

NOVARTIS AG  
Form 6-K  
February 06, 2004

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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 6-K

### REPORT OF FOREIGN PRIVATE ISSUER Pursuant to Rule 13a-16 or 15d-16 of the Securities Exchange Act of 1934

Report on Form 6-K dated February 6, 2004  
(Commission File No. 1-15024)

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## Novartis AG

(Name of Registrant)

Lichtstrasse 35  
4056 Basel  
Switzerland

(Address of Principal Executive Offices)

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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F:  Form 40-F:

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes:  No:

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Yes:  No:

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

Yes:  No:

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Enclosures:

Novartis AG Annual Report 2003 to Shareholders

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[insert invitation here]

## Contents

### Overview

Financial Highlights	2
News in 2003	3

### Letter from Daniel Vasella

The New Number Five in Pharmaceuticals	4
----------------------------------------	---

### Division and Business Units

Pharmaceuticals	7
-----------------	---

Giving Thalassemia Patients a Choice	
Discovering Pharmaceuticals Reliably and Predictably	
The Long Road to Blood-Pressure Control	
Treating Breast Cancer Will Never Be the Same	
Epilepsy Putting Children First	
A New Frontier in the Fight Against Severe Allergic Asthma	
Two Decades of Leadership in Transplantation	
Hearing the Patient, Healing the Patient Irritable Bowel Syndrome	
The Right Note: Saving a Singer's Sight	
Consumer Health	35

Sandoz Building a World Leader in Generics	
OTC The Value of Global Brands	
Animal Health Up and Running, Despite Arthritis	
Medical Nutrition A New Relevance for Cancer Patients	
Infant & Baby Alerting Parents to the Dangers of Childhood Obesity	
CIBA Vision Innovation in Focus	

### Corporate Citizenship

Active Societal Engagement	49
----------------------------	----

### Health, Safety and Environment

Turning Strong Commitment Into Firm Actions	61
---------------------------------------------	----

### Human Resources

Fulfilling Career Aims	74
------------------------	----

### Corporate Governance Section

Corporate Governance	83
Board of Directors	103
Executive Committee	110
Business Unit Heads	114

### Financial Report

Operating and Financial Review	116
Equity Strategy and Share Information	135
Group Consolidated Financial Statements and Notes	145
Principal Companies	190
Reconciliation to US GAAP	196
Financial Statements of Novartis AG	213

<b>Due Dates for Reporting in 2004</b>	219
<b>Contacts</b>	220

## Financial Highlights

### Key ratios

	2003	2002
Return on sales (%)	23.7	24.4
Return on average equity (%)	17.1	17.7
Group research and development as % of sales	15.1	13.6
Debt/equity ratio	0.20:1	0.20:1
Current ratio	2.4:1	2.5:1

### Share information

	2003	2002
Average number of shares outstanding	2 473 522 565	2 515 311 685
Earnings per share (USD)	2.03	1.88
Operating cash flow per share (USD)	2.68	2.08

	2003	2002
American Depositary Share (ADS) price at end of year (USD)	45.89	36.73
Share price at end of year (CHF)	56.15	50.45
Dividend per share <sup>(1)</sup> (CHF)	1.00	0.95
Pay-out ratio based on outstanding shares (%)	39	36

(1) 2003: Proposal to the Annual General Shareholder Meeting

2

## News in 2003

<b>Group sales</b>	Strong volume growth in Pharmaceuticals and Sandoz: Group sales up 19% in USD (+11% in local currencies); Novartis is one of the fastest growing top-ten pharmaceutical companies
<b>Pharmaceuticals</b>	Pharmaceuticals steadily gaining market share in all major markets, with sales growth of 18% in USD, driven by the Cardiovascular and Oncology franchises
<b>Consumer Health</b>	Consumer Health ongoing sales up 24% driven by 60% sales growth at Sandoz
<b>New drugs</b>	With seven major approvals and 79 projects in clinical development and registration Novartis has one of the leading pipelines in the industry
<b>Operating income</b>	Double-digit (16%) rise in full-year operating income is driven by volume expansion, product mix enhancements and productivity gains
<b>Net income</b>	Net income is up 6% to a new record level of USD 5.0 billion, lifting earnings per share by 8%
<b>Dividend</b>	Based on solid performance, a dividend increase of 5% to CHF 1.00 per share will be proposed to shareholders

3

## Letter from Daniel Vasella

Dear Shareowner

It gives me great pleasure to be able to present record results again. Today, Novartis is one of the fastest growing global pharmaceutical companies. Thus, we have overtaken competitors and are now in fifth position in the Global Pharmaceuticals sector. At the same time, we have gained market segment share in all of our other businesses. Let me summarize the key results in 2003:

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Increase in group sales of 19% to USD 24.9 billion (+11% in local currencies).

Expansion of operating income to USD 5.9 billion (+16%), of net income to USD 5.0 billion (+6%) and of earnings per share by 8% to USD 2.03.

Growth of free cash flow by 23% to USD 3.6 billion.

Pharmaceutical sales climbed 18% with the especially successful enlargement of our product line in Oncology (+36%) and Cardiovascular medicine (+36%), combined with a further rejuvenation of our product portfolio.

Dynamic growth of our Consumer Health business (+24%) and particularly of our Generics business, Sandoz (+60%).

Expansion of our development pipeline to 79 projects, of which 34 are in late stage development or registration.

Extension of our access to medicine programs for uninsured and indigent patients suffering from leprosy, malaria, tuberculosis, chronic myeloid leukemia and other diseases.

We attribute our success to our clear focus on sustainable growth, our corresponding, consistently innovation-oriented strategy, and the capabilities and commitment of our associates. Accordingly, we see our investments in Research and Development as being of primary importance. Last year we increased our investment in Research and Development by 32%. In Pharmaceuticals alone, we invested more than USD 3 billion in 2003 to discover and develop innovative medicines, and to improve treatments for patients. The first phase in the buildup of our new research center in Cambridge, Massachusetts was successfully completed. Nearly 400 scientists are already working in the new laboratories. In 2004, we will continue the expansion. This demands continued over-proportional investments that will yield mid- to long-term returns.

Our development pipeline is among the best in the world, based on quality and productivity. Most promising are our novel compounds for patients with diabetes, hypertension, cancer and osteoporosis, and for transplantation medicine which will, if successful, significantly improve treatments and thus have an attractive commercial potential.

In 2003, we received first major market approvals for *Certican* and *Myfortic* for use in transplantation medicine, *Stalevo* for the treatment of Parkinson's disease and *Xolair* for allergic asthma therapy in the US. Furthermore, *Prexige*, a new treatment for pain and osteoarthritis, was approved in the UK. Its approval in the US is as yet uncertain, pending results of additional trials.

4

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To complement our own research activities, we have established several new collaborations with universities and biotechnology companies. The acquisition of 51% of the capital stock of Idenix Pharmaceuticals Inc., a biotechnology company based in Boston, Massachusetts, offers us rapid entry into anti-viral research, and access to development compounds for the treatment of hepatitis B and C. Additionally, we acquired the commercial rights for *Lucentis* outside the US, Canada and Mexico. In combination with our product *Visudyne*, this drug may improve the treatment options in age-related macular degeneration, a frequent cause of blindness in adults. We also obtained rights to a promising cancer drug, *Gimatecan*, from Sigma Tau and the drug *Enblex/Emselex* for the treatment of urinary incontinence from Pfizer.

Our market position improved in most countries, most notably in the US. This we achieved thanks to the success of our blood pressure-regulating medicines *Diovan* and *Lotrel*; our cancer drugs *Gleevec/Glivec* and *Zometa*; *Elidel*, our eczema treatment; as well as to the attractive sales of *Zelnorm/Zelmac*, our irritable bowel treatment, to name just some of our most important products.

The dynamic growth of our Generics business is primarily based on the success of AmoxC, loratadine and omeprazole in the US market. The development of activities at Lek, a generics company we acquired in 2002, also exceeded expectations.

In light of the increasing age of our society, and the associated rise in healthcare expenditure, generics will play an even more important role as a cost effective therapeutic option. These cost savings can and should be used to provide patients with innovative, patent-protected medicines that

have improved efficacy and safety profiles.

Unavoidably, governments, insurers and employers will continue to put pressure on the price of pharmaceuticals, despite the fact that the overall cost of drug therapies amounts to less than 20% of all healthcare-related costs in most countries. Also, medicines not only extend patients' life expectancy, but also improve their quality of life and reduce their lost working hours and absence from work due to illness.

Increasingly, health is regarded as a fundamental right. The introduction of prescription drug coverage into the US Medicare insurance system for senior citizens must also be seen from this perspective.

The enlargement of the EU from 15 to 25 member states will not only improve the standard of living in the new member states, but also lead to demands for better health-related products and services. A similar trend can be observed in countries with rapidly growing Gross National Product (GNP), such as China and India. In each of these countries, the new middle class already comprises more than 150 million people.

A fundamentally different situation prevails in the poorest countries, for example in parts of Africa, where HIV/AIDS, malaria, tuberculosis and various other infectious diseases kill millions of people every year. The pharmaceutical industry is neither the cause of this plight, nor can it prevent it on its own. Nevertheless, the pharmaceutical industry is able and ready to make a valuable contribution. Accordingly, at the World Trade Organization (WTO) negotiations in Cancun, the industry did not insist on patent rights for essential medicines in the poorest countries. Novartis, however, has gone even further. Thanks to our good results last year we were able to provide, at no charge, all the drugs used by the World Health Organization (WHO) for the treatment of leprosy patients worldwide. Furthermore, we are providing the WHO with our new malaria drug *Coartem* at cost. Recently, we additionally committed to supply medicines for the treatment of 500 000 tuberculosis patients over the next five years, free of charge.

5

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We continue our endeavors to fulfill every regulation, no matter how work-intensive or formalistic it may be. In 2004 we will comply with every part of the Sarbanes-Oxley Act, including Section 404, thus fulfilling every demand made by US authorities. Despite all internal and external controls, and our declared intention and related efforts to comply with all laws and regulations, it is unlikely given our 78 000 associates that we will be successful everywhere at all times. But at a minimum, the transparency of our report will enable you, our shareowners, to assess the current situation, risks and opportunities of your company. I can assure you that the Board of Directors and I are fulfilling our leadership and controlling responsibilities to the best of our knowledge and abilities.

At the next Annual General Shareholder Meeting, Heini Lippuner and Walter Frehner will retire from the Board. After last year's meeting, you, the shareholders, have already prepared the succession. Professor Srikant Datar is professor of accounting at Harvard Business School, and Dr.-Ing. Wendelin Wiedeking is Chairman of the Executive Board at Porsche AG.

Here, I also wish to express my deep regrets regarding the death of our honorary Chairman, Dr. Louis von Planta, who played a decisive role in the founding of our company.

Finally, I would like to take this opportunity to thank everyone who contributed to last year's good results especially all our associates. And I wish to thank you, as shareowners of Novartis, for your loyalty and confidence.

Daniel Vasella, MD  
Chairman and CEO

6

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**Industry-leading growth** Novartis one of the fastest-growing companies in the pharmaceutical industry, gaining market segment share and climbing one notch, to fifth place in global rankings.

**Key growth drivers** The Cardiovascular and Oncology franchises *Diovan* becomes the world's leading angiotensin receptor blocker (ARB).

**Strong patent position** Low exposure to generic competition during the next five years.

**Sustained research and development productivity** Seven major approvals during 2003; 11 new medicines launched in the US since 2000.

**Deep pipeline again rated as one of the industry's strongest by financial analysts** 79 projects in clinical development or registration.

**Research and Development spending reaches 19% of sales** Reflecting high-level investment in the new US research center at Cambridge, Massachusetts and the addition of new development projects.

	2003 USD millions	2002 USD millions	Change in USD %
Sales	16 020	13 528	18
Operating income	4 423	3 891	14
Research and development	3 079	2 355	31
Research and development as % of sales	19.1%	17.3%	
Free cash flow	4 690	4 418	6
Net operating assets	8 969	8 041	12
Investments in tangible fixed assets	771	505	53

**Sales by region**

	2003	2002	% change
Number of employees	44 640	44 110	1

Top ten products	2003 sales in USD millions	Change in USD %	Change in local currencies %
<i>Diovan/Co-Diovan</i>	2 425	46	38
<i>Gleevec/Glivec</i>	1 128	84	68
<i>Neoral/Sandimmun</i>	1 020	-2	-10
<i>Lamisil (group)</i>	978	12	5
<i>Zometa</i>	892	83	74
<i>Lotrel</i>	777	20	20
<i>Lescol</i>	734	27	18
<i>Sandostatin (group)</i>	695	15	7
<i>Voltaren (group)</i>	599	1	-6
<i>Cibacen/Lotensin/Cibadrex</i>	433	-6	-9

The Novartis Pharmaceuticals Division is a world leader in the discovery, development, manufacture and marketing of prescription medicines. Our goal is to provide a broad portfolio of innovative, effective and safe products and services to patients through healthcare professionals around the world. This goal is supported by a dedicated organization operating in more than 140 countries.

## Development Pipeline

The Novartis pipeline holds a broad stream of promising future products, with 64 projects in Phase II and beyond as of December 2003, including both new molecular entities and additional indications or formulations for marketed products.

### Compound

Molecular entity.

### Generic name

Designation assigned to compound.

### Indication



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A disease or condition for which a particular drug is believed to be an appropriate therapy.

**Phase II**

Clinical trials in patients to determine dose ranging, safety and efficacy.

**Phase III**

Large clinical trials to determine definitive safety and efficacy in patients.

**Filed**

In registration.

Therapeutic area	Project/compound	Generic name	Indication
<b>Cardiovascular and metabolism</b>	<i>Diovan</i>	valsartan	Congestive heart failure
	<i>Diovan VALIANT</i>	valsartan	Post-myocardial infarction
	<i>Lotrel 10-40, 5-40</i>	benazepril, amlodipine	Hypertension
	<i>Diovan VALUE</i>	valsartan	High risk hypertension
	<i>Navigator*</i>	valsartan, nateglinide	Progression to type-II diabetes
	<i>Sandostatin LAR</i>	octreotide acetate	Diabetic retinopathy, other indications
	<i>Lotrel ACCOMPLISH</i>	benazepril, amlodipine	High risk hypertension
	<b>SPP100</b>	aliskiren	Hypertension
	<b>LAF237</b>		Type-II diabetes
	<b>NKS104</b>	pitavastatin	Dyslipidemia
<b>Oncology</b>	<i>Zometa</i>	zoledronic acid	Hypercalcemia of malignancy (HCM)
	<i>Femara</i>	letrozole	Breast cancer (extended adjuvant therapy)
	<i>Femara</i>	letrozole	Breast cancer (early adjuvant therapy)
	<b>ICL670</b>		Chronic iron overload
	<b>PTK787</b>	vatalanib	Solid tumors
	<i>Gleevec/Glivec</i>	imatinib mesylate	Solid tumors
	<i>OctreoTher</i>	edotreotide	Somatostatin receptor positive tumors
	<b>EPO906</b>		Solid tumors
	<b>PKC412</b>	midostaurin	Acute myeloid leukemia
	<b>SOM230</b>		Acromegaly, GEP neuroendocrine tumors
	<b>LBQ707</b>	gimatecan	Solid tumors
	<b>RAD001</b>	everolimus	Solid tumors
	<b>Nervous system</b>	<i>Focalin LA</i>	dexmethylphenidate
<b>ILO522</b>		iloperidone	Schizophrenia
<i>Exelon</i>		rivastigmine	Non-Alzheimer's dementia
<i>Exelon TDS</i>		rivastigmine	Alzheimer's disease
<i>Trileptal</i>		oxcarbazepine	Neuropathic pain
<b>TCH346</b>			Parkinson's disease
<b>TCH346</b>			ALS <sup>(1)</sup>
<b>AMP397</b>			Epilepsy
<b>SAB378</b>			Chronic pain
<b>LIC477</b>		licarbazepine	Bipolar disorder
	<b>FTY720</b>		Multiple sclerosis
<b>Transplantation, immunology</b>	<i>Certican</i>	everolimus	Transplantation
	<i>Myfortic</i>	mycophenolate sodium	Transplantation
	<b>FTY720</b>		Transplantation
<b>Dermatology</b>	<i>Lamisil</i>	terbinafine	Tinea capitis
	<i>Lamisil</i>	terbinafine	New Oral Formulation (NOF) onychomycosis
	<b>ASM981</b>	pimecrolimus	Inflammatory skin diseases

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Therapeutic area	Project/compound	Generic name	Indication
	<i>Elidel (ASM981)</i>	pimecrolimus	Inflammatory skin diseases
<b>Respiratory</b>	<i>Foradil</i>	formoterol	Multi dose dry powder inhaler for asthma
	<i>Xolair</i>	omalizumab	Asthma
	<b>QAB149</b>		Asthma/COPD <sup>(2)</sup>
	<b>ASM981</b>	pimecrolimus	Asthma
<b>Arthritis, bone, gastrointestinal diseases, HRT and urinary incontinence</b>	<i>Zelnorm/Zelmac</i>	tegaserod	Chronic constipation
	<i>Enablex/Emselex</i>	darifenacin	Overactive bladder
	<i>Prexige</i>	lumiracoxib	Osteoarthritis, rheumatoid arthritis, pain
	<i>Zelnorm/Zelmac</i>	tegaserod	Irritable bowel syndrome
	<b>ZOL446</b>	zoledronic acid	Post-menopausal osteoporosis
	<b>ZOL446</b>	zoledronic acid	Paget's disease
	<i>Zelnorm/Zelmac</i>	tegaserod	Functional dyspepsia
	<i>Zelnorm/Zelmac</i>	tegaserod	Gastroesophageal reflux disease
	<b>ZOL446</b>	zoledronic acid	Rheumatoid arthritis
	<b>RAD001</b>	everolimus	Rheumatoid arthritis
	<b>AAE581</b>		Osteoporosis
	<b>SMC021</b>	calcitonin	Osteoporosis
	<b>RGN303</b>		Rheumatoid arthritis
<b>Ophthalmics</b>	<i>Visudyne</i>	verteporfin	AMD <sup>(3)</sup> (occult)
	<i>Visudyne</i>	verteporfin	AMD <sup>(3)</sup> (minimally classic)
	<i>Lucentis</i>	ranibizumab	AMD
	<i>Elidel</i>	pimecrolimus	Ophtha indications
	<b>PIR335</b>	pirenzapine	Myopia
<b>Infectious diseases</b>	<b>LDT600</b>	telbivudine	Hepatitis B
	<b>LDC300</b>	valtorcitabine	Hepatitis B

\*

Navigator trial examining combination therapy of *Diovan* and *Starlix*.

- (1) Amyotrophic lateral sclerosis.
- (2) Chronic obstructive pulmonary disease.
- (3) Age-related macular degeneration.

