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SERONO S A  
Form 20-F  
April 17, 2003

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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FORM 20-F  
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(Mark One)

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

or

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

For the fiscal year ended December 31, 2002

or

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

COMMISSION FILE NUMBER: 1-15096  
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SERONO S.A.

(Exact name of Registrant as specified in its charter)

NOT APPLICABLE  
(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:	NAME OF EACH EXCHANGE ON WHICH REGISTERED:
Bearer Shares, nominal value CHF25 per share	New York Stock Exchange*

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

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

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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  
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Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of December 31, 2002.

Bearer Shares, nominal value CHF 25 per share: 11,446,444 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

SERONO S.A.  
 ANNUAL REPORT ON FORM 20-F  
 FOR THE YEAR ENDED  
 DECEMBER 31, 2002

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SIGNATURES AND CERTIFICATIONS

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The registered ((R)) and the filed ((TM)) trademarks, Cetrotide(TM), click.easy(TM), cool.click(TM), Crinone(R), EasyJect(R), Ferti.net(R), Fertinex(R), Geref(R), Gonal-F(R), Luveris(R), Metrodin HP(R), Novantrone(TM), one.click(TM), Ovidrel(R), Ovitrelle(R), Pergonal(R), Profasi(R), Raptiva(TM), Rebif(R), Rebiject(R), Reliser(R), Saizen(R), SeroJet(TM), Serono(R), Serophene(R), Serostim(R) and Stilamin(R), as well as the filed trademarks ((TM)) for the "S" symbol, used alone or with the words "Serono biotech and beyond," are trademarks of, or are licensed to a subsidiary of, Serono S.A. Trade names and trademarks of other companies appearing in this report are the property of their respective owners.

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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.

	YEAR ENDED DECEMBER 31,			
	-----	-----	-----	-----
	2002	2001	2000	1999
	-----	-----	-----	-----

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

INCOME STATEMENT DATA:

Product sales . . . . .	\$1,423,130	\$1,249,405	\$1,146,998	\$1,054,144
Royalty and license income . . . . .	123,399	127,065	92,656	78,400
	-----	-----	-----	-----
Total revenues . . . . .	1,546,529	1,376,470	1,239,654	1,132,544
Operating expenses:				
Cost of product sales . . . . .	223,751	213,160	229,907	260,748
Selling, general and administrative . . . . .	512,942	446,945	393,716	369,747
Research and development, net . . . . .	358,099	308,561	263,152	221,629
Restructuring . . . . .	16,303	-	-	-
Other operating expense, net . . . . .	85,811	70,152	31,147	58,718
	-----	-----	-----	-----
Total operating expenses . . . . .	1,196,906	1,038,818	917,922	910,842
	-----	-----	-----	-----
Operating income . . . . .	349,623	337,652	321,732	221,702
Financial income/(expense), net . . . . .	36,476	51,381	52,277	2,458
Other expense, net . . . . .	1,658	2,548	2,411	1,078
	-----	-----	-----	-----
Total non-operating income/(expense), net . . . . .	34,818	48,833	49,866	1,380
	-----	-----	-----	-----
Income before taxes and minority interests . . . . .	384,441	386,485	371,598	223,082
Taxes . . . . .	63,127	69,816	70,384	39,778
	-----	-----	-----	-----
Income before minority interests . . . . .	321,314	316,669	301,214	183,304
Minority interests . . . . .	536	(52)	174	8
	-----	-----	-----	-----
Net income . . . . .	\$ 320,778	\$ 316,721	\$ 301,040	\$ 183,296
	=====	=====	=====	=====

PER SHARE DATA:

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

SUPPLEMENTAL PER EQUIVALENT

BEARER SHARE DATA:

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

YEAR ENDED DECEMBER 31,

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2002                      2001                      2000                      1999  
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(U.S. dollars in thousands, except per share)

BALANCE SHEET DATA:

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Cash, cash equivalents and short-term investments . . . . .	\$1,064,898	\$1,475,504	\$1,438,485	\$ 398,812
Working capital (6) . . . . .	1,258,352	1,527,359	1,505,534	405,721
Property, plant and equipment . . . . .	554,509	460,767	462,425	460,712
Total assets . . . . .	3,494,674	3,018,769	2,794,777	1,591,298
Outstanding share capital(4) . . . . .	249,408	252,955	252,992	236,978
Short-term debt . . . . .	93,598	173,254	238,585	238,738
Long-term debt . . . . .	25,857	37,325	56,626	116,381
Shareholders' equity . . . . .	2,461,198	2,218,914	2,006,416	826,785
AMOUNTS IN ACCORDANCE WITH U.S. GAAP:				
Net income. . . . .	280,176	291,470	304,389	170,952
Basic income per share (1) (7):				
Bearer shares . . . . .	17.53	18.15	19.72	11.41
Registered shares . . . . .	7.01	7.26	7.89	4.56
Diluted income per share (1) (7):				
Bearer shares . . . . .	17.51	18.11	19.68	11.40
Registered shares . . . . .	7.00	7.24	7.87	4.56
Total shareholders' equity . . . . .	2,456,683	2,239,711	2,015,860	862,634
Total assets . . . . .	3,483,295	3,069,873	2,794,465	1,623,385
MARGINS AND OTHER DATA:				
Gross margin (8) (9) . . . . .	84.3%	82.9%	80.0%	75.3%
Operating margin (8) (10) . . . . .	22.6%	24.5%	26.0%	19.6%
Net margin (8) (11) . . . . .	20.7%	23.0%	24.3%	16.2%
Cash dividends paid (4) . . . . .	\$ 64,238	\$ 53,759	\$ 17,755	\$ 19,310
Cash flows provided from operating activities . . . . .	\$ 531,982	\$ 404,950	\$ 255,443	\$ 274,632
Depreciation and amortization.. . . .	\$ 100,552	\$ 98,906	\$ 86,266	\$ 71,960
Additions to plant, property and equipment. \$ 125,324	\$ 97,131	\$ 67,080	\$ 66,420	
Average number of employees.. . . .	4,559	4,384	4,117	4,022

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YEAR ENDED DECEMBER 31,

2002		2001		2000	
SALES	% TOTAL	SALES	% TOTAL	SALES	% TOTAL

(U.S. dollars in millions)

PRODUCT SALES BY REGION:

Europe . . . . .	\$ 620.4	43.6%	\$ 542.2	43.4%	\$ 460.1	40.1%
North America. . . . .	479.6	33.7	390.6	31.2	404.9	35.3
Latin America. . . . .	109.2	7.7	130.9	10.5	113.6	9.9
Other regions. . . . .	213.9	15.0	185.7	14.9	168.4	14.7
Total product sales	\$1,423.1	100.0%	\$1,249.4	100.0%	\$1,147.0	100.0%

YEAR ENDED DECEMBER 31,

2002		2001		2000	
SALES	% TOTAL	SALES	% TOTAL	SALES	% TOTAL

(U.S. dollars in millions)

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PRODUCT SALES BY THERAPEUTIC

AREA:

Reproductive Health:

Gonal-F . . . . .	\$ 450.4	31.7%	\$ 410.5	32.9%	\$ 365.9	31.9%
Metrodin HP . . . . .	50.1	3.5	67.1	5.4	96.1	8.4
Other . . . . .	121.4	8.5	96.7	7.7	130.3	11.3
	-----	-----	-----	-----	-----	-----
Total . . . . .	621.9	43.7	574.3	46.0	592.3	51.6

Neurology:

Rebif . . . . .	548.8	38.6	379.6	30.4	254.2	22.2
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Growth and Metabolism:

Saizen . . . . .	124.0	8.7	107.3	8.6	90.0	7.8
Serostim . . . . .	95.1	6.7	125.3	10.0	137.1	12.0
	-----	-----	-----	-----	-----	-----
Total . . . . .	219.1	15.4	232.6	18.6	227.1	19.8

Other products . . . . .	33.3	2.3	62.9	5.0	73.4	6.4
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Total product sales	\$1,423.1	100.0%	\$1,249.4	100.0%	\$1,147.0	100.0%
	=====	=====	=====	=====	=====	=====

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

	Year ended December 31,				
	2002	2001	2000	1999	1998
	-----	-----	-----	-----	-----
BASIC PER SHARE:					
Bearer shares . . . . .	11,580,611	11,658,108	11,032,835	10,581,187	10,581,140
Registered shares . . . . .	11,013,040	11,013,040	11,013,040	11,013,040	11,013,040
Equivalent bearer Shares . . . . .	15,985,827	16,063,324	15,438,051	14,986,403	14,986,356
DILUTED PER SHARE:					
Bearer shares . . . . .	11,598,154	11,687,609	11,063,889	10,584,790	10,581,180
Registered shares . . . . .	11,013,040	11,013,040	11,013,040	11,013,040	11,013,040
Equivalent bearer Shares . . . . .	16,003,370	16,092,825	15,469,105	14,990,006	14,986,396

- (2) The portion of net income allocated to bearer and registered shares was \$232,381 and \$88,397, respectively, for the year ended December 31, 2002, \$229,863 and \$86,858, respectively, for the year ended December 31, 2001 and \$215,139 and \$85,901, respectively, for the year ended December 31, 2000. On a diluted basis, the portion of net income allocated to bearer shares and registered shares was \$232,478 and \$88,300, respectively, for the year ended December 31, 2002, \$230,022 and \$86,699, respectively, for the year ended December 31, 2001 and \$215,311 and \$85,729, respectively, for the year ended December 31, 2000.
- (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

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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.

- (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.

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- (7) The portion of net income in accordance with U.S. GAAP allocated to bearer shares and registered shares was \$202,968 and \$77,208, respectively, for the year ended December 31, 2002, \$211,537 and \$79,933, respectively, for the year ended December 31, 2001 and \$217,532 and \$86,857, respectively, for the year ended December 31, 2000. On a diluted basis, the portion of net income allocated to bearer shares and registered shares was \$203,053 and \$77,123, respectively, for the year ended December 31, 2002, \$211,684 and \$79,786, respectively, for the year ended December 31, 2001 and \$217,706 and \$86,683, respectively, for the year ended December 31, 2000.
- (8) These measures are not defined in IFRS or U.S. GAAP and should not be considered as an alternative to any IFRS and U.S. GAAP data. The method of calculating these measures may be different from methods used by other companies.
- (9) Gross margin means gross profit divided by product sales.
- (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

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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:

- products may be found to be ineffective or to have harmful side effects in preclinical or clinical testing. For example, in 2002 we discontinued clinical development of IFN-beta-1a for the treatment of rheumatoid arthritis due to evidence in a Phase II trial of patients with active rheumatoid arthritis who do not respond adequately to methotrexate, which suggested that IFN-beta-1a did not provide additional benefit over methotrexate;
- we may not successfully complete clinical trials for our products within any specific time period, or at all, for a variety of reasons, such as our inability to attract a sufficient number of investigators, our inability to enroll and maintain a sufficient number of patients in the clinical trials and suspension of the trials by regulatory authorities;
- products may fail to receive necessary regulatory approvals; and
- 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

We use biological materials, in particular animal 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 materials generally, including their use in biotechnology products and for research and development. Although we are developing manufacturing processes for our major molecules that will be free of animal-derived components, we may not be successful in that development and we cannot be certain that regulatory authorities will approve the new processes. If a government bans or regulates our use of animal materials, we would incur additional costs that could make the production of our products less profitable or economically impractical.



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IF WE ENCOUNTER PROBLEMS WITH ANY OF OUR KEY SUPPLIERS OR SERVICE PROVIDERS, WE COULD EXPERIENCE HIGHER COSTS OF SALES OR DELAYS IN OUR MANUFACTURING

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 might experience significant delays in our ability to manufacture or sell our products and incur significant expense or fail to realize significant revenues.

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, in the field of multiple sclerosis treatment, Schering AG, a pharmaceutical company, and Biogen, a biotechnology company, each introduced beta interferon products to the market prior to our introduction of Rebif. Because of protections provided to Schering AG and Biogen under the U.S. Orphan Drug Act, we were not able to sell Rebif in the United States until March 2002. The 2002 roll-out by Teva Pharmaceuticals 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.

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

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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 2002, \$620.4 million (43.6%) 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

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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 REBIF OR GONAL-F DECLINE, OUR PROFITABILITY WOULD BE REDUCED

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In 2002, Rebif, our recombinant beta interferon, accounted for 38.6% (\$548.8 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.

In 2002, Gonal-F, our recombinant follicle stimulating hormone, accounted for 31.7% (\$450.4 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.

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 2003 the Federal Republic of Germany, Europe's largest pharmaceutical market, announced an across-the-board reduction of 6% in reimbursement rates for all pharmaceuticals, including our products.

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In certain markets, the pricing and reimbursement of our products are subject to government controls. In Europe, some third-party payers link the reimbursement price to maximum quantities of the product sold in a given year. Single payer medical insurance systems, which are predominant in Europe, are under increasing financial strain, which creates an incentive to decrease the amount that such systems will pay to reimburse the cost of drugs. In the United States, there have been, and we expect there will continue to be, a number of state and federal proposals that limit the amount that state or federal governments will pay to reimburse the cost of drugs, and we believe the increasing emphasis on managed care will put pressure on the price and usage of our products, which may impact product sales. For example, in 2001 and 2002 many states in the 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.

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

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license income. Our net royalty income was \$78.3 million in 2002 and \$76.4 million in 2001, relating primarily to royalties received from Biogen on its sales of Avonex, Organon on its sales of Puregon, Amgen (formerly Immunex) on its sales of Enbrel, and the divestiture of a product that was not core to our business. 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. 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

We have significant cash and short-term investments on which we earn interest. In view of the relatively short-term nature of these investments, the interest income correlates closely to movements in interest rates. For example, short-term U.S. dollar interest rates fell by more than 26% in 2002 and were under 1.4% by the year end. As a result, in 2002, our net financial income (\$36.5 million) was significantly lower than in 2001 (\$51.4 million). The decrease in interest rates was by far the main reason for the decrease in net financial income. We cannot predict how interest rates will move in the future. If interest rates fall further or continue to stay low, our investment income may be reduced when compared to previous periods.

In addition to cash and short-term investments, we have significant amounts invested in rated Eurobonds with maturities of up to three years. If we were required to sell these investments prior to maturity, we could realize gains or losses arising from movements in interest rates or changes in the credit quality of the bond issuer.

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.

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

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from our sales figures as measured in local currencies. For example, in 2002 our sales growth was 11.5% in local currencies, but 13.9% 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 2002 our expenses growth was 15.2% as reported in U.S. dollars, but 11.7% in local currencies. Due to this translation effect, the prevailing foreign exchange rate could cause our net income growth rate to not meet expectations.

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### 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 88 countries including the United States and the countries of the European Union, in order to obtain regulatory approval to sell the product in Japan we have been required to conduct additional local clinical studies, which will delay potential registration of Gonal-F in this market. Even if we are able to obtain regulatory approval for our products, both our manufacturing processes and our marketed products are subject to continued review. Later discovery of previously unknown problems with the safety or efficacy of our products or manufacturing processes may result in restrictions on these products or processes, including withdrawal of the products from the market or suspension of our manufacturing operations. For example, in February 2003, the Committee on Safety of Medicines advised that Metrodin HP should no longer be used in the United Kingdom. The Committee based its advice on the precautionary principle that products manufactured from human urine sourced from a country with one or more cases of variant Creutzfeldt-Jakob Disease, or vCJD, should not be used whenever practicable. Metrodin HP was manufactured from urine sourced from Italy, and the withdrawal of Metrodin HP from the United Kingdom market was a precautionary measure following the confirmation of a case of vCJD in Italy.

