31. Collaborative agreements

Financial terms for certain collaborative agreements described below have not been disclosed, in accordance with confidentiality requirements within the agreements.

Upfront fees related to collaborative agreements totaled \$4.0 million in 2003, \$24.8 million in 2002 and \$9.2 million in 2001. Under the same agreements, milestone payments totaled \$32.5 million in 2003, \$0.3 million in 2002 and \$4.4 million in 2001 and research and development payments totaled \$17.2 million, \$11.9 million and \$24.7 million in 2003, 2002 and 2001, respectively. The amortization charges in respect of the amounts capitalized for collaborative agreements totaled \$19.2 million, \$15.8 million and \$8.2 million in 2003, 2002 and 2001, respectively.

#### 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 United States. Serono will continue to market and promote Novantrone® in the United States for its approved multiple sclerosis indication and will record all sales of Novantrone® in the United States 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 United States and Japan. All payments under the extension of the international license agreement have been expensed as research and development expense.

**Collaborative agreements for 2002**

Serono entered into an agreement with Regeneron Pharmaceuticals Inc. under which Regeneron will use its proprietary Verlocigene technology platform to provide Serono with knockout and transgenic models of gene function. Under the terms of the agreement, Serono will pay Regeneron up to \$3.0 million annually for up to five years, which will be expensed as research and development expense.

Serono signed a license and commercialization agreement with Amgen Inc. under which Serono will sell Amgen's Novantrone® in the United States. Novantrone® is indicated for the treatment of certain forms of multiple sclerosis and certain types of cancer. An upfront 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 United States, 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. Phase 3 clinical trials of Raptiva™ in psoriasis have been completed. 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.

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Serono and Pfizer Inc. entered into a co-promotion agreement for Serono's multiple sclerosis treatment Rebif® in the United States. 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 United States, and will receive payments based on Rebif® sales in the United States. Serono will record all sales and continue to distribute the product in the United States. 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.

**Collaborative agreements for 2001**

Serono entered into a multi-year subscription agreement with The Celera Genomics Group ("Celera"). Under the terms of the agreement, Serono gains access to Celera's proprietary genomic databases. All payments under the agreement have been expensed as research and development expense.

Serono entered into an exclusive co-development and commercialization agreement with ZymoGenetics, for two preclinical product candidates discovered by ZymoGenetics. The companies intend to focus their activities on the development of one or more products based on the TACI and BMCA receptors for the treatment of B-cell mediated autoimmune diseases. Serono paid an initial fee upon signature of the agreement, made and will make certain milestone payments, and will pay royalties on the sales of



products resulting from the collaboration. All payments have been expensed as research and development expense.

Serono entered into a collaborative research agreement with Inpharmatica Limited, focusing on the discovery of novel proteins. The collaboration highlights the growing importance of protein structures in understanding the function of proteins coded by the human genome. Serono paid an initial fee upon signature of the agreement, made and will make additional milestone payments and will pay royalties on the sales of any products resulting from the collaboration. The collaborative research agreement has been expanded in size and scope in 2003 to apply Inpharmatica's technology platform to additional proteins families and proprietary genomic sequence data. Under the terms of this expansion, Serono will make additional research funding, milestone and royalty payments on the sales of any products resulting from the collaboration. All payments have been expensed as research and development expense.

Serono entered into a collaborative assay development and screening agreement with Evotec OAI AG ("Evotec") to detect direct or indirect interaction of target compounds. Under the terms of the agreement, Evotec will develop a biological assay and will perform screening and profiling services for Serono. Serono has made an initial payment and will make certain milestone payments to Evotec based on the success of the project. All payments have been expensed as research and development expense.

## 32. Related parties

### Transactions with related parties

In 2003, the group continued to lease from an unaffiliated company, under a lease that expires in 2006, a building that is used as our headquarters facilities. The lease provides for a rent of approximately \$1.0 million (2002: \$0.8 million) per year. In addition, the Serono group has sub-rented a portion of the same building mentioned above to a company, which is controlled by Ernesto Bertarelli, our Chief Executive Officer. The lease payments to Serono in 2003 amounted to approximately \$0.2 million (2002: \$0.2 million).

In 2003, 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 Mr. Bertarelli. During 2003, the group paid fees for the jet totaling approximately \$1.6 million (2002: \$2.0 million).

There are three loans outstanding to members of the Executive Management Board. The most recent loan was issued on June 12, 2002 for the amount of CHF300,000 (approximately \$224,000). All loans to executives accrue fixed interest at 3% per year. The total amount outstanding as of December 31, 2003 is CHF1.1 million (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, 2003 were \$2.4 million (2002: \$2.0 million). As at December 31, 2003, there was an amount of \$10,000 (2002: \$186,000) payable to Cansera.

### Remuneration of the Board of Directors and the Executive Management Board

Details of the members of the Board of Directors and the Executive Management Board including the amount of remuneration paid are provided elsewhere within this Annual Report.