Mechanism of action	Formulation	Planned filing dates	Phase I	Phase II	Phase III	Filed
Angiotensin-II receptor blocker	Oral	Filed (EU)	██████████	██████████	██████████	██████████
Angiotensin-II receptor blocker	Oral	Filed	██████████	██████████	██████████	██████████
ACE inhibitor/calcium channel blocker	Oral	Filed (US)	██████████	██████████	██████████	██████████
Angiotensin-II receptor blocker	Oral	2004	██████████	██████████	██████████	██████████
	Oral	>2006	██████████	██████████	██████████	██████████
Growth hormone + IGF-1 inhibitor	Intramuscular	2005	██████████	██████████	██████████	██████████
ACE inhibitor/calcium channel blocker	Oral	>2006	██████████	██████████	██████████	██████████

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Mechanism of action	Formulation	Planned filing dates	Phase I	Phase II	Phase III	Filed
Renin inhibitor	Oral	2005	██████████			
Dipeptidylpeptidase (DPP-4) inhibitor	Oral	2006	██████████			
HMG CoA reductase inhibitor	Oral	>2006	██████████			
Bisphosphonate, osteoclast inhibitor	Intravenous	Filed (Japan)	██████████			
Non-steroidal aromatase inhibitor	Oral	2004	██████████			
Non-steroidal aromatase inhibitor	Oral	2005	██████████			
Iron chelator	Oral	2005	██████████			
Tyrosine kinase inhibitor	Oral	2005	██████████			
Tyrosine kinase inhibitor	Oral	tbd	██████████			
Radiation therapy	Intravenous	tbd	██████████			
Microtubule depolymerization inhibitor	Intravenous	>2006	██████████			
Protein kinase inhibitor	Oral	2006	██████████			
Somatostatin (sst)1/2/3/5 binder Int and hormone inhibitor	ravenous	2005	██████████			
Topoisomerase-I inhibitor	Oral	>2006	██████████			
Growth-factor-induced cell proliferation inhibitor	Oral	2006	██████████			
Dopamine transport blocker	Oral	2004	██████████			
Mixed 5HT2A/D2 antagonist	Oral	tbd	██████████			
Cholinesterase inhibitor	Oral	tbd	██████████			
Cholinesterase inhibitor	Transdermal	2006	██████████			
Voltage dependent sodium current blocker	Oral	tbd	██████████			
Neuronal GAPDH dep. programmed cell death inhibition	Oral	>2006	██████████			
Neuronal GAPDH dep. programmed cell death inhibition	Oral	>2006	██████████			
AMPA receptor antagonist	Oral	>2006	██████████			
Cannabinoid-1 receptor agonist	Oral	>2006	██████████			
Voltage dependent sodium current blocker	Oral	>2006	██████████			
Sphingosine-1-phosphate receptor agonist	Oral	>2006	██████████			
Growth-factor-induced cell proliferation inhibitor	Oral	Filed (US)	██████████			
Inosine monophosphate dehydrogenase inhibitor	Oral	Filed	██████████			
Sphingosine-1-phosphate receptor agonist	Oral	2005	██████████			
Fungal squalene epoxidase inhibitor	Oral	tbd	██████████			
Fungal squalene epoxidase inhibitor	Oral	2004	██████████			
T-cell and mast cell inhibitor	Oral	tbd	██████████			
T-cell and mast cell inhibitor	Ointment	2006	██████████			

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Mechanism of action	Formulation	Planned filing dates	Phase I	Phase II	Phase III	Filed
Long-acting beta-2 agonist	Dry powder for inhalation	Filed	██████████	██████████	██████████	██████████
Anti-IgE monoclonal antibody	Subcutaneous	2004 (EU)	██████████	██████████	██████████	██████████
Long-acting beta-2 agonist	Inhalation	>2006	██████████	██████████	██████████	██████████
T-cell and mast cell inhibitor	Oral	tbd	██████████	██████████	██████████	██████████
5HT4-receptor agonist	Oral	Filed (US)	██████████	██████████	██████████	██████████
M3 antagonist	Oral	Filed	██████████	██████████	██████████	██████████
Cyclo-oxygenase-2 inhibitor	Oral	2005 (US)	██████████	██████████	██████████	██████████
5HT4-receptor agonist	Oral	2004 (EU)	██████████	██████████	██████████	██████████
Bisphosphonate: osteoclast inhibitor	Intravenous	>2006	██████████	██████████	██████████	██████████
Bisphosphonate: osteoclast inhibitor	Intravenous	2004	██████████	██████████	██████████	██████████
5HT4-receptor agonist	Oral	2005	██████████	██████████	██████████	██████████
5HT4-receptor agonist	Oral	2006	██████████	██████████	██████████	██████████
Bisphosphonate: osteoclast inhibitor	Intravenous	>2006	██████████	██████████	██████████	██████████
Growth-factor-induced cell proliferation inhibitor	Oral	>2006	██████████	██████████	██████████	██████████
Cathepsin K inhibitor	Oral	>2006	██████████	██████████	██████████	██████████
Regulator of calcium homeostasis	Oral	>2006	██████████	██████████	██████████	██████████
IL-1 alpha and IL-1 beta inhibitor	Intravenous	>2006	██████████	██████████	██████████	██████████
Photosensitizer for photodynamic therapy	Intravenous	2006 (US)	██████████	██████████	██████████	██████████
Photosensitizer for photodynamic therapy	Intravenous	>2006	██████████	██████████	██████████	██████████
VEGF blocker	Intra-vitreous	2006	██████████	██████████	██████████	██████████
T-cell and mast cell inhibitor	Eye drops	>2006	██████████	██████████	██████████	██████████
Selective MI-muscarine antagonist	Ocular	tbd	██████████	██████████	██████████	██████████
Viral polymerase inhibitor	Oral	2005	██████████	██████████	██████████	██████████
Viral polymerase inhibitor	Oral	2006	██████████	██████████	██████████	██████████

## Development

### Giving Thalassemia Patients a Choice

Mario Rossi\* is a 27-year old computer consultant who lives in Torino, Italy. His job forces Mario to travel often and he recently moved out of the family home, into an apartment of his own.

\*  
Not the patient's real name. Use of a pseudonym is required under Italian patient-privacy laws.

That independence was hard-won. Because Mario suffers from beta-thalassemia, an inherited genetic defect that damages red blood cells in his body, he needs a blood transfusion every month to survive. Yet repeated transfusions have a serious side-effect—a potentially fatal build-up of iron in the body. To control that iron overload, Mario took a Novartis drug called *Desferal* for most of his life.

Launched more than 40 years ago *Desferal* remains the gold standard of iron chelation—removing excess iron and extending the lives of tens of thousands of thalassemia patients from Torino to Tehran. The treatment is cumbersome, however, and many patients aren't able to adhere to the lifelong regimen of painful infusions via a portable pump for up to 12 hours a day, five to seven days per week.

Novartis scientists have spent decades and tens of millions of dollars to develop a more convenient alternative. Success finally seems to be in sight. A new iron chelator which can be taken as a dispersible tablet has reached the final, pivotal phase of clinical testing. If ongoing trials are successful for the new medicine, still known only by its research number ICL670, regulatory applications could be submitted as early as next year, followed by launches in major markets during 2006.

Mario has been taking ICL670 since September 2001, when he joined an early clinical study being conducted at the Thalassemia Center at Ospedale Regina Margherita in Torino.

"It's completely changed my life," he says.

The daily drill of *Desferal* therapy made it impossible for Mario to travel as he does today—or to even consider moving from home where his parents played a crucial role in his care.

"It's very difficult to sleep with an infusion line attached to a *Desferal* pump," he says. And there were frustrating occasions when he'd wake and realize that after mixing the *Desferal* solution and finishing elaborate preparations with the infusion line the preceding evening, he'd forgotten to switch on the pump, losing a treatment cycle.

"If I had to go back to *Desferal*, I'm not sure I could manage," Mario says, with a grimace.

### **A Distant Dream**

Dr. Antonio Piga, Professor of Medicine at the Department of Pediatric Hematology, University of Torino, has watched Mario and hundreds of other patients struggle with *Desferal* treatment. Part of the problem is that the benefits of therapy don't show immediately. Damage from iron overload to organs such as the liver or heart takes up to 15 years to become apparent—but by the time symptoms appear, the consequences are virtually impossible to reverse. To address the crucial, mental dimension of treatment compliance, Dr. Piga added a psychologist to his staff a few years ago.

In all, Dr. Piga has 45 patients currently participating in ICL670 trials. "Every patient and family who has experience with *Desferal* dreams of an oral iron chelator," he says. Yet joining a trial wasn't an easy decision since most of Dr. Piga's patients were well-controlled on *Desferal*. Mario, for example, pondered for three weeks before finally deciding to switch to ICL670.

Until recently, it looked like patients might never have a choice. *Desferal* was derived from a natural substance originally discovered in an iron-eating bacterium called *Streptomyces pilosus*. But the hunt for a replacement floundered as scientists repeatedly encountered obstacles in their attempts to develop a safe and effective oral iron chelator—or even a more convenient version of *Desferal*.

Then, in the mid-1990s, as most major pharmaceutical companies continued to ignore the iron-chelation field, Novartis researchers made one final push. Applying cutting edge "molecular modeling" tools in the lab, researchers synthesized hundreds of molecules before finally choosing a single candidate compound, ICL670, to enter clinical testing. Dr. Rene Lattmann, a Basel-based chemist, was named a Novartis Leading Scientist last year in recognition of his role in the synthesis of ICL670.

## Edgar Filing: NOVARTIS AG - Form 6-K

The new medicine seemed full of promise. Two molecules of ICL670 folded snugly around each iron molecule in the body, dispatching it for excretion. Along with once-daily dosing, and high affinity and selectivity for iron, ICL670 was far more potent than *Desferal*, yet seemed free of the toxicity that had derailed so many predecessors.

Clinical testing had barely begun when the project hit an unexpected complication: the December 1996 merger of Ciba-Geigy AG and Sandoz AG that created Novartis in its current form.

The new company couldn't afford to develop all the drugs inherited from its predecessors so management weeded out the weakest prospects from the combined development pipeline. ICL670 faced tough scrutiny: previous failures had bred skepticism about oral iron chelators. With a potential market of roughly 85 000 patients worldwide, the drug had modest commercial potential; and that limited pool of patients also made recruitment for clinical trials unusually expensive and time-consuming.

ICL670 was briefly designated a candidate for out-licensing but Novartis management agreed to complete a clinical trial already underway before making a final decision. That study delivered a crucial proof-of-concept careful measurements showed that more iron came out of human patients treated with ICL670 than went in through diet. The net reduction of iron more than compensated for the effect of blood transfusions.

"All of a sudden we were back in business," recalls Hanspeter Nick, a chemist who had joined the iron chelator program in 1990.

### Fast Track

By May 2002, ICL670 had become a "key project" the designation reserved for the most promising drugs in development at Novartis. That same year, ICL670 was granted orphan-drug status in both the US and Europe. (Orphan-drug legislation provides incentives to develop medicines for rare neglected diseases.) Last year, the US Food and Drug Administration (FDA) added "fast track" status confirming that ICL670 targeted a major unmet medical need and raising prospects of an expedited, six-month regulatory review.

The phase III trial now underway is the biggest study yet of an iron chelator. The study is designed to assess safety and efficacy of ICL670 compared with *Desferal* in a head-to-head comparison involving roughly 500 beta-thalassemia patients from 12 countries.

A parallel trial is testing the efficacy of ICL670 in *Desferal*-intolerant patients who developed iron overload as a result of transfusions treating a variety of anemias, including myelodysplastic syndrome or MDS, a form of leukemia. While iron chelation has focused traditionally on the tight-knit thalassemia community in countries ringing the Mediterranean Sea and stretching eastward into India and China, transfusion-related iron overload is recognized as a truly global disorder.

13

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At the 2003 biennial conference of the Thalassemia International Federation (TIF) in Palermo, Italy, Daniele Alberti, the Clinical Program Leader for ICL670, informed patients and physicians that results from initial clinical studies of ICL670 showed that the drug appeared to have a favorable safety profile and comparable efficacy to *Desferal* in reducing liver-iron concentrations over a one-year treatment period. "Many of the objectives of the development program already have been attained, others are near completion," Dr. Alberti said.

He cautioned, however, that it's still too early to assume the pivotal phase III trial will be successful. "It's a terrific opportunity but still a challenging one," Dr. Alberti said.

14

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## Research

### Novartis Institutes for BioMedical Research

The Novartis Institutes for BioMedical Research (NIBR) encompass the global research activities of Novartis. Primary NIBR sites include Basel, Switzerland; Horsham, UK; Vienna, Austria; Tsukuba, Japan; and the new global headquarters in Cambridge, Massachusetts, US.

Under the leadership of Mark C. Fishman, President of the Institutes, the goal of NIBR is to discover new medicines reliably and predictably. To attain this goal, our work must be at the frontier of science and medicine, combining modern biology, chemistry, clinical pathophysiology and genomics. There is no simple method to harvest the estimated 30 000 different human genes in a way that leads directly to drug discovery. NIBR scientists, however, are dedicated to using the tools at our disposal today to discover medicines, while at the same time developing new approaches for future pharmaceutical discovery.

Within NIBR, some groups of scientists specialize in disease areas, while others focus on "Platforms" fundamental scientific disciplines that apply across a broad spectrum of diseases. Whether their research is dedicated to specific diseases or to fundamental scientific tools, NIBR scientists work closely with each other. They also work together with colleagues in Development to ensure that discoveries are translated effectively into safe medicines. This emphasis on cross-functionality means that NIBR scientists are involved from the identification of a potential drug target, through testing in the clinic, all the way to the market.

Our prime resource is talent. NIBR leaders have come from within Novartis, from other pharmaceutical companies, from biotech and from academia. The unique mixture of talents and experience is rejuvenating and synergistic, both at the bench and in the clinic.

The interface between NIBR and external academic colleagues is being expanded and is proving beneficial to both parties. Continued outreach to small biotech companies is opening new horizons and possibilities. The NIBR culture of creativity thrives on this sense of openness, entrepreneurial spirit, and scientific rigor.

In 2003, the new Cambridge headquarters was integrated into the global research effort. The first new laboratory building was completed and brought online and now it is the center of research activity in Oncology, Diabetes, Cardiovascular Diseases and Infectious Diseases. In addition, scientists dedicated to Platforms are in place working on genomic approaches, high-throughput technologies and novel chemistry tools.

In 2004 it is expected that our second research laboratory building will be completed and the number of research scientists in Cambridge will double. More importantly, as the number and quality of research scientists increase, and we continue to tap into scientific expertise worldwide, we believe it holds great promise for significant new discoveries that may potentially lead to the medicines of the future.

#### **NIBR: A Global Organization**

The new Institutes are designed to function globally, says John Hastewell, Head of NIBR's Program Office. "I believe that the advantages of global talent far outweigh the inconvenience of inter-site communication," he adds. Some groups are localized, such as the Respiratory Disease Area in Horsham. Many of their programs utilize the expertise of other NIBR groups elsewhere in the world, including Transplantation in Basel and Molecular Pathways in Cambridge. Some groups, such as Oncology, are split between two sites.

15

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Science by its nature transcends traditional boundaries so that discoveries in one area often have an even more powerful impact on another. It is crucial to keep groups apprised of discoveries made by NIBR colleagues worldwide.

New technologies adopted by NIBR have led to advances in the invention and utilization of tools making it possible to visualize the structure of a drug target, according to Rene Amstutz, Head of Discovery Technologies. These tools, from nuclear magnetic resonance and x-rays, to a novel fluorescence-based technology to view individual molecules, allow us to "rationally" design a drug to fit the target, he adds.

Advanced computing, known as "grid" computing, permits the intensive mathematical calculations needed for this purpose. NIBR scientists have linked together hundreds of our computers to create a supercomputer capable of those calculations.

The Institutes also have an outstanding archive of natural products, traditionally a source of novel compounds that have been successfully developed into major medicines. The most rapid high-throughput technologies often redesigned by NIBR scientists have been brought to bear to examine "combinatorial" chemical libraries containing millions of compounds, in search of "hits" that start the process of drug design.

#### **Major Unmet Medical Need**

Novartis scientists have had great success in designing drug candidates for cancers where the cause of the disease is known. *Gleevec/Glivec* is targeted at the abnormal Abl protein in chronic myeloid leukemia, says Alexander Kamb, Head of the Oncology Disease Area. Many cancers, however, result from more complex mechanisms; for example, many solid tumors result from the activation or repression of several genes. Using the new genomic techniques, NIBR scientists probe for the weak points in such cancers and attempt to design the best drugs or

combinations of drugs to attack those weaknesses.

Several recent breakthrough discoveries have shown that the aggregation of abnormal proteins in neural tissue is an underlying cause of neurodegenerative diseases like Alzheimer's disease, Parkinson's disease, amyotrophic lateral sclerosis, and Huntington's disease, among others. These findings open new opportunities to identify novel therapeutic approaches according to Graeme Bilbe, Head of Neuroscience Disease Area. Therapies could halt or delay disease progression based on a molecular understanding.

In addition, new imaging techniques allow NIBR researchers to examine the living brain. For example, scientists are developing a molecular probe, a so-called bio-marker, that may help to image Alzheimer's disease plaques in the brain earlier than is possible today.

### **Interesting New Leads**

"Historically, most chemistry was 'hand-crafted' one compound at a time," says Scott Biller, Head of Global Discovery Chemistry. Today, using sophisticated techniques such as combinatorial chemistry together with cutting edge automation, chemists can synthesize hundreds or even thousands of biologically interesting molecules simultaneously.

"The libraries now being made are the best I've seen in my years in pharmaceutical chemistry," he adds. "We are doing an excellent job at true structure-based drug design."

NIBR chemists are exploiting the x-ray crystal structures of complexes of proprietary molecules with the target protein to design novel and superior drug candidates. "We have also implemented small fragment-based screening by nuclear resonance spectroscopy and x-ray crystallography, and have already found interesting new leads that we plan to optimize into drug molecules," Dr. Biller says.

16

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"NIBR is a real chance to build a new vision on top of the successful and solid foundation that Novartis already has. Frankly, this is the most significant medicinal chemistry opportunity in the world."

### **Corporate Research**

The mission of Corporate Research is to leverage the specific scientific expertise of its three member institutes to address unmet medical needs, with a particular focus on the developing world and neglected diseases.

Corporate Research at Novartis comprises three independent institutes with a total staff of more than 750 scientists. The institutes are: The Genomics Institute of the Novartis Research Foundation (GNF), based in La Jolla, California; The Novartis Institute for Tropical Diseases (NITD) in Singapore; and The Friedrich Miescher Institute (FMI), based in Basel, Switzerland.

GNF, formed in 1999, has a staff of 400 scientists who focus on development of advanced technologies in fields ranging from cellular genomics and proteomics, to combinatorial chemistry and structural biology. The Institute has also begun putting those new technologies to work in its own drug discovery programs where its scientists increasingly work in collaboration with counterparts at NIBR.

For example, GNF has developed cutting edge systems to screen proteases that complement the protease research platform established by NIBR at its main European research hub in Basel. Proteases are cellular enzymes that represent important targets for new drugs in diseases from HIV/AIDS and oncology to neurodegeneration and dengue fever. Research in dengue fever is conducted in collaboration with the NITD.

### **Growing Interaction**

Underscoring growing interaction among Group research units, NIBR and GNF formed a joint research committee last year. GNF will host its first portfolio review this year, with external experts assessing the potential of candidate compounds identified by the Institute. Corporate Research will hold its first global science meeting in Cambridge, Massachusetts, US this year, which also will be attended by many NIBR scientists.