### 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

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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.

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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 assert cover the recombinant manufacture of interferon beta. Following receipt of marketing approval in the United States for Rebif in March 2002, we filed a declaratory judgment action against Berlex and Schering AG in the U.S. District Court for the District of Massachusetts, asserting that Serono does not infringe Berlex's and Schering AG's patent rights related to the recombinant manufacture of human beta interferon. We settled this litigation and agreed to make a one-time payment to Berlex and pay Berlex royalties on our U.S. sales of Rebif in the United States for a limited period of time.

Litigation and administrative proceedings, which could result in substantial costs to us, may be necessary to enforce any patents issued to us or to determine the scope and validity of third-party proprietary rights. We have in the past been, are currently, and may in the future be involved in patent litigation. If we lose one of these proceedings, we may be required to obtain third-party licenses at a material cost or cease using the technology or product in dispute. If others have or obtain patents or proprietary rights with respect

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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 BECOME SUBJECT TO SIGNIFICANT LEGAL ACTION, WE MAY INCUR SUBSTANTIAL COSTS RELATED TO LITIGATION

We participate in an industry that has been subject to significant product liability, intellectual property and other litigation. Many of these actions involve large claims and significant defense costs. To protect ourselves from the cost of these claims we generally maintain appropriate liability insurance coverage in amounts and with deductibles that we believe are consistent with industry practice. However, our insurance coverage may not cover all claims against us or continue to be available at a reasonable cost for us to maintain adequate levels of insurance.

### 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 2002, 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.

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### RISKS RELATED TO OUR SHARE PRICE AND CORPORATE CONTROL

#### OUR SHARE PRICE IS LIKELY TO BE VOLATILE AND MAY DECLINE

The market price for our shares has been volatile and may continue to be volatile in the future. During 2002 and the first quarter of 2003, based on prices on the virt-X, our bearer share price ranged from CHF 562 to CHF 1537. During the same period, based on prices on the New York Stock Exchange, the price range for our ADSs ranged from \$10.25 to \$23.19. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of the shares and may cause the price to decline:

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

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- changes in the exchange rate of the U.S. dollar against the euro and the Swiss franc; and
- period-to-period fluctuations in our financial results.

### THE VALUE OF DIVIDENDS ON OUR ADSS WILL BE AFFECTED BY EXCHANGE RATES

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

### OUR CONTROLLING SHAREHOLDERS MAY HAVE INTERESTS THAT ARE ADVERSE TO YOURS

As of December 31, 2002, Bertarelli & Cie held 52.38% of our capital and 61.52% 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 Spaeth own as individuals in the aggregate 7.13% of our capital and 9.91% 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.

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### IT MAY NOT BE POSSIBLE TO ENFORCE JUDGMENTS OF UNITED STATES COURTS AGAINST OUR 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.



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OUR ACTUAL RESULTS MAY DIFFER FROM FORWARD-LOOKING STATEMENTS THAT WE MAKE IN THIS ANNUAL REPORT

Many statements made in this Annual Report under Items 3, 4 and 5 and elsewhere are forward-looking statements relating to future events and/or future performance, including, without limitation, statements regarding our expectations, beliefs, intentions or future strategies that are signified by the words "expects," "anticipates," "intends," "believes" 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.

### ITEM 4. INFORMATION ON THE COMPANY

#### OVERVIEW

We are the third largest biotechnology company in the world based on 2002 total revenues of \$1,546.5 million. Biotechnology companies use human genetic information to discover and manufacture therapeutic products for the treatment of human diseases. We currently focus on the niche markets of reproductive health, neurology, growth and metabolism, where we have established strong positions, and we expect to move into the psoriasis market in 2004. We have a global presence with operations in 45 countries, production facilities in six countries and sales in over 100 countries.

As a biotechnology company, research and development are central to our efforts to grow our business. We currently employ approximately 1,400 research and development personnel, and in 2002 we spent \$358.1 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 over 30 post-discovery 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 84.3% in 2002 from 67.7% in 1995 and to increase our net margin to 20.7% of revenues in 2002 from 4.2% in 1995.

Our 1,700 sales and marketing personnel sell our products primarily by targeting prescribing physicians in our highly specialized niche markets.

We are a Swiss corporation, with our principal executive offices in Geneva. In May 2000, we changed the name of our holding company from Ares-Serono S.A. to Serono S.A. We were incorporated in 1987, and our bearer shares have been listed in Switzerland since that time. Our American depository shares have been

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listed on the New York Stock Exchange since July 2000.

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

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### RECOMBINANT TECHNOLOGY

We currently market six recombinant products—Gonal-F, Rebif, Saizen, Serostim, Luveris and Ovidrel—and we are continuing to transition our existing urine-derived products to recombinant products. Recombinant DNA technology gives us a more efficient, less expensive and more 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.

### 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 billion global gonadotropin market and sales of Gonal-F currently account for about 58% of the approximately \$780 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

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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. We plan to cease production at all of our urine-derived production facilities in the first half of 2003, though we expect to continue to sell our inventory of these products during the next couple of years.

### INFERTILITY TREATMENT PROCESS

1. Medical work-up
2. Pituitary down-regulation-Cetrotide
3. Ovarian stimulation-Gonal-F, Metrodin HP, Pergonal, Luveris
4. Follicular maturation-Profasi, Ovidrel
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

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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 79.4% 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 and we are 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 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 formulation of Gonal-F is approved in the European Union and United States, and Gonal-F is also approved in the European Union, the United States and other countries for treating a form of male infertility. In 2002, Gonal-F was our second largest selling product, accounting for \$450.4 million (31.7%) of total product sales.

A recent peer-reviewed analysis of historical data 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 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. Based on the latter studies, the European Commission permitted the labeling of Gonal-F to be amended to include a statement that it is more effective than urine-derived FSH preparations.

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In order to control product variability, we have developed a highly controlled manufacturing process for Gonal-F. This manufacturing process allows us to produce recombinant human FSH with a highly consistent isoform profile. 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.

#### Ovidrel

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. Prior to the development of recombinant technology, we had to extract this hormone from the urine of pregnant women, which limited the commercial feasibility of producing hCG. In addition,

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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. We received regulatory approval of Ovidrel in the United States in the fourth quarter of 2000 and in the European Union in the first quarter of 2001. We began selling Ovidrel in the United States in the first quarter of 2001 and in the European Union in the fourth quarter of 2001.

### 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 received regulatory approval of Luveris in the European Union in the fourth quarter of 2000 and began rollout of the product in mid-2001. We submitted Phase III clinical data from an additional trial to the U.S. FDA in 2001.

### URINE-DERIVED PRODUCTS

We plan to cease production of our urine-derived reproductive health products in the first half of 2003, though we expect to continue to sell our existing inventories of the products in the near term.

### 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. Due to its high purity, Metrodin HP can be administered by subcutaneous injection, a significant patient advantage over earlier urine-derived products, which had to be given by more painful intramuscular injection. Metrodin HP is used for many of the same indications as Gonal-F, which is replacing Metrodin HP. In 2002, Metrodin HP was our fifth largest product, accounting for \$50.1 million (3.5%) of total product sales.

### 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 2002, Pergonal accounted for \$46.0 million (3.2%) of total product sales.

### Profasi

Profasi consists of hCG derived from the urine of pregnant women. It is a hormone produced by the human placenta and acts in a manner similar to LH. A monthly surge in the production of LH is responsible for ovulation. The hCG contained in Profasi provokes ovulation in a way similar to the way LH does in a natural monthly menstrual cycle. 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 2002, Profasi accounted for \$19.8 million (1.4%) of total product sales.

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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 seven 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 result of the recall, sales of Crinone in 2002 were \$10.9 million. 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.

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 has a remaining term of two years and is renewable for one additional five-year term and for additional three-year terms thereafter. We currently market Cetrotide in more than 70 countries. Sales of Cetrotide were \$18.4 million in 2002.

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 first half of 2003 we expect to start a Phase II trial with recombinant human Leukemia Inhibitory Factor, or LIF, and we have ongoing preclinical trials on an oxytocin receptor antagonist and a prostanoid FP receptor antagonist, other potential drugs relevant to the treatment of infertility.

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. We have successfully completed one Phase I clinical trial with males and two additional Phase I clinical trials in females are ongoing with Gonal-F microencapsulated using the Alkermes

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delivery system. We have begun preparations for a Phase II study. In addition, we are engaged in other potential improvements to Gonal-F.

### Anastrozole

We have recently entered into a Phase II trial with anastrozole, which we licensed for development from AstraZeneca in July 2002, for ovulation induction and improvement of follicular development. Because of its characteristics, we hope it will have benefits over currently available treatments, both in terms of efficacy and having fewer side effects.

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### Leukemia Inhibitory Factor

We are developing the recombinant protein LIF 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 LIF 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 expect to initiate a Phase II clinical trial in the first half of 2003.

### Oxytocin Receptor Antagonist

We are developing a low molecular weight oxytocin receptor antagonist with 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.

## 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 \$2.9 billion global market in 2002, based on publicly reported sales data for our product and three competing products.

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### 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 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 2002, Rebif was our largest selling product, accounting for \$548.8 million (38.6%) of total product sales. We began marketing Rebif in the United States in March 2002. At the end of 2002, over 13,000 patients were being treated with Rebif in the United States, and our estimated market share in terms of dollar-value of sales was about 5% for the whole year.

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.

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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 the second quarter of 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



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patients. The comparative figure during the first 24 weeks was also 19% in favor of Rebif. 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 3 times per week over Avonex 30 mcg once per week in reducing exacerbations, were published in the November 2002 issue of Neurology.

We have registered Rebif for the treatment of MS in 102 countries, including the United States, Canada, Australia and all of the countries of the European Union.

### LICENSING ARRANGEMENTS

We seek to expand our neurology franchise through selected licensing arrangements.

#### 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 chemotherapy 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. In March 2003, we entered into an agreement with OSI Pharmaceuticals pursuant to which OSI will market and promote Novantrone in the United States for its approved oncology indications. Novantrone had U.S. sales of approximately \$80 million in 2002.

### 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 IVAX's product, 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 plan to work with IVAX to establish an oral formulation of cladribine and then initiate a Phase I clinical trial in 2003.

#### IFNAR-2

In December 2002, we announced that we had successfully completed a Phase I trial with IFNAR-2, the soluble receptor for Type I interferons, including Rebif. IFNAR-2 prolongs the half-life of interferon beta in the bloodstream, which could allow us to administer Rebif less frequently to patients, thereby significantly improving patient convenience and compliance.

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#### 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

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and prion diseases. Under the terms of the agreement we will have exclusive rights to develop and commercialize drug candidates that emerge from this program, which could involve payments to Axonyx of up to \$22.5 million, plus royalties on sales of resulting drugs. We have identified a peptide inhibitor of amyloid plaque formation as a potential treatment for Alzheimer's disease and initiated a Phase I clinical of this peptide in March 2003.

### GROWTH AND METABOLISM

Human growth hormone is used in the treatment of growth-related disorders in children and AIDS wasting and growth hormone deficiency in adults. We estimate that the worldwide human growth hormone market generated approximately \$1.7 billion in sales in 2002, based on publicly reported sales data for our two products 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 81 countries for the treatment of growth hormone deficiency in children. It is also registered in 71 countries for treatment of Turner's syndrome and in 36 countries for treatment of children with growth failure associated with chronic renal failure. We have successfully completed the Mutual Recognition Procedure in Europe for the use of Saizen in the treatment of adult growth hormone deficiency, a condition caused by a reduction in the secretion of growth hormone from the pituitary gland. The use of Saizen as a treatment for adult growth hormone deficiency has been approved in 24 countries. In 2002, Saizen was our third largest selling product, accounting for \$124.0 million (8.7%) 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 the third quarter of 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 hormone products and indications worldwide. The products include both Saizen and Serostim. In addition, we obtained exclusive options to use all new technologies developed by Bioject for the delivery of human growth hormone.

#### METABOLISM

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

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infection. AIDS wasting is associated with decreased survival in AIDS patients. It is believed to be 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.

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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 2002, Serostim was our fourth largest selling product, accounting for \$95.1 million (6.7%) of total product sales. Due to continuing reimbursement restrictions and other issues currently under investigation in the United States, we believe that Serostim sales during 2003 may decline.

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. In 2002, we obtained the results of a study of over 750 patients that confirmed that Serostim improved physical performance, increased lean body mass and decreased truncal fat.

Serostim is also the first and only biotechnology-derived drug approved for AIDS wasting by the FDA, which has granted Serostim orphan drug status, and therefore marketing exclusivity, in the United States until August 2003. 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. 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.

### PRODUCT PIPELINE

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 this indication, Serostim therapy significantly reduced visceral adipose tissue, truncal fat and dyslipidemia. We filed for Orphan Drug Status in this indication in the United States in February 2003.

In December 2002, we commenced a Phase I clinical trial on pegylated growth hormone releasing factor, which has the potential to treat conditions related to growth hormone deficiency.

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### PSORIASIS

In addition to strengthening our existing core therapeutic areas, our strategy is to expand our product offerings into new niche 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. It 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.

#### Raptiva

Raptiva 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. We filed an

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application for approval of Raptiva for moderate to severe psoriasis in Europe in February 2003. We also filed in Switzerland and Norway in the first quarter of 2003, and expect to file for further approval in other countries late in 2003 and in 2004 in the territory countries covered by our agreement. Genentech and Xoma filed a Biologics License Application with the U.S. FDA for approval of Raptiva in psoriasis in December 2002.

#### TBP-1

TBP-1 is an inhibitor of tumor necrosis factor alpha, which is a cytokine that can cause irreversible damage to organs when secreted in excessive amounts by people with inflammatory and other diseases. We have completed several Phase I and early Phase II trials of TBP-1. Further Phase II trials are ongoing in psoriasis.

#### IL-18bp

In 2002, we completed Phase I studies of Interleukin-18 binding protein, or IL-18bp, a potential treatment for psoriasis. We plan to initiate a Phase II study in this indication in the second half of 2003.

### RESEARCH AND DEVELOPMENT

Research and development is vital to our ability to continue to grow our business. We employ approximately 1,400 research and development personnel, and our R&D expenses were 23.2% of our total revenues in 2002. R&D efforts are spearheaded by our scientists at the Serono Pharmaceutical Research Institute in Geneva, Serono Reproductive Biology Institute in Boston, Genset 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

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neurological diseases like MS, autoimmune diseases and wasting. The Serono Reproductive Biology Institute concentrates on reproductive health and related clinical indications. Genset focuses on genomics research. During 2000, 2001 and 2002, we spent \$263.2 million, \$308.6 million and \$358.1 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 two primary goals:

- pursuing drug discovery efforts that may lead to products in new therapeutic areas; and
- strengthening our key therapeutic areas through new products and line extensions.

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.

### PURSUIING 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, gene filters and serial analysis of gene expression. Working with clinical groups around the world, we are able to use our data to identify how genes are expressed in connection with different diseases. By understanding how genes are expressed in connection with different diseases, we identify points of intervention at which molecules may alter the progression and development of the diseases. We then determine whether the point of intervention would be best addressed through the use of protein therapeutics or therapies using smaller molecules.