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## 33. Principal operating companies

As of December 31, 2003

Company	Currency	Capital	Ownership	Location
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Serono International S.A.	CHF	5,500,000	100%	Switzerland <sup>(1)</sup>	#
Serono Pharma Schweiz, branch of Serono International S.A.	CHF		100%	Switzerland	
Ares Trading S.A.	CHF	500,000	100%	Switzerland	\$
Laboratoires Serono S.A.	CHF	11,009,000	100%	Switzerland	*
Laboratoires Serono S.A., branch in Corsier-sur-Vevey	CHF		100%	Switzerland <sup>(2)</sup>	*
Serono Argentina S.A.	ARS	1,100,000	100%	Argentina	
Serono Australia Pty Ltd	AUD	60,000	100%	Australia	
Serono Austria GmbH	EUR	108,065	100%	Austria	
Serono Benelux BV, Belgian Branch	EUR		100%	Belgium	
Serono Produtos Farmaceuticos Ltda	BRL	8,882,288	100%	Brazil	
Serono Canada, Inc.	CAD	1	100%	Canada	
Serono de Colombia S.A.	COP	52,200,000	100%	Colombia	
Serono Pharma Services, s.r.o.	CZK	1,400,000	100%	Czech Republic	
Serono France S.A.	EUR	1,456,560	100%	France <sup>(3)</sup>	
Genset S.A.	EUR	60,160,692	100%	France <sup>(4)</sup>	
Serono GmbH	EUR	512,000	100%	Germany	
Serono Hellas A.E.	EUR	1,205,102	100%	Greece	
Serono Hong Kong Ltd	HKD	1,000,020	100%	Hong Kong	
Serono Israel Ltd	ILS	7,000	100%	Israel <sup>(5)</sup>	
InterPharm Laboratories Ltd	ILS	6,242	100%	Israel	*
Inter-Lab Ltd	ILS	61,478	100%	Israel	*
InterPharm Industries (1991) Ltd	ILS	4,110	100%	Israel	*
Industria Farmaceutica Serono S.p.A.	EUR	656,250	96.67%	Italy <sup>(6)</sup>	*
Istituto di Ricerche Biomediche S.p.A.	EUR	5,046,000	96.82%	Italy	&
Serono Japan Co. Ltd	JPY	4,300,000,000	100%	Japan	
Serono Korea Co. Ltd	KRW	4,376,800,000	100%	Korea	
Serono de Mexico S.A. de C.V.	MXN	25,653,492	100%	Mexico	*
Serono Produtos Farmaceuticos Lda	EUR	523,739	100%	Portugal	
Serono Puerto Rico, a Branch of Ares Trading S.A.	USD		100%	Puerto Rico	*
Serono Singapore Pte Ltd	SGD	630,000	100%	Singapore	
Serono South Africa (Pty) Ltd	SAR	1,000	100%	South Africa	
Serono España S.A.	EUR	2,400,000	100%	Spain	*
Serono Nordic AB	SEK	250,000	100%	Sweden	
Serono Singapore Pte Ltd, Taiwan Branch	TWD		100%	Taiwan	
Serono (Thailand) Co., Ltd	THB	1,250,000	100%	Thailand	
Serono Benelux B.V.	EUR	613,808	100%	The Netherlands	
Serono İlaç Pazarlama ve Ticaret A.S.	TRL	153,835,000,000	100%	Turkey	
Serono Ltd	GBP	800,000	100%	UK	
Bourn Hall Clinic	GBP	8,800,601	100%	UK <sup>(7)</sup>	
Serono Europe Ltd	GBP	50,001	100%	UK	
Ares Trading Uruguay S.A.	UYP	570,000	100%	Uruguay	\$
Serono Inc.	USD	40,867,094	100%	USA	
Serono Reproductive Biology Institute Inc.	USD	4,000,100	100%	USA	

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Serono de Venezuela S.A.	VEB	117,900,000	100%	Venezuela
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The companies above are all fully consolidated subsidiary companies of Serono S.A.

- \* Production
- Research
- & Development
- Marketing
- § Export
- & Trading
- # Headquarters

- (1) The Serono Pharmaceutical Research Institute is a division of Serono International S.A.
- (2) Laboratoires Serono S.A., succursale de Corsier-sur-Vevey, is a branch of Laboratoires Serono S.A. and is generally referred to as The Serono Biotech Centre.
- (3) Sorebio S.à.r.l. merged into Serono France S.A. on March 31, 2003 with retroactive effect on January 1, 2003. As a result, Sorebio S.à.r.l. has become Etablissement de Martillac and is an établissement secondaire of Serono France S.A., without independent legal status.
- (4) Full ownership of Genset S.A. was acquired further to a capital increase announced on March 4, 2003 and a squeeze-out procedure launched in May 2003, which ended June 16, 2003.
- (5) ASI Pharma Ltd changed name to Serono Israel Ltd. on February 7, 2003.
- (6) Industria Farmaceutica Serono S.p.A. holds 3.03% of its own shares (treasury shares).
- (7) Bourn Hall Clinic is a clinic specializing in the treatment of infertility disorders.

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### 34. Significant differences between IFRS and United States Generally Accepted Accounting Principles (US 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 US GAAP. The effects of the application of US GAAP to net income and shareholders' equity are set out in the tables below:

	Year ended December 31		
	2003 US\$000	2002 US\$000	2001 US\$000
<b>Net income reported under IFRS</b>	<b>389,963</b>	320,778	316,721
US GAAP adjustments			
a. Purchase Accounting: Genset S.A.	(8,916)	(26,829)	
b. Purchase accounting: Business combinations	(3,303)	(5,662)	(3,088)
c. Purchase accounting: IFRS goodwill amortization	6,358	2,957	
d. Pension provisions	(374)	(147)	(909)
e. Available-for-sale securities	6,190	(17,789)	(22,326)
f. Derivative financial instruments			(1,209)
g. Deferred taxes	903	(822)	3,728
h. Other intangible assets			761

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i. Employee Share Purchase Plan	3,855	389	(4,244)
j. Convertible bond	366		
Deferred tax effect of US GAAP adjustments	3,304	7,301	2,036
<b>Net income reported under US GAAP</b>	<b>398,346</b>	<b>280,176</b>	<b>291,470</b>