NITD is a joint development funded by Novartis and the Singapore Economic Development Board (EDB). The Institute and its 70 scientists will move to permanent labs in the Biopolis science park in Singapore, this year.



At least initially, NITD will focus on research in dengue fever and tuberculosis, two of the most threatening tropical diseases worldwide. Though the center only opened last year, two drug-discovery projects have already progressed to the stage of lead optimization, or chemical fine-tuning of potential candidate compounds. NITD will host its second scientific review this year conducted by the review board which includes Nobel laureates Rolf Zinkernagel, a member of the Novartis Board of Directors, and Sydney Brenner.

NITD's mission also includes graduate and post-graduate training programs open to scientists from developing countries. At full capacity, the training programs are expected to accommodate roughly 30 students. Parallel with its drug discovery programs, the Institute is tapping regional acumen about its two target diseases. In 2003, NITD formed a "Dengue Consortium" bringing together six partners, including the Genomics Institute of Singapore and other academic groups, that will cooperate on research in dengue fever. NITD also arranged a conference with clinicians and epidemiologists from Singapore to assess whether compounds and treatment models under consideration are appropriate for use under the conditions that prevail in healthcare systems of poor countries. A similar meeting will be held in Cambodia, in 2004.

17

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At Basel-based FMI, the main areas of scientific focus range from epigenetics and growth control, to neurobiology. Fundamental biomedical research conducted at FMI has generated a number of potentially interesting drug targets. One particular strength is the area of kinases where work by FMI scientists has led to candidate compounds in both cancer and infectious diseases. FMI also trains young scientists and has been a prime recruiting ground for Novartis more than 50 scientists have moved from the Institute to the company's labs.

18

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## Cardiovascular

### The Long Road to Blood-Pressure Control

The perils of high blood pressure have been known for decades but awareness still hasn't translated into effective control for the majority of the 58 million Americans and 1 billion people worldwide who suffer from hypertension.

Last year, in the Seventh Report of its Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC7), the US National Institutes of Health (NIH) reiterated the risks: "The higher the blood pressure, the greater the chance of heart attack, heart failure, stroke and kidney disease." Yet only 54% of US patients with hypertension receive treatment and only 28% have adequately controlled blood pressure, according to a review of clinical practice published in the New England Journal of Medicine.

Some groups such as African Americans and older women are particularly vulnerable. According to the American Heart Association, the rate of heart disease is 1.5 times higher among black Americans than among whites. The corresponding rates of fatal stroke and end-stage kidney disease are 1.8 and 4.2 times higher respectively.

Novartis is committed to protecting and improving the lives of all people with cardiovascular disease. That commitment is underscored by one of the pharmaceutical industry's biggest clinical-trial programs where *Diovan* and *Lotrel*, two of the fastest growing antihypertensives in the US, are being tested in potential new applications in tens of thousands of patients.

The rise of *Diovan* to its current position as the number one angiotensin-II receptor blocker (ARB) globally has been buoyed by a bold clinical program designed to involve 50 000 patients.

The "megatrial" program has delivered positive outcomes in the first two trials and continues to investigate further potential new applications across the cardiovascular continuum, from pre-diabetes to heart failure.

Meanwhile, the *Lotrel* clinical-trial program includes more than 25 000 patients. *Lotrel* a fixed-dose combination of amlodipine besylate and the angiotensin-converting enzyme (ACE) inhibitor benazepril has been on the US market since 1995. Clinical trials have demonstrated that the dual mechanism provides synergistic effects on blood-pressure lowering and reduction of hemodynamic side effects, such as edema.

Combination treatments like *Lotrel* are becoming increasingly common and the JNC7 guidelines issued last year emphasize that "most patients with hypertension will require two or more antihypertensive medications to achieve goal blood pressure."

Such guidelines are important for physicians. But large clinical trials still provide the crucial data on which physicians rely to make patient decisions, says Dr. Kenneth Jamerson, Professor of Medicine at the University of Michigan Medical Center and a key figure in both the *Diovan* and *Lotrel* megatrial programs.

"What clinicians and academics really respect is a study that asks a question we don't know the answer to right off the bat," Dr. Jamerson adds. "If a company really wants to know the maximum potential of a medicine, it has to be tested to the limits, even though pushing to the limits doesn't always guarantee dramatic successes."

### "Gradations of Good"

The initial *Diovan* megatrial was the groundbreaking Val-HeFT study of more than 5 000 heart failure patients from 16 countries. Val-HeFT has led to approval of *Diovan* for treatment of heart failure in patients intolerant of ACE inhibitors in the US and more than 40 other countries.

Late in 2003, researchers reported the results of VALIANT, the biggest long-term study to date in people who have survived a heart attack. VALIANT demonstrated that *Diovan* has all the established, lifesaving benefits of captopril, the ACE inhibitor also known by its brand name Capoten®. In a head-to-head comparison in nearly 15 000 patients at the highest risk of death following a heart attack, *Diovan* was at least as effective as captopril in reducing cardiac events following a heart attack, including repeat heart attacks, and hospitalizations for heart failure.

Heart attack remains one of the world's deadliest conditions. Every year 600 000 people from EU countries, and 1.1 million Americans, suffer a heart attack.

About half of these victims die. In addition, all the survivors have permanently damaged hearts and a greatly increased risk of repeat attacks, heart failure or other deadly complications. As a result of the VALIANT data, Novartis has filed a supplementary application seeking regulatory approval of *Diovan* to treat patients following a heart attack.

Results from the next major *Diovan* study, VALUE, are expected this year. VALUE is a head-to-head comparison of *Diovan* and amlodipine, a calcium channel blocker marketed under the brand name Norvasc®, in more than 15 000 hypertensive patients with at least one additional risk factor for cardiovascular events.

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Capoten® and Norvasc® are registered tradenames of Bristol-Myers Squibb and Pfizer respectively.

Head-to-head comparisons with established drugs are particularly challenging because of what Dr. Jamerson calls "gradations of good." Success requires increased efficacy, or a relative risk reduction, of at least 15% above what a successful drug like captopril already offers patients.

Still, in a crowded market like hypertension, the cumulative effect of megatrials is essential to distinguish *Diovan* from rivals. "There are only a few ARBs that have end-point data and they get the lion's share of the market," Dr. Jamerson says.

When VALUE began in 1997, researchers set their sights on solving a vexing medical mystery. Epidemiological studies of cardiovascular disease clearly show that as blood pressure increases, there is a corresponding rise in the risk of both stroke and heart attack. Yet while antihypertensive treatment led to a reduced risk of stroke, trials weren't able to prove a similar benefit against heart attacks. "There was always this gap and the real unmet need in the cardiovascular arena at that time was the lack of benefit from antihypertensive drugs on heart-related outcomes," Dr. Jamerson recalls.

There were tantalizing hints that ARBs and potentially *Diovan* might reduce blood pressure in a way that provided that elusive, beneficial effect against heart attacks. "Seeing if *Diovan* could outperform amlodipine, which was perceived to be the best treatment option, was definitely on the edge for the time," says Dr. Jamerson, who has acted as national coordinator for more than 200 US medical centers participating in VALUE.

The same scientific riddle caught the attention of major research organizations such as the NIH, and a succession of studies during the past seven years has compared effects of various antihypertensive drugs. So far no antihypertensive class has significantly outperformed the others in terms of a benefit on heart-related outcomes but until VALUE, ARBs had not been given a definitive trial.

"VALUE is positioned to be the pivotal study that could settle the debate about drug-specific mechanisms," Dr. Jamerson predicts.

20

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## A Higher Road

With the *Lotrel* clinical program, Novartis is pushing the limits of combination therapy. ACCOMPLISH a five-year study that began during 2003 and will involve more than 12 000 patients is the first head-to-head comparison of fixed-dose combination antihypertensives. It pits *Lotrel* against the combination of a diuretic plus ACE inhibitor, generally regarded as the current gold standard of therapy and recommended in the JNC7 guidelines.

Dr. Jamerson, who is also the lead investigator of ACCOMPLISH, insists there's scant clinical data to demonstrate superiority of the diuretic/ACE inhibitor combination. "ACCOMPLISH is the next generation in trials the right study that asks the right question at the right time," he says. "If there is no one magic bullet and you end up needing a combination to achieve blood-pressure control, physicians want to know what that combination should be."

ACCOMPLISH is also breaking new ground by including an usually high (40%) proportion of African American patients among participants. This trial design ensures sufficient statistical power to determine if either combination shows a particular benefit among the black population a key clinical question considering the elevated rates of hypertension and cardiovascular mortality among blacks. Last year the International Society on Hypertension in Blacks urged more aggressive treatment of high blood pressure among African-Americans and predicted that most "would likely require combination antihypertensive therapy to reach appropriate blood pressure goals."

Ironically, there isn't much data to support that recommendation because few compounds are tested specifically among minorities. According to the Association of Black Cardiologists, "the need for increased enrollment of minorities in clinical trials is particularly acute in development of new treatments for cardiovascular disease."

Dr. Jamerson himself an African American says that with ACCOMPLISH Novartis "is really extending the limits in industry-sponsored trials." Government-sponsored studies in the US require broad participation from ethnic or gender groups that have a disproportionate burden of the disease of interest, he says, but company-sponsored trials are exempt from that rule.

"Novartis has adopted a higher road by looking at the ethnic diversity of the country in which it markets the product," Dr. Jamerson adds.

21

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## Oncology

### Treating Breast Cancer Will Never Be the Same

Labor Day is the last big summer holiday in the United States and Greg Burke, Global Head of Oncology Development at Novartis, was relaxing at his home in New Jersey when his cell phone rang.

The caller was Dr. Paul Goss, Director of Breast Cancer Research at Princess Margaret Hospital in Toronto, Canada and international chair of a major study involving *Femara*, a treatment for breast cancer developed by Novartis.

Dr. Goss had spectacular news. His *Femara* study, known as MA-17, had reached its objectives more than two years ahead of schedule. The trial's Data Safety and Monitoring Committee had recommended that the trial be modified immediately so that nearly 2 600 trial participants who were receiving a placebo, or sugar pill, could be given a chance to "cross over" to treatment with *Femara*.

That phone conversation set off an intense chain of events that culminated a month later with publication of the MA-17 results in the prestigious New England Journal of Medicine (NEJM). A simultaneous press briefing in Toronto, headed by Dr. Goss and fellow investigators, ensured that the study made headlines around the world. Treatment of breast cancer will never be the same.

MA-17 focused on treatment of postmenopausal survivors of hormone-receptor-positive breast cancer, an estimated 250 000 women in North America alone. These women normally undergo surgery, followed by chemotherapy, which attacks tumor cells the surgeon may have missed or ones which have spread to distant parts of the body. Then comes "adjuvant" treatment with tamoxifen, a drug which dramatically improves a woman's odds of remaining cancer-free.

Tamoxifen treatment is only considered beneficial for five years, however, leaving women who complete those five years uncertain about what to do next.

"When you get the initial diagnosis, it's scary facing your mortality. Then, coming to the end of tamoxifen, it's frightening again," says Kathy Anderson, a Canadian elementary-school principal who took part in MA-17. "These results send a message of hope I'd hope that all women would have a chance at this standard of care."

### **Model for Megatrials**

In MA-17, treatment with *Femara* after completion of the standard tamoxifen regimen reduced the risk of recurrence by 43%, compared to women who received no further treatment. Along with a reduction in recurrence of breast cancer in the previously affected breast, women taking *Femara* also had reductions in the number of new cancers in their opposite breast and the spread of cancer outside the breast. And *Femara* was generally well-tolerated, with side effects similar to those experienced by women undergoing menopause.

Dr. Goss calls MA-17 one of the most important breast-cancer studies of the past 20 years. "The reason it's so important is that it was a comparison against nothing," he adds. "It was like adding something that never had been tried before but turned out to have a massive effect. So that on top of chemotherapy and tamoxifen, women could add *Femara* and get another whole chunk of insurance against recurrence of breast cancer."

22

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Novartis scientists were equally jubilant. "We always thought that *Femara* was going to work in the extended-adjuvant setting but these trials usually take a long time to get results. To see such a positive outcome all of a sudden was incredibly exciting," says Dr. Diane Young, Head of Global Clinical Development at Novartis Oncology. "It's extremely rare in an industry research career to be involved in something that's hailed as a change in medical practice," Dr. Young adds. "What's really amazing is that this comes so soon after another totally novel breakthrough from Novartis Oncology the development of *Gleevec/Glivec* that revolutionized treatment of chronic myeloid leukemia."

While breast-cancer patients and their physicians are the big winners from MA-17, the study also offers a model for conducting cancer megatrials where close cooperation between a pharmaceutical company and independent research groups can lend further weight to trial results and their rapid adoption in clinical practice.

MA-17 was designed mainly by Dr. Goss, but treatment of the study's 5 187 participants was conducted at dozens of centers linked in an unprecedented, trans-Atlantic network of cooperative clinical trial groups from Canada, the US, and Europe.

"Cooperation is essential to get these very large trials done," Dr. Young says. "The cooperative groups are used to working together, and they have established, standard procedures in place that make it possible to accomplish great things quickly."

Involving physicians at the community level boosts patient recruitment and also spreads first-hand knowledge about cutting edge medicines and novel clinical approaches beyond the rarified circles of key opinion leaders at renowned teaching hospitals. "The structure of these groups couldn't be better for penetration of a new therapy. Along with key opinion leaders from all over the world, you've got hundreds of community physicians who are local experts on MA-17, feeling part of it and wanting to share the results with colleagues," Dr. Goss muses.

### **Estrogen Deprivation**

*Femara* belongs to a class of drugs known as aromatase inhibitors, which work by blocking aromatase, the enzyme primarily responsible for synthesis of estrogen in the body. Estrogen is the major growth factor in hormone-receptor-positive tumors, which account for about two-thirds

of all breast cancer cases. Estrogen deprivation is the main therapeutic approach.

Tamoxifen, by contrast, inhibits stimulation of tumor growth by preventing the binding of estrogens to estrogen receptors in cancer cells. Studies show that tamoxifen treatment reduces the risk of breast-cancer recurrence by nearly 50% and the risk of death by 26%. But after five years of treatment, tumors tend to become resistant to tamoxifen and the drug's therapeutic benefits are gradually outweighed by side effects.

The ability of aromatase inhibitors to reduce estrogen levels by up to 95% and starve hormone-receptor-positive tumors marked them as competitors to tamoxifen as the gold standard of care. But proving that potential has required a marathon of giant clinical trials.

In the time-honored calendar of drug development, an anticancer agent must first prove its mettle against the most advanced tumors. *Femara* won approval for treatment of advanced breast cancer in the UK in 1996, in the US a year later, and today it is available in more than 75 countries. Three years ago, *Femara* proved to be more effective than tamoxifen in a head-to-head trial involving more than 900 postmenopausal women with advanced breast cancer. Patients taking *Femara* had a significantly longer time to disease-progression, and higher response rates, than women receiving tamoxifen.

23

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Adjuvant therapy loomed as an even bigger prize and in 1998, Novartis opened a head-to-head comparison of *Femara* against tamoxifen in the early adjuvant treatment of postmenopausal, breast-cancer survivors. Known as BIG 1-98, the trial involves more than 8 000 patients and is being conducted by the Breast International Group, a network of cooperative clinical groups from Europe, Canada and Australasia. The study compares the efficacy of *Femara* and tamoxifen in adjuvant therapy for five years after primary treatment as well as sequential variations of *Femara* and tamoxifen during the treatment period.

### **Traveling the World**

MA-17 also started in 1998. Dr. Goss was convinced that the uncertainty facing breast-cancer survivors after five years of tamoxifen treatment so-called extended adjuvant treatment represented an urgent medical question. However, the study was originally designed to test vorazole, an aromatase inhibitor being developed by Johnson & Johnson.

"I spent a year traveling around the world, presenting the idea to cooperative groups in Europe and North America and getting buy-in for the trial," Dr. Goss recalls with a sigh. But two weeks before the first patient was due to be enrolled, Johnson & Johnson abruptly halted development of vorazole and bailed out of MA-17.

Scrambling to find a new industry sponsor and salvage the study, Dr. Goss called Novartis. Despite the short notice, ongoing summer vacations in Europe and skepticism from some scientists that *Femara* could achieve the ambitious goals set for MA-17, Novartis agreed to join the study.

It was a bold step. After all, tamoxifen generally is credited with saving more lives than any other anticancer medicine and had also demonstrated a sustained, carryover effect for several years following cessation of the initial five years of adjuvant therapy. Underscoring that point in an editorial accompanying the NEJM's publication of MA-17 results, Dr. John Bryant and Dr. Norman Wolmark recall: "It was anticipated that the initial effect of (*Femara*) therapy would be moderate, with increased benefits becoming evident only with longer follow-up."

So when MA-17's Data Safety and Monitoring Committee began a scheduled interim analysis in late August, nobody was prepared for the bombshell the Committee delivered.

"We simply found what we were looking for sooner than expected," Dr. Goss says. "The study had set out to discover if [*Femara*] could reduce disease occurrence by 22%. When we knew it could, by 43%, we said "Good enough, that's it. The study is over. *Femara* works fabulously well."

The next step was to comply with the committee's order to unblind the study as promptly as possible. The trial's executive committee, representing the cooperative groups, agreed unanimously that the trial should end ahead of schedule.

Dr. Goss then contacted the NEJM to see if the study was considered to be important enough to receive an expedited review. When the journal agreed, the Data Safety and Monitoring Committee consented to a delay of roughly three weeks, during which the paper was written and peer reviewed. At the same time, press releases were prepared and coordinated among study co-sponsors: Cancer Institute of Canada, the US National Cancer Institute and the European Organization for Research and Treatment of Cancer (EORTC).

## Making a Difference for Patients

Though no one seriously questioned the ethical obligation to give MA-17 placebo participants the right to "cross over" as soon as the superior efficacy of *Femara* was clear, the premature modification left some key questions unanswered. Novartis and the cooperative groups are moving to address many of those loose ends.

24

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Perhaps most importantly, Novartis plans to submit applications to regulatory agencies during the first half of 2004 seeking the additional indication of "extended adjuvant" therapy for *Femara*. Since *Femara* is already on the market, physicians can prescribe the drug for medically appropriate uses but without formal regulatory approval, insurers and governments might balk at reimbursing the cost of the treatment.

While MA-17 ended early, patients will continue to receive treatment for the full five years promised when they joined the study. Long-term safety of extended adjuvant treatment with *Femara* will be followed closely. Meanwhile, Novartis and the cooperative groups are discussing a possible extension of MA-17 to evaluate *Femara* treatment for a further five years, and to attempt to establish the optimal duration of treatment and assess long-term side effects.

"There's no doubt that it's an important question," Dr. Goss says. "There's nothing from the MA-17 result to suggest that *Femara* therapy shouldn't be chronic."

Separately, Novartis is exploring use of *Femara* in combination treatments. One important side effect of *Femara* treatment observed during MA-17 was a potentially increased risk of osteoporosis and resulting fractures. Studies in Europe and the US are testing whether a combination of *Femara* and *Zometa* can mitigate the potential risk to bone safety in adjuvant treatment. *Zometa* is a bisphosphonate, used to treat bone-related cancer complications and it is also under development as a treatment for osteoporosis.