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

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

Our research has helped us to identify several potential new therapeutic compounds:

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- An orally active small molecule inhibitor of apoptosis, which is an inhibitor of JNK, is in preclinical development as a potential treatment for MS and inflammatory conditions.
- A chemokine inhibitor with promising activity in a MS model entered preclinical development in 2001.
- An orally active low molecular weight oxytocin receptor antagonist with potential as a treatment for premature labor entered preclinical development in 2001.
- A prostanoid FP receptor antagonist with potential as a treatment for premature labor entered preclinical development in 2003.
- A protein tyrosine phosphatase 1b inhibitor with potential as a treatment for diabetes and obesity is planned to enter preclinical development in 2003.
- We have identified a class of modified peptides based on the structure of the amyloid beta protein which have been shown to reduce the size of disease-related plaques in animal models of Alzheimer's Disease. One of these molecules is scheduled to start its first testing in Phase I in March 2003. We believe that the approach used here may be applicable to other diseases where plaque formation is part of the pathology, such as serum amyloidosis.

In September 2002, we significantly increased our drug discovery capability through our acquisition of Genset S.A. Genset 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.

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, including:

British Biotech. In October 2000, we entered into an exclusive agreement with British Biotech to jointly research, develop and commercialize metalloenzyme inhibitors for the treatment of inflammatory diseases. During 2001, development of BB-2827, a collagenase inhibitor with potential in the treatment of rheumatoid arthritis, was discontinued due to toxicological side-effects in long-term pre-clinical and early clinical studies, and development of BB-76163, an aminopeptidase inhibitor, was discontinued after failing to show sufficient efficacy in pre-clinical models. In October 2002, the agreement was extended for a third year in order to optimize certain selective metalloenzyme inhibitors for potential clinical development.

Vertex Pharmaceuticals. In December 2000, we entered into a collaboration agreement with Vertex Pharmaceuticals pursuant to which we will collaborate to discover, develop and market caspase inhibitors. Caspase inhibitors are a class of compounds with the potential to treat serious neurological and inflammatory diseases. Vertex is a leader in the field of chemogenomics, which unites genomic information, structural biology and computational chemistry with other aspects of drug discovery. Under the terms of the agreement, we will provide certain research funding and we and Vertex will share development costs. We will form a joint venture with Vertex for the commercialization of caspase inhibitors in the United States and Canada, and we will have exclusive rights to market the products outside the United States and Canada, Japan and certain other countries in the Far East. In January 2002, Vertex announced that it had advanced a lead compound, VX-799, into preclinical development. We hold an option to develop and commercialize VX-799 in those countries where we have

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exclusive rights and, as part of a joint venture with Vertex, in the United States and Canada.

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Inpharmatica. In July 2001, we entered into an agreement with Inpharmatica Ltd, focused on the discovery of novel protein therapeutics. Inpharmatica's scientists predict protein function using sequence and structure relationships of proteins (structural bioinformatics), thereby providing a rational basis for the identification of novel drug targets. Under the terms of the agreement, we will provide research funding and we will have the right to select an unlimited number of proteins for clinical development and eventual commercialization. We also have the right to develop antibodies and small molecules against protein targets identified by Inpharmatica. In January 2003, we agreed to expand the size and scope of our collaboration to apply Inpharmatica's technology platform to additional protein families and proprietary genomic sequence data. Under the terms of this expansion, Inpharmatica will receive additional research funding and, as under the July 2001 agreement, milestone and royalty payments based on the development and sale of products arising from the collaboration.

ZymoGenetics. 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. 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.

Celera Genomics. In December 2001, we entered into a multi-year agreement with Celera Genomics to gain access to their genomic databases.

Cellular Genomics. In October 2002, we entered into a collaborative research agreement with Cellular Genomics. Under the terms of the agreement, Cellular Genomics will apply its chemical genetics technologies to four target kinases that we have selected and will map clinically important kinase signaling pathways. Protein kinases regulate critical pathways involved in cell growth, activation and death. They have been implicated in a number of diseases, including cancer and autoimmune/inflammatory diseases. Under the agreement, Cellular Genomics received an upfront fee and will receive a series of milestone payments over two years, and we have the right to acquire licenses to intellectual property arising from the collaboration.

Regeneron. In December 2002, we entered into an agreement with Regeneron Pharmaceuticals Inc. under which Regeneron will use its proprietary Velocigene Technology platform to provide us with knock-out and transgenic models of gene function. Under the terms of the agreement, we will pay Regeneron up to \$3 million annually for up to five years.

### DRUG DELIVERY

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,

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such as Rebif, Gonal-F, Saizen and Serostim, must be administered frequently and Saizen is used mostly for children, we believe that many of our potential customers would consider the ease of administration to be an important factor when selecting between our products and those of our competitors. As a result, we have set up our own drug delivery laboratory and have established major collaborations with specialist drug delivery companies on projects designed to improve the delivery of all of our major protein and peptide products.

Alkermes. In December 1999, we entered into an agreement with Alkermes for development of its ProLease drug delivery system for use with 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 one Phase I clinical trial in males and two additional Phase I clinical trials in females are ongoing with Gonal-F microencapsulated using the Alkermes delivery system. We have begun preparations for a Phase II study.

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### 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.

#### Reproductive Health

We are currently seeking registrations in additional countries of our two recombinant gonadotropins, Ovidrel and Luveris, and also are seeking additional registrations for a multi-dose formulation of Gonal-F in several countries. We have successfully completed one Phase I clinical trial in males and two additional Phase I clinical trials in females are ongoing with Gonal-F microencapsulated using the Alkermes delivery system. We have begun preparations for a Phase II study. In the first half of 2003, we expect to initiate a Phase II study with recombinant LIF protein, which is being developed to reduce embryo implantation failure.

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 the first quarter of 2003. 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.

#### Neurology

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. The comparative figure during the first 24 weeks was also 19% in favor of Rebif. 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



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superiority of Rebif 44 mcg 3 times per week over Avonex 30 mcg once per week in reducing exacerbations, were published in the November 2002 issue of Neurology.

In October 2002, we entered into a worldwide agreement with IVAX to develop and commercialize IVAX's product, 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 plan to work with IVAX to establish an oral formulation of cladribine and then initiate a Phase I clinical trial in 2003.

In December 2002, we announced that we had successfully completed a Phase I trial with IFNAR-2, the soluble receptor for Type I interferons, including Rebif. IFNAR-2 prolongs the half-life of interferon beta in the bloodstream, which could allow us to administer Rebif less frequently to patients, thereby significantly improving patient convenience and compliance.

In May 1999, we entered into an agreement with Axonyx Inc. to conduct preclinical development and trials of Axonyx's patented peptides identified by their platform peptide technology as showing potential to treat neuro-degenerative diseases, such as Alzheimer's Disease and prion-related diseases that are associated with accumulations of abnormal forms of proteins. Under the terms of the agreement Serono will have the exclusive right to license from Axonyx any drug candidates that emerge from this program, which could involve payments to Axonyx of up to \$22.5 million, plus royalties on sales of drugs resulting from the development project. In collaboration with Axonyx, we have identified a peptide inhibitor of amyloid plaque formation as a potential treatment for Alzheimer's disease. We initiated a Phase I clinical trial in this indication in March 2003.

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### Growth and Metabolism

In a double-blind, placebo-controlled trial in HARS/lipodystrophy, Serostim therapy significantly reduced visceral adipose tissue, truncal fat and dyslipidemia. We filed for Orphan Drug Status in this indication in the U.S. in February 2003.

In December 2002, we commenced Phase I clinical trials on pegylated growth hormone releasing factor, which has the potential to treat conditions related to growth hormone deficiency.

### OTHER PRODUCTS UNDER DEVELOPMENT

Interferon beta, human growth hormones and fertility hormones are natural proteins, several of which have multiple biological functions. As a consequence, some of our therapeutic proteins have the potential for beneficial effects in a variety of disease indications.

**Interferon beta.** We are conducting clinical trials with interferon beta-1a in a variety of diseases. Following early Phase II trials in Crohn's disease and ulcerative colitis we have entered expanded Phase II trials in these two inflammatory bowel diseases. We are also conducting a Phase III trial of interferon beta-1a for the treatment of Asian patients suffering from chronic hepatitis C.

**Human growth hormone.** In the fourth quarter of 2002, we submitted an application to the U.S. FDA for the use of human growth hormone to treat short bowel syndrome in patients who have had part of their bowel removed.

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Efalizumab. The human monoclonal antibody efalizumab, which we expect to begin marketing under the name Raptiva for psoriasis, may also be useful for treating psoriatic as well as rheumatoid arthritis. Phase II trials are currently being conducted in these indications.

TBP. A Phase II study of TBP-1 for the treatment of Crohn's disease is ongoing.

IL-6. Based on pre-clinical work, we are planning a Phase II study of r-IL-6 (atexakin alpha) in neuropathy.

### PRODUCTS AND PRODUCT PIPELINE

PRODUCT TYPE	TRADE NAME	INDICATIONS	STAT
Recombinant human follicle stimulating hormone (r-hFSH)	Gonal-F	Female infertility	Approved other co
	Gonal-F	Male infertility - hypogonadotropic hypogonadism	Approved other co
	Gonal-F	Multi-dose formulation	Approved and 19 o
	Gonal-F	Fill by mass formulation	Approved countrie
Microencapsulated r-FSH	*	To reduce the frequency of administration of r-hFSH	Phase I
Recombinant human luteinizing hormone (r-hLH)	Luveris	Severe FSH and LH deficiency	Approved other co
Recombinant human chorionic gonadotropin (r-hCG)	Ovidrel/Ovitrelle	Female infertility/ovulation Induction and use in assisted Reproductive technology	Approved 18 other
Cetrorelix (GnRH antagonist)	Cetrotide	Premature ovulation prevention	Approved other co
Progesterone gel	Crinone	Luteal phase support	Approved countrie other co
Anastrozole (aromatase inhibitor)	*	Ovulation induction and improvement of follicular development	Phase II
Recombinant human growth hormone (r-hGH)	Saizen	Growth hormone deficiency	Approved
	Saizen	Growth hormone deficiency in adults	Approved and 11 o
	Saizen	Growth failure due to Turner's syndrome	Approved

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PRODUCT TYPE	TRADE NAME	INDICATIONS	STAT
	Saizen	Growth failure associated with chronic renal failure	Approved
Recombinant human growth hormone (r-hGH) high dose	Serostim	AIDS wasting (cachexia)	Approved
	Serostim	HARS/Lipodystrophy	Phase II for Orph in U.S. Filed in
	*	Short bowel syndrome	
Recombinant human interferon1a (r-IFN- 1a)	Rebif	Relapsing or remitting multiple sclerosis	Approved and 80 o
	*	Multiple sclerosis	Approved
	*	Crohn's disease	Phase II
	*	Ulcerative colitis	Phase II
	*	Chronic hepatitis C in Asian patients	Phase II
Topoisomerase II inhibitor	Novantrone	Multiple sclerosis, certain cancers	Rights t approved
Efalizumab	Raptiva	Psoriasis	Filed in
	Raptiva	Psoriatic arthritis	countries
	Raptiva	Rheumatoid arthritis	Phase II Phase II
Onercept 1 (r-TBP-1)	*	Crohn's disease	Phase II
	*	Psoriasis	Phase II
Soluble type I interferon receptor (IFNAR-2)	*	To increase the half-life of r-IFN- 1a in multiple sclerosis	Phase I
Cladribine	*	Multiple sclerosis	Phase I
Emfilermin (r-LIF)	*	Embryo implantation failure	Phase II
Recombinant interleukin-18 binding protein (r-IL-18bp)	*	Rheumatoid arthritis	Phase I
	*	Crohn's disease	Phase I
	*	Psoriasis	Phase I
Pegylated GHRF	*	Conditions related to growth hormone deficiency	Phase I
Atexakin alpha (r-IL-6)	*	Neuropathy	Phase II
Breaker peptide	*	Alzheimer's disease	Phase I
JNK inhibitor	*	Multiple sclerosis	Preclini
	*	Inflammatory conditions	Preclini
Chemokine inhibitor	*	Multiple sclerosis	Preclini

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FSH-LH chimera	*	Female infertility	Preclinical
Oxytocin receptor antagonist	*	Pre-term labor	Preclinical
Prostanoid FP receptor antagonist	*	Pre-term labor	Preclinical
PTP1b inhibitor	*	Diabetes and obesity	Preclinical
TACI-Ig	*	Autoimmune conditions	Preclinical
Type 1 5-alpha reductase inhibitor	*	Acne	Phase I
Pegylated interferon beta	*	Anti-viral	Phase I
Iturelix nanospheres (GnRH antagonist)	*	Prostate cancer and BPH	Preclinical

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\* Trade name not yet determined

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### 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 1,700 people worldwide. Because we focus on niche 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.

### 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, health care professionals and couples 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.

We also have a number of ongoing initiatives that are designed to support access to infertility treatment. We have implemented BABIES, an infertility benefit assessment software program aimed at helping employers and health plans develop a cost-effective infertility benefit and manage it effectively with

guidelines for infertility treatment. In particular, we use this software in the U.S. in our discussions and negotiations with managed care providers. We also have an exclusive distribution agreement with CostDoctor, Inc. to make this activity-based costing software available to reproductive endocrinologists and fertility specialists in the U.S. The CostDoctor software can help medical practices control escalating costs, manage declining reimbursements, determine managed care contract value and increase practice productivity. 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.

#### 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, since October 2002, through a 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 strong ties to the MS prescribing community in the United States, as it already has an established neurology franchise. The dedicated sales forces of our two companies provide Rebif with significantly greater reach and frequency than our competitors in the United States.

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In the United States, the majority of MS prescriptions have historically been written by specialists. However, general neurologists and community-based neurologists are accounting for an increasing share of MS prescriptions. Our agreement with Pfizer allows us to contact a much larger proportion of this expanded prescriber base more frequently than we would have been able to contact acting alone. In addition, 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

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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.mslifelines.com](http://www.mslifelines.com) website. Through MS

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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 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.

### 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 are also developing new drug delivery devices for use in this market, where patient convenience is particularly important. In September 2000, we launched cool.click, a needle-free delivery system for Saizen, which is the first needle-free delivery system for human growth hormone in the United States and Canada. We launched cool.click in Europe in the third quarter of 2002 and are currently rolling it out worldwide. In the third quarter of 2001, we launched in Europe one.click, an autoinjector pen that enables the needle to be introduced automatically under the skin, significantly reducing the pain of injection.

#### 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. However, during 2002 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, investigations were initiated by both us and the relevant authorities 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 market in the product. 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

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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.

### MANUFACTURING

Our principal manufacturing facilities are located in Aubonne and Corsier-sur-Vevey, Switzerland; Bari, Italy; Tres Cantos, Spain; and Ness-Ziona, Israel. 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 have either 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 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

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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 ((R)) and the filed ((TM)) trademarks, Cetrotide(TM), click.easy(TM), cool.click(TM), Crinone(R), EasyJect(R), Ferti.net(R), Fertinex(R), Geref(R), Gonal-F(R), Luveris(R), Metrodin HP(R), Novantrone(TM), one.click(TM), Ovidrel(R), Ovitrelle(R), Pergonal(R), Profasi(R), Raptiva(TM), Rebif(R), Rebiject(R), Reliser(R), Saizen(R), SeroJet(TM), Serono(R), Serophene(R), Serostim(R) and Stilamin(R), as well as the filed trademarks ((TM)) 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.