	US\$	US\$	US\$
Basic earnings per bearer share reported under US GAAP	25.16	17.53	18.15
Basic earnings per registered share reported under US GAAP	10.06	7.01	7.26
Diluted earnings per bearer share reported under US GAAP	25.12	17.51	18.11
Diluted earnings per registered share reported under US GAAP	10.05	7.00	7.24

	As of December 31	
	2003 US\$000	2002 US\$000
<b>Shareholders equity reported under IFRS</b>	<b>2,880,190</b>	<b>2,461,198</b>
US GAAP adjustments		
a. Purchase accounting: Genset S.A.	(35,745)	(26,829)
b. Purchase accounting: Business combinations	12,158	15,142
c. Purchase accounting: IFRS goodwill amortization	9,315	2,957
d. Pension provisions	10,773	11,147
d. Minimum pension liability	(128)	(2,886)
e. Available-for-sale securities		
f. Derivative financial instruments		
g. Deferred taxes	(1,608)	(2,511)
h. Other intangible assets		
i. Employee Share Purchase Plan		(3,855)
j. Convertible bond	(25,344)	
Deferred tax effect of US GAAP adjustments	5,862	2,320
<b>Shareholders equity reported under US GAAP</b>	<b>2,855,473</b>	<b>2,456,683</b>

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Components of shareholders equity in accordance with US GAAP are as follows:

As of December 31

	2003 US\$000	2002 US\$000
Share capital	253,895	253,416
Share premium	1,002,991	989,141
Treasury shares	(157,642)	(126,460)
Retained earnings	1,634,947	1,321,490
Accumulated other comprehensive income		
Currency translation adjustment	88,883	26,386
Unrealized market value adjustment on available-for-sale securities (net of taxes of \$1,693 and \$2,147)	32,943	(4,693)
Unrealized market value adjustment on cash flow hedges (net of tax of \$0)	(467)	
Minimum pension liability adjustment (net of taxes of \$51 and \$289)	(77)	(2,597)
<b>Shareholders equity reported under US GAAP</b>	<b>2,855,473</b>	<b>2,456,683</b>

The changes of shareholders equity in accordance with US GAAP are as follows:

	2003 US\$000	2002 US\$000
<b>Balance as of January 1 reported under US GAAP</b>	<b>2,456,683</b>	<b>2,239,711</b>
Issue of share capital	15,608	14,269
Issue of treasury shares	9,440	
Written calls	945	
Net income for the year reported under US GAAP	398,346	280,176
Purchase of treasury shares	(42,026)	(117,422)
Dividends paid - bearer shares	(61,849)	(46,637)
Dividends paid - registered shares	(23,860)	(17,601)
Foreign currency translation adjustment	62,497	108,668
Net unrealized market value adjustment on available-for-sale securities	37,636	(1,884)
Net unrealized market value adjustment on cash flow hedges	(467)	
Minimum pension liability adjustment	2,520	(2,597)
<b>Balance as of December 31 reported under US GAAP</b>	<b>2,855,473</b>	<b>2,456,683</b>

a) The accounting treatment for the 2002 acquisition of Genset S.A. under IFRS is different from the accounting treatment under US 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. During 2003, \$8.9 million of IPR&D has been identified and expensed for US GAAP purposes in connection with the acquisition of the remaining 7.53% of the outstanding shares of Genset S.A.

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 US 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 2003 and 2002 under US GAAP. In 2003 in accordance with SFAS No. 142, non-cash charges of \$3.3 million (2002: \$5.7 million) were recorded for impairment of goodwill and divestments. The impairment loss under US GAAP related primarily to the write-off of pre-1995 goodwill.

c) In accordance with SFAS No. 142, goodwill is no longer amortized but is only subject to impairment testing under US GAAP as of January 1, 2002. The goodwill amortization that was recognized in accordance with IFRS in 2003 was \$6.4 million (2002: \$3.0 million) and has been added to arrive at net income reported under US GAAP.

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d) For purposes of US 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 US 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 US GAAP accounting rules in this area are essentially the same. However, adjustments arise when reconciling from IFRS to US GAAP due to the pre-1999 accounting rule differences. In addition, US 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 US 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 US 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 US 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 loss upon the disposal of an investment. The amount of the loss was \$4.0 million under IFRS. The carrying amount of the investment under US GAAP prior to the disposal was lower than the carrying amount under IFRS such that the disposal resulted in a \$2.2 million gain under US GAAP.

f) Prior to the adoption of IAS 39, "Financial Instruments: Recognition and Measurement" as of January 1, 2001, there was no specific IFRS accounting standard dealing with the recognition and measurement of financial instruments and the qualifying criteria for hedge accounting. US GAAP existing at that time had various standards covering derivative instruments and hedging activities with more prescriptive requirements for hedge accounting. From January 1, 2001, IFRS and US GAAP accounting rules are essentially the same. The reconciling item in the US GAAP reconciliation solely represents the add back of adjustments arising before the adoption of IAS 39.

g) Under IAS 12 (revised 2000), Income Taxes, and US 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, US GAAP requires the tax effect to be calculated with reference to the local tax rate in the seller or manufacturer's jurisdiction.

h) Prior to the group's adoption of IAS 38, Intangible Assets, on January 1, 1999, certain costs mainly relating to payments for licenses and patents for technology that had not yet reached technological feasibility were capitalized under IFRS instead of being expensed as incurred under US GAAP. The reconciling item recorded in 2001 solely represents the add-back of amortization

expense that was taken under IFRS related to capitalized research and development costs that would not have been capitalized under US GAAP. These capitalized costs were fully amortized for IFRS purposes in the year ended December 31, 2001.

i) For US GAAP purposes, the Employee Share Purchase Plan (the ESPP) as described in note 27 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 US GAAP as of December 31, 2002 has been added back as income in the US GAAP reconciliation.

j) 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 US GAAP due to the differences in the amounts initially recognized under IFRS and US GAAP. In 2003, \$0.4 million has been added back to arrive at net income under US GAAP. The equity component recognized under IFRS, \$24.6 million, was reported as a reserve within shareholders' equity. However, under US GAAP, this reserve is removed from shareholders' equity and recorded as long-term debt on the consolidated balance sheet.