In yet another study, *Femara* is being combined with *Certican*, an immunosuppressant drug already approved in transplantation. There is preliminary evidence that *Certican* could block a signaling pathway that plays an important part in stimulating breast cancer, in a manner similar to the role of estrogen in hormone-receptor-positive tumors.

"These combinations of *Femara* with other agents reflect the breadth of our oncology portfolio and how it fits together to create unique opportunities to make a difference for cancer patients," Dr. Young says. "There's a lot of thinking and talking today about how to answer remaining questions that need to be answered, and the studies that need to be done. I expect Novartis to remain fully involved in these conversations."

25

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## Neuroscience

### *Trileptal*: Putting Children First

Last year *Trileptal* became the first anti-epileptic medicine in 25 years to win approval from the US Food and Drug Administration for use as monotherapy in children as young as four years of age.

The approval reflected an ambitious global clinical program that aims to extend the benefits of *Trileptal* therapy to very young children, a group with a major unmet medical need. The drug is already available in more than 70 countries but pediatric age limits approved by regulators vary widely.

Prior to the FDA's new age limit, *Trileptal* monotherapy in the US was limited to adults. In the EU, however, *Trileptal* was approved five years ago as the first approved monotherapy for epileptic children from age six. In Australia and countries of Latin America, *Trileptal* is either approved for all patients without an age limit, or to treat children as young as two.

## Edgar Filing: NOVARTIS AG - Form 6-K

An estimated 50 million people worldwide suffer from epilepsy. Up to 5% of the world's population may report a seizure at some point in their lives but the very young are particularly vulnerable. Incidence is high in children up to the age of 10 but also common in infants below one year of age. In these youngest patients, seizures often signal serious disease which, without effective treatment, can lead to permanent disability.

The pediatric clinical program now underway with *Trileptal* involves roughly 300 patients. More than 50 of these patients are infants less than one year of age, the youngest only one month. While eight new anti-epileptic drugs have been launched during the past decade, only a handful have been tested in children, mainly as adjunctive therapy. Physicians welcome more studies in children even expert epileptologists readily acknowledge they need all the help they can get.

Professor Christian Elger, Head of the Department of Epileptology at the University of Bonn, personally sees more than 1 000 patients annually, and supervises cases of thousands more treated each year in his hospital. "Even with all that experience, you simply can't foresee how a drug will work in epilepsy patients especially young children," Dr. Elger says. "If a new drug comes on the market, it can work perfectly for the first 10 patients but then be ineffective for the next patient who has exactly the same symptoms as the others. Everything exactly the same but the drug doesn't work. You can't understand it."

*Trileptal* is widely used in pediatric cases, partly as a result of demonstrated efficacy and safety but also the availability of a pediatric oral-suspension formulation. "When we look at how to take care of these kids, especially the youngest less than a year old, not only do you need to pick the right drug but it needs to have a formulation which can be used. A suspension formulation is very important," says Dr. Tracy Glauser, a specialist in pediatric epilepsy at the Children's Hospital Medical Center, Cincinnati, Ohio, US.

One of the trials now in progress explores the effect of *Trileptal* on cognition, a key question since children with epilepsy also have a high incidence of other neurological problems and learning disorders. The European Agency for the Evaluation of Medicinal Products, or EMEA, Europe's main regulatory agency, asked Novartis to conduct the cognition study when it approved *Trileptal* in 1999.

More than 110 patients, with a minimum age of six years, are being treated for six months with either *Trileptal*, or two older-generation, standard anti-epileptic drugs. After six months' treatment patients will be evaluated with a neuropsychological test battery on criteria ranging from attention and reaction-time, to decision-making and memory. "This will give us important information about the effect of *Trileptal* on cognitive function which may have an impact on behavior and any psychiatric problems these kids may have," Dr. Glauser says.

26

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Novartis is also conducting two trials requested by the FDA to document the safety, efficacy and pharmacokinetic characteristics of *Trileptal* in children and infants as young as one month in both the drug's approved indications, monotherapy and adjunctive treatment. The trials are complex and challenging, requiring hospitalization of a child for extended video-electroencephalographic (EEG) monitoring.

The monotherapy trial involves 80 patients ranging in age from one month to sixteen years who will receive different doses of *Trileptal*. After treatment for five days, each patient will undergo video-EEG monitoring for up to 72-hours, to assess effects of the different doses on seizure frequency.

The adjunctive-therapy study investigates the effect of adding different doses of *Trileptal* to combinations of up to two other anti-epileptic drugs during 30 days of treatment. Patients will undergo continuous video-EEG monitoring both before and at the end of the trial treatment period to assess the reduction in seizure frequency from baseline.

Successful completion of these trials would lead to a six-month extension of market exclusivity for *Trileptal* in the US. Data from these three studies will be submitted to regulatory agencies worldwide in an attempt to further reduce current age limits or revise prescribing guidance to include safety and dosing information for very young children.

"There haven't been many studies done in very young kids because they're so hard to do," Dr. Glauser says. "If these trials succeed, it would set a standard which other companies will be expected to match."

27

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## Respiratory and Dermatology

### A New Frontier for Fighting Severe Allergic Asthma

The approval of *Xolair* in the US in June 2003 brought a breath of hope to many patients like 15-year old Jeremy Holliman. He has lived under constant threat from allergic asthma since suffering his first attack at the age of six months. Medical science seemed powerless to relieve the condition that disrupted his schooling, sports and social activities, and periodically led to severe exacerbations that left him fighting for life in a hospital emergency room.

For Jeremy and his family, the breakthrough came with his enrollment in a clinical trial for *Xolair*, a biological therapy unique in targeting a root cause of allergic asthma and other allergic diseases. It took more than 15 years for scientists at Novartis, and our collaborators Genentech and Tanox, to develop a molecule that is effective against an antibody called IgE. This produces the inflammatory symptoms of allergic asthma in individuals such as Jeremy, who are "atopic" or sensitive to a range of normally harmless substances.

The result was *Xolair*, now approved in the US for treating moderate-to-severe allergic asthma in adolescents and adults whose condition is inadequately controlled by inhaled corticosteroids.

For Jeremy, life was transformed: "It was great...I could play with my friends; I could go swimming for extended periods of time, even run around at school during Physical Education. I just want to thank the doctors so much, because without them I would never have found *Xolair*."

In time, the benefits could be even more widely felt because *Xolair* offers the potential to address a number of other allergic conditions. For example, a clinical trial is planned to evaluate the effectiveness of *Xolair* in treating severe and potentially fatal reactions in people who are allergic to peanuts.

### Growing Relief

Another Novartis therapy, *Elidel*, has brought relief to a growing number of patients who suffer from a different, but still highly distressing, form of allergic disorder—the inflammatory skin disease known as atopic eczema. During 2003 Novartis stepped up its program to make *Elidel* cream as widely available as possible. The therapy has now been approved in 69 countries and introduced in almost 40 countries.

There was a special significance to the launch in Austria in March 2003, since *Elidel* was in a sense coming home. The product was developed by Professor Dr. Anton Stütz and his team at the Novartis Research Institute in Vienna, the company's centre of excellence for discovering treatments and cures for skin diseases and allergic disorders.

Their mission was to tackle the misery of atopic eczema, vividly described by one Austrian mother on a Novartis-sponsored patient website: "From the age of two months, my son Stefan suffered quite severely from eczema. There wasn't a single clear spot on his whole body," she says. "We tried pretty well everything: diets, ointments, and so on, and I became desperate because the sleepless nights took their toll on the whole family. But Stefan is the sunshine of my life, although he suffered so much."

The mainstay of therapy since the 1950s had been corticosteroids, whose use was limited by side-effect concerns. The pioneering research in Vienna produced a cream that was steroid-free, but also highly effective in relieving the itching and redness of atopic eczema, and in preventing the severe outbreaks known as flares. *Elidel* is generally licensed for use in adults and children from the age of two with mild-to-moderate atopic eczema. In some countries outside the US, *Elidel* has received approval for treatment of infants as young as three months.

According to Professor Klaus Wolff, MD, Head of the University Dermatology Department at the General Hospital of Vienna, *Elidel* enabled a new strategy to be adopted for treating the disease. "Until now, effective therapy could be initiated only when the disease was at an advanced stage because the risk of side effects was too high," Dr. Wolff says. "Now, at the first sign of itch and reddened skin, an effective medication can be used that prevents flare progression and can help avoid the need for corticosteroid creams."



## Transplantation

### *Neoral* and Beyond

In 2004, Novartis is celebrating two decades of leadership in transplantation.

Since the 1984 launch of cyclosporine, a pioneering medicine which revolutionized transplantation, the company has continued to discover and develop new treatments and to improve administration of lifesaving therapies to patients. Today Novartis has one of the pharmaceutical industry's largest portfolios of transplant treatments, and one of the biggest research budgets in the field. About 120 scientists work on solutions to unmet medical needs in transplantation, such as chronic rejection and vasculopathies.

"We believe that long-term demand for transplant drugs will remain attractive," says Tony Rosenberg, Head of the Novartis Transplantation and Immunology Business Unit. "Broadening our portfolio to rejuvenate our franchise will enable Novartis to maintain a solid leadership position in this area."

*Neoral*, a micro emulsion formulation of cyclosporine remains a cornerstone of immunosuppression therapy. Physicians today usually blend drug "cocktails" with cyclosporine or another primary immunosuppressant as the base ingredient, combined with other medicines like *Simulect*, *Certican* and *Myfortic* to meet the needs of individual patients.

*Certican* and *Myfortic*, two new medicines from Novartis in early stages of their global roll out, are extending physicians' options for individualized therapy with the goal of improving quality of life for patients. The development pipeline includes other promising Novartis compounds with potential applications in kidney, heart, liver and lung transplants.

Immunosuppressants prevent rejection by blunting the immune system's response to the presence of a transplanted organ. Therapy must continue for the duration of a transplant recipient's life and with organ survival now measured in decades, there is increasing emphasis by physicians on side effects that influence a patient's quality of life.

For example, a study presented last year at the International Liver Transplant Society showed that *Neoral* was associated with significantly fewer cases of new-onset diabetes than the rival immunosuppressant Prograf® in a randomized, multi-center study involving nearly 500 patients. New-onset diabetes after transplantation increases the risk of organ failure. Last year, a group of leading transplantation experts from Europe and North America published the first consensus guidelines on management of new-onset diabetes after transplantation recommending careful monitoring of the choice of immunosuppressant.

### **A Relentlessly Progressive Complication**

*Myfortic* belongs to the mycophenolic-acid (MPA) class of immunosuppressants which is widely used in combination with *Neoral*. The advanced enteric-coated formulation of *Myfortic* has the potential to reduce gastrointestinal side effects seen with other MPA formulations, which can lead to dose reduction or discontinuation of therapy.

*Certican* is a novel, proliferation-signal inhibitor which was extensively tested in a clinical trial program involving more than 3 000 renal and heart transplant patients. In those studies, *Certican* demonstrated an ability to target primary causes of "chronic rejection," one of the most pressing, unmet medical needs in transplantation.

30

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Chronic rejection occurs gradually in the years following a transplant appearing eventually in the form of occlusion and narrowing of the arteries in a transplanted heart, and fibrosis, or scarring, in microscopic blood vessels in the kidney. This thickening of arteries or vasculopathy is a relentlessly progressive complication which occurs in about half of heart-transplant patients in the first several years after surgery.

A study involving more than 630 patients at 52 medical centers in the Americas and Europe which was published in the New England Journal of Medicine last year, showed that *Certican* was more effective than current treatment with azathioprine in reducing indicators of the development of cardiac vasculopathy 12 months after transplantation. An accompanying NEJM editorial by Dr. Robin Avery, MD, called the study "unique among large randomized studies in showing the effect of a particular immunosuppressive regimen on the development of allograft

vasculopathy." If these differences persist in subsequent years, Dr. Avery added, "this effect of *Certican* could translate into a substantial long-term benefit for patients who received the drug."

*Certican* has completed the EU's mutual recognition procedure in 15 countries which are expected to issue marketing authorization in 2004. *Myfortic* is currently undergoing the EU's mutual recognition procedure. Regulatory applications for both *Myfortic* and *Certican* are pending with the US Food and Drug Administration.

Although *Myfortic* and *Certican* represent significant treatment advances, a new Novartis drug still known only by its research number FTY720 could be an even bigger breakthrough. FTY720, currently in phase III clinical development, is a new and unique immunomodulator that may significantly improve transplant therapy. The drug is the first sphingosine-1-phosphate receptor (S1PR) agonist and protects transplanted organs from immune-system attack by reducing the re-circulation of white blood cells which remain sequestered in lymph nodes.

By contrast to classical immunosuppressive agents that, in effect, shut down a patient's immune system, studies have shown that immunity to some infections remains intact during treatment with FTY720, without jeopardizing the transplanted organ. Moreover, pre-clinical results indicate that FTY720 works synergistically with both *Neoral* and *Certican* and that the addition of FTY720 at clinically relevant doses doesn't result in increased side effects. Combination therapy may allow dose reductions of *Neoral* and *Certican*, and thus improve tolerability of the immunosuppressive regimen.

Transplantation remains an attractive long-term growth segment where Novartis is strategically placed to provide a product portfolio covering all therapeutic classes and addressing unmet medical needs while also allowing physicians to tailor therapy to individual patient needs. *Simulect*, *Neoral*, *Certican*, *Myfortic* and FTY720 all have therapeutic advantages that will ensure that Novartis remains a key player in transplantation.

## Gastrointestinal

### Hearing the Patient, Healing the Patient

Novartis is always mindful of the burden diseases place on families because it allows us to speak the patient's language. By properly addressing patients' concerns and priorities regarding treatments, Novartis was able to educate a patient population of millions about a disease category no one was talking about - irritable bowel syndrome (IBS).

The challenges in developing and marketing *Zelmac/Zelnorm*, our treatment for IBS have been considerable. Market research conducted in 2002 and 2003 showed consumer awareness of IBS was surprisingly low - especially when one considers that IBS affects up to one in five Americans, costs the US healthcare system billions annually and is second only to the common cold as a cause of workplace absenteeism. This research also unearthed a deeper problem: due to extreme embarrassment about their symptoms, or a genuine lack of awareness, IBS sufferers were shying away from visiting their doctors or talking about their symptoms.

Difficulties marketing to the IBS population were apparent as early as March 1999, when initial patient insight studies revealed that doctors and patients weren't speaking the same language. While physicians tended to focus on the bowel symptoms of IBS with constipation (IBS-C), patients were troubled by abdominal pain and bloating as well.

"These insights helped Novartis reshape the IBS market place, expand patient diagnosis potential, and fundamentally position the brand on a broader platform as the leading agent for the multiple symptoms of IBS-C," says Kurt Graves, Chief Marketing Officer at the Novartis Pharmaceuticals Division. "We realized that we could not just rely on good scientific data, thinking that is enough. The most important part of consumer marketing is understanding the customer's mindset. You've got to invest to get that."

The investment paid off. The marketing platform ("ABCs of IBS") emphasized a key learning from the insight studies - almost all patients have three major symptoms, not just IBS with constipation.

The challenge was to establish the patient/physician dialogue. These efforts commenced with the launch of Talk IBS, a national public awareness campaign designed in the US to teach consumers about the symptoms and management of IBS. Novartis enlisted the help of actress Lynda Carter and the Society for Women's Health Research to help bring the story of IBS into the hearts and minds of Americans. Ms. Carter was able to bring her own personal experience with IBS to the table. Her mother suffered with the multiple symptoms of IBS for more than

30 years.

Lynda Carter and the Talk IBS campaign spread unbranded IBS awareness to audiences across the US, reaching 99 of the top 100 markets and a potential audience of 158 million people. Further IBS awareness tracking research found that over the course of the campaign, US awareness of IBS had increased from 14% to 32%. The Talk IBS campaign messages were clear: "You are not alone. Help for IBS is available. Visit your doctor."

Consider the case of Gloria Swanson, who suffered for 15 years before getting a correct diagnosis of IBS-C. On several occasions the physical pain, gas and bloating landed her in emergency rooms where she was either given a nurse-administered enema or told to go home and drink half a bottle of laxative. Any relief was always shortlived with symptoms returning in a few days.

Gloria frequently missed work when her pain and bloating was so bad she was unable to sit on a bus, or at her desk, for extended periods of time. The harsh laxatives she took to try to alleviate the pain often forced her to take an additional day off to manage the resulting diarrhea. Even her honeymoon in Paris was affected by IBS as Gloria chose to take shortcuts back to the hotel instead of going sightseeing with her husband.

32

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Gloria is now taking *Zelnorm* and is happy that understanding of her IBSC has come a long way from the days when doctors were telling patients to take a cigarette and magazine to the bathroom and just sit. Gloria also says that her doctor has a lot of confidence in *Zelnorm* based on the information that he received from the Novartis sales force, and the successful experiences that she shared with him.

The close of 2003 also saw exciting results for the brand. With the launch of the US Direct-to-Consumer (DTC) advertising campaign in July, *Zelnorm* sales have exceeded USD 100 million for the year and will soon reach one million prescriptions.

Novartis also filed for a Supplemental New Drug Application (sNDA) for *Zelmac/Zelnorm* for the treatment of chronic constipation in the US, Mexico and other countries, with global approvals expected during 2004.

33

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## Ophthalmics

### The Right Note: How *Visudyne* Saved a Singer's Sight

When near-vision in Jacques Spoerry's left eye began to deteriorate in 1996, alarm bells sounded for the retired pediatrician. As a student during the 1950s he had lost much of the sight in his right eye to choroiditis. If his left eye went bad as well, he would descend into near blindness.

Failing vision also threatened one of Mr. Spoerry's favorite hobbies—singing with a local choir in Neuchâtel, the city in western Switzerland where he has lived for nearly 40 years. "Along with my medical practice and gardening, music has been one of my greatest interests," he says.

For help in reading music, Mr. Spoerry began using a large magnifying glass—but it proved so cumbersome that he turned to local ophthalmologists for help. Eventually, he was referred to a hospital in Lausanne where physicians confirmed diagnosis of neovascular, or "wet", age-related macular-degeneration, (AMD).

A degenerative condition characterized by growth of new blood vessels into the retina, wet AMD leads to rapid and severe vision loss in roughly 500 000 new patients each year. It is the most common cause of blindness for people over 50 in western nations.

Things began looking up for Mr. Spoerry when the physicians in Lausanne suggested that he join a clinical study of *Visudyne*, a therapy from Novartis. *Visudyne* is a photodynamic therapy, which combines an intravenous injection and laser therapy to destroy the abnormal blood vessels that cause AMD, without harming surrounding healthy tissue. During the first half of 1997, Mr. Spoerry received three sessions of *Visudyne* treatment with exceptional results—his vision actually improved and he happily discarded the magnifying glass.

His vision has remained stable, according to semi-annual checkups during the five years since his last *Visudyne* treatment. "More people need to know about this therapy," Mr. Spoerry says. Like many physicians, he urges patients who notice signs of failing vision to seek help quickly. In severe cases AMD can cause major vision loss within a few months. There's no time to lose, he adds, "and no reason to miss out on the benefits of *Visudyne* therapy."