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### 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 with respect to the following products:

- Avonex. We receive royalty payments from Biogen on its worldwide sales of Avonex under an agreement entered into in 1993.
- Puregon. In 1995, pursuant to a patent settlement agreement, we granted to Organon a non-exclusive license under certain patents relating to recombinant gonadotropin technology. In return we receive royalties on worldwide sales of Puregon.
- Enbrel. Pursuant to a patent settlement agreement signed in January 1999, we receive royalty payments from Amgen (formerly Immunex) on its sales of Enbrel. In addition, milestone payments have been paid under this agreement.
- Monoclonal Antibodies to TNF (Tumor Necrosis Factor). In July 2000, pursuant to a patent settlement agreement, we granted Centocor a non-exclusive patent license with respect to its monoclonal antibody product. In return, we received a one-time payment. We also granted Abbott Laboratories (formerly Knoll) a non-exclusive license under the same patents with respect to two products in development. In return, we are entitled to receive a license fee, milestone payments upon the occurrence of certain development events and royalties if the products are ever marketed. Abbott Laboratories recently received approval from the U.S. FDA to market one of these products, Humira (adalimumab). A Marketing Authorization Application to the European Agency for the Evaluation of Medicinal Products has been submitted for Humira.
- Roche. Since the third quarter of 2000, we 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



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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 already face increased competition from generic products.

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### DRUG DELIVERY SYSTEMS

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

### REPRODUCTIVE HEALTH

Our reproductive health products compete with Organon's recombinant FSH, Puregon, which is marketed as Follistim in the United States, and their urine-derived human menopausal gonadotropin product, Humegon. Our products also compete with generic 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

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urine-derived human menopausal gonadotropins, which are impure preparations of FSH and LH, including our own product Pergonal. 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.

### 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. During the second quarter of 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, which we believe provides us with a marketing advantage in the United States. Rebif also competes with Copaxone in the United States, Europe and certain other countries for the treatment of RRMS. A number of other companies are working to develop products to treat multiple sclerosis that may in the future compete with Rebif.

### GROWTH AND METABOLISM

#### Growth

Saizen competes with human growth hormone products produced by companies such as Eli Lilly, BioTechnology General, Novo Nordisk, Pharmacia 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 also offer patient-friendly delivery systems for their products.

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

We currently have orphan drug protection for Serostim in the United States, which means that competitors cannot sell human growth hormone in the United States for AIDS wasting indications until August 2003. After that date, our competitors may receive approval of applications for their products in the

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United States for that indication, unless we are able to distinguish Serostim from their products. 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, it competes with weight-promotion drugs that are used off-label in AIDS wasting, such as other appetite stimulants and anabolic steroids.

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### 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," which 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

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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.

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Manufacturers of drugs also are required to comply with current Good Manufacturing Practice regulations and similar regulations in the countries in which they operate, which 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 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 2002 totaled \$125.3 million (8.1% of revenues), compared to \$97.1 million (7.0% of revenues) in 2001 and \$67.1 million in 2000 (5.4% of revenues). 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.

In 2000, we placed into operation the Serono Biotech Center in Corsier-sur-Vevey, Switzerland, which is our newest biotech R&D and production

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facility. Since the beginning of 2000, we have incurred accumulated capital costs of \$46.2 million in connection with this facility.

In February 2001, we sold back to Chiesi Farmaceutici SpA the exclusive rights to market Curosurf, a porcine surfactant, throughout Europe for an undisclosed sum.

In the fourth quarter of 2001, we participated along with a large group of private and public Swiss investors, including some of the largest industrial and financial firms in Switzerland, in the refinancing of Crossair AG, a Swiss airline. During the fourth quarter of 2001, we purchased Crossair shares valued at approximately \$15.0 million. We made a cash payment of approximately \$4.5 million, which represented 30% of the purchase price for the investment. We paid the remaining 70% of the purchase price in March 2002 of approximately \$10.5 million. We own 1% of the share capital of Crossair, which has since been renamed Swiss International Air Lines Ltd.

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 will increase Serono France Holding S.A.'s stake in Genset S.A. to not less than 95.4%. Consequently, having acquired more than 95% of the share capital of Genset S.A., Serono France Holding S.A. expects to launch, in the course of 2003, a squeeze-out merger which will ultimately enable it to gain control of all of the outstanding equity securities of Genset S.A.

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### 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 43 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.

In 2003, we exercised an option to purchase the 40,000 square meter Secheron complex 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 purchased the complex for a total price of approximately \$34 million. We expect

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to complete work on the first phase of the project by the end of 2006 and to complete work on the second phase of the project by the end of 2008.

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. me
Geneva, Switzerland	Research and Development	Leased-Expires 2011	12,698 sq. me
Rockland, Massachusetts, U.S.A.	U.S. Headquarters	Leased-Expires 2016	200,000 sq.
Rome, Italy	Research and Development	Owned	4,424 sq. me
Rome, Italy	Research and Development	Leased-Expires 2009	1,260 sq. me
Rome, Italy	Italian Headquarters	Owned	10,212 sq. me
Ivrea, Italy	Research and Development	Leased-Expires 2010	2,736 sq. me
Evry, France	Research and Development	Leased-Expires 2005	13,696 sq. me
Corsier-sur-Vevey, Switzerland	Manufacturing	Owned	36,395 sq. me
Aubonne, Switzerland	Manufacturing	Owned	43,800 sq. me
Coinsins, Switzerland	Manufacturing	Owned	19,800 sq. me
Rome, Italy	Manufacturing, Research and Development	Owned	51,015 sq. me
Bari, Italy	Manufacturing	Owned	122,150 sq. me
Ness-Ziona, Israel	Manufacturing	Leased-Expires 2005	9,700 sq. me
Ness-Ziona, Israel	Manufacturing	Leased-Expires 2007	3,670 sq. me
Tres Cantos, Spain	Manufacturing	Owned	6,028 sq. me

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### ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

YOU SHOULD READ THE FOLLOWING OPERATING AND FINANCIAL REVIEW 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.

#### 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 U.S. GAAP. The preparation of financial statements in conformity with IFRS and the reconciliation under U.S. GAAP require us to make estimates and assumptions that affect the amounts we report in the financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates, including those related to reserves for fiscal and legal claims, sales returns, inventory obsolescence, bad debt reserves and the assessment of impairment of intangible assets and available-for-sale investments, income taxes, 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, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or

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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, nevertheless unsold products in the distribution channels can be exposed to rapid changes in market conditions or obsolescence due to new competitive environments, product updates or competing products. Accordingly, it is possible that these estimates will change in the near future or that the actual amounts could vary significantly from our estimates.

### INVENTORY PROVISION

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

### BAD 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

As described in note 1 to our consolidated financial statements, we evaluate the carrying value of our tangible and intangible assets for impairment whenever indicators of impairment exist. If we determine that such indicators are present, we prepare a discounted future net cash flow projection for the asset ("value in use"). In preparing this projection, we must make a number of assumptions and estimates concerning such things as future sales performance of our various products and the rates of increase in operating expenses over the remaining useful life of the asset. If calculation of value in use is in excess of the carrying value of the recorded asset, no impairment is recorded. In the event the carrying value of the asset exceeded the value in use, we would estimate the net selling price of the asset, and, where appropriate, we would use the assistance of an external valuation expert. If the carrying value also

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exceeds 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.

### 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

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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

We determine pension assets and liabilities on an actuarial basis. These are affected by the estimated market value of plan assets, estimates of the expected return on plan assets and discount rates. Actual changes in the fair market value of plan assets and differences between the actual return on plan assets and the expected return on plan assets will affect the amount of pension expense that we ultimately recognize.

### OVERVIEW

As the third largest biotechnology company in the world based on 2002 revenues, we are active in the research, development, production and marketing of products that address our three main therapeutic areas of reproductive health, neurology and growth and metabolism.

### TOTAL REVENUES

#### PRODUCT SALES

In 2002, four products accounted for 85.6% 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.

In addition to the main products highlighted above, we also sell a variety of other products in our three therapeutic areas, some of which we license in from third parties.

We also include in product sales contract service revenue from a contract research laboratory, Istituto di Ricerche Biomediche "Antoine Marxer" RBM, located in Ivrea, Italy, which offers a full range of services in toxicology and pharmacology to the pharmaceutical, chemical, cosmetic and food industries, and from Bourn Hall, a clinic located in Cambridge, England, which specializes in the treatment of infertility disorders. In 2002, this contract service revenue represented less than 1.0% of our total product sales (less than 1.3% in 2001 and less than 1.5% in 2000).



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### ROYALTY AND LICENSE INCOME

We currently receive ongoing royalties and fees under licensing agreements with Biogen for its sales of Avonex, Organon for its sales of Puregon, Amgen for its sales of Enbrel and Roche for its sales of Recormon and NeoRecormon. Our revenues from these agreements increase or decrease in proportion to our

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licensees' sales of their products. We derive license income from out-licensing certain products to third parties including, for example, Pfizer's co-promotion of Rebif in the United States. In addition, we also receive non-recurring amounts through patent settlements with third parties.

### OPERATING EXPENSES

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

### 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.

### SELLING, GENERAL AND ADMINISTRATIVE

Our selling, general and administrative expenses (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 maintain a marketing and sales force of approximately 1,700 employees in 2002 (1,650 employees in 2001) to sell or manage distribution of our products in over 100 countries. Our selling and marketing expenditures consist primarily of employee-related expenses and costs associated with congresses, exhibitions and advertising. When we introduce products into new markets, selling and marketing expenses typically increase because we hire additional sales personnel to undertake product launch.

**GENERAL AND ADMINISTRATIVE** We incur general and administrative expenses in maintaining our headquarters in Geneva and our operations in 45 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 (R&D) is one of our key functions, and we employ approximately 1,400 R&D personnel in 2002 (1,300 employees in 2001). 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

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Marxer" RBM in Italy and our corporate R&D organization.

In 2002, we acquired, through cash tender offer, Genset S.A., a genomics-based biotechnology company. The cash tender offer expired on October 31, 2002, resulting in an ownership of 91.8%. We continued to buy shares on the market and as of December 31, 2002, we held 92.47% of the share capital and voting rights of Genset S.A. We believe that the acquisition of Genset S.A., will create an excellent integrated genomics discovery platform to enhance our development pipeline of novel proteins and small molecules.

### OTHER OPERATING EXPENSE, NET

Our net other operating expense includes royalty and licensing expenses. We incur royalty and licensing expenses under agreements that we have with Yeda, the commercial arm of the Weizmann Institute in Israel, for royalties received from Biogen and Amgen and also for sales of Rebif, Columbia University for sales of Gonal-F, Roche for sales of Rebif, Berlex Laboratories Inc., the U.S. subsidiary of the Schering AG Group, for sales of Rebif only in the United States, and others for sales of certain other products. Our expenses under these licenses vary with the royalties received and the sales of the applicable products. Other operating expense, net also includes movements in litigation provisions, amortization of intangibles and other long-term assets, patent and trademark expenses and other non-recurring payments.

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### RESULTS OF OPERATIONS

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

Year ended December 31,					
	2002	% Change	2001	% Change	2000
(U.S. dollars in millions)					
<b>PRODUCT SALES BY REGION:</b>					
Europe . . . . .	\$ 620.4	14.4%	\$ 542.2	17.9%	\$ 460.1
North America . . . . .	479.6	22.8	390.6	(3.5)	404.9
Latin America . . . . .	109.2	(16.5)	130.9	15.2	113.6
Other regions . . . . .	213.9	15.2	185.7	10.3	168.4
	-----		-----		-----
Total product sales.	\$1,423.1	13.9%	\$1,249.4	8.9%	\$1,147.0
	=====		=====		=====

Year ended December 31,					
	2002	% Change	2001	% Change	2000
(U.S. dollars in millions)					
<b>PRODUCT SALES BY THERAPEUTIC AREA:</b>					
<b>REPRODUCTIVE HEALTH:</b>					
Gonal-F . . . . .	\$ 450.4	9.7%	\$ 410.5	12.2%	\$ 365.9
Metrodin HP . . . . .	50.1	(25.3)	67.1	(30.1)	96.1

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Pergonal . . . . .	46.0	20.7	38.1	(31.3)	55.4
Profasi. . . . .	19.8	(16.9)	23.8	2.2	23.3
Cetrotide. . . . .	18.4	73.6	10.6	1,568.1	0.6
Other products . . . . .	37.2	53.7	24.2	(52.5)	51.0
	-----		-----		-----
TOTAL. . . . .	\$ 621.9	8.3%	\$ 574.3	(3.0%)	\$ 592.3
NEUROLOGY:					
Rebif. . . . .	\$ 548.8	44.6%	\$ 379.6	49.3%	\$ 254.2
GROWTH AND METABOLISM:					
Saizen . . . . .	\$ 124.0	15.6%	\$ 107.3	19.2%	\$ 90.0
Serostim . . . . .	95.1	(24.1)	125.3	(8.6)	137.1
	-----		-----		-----
TOTAL . . . . .	\$ 219.1	(5.8%)	\$ 232.6	2.4%	\$ 227.1
Other products. . . . .	\$ 33.3	(47.0%)	\$ 62.9	(14.4%)	\$ 73.4
	-----		-----		-----
TOTAL PRODUCT SALES . . . . .	\$1,423.1	13.9%	\$1,249.4	8.9%	\$1,147.0
	=====		=====		=====
Recombinant products. . . . .	\$1,232.0	19.9%	\$1,027.4	20.9%	\$ 849.6
Non-recombinant products. . . . .	\$ 191.1	(13.9%)	\$ 222.0	(25.4%)	\$ 297.4

YEAR ENDED DECEMBER 31, 2002 COMPARED TO YEAR ENDED DECEMBER 31, 2001

TOTAL REVENUES

Our total revenues increased by 12.4% to \$1,546.5 million compared to \$1,376.5 million in 2001.

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PRODUCT SALES

Our consolidated worldwide product sales increased by 13.9% to \$1,423.1 million in 2002 from \$1,249.4 million in 2001. There was a favorable currency effect of \$29.6 million on product sales that was offset by a corresponding increase in operating expenses due to an adverse currency effect.

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.

REPRODUCTIVE HEALTH

Our reproductive health product sales increased by 8.3% 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

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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, we are now proceeding with the final closure of our production facilities for urine-derived products. As a result, we have 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 Rebif increased by 44.6% to \$548.8 million in 2002 from \$379.6 million in 2001. Following the FDA approval on March 7, 2002, Rebif was launched in the United States on March 11, 2002. During 2002, we announced an agreement with Pfizer to co-promote Rebif 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 was approximately 36%, compared with 36% at the end of 2001. Finally, we estimate that our dollar market share was about 5% in the United States for the whole of 2002.

### GROWTH AND METABOLISM

Our growth and metabolism product sales decreased by 5.8% 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.

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### OTHER PRODUCTS

Our sales of other products declined by 47.0% to \$33.3 million in 2002 from

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\$62.9 million in 2001. This decrease was primarily due to the discontinuation of Curosurf sales, lower sales of generics drugs in Latin America, and lower sales of Stilamin.

### 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 economical 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 urinary 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.

### ROYALTY AND LICENSE INCOME

	Year ended December 31,				
	2002	% Change	2001	% Change	2000
Royalty income	\$113.1	14.0%	\$ 99.2	27.0%	\$78.1
License income	10.3	(63.1)	27.9	91.1	14.6
	-----		-----		-----
TOTAL . .	\$123.4	(2.9%)	\$127.1	37.1%	\$92.7
	=====		=====		=====

Our revenues from royalty and license income decreased by 2.9% to \$123.4 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.

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Our license income decreased to \$10.3 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. The license income for 2002 reflected primarily the amortization of the deferred up-front payment from the co-promotion agreement with Pfizer for Rebif in the United States. We received an up-front payment of \$200 million from Pfizer, which has been recorded as deferred income and will be recognized as license income on a straight-line basis over the life of the agreement, which ends in 2013.

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### OPERATING EXPENSES

#### 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 product cost of 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 14.8% to \$512.9 million in 2002 from \$446.9 million in 2001. SG&A expenses represented 33.2% 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;
- 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
- Roll-out of new devices in the area of growth hormone deficiency (cool.click and one.click).