### Additional US 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 business combination in accordance with SFAS 141, "Business Combinations". During 2003, the

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group increased its ownership to 100% by acquiring the remaining outstanding shares of Genset S.A. The final purchase price allocation under US GAAP is as follows:

	Final purchase price allocation 2003 US\$000	Changes 2003 US\$000	Purchase price allocation 2002 US\$000
Current assets	33,634		33,634
Property, plant and equipment	11,221		11,221
Acquired IPR&D	35,745	8,916	26,829
Goodwill	47,456	(37,208)	84,664
Deferred tax assets	40,321	40,321	
Other long-term assets	3,995	(631)	4,626
Short-term liabilities	(16,989)	336	(17,325)
Long-term liabilities	(5,669)	(2,083)	(3,586)
<b>Net assets</b>	<b>149,714</b>	<b>9,651</b>	<b>140,063</b>

The components of shareholders' equity and net income adjustments related to the US GAAP purchase accounting adjustments are as follows:

As of December 31, 2003

	Shareholders equity US\$000	Net income US\$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>

As of December 31, 2002

	Shareholders equity US\$000	Net income US\$000
IPR&D	(26,829)	(26,829)
IFRS Goodwill amortization	1,672	1,672
<b>Total</b>	<b>(25,157)</b>	<b>(25,157)</b>

**B. Purchase accounting: Goodwill and other intangibles**

Changes in the carrying amount of goodwill under US GAAP for the years ended December 31, 2003 and 2002 are as follows:

	2003 US\$000	2002 US\$000
Balance as of January 1	115,380	38,478
Goodwill acquired	(37,208)	84,664
Impairment losses	(3,303)	(5,662)
Goodwill written off relating to disposals of operating companies		(2,232)
Currency adjustments	76	132
<b>Balance as of December 31</b>	<b>74,945</b>	<b>115,380</b>

All goodwill components were tested for impairment during 2003. The fair value of the business was determined using the expected present value of future cash flows. The impairment losses primarily relate to goodwill occurring on acquisition prior to January 1, 1995.

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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 US GAAP by the geographical area in which the reporting unit is located:



As of December 31

	2003 US\$000	2002 US\$000
Europe	52,563	91,356
North America		1,218
Latin America		240
Other	22,382	22,566
<b>Total</b>	<b>74,945</b>	<b>115,380</b>

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. Pro forma net income under US GAAP for the current year and prior two years after adding back the amortization expense related to goodwill is as follows:

	Year ended December 31		
	2003 US\$000	2002 US\$000	2001 US\$000
<b>Reported net income</b>	<b>398,346</b>	280,176	291,470
Add back: Goodwill amortization			4,466
<b>Pro forma net income</b>	<b>398,346</b>	280,176	295,936
	<b>US\$</b>	<b>US\$</b>	<b>US\$</b>
<b>Basic earnings per bearer share</b>			
Reported	25.16	17.53	18.15
Add back: Goodwill amortization			0.27
Pro forma	25.16	17.53	18.42
<b>Basic earnings per registered share</b>			
Reported	10.06	7.01	7.26
Add back: Goodwill amortization			0.11
Pro forma	10.06	7.01	7.37
<b>Diluted earnings per bearer share</b>			
Reported	25.12	17.51	18.11
Add back: Goodwill amortization			0.27
Pro forma	25.12	17.51	18.38

<b>Diluted earnings per registered share</b>			
Reported	<b>10.05</b>	7.00	7.24
Add back: Goodwill amortization			0.12
Pro forma	<b>10.05</b>	7.00	7.36

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The remaining weighted average amortization period of intangible assets as of December 31, 2003 was 6.9 years (2002: 5.9 years). The estimated amortization expense for intangibles assets for the next five years is as follows:

	<b>2003</b>	2002
	<b>US\$000</b>	US\$000
Aggregated amortization expense for the year ended December 31	<b>25,104</b>	19,834

	<b>2003</b>	2002
	<b>US\$000</b>	US\$000
Estimated amortization expense for the years ended December 31		
2003		25,270
2004	<b>29,212</b>	25,270
2005	<b>29,212</b>	25,270
2006	<b>29,212</b>	11,524
2007	<b>17,477</b>	9,714
2008	<b>16,810</b>	

### 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, 2003 and 2002, respectively:

	As of December 31	
	<b>2003</b>	2002
	<b>US\$000</b>	US\$000
<b>Benefit obligation</b>		
As of January 1	<b>185,519</b>	139,039
Service cost	<b>21,077</b>	18,974
Interest cost	<b>6,014</b>	6,206
Actuarial (gain)/loss	<b>(52,638)</b>	986