Demographic trends suggest that the prevalence of AMD and other "back of the eye" disorders will increase as the "Baby Boom" generation ages and approaches retirement.

Eyeing future expansion, the Ophthalmics Business Unit strengthened its new drug pipeline last year by obtaining marketing rights outside North America to *Lucentis*, a promising treatment for wet AMD being developed by Genentech.

*Lucentis* is a humanized, therapeutic-antibody fragment which blocks new blood vessel growth by inhibiting vascular endothelial growth factor, or VEGF, a protein that plays a critical role in formation of new vessels. In addition to the use of *Lucentis* as monotherapy, the drug may have potential as a combination therapy together with *Visudyne*.

During 2003, the Ophthalmics Unit narrowed its strategic focus, and concentrated marketing resources to core brands with high growth potential, by pruning about 50 brands, or roughly one-fourth of the overall portfolio. Heading into 2004, these moves leave the Ophthalmics Business Unit with two strong branches the AMD franchise with *Visudyne* and *Lucentis*, and Core Brands.

The Unit also integrated its operations more closely with the Pharmaceuticals Division by moving global headquarters from Buelach, Switzerland to Basel and its US head office from Duluth, Georgia to New Jersey, close to the head office of the US Pharmaceuticals Division in East Hanover, New Jersey.

In October, *Visudyne* was approved by regulatory authorities in Japan for treatment of all types of lesions associated with wet AMD. The laser also used in treatment was approved separately in early December. Work toward reimbursement is continuing and the Ophthalmic unit plans to launch *Visudyne* in Japan in 2004.

## Consumer Health

In 2003 we:

**Gained market segment share across all business units.**

**Achieved strong performance, driven by Sandoz and OTC.**

**Successfully launched new products in all business units, especially in the US.**

**Achieved substantial sales growth of +24% versus previous year in USD (+16% in LC), reaching USD 8.8 billion.**

**Increased operating income by +40% versus previous year in USD.**

## Shaping Consumer Health

## Edgar Filing: NOVARTIS AG - Form 6-K

The Consumer Health Division focuses on creating, developing, manufacturing and marketing a wide range of competitively differentiated products that restore, maintain or improve the health and well being of our consumers. The Division, which includes our Sandoz generics, OTC self-medication, Animal Health, Medical Nutrition (including our Nutrition & Santé franchise), Infant & Baby, and CIBA Vision business units, places considerable emphasis on the development of strong, consumer oriented and trustworthy brands. Each business unit has a leading market position in growth oriented healthcare segments beyond our core pharmaceuticals business, providing essential, high quality health-related products.

In the dynamic world of consumer healthcare, aging populations are increasingly affluent and knowledgeable about their health, and the benefits of self-medication. The success of each business unit depends upon its ability to anticipate and meet the needs of consumers and health professionals worldwide.

Our mission at Novartis Consumer Health is to give a voice to the consumer in everything we do, in order to deliver accelerated sales growth and leadership positions.

	2003 USD millions	2002 <sup>(1)</sup> USD millions	Change in USD %
Sales	8 844	7 140	24
Operating income	1 320	946	40
Research and development	529	378	40
Research and development as % of sales	6%	5%	
Free Cash Flow	1 034	882	17
Net operating assets	6 727	5 794	16
Investments in tangible fixed assets	530	361	47

	2003	2002	% change
Number of employees	32 464	27 552	18

(1) Excludes divested Health & Functional Food activities except for Free Cash Flow

35

Sales by business unit	2003 sales in USD millions	Change in USD (%)	Change in local currencies (%)
Sandoz	2 906	60	47
OTC	1 772	17	7
Animal Health	682	9	3
Medical Nutrition	815	15	3
Infant & Baby	1 361	2	3
CIBA Vision	1 308	15	7
<b>Total</b>	<b>8 844</b>	<b>24</b>	<b>16</b>

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## Sandoz

### Outpacing our Rivals

Our generics business unit, now unified under the Sandoz brand, has become a world leader in its industry by combining organic growth and strategic acquisitions a strategy that continued to pay dividends last year.

Lek, the Slovenian generics company acquired by Novartis in 2002, provided one of the highlights of 2003 with its US launch of omeprazole, a cost-effective generic alternative to the antiulcer treatment Losec/Prilosec®. It was the world's biggest-selling prescription medicine during the late 1990s until patent protection expired. Lek had already marketed omeprazole successfully in Slovenia and certain other European markets where the drug no longer had patent coverage.

Another new Sandoz product launched last year is loratadine, a generic version of the blockbuster antihistamine Claritin® used to treat allergy.

Sales in 2003 were also fueled by buoyant demand for Amoxicillin Clavulanate Potassium (AmoxC), the generic version of the antibiotic Augmentin®. AmoxC was launched in July 2002, but Sandoz remained the sole supplier of a cost-effective generic alternative for several months following a US court ruling invalidating certain Augmentin® patents challenged by Sandoz.

### Investing for Global Cost Leadership

While Sandoz already markets more than 400 generic products, a steady stream of new products is crucial to success. The next few years are expected to spur rapid growth in the global generics market, where annual sales have reached USD 60 billion. Blockbuster medicines representing combined annual sales of USD 20 billion will lose patent protection between 2004 and 2006, offering lucrative targets for generic manufacturers.

Worldwide sales in the generics retail market are projected to climb at an average annual rate of 10% between 2003 and 2008, slightly higher than the 8.4% growth projected for patent-protected prescription drugs during the same period. To make the most of that opportunity, Sandoz already has applications pending with US regulators, seeking authorization to launch more than 40 new generic products once patents expire on the original branded medicines.

Speed of development is crucial to success in generics. Underscoring its global reach, Sandoz has one of the industry's biggest development programs, with teams of scientists now based in India and Slovenia, as well as the US and Austria.

Vertical integration at Sandoz also provides valuable synergies and a nimble production network that speeds the flow of new products to market. Sandoz is a major producer of bulk active pharmaceutical ingredients, including anti-infectives, where it ranks as world leader in bulk amoxicillin penicillins as well as the cephalosporin 7-ACA business.

As the generics industry becomes increasingly global, cost leadership is essential for success. Sandoz has invested about USD 100 million in recent years to upgrade its plants in Austria and Slovenia, and new factories are also under construction in India and Poland.

### Protecting First Mover Advantage

In the fiercely competitive US market, prices of original, patent-protected medicines can fall significantly following the introduction of generic competition. This is partly the result of a complex system of legislative incentives to encourage the development of cost-effective generic products. However legislation leads to frequent legal disputes.

AmoxC is an example of how battles in court usually precede battles in the market. The key US patents on Augmentin® were due to expire in 2002, but GlaxoSmithKline PLC (GSK), which discovered and developed the antibiotic, claimed that additional patents provided another round of coverage lasting until 2018.

37

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Sandoz challenged the patents extending beyond 2002, and in May 2002 the US District Court for the Eastern District of Virginia agreed and invalidated them. Sandoz launched AmoxC two months later, and this confident move was vindicated when, late last year, the Court of Appeals for the Federal Circuit affirmed the earlier District Court ruling.

"Being first or second to launch is crucial in the US," says Dr. Harald Summer, Project Manager for AmoxC at Sandoz. "Sales crumble very rapidly if several generic players are on the market and experience has shown that if you are third to launch, you are almost too late."

Lek was also forced into the courts to defend its procedure for the synthesis of omeprazole, which the Slovenian company began developing in 1997. Shortly before Christmas last year, the Board of Appeal of the European Patent Office upheld the validity of Lek's European patent, which protects the manufacturing procedure for synthesis of omeprazole. In all, Lek holds five patents covering the process in the US as well as Europe.

### **Global Network, Global Success: Rebranding Generics**

In January 2003, the industry experience, production skills, and product portfolios of our 14 individual generics companies were merged to create a unified world-class entity. The generics unit was relaunched under the well known name Sandoz, previously used by one of the predecessor companies that merged to create Novartis in its present form. The Sandoz name stands for quality and reliability of supply.

The clear objective: to better take advantage of synergies in production (the importance of global production networks for multinational companies cannot be overestimated), supply chain management, sourcing, and drug development and registration. We are also aiming to consolidate our overall leadership position by joining forces and speaking with one unique and strong voice.

The re-branding process will be completed in 2005, except for the integration of Lek, which will remain a separate Slovenia-based brand for the time being.

With global headquarters in Vienna, at the crossroads of Eastern and Western European cultures, Sandoz is well positioned as a global industry leader in the generics business. Sandoz is looking to attract talent and, local expertise from diverse markets. Harnessing diversity is a key to market penetration, and at the new headquarters in Vienna, 15 nations are already represented among the associates, whose numbers will increase further in 2004.

As well as consolidating our existing position, we are continually looking to increase our global market segment share, and have recently broadened our operations through several strategic site acquisitions.

Antibiotics remain an important priority. The Amifarma S.L. plant in Palafolls, Spain, which we acquired in December 2003, offers us an opportunity to strengthen our leading position in the sterile penicillins segment. Providing freeze-drying technology and expanding production capacity of sterile antibiotics, the plant is an ideal complement to our existing center of excellence for oral semi-synthetic penicillins in Spain, the state-of-the-art Les Franqueses site.

Sandoz also plans to leverage its global influence in industrial antibiotics by moving further downstream, into the development of finished, retail antibiotics.

Furthermore, Sandoz intends to build on its competitive advantages in the development and production of highly promising Biopharmaceuticals.

Sandoz continues to be driven by proven marketing expertise and strategic acuity, but the global leadership role will be strengthened through the increased efficiency which comes from centralizing under the Sandoz brand.

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## Over-the-Counter (OTC)

### The Value of Global Brands

All over the world, rather than turn to a doctor, people increasingly prefer to find their own solutions to their most common medical conditions. There are many reasons for this. They include pressure on government health funding, higher individual expectations for personal well being, a rising confidence in self-care, and increasing availability of prescription products in OTC formats. Nowadays people are looking for innovative, effective and accessible OTC medicines with which to enhance their overall health and well being, and they are finding the medicines they want in a widening range of outlets.

Elke Winter lives in Munich, Germany and works in marketing. Her rewarding but physically demanding job involves traveling the world organizing seminars and trade shows from Asia to the US. But Elke has a history of back trouble, and nearly four years ago was diagnosed with a slipped disc. The orthopedic clinicians decided not to operate, but put Elke into a clinic for treatment.

After this she felt much better, but continued to suffer back pain from time to time. She tried a Novartis OTC product that she had heard about, *Voltaren Emulgel*, and now continues to use it regularly. "If I feel the pain coming on and I apply *Voltaren Emulgel*, I only have to wrap myself up in a blanket and I feel better," says Elke. This is progress indeed. As Elke, a keen sportswoman added: "During the times when I was badly in pain I really considered quitting my job. Now I am back doing everything again. And when I need to lift something heavy, there is always someone there to help!"

### Building a Bigger Picture from Smaller Pieces

Similar stories reach us from people all over the world, describing the many small but significant ways in which Novartis OTC products are improving the quality of life of many of our consumers.

When one consumer called us up asking if he could make a commercial for *Lamisil*, we were obviously a little surprised, and asked him why. He explained that he had reached the age of seventy, and had suffered from athlete's foot since he was a boy. "I have tried several products, but to no avail," he told us. "But then, my son told me to try *Lamisil*. I did, and it worked. Now I am really happy about that, I feel like a million dollars. I just want to let the world know how great it is by doing a TV commercial for you!" *Lamisil* is the only treatment for athlete's foot which is approved by the US Food and Drug Administration (FDA) for a seven-day treatment, while competitive products usually require multiple applications per day for several weeks.

Milagros German is a beauty queen in the Dominican Republic. She is something of a national celebrity. In a recent interview she was asked to name the ten most important things she carries in her handbag. Included on her list among the indispensable cosmetics was a Novartis OTC product, *Otrivin*, a nasal decongestant.

Global success with global brands means enhancing our customers' lives. Our brands bring relief from the symptoms of the most common ailments almost everywhere, every day. By focusing on the strongest brands and creating global consistency for them, Novartis is building on its marketing strengths and improving both patient benefit delivery and profits.

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## Novartis OTC Medicines

The Novartis OTC Business Unit manufactures and distributes products for the treatment and prevention of common medical conditions and ailments, to enhance people's overall health and well being. Treatments are marketed in key product categories: cough, cold and allergy; gastrointestinal; dermatological; analgesics; vitamins, minerals and supplements; venous disorder; and smoking cessation. Overall performance in 2003 saw successes for five global brands. *Lamisil*, the one week treatment for athlete's foot posted strong sales growth of 16%. *Voltaren Emulgel* the topical analgesic for muscle pain, strengthened its number one position within the category. *Nicotinell/Habitrol* our smoking



cessation franchise, increased sales by 49% over 2002 *Otrivin*, the nasal decongestant is close to market segment leadership on a global basis. Building on the long tradition and significant equity of the Sandoz name, the Business Unit is committed to driving *Sandoz Calcium* to a USD 200 million brand.

### **Going Global with Five Brands**

Given their success it is not surprising that *Voltaren*, *Lamisil*, *Nicotinell/Habitrol*, *Sandoz Calcium* and *Otrivin* have been selected to become the first "official" global brands. Each will benefit from increased spending in research and development (R&D), increased advertising and promotion, and the commitment of a Global Brand Team (GBT) to drive their success. Our goal is to achieve continuous and sustained combined growth of 10% for these five brands. Mike Prebenda explains what sets them apart from the other 155 brands in the Novartis OTC portfolio.

"A global brand is one that has a solid presence in two or more of the four regions around the world, and possesses strong growth and profit potential."

Beyond a global presence, the brands were evaluated on other criteria including profitability, potential for growth and a significant competitive advantage or opportunity. Strong brands, science-based products and in-house marketing and sales organizations are the key strengths that continue to drive the Business Unit forward towards the leadership objective.

### **Driving Brand Awareness**

The growing number of distribution channels is a key feature of the OTC landscape, bringing many brand-building benefits. As well as distributing through pharmacies, our brands are available through food, drug and other massretail outlets. For example, the launch of the first WalMart "Health Screening" initiative occurred in September, in the US. Nearly 3 000 WalMart stores provided free glucose and bloodpressure screenings to 122 000 consumers, driving awareness and trial of Novartis OTC (*Benefiber*, *Maalox*, *Lamisil*) and Pharmaceuticals (*Diovan*) brands.

Two further important strategic factors are in place to secure the global foothold. The first is the proven ability to switch products from prescription to OTC, and the second is the globalization of R&D, both factors which increase efficiency dramatically.

### **Globalization of Research and Development**

A new product development and commercialization process has been implemented in 2003, which will drive innovation in a more effective and efficient manner. A new structure provides the flexibility to closely align people and skills with projects, and to facilitate the development of technology platforms, skills, knowledge sharing and individual development across the globe. The primary OTC R&D facility is based in Switzerland, where it can operate closely with the Pharmaceuticals Division. Currently OTC R&D employs 200 associates worldwide, with local country organizations mainly managing compliance, regulatory needs and medical affairs.

40

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For Novartis OTC the vision is global, and the emphasis now is on results. Global brands will have a more consistent look and feel, and a more focused delivery in the market place. With participation from everyone on the new multifunctional teams, time will be gained between concept and product launch. And now within the GBTs, success is being defined as one major idea with high consumer impact for each brand in each year.

## **Animal Health**

### **Up and Running, Despite Arthritis**

Six-year old Sasha's favorite game is chasing her playmates George and Eek around their one-acre field in Alton, New Hampshire, US. Her second favorite is dragging Jill DeCubellis for three miles around the local woods. If this all sounds a little energetic for someone aged six, that's because Sasha is a ninety-pound rottweiler and George and Eek are cats, the companion animals who share Jill's life.

A year ago Sasha started to drag her left hind leg, so Jill took her to the local veterinarian. There things took an unexpected turn for the worse. Sasha jumped up on the exam table, couldn't make it and slipped off, injuring her knee. "She was limping badly," DeCubellis said.

### **A Stark Diagnosis**

Sasha had arthritis in her left hip, and a newly acquired torn ligament. The veterinarian recommended surgery at the Angell Memorial Hospital in Boston, where Sasha was prescribed *Deramaxx*, a new arthritis drug made specifically for dogs, by Novartis Animal Health US. Within days Sasha was limping less. Soon she was running again.

Like Sasha, our pets are living longer, and consequently suffer many of the same health problems that humans do. Until recently little attention was paid to why oncelively dogs gradually turn into couch potatoes. According to Dr. Brian Beale, veterinary surgeon and canine arthritis expert at Gulf Coast Veterinary Specialists, Houston, US: "Many dog owners don't realize their pets are suffering. They often think their dogs are just getting old. Or they don't connect subtle changes in behavior to the pain of arthritis." One in five adult dogs suffers from osteoarthritis, and untreated pain can stress a pet and impair natural bodily functions.

Once a human medication makes the news, veterinarians know their clients will soon expect the same benefits for their pets. "Novartis is raising the bar to meet those expectations," says Elaine May, Senior Product Manager, *Deramaxx*. The breakthrough drug was launched in 2003 in chewable tablet form, and is the first and only drug that controls canine pain in a way similar to the Cox2 class of non-steroidal anti-inflammatories (NSAIDS) that has revolutionized the treatment of human arthritis.

"*Deramaxx* makes it easier for dogs to move more freely, and be more active," says Dr. Darryl Millis, Associate Professor of Orthopedic Surgery at the University of Tennessee College of Veterinary Medicine.

Jill DeCubellis certainly agrees. Sasha has gone back to teasing George and Eek, and is straining at the leash once more, urging Jill to go further and faster on their daily walks. "It was a tough few months for Sasha," admits DeCubellis, "but her quality of life is such that she doesn't know she's sick and that's all that matters to me."

### **Saving, Prolonging, and Improving Animal Lives**

The Animal Health Business Unit is dedicated to maintaining and improving the health and welfare of both pets and farm animals. The Business Unit is active in three areas. Pet, Farm Animal and Aqua-Health. We research, develop and commercialize leading animal treatments that meet the needs of pet owners, farmers and veterinarians, and in general, the products are available by prescription. For the Animal Health Business Unit the story continues to be one of successful new product launches, and of growth through innovation and geographical expansion.

In companion animal health, the *Deramaxx* launch quickly achieved a 21% market segment share in the US. But around the world and in other categories Novartis products have clearly led through innovation. Canine atopic dermatitis is prevalent in about 10% of dogs. Being an allergy, it is a lifelong condition, but *Atopica*, launched in 2003, relieves the symptoms without the side effects of steroids. *Fortekor* prolongs the active life of cats and dogs suffering chronic renal failure or heart disease. In the EU, *Milbemax* intestinal parasite control, with variants for both cats and dogs, achieved outstanding success. On the farm, *Agita* is an effective new product for the control of disease-carrying flies. *Vetrazine*, which controls blowfly strikes in sheep, reached its 25th anniversary, now followed by *Click*, providing season-long protection.

Future growth lies in continuing innovation fueled by responsiveness to consumers' needs. Ask Jill and Sasha!

## **Medical Nutrition**

### **A New Relevance for Cancer Patients**

Nutrition makes a difference to people fighting cancer. Those who keep their weight stable are known to have a better outlook, yet as the disease and the treatments take their toll, even favorite foods prove unappetizing, and the scales tend to plunge. Even a minor drop in weight can lower a person's chance of survival.