#### RESEARCH AND DEVELOPMENT, NET

	Year ended December 31,		
	2002	2001	2000
	-----	-----	-----
	(U.S. dollars in millions)		
R&D expense, gross. . . . .	\$358.3	308.8	263.4
Government grants . . . . .	(0.2)	(0.2)	(0.2)
	-----	-----	-----
R&D EXPENSE, NET. . . . .	\$358.1	\$308.6	\$263.2
	=====	=====	=====
R&D EXPENSE, NET AS A % OF REVENUES	23.2%	22.4%	21.2%

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Our net research and development expenses increased by 16.1% to \$358.1 million, or 23.2% of revenues, in 2002 from \$308.6 million, or 22.4% of revenues, in 2001. This increase in our research and development expenses was due to several factors:

- Our investment in strategic external collaborations. In 2002, we made significant progress in the area of business development with the achievement of agreements with leading biotechnology partners for late-stage and marketed products;
- The further development of our functional genomics and discovery activities with the integration of the genetic genomic capabilities of Genset S.A.; and
- 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:

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- 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
- 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:

- Our net royalty expenses increased to \$34.8 million in 2002 compared to \$22.9 million in 2001, in line with the increase in royalty income. In 2002, we reached an agreement with Berlex Laboratories Inc., the U.S. subsidiary of Schering AG, concerning patents No. 5 376 567, which relate 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;
- Amortization of intangibles and other long-term assets decreased to \$22.8 million in 2002 compared to \$31.6 million in 2001; and
- 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

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22.6% 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 20.7% of revenues, compared to 23.0% in 2001.

YEAR ENDED DECEMBER 31, 2001 COMPARED TO YEAR ENDED DECEMBER 31, 2000 TOTAL

### REVENUES

Our total revenues increased by 11.0% to \$1,376.5 million compared to \$1,239.7 million in 2000.

### PRODUCT SALES

Our consolidated worldwide product sales increased by 8.9% to \$1,249.4 million in 2001 from \$1,147.0 million in 2000. There was an adverse currency effect of \$30.5 million that was primarily due to the weakness of the Euro, Swedish Krone, Canadian Dollar, Japanese Yen and Australian Dollar against the U.S. Dollar. Our product sales were impacted by two major events during 2001:

- On April 4, we announced the voluntary recall of Crinone due to a drug application problem of the gel in some applicators. This decision was based on the recommendation of Columbia Laboratories Inc., the manufacturer of Crinone. Between April 4 and December 31 we incurred product returns from our wholesalers for a total of \$3.1 million, which were recorded in reduction of our product sales.

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Consequently, our sales of Crinone reached \$2.4 million in 2001 (net of product returns) compared to \$27.4 million in 2000; and

- On February 22, we signed a termination agreement with Chiesi Farmaceutici S.p.A., a pharmaceutical company with headquarters in Parma, Italy, bringing to an end the right for our company to use the trademark Curosurf and the right to use and employ the know-how related to this surfactant product. We initially obtained these rights from Chiesi in July 1991. This termination agreement was signed for an undisclosed amount, to be paid by Chiesi in several installments.

As a result of this agreement, we discontinued gradually our sales of Curosurf, which were brought to an end in December 2001. Our total Curosurf



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sales were \$10.4 million in 2001 compared to \$18.3 million in 2000. Excluding Crinone and Curosurf sales in 2001 and 2000, our product sales were \$1,236.6 million and \$1,101.3 million respectively, representing an increase of 12.3% year on year.

Our sales of recombinant products increased by 20.9% to \$1,027.4 million, or 82.2% of total product sales, in 2001 from \$849.6 million, or 74.1% of total product sales, in 2000. Our sales of urine-derived and other non-recombinant products decreased by 25.4% to \$222.0 million, or 17.8% of total product sales, in 2001 from \$297.4 million, or 25.9% of total product sales, in 2000. The changing sales mix reflects our strategy of focusing on biotechnology products, the transition from urine-derived products to recombinant products, and the voluntary recall of Crinone as discussed above.

### REPRODUCTIVE HEALTH

Our reproductive health product sales decreased by 3.0% to \$574.3 million in 2001 from \$592.3 million in 2000. Excluding the impact of the Crinone recall, our reproductive health product sales increased by 1.2%. Our sales of Gonal-F increased by 12.2% to \$410.5 million in 2001 from \$365.9 million in 2000. As a result of the continued switch to biotechnology products, our sales of Metrodin HP declined by 30.1% to \$67.1 million in 2001 from \$96.1 million in 2000. We expect that we will continue to gradually replace Metrodin HP with Gonal-F. Our sales of Pergonal declined by 31.3% to \$38.1 million in 2001 from \$55.4 million in 2000. Our sales of Cetrotide reached \$10.6 million in 2001 compared to \$0.6 million in 2000. We had purchased the marketing rights of this product from ASTA Medica in 2000 for an undisclosed amount.

### NEUROLOGY

Our sales of Rebif increased by 49.3% to \$379.6 million in 2001 from \$254.2 million in 2000. At the end of 2001, approximately 38,000 patients had been treated with Rebif, compared with approximately 28,000 at the end of 2000. Following FDA approval on March 7, 2002, Rebif was launched in the United States on March 11, 2002. Outside the United States, we estimate that our market share at the end of 2001 was approximately 36%, compared with 32% at the end of 2000.

### GROWTH AND METABOLISM

Our growth and metabolism product sales increased by 2.4% to \$232.6 million in 2001 from \$227.1 million in 2000. Our sales of Saizen increased by 19.2% to \$107.3 million in 2001 from \$90.0 million in 2000. This increase was due to higher demand in the United States, where we introduced the first needle free device, cool.click, and higher demand in Europe where we introduced an improved auto-injector, one.click. These results are net of sales return provisions of \$4.4 million for the year 2000 in respect of a dispute with a co-promoter in the United States. Excluding this adjustment, sales increased by 13.6% in the year.

Our sales of Serostim decreased by 8.6% to \$125.3 million in 2001 from \$137.1 million in 2000. Serostim sales declined as a result of tighter reimbursement and usage guidelines in key U.S. states.

### OTHER PRODUCTS

Our sales of other products declined by 14.4% to \$62.9 million in 2001 from \$73.4 million in 2000. This decrease was essentially due to the discontinuation of Curosurf sales, as discussed above, and the discontinuation of Ukidan sales during 2000.

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### EUROPE

Our total European product sales increased by 17.9% to \$542.2 million in 2001 from \$460.1 million in 2000. The increase was primarily due to the strong sales of Rebif throughout Europe and, to a lesser extent, increasing sales of reproductive health products and sales of Saizen.

### NORTH AMERICA

Our total North American product sales decreased by 3.5% to \$390.6 million in 2001 from \$404.9 million in 2000. This decrease was essentially due to the recall of Crinone and lower Serostim sales. Meanwhile our sales of Rebif in Canada continued to progress well. Adjusted for the recall of Crinone, like-for-like product sales in North America grew 2.0%.

In spite of the economic difficulties observed in some Latin American countries, notably Argentina, our total Latin American product sales increased by 15.2% in dollar terms, to \$130.9 million in 2001 from \$113.6 million in 2000. The increase was due primarily to the increased demand for Rebif and Gonal-F.

### OTHER REGIONS

In the Middle East, Africa and Eastern Europe regions, our product sales increased by 15.8% to \$84.1 million in 2001 from \$72.6 million in 2000, due primarily to the continued sales growth of Rebif, and also Gonal-F, in these markets. In the Asia-Pacific region, which excludes Japan, our product sales increased by 28.8% to \$54.4 million in 2001 from \$42.2 million in 2000, due largely to higher sales of Stilamin and Gonal-F, notably in China. In Japan, our product sales decreased by 22.5% to \$29.3 million in 2001 from \$37.9 million in 2000, due primarily to the weakening of the Japanese Yen, and lower demand for Saizen and Metrodin HP in the Japanese market. In Oceania, our product sales increased by 13.3% to \$17.9 million in 2001 from \$15.8 million in 2000, due primarily to the good progression of Rebif in Australia.

### ROYALTY AND LICENSE INCOME

	Year ended December 31,				
	2001	% Change	2000	% Change	1999
	(U.S. dollars in millions)				
Royalty income	\$ 99.2	27.0%	\$78.1	42.0%	\$55.0
License income	27.9	91.1	14.6	(37.6)	23.4
TOTAL . .	\$127.1	37.1%	\$92.7	18.2%	\$78.4
	=====		=====		=====

Our revenues from royalty and license income increased by 37.1% to \$127.1 million in 2001, compared to \$92.7 million in 2000. This increase was due to two factors:

- A non-disclosed license income arising from the payment from Chiesi in 2001 in respect of the termination of our agreement on Curosurf, as discussed above; and
- Higher royalty income from Biogen on its sales of Avonex, from Organon on its sales of Puregon and from Immunex on its sales of Enbrel.

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### OPERATING EXPENSES

#### COST OF PRODUCT SALES

Our cost of product sales decreased by 7.3% to \$213.2 million in 2001 from \$229.9 million in 2000. This decrease was due to increased production yields due to technical improvements in our biotechnology manufacturing processes and an increasing proportion of our product sales from higher margin recombinant products. As a result, our gross profit on product sales, which is product sales less product cost of sales, increased by 13.0% to \$1,036.2 million, or 82.9% of product sales in 2001 from \$917.1 million, or 80.0% of product sales in 2000.

#### SELLING, GENERAL AND ADMINISTRATIVE

Our SG&A expenses increased by 13.5% to \$446.9 million in 2001 from \$393.7 million in 2000. This increase was primarily due to higher product sales volumes, our marketing investment in the second half of 2001 in anticipation of

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a potential launch of Rebif in the United States in 2002 and selling and marketing expenses associated with the launch of three new recombinant products in the area of reproductive health (Ovidrel, Luveris and Gonal-F multidose). SG&A expenses represented 32.5% of revenues in 2001, compared to 31.8% in 2000.

#### RESEARCH AND DEVELOPMENT, NET

	Year ended December 31,		
	2001	2000	1999
	-----	-----	-----
	(U.S. dollars in millions)		
R&D expense, gross. . . . .	\$308.8	\$263.4	\$222.1
Government grants . . . . .	(0.2)	(0.2)	(0.5)
	-----	-----	-----
R&D EXPENSE, NET. . . . .	\$308.6	\$263.2	\$221.6
	=====	=====	=====
R&D EXPENSE, NET AS A % OF REVENUES	22.4%	21.2%	19.5%

Our net research and development expenses increased by 17.3% to \$308.6 million, or 22.4% of revenues, in 2001 from \$263.2 million, or 21.2% of revenues, in 2000. This increase in our research and development expenses was due to several factors:

- The continuation of the head-to-head trial between Rebif and Avonex (also known as the EVIDENCE study);
- Seven molecules entering the development process;
- Projects already in development progressing through the development pipeline; and
- The further development of our genomic activities.

#### OTHER OPERATING EXPENSE, NET

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Our net other operating expense was \$70.2 million in 2001, compared to \$31.1 million in 2000. This 125.2% increase was principally a recognition of an unrealized capital gain of \$27.2 million resulting from the acquisition of Signal Pharmaceuticals Inc. by Celgene Inc. At the end of 1997, we invested \$10.1 million in Signal Pharmaceuticals Inc. In return for this cash payment, we received 2,722,513 shares of series F preferred stock and 986,302 shares of series E preferred stock. During 2000, Celgene purchased Signal and, as a result of this transaction, Serono holds 466,198 shares in Celgene. This investment was valued at the Celgene stock price on the date of the acquisition agreement, of \$74, giving rise to an unrealized gain of \$27.2 million.

### OPERATING INCOME

Our operating income increased by 4.9% to \$337.7 million in 2001 from \$321.7 million in 2000. As a percentage of revenues, our operating income was 24.5% in 2001 compared to 26.0% in 2000.

### FINANCIAL INCOME, NET

Our net financial income decreased to \$51.4 million in 2001 from \$52.3 million in 2000. This decrease was due to several factors:

- We earned interest income on the proceeds of the capital raised in 2000 during an entire year as opposed to five months in 2000. However, interest rates on U.S. dollar deposits declined sharply throughout 2001;
- We recognized a net foreign currency loss of \$3.1 million on our 2001 results, arising from the devaluation of the Argentine Peso during the period from December 2001 to January 2002; and

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- We realized an exceptional gain of \$20.7 million in 2000 on our investment in an open-ended fund, prior to our sale of the investment in November 2000.

### TAXES

Our total taxes decreased by 0.8% to \$69.8 million in 2001 from \$70.4 million in 2000 due primarily to our manufacturing process improvements, as referred to above, which resulted in comparatively higher profit recognition in countries with more favorable tax jurisdictions. Our overall tax rate, including capital taxes, decreased to 18.1% in 2001 from 18.9% in 2000.

### NET INCOME

Our net income increased by 5.2% to \$316.7 million in 2001 from \$301.0 million in 2000. Our net income represented 23.0% of revenues, compared to 24.3% in 2000.

### LIQUIDITY AND CAPITAL RESOURCES

Our principal sources of liquidity have historically consisted of cash generated from operations and short-term and long-term borrowings. In 2000, we completed a global public offering of 1,070,670 bearer shares in the form of bearer shares and American depositary shares for gross proceeds of \$1,006.0 million and net proceeds of \$951.8 million. At December 31, 2002, we had net financial assets in the amount of \$1,615.9 million compared to \$1,453.8 million in 2001, an increase of 11.2%. The following table represents the components and the total amount of financial assets as of December 31, 2002, 2001 and 2000:

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FINANCIAL ASSETS

	As of December 31,		
	2002	2001	2000
	(U.S. dollars in millions)		
Cash and cash equivalents . . . . .	\$ 686.0	\$1,131.1	\$ 223.0
Short-term financial assets . . . . .	378.9	344.4	1,215.5
Long-term financial assets . . . . .	670.5	188.8	19.1
Bank advances . . . . .	(70.1)	(154.2)	(162.1)
Current and long-term portion of debt	(49.4)	(56.3)	(133.1)
	-----	-----	-----
NET FINANCIAL ASSETS . . . . .	\$1,615.9	\$1,453.8	\$1,162.4
	=====	=====	=====

At December 31, 2002, we had unused lines of credit for short-term financing of \$112.7 million (2001: \$94.1 million).

Our cash flows from operating activities are a significant ongoing source of funds to finance operations. Cash flows from operating activities increased by 31.4% to \$532.0 million in 2002 from \$405.0 million in 2001. This increase was primarily due to an increase in deferred income from the payment received from Pfizer on our co-promotion agreement for Rebif in the United States. Excluding net cash items, net working capital increased to \$287.1 million at December 31, 2002, from \$225.1 million at December 31, 2001.

Net cash used in investing activities was \$(700.6) million in 2002 compared to net cash flows from investing activities of \$648.3 million in 2001. Key movements were:

- The change in investment strategy from investment in short-term financial assets to long-term financial assets; and
- An increase in intangible assets due primarily to the acquisition of Genset S.A. in 2002.