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Benefit payments	(8,839)	(2,319)
Settlements	(451)	
Currency adjustments	17,862	22,633
<b>As of December 31</b>	<b>168,544</b>	<b>185,519</b>
<b>Plan assets at fair value</b>		
As of January 1	108,288	87,575
Actual return on plan assets	12,934	(10,126)
Employer contributions	12,825	11,244
Employee contributions	6,117	4,980
Benefit payments	(8,839)	(2,319)
Currency adjustments	14,362	16,934
<b>As of December 31</b>	<b>145,687</b>	<b>108,288</b>
<b>Funded status</b>		
As of December 31	(22,857)	(77,231)
Unrecognized transition obligation		374
Unrecognized actuarial (gain)/loss	(21,637)	37,957
Minimum pension liability	(128)	(2,886)
<b>Net amount recognized</b>	<b>(44,622)</b>	<b>(41,786)</b>
Accrued benefit liability	(44,494)	(38,900)
Accumulated other comprehensive income, gross	(128)	(2,886)
<b>Net amount recognized</b>	<b>(44,622)</b>	<b>(41,786)</b>

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The accumulated benefit obligation for the group's defined benefit pension plans was \$159.0 million as of December 31, 2003 (\$133.4 million as of December 31, 2002).

	Year ended December 31		
	2003 US\$000	2002 US\$000	2001 US\$000
Current service cost	14,960	13,995	10,902
Interest cost	6,014	6,206	4,810
Expected return on plan assets	(6,762)	(5,960)	(5,226)
Amortization of transition obligation	374	147	1,688
Amortization of unrecognized Actuarial (gain)/loss	(1,342)	113	

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<b>Net periodic benefit cost</b>	<b>13,244</b>	14,501	12,174
(Decrease)/increase in minimum pension liability included in other comprehensive income, gross	<b>(2,758)</b>	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 to determine net period benefit costs for the years ended December 31, 2003 and 2002 and to determine the benefit obligation as of December 31, 2003 and 2002 for the group's defined benefit pension plans are as follows:

	<b>2003</b>	2002
	%	%
<b>Weighted average actuarial assumptions used to determine benefit obligation as of December 31</b>		
Discount rate	<b>4.24</b>	4.23
Future salary increases	<b>2.67</b>	3.12
<b>Weighted average actuarial assumptions used to determine net period benefit costs for years ended December 31</b>		
Expected return on plan assets	<b>5.65</b>	6.11
Future salary increases	<b>2.67</b>	3.12
Future pension increases		0.90

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, 2003.

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 for the Swiss defined benefit pension plan:

Serono's Swiss defined benefit pension plan asset allocation as of December 31, 2003 and 2002, by asset category are as follows:

	<b>2003</b>	2002
	%	%
Equity securities	<b>27</b>	16
Debt securities	<b>53</b>	55
Real estate	<b>7</b>	13
Other	<b>13</b>	16
<b>Total</b>	<b>100</b>	100

The investment policy is set by the Foundation Board of Serono's Swiss defined benefit pension plan, 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

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derivatives on Serono shares are not allowed. The expected contributions to the Swiss defined benefit pension plan amounts to \$11.8 million in 2004.

The group's US 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 \$1.2 million, \$1.2 million and \$0.9 million for the three years ended December 31, 2003, 2002 and 2001, respectively.

#### D. Financial assets

The US 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 16. Proceeds from the sale of available-for-sale securities in 2003 were \$8.1 million (2002: \$313.7 million). Gross realized gains in 2003 were \$2.1 million (2002: \$1.9 million). The net unrealized gain from available-for-sale securities included as a separate component of shareholders' equity under US GAAP was \$25.9 million as of December 31, 2003 (2002: net unrealized loss of \$19.7 million). The maturities of the available-for-sale debt securities as of December 31, 2003 and 2002, respectively, are as follows:

	2003 US\$000	2002 US\$000
2003		358,619
2004	294,002	176,792
2005	218,957	93,246
2006	363,707	16,804
2007	241,332	
Thereafter		
<b>Total</b>	<b>1,117,998</b>	<b>645,461</b>

#### E. Derivative financial instruments

Total losses recognized in 2003 on options settled in Serono bearer shares that require a net cash settlement were \$1.7 million (2002: gain of \$0.8 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 sheet as of December 31, 2003 for US GAAP purposes as follows:

	US\$000
Face value of convertible bond issued	465,261

Transaction costs	(6,611)
Liability on initial recognition	458,650
Interest expense	729
Cumulative translation adjustment	20,931
<b>Liability as of December 31</b>	<b>480,310</b>

The US 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, 2003. The estimated fair values and maturities of the long-term financial debts are provided in note 20.

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**G. Current and deferred taxes**

Deferred tax assets and liabilities under US GAAP consist of the following:

	As of December 31	
	2003 US\$000	2002 US\$000
<b>Deferred tax assets</b>		
Tax losses carried forward	60,800	91,242
Various research and development tax credits carried forward	32,943	30,757
Depreciation and amortization	49,797	24,770
Inventories	59,966	51,511
Accrued expenses	21,234	11,598
Return reserve	12,353	18,933
Other	(4,327)	13,143
Total deferred tax assets	232,766	241,954
Less valuation allowance	(58,819)	(115,854)
<b>Total net deferred tax assets</b>	<b>173,947</b>	<b>126,100</b>
<b>Deferred tax liabilities</b>		
Depreciation and amortization	8,232	3,841
Inventories	13,915	12,643
Other	(6,228)	(4,404)
<b>Total deferred tax liabilities</b>	<b>15,919</b>	<b>12,080</b>

<b>Net deferred taxes</b>	<b>158,028</b>	114,020
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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 2003, the valuation allowance decreased by \$57.0 million (2002: increase of \$80.5 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. Deferred tax assets and liabilities under US GAAP, broken out into current and non-current, are as follows:

	As of December 31	
	2003 US\$000	2002 US\$000
Current deferred tax assets	99,258	101,410
Non-current deferred tax assets	74,689	24,690
<b>Total net deferred tax assets</b>	<b>173,947</b>	126,100
Current deferred tax liabilities	2,133	3,813
Non-current deferred tax liabilities	13,786	8,267
<b>Total deferred tax liabilities</b>	<b>15,919</b>	12,080

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#### 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 US GAAP purposes. Had the group accounted for stock options in accordance with SFAS 123, net income under US GAAP and earnings per bearer and registered share under US GAAP would have decreased to the pro forma amounts indicated below:

	Year ended December 31		
	2003 US\$000	2002 US\$000	2001 US\$000
Net income as reported	398,346	280,176	291,470
Compensation expense recognized in net income	1,375 (18,909)	1,045 (14,385)	481 (7,731)

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Compensation expense that would have been included in the determination of net income if SFAS No. 123 had been adopted

<b>Pro forma net income</b>	<b>380,812</b>	266,836	284,220
	<b>US\$</b>	US\$	US\$
<b>As reported</b>			
Basic earnings per bearer share	<b>25.16</b>	17.53	18.15
Basic earnings per registered share	<b>10.06</b>	7.01	7.26
Diluted earnings per bearer share	<b>25.12</b>	17.51	18.11
Diluted earnings per registered share	<b>10.05</b>	7.00	7.24
<b>Pro forma</b>			
Basic earnings per bearer share	<b>24.05</b>	16.69	17.69
Basic earnings per registered share	<b>9.62</b>	6.68	7.08
Diluted earnings per bearer share	<b>24.01</b>	16.67	17.66
Diluted earnings per registered share	<b>9.61</b>	6.67	7.06

The fair value of stock options granted to employees in 2003, 2002 and 2001 were \$142, \$317 and \$302, respectively. The fair value of stock options granted to directors in 2003 was \$170. There were no stock options granted to directors in 2002 and 2001. 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, 2003, 2002 and 2001, respectively:

	<b>2003</b>	2002	2001
	<b>%</b>	%	%
Dividend gross rate	<b>1.07</b>	0.47	0.44
Expected stock price volatility	<b>34.6</b>	33.6	31.0
Risk-free interest rate	<b>3.5</b>	3.5	4.0
Expected lives, in years	<b>7.9</b>	7.5	8

**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 \$77.0 million, \$77.2 million and \$69.5 million for the three years ended December 31, 2003, 2002 and 2001, 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 \$25.7 million, \$18.6 million and \$16.9 million for the three years ended December 31, 2003, 2002 and 2001, respectively.

**K. Foreign currency translation**

The group has accounted for operations in highly inflationary economies in accordance with IAS 21 (revised 1993), The effect of changes in Foreign Exchange Rates, and IAS 29, Financial Reporting in Hyperinflationary Economies. The accounting under IAS 21 (revised 1993) and IAS 29 complies with the rules as promulgated by the US Securities and Exchange Commission in Item 18 of Form 20-F, although it is different from that required by US GAAP. For this reason, no reconciling adjustment has been included for this difference between IFRS and US GAAP.



**L. 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.

**M. 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 US Securities and Exchange Commission in Regulation S-X, no reconciliation to US GAAP has been performed.

**N. 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 and cash flow hedges and minimum pension liabilities.

The additional disclosures required under US GAAP are as follows:

	Year ended December 31		
	2003 US\$000	2002 US\$000	2001 US\$000
Net income reported under US GAAP	398,346	280,176	291,470
<b>Other comprehensive income</b>			
Currency translation adjustment	62,497	108,668	(23,579)
Unrealized market value adjustment on available-for-sale securities (net of taxes of \$454, \$2,147 and \$5,380, respectively)	37,636	(1,884)	12,042
Unrealized market value adjustment on cash flow hedges (net of taxes of \$0)	(467)		
Minimum pension liability adjustment (net of taxes of \$238 and \$289, respectively)	2,520	(2,597)	
<b>Comprehensive income reported under US GAAP</b>	<b>500,532</b>	<b>384,363</b>	<b>279,933</b>

**35. 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, Property, Plant and Equipment, 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. The amendments 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 Payment, 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. Management estimates that the adoption of this statement will result in additional compensation expense

that is similar to the amount of compensation expense disclosed under the current US GAAP treatment in note 34.

#### US GAAP

SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*, was issued in April 2003 and became effective for contracts entered into or modified and hedging relationships designed after June 30, 2003. SFAS No. 149 improves financial reporting by requiring that contracts with comparable characteristics be accounted for similarly and by clarifying when a derivative contains a financial component that warrants special reporting in the statement of cash flow. The adoption of this standard did not have a material impact on the reconciliation.

SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equities*, was issued in May 2003 and became effective for all financial instruments entered into or modified after May 31, 2003. In accordance with SFAS No. 150, financial instruments within the scope of this standard must be classified as liabilities. The FASB decided to split SFAS No. 150 into two phases. Phase two, which will address the accounting for compound financial instruments such as convertible debts, is expected to be completed in 2004. Until the FASB issues a final standard on phase two, the standards established in SFAS No. 150 have been applied to the convertible bond issued in November 2003 as described in note 34.

FASB Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*, was issued in November 2002. In accordance with this interpretation, any guarantee entered into after December 31, 2002 is required to be recognized as a liability at fair value. The disclosure requirements have been adopted as of

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December 31, 2002. The adoption of the initial recognition and measurement requirements had no impact on the reconciliation as no guarantees were issued or modified after December 31, 2002.