Some facts about nutrition and cancer:

**1.3 million new cases of cancer were estimated for the US in 2003.**

**Over 3 million people are diagnosed with cancer in Europe every year.**

**20% of cancer patients who do not survive the disease are thought to die of malnutrition alone rather than from the direct effects of the disease.**

**40% of cancer patients are malnourished.**

**A 5% cancer-induced weight loss coincides with increased mortality of 30-50%.**

A specialized nutritional formula developed by Novartis Medical Nutrition is now available to address this malnutrition problem. *Resource Support* helps cancer patients gain weight, build muscle and strengthen their immune systems.

Since its launch in 2003, the response to *Resource Support* has been tremendous. "My husband was put on *Resource Support* by his doctor, and in two weeks he has made such progress that I can hardly put it into words. He is eating again and even has energy to take short walks," is just one comment received by the US sales team.

In response to a questionnaire, another person told how *Resource Support* helped her mother who was bedbound, weak and not eating due to cancer. "She started on three servings of *Resource Support* a day, with amazing results. When she walked into the clinic for her next visit, the oncologist and the nurses couldn't get over the difference," she related.

*Resource Support* is a high-calorie formula with a unique blend of nutrients designed to boost the immune system and help rebuild muscle. Proteins and specific essential amino acids, vitamin E and omega-3 polyunsaturated fatty acids act in concert to promote weight gain, while improving patients' tolerance to cancer treatment such as radiotherapy and chemotherapy. The outcome is what patients value most highly: being physically and emotionally prepared to fight the disease.

#### **Fit for Surgery**

Surgery and trauma often plunge the body into a state of immune-suppression, exposing patients to a greater risk of infection. "Despite significant advances in surgery, post-operative complications, particularly infections, remain common, adding to the length of hospital stay, healthcare costs and potential mortality," says Mr. Alistair Windsor, Consultant Surgeon, St Mark's Hospital, Harrow, UK. For this reason the surgical community is increasingly taking notice of the benefits of nutritional products containing specific substrates.

*IMPACT*, an immune-enhancing formula developed by the Medical Nutrition Business Unit originally for the critically ill, has been at the forefront of this interest. *IMPACT* has also been widely investigated with surgical patients. Further research has extended its use before surgery, thereby providing a boost to the immune system to counter the slump that follows the operation.

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"The major cost of surgical complications, particularly infectious complications, is due to prolonged hospital stays," said Dr. Luca Gianotti, Department of Surgery, University of Milano-Bicocca, Monza, Italy at the 2003 annual meeting of the Surgical Infection Society Europe. "The benefit of immunonutrition [*IMPACT*] is mainly in reducing the rate of infectious complications. The cost of providing a pre-operative immune-enhancing diet was more than offset by the reduced length of stay." Dr. Gianotti's research findings showed that immunonutrition reduced hospital stays following GI cancer surgery by nearly two-and-one-half days, from 14 to 11.6. The findings also showed a halving of

postoperative infections from 30% to 14%, as a result of the new diet.

By being "fit for surgery" with appropriate nutrition, patients can look forward to returning home sooner.

## **Going Global**

As nutrition gains recognition in medical practice, Novartis has remained one step ahead and expanded the medical nutrition business in a big way. In December 2003, Novartis announced its intention to acquire the brands, trademarks, patents and intellectual property assets of Mead Johnson & Company's global adult medical nutrition business. Mead Johnson & Company, a subsidiary of Bristol-Myers Squibb Company, is a leader in sales and marketing of adult medical nutrition products.

Successful completion of the transaction will offer Novartis Medical Nutrition a strong presence in the fastgrowing US retail channel for medical nutrition products, expand its existing institutional medical nutrition business and enhance its access to the Japanese market.

"The acquisition of Mead Johnson & Company's adult medical nutrition business reconfirms our commitment to delivering high quality products that help people maintain good health, recover from illnesses more quickly, and build the strength and vitality to combat disease," says Michel Gardet, Global Head of Novartis Medical Nutrition. "Enhancing our medical nutrition portfolio will allow us to better serve the needs of the growing outpatient and aging populations."

Headquartered in Evansville, Indiana, US, Mead Johnson & Company will continue to manufacture and supply the majority of the acquired products for Novartis on an ongoing basis. Sales of the products in the process of being acquired exceeded USD 220 million in 2002.

Expansion is not entirely new to the medical nutrition unit. In June 2003, its range of products received a boost with the acquisition of Semper Clinical Nutrition, a business with whom Novartis has enjoyed a successful alliance since 2001. Semper is the second largest medical nutrition business in the European Nordic region with sales of approximately USD 10 million.

With expansion comes reorganization and, as from August 2003, the Medical Nutrition Business Unit has further globalized its activities and functions. One way to accelerate the time to market of its new product innovations is by spreading the R&D for both the existing product portfolio and the growing number of disease-specific products strategically across continents. The leading unit for R&D is now in Minneapolis, and is charged with research and product development, while the Clinical Sciences group responsible for driving pre-clinical and clinical studies continues to be based at the Business Unit's global headquarters in Nyon, Switzerland.

The Unit's aim is to become a leader in disease-specific nutrition in selected areas including oncology, digestive health, diabetes and wound care, while continuing as market leader for nutritional solutions in the management of dysphagia and the critically ill. This is being achieved by identifying market requirements and developing innovative products that meet the different needs of patients and healthcare professionals. It is undoubtedly a tall order, but one that the medical nutrition business is set to deliver.

## **Infant & Baby**

### **Healthy Eating Starts Early**

Gerber's landmark Feeding Infants and Toddlers Study (FITS), the results of which were published in 2003, during its 75th anniversary year, provides hard evidence of a serious nutrition problem among the youngest segment of the US population. According to the study, large numbers of infants and toddlers are already showing signs of the same unhealthy diet followed by many adults. FITS revealed that on any given day, 25 to 30% of children between 7 and 24 months eat no fruit, and 20 to 25% do not eat vegetables. French fries are the most commonly consumed "vegetable" for children of 19 to 24 months.

Commissioned by Gerber, FITS is the largest survey ever of eating habits and nutrient intakes of American children from 4 to 24 months. The two-year study of over 3 000 children is also the first of this magnitude to apply the Institute of Medicine's new Dietary Reference Intake standards to this age group.

As an accomplished dietitian and Gerber's Director of Nutrition Sciences and regulatory affairs, Dr. Kathleen Reidy was not overly surprised by the FITS results. However, that did not make the recent findings any less urgent for Dr. Reidy and others who are concerned about the growing epidemic of childhood obesity.

"Since we unveiled FITS at an American Dietetic Association conference in October 2003, the interest from health professionals and the media worldwide has been beyond our expectations," explains Dr. Reidy. "We have a tremendous opportunity here to alert the public that lifelong eating habits start at an early age, and that it's critical to teach our children healthy eating habits right from the start."

Dr. Reidy praises the extreme dedication and quick action of FITS Project Leader, Dr. Paula Zeiger and other Gerber associates in spreading the word. Actions range from a high-profile conference in Washington, D.C. to a series of ten comprehensive research papers published in a special supplement to the Journal of the American Dietetic Association in January 2004.

The FITS findings received wide media coverage in North America with features in over 100 major market newspapers, and placements in national magazines and broadcast outlets. Word spread like wildfire around the world, further fueled by hundreds of websites.

### **Reducing Childhood Obesity**

While it is too early to evaluate the full impact of the Gerber study, Dr. Reidy is confident that nutrition education initiatives that provide parents with concrete and actionable advice can make an important difference in children's lives. She recalls one young mother who, after hearing the study results, told her: "I didn't feed my baby a vegetable yesterday...I think I'll do that today."

But Gerber's achievements in 2003 were not confined to the publication of the FITS results, and building further on its long-standing reputation of commitment to babies and their families, the company successfully continued the development of its Start Healthy campaign. This education and research initiative aims to reduce childhood obesity, and has been supported by Tommy G. Thompson, Secretary of the US Department of Health and Human Services. During 2003, the campaign was launched in Mexico and Puerto Rico, where Gerber built on existing partnerships with pediatric associations and government organizations. In Israel, a Start Healthy magazine was launched and circulated among health professionals and consumers.

### **Marketing Initiatives in 2003**

Furthering its position as an innovative industry leader, Gerber converted from glass to plastic packaging for fruits, resulting in an outstanding performance of Gerber Products in the US.

45

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Consumer and customer satisfaction were, as always, top priorities. The company earned the highest industry rating for consumer satisfaction from Planet Feedback, a web-based survey organization, in recognition of the 24/7, one-on-one assistance offered by the Gerber Parent Resource Center. But perhaps the most impressive accolade came from the original Gerber Baby herself, Ann Turner Cook, whose childhood image has been used to represent Gerber from the start, and with whom the company worked closely during its 75th anniversary year. Ms. Cook, now a grandmother and mystery writer said: "I'm delighted to be associated with a company that has done so much for children and continues to do so."

46

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## **CIBA Vision**

### **Innovation in Focus**

Discovering *Focus NIGHT & DAY* continuous-wear lenses can be quite enlightening. At CIBA Vision we know this from the many testimonial emails we receive via our web-site.<sup>(1)</sup> For one correspondent, using *Focus NIGHT & DAY* continuous-wear lenses for up to thirty nights and days was just such an experience. "Before, I couldn't get out of bed in the morning without first putting on my glasses," the email enthuses. "Now when I wake up in the morning and look out of the window, I can see!"

(1)

[www.nightanddaycontacts.com/html/testimonials.shtml](http://www.nightanddaycontacts.com/html/testimonials.shtml)

For the many people with impaired eyesight, a dream has come true. They no longer worry about the inconvenience of wearing glasses. For anyone who does not need glasses this must seem like a big deal about nothing, but for those who wear them regularly, it is almost a miracle.

*Focus NIGHT & DAY* contact lenses are the result of dedication to research and development (R&D) at CIBA Vision. A continuous flow of innovative advances in contact lens and lens care products is brought from the labs to the consumer. And once on the market, work does not stop. One of the latest achievements is US FDA approval of *Focus NIGHT & DAY* for therapeutic use as a bandage lens. Other achievements in 2003 include the launch of a number of new product additions to the CIBA Vision range of leading brands of cosmetic and color lenses.

*FreshLook Dimensions*, the new generation of enhancing color contact lenses designed specifically for light eyes, was launched in June in the US, as well as two new *FreshLook ColorBlends* colors, Pure Hazel and True Sapphire. These provide a more intense eye color change than other *FreshLook ColorBlends* colors.

Customer comfort plays an important role in new lens care product developments. *SOLO-care AQUA* is the latest generation of no-rub multipurpose lens care solution and was introduced in Europe in 2003. Its *HydroLock* formulation includes Provitamin B5, which is also used in hair care and wound healing products to lock in moisture. In addition, every bottle of *SOLO-care AQUA* comes with a specially designed *MicroBlock* antibacterial lens case that kills bacteria and other microorganisms on contact and resists the growth of new bacteria.

*AOSEPT* saw a number of new developments, with *Clear Care* (in Europe: *AOSEPT Plus*) receiving FDA approval for several new applications, becoming the fastest growing contact lens solution in the US.

The driving force behind the flow of innovations is the team at CIBA Vision. Lynn Winterton is one example. A Distinguished Research Fellow and a member of the CIBA Vision Lens R&D team, he was honored with the Novartis Leading Scientist Award in 2003. This award recognizes Novartis R&D scientists worldwide for creative and innovative achievements. Lynn, who has been with CIBA Vision for almost twenty years, was recognized for his key role in the development of plasma surface coatings for *Focus NIGHT & DAY*. Over the course of his career, Lynn has been named as an inventor on nineteen US patents and has another twenty-six patent applications pending. "I was so surprised and honored to receive the award, which I consider to be an award for CIBA Vision as a whole," Lynn said. "Nothing I've accomplished has been without the help of countless other people, so I feel very blessed to be working with such amazing people here at CIBA Vision. I am proud that our innovation was recognized."

47

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CIBA Vision associates always go the extra mile in their support of people affected by bad eyesight. They and the company contribute regularly to vision-related community organizations including The Guide Dog Foundation for the Blind, The Center for the Visually Impaired, Prevent Blindness, and Project Read, a program which provides recordings for the blind and dyslexic. Associates at CIBA Vision share in one mission: "better eyes for a better life" for our delighted email correspondents and for millions of others around the globe.

48

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## Corporate Citizenship

### Rolling Back Malaria

During the rainy season of 1999-2000, South Africa was racked by a major malaria epidemic. KwaZulu-Natal province, home to 9.4 million predominantly poor people, had been left virtually defenseless against malaria because the main weapons had stopped working. Malaria parasites had developed resistance to the antimalarial medicines on which the province traditionally relied. Studies showed that sulfadoxine pyrimethamine or SP, first-line therapy for more than a decade, was curing only one in every ten patients. Moreover, the epidemic was being spread by a lethal species of mosquito *Anopheles Funestus* which had not been seen in KwaZulu-Natal for more than 50 years. The invading mosquitoes were resistant to the insecticides which the province had adopted a few years earlier.

To handle the flood of malaria patients at Ndumo, a small clinic near the border with Swaziland, South Africa's defense forces erected a tent clinic staffed by army nurses. From there the most serious cases were despatched to Mosvold hospital, over thirty miles away. Mosvold serves 100,000 people scattered across 1,000 square miles, and was reeling under the burden of 500 malaria patients a day. This was double the normal out-patient caseload for all diseases combined.

At the peak of the epidemic, about half of Mosvold's 250 beds were filled by malaria patients. Sharing beds was common and dozens of patients took refuge on the floor of the hospital's physiotherapy center.

"We had patients spread all over the place, day and night; mothers with small children, people lying unconscious, having convulsions or vomiting," says Dolly Makhunga, a veteran outpatient nurse at Mosvold, shaking her head at the memory.

"It was a crisis and we had to do something urgently," recalls Professor Ronald Green-Thompson, Head of KwaZulu-Natal's Department of Health.

### **A Bold Strategy**

The prescription was a bold strategy in a seemingly hopeless situation. Professor Green-Thompson replaced the ineffective antimalarial drugs he and his team had been using with *Coartem*, a promising new medicine from Novartis. *Coartem* is a fixed combination that includes lumefantrine and artemether, a chemical derivative of artemisinin, a plant extract used for centuries in traditional Chinese medicine to treat malaria.

Artemisinin derivatives remain the most potent killers of malaria parasites yet discovered. In clinical studies, *Coartem* demonstrated cure rates above 95 percent, even in areas of multi-drug resistance. Though *Coartem* had not been widely tested in sub-Saharan Africa, South Africa's Medical Control Council completed a rapid regulatory review of the medicine during 2000, enabling KwaZulu-Natal to launch the drug as first-line antimalarial therapy in January 2001.

Harried doctors and nurses at the epicenter of the epidemic feared the worst. "We didn't know if this was going to work or not. The cat had got so much out of the bag, it didn't seem that even an effective new drug was going to work miracles," recalls Dr. Hervey Vaughan Williams, Medical Manager at Mosvold Hospital.

Yet against all odds, the switch in therapy plus the resumption of spraying with DDT managed to quell KwaZulu-Natal's malaria outbreak faster than almost anyone believed possible. Hospital admissions thinned and during the following two years, both the total number of malaria cases and associated deaths reported in the province shrank by more than 90 percent from 42 284 cases and 342 deaths in 2000, to 2 345 cases and 16 deaths in 2002.

### **A Beacon of Hope**

Success in rolling back malaria has made KwaZulu-Natal a beacon of hope at a critical point in the battle against a disease that causes an estimated 350 million infections and more than one million deaths worldwide every year.

Dr. Richard Feachem, Executive Director of the Global Fund to Fight AIDS, Tuberculosis and Malaria, warns that malaria has become more difficult to control over the past two decades, as drug-resistant forms of the disease have spread across tropical Africa and even reappeared in some regions where it had been virtually eradicated.

"Paradoxically," Dr. Feachem adds, "effective tools are now available to control malaria and to reduce dramatically malaria-related mortality among vulnerable groups such as children under five and pregnant women. It's not that we can't do it," he says. "We're just *not* doing it."

However, "doing it" requires political will in the form of well managed malaria control programs in countries where the disease is endemic. It also requires ample donor funding, such as the multi-million dollar grants now beginning to flow from the Global Fund, to pay for effective malaria treatment and prevention programs. They cover everything from drugs and rapid diagnostic tests to insecticide-treated bednets.

In a financial lifeline to developing countries, Novartis and the World Health Organization (WHO) are making *Coartem* available at cost under a unique public-private partnership. Moreover, Novartis and Medicines for Malaria Venture, a not-for-profit health organization, are jointly developing a pediatric formulation of *Coartem* which will be easier for children to take and could make treatment more effective by improving compliance.

The WHO now recommends that countries adopt artemisinin-based combination therapies (ACT), such as *Coartem*, "when there is strong evidence that existing conventional medicines are no longer working."

Several countries in sub-Saharan Africa are following that advice. Zambia revised its national malaria-control policy during 2002, adopting *Coartem* as first-line treatment. Other countries, from Mozambique and Burundi to Swaziland and Sudan, have added ACT options to their national malaria policies, or are considering use of *Coartem* in emergency settings, such as refugee camps, where drug-resistant malaria is often rife.

In addition to the agonizing death toll, malaria costs sub-Saharan Africa an estimated USD 12 billion a year in lost economic growth. Preliminary health-economic analysis of the KwaZulu-Natal data suggests that while *Coartem* therapy is more expensive than the older treatments (USD 2.40 per adult treatment course at the preferential WHO price for *Coartem*, versus 10–20 cents for sulfadoxine pyrimethamine (SP) or chloroquine), total treatment costs with *Coartem* are significantly lower, due to the dramatic reductions in the overall number of patients needing treatment and in the number of complications requiring hospitalization.

"The *Coartem* approach has clearly been cost effective. Even if the unit costs are more, total costs are less," Professor Green-Thompson explains. "But the ultimate equation is not in currencies but in human lives."

50

## Corporate Citizenship at Novartis

Novartis tirelessly aspires to responsible and conscientious global citizenship based on trust, transparency and accountability. This involves active societal engagement in areas where we have expertise and know-how to contribute, helping proactively where help is most needed, and establishing and implementing transparent ethical standards, policies and processes across all of our activities. Novartis applies all of its ethical standards globally and often exceeds the provisions of national standards and legal regulations.

Our primary and most important mission is to discover, develop, sustainably produce, and distribute high quality medicines, addressing unmet medical needs. We want to provide affordable, and thus accessible, well established treatment options to the best of our abilities and as far as our resources permit, for as many people as possible. By pursuing these goals we can best provide value to our customers and to society as a whole.

Our second mission is to try to help on a case by case basis where there is immediate need with products, funds, and other supportive measures. This encompasses free or subsidized treatment programs in developing countries, discounts and support programs for people without adequate medical insurance or other means in industrialized countries, as well as *ad hoc* donations addressing special needs such as leprosy, tuberculosis and disaster relief in various parts of the world (see table on page 52).