As a result of the factors discussed above, our free cash flow, which is the cash provided from our operating activities plus the cash from our investing activities, decreased to \$(168.6) million in 2002 from \$1,053.3 million in 2001 and \$(749.3) million in 2000, as set forth below:

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	Year ended December 31,		
	2002	2001	2000
	(U.S. dollars in millions)		
FREE CASH FLOWS:			
Net cash flows from operating activities	\$ 532.0	\$ 405.0	\$ 255.4
Net cash flows from investing activities	(700.6)	648.3	(1,004.7)
	-----	-----	-----

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FREE CASH FLOW. . . . .	(\$168.6)	\$1,053.3	(\$749.3)
	=====	=====	=====

Net cash flows from financing activities decreased to \$(288.8) million in 2002 from \$(144.4) million in 2001. This decrease was due primarily to:

- Cash paid for shares under our share buy back program. On July 15, 2002 we announced a share buy back program for the repurchase of bearer shares up to CHF500 million over a three-year period. At the year-end, 226,507 shares had been purchased for an amount of CHF173 million or \$112.5 million. This amount represented 34.6% of the authorized amount; and
- The repayment of bank advances and long-term debt in the amount of \$112.1 million.

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

### CONTRACTUAL CASH OBLIGATIONS

Our future minimum non-cancelable contractual obligations at December 31, 2002 are described below:

TOTAL	Payments due by year				
	Less than 1 year	1-3 years	4-5 years	After 5 years	
-----					
(U.S. dollars in millions)					
Borrowings. . . . .	48.3	23.0	10.9	4.5	9.9
Lease - operating .	130.3	26.5	40.1	22.7	41.0
Lease - finance . .	1.1	0.5	0.6	0.0	0.0
Capital commitments	51.8	51.8	0.0	0.0	0.0

The capital commitments relate to construction costs and contractors' compensations for a building, which is expected to be completed before the end of 2003. Given the strength of our net financial assets, 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 30 to the consolidated financial statements. As part of these agreements 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 the collaborators were to achieve all the contractual milestones, we would be required to pay approximately \$200 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 \$67.5 million at December 31, 2002 (2001: \$97.3 million) have been pledged as security against long-term debt and certain unused long-term lines of credits.

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## INFLATION

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

## RECENT ACCOUNTING PRONOUNCEMENTS

You can find a discussion of recent accounting pronouncements related to IFRS and U.S. GAAP applicable to our company in note 34 to our consolidated financial statements. In addition, you can find a discussion of the potential impact of some IFRS exposure drafts published by the International Accounting Standards Board in note 1 to our consolidated financial statements that could have a material impact on our results.

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## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

## BOARD OF DIRECTORS

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

NAME	AGE (1)	POSITION
Georges Muller . .	63	Chairman
Ernesto Bertarelli	37	Vice-Chairman and Managing Director
Jacques Theurillat	44	Director
Pierre E. Douaze .	62	Director
Bernard Mach . . .	70	Director
Sergio Marchionne.	50	Director
Hans Thierstein. .	71	Director

(1) As of March 31, 2003

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 the past 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 Societe Generale de Surveillance, Chairman of the board of directors of "La Suisse" Assurances and Vice-Chairman of Bertarelli & Cie. He is a director of Banque du Gothard; Rentenanstalt-Swiss Life; Schindler Aufzuege AG; and Kedge Capital (Jersey). He participates on the boards of various foundations and associations, namely CVCI; Fondation pour la creation d'un musee des Beaux Arts, Lausanne (Chairman); ISREC Institut Suisse de Recherche Experimentale sur le Cancer (Chairman); Pro CICR; and World Arts Forum. He has worked at the Federal Tax Administration, Division of International Tax Law, in Berne, 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

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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 a director of Bertarelli & Cie, and a director of UBS AG, PHRMA, BIO, Interpharma and the Bertarelli Foundation. Mr. Bertarelli is the Vice-President of EBE (Emerging Biopharmaceutical Enterprises, an EFPIA specialized group). He is also a member of the Harvard Medical School Biological Chemistry and Molecular Pharmacology Advisory Council. He received a BS degree from Babson College in Boston, Massachusetts, and an MBA from Harvard Business School. Mr. Bertarelli is a Swiss national and resident.

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. Mr. Douaze received a MS degree from Federal Polytechnical School and an MBA from INSEAD Fountainebleau. Mr. Douaze is a French national and a resident of Switzerland.

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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 a Vice-Chairman of Lonza AG. Dr. Mach received an MD degree from the University of Geneva and did his internship and residency at the 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 a member of the board of directors of Societe Generale de Surveillance. From October 2000 until February 2002, Mr. Marchionne served as Chief Executive Officer of Lonza Group, which was spun-off from Alusuisse-Lonza in October 2000. Mr. Marchionne still



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serves as Vice-Chairman of the Lonza Group. Prior to that he worked at Alusuisse-Lonza Group in various capacities, including Chief Financial Officer, and from 1997 as Chief Executive Officer. Mr. Marchionne received an LLB from Osgoode Hall Law School in Toronto, Canada and an MBA from the University of Windsor, Canada. He is a barrister and solicitor and a Chartered Accountant. Mr. Marchionne is a Canadian national and 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. Mr. Thierstein is a director of Temtrade S.A. Mr. Thierstein is a Swiss national and resident.

### EXECUTIVE OFFICERS

NAME	AGE (1)	POSITION
Ernesto Bertarelli	37	Chief Executive Officer
Jacques Theurillat	44	Deputy Chief Executive Officer; President of European and International Sales and Marketing
Roland Baumann . .	57	Senior Executive Vice President, Head of the CEO Office and Strategic Planning
Leon Bushara . . .	36	Senior Executive Vice President, Business Development
Giampiero De Luca .	48	Chief Intellectual Property Counsel
Fereydoun Firouz .	39	President, Serono, Inc.
Nathalie Joannes .	42	General Counsel
Franck Latrille . .	46	Senior Executive Vice-President, Global Product Development
Francois Naef . . .	40	Senior Executive Vice-President, Human Resources
Paola Ricci . . . .	44	Senior Executive Vice-President, Worldwide Regulatory Affairs and Quality Assurance
Allan L. Shaw . . .	39	Chief Financial Officer
Timothy Wells . . .	41	Senior Executive Vice President, Research

(1) As of March 31, 2003

Roland Baumann is our Senior Executive Vice President, Head of the CEO Office and Strategic Planning. Prior to his appointment to this position in March 2003, he was our Senior Vice President, Head of Strategic Business Planning and Corporate Administration. Before his appointment to that position in March 2000, Mr. Baumann worked for us in positions of increasing responsibility related to finance, information systems, internal audit and strategic business planning since 1991. Before joining us, Mr. Baumann was a senior vice president with La Suisse Assurance, where he was the head of process engineering and accounting and finance services. Mr. Baumann holds a degree in economics and business administration from the Ecole Superieure pour l'Economie et l'Administration in Basel.

Leon Bushara is our Senior Executive Vice President, Business Development. Prior to his appointment to this position in March 2003, he served as our Vice President of 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 cafes and restaurants in New York City from 1988 until 1993. Mr. Bushara holds a BA degree from Brown University.

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 since 1988. Prior to joining us, Mr. De Luca worked as a patent examiner at the European Patent Office, where he focused on patents related to genetic engineering. Mr. De Luca holds a doctoral degree in industrial chemistry from the University of Milan and a diploma from the Institut Pasteur in general microbiology. He is a chartered European patent attorney.

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 since 1991 and in our government affairs office in Washington, D.C. from 1989 to 1991. Mr. Firouz holds a BS degree from George Washington University.

Nathalie Joannes has been our General Counsel since May 2001. Prior to joining us, Ms. Joannes was assistant general counsel of Pharmacia Corporation and of one of its predecessor companies, Monsanto Company, from 1996 to 2001. From 1989 to 1996, she held positions of increasing responsibility in Monsanto's legal department. Ms. Joannes holds a law degree from the University of Liege and an LLM from the University of Pennsylvania. She is a member of the New York bar.

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

Francois Naef is our Senior Executive Vice-President, Human Resources. Prior to his appointment to this position in February 2001, Mr. Naef had served as our General Counsel since November 1999 and had worked in positions of increasing responsibility in our legal department since 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 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.

Paola Ricci is our Senior Executive Vice-President, Worldwide Regulatory Affairs and Quality Assurance. Prior to her appointment to her current position in October 2000, Ms. Ricci was responsible for our corporate regulatory affairs.

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She joined us in 1978 and has worked in positions of increasing responsibility in the research and development organization since that time. Ms. Ricci holds a modern languages degree from the International School of Modern Languages in Rome, Italy.

Allan L. Shaw has been our Chief Financial Officer since November 11, 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 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.

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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, a MA degree in natural sciences from the University of Cambridge and is a fellow of the Royal Society of Chemistry.

### COMPENSATION

During the year ended December 31, 2002, we paid our directors and executive officers as a group, for services in all capacities, \$8.7 million. Of this amount, we paid \$2.8 million 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, 2002, we set aside or accrued approximately \$180,978 to provide pension, retirement or similar benefits for our executive officers. During the year ended December 31, 2002, we also granted to our directors and executive officers options to purchase 8,600 and 1,500 bearer shares at exercise prices of CHF 1,434 and CHF 810, respectively, expiring on April 1, 2012 and November 11, 2012, respectively. During the year ended December 31, 2002, we paid our most highly compensated director a total of \$2,867,123, which includes the tax value of stock options granted during the year calculated based on the Black-Scholes option pricing model (inclusive of honoraria, salary, credits, bonuses and benefits of every kind valued according to market value at the time they were conferred).

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 Douaze and Hans Thierstein, all non-executive directors. These directors have sufficient financial and compliance experience and ability to enable them to discharge their responsibilities as members of the Audit Committee. In discharging its oversight role, the Audit Committee is empowered to investigate any matter relating to our accounting, auditing, internal control, or financial reporting practices brought to its attention, with full access to all of our books, records, facilities and personnel.

The Audit Committee has the following responsibilities:

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- 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);
- Assure that the independence of the independent auditors is maintained;
- Review with the independent auditors any questions, comments or suggestions they may have regarding the internal control, accounting practices and procedures of the company and its subsidiaries;
- Review and oversee the internal audit activities, including discussing with management and the internal auditors the internal audit function's organization, objectivity, responsibilities, plans, results, budgets and staffing;
- Discuss with management, the internal auditors and the independent auditors the quality and adequacy of the compliance with the company's internal controls;
- Receive summaries of the audit reports issued by the internal audit department;
- Review with management and the independent auditors the annual audited financial statements of the company and the quarterly financial statements and any material changes in the accounting principles or practices used in preparing the statements prior to publication and the filing of reports with the Swiss Stock 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;

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- 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; and
- Set the compensation of the independent auditors and approve all non-audited related engagements performed by the independent auditors.

### COMPENSATION COMMITTEE

In 2001, the Board of Directors also established a Compensation Committee, which consisted as of December 31, 2002, of Georges Muller, Pierre Douaze and

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Sergio Marchionne, all non-executive directors. Since December 31, 2002, Hans Thierstein, who is a non-executive director, has replaced Mr. Muller on the Compensation Committee. The Compensation Committee ensures that our senior executives are compensated in a manner consistent with our stated compensation strategy, internal equity considerations, competitive practice, and applicable legal requirements.

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

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

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

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

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

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

The Compensation Committee is also responsible to:

- Approve our Stock Option Plan and any modification thereof;
- Approve the number of options which are granted to the Chief Executive Officer; and
- Approve the global number of options that the Chief Executive Officer is authorized to distribute to senior management during the year.

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

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

The Compensation Committee reports to the Board on its activities at least

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once in each calendar year. Its Chairman is responsible to summon meetings, prepare the agenda and ensure 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, 2002, 2001 and 2000, respectively, we had 4,694, 4,501 and 4,268 employees, of whom approximately 1,160, 1,300 and 1,200, respectively, were engaged in research and development, approximately 1,690, 1,300 and 1,200, respectively, were engaged in sales and marketing, approximately 1,465, 1,200 and 1,300, respectively, were engaged in manufacturing and approximately 380, 700 and 500 were engaged in other areas such as finance, information technology and human resources. As of December 31, 2002, 2001 and 2000, respectively, we had approximately 2,900, 2,900 and 2,700 employees in Europe, approximately 655, 600 and 500 employees in North America, approximately 300, 300 and 400 employees in Latin America and approximately 840, 700 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.

### SHARE OWNERSHIP

As of December 31, 2002, Bertarelli & Cie, a partnership limited by shares with its principal offices at Cheserex (Vaud), Switzerland, held 52.38% of our capital and 61.52% of our voting rights. Ernesto Bertarelli, our Chief Executive Officer, Vice-Chairman and Managing Director, controls Bertarelli & Cie.

As of December 31, 2002, there were 11,446,444 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	4,746,800	41.5	65.5
Roland Baumann . . . . .	0	0	*	*	*
Leon Bushara . . . . .	0	0	*	*	*
Giampiero De Luca . . . . .	0	0	*	*	*
Pierre E. Douaze . . . . .	0	0	*	*	*
Fereydoun Firouz . . . . .	0	0	*	*	*
Nathalie Joannes . . . . .	0	0	*	*	*
Franck Latrille . . . . .	0	0	*	*	*
Bernard Mach . . . . .	0	0	*	*	*
Sergio Marchionne . . . . .	0	0	*	*	*
Georges Muller . . . . .	0	0	*	*	*
Francois Naef . . . . .	0	0	*	*	*
Paola Ricci . . . . .	0	0	*	*	*
Allan L. Shaw . . . . .	0	0	*	*	*
Jacques Theurillat . . . . .	0	0	*	*	*
Hans Thierstein . . . . .	0	0	*	*	*
Timothy Wells . . . . .	0	0	*	*	*

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All directors and executive officers as a group

(17 persons) (1) (2) . . . 9,973,200                      90.6    4,755,480                      41.5                      65.5

\* Less than one percent.

- (1) Includes all registered shares and bearer shares reported by Bertarelli & Cie. Ernesto Bertarelli controls Bertarelli & Cie. Includes 3,350 bearer shares that we may issue to Mr. Bertarelli upon the exercise of stock options.
- (2) Includes 10,028 bearer shares that we may issue if our directors and current executive officers exercise stock options. As of December 31, 2002, our directors and current executive officers held a total of 40,075 stock options, which have the following exercise prices and expiration dates:

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### 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
2,420	546.25	April 1, 2008
3,115	546.00	April 1, 2009
6,400	512.50	June 10, 2009
3,770	1,520.50	April 1, 2010
3,200	1,397.50	May 16, 2010
8,850	1,346.00	April 1, 2011
9,500	1,434.00	April 1, 2012
1,500	810.00	November 11, 2012

### 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 19,535 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, 2002, the total nominal capital authorized for the grant of options to employees and directors under our option plans, as adjusted for the exercise of 4,159 options under our Stock Option Plan and purchase of 14,511 shares under our Employee Share Purchase Plan from January 1, 2002 to and including December 31, 2002, consisted of CHF 9,474,150, corresponding to 378,966 bearer shares

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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 now, the option price for our ADSs has been set based on the price of the underlying bearer share at the date of the grant. In the future, the option price of our ADSs will be set based on the fair market value of our ADSs on the New York Stock Exchange at the date of the grant. In 1998, we granted 26,120 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. Of these options, options for 19,535 bearer shares have been exercised, options for 27,440 bearer shares have been cancelled and are available for re-grant under the plan, and options for 209,455 bearer shares remain outstanding.

In addition to the options we have granted to employees under our stock option plan, we have made a single grant of options to each of our directors, and we expect that we will make additional option grants to directors when their current grants have vested in full. 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.

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 158,591 bearer shares.

A compensation charge in the amount of \$1.0 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.

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### EMPLOYEE SHARE PURCHASE PLAN

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

A participant may contribute up to 15% of his or her salary through payroll



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

On January 3, 2002, January 18, 2002 and November 19, 2002, we issued 14,500, 10 and 1 bearer shares, respectively, under this plan. On January 3, 2003 and January 27, 2003, we issued 23,181 and 18 bearer shares, respectively, 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.