FASB Interpretation No. 46, *Consolidation of Variable Interest Entities*, was issued in January 2003 and determines whether consolidation is required under the *controlling financial interest* model of Accounting Research Bulletin No. 51 (ARP 51), *Consolidated Financial Statements*. The adoption of this interpretation had no impact on the reconciliation.

In January 2003, the Emerging Issues Task Force (EITF) issued EITF 00-21, *Accounting for Reserve Arrangements with Multiple Deliverables*. EITF 00-21 addresses the issues of how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting and how arrangement consideration should be measured and allocated to the separate units of accounting in the arrangement. EITF 00-21 does not change otherwise applicable revenue recognition criteria. EITF 00-21 is effective for revenue arrangements entered into in financial periods beginning after June 15, 2003. EITF 00-21 had no impact on the reconciliation.

### 36. Subsequent events

The primary financial statements were approved by the Board of Directors on January 29, 2004. On March 1, 2004, the full 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 25.

### 37. Principal currency translation rates

	2003 US\$	2002 US\$	2001 US\$
Year-end exchange rates used for the consolidated balance sheets			
1 CHF	1.2334	1.3871	1.6682
1 EUR	0.7915	0.9557	1.1265

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Average exchange rates used for the consolidated income statements and cash flow statements

1 CHF	<b>1.2896</b>	1.4852	1.6502
1 EUR	<b>0.8331</b>	1.0075	1.1204

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**PricewaterhouseCoopers SA**  
Avenue Giuseppe-Motta 50  
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1211 Genève 2  
Telephone 22 748 51 11  
Fax 22 748 51 15

**Report of Independent Accountants on  
Financial Statement Schedule**

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 March 1, 2004, 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, March 1, 2004

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## Schedule II Valuation and qualifying accounts

For the years ended December 31, 2003, 2002 and 2001	Balance at the beginning of the period US\$000	Additions US\$000	Deductions (1) US\$000	Balance at the end of the period US\$000
<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>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>65,854</b>	<b>106,697</b>	<b>(30,973)</b>	<b>141,578</b>
<b>Year ended December 31, 2001</b>				
Provisions for doubtful accounts	15,545	2,230	(5,073)	12,702
Provision for inventories	19,832	9,590	(11,575)	17,847
Allowance for deferred taxes	37,394	21,511	(23,600)	35,305
	<b>72,771</b>	<b>33,331</b>	<b>(40,248)</b>	<b>65,854</b>

(1) Represents amounts used for the purposes for which the accounts were created and reversal of amounts no longer required.

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Report of the statutory auditors  
to the general meeting of  
Serono SA

Coinsins

As statutory auditors, we have audited the accounting records and the financial statements (balance sheet, income statement and notes) of Serono SA for the year ended December 31, 2003.

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

Our audit was conducted in accordance with auditing standards promulgated by the Swiss profession, which require that an audit be planned and performed to obtain reasonable assurance about whether the financial statements are free from material misstatement. We have examined on a test basis evidence supporting the amounts and disclosures in the financial statements. We have also assessed the accounting principles used, significant estimates made and the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the accounting records and financial statements and the proposed appropriation of available earnings comply with Swiss law and the company's articles of incorporation.

We recommend that the financial statements submitted to you be approved.

PricewaterhouseCoopers SA

/s/ M Aked            /s/ H-J. Hofer

M Aked                H-J. Hofer

Geneva, March 1, 2004

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## Holding company income statements

Year ended December 31

	Notes	2003 CHF000	2002 CHF000
<b>Income</b>			
Dividend income		407,795	317,063
Interest income		11,776	3,612
Gain on investment		14,859	
<b>Total income</b>		<b>434,430</b>	<b>320,675</b>
<b>Expenses</b>			
General and administrative	2	10,876	2,669
Amortization		11,868	11,505
Write-down of investments		5,725	6,429
Loss on sale of subsidiary			19,132

Financial and other expenses		6,641	2,649
Net exchange loss	3	10,400	12,651
Taxes	4	2,641	3,119
<b>Total expenses</b>		<b>48,151</b>	<b>58,154</b>
<b>Net income for the year</b>		<b>386,279</b>	<b>262,521</b>

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## Holding company balance sheets

As of December 31

	Notes	2003 CHF000	2002 CHF000
<b>ASSETS</b>			
<b>Current assets</b>			
Cash		618	1,057
Receivables from affiliates		110,092	9,220
Prepaid expenses and other receivables		264	506
<b>Total current assets</b>		<b>110,974</b>	<b>10,783</b>
<b>Non-current assets</b>			
Investments in non-group companies		26,707	27,801
Investments in and advances to affiliates	5	3,538,508	3,153,653
Other non-current assets	6	12,886	24,043
<b>Total non-current assets</b>		<b>3,578,101</b>	<b>3,205,497</b>
<b>Total assets</b>		<b>3,689,075</b>	<b>3,216,280</b>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Accounts payable		35	2
Accounts payable to affiliates		18	4,200
Accrued liabilities		6,932	3,669
Advances from affiliates		247,711	72,776
Taxes payable	4	2,312	2,324
<b>Total current liabilities</b>		<b>257,008</b>	<b>82,971</b>
<b>SHAREHOLDERS EQUITY</b>			

Share capital	8	402,926	402,277
General legal reserves	11	1,760,629	1,738,029
Reserve for treasury shares	11	227,148	189,355
Available earnings	11	1,041,364	803,648
<b>Total shareholders equity</b>		<b>3,432,067</b>	<b>3,133,309</b>
<b>Total liabilities and shareholders equity</b>		<b>3,689,075</b>	<b>3,216,280</b>

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## Notes to the holding company financial statements

### 1 General

Serono is a leading global biotechnology company with executive headquarters in Geneva, Switzerland. The bearer shares of Serono S.A., the holding company of the group, incorporated in Coinsins (Vaud), Switzerland, are listed on the Swiss Stock Exchange and, in the form of American depositary shares, on the New York Stock Exchange. These financial statements have been prepared in accordance with the provisions of the Swiss Code of Obligations.