Thirdly, we have established a comprehensive set of policies and guidelines defining all important areas of Corporate Citizenship. This includes our Policy on Corporate Citizenship based on the obligations we endorsed by signing the United Nations Global Compact, our Code of Conduct, and our five Corporate Citizenship Guidelines. These Guidelines address: Management of Corporate Citizenship, Fair Working Conditions, Business Ethics, Human Rights, and Third-Party Management (see detailed sections and the table on page 57-58). Each of these policies and guidelines has been, or is currently being rolled out, supported by training and test programs.

51

## Novartis Access to Medicine Projects 2003

Project	Objective	Target Region	2003 market price USD millions	2002 market price USD millions	New patients reached in 2003	Patients reached since launch
Malaria/WHO	Providing <i>Coartem</i> at cost for public sector use	Africa, Asia, Latin America	4	1	460 000 <sup>(1)</sup>	650 000
Leprosy	Eliminate leprosy by 2005 by providing free MDT-treatment <sup>(2)</sup> through WHO	Global	4 <sup>(3)</sup>	7	600 000	2 500 000



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Project	Objective	Target Region	2003 market price USD millions	2002 market price USD millions	New patients reached in 2003	Patients reached since launch
Tuberculosis	100 000 FDCs (Fixed Dose Combinations) donated annually for five years	Tanzania	0		Initiated Dec. 2003	
Novartis Institute for Tropical Diseases (NITD), Singapore	Discover novel treatments and prevention methods for major tropical diseases and make available without profit <sup>(4)</sup>	Developing world	10	10		
Novartis Foundation for Sustainable Development (NFSD)	Work at policy and field level to improve access to healthcare for the world's poorest people. Supports programs which deliver a range of services such as psycho-social support for AIDS orphans, and rural health insurance.	Developing countries	7	7	n/a	n/a
Patient Assistance Programs (PAP); excl. <i>Gleevec/Glivec</i>	Assistance to patients experiencing financial hardship, with no third-party insurance coverage for their medicines	US	128	81	140 000	340 000
<i>Gleevec</i> US PAP	Within Novartis capabilities, continue to ensure access for patients who cannot afford the drug in the US	US	78	52	1 600	5 200
<i>Glivec</i> Global PAP	Within Novartis capabilities, continue to ensure access for patients who cannot afford the drug in the rest of the world	Global	60	29	1 900	2 900
Together Rx/Novartis Care Card	Prescription savings program for elderly low income Medicare recipients without other insurance	US	60	30	1 200 000 enrolled	230 000 used Novartis drugs
Emergency Relief	Support of major humanitarian organizations (emergency medical needs)	Global	19	15	325 000	1 300 000
Blindness	Donated intraocular lenses to NGOs for cataract surgery for patients with inadequate means	Developing countries	1	1	34 500	65 000
Health Alliances	No longer classified as access-related in 2003	Global	0	22	n/a	n/a
<b>Total</b>		<b>Worldwide</b>	<b>371</b>	<b>255</b>		

- (1) Shipments of 1.3 million treatments made in 2003 are expected to reach malaria patients in 2004.
- (2) Multi Drug Therapy Treatment.
- (3) Reduced cost of leprosy program can be attributed to the success of the program leading to a reduction in the number of patients.
- (4) Many research projects currently planned at the NITD would, by normal commercial standards, not gain funding.

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## Half a Million Tuberculosis Treatments Free

In 2002 more than 1.6 million people worldwide died of tuberculosis, making this disease the third biggest threat to human life, exceeded only by HIV and ischemic heart disease. In Africa, all attempts in recent years to control tuberculosis have been severely impaired by limited access to effective treatment. Now, with the help of a Novartis donation, half a million of the world's poorest tuberculosis patients are to receive the best available treatment, as recommended by the WHO. Under an agreement signed on December 19, 2003, by the WHO and Novartis, the drugs will be provided over a five-year period to countries scaling up tuberculosis control, with support from the Global Fund to Fight AIDS, Tuberculosis and Malaria.

The tuberculosis medication provided through this program consists of four different drugs (rifampicin, isoniazid, ethambutol, and pyrazinamide) in one tablet, in a fixed-dose combination for the first two months of treatment, and two drugs (rifampicin and isoniazid) in one tablet for the four-month continuation phase. This offers significant advantages over single drug regimens. Patients take just two or three tablets each day in the intensive phase of treatment rather than the 12 to 14 needed before, greatly improving the likelihood of compliance. The fixed-dose combination also lowers the risk of drug resistance and prescription errors as well as reducing the necessary duration of therapy from eight to six months. Novartis will provide the fixed-dose combination tablets in blister packs within specially designed patient kits. Blister packs protect the drugs from heat, moisture and insects, and improve patient compliance while the kits help to simplify logistics.

This donation brings together key players involved in tuberculosis control measures and programs. Health ministries provide political commitment and appropriate health policies; the WHO and the Global Tuberculosis Drug Facility contribute technical support at a country level; the Global Fund and other donors make resources available to enhance tuberculosis control efforts; and Novartis produces and provides the necessary high quality medicines.

## Novartis Human Rights Guideline Established

Globally operating companies can and should play a considerable role in promoting human rights in many parts of the world. Sustainable economic activity contributes towards providing environmental and industrial climates in which human rights can more easily flourish. Furthermore, in countries where the government is unwilling or unable to uphold its human rights responsibilities, global companies can choose to adhere to international rather than local standards thereby setting powerful examples. No reasonable person would dispute that corporate activities must be managed in a manner that upholds the rights of employees and recognizes the circumstances of the cultures of the local communities in which they operate. The issue at stake is to define the reasonable boundaries of the human rights responsibilities of business enterprises. It is relatively easy to determine where they begin. A company should adopt explicit corporate guidelines on human rights and establish procedures to ensure that all business activities are examined and monitored in respect to their alignment with human rights concepts. This Novartis has done.

In November 2003, we published new Corporate Citizenship Guidelines with regard to human rights. The purpose of these Guidelines is to define our commitment to "support and respect the protection of internationally proclaimed human rights."

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## Obligations in the Context of Civil and Political Human Rights

The civil and political rights of the Universal Declaration of Human Rights (UDHR) are, above all, essential responsibilities of states and their institutions. But the preamble of the UDHR stipulates that "every individual and every organ of society" should respect and promote these rights. Novartis perceives itself as an "organ of society" and therefore accepts, to varying degrees, human rights related responsibilities. The prime responsibility for Novartis is to ensure that its corporate activities do not contribute directly or indirectly to civil and political human rights abuses, and that the company, under no circumstances, will knowingly benefit from such abuses.

## Obligations in the Context of Economic, Social and Cultural Human Rights

The respect and promotion of economic, social and cultural rights is an essential part of the duties of states and regulatory authorities. Compared with civil and political rights, which aim to prevent state interference with individual freedoms, these positive rights are more difficult to enforce, as their implementation requires the material support of responsible stakeholders.

Today, many rights contained in the UDHR are not enjoyed by a large number of poor people. The lives of more than 1.2 billion people living in absolute poverty are characterized by the sad fact that their right to adequate food, clothing, and housing as well as their right to the highest attainable standard of physical and mental health remain unfulfilled.

The sheer scale of today's global poverty problems makes it obvious that private companies can only contribute towards the support and respect of economic, social, and cultural rights in the context of their normal business activities. Economic and social rights such as the right to work (Article 23 of the UDHR), the right to a standard of living adequate for the health and well being of a human and his or her family, including a right to medical care (Article 25), and the right to education (Article 26) cannot be progressively implemented without good governance, effective public services, and appropriate allocation of resources.

Novartis, however, contributes towards the fulfillment of economic, social and cultural rights by manufacturing pharmaceuticals and other products and by selling these in the market place. Novartis, like other responsible corporations, creates jobs and thus livelihoods for many people, compensates associates fairly and pays social security contributions. It buys goods, pays market prices for these and, last but not least, contributes to the financing of the community by paying taxes. However, in addition, Novartis offers voluntary benefits to employees within the framework of its Corporate Citizenship Policy, provides financial support for foundations, makes donations and contributes to the fulfillment of economic, social and cultural rights in other ways on a case-by-case basis.

## Code of Conduct

The Novartis Code of Conduct is an integral part of our Corporate Citizenship effort. It contains the key rights and duties (especially personal obligations) of all associates, including their right to air grievances or complain of violations of the Code of Conduct, the Policy on Corporate Citizenship or about financial matters through the Complaints Organizations and ultimately to the Audit and Compliance Committee of the Board (the "whistleblower" provisions). The state of compliance with the Code of Conduct is annually reported on by the Group Compliance Officer to this Committee.

Cases handled by the Compliance Organization in 2003 include instances where marketing practices may not have met our stringent standards, allegations in South America of anti-trust law violations and unfair trade practices, alleged failures to comply with local law, and possible conflicts of interests.

As might be expected, a number of employment related cases and complaints relating to discrimination, harassment and unfair behavior were reported.

All issues raised are under investigation. Disciplinary action will be taken where necessary and remedial actions, including improved training, will be implemented where required.

Training tools for the Code of Conduct are used world-wide to facilitate a consistent approach. The Pharmaceuticals Division has already trained more than 60% of its associates worldwide regarding legal requirements and ethical standards, and the Consumer Health Division has started a similar program, with a rollout in Switzerland as the first step. The US organizations have developed a comprehensive web-based training regimen. This comprises 12 training modules on Code of Conduct related subjects which were implemented in 2003.

Periodic and case by case reporting on Code of Conduct topics has also been improved. Tools are now in place enabling Novartis to measure and evaluate its performance systematically vis-a-vis ethical conduct expectations. We intend to develop and adapt these tools as required by the changing environment in which we operate.

This year, our annual Compliance Survey was sent to 2 600 associates in the US and to 16 000 associates in the rest of the world. In this survey we ask our associates to provide their opinion and information about compliance with the Code of Conduct and the Corporate Citizenship Policy. In addition, we specifically remind them of the existence of the Code's complaints procedure (the right and duty of every associate to complain about violations of the Code of Conduct and of the Corporate Citizenship Policy). As intended, this reminder has triggered an additional number of complaints about possible code violations which are now being followed up.

Audit activities have been strengthened, too. There is now a standard auditing tool for compliance with the Code of Conduct that is being used in all regular internal audits, as well as for self-audits by local operating companies. Special audit procedures will be expanded next year to include the Corporate Citizenship Policy.

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As a result of changes in US legislation, in 2003 we adopted an improved "whistleblower" procedure regarding complaints concerning financial matters, and an additional Ethics Code. The complaints procedure ensures that everybody can ask questions or complain about financial matters involving our businesses, even to the Audit and Compliance Committee. Our Ethics Code imposes additional ethical obligations on all our employees.

During 2004, we will focus our training, education and controls on:

Marketing practices

Prevention of healthcare fraud

Human rights related issues

Third-Party Management: working with our business partners to establish standards similar to those we observe ourselves

Compliance with laws

Conflict of interest issues

### New Marketing Code

In 2003, our Pharmaceuticals Division implemented its own marketing code to ensure consistently high ethical standards in promotional practices throughout the world. The code supplements national and international legislation, as well as industry codes. Its ten main principles, which are also being applied in the Consumer Health Division, will be complemented by business specific provisions in all of its business units in the course of 2004. Our US marketing standards are even higher.

55

In order to secure adherence to this code, marketing, sales and management personnel are being trained in workshops with the help of presentations and case studies. Moreover, a self-assessment tool has been launched and a compliance organization established throughout the Pharmaceuticals Division. In 2003, various on-site audits were conducted in countries including Russia, the UK and Canada. Violations of the code in 2003 resulted in the dismissal of several associates. For 2004, further training and on-site audits are scheduled, as well as a revision of the code based on our experiences in 2003.

56

### Results of our Corporate Citizenship Related Projects in 2003 and Targets for 2004

	Steps planned for 2003	Results 2003	Targets 2004
<b>Access to medicine</b>	Strengthen priority programs such as <i>Coartem</i> /malaria program.	Progress made in malaria program with the WHO; substantially increased financial engagement in key markets.	Develop pediatric form of <i>Coartem</i> (with MMV), <sup>(1)</sup> complete treatment guidelines, improve distribution to rural patients.
	Novartis Institute for Tropical Diseases (NITD) in Singapore: complete staffing. Become operational, establish networks and collaboration partners, initiate first research project.	Staffing on track, research projects initiated, first international conferences staged, external scientific reviews held.	Operational in new facilities, student training program commenced, second International Symposium in July 2004.

### Policy framework

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	<b>Steps planned for 2003</b>	<b>Results 2003</b>	<b>Targets 2004</b>
	Add fifth guideline that addresses relationship with third parties: application of Corporate Citizenship standards to suppliers, contractors, consultants, etc.	Corporate Citizenship Guideline 5: Third-Party Management approved, implementation process started.	Focus on implementation and integration into the corporate culture; coaching of local management; internal audit of compliance.
<b>Third-Party Management</b>	Expand existing HSE Third-Party Management Guideline to include all aspects of Corporate Citizenship.	Corporate Citizenship Guideline 5: Third Party Management approved, implementation process started.	Inform all suppliers of our commitment and expectations; categorize suppliers; send questionnaire to key suppliers; pilot Corporate Citizenship supplier audits.
<b>Respect for human rights</b>	Articulate comprehensive position covering the current human rights issues affecting the industry.	Corporate Citizenship Guideline 4 on Human Rights approved, public symposium organized.	Regional human rights workshops for managers.
<b>Code of Conduct</b>	Develop training tool.	Developed global e-learning tool; 60% of all Pharmaceuticals associates have already participated successfully.	Expand e-learning to employees of Consumer Health.
<b>Accountability of Management (integration in operational processes)</b>	Execute complete Corporate Citizenship management cycle including objective setting, performance measurement and year-end incentives.	Review meetings with all global Business Units, two meetings of the steering committee. All country heads and many managers have individual targets to meet.	As in 2003. Additionally, implement Guidelines 4 and 5, and close identified gaps.
<b>Working conditions</b>	Strengthen programs to ensure fair-living wage, diversity and adequate dialogue with all employees.	Project with BSR; <sup>(2)</sup> diversity programs in all bigger organizations; meetings with over 80% of all employees.	Close identified gaps, establish binding process for fixing local-basic-need wages.
<b>Fair-marketing practices</b>	Implement detailed standards and procedures in markets around the world.	Pharmaceuticals marketing code established. Global training program started.	Follow-up training and audits in Pharmaceuticals, full rollout of modified code in Consumer Health.
<b>Bioethics</b>	Adopt revised ethical framework for biomedical research due to revision of Helsinki Declaration.	Policy on Communication and Publication of Clinical Research Results updated to reflect revisions. Internal process established.	Review positions on biodiversity, animal welfare and stem cells.
57			
<b>Involvement of employees</b>	Roll out information program on Corporate Citizenship to all employees by mid-2003; communicate Corporate Citizenship concept to external stakeholders.	Face-to-face meetings on Corporate Citizenship with over 80% of all employees achieved by the end of 2003.	Workshops as follow-up with remaining employees and all new employees.
<b>Stakeholder engagement</b>	Deepen relationships with leading academic institutions, NGOs and think tanks.	Many projects/contacts established (e.g. Harvard Business School, BSR, MMV, financial markets, conferences).	Develop further platforms to intensify cooperation and joint projects with NGOs.
<b>Transparent reporting</b>	Continue to improve data quality and transparency for the Annual Report 2003. Adapt Corporate Citizenship reporting on the website to GRI <sup>(3)</sup> format.	Data quality of internal reporting improved, through clearer data definitions.	Make data available in GRI format. <sup>(4)</sup>
<b>External assurance</b>	Institutionalize independent Corporate Citizenship assurance process.	Corporate Citizenship assurance process established.	Consolidate Corporate Citizenship assurance process.

- (1) Medicines for Malaria Venture: [www.mmv.org](http://www.mmv.org)
- (2) Business for Social Responsibility: [www.bsr.org](http://www.bsr.org)
- (3) Global Reporting Initiative
- (4) [www.globalreporting.org](http://www.globalreporting.org)

### External Ratings

Benchmarking shows that Novartis is consistently rated by financial analysts to be among the leading companies for sustainability performance. Novartis is not included in one index, the FTSE4Good. This index strongly penalizes producers of baby food at present. However, the criteria applied are currently under review. We are proud to include the Gerber baby-food business among our many strong brands.

### The Novartis Foundation for Sustainable Development (NFSD)

Multinational companies operating throughout the world need to recognize the wider social, economic and environmental impact of their activities. This knowledge and understanding requires companies to be active and not reactive, for example, in health matters. Companies should as much as possible be part of the solution to a problem rather than purely observing it and being perceived as part of the problem.

The NFSD has been a leading private-sector organization for international development for 25 years and is committed to innovative, performance-related development cooperation. The Foundation is funded by the Novartis Group but works independently of the economic interests of the Group.

The Foundation aims to improve the quality of life for poor people in developing countries by improving access to healthcare through innovative development projects, think tank efforts and dialogue facilitation.

### Foundation Activities

The activities of the NFSD are based on four cornerstones:

1. Supporting projects that enable the sick and poor in developing countries to improve their health situation through better access to healthcare services as a pre-requisite for both individual well being and social and economic development.
2. Assisting the Novartis Group with its use of corporate assets for the benefit of developing countries and in particular, with the delivery of donated medicines by supporting programs that enhance the uptake and health impact of these donations.
3. Contributing its knowledge of development issues to the Novartis Group and advising the company with respect to corporate-social-responsibility policies in developing countries.
4. Engaging in research and promoting dialogue around sustainable involvement of the pharmaceutical industry in the social and economic development of the poorest regions of the world.

### Project Examples

The Foundation concentrates its financial and human resources on pilot projects within a manageable frame-work, where innovative solutions to health-access problems can be elaborated and where it can make a significant contribution. Examples include:

Understanding and improving access to malaria treatment in Tanzania

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Enhancing financial access to basic healthcare in Mali through community-based health insurance

Developing a computer-based training tool for health workers in developing countries to improve accessibility and quality of care

Providing free leprosy treatment to patients worldwide through 2005 together with the WHO, national health authorities and Novartis

59

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Providing free of charge 500 000 Directly Observed Treatment Short-Courses (DOTS) for tuberculosis over a five-year period through the WHO and the Global Tuberculosis Drug Facility for programs supported by the Global Fund to Fight AIDS, Tuberculosis and Malaria

Exploring ways to improve patient adherence to tuberculosis treatment

[www.novartisfoundation.com](http://www.novartisfoundation.com)

### Other Novartis Foundations

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#### Novartis US Foundation

Its purpose is to support efforts among communities, businesses and non-profit organizations on a range of social, health and education issues related to healthcare.

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#### Novartis Foundation France

The Novartis Foundation France provides persons with difficulties due to age, illness, handicap or family environment with personal and social support.

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#### Novartis Foundation Japan

The Novartis Foundation Japan contributes to the improvement of welfare, by aiding and promoting creative research and pursuing international exchange.

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#### Foundation for Health, Innovation and Society (Spain)

[www.fundsis.org](http://www.fundsis.org)

The Foundation promotes the study, investigation, analysis and improvement of health in its ethical, biological, psychological, sociological and economic dimensions.

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#### Novartis Venture Fund

[www.venturefund.novartis.com](http://www.venturefund.novartis.com)

The Novartis Venture Fund was founded six years ago with the mission to foster entrepreneurship and create new jobs, particularly for Novartis employees affected by the merger. It supports new business projects that show exemplary entrepreneurial spirit in future-oriented health science areas.