### 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 issued 4,208 additional shares pursuant to the plan. For the second plan year, which ended on December 31, 2002, for every three shares purchased in the Employee Share Purchase Plan on January 3, 2003 that are still held by an employee on December 31, 2003, we will issue 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, 2002, Bertarelli & Cie, a partnership limited by shares with its principal offices at Cheserex (Vaud), Switzerland, held 52.38% of our capital and 61.52% 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 Spaeth owned in the aggregate 7.13% of our capital and 9.91% of our voting rights. Our registered shares and our bearer shares are each entitled to one vote per share.

As of December 31, 2002, there were 11,446,444 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
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Bertarelli & Cie (1) . . . .	9,189,300	83.4	4,626,930	40.4	61.5
Ernesto Bertarelli (2) . . .	9,973,200	90.6	4,746,800	41.5	65.5
Maria-Iris Bertarelli (3). .	255,940	2.3	154,000	1.3	1.8
Donata Bertarelli Spaeth (3).	783,900	7.1	130,520	1.1	4.1

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- (1) Bertarelli & Cie is a partnership limited by shares with its principal offices in Cheserex (Vaud), Switzerland.
- (2) Includes all registered shares and bearer shares reported by Bertarelli & Cie. Ernesto Bertarelli controls Bertarelli & Cie. Includes 3,350 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.

During 1999 and 2000, Bertarelli & Cie and members of the Bertarelli family sold an aggregate of 2,014,110 bearer shares in a private placement and two global share offerings. As a result of these sales, Bertarelli & Cie reduced its holdings from approximately 59.9% of the capital and 67.1% of the voting rights to approximately 51.7% of the capital and 60.9% of the voting rights, and members of the Bertarelli family reduced their aggregate holdings from approximately 10.8% of the capital and 12.6% of the voting rights to approximately 7.0% of the capital and approximately 9.8% of the voting rights.

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 depository 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 depository for the ADS program, there were 47 holders of record of our ADSs in the United States as of February 28, 2003. We believe that approximately 12.4% 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 2002, 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 2002, we paid market-rate rental fees for the jet totaling approximately \$2.0 million.

In 2002, we continued to lease 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 market rate rent of approximately \$849,000 per year. Subsequent to the negotiation of the lease, Mr. Bertarelli acquired a controlling interest in the company that owns the building. During 2002, we subleased a portion of the building to another company controlled by Mr. Bertarelli for a market-rate rent of approximately \$227,000 per year.

In 2002, we provided funding in the amount of \$223,000 to the Bertarelli Foundation, which is a not-for-profit organization formed to promote and improve the understanding of the many dimensions of infertility and to mobilize the resources necessary for effective treatment. Mr. Bertarelli is a director of this foundation.

In 2002, we paid consulting fees to a company that is controlled by Mr. Bertarelli, in the amount of approximately \$154,000, to advise us on our real estate strategy.

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In the course of 1999, we made a loan of CHF 325,600 (approximately \$195,000) to one of our executive officers. The interest rate of the loan is calculated on the basis of LIBOR and is updated on a yearly basis. Fifty percent (50%) of the loan is repaid via monthly installments over a period ending May 2010 and, as of December 31, 2002, the outstanding amount of this portion of the loan was equivalent to CHF 134,540 (approximately \$97,000). The remaining 50% of the loan, of which on December 31, 2002 CHF 162,800 (approximately \$97,500) was outstanding, is payable in May 2010.

On May 21, 2002, we made a loan of CHF 600,000 (approximately \$433,000) to one of our executive officers. The interest rate of the loan is fixed at 3%. The loan is to be reimbursed in three equal annual installments plus interest over a period ending April 2005. As of December 31, 2002, the full amount of the loan was outstanding.

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, 2002 were \$2.0 million (2001:\$1.7 million). As of December 31, 2002, we had \$186,000 (2001:nil) payable to Cansera.

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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-51.

#### LEGAL PROCEEDINGS

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

Interpharm Laboratories and others of our subsidiaries are defendants in a lawsuit, filed by the Israel Bio-Engineering Project Limited Partnership, or IBEP, in 1993 in the District Court of Tel Aviv-Jaffa, Israel, concerning certain proprietary rights and royalty rights and other claims of IBEP arising out of funding provided for the development of recombinant human interferon beta as well as certain other products in the early to mid-1980s. In the spring of 2002, following the failure of mediation efforts, the court ordered the trial of certain preliminary issues, including ownership and contractual issues, which are to be tried before the financial issues are heard. The trial of the preliminary issues has reached the evidence stage, which is expected to continue through 2003.

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

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default in the execution of the agreement and claiming monetary damages. The most recent hearing before the arbitral tribunal was held on February 19, 2002, and the parties have been asked to exchange new briefs.

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 Metrodin HP 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. At the pre-trial hearing held on October 5, 2000, the court appointed the court's technical expert to prepare and submit expert testimony as to the validity or nullity of the patent in question and whether IBSA's processes infringe the patent. On August 13, 2001, the court's technical expert submitted his expert testimony, in which he concluded that the patent is valid. The technical expert left open the matter of infringement. The court has scheduled the final pre-trial hearing for October 2002 and, in accordance with usual practice in Italy, we expect that the final hearing will be held in the first quarter of 2003. In 1999, IBSA also filed an administrative action to challenge the validity of our German patent before the German patent office. A hearing took place in November 2000. The patent has been maintained in amended form. IBSA has appealed this decision. In the United States, where the previous request for re-examination had been rejected, a new request was filed on February 27, 2001. Although we cannot predict with any certainty the outcomes of these claims, legal proceedings and other matters, we do not believe, based upon the nature of the claims made and the information available to date to us and our counsel through investigation or otherwise, that any liability from the resolution of any such claim or proceeding would have a material adverse effect on our financial condition, results of operations or cash flows. However, were an unfavorable ruling to be made in any fiscal period, a possibility exists there would be a material impact on our net income for that period.

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,

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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. However, it is not possible to predict the outcome of the investigation.

On March 8, 2002, our U.S. subsidiary, Serono, Inc., filed a declaratory judgment action in U.S. District Court in Boston against Berlex Laboratories to prevent Berlex, a unit of Schering AG, from challenging our patent on Rebif. We filed the declaratory judgment action based upon representations made by Berlex in 1996 that it would file a patent infringement lawsuit upon our introduction of Rebif into the U.S. market. We reached a settlement with Berlex in this matter, pursuant to which we received a non-exclusive license to import, manufacture and sell Rebif in the United States in exchange for paying royalties to Berlex and a one-time licensing fee.

DIVIDENDS AND DIVIDEND POLICY

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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.

	2002(1)	2001	2000	1999(2)	1998
Declared dividend per bearer share (CHF) . .	7.00	6.25	6.00	2.00	2.00
Declared dividend per bearer share (US\$) . .	4.52	3.69	3.55	1.32	1.38
Declared dividend per ADS (US\$) (3) . . . . .	0.11	0.09	0.09	-	-
Declared dividend per registered share (CHF)	2.80	2.50	2.40	0.80	0.80
Declared dividend per registered share (US\$)	1.81	1.48	1.42	0.53	0.55

- 
- (1) Our dividend for the 2002 fiscal year will not be declared and paid until our annual general meeting on May 6, 2003.
- (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 Depositary in converting dividends from Swiss francs to U.S. dollars and on the expenses of the Depositary.

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

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

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

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

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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

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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.

### ITEM 9. THE OFFER AND LISTING

#### MARKET PRICES OF BEARER SHARES AND ADSS

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

PERIOD	SWX SWISS EXCHANGE OR VIRT-X		NYSE PER ADS	
	PER BEARER SHARE			
	HIGH	LOW	HIGH	LOW
	(CHF)		(US\$)	
1998 . . . . .	650	421		
1999 . . . . .	875	483		
2000(1) . . . . .	2,160	801	31.94	20.81
2001 . . . . .	1,820	1,100	25.50	16.85
First Quarter . . . . .	1,570	1,132	24.06	16.85
Second Quarter . . . . .	1,810	1,306	25.50	19.25
Third Quarter . . . . .	1,820	1,100	25.24	17.62
Fourth Quarter . . . . .	1,527	1,195	23.24	18.26
2002 . . . . .	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
October . . . . .	866	627	14.83	10.65
November . . . . .	894	798	15.00	13.62
December . . . . .	893	725	14.45	12.80
2003 . . . . .				
First Quarter . . . . .	800	562	14.35	10.58
January . . . . .	800	645	14.35	12.11
February . . . . .	698	575	12.67	10.60

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March . . . . . 689 562 12.15 10.58

(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 societe 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 20, 2003. 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."

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#### 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.

##### REGISTERED SHARES

The transfer of registered shares is subject to approval by our board of directors or the executive committee of our board of directors. The board of directors 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 board of directors 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 board of directors 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 board of directors 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

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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 our board of directors or the executive committee of the 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.

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

- changes in our purpose;
- the creation of shares with privileged voting rights;
- the restriction of the transferability of registered shares;
- an authorized or conditional increase in share capital;
- an increase in share capital by way of transformation of reserves, against contribution in kind, for the acquisition of assets or involving the grant of special benefits;
- the restriction or elimination of preemptive rights of shareholders;
- a transfer of our registered office; or



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- 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

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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:

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

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

### NOTICES

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

### DURATION AND LIQUIDATION

Our Articles of Association do not limit our duration.

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

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

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

### NOTIFICATION OF SHARE INTERESTS

Under the Swiss Stock Exchange Act, shareholders, or shareholder groups acting in concert, who acquire or dispose of shares and thereby reach, exceed or fall below the respective threshold of 5%, 10%, 20%, 33 1/3%, 50% or 66 1/2% of the voting rights of a Swiss listed corporation must notify the corporation and the stock exchange on which such shares are listed of the acquisition or disposition in writing within four business days, whether or not the voting rights can be exercised. However, the sale of shares acquired prior to January 1, 1998 was not subject to this reporting duty if the sale occurred before January 1, 2001. Following receipt of such notification, a corporation must inform the public.

In addition, under Swiss company law we must disclose the identity of all

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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.

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### 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, 2002, the Bertarelli family controlled approximately 71.4% of the outstanding voting power. As a result, no third party can take over our company without the approval of the Bertarelli family.

### 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

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a general meeting of shareholders by an absolute majority of the shares represented at the meeting in person or by proxy. A majority of two-thirds of the shares represented in person or by proxy and the absolute majority of the nominal value of the shares represented is required:

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

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

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

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

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### EXCHANGE CONTROLS AND OTHER LIMITATIONS AFFECTING SHAREHOLDERS

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

### TAXATION

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

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

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

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

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

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:

- is a resident of the United States for purposes of the Treaty;
- does not maintain a permanent establishment or fixed base in Switzerland to which bearer shares or ADSs are attributable and through which the beneficial owner carries on or has carried on business (or, in the case of an individual, performs or has performed independent personal services); and
- who is not otherwise ineligible for benefits under the Treaty with respect to income and gain derived in connection with the bearer shares or ADSs.

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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

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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 Depositary 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

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obtained from any Swiss Consulate General in the United States or from the Swiss Federal Tax Administration at the address above. The form must be filled out in triplicate with each copy duly completed and signed before a notary public in the United States. The form must be accompanied by evidence of the deduction of Withholding Tax withheld at the source. We will provide this information on request.

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### STAMP DUTIES UPON TRANSFERS OF SECURITIES (UMSATZABGABE)

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

### UNITED STATES FEDERAL INCOME TAXATION

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

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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.

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### 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 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 was "passive income" or (2) at least 50% of the value (determined on the basis of a quarterly average) of our assets was 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 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 30%. 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



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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 exchange, interest rates and the market value of our investment in financial assets. These exposures are actively managed by the Serono group treasury in accordance with a written treasury policy approved by the Board of Directors and subject to internal controls. To minimize earnings or cash flow volatility relating to these exposures, to protect the yield on the investment of liquid funds, and to manage the cost of our debt, we use a variety of derivative financial instruments. We do not use financial derivatives for speculative reasons or 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.

#### EXCHANGE RATE EXPOSURE

##### CURRENCY RISK MANAGEMENT

As a consequence of the global nature of our businesses, our operations and reported financial results and cash flows are exposed to the risks associated with fluctuations in the exchange rates between the major world currencies. Our transactional currency risk exposure occurs on revenues and expenses that are generated in currencies other than the U.S. dollar. The following table provides information about our product sales and operating expenses (comprising SG&A and R&D) by major currencies for 2002, 2001 and 2000:

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	Year ended December 31		
	2002	2001	2000
<b>PRODUCT SALES</b>			
In U.S. dollar . . . . .	46.0%	46.0%	50.0%
In Euro. . . . .	37.0	35.0	32.0
In other currencies. . . . .	17.0	19.0	18.0
	-----	-----	-----
<b>TOTAL . . . . .</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>
	=====	=====	=====

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OPERATING EXPENSES (SG&A AND R&D)			
In U.S. dollar . . . . .	34.0%	38.0	36.0%
In Swiss franc . . . . .	30.0	32.0	32.0
In Euro. . . . .	27.0	19.0	21.0
In other currencies. . . . .	9.0	11.0	11.0
	-----	-----	-----
TOTAL . . . . .	100.0%	100.0%	100.0%
	=====	=====	=====

The primary purpose of our currency exchange risk management is to achieve stable and predictable cash flows. Consequently, we use various financial derivatives that change in value as foreign exchange rates change, to preserve the value of assets, commitments and anticipated transactions. Our current policy is to enter into forward foreign exchange contracts and currency options to cover the currency risk associated with existing assets, liabilities and other contractually agreed transactions, as well as a portion of the currency risk associated with transactions that we anticipate conducting within the following six months. We report our results in U.S. dollars but we have significant revenues and expenses in currencies other than the U.S. dollar. The impact of a movement in the U.S. dollar against the Euro and the Swiss franc is limited by the natural hedging effect of those non-U.S. dollar expenses. The maturity dates of our forward contracts and currency options do not currently exceed eight months. At December 31, 2002 and 2001, we had entered into forward foreign exchange contracts and currency options with a nominal face value of \$1,188.0 million and \$585.6 million, respectively. At December 31, 2002, the fair value of our open derivative instruments for managing our foreign exchange exposures was negative \$1.8 million, compared to a positive value of \$5.4 million at December 31, 2001. The fair value represents the market value if the instruments were closed out at year-end, based on available market prices. We use financial instruments that are contracted with banks, which in most cases have credit ratings of A or better, and that have a maximum maturity of eight months.

The currencies in which our derivative financial instruments are denominated match those in which we have transaction or translation risk. We pursue a risk-averse approach to foreign exchange risk management with the intention to minimize the impact of short-term movements in exchange rates on our cash flows.