### 2. General and administrative

Included within general and administrative expenses are personnel costs related to the Employee Share Purchase Plan (the ESPP ). Details related to the plan are set out in note 27 to the consolidated financial statements.

### 3. Conversion of foreign currencies

Assets and liabilities denominated in a foreign currency are translated into Swiss francs at year-end exchange rates, except investments in non-group companies and investments in affiliates, which are translated at historical rates. Income and expense items are translated at average exchange rates prevailing during the year. Net unrealized exchange gains, if any, are deferred on the balance sheet, while exchange losses, whether realized or not, are included in determining net income.

### 4. Taxes

Provision is made for all taxes due on the company's taxable income and capital.

### 5. Investment in and advances to affiliates

	As of December 31	
	2003 CHF000	2002 CHF000
Investments	3,206,724	2,995,523
Advances to affiliates	331,784	158,130
<b>Total</b>	<b>3,538,508</b>	<b>3,153,653</b>

Serono S.A.'s investments in its affiliates are stated at cost. The details related to the principal operating companies of Serono S.A. are set out in note 33 to the consolidated financial statements.

**6. Other non-current assets**

Other non-current assets consist mainly of the capitalized costs related to the company's global offering of 1,070,670 bearer shares in July 2000, and are being amortized over 5 years.

**7. Contingent liabilities**

	As of December 31	
	2003 CHF000	2002 CHF000
Bank guarantees in respect of affiliates' borrowing facilities - total facility amount utilized 2003 CHF118.0 million (2002: CHF76.5 million)	574,251	240,082
<b>Total</b>	<b>574,251</b>	<b>240,082</b>

**8. Share capital**

The details related to the capital structure of Serono S.A. are set out in note 24 to the consolidated financial statements. At December 31, 2003 treasury shares with a total value of CHF227.1 million (2002: CHF189.4 million) were held by subsidiaries of Serono S.A. Treasury shares purchased during the year 2003 totaled CHF55.0 million (2002: CHF174.7 million) with an average purchase price of CHF686 (2002: CHF766). 10,000 treasury shares were issued upon the exercise of 10,000 call options that were written during 2003 (2002: Nil). 4,630 treasury shares were issued to employees during 2003 (2002: 200) for compensation expense in the amount of CHF5.9 million (2002: CHF0.3 million). The 304,939 treasury shares held as of December 31, 2003 (2002: 239,412) are non-dividend bearing.

**9. Stock option plan**

The details related to the Stock Option Plan of Serono S.A. are set out in note 26 to the consolidated financial statements.

**10. Principal shareholders**

The details related to the principal shareholders of Serono S.A. are set out in note 30 to the consolidated financial statements.

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**11. Available earnings and legal reserves**

The movements in the available earnings are as follows:

	2003 CHF000	2002 CHF000
As of January 1	803,648	816,060
Transfer to reserve for treasury shares	(37,793)	(174,449)
Appropriation of available earnings resolved by General Meeting:		
Dividends	(110,770)	(100,484)
Net income for the year	386,279	262,521
<b>As of December 31</b>	<b>1,041,364</b>	<b>803,648</b>



The movements in the legal reserves are as follows:

	Agio (share premium) CHF000	General reserve CHF000	Total general legal reserves CHF000	Reserve for treasury shares CHF000
As of January 1, 2003	1,706,229	31,800	1,738,029	189,355
Transfer for treasury shares	-	-	-	37,793
Stock options exercised during 2003	5,386	-	5,386	-
Shares issued under the Employee Share Purchase Plan	17,214	-	17,214	-
<b>As of December 31, 2003</b>	<b>1,728,829</b>	<b>31,800</b>	<b>1,760,629</b>	<b>227,148</b>

## Proposed appropriation of available earnings

	2003 CHF	2002 CHF
<b>Proposal of the Board of Directors</b>		
Available earnings	1,041,363,738	803,647,842
<b>Cash dividends</b>		
Registered shares: CHF3.20 (CHF2.80) per share	35,241,728	30,836,512
Bearer shares: Payment of a dividend of CHF8.00 (CHF7.00) per share on 11,406,887 (11,449,599) dividend bearing shares	91,255,096	80,147,193
<b>Total cash dividends</b>	<b>126,496,824</b>	<b>110,983,705</b>
<b>Retained earnings to carry forward</b>	<b>914,866,914</b>	<b>692,664,137</b>

Shares issued following the exercise of stock options up to the dividend payment date are entitled to receive the 2003 dividend. Further details of the dividends are set out in note 25 to the consolidated financial statements.

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### Exhibit Index

Exhibit Number	Description
1.1	<u>Articles of Association, dated March 18, 2004</u>

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- 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)
  - 2.8 Guarantee, dated as of November 26, 2003, of Serono S.A. in respect of the Convertible Bonds
  - 8.1 List of Subsidiaries of the Registrant
  - 11.1 Code of Ethics for Principal Executive Officer and Senior Financial Officers
  - 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)
  - 14.1 Consent of PricewaterhouseCoopers S.A.
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