The following table provides information about our significant derivative financial instruments that are sensitive to fluctuations in foreign currency exchange rates, as of December 31, 2002:

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	Forward foreign exchange		Foreign currency options	
	Nominal amount	Fair value at Dec 31, 2002	Nominal amount	Fair value at Dec 31, 2002
	-----	-----	-----	-----
	(U.S. dollar equivalents in thousands)			
1. U.S. DOLLAR AGAINST				
Swiss franc	109,586	(1,754)	-	-
Canadian dollar	2,154	(37)	-	-
British pound	15,927	(155)	-	-

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Euro	395,522	(4,562)	186,860	154
Japanese yen	2,530	(54)	-	-
Australian dollar	1,129	1	-	-
Israeli shekel	10,836	177	-	-
Danish krone	1,130	(39)	-	-
Mexican peso	1,959	45	-	-
Bolivar	1,691	(191)	-	-
Swedish krona	1,354	(1)	-	-
2. SWISS FRANC AGAINST				
Canadian dollar	5,069	461	36,049	1,553
Australian dollar	2,539	107	13,502	299
British pound	4,505	69	-	-
Japanese yen	675	26	5,575	239
Euro	47,643	307	310,292	1,544
Swedish krona	3,081	39	12,097	130
Danish krone	10,712	(11)	-	-
Norwegian krone	5,614	(170)	-	-
TOTALS	----- 623,656 =====	----- (5,742) =====	----- 564,375 =====	----- 3,919 =====

### EXCHANGE RATE SENSITIVITY

During 2002, the U.S. dollar weakened against most major currencies including the Swiss franc and the Euro. The Swiss franc is the most significant source of our non-U.S. dollar denominated expenses. The Euro is a significant source of our non-U.S. dollar denominated revenues. A weaker dollar increases the value of sales denominated in currencies other than the U.S. dollar such as the Euro, however, this positive impact is largely offset by the negative impact of higher Swiss-based costs in U.S. dollar terms. In 2002, the U.S. dollar fell by 6.9% against the Swiss franc; however, the negative impact of the lower U.S. dollar on the net income of Serono was less than 1%.

Because we enter into financial instruments to hedge a significant portion of our contracted and forecasted foreign exchange exposures up to eight months forward, a significant increase or decrease in the exchange rate of the U.S. dollar relative to other major world currencies should not, in the short-term, have a material adverse effect on our cash flows. Over time, however, to the extent that such exchange rate movements are unable to be reflected in the pricing of our products in local currencies, such exchange rate movements could materially affect our cash flows.

### INTEREST RATE EXPOSURE

We actively manage our interest rate exposure through various risk management techniques. In the context of our goal of maintaining stable and predictable cash flows, we attempt to limit the impact of a significant increase or decrease in interest rates in the short term. As of December 31, 2002, we had net financial assets (excluding equity securities) of \$1,615.9 million, compared with \$1,453.8 million as of December 31, 2001. Our exposure to fluctuations in net interest income is managed by making investments in high quality financial assets and through the use of several types of derivative financial instruments that are sensitive to interest movements. The group's 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. Our interest risk exposure is monitored on an ongoing basis using various measures including, a repricing gap analysis, calculated using assets and liabilities that are

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sensitive to interest rates. This repricing gap analysis forms the basis of our calculation of our expected net interest profit/loss movements. This analysis determines the expected increase or decrease of the future interest profit/loss compared to the interest profit/loss resulting from our presently prevailing net financial assets.

### INTEREST RATE RISK MANAGEMENT

The total notional principal amount of our interest rate swap contracts excluding swaps that qualify as fair value hedges at December 31, 2002 was \$29.7 million, compared to \$33.1 million at December 31, 2001. The entire 2002 balance matures during the period to April 2004. At December 31, 2002, we had no forward rate agreements. At December 31, 2001, we had forward rate agreements with a total nominal amount of \$825 million and a fair value of \$0.6 million.

At December 31, 2002, the fair value of the interest rate swaps was negative \$0.9 million, compared to negative \$0.3 million at December 31, 2001. The fair value represents the market value if the instruments were closed out at the year-end.

### FAIR VALUE HEDGES

We maintain interest rate swaps that qualify for hedge accounting as fair value hedges relating to bond investments. The fair value movements of these swaps are included in the fair value hedge reserve and are recorded in the income statement in order to reflect the impact of derivatives on the interest charges related to the bond. There is an immaterial amount of hedge ineffectiveness related to these hedges.

### INTEREST RATE EXPOSURE ON LONG-TERM DEBT

The following tables present certain information regarding our use of derivative financial instruments, and other financial instruments that are sensitive to changes in interest rates, as of December 31, 2002. With respect to fixed rate and variable rate debt, the first table presents principal amounts of long-term debt (including current portion) at the December 31, 2002 exchange rates, and the related weighted average interest rates at the expected maturity date. Actual weighted average variable rates are applied for all periods. With respect to interest rate swaps, the second table presents notional amounts and weighted average interest rates at the expected maturity date. Weighted average variable rates are based on the implied forward rates as of December 31, 2002.

### INTEREST RATE RISK MANAGEMENT PRINCIPAL (NOTIONAL) AMOUNT BY EXPECTED MATURITY AVERAGE INTEREST RATE

	2003	2004	2005	2006	2007	Thereafter	TOTAL
	-----	-----	-----	-----	-----	-----	-----
	(U.S. dollar equivalents in thousands)						
Variable rate (USD)	1,500	-	-	-	-	-	1,500
Average interest rate	2.35%	-	-	-	-	-	-
Fixed rate (EUR)	3,719	2,497	934	913	163	347	8,573
Average interest rate	2.48%	2.53%	2.20%	2.06%	4.00%	1.87%	-
Fixed rate (CHF)	721	360	-	-	-	-	1,081
Average interest rate	4.69%	4.69%	-	-	-	-	-
Variable rate (CHF)	17,315	5,781	1,455	1,455	1,455	9,453	36,914
Average interest rate	2.67%	3.60%	3.91%	3.91%	3.91%	3.91%	-
Fixed rate (JPY)	250	250	250	250	250	44	1,294
Average interest rate	3.50%	3.50%	3.50%	3.50%	3.50%	3.50%	-

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TOTAL DEBT, LONG-TERM AND  
CURRENT PORTION

-----  
49,362  
=====

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INTEREST RATE RISK MANAGEMENT PRINCIPAL (NOTIONAL) AMOUNT BY EXPECTED MATURITY  
AVERAGE INTEREST (SWAP) RATE

	2003	2004	TOTAL	FAIR VALUE AT DEC 31, 2002
	-----	-----	-----	-----
	(U.S. dollar equivalents in thousands)			
Swiss Franc interest rate swaps:				
Payer swap (variable to fixed)	10,106	19,598	29,704	(885)
Average pay rate (fixed)	3.73%	3.73%		
Average received rate (variable)	1.86%	1.86%		

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

Not applicable.

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  
Effective Date: July 26, 2000

- 4.g. As of December 31, 2002, 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 3 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 a date within 90 days of the filing date of 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 us, including our consolidated subsidiaries, with respect to the matters covered in this annual report was made known to such officers by others within those entities.

There were no significant changes in our internal controls or in other

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factors that could significantly affect those controls subsequent to the date of the evaluation described above.

ITEM 16. [RESERVED]

PART III

ITEM 17. FINANCIAL STATEMENTS

Not applicable.

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ITEM 18. FINANCIAL STATEMENTS

See pages F-1 through F-51.

ITEM 19 EXHIBITS

EXHIBIT

NUMBER DESCRIPTION

-----

- 1.1 Articles of Association, dated March 20, 2003
- 2.1 Deposit Agreement among the registrant, The Bank of New York, as Depositary, and all Own and Beneficial Owners from time to time of ADRs issued thereunder, including the form of (incorporated by reference to Exhibit 4.6 to Registrant's Registration Statement on Form (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 Am No. 1 to Registrant's Registration Statement on Form F-1 (Registration No. 333-12192), a the Commission on July 10, 2000)
- 2.3 Form of Certificate for Ten Bearer Shares (incorporated by reference to Exhibit 4.3 to A No. 1 to Registrant's Registration Statement on Form F-1 (Registration No. 333-12192), a the Commission on July 10, 2000)
- 2.4 Form of Certificate for One Hundred Bearer Shares (incorporated by reference to Exhibit 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 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)
- 8.1 List of Subsidiaries of the Registrant
- 10.1 Consent of PricewaterhouseCoopers S.A.
- 10.2 Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley A
- 10.3 Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley 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.

Serono S.A.  
(Registrant)

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/s/ Ernesto Bertarelli

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

Date: April 17, 2003

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CERTIFICATIONS

I, Ernesto Bertarelli, the Vice Chairman of the Board, Managing Director and Chief Executive Officer of Serono S.A., certify that:

1. I have reviewed this annual report on Form 20-F of Serono S.A.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

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6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ Ernesto Bertarelli

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

Date: April 17, 2003

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I, Allan L. Shaw, the Chief Financial Officer of Serono S.A., certify that:

1. I have reviewed this annual report on Form 20-F of Serono S.A.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) Any fraud, whether or not material, that involves management or other



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employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ Allan L. Shaw

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Allan L. Shaw  
Chief Financial Officer  
(Principal Financial Officer)

Date: April 17, 2003

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### FINANCIAL STATEMENTS AND AUDITORS' REPORTS

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#### REPORT OF THE GROUP AUDITORS

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, 2002 and 2001 and for each of the three years in the period ended December 31, 2002.

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

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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, 2002 and 2001, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2002, 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, 2002 and the determination of consolidated shareholders' equity at December 31, 2002 and 2001 to the extent summarized in Note 34 to the consolidated financial statements.

PricewaterhouseCoopers S.A.

/s/ M. Aked                      /s/ H-J. Hofer  
M. Aked                          H-J. Hofer

Geneva, March 14, 2003

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### CONSOLIDATED INCOME STATEMENTS Year ended December 31

	Notes	2002 US\$000	2001 US\$000	2000 US\$000
-----				
Revenues				
Product sales	2	1,423,130	1,249,405	1,146,998
Royalty and license income	2	123,399	127,065	92,656
-----				
<b>TOTAL REVENUES</b>	<b>2</b>	<b>1,546,529</b>	<b>1,376,470</b>	<b>1,239,654</b>
-----				
Operating expenses				
Cost of product sales		223,751	213,160	229,907
Selling, general and administrative		512,942	446,945	393,716
Research and development, net	3	358,099	308,561	263,152
Restructuring		16,303	-	-
Other operating expense, net	4	85,811	70,152	31,147
-----				
Total operating expenses		1,196,906	1,038,818	917,922
-----				
<b>OPERATING INCOME</b>		<b>349,623</b>	<b>337,652</b>	<b>321,732</b>
-----				
Non-operating income, net				
Financial income, net	5	36,476	51,381	52,277
Other expense, net	6	1,658	2,548	2,411

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Total non-operating income, net		34,818	48,833	49,866
INCOME BEFORE TAXES AND MINORITY INTERESTS		384,441	386,485	371,598
Taxes	20	63,127	69,816	70,384
INCOME BEFORE MINORITY INTERESTS		321,314	316,669	301,214
Minority interests		536	(52)	174
NET INCOME		320,778	316,721	301,040

		US\$	US\$	US\$
BASIC EARNINGS PER SHARE				
Bearer shares	8	20.07	19.72	19.50
Registered shares	8	8.03	7.89	7.80
American depositary shares	8	0.50	0.49	0.49
DILUTED EARNINGS PER SHARE				
Bearer shares	8	20.04	19.68	19.46
Registered shares	8	8.02	7.87	7.78
American depositary shares	8	0.50	0.49	0.49

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

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CONSOLIDATED BALANCE SHEETS  
As of December 31

	Notes	2002 US\$000	2001 US\$000
ASSETS			
CURRENT ASSETS			
Cash and cash equivalents	9	686,033	1,131,091
Short-term financial assets	16	378,865	344,413
Trade accounts receivable	10	257,313	234,490
Inventories	11	259,477	196,063
Prepaid expenses	12	26,609	21,857
Other current assets	13	208,100	134,955
TOTAL CURRENT ASSETS		1,816,397	2,062,869
LONG-TERM ASSETS			
Property, plant and equipment	14	554,509	460,767
Long-term financial assets	16	711,201	241,009
Intangible assets	15	216,371	110,615
Deferred tax assets	20	136,687	107,115
Other long-term assets	17	59,509	36,394
TOTAL LONG-TERM ASSETS		1,678,277	955,900
TOTAL ASSETS	2	3,494,674	3,018,769
LIABILITIES			

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CURRENT LIABILITIES			
Bank advances	18	70,093	154,295
Trade accounts payable		60,591	60,151
Current portion of long-term debt	18	23,505	18,959
Income taxes		55,152	55,948
Other current liabilities	19	348,704	246,157
TOTAL CURRENT LIABILITIES		558,045	535,510
TOTAL LONG-TERM LIABILITIES			
Long-term debt	18	25,857	37,325
Deferred tax liabilities	20	12,080	9,003
Other long-term liabilities	21	436,329	217,430
TOTAL LONG-TERM LIABILITIES		474,266	263,758
TOTAL LIABILITIES		2 1,032,311	799,268
MINORITY INTERESTS		1,165	587
SHAREHOLDERS' EQUITY			
Share capital	23	253,416	253,137
Share premium	24	989,141	975,335
Treasury shares	23	(126,460)	(9,222)
Retained earnings	24	1,364,626	1,108,086
Fair value reserves	16	(44,807)	(25,135)
Cumulative foreign currency translation adjustments		25,282	(83,287)
TOTAL SHAREHOLDERS' EQUITY		2,461,198	2,218,914
TOTAL LIABILITIES, MINORITY INTERESTS AND SHAREHOLDERS' EQUITY		3,494,674	3,018,769

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

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CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Notes	Share capital(1) US\$000	Share premium US\$000	Treasury shares US\$000	Retained earnings(1) US\$000	Fair value reserves
BALANCE AS OF JANUARY 1, 2000		236,978	33,965	-	621,615	-
Issue of share capital - stock options		157	3,309	-	(21)	-
Issue of stock options to employees		-	140	-	-	-
Net income for 2000		-	-	-	301,040	-
Shares issued during the year		15,937	935,837	-	-	-
Purchase of treasury shares		-	-	(4,750)	-	-
Withholding tax on free share dividend		-	-	-	(59,755)	-
Dividend for 1999 - bearer shares		-	-	-	(12,537)	-
Dividend for 1999 - registered shares		-	-	-	(5,218)	-
Foreign currency translation adjustments		-	-	-	-	-

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BALANCE AS OF DECEMBER 31, 2000		253,072	973,251	(4,750)	845,124
BALANCE AS OF JANUARY 1, 2001					
As previously reported		253,072	973,251	(4,750)	845,124
Effect of adopting IAS 39		-	-	-	-
AS RESTATED		253,072	973,251	(4,750)	845,124
Issue of share capital - stock options	25	65	1,760	-	-
Issue of stock options to employees	25	-	482	-	-
Issue of share capital - employee	23	-	(158)	1,106	-
Net income for 2001		-	-	-	316,721
Purchase of treasury shares	23	-	-	(5,578)	-
Dividend for 2000 - bearer shares	24	-	-	-	(39,017)
Dividend for 2000 - registered shares	24	-	-	-	(14,742)
Revaluation adjustments		-	-	-	-
Foreign currency translation adjustments		-	-	-	-
BALANCE AS OF DECEMBER 31, 2001		253,137	975,335	(9,222)	1,108,086
BALANCE AS OF JANUARY 1, 2002		253,137	975,335	(9,222)	1,108,086
Issue of share capital - stock options	25	66	1,388	-	-
Issue of stock options to employees	25	-	1,045	-	-
Issue of share capital - ESPP	26	213	11,397	-	-
Issue of share capital - employee	23	-	(24)	184	-
Net income for 2002		-	-	-	320,778
Purchase of treasury shares	23	-	-	(117,422)	-
Dividend for 2001 - bearer shares	24	-	-	-	(46,637)
Dividend for 2001 - registered shares	24	-	-	-	(17,601)
Revaluation adjustments		-	-	-	-
Foreign currency translation adjustments		-	-	-	-
BALANCE AS OF DECEMBER 31, 2002		253,416	989,141	(126,460)	1,364,626