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#### The Novartis Foundation (UK)

[www.novartisfound.org.uk](http://www.novartisfound.org.uk)

The Novartis Foundation (UK) is a scientific and educational charity, intended to promote scientific excellence.

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60

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## Health, Safety and Environment

This section summarizes the Group's Health, Safety and Environmental (HSE) performance in 2003. Our HSE targets focused once again on reducing the number of accidents, lowering energy use/CO<sub>2</sub> emission, safely disposing of the hazardous waste we produce, and successfully integrating recently acquired partners and newly founded organizations. This report describes the most important measures undertaken to fulfill our ambitious targets, and discusses our achievements as well as areas in which we intend to improve. The full Novartis HSE report is available on our website at [www.novartis.com/hse](http://www.novartis.com/hse). There you will also find additional information on all the issues mentioned in this report.

## Strong Commitment

Protection of the environment has a high priority in all our activities. We strive to make efficient use of natural resources and minimize the environmental impact of our activities and products.

Between 2001 and 2003, we set ourselves the target of reducing our direct CO<sub>2</sub> emission by 3% (based on 2000 emission levels). As can be seen in our report on Air Emission (see page 66) we achieved a reduction of 2.8%, in spite of a 4.8% growth in production. The reduction was facilitated by a move to more energy-efficient facilities, and has resulted in a CO<sub>2</sub> emission level, relative to sales, that is well below the industry average.

In light of these achievements and with the goal of further improvement, we have proposed individual energy-efficiency targets for the Pharmaceuticals and the Consumer Health Divisions for 2004-2006. We will continue to report our absolute CO<sub>2</sub> emission and will also include indirect emission (e.g. from electricity and purchased energy).

Our focus on energy efficiency as opposed to absolute CO<sub>2</sub> emission better reflects our commitment to the sustainable use of natural resources<sup>(1)</sup>. Energy-efficiency improvement targets for each Business Unit will be 2% per year, based on their most representative denominator (e.g. sales, production, employees). Moreover, each Business Unit must report energy-saving projects that amount to a total reduction of 1% of the previous year's energy consumption.

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- (1) CO<sub>2</sub> emission reduction could also be achieved by switching to alternative fuels or purchasing steam, without reducing energy consumption.

## Enough Water for a Small City

When Sandoz, our generic pharmaceuticals Business Unit, originally acquired the Roferm S.p.A. plant at Rovereto in Italy in 1995, there was considerable room for improvement both economically and environmentally. Following the acquisition, the product portfolio was adapted to the needs of Sandoz and focused on the production of antibiotics. Investments worth approximately USD 170 million were also made in new technologies and equipment, together with logistical and environmental improvements.

In 2002, Rovereto achieved a reduction of more than 50% in halogenated VOC emission by cryocondensation, a major first step towards an HSE performance that is in-line with the highest environmental standards. During 2003, further progress was made through energy conservation and groundwater saving initiatives.

To reduce energy consumption, two new air compressors were fitted with heat recovery exchangers. The compression heat generated (2x360 kW) is now recovered and used to preheat the feed water for the plant's steam generators. This process has increased efficiency, reduced CO<sub>2</sub> emission by approximately 800 tonnes per year, and provided a cost saving of around USD 90 000 per year.

Rovereto's reduction of approximately 40% in its groundwater consumption during 2003 is an equally important achievement. Cooling water at the plant was previously used only once, before being discharged into the River Adige. Thanks to the investment in new technology, a recycling system has been installed that allows the water to be reused for cooling condensers and solvent recovery processes. The new system has resulted in an overall saving in groundwater consumption of around 510 m<sup>3</sup>/h, equal to the hourly water consumption of an Italian city of 50 000 inhabitants.

Now Rovereto is looking to go further and formalize its commitment to environmental management by applying for ISO 14001 and OHSAS 18001 certification in 2004.<sup>(2)</sup> Kurt Gstrein, Head of HSE, Sandoz is delighted with what has been achieved at the plant: "Rovereto's success shows how HSE management can combine with top-level engineering at acquired sites to bring about exceptional improvements in HSE



performance. It is an excellent model for the integration of new partners in the future".

- (2) ISO issued the international standard ISO 14001 for environmental management systems in 1996.

### Successfully Protecting our Personnel

At the end of 1997, Novartis took full ownership of the Queretaro baby-food site in Mexico, a plant that had a high rate of accidents attributable to a lack of safety awareness.

Operations management invested significantly in personal-protection equipment, fire-fighting systems, alarms, sprinklers, and noise-reduction measures. Employee training was also increased, and the Corporate HSE Guidelines as well as national/international standards were instituted together with a safety-improvement plan.

These actions brought swift and sustainable results, and the Lost-Time Accident Rate (LTAR) has fallen from 1.25 in 1998, to an impressive 0.15 in 2003: proof of just how effective good HSE management can be.

### Building a New Culture

The Des Plaines Illinois, US, site which manufactures the complete *FreshLook* contact lens product range was acquired by Ciba Vision in 2000. One of the major challenges since the acquisition of Wesley Jessen Corporation has been the adoption of Novartis/CIBA Vision HSE guidelines at this site. Over the last three years, thanks to the outstanding commitment of all site employees, considerable progress has been made.

HSE awareness has been raised using a variety of methods. These, combined with direct senior-management involvement in follow-up investigations of serious incidents and improved case management by site health services, have led to real improvements in on-site safety. Since 2002 the number of accidents needing first aid treatment has decreased by 38%. Accidents leading to an absence of more than one day have fallen by 78% and the number of accidents resulting in impairment of an individual's working capacity has been reduced by 46%. Over the last three years, costs associated with accident related absences have decreased by 75%.

The responsible HSE Officer, Shankar Sarkar, is enthusiastic about the site's success: "Our achievements, especially in accident prevention, have turned Des Plaines from a problem site into a role model that others can emulate."

62

### Remediation

Since our past operations may have led to the contamination of soil and/or groundwater, we have set aside financial reserves of USD 179 million for estimated potential-environmental liabilities. In and around Basel, the local chemical and pharmaceutical industries (including predecessor companies of Novartis) have established an organization to seek timely solutions to the possible consequences of past disposal practices at a number of landfills. The objective of this organization is to eliminate acute and long-term risks through pragmatic, eco-efficient measures that are developed in cooperation with the authorities, and are based on professional studies and assessment. During 2003, progress was made in the assessment of seven landfill sites in the Basel region, two of which may soon be excluded by the authorities from further investigation. We expect the authorities to take decisions on remediation for the five remaining sites in 2005 or 2006.

63

### Division/Business Unit Objectives and Achievements 2003-2004

Targets 2003	Results 2003	New targets 2004
<b>Pharmaceuticals</b>		

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<b>Targets 2003</b>	<b>Results 2003</b>	<b>New targets 2004</b>
Overall Lost-Time Accident Rate (LTAR) 0.5	LTAR 0.64 Positive trend emerging	LTAR 0.5
Prevention of drug substance release into aquatic environments from manufacturing sites	The presence of drug substances in wastewater was reduced by 49%	Further efforts towards the prevention of drug substance release into aquatic environments from manufacturing sites
Continued implementation of HSE management procedures in line with International standards	ISO 14001 certification of four additional strategic pharmaceutical manufacturing sites, one of which also achieved OHSAS 18001	Implementation of HSE management systems at manufacturing sites comparable with ISO 14001/OHSAS 18001 standards
Integration of Business Continuity Management (BCM) in Development and Technical Operations departments and in Pharmaceuticals business units	Reduction of key business continuity risks in Development and Technical Operations departments, and Pharmaceuticals business units	Assessment of business continuity risks for main Pharmaceuticals head offices and business units
3% reduction in CO <sub>2</sub> emission (based on data from 2000)	14.5% reduction achieved, primarily through a move to more energy-efficient facilities	Improvement of energy efficiency by 2%
		Promote health of employees by improving ergonomics of workplaces at head offices and in Development

**Novartis Institutes for BioMedical Research (NIBR)**

<b>Targets 2003</b>	<b>Results 2003</b>	<b>New targets 2004</b>
LTAR 0.5	LTAR 0.70	LTAR 0.5
	Research-specific risk portfolio developed	Development of a handling-classification scheme for research compounds
Continued BCM implementation aligned with Pharmaceuticals' schedule	Vulnerability assessments of disease areas 73% complete	Develop inventory key business processes and complete two BCM plans
		Improve energy efficiency by 2%; Establish energy teams at each site; Identify and implement fast action projects for energy savings to achieve targets

64

<b>Targets 2003</b>	<b>Results 2003</b>	<b>New targets 2004</b>
<b>Consumer Health</b>		
<b>Sandoz</b>		
LTAR <0.8 LT	AR 0.67 (0.99 including Lek)	LTAR <= 1.0
70 000 GJ reduction in energy consumption at Kundl, Austria resulting in a 1.6% reduction in overall Group CO <sub>2</sub> emission (based	Target exceeded through recent projects in Kundl, Austria with energy reduction of 68 000 GJ (compressor project), 50 000 GJ (yield	Improvement of energy efficiency by 2%

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<b>Targets 2003</b> on data from 2000)	<b>Results 2003</b> improvement), 70 000 GJ (municipal heating)	<b>New targets 2004</b>
50% staged reduction in halogenated VOC emission at the Turbhe site in India by 2004	Target exceeded with a 70% reduction in halogenated VOC emission at Turbhe	
The successful integration of Lek, Slovenia	Lek successfully integrated; HSE organization, risk portfolio and reporting established	Further improvements in Lek HSE performance
Pilot implementation of BCM	BCM pilot project successfully conducted; In addition joint BCM approach with IT establishing disaster-recovery plan for Kundl site	Definition of scope and objectives; Organization and inventory of key business processes; Continuation of BCM implementation for defined key business processes

**Over-the-Counter (OTC)**

<b>LTAR 0.45</b>	<b>LTAR 0.39</b>	<b>LTAR 0.45</b>
Ongoing reduction in energy consumption relative to production at defined sites	Economically viable energy-conservation programs implemented at major sites; Target of 2% reduction not achieved in 2003 on top of previous reductions	Improvement of energy efficiency by 2%
Continuation of audit reviews of third-party contractors	Risk portfolios for third-party contractors completed; HSE auditing of major third party contractors; including them in the BCM target; and committing them to the Corporate Citizenship initiative	Continuation of audit reviews with four or five selected third-party manufacturers
Pilot implementation of BCM	BCM pilot project implemented; Tools developed for the global roll out	Establishment of BCM plans for remaining main brands; completion of BCM studies of potential issues according to the strategic risk portfolio

65

<b>Targets 2003</b>	<b>Results 2003</b>	<b>New targets 2004</b>
<b>Animal Health</b>		
LTAR < 0.5	LTAR 0.53 (0.72 including NAVI)	LTAR < 0.5
Evaluation and improvement of third-party contractors' risk portfolios	Risk control improved for several third-party contractors with high impact; Four out of five of all third party contractors audited	Completion of third-party contractor audits
Pilot implementation of BCM	Pilot BCM study conducted according to schedule	Complete study of manufacturing and supply chain processes for five active ingredients and products; Investigate vulnerabilities at head offices
Initiation of a project for the reduction of energy consumption and	Measures successfully implemented; Results to be published in 2004	Improvement of energy efficiency by 2%

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Targets 2003	Results 2003	New targets 2004
SO <sub>2</sub> /CO <sub>2</sub> emission at Wusi Farm, China		

**Medical Nutrition**

LTAR 1.0	LTAR 0.04	LTAR < 0.6
Ongoing reduction in energy consumption relative to production at defined sites	Both Osthofen, Germany and Minneapolis, US achieved a 2% reduction in energy consumption	Improvement of energy efficiency by 2% (or 4% over 2 years)
Continuation of audit reviews of third-party contractors	Six contract manufacturers inspected by HSE and Quality Assurance teams	Continuation of four additional audit reviews for third-party contractors
Pilot implementation of BCM	Pilot Business Continuity Study conducted, addressing all key business processes at the Osthofen site	Address major risks and develop a business-resumption plan for the Osthofen site. Carry out full-process inventory and originate business-resumption plan for Minneapolis site

66

Targets 2003	Results 2003	New targets 2004
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**Infant & Baby**

LTAR 0.45	LTAR 0.26	LTAR <= 0.33
Ongoing reduction in energy consumption relative to production at defined sites	Target 2% reduction in energy consumption partly met; Ft. Smith, US exceeded the target	Improvement of energy efficiency by 2% (or 6% over 3 years)
Continuation of audit reviews of third-party contractors	Five audits of third-party contractors completed in China	Two further audit reviews of third-party contractors, combining HSE and Corporate Citizenship issues
Pilot implementation of BCM	Pilot BCM study of Fremont, US Customer Service Center completed in full, including business-resumption plan	Continuation of BCM implementation for selected processes

**CIBA Vision**

LTAR 0.6, by a reduction of 10% at every site	LTAR 0.42	LTAR 0.5
Continuation of water conservation activities	Outstanding achievements in water conservation: water recycling rate currently exceeding water consumption rate	Ongoing water conservation activities; Strengthening of leadership position in the field of water recycling
Establishment of energy-efficiency-improvement targets at major sites	Energy-conservation concepts elaborated; quantitative improvements achieved overall, mainly through energy-reduction projects in Sydney, Australia; Atlanta, US; and Mississauga, Canada	Improvement of energy efficiency by 2%

Targets 2003	Results 2003	New targets 2004
Conducting of three additional risk analyses and the establishment of an action plan at each site	Risk analysis of top three processes conducted at all sites	Recompilation of risk portfolio
Pilot implementation of BCM	Pilot study of Batam logistics conducted and joint study with IT disaster-recovery unit in Atlanta initiated	Continuation of BCM implementation for defined key business processes

67

## Abbreviations

BCM	Business Continuity Management	KPI	Key Performance Indicator
CO <sub>2</sub>	Carbon dioxide	LTAR	Lost-Time Accident Rate (measured as accidents per 200000 hours worked)
GJ	Giga Joule	NAVI	Novartis Animal Vaccines Inc.
GRI	Global Reporting Initiative	OHSAS	Occupational Health & Safety Management System
HSE	Health, Safety and Environment	SO <sub>2</sub>	Sulphur dioxide
ISO	International Organization for Standardization	VOC	Volatile organic compound
IT	Information Technology		

68

## HSE Management Procedures and Organization

Our HSE organization is focused on establishing systematic risk assessments, preventive measures and regular reviews including audits regarding the health, safety and environment performance at all our sites. It is crucial that such processes are in place throughout the organization to ensure that we continuously improve HSE performance and successfully integrate new acquired sites.

### Integrating our New Partner

Following our acquisition of the Slovenian-based generics company Lek in 2002, a key priority was to align standards, harmonize the HSE organizations, and synchronize the various environmental reporting processes.

Lek has the potential to significantly influence the overall Sandoz HSE data, and we were keen to preserve uniformly high standards. New HSE performance targets were set almost immediately, and thanks to the hard work, cooperation and initiative of our new colleagues at Lek, we achieved an important first step in 2003: a full report of HSE data for their 28 sites, which is contained in the HSE Data 2003 Overview Table on page 72.

### The Environmentally Friendly Site

In 2002, our US pharmaceutical research was consolidated in the new Novartis Institutes for BioMedical Research Inc. (NIBRI) in Cambridge, Massachusetts, US. The first new lab complex at 100 Technology Square opened in March 2003.

NIBRI is a cause for celebration not just within the research community, but also among those who have an eye on the future of our environment. The new building has been equipped using energy- efficient technologies and environmentally friendly finishes that incorporate recycled, recyclable or sustainable elements. It has been decorated using materials produced with minimum impact on the environment, and easily dismantled office partitions and modular workstations permit reconfiguration with minimal waste.

The Headquarters of NIBRI, at 200 Massachusetts Avenue are scheduled to open in April 2004, and the formerly disused building is currently undergoing an unusual transformation from candy factory to state-of-the-art research facility.

### Initiating a Cultural Shift

Certification according to ISO 14001 and/or OHSAS 18001 is an independent acknowledgement of the fact that sites are committed to implementing sound HSE management procedures, and continually strive to improve performance. While certification is a desirable objective in itself, on site, the work involved in achieving it has had a positive impact on attitudes to HSE.

The Pharmaceuticals site at Torre Annunziata in Italy has recently attained ISO certification, and Giorgio Lazza, Head of Pharmaceutical Manufacturing Italy, believes that this has made a significant difference: "During the certification process we underwent a major shift from simply observing existing procedures to an attitude of continuous improvement."

Pharmaceuticals aims to ensure that all its manufacturing sites conform to ISO 14001/OHSAS 18001 standards. Torre Annunziata (Italy), Huningue (France), Stein (Switzerland) and Taboão da Serra (Brazil) all received ISO 14001 certification in 2003. A complete list of sites with ISO 14001 certification can be found on the Internet at: [www.novartis.com/hse](http://www.novartis.com/hse)

### **HSE Risk Performance Management 2003**

Our two most important tools for HSE risk-performance management are our HSE risk portfolios and our HSE audits.

The risk portfolios are based on a bottom-up approach. Since 1997, our sites have been elaborating their local risk portfolios. These are consolidated at Business Unit and Division level, and finally at Group level in the Corporate HSE Risk Portfolio. This is regularly presented to, and discussed with, the Executive Committee of Novartis (ECN). In June 2003, 66 risks warranting priority action were reported. As a result of actions taken, eight priority risks from the previous risk portfolio have been declassified. Action plans for all remaining priority-listed risks have been developed and are currently being implemented. The next comprehensive risk review at Group level is scheduled for the second quarter of 2004.

As well as a control function, HSE audits serve to provide consultancy and support to our sites. During 2003, twelve corporate HSE audits and twelve Division/Business Unit HSE audits were carried out. Action programs based on the audits were defined by the sites and controlled by the Division/Business Unit; the Business Units have now completed between 85% and 100% of all necessary follow-up actions based on audits conducted.

### **HSE Performance and Data Management**

Globally, we now have over 400 dedicated HSE specialists at our sites who are continually analyzing our risk portfolio and driving the resulting action plans forward. Together with Group senior management, they have defined key performance indicators (KPIs) for our HSE related objectives. The KPIs are based on the data input of 150 sites managed by Novartis Group companies in 2003. These include all sites with significant impact on the Group's overall HSE-related performance (i.e. all production, formulation and R&D sites). Forty-one sites reported for the first time in 2003, the majority of which originated from the Lek acquisition. Ten sites, mainly impacting our Health and Functional Food business, were sold or closed.

HSE data are collected and reviewed on a quarterly basis. The emission and resource data published in this report, and on our website, are actual data for the period from January through September 2003 and estimates for the last quarter, which will be updated in the first quarter of 2004. Significant deviations will be reported on our website and in the 2004 Annual Report. The accident and financial data are actual data from January through December 2003.

The emission and resource data contained in the Annual Report 2002 were based on actual data for January to September and an estimate for the last quarter. The estimates have since been updated, and in two areas there were major deviations from the figures published last year. Waste rose significantly due to the demolition of a large pharmaceutical building in Basel, as well as a significant amount of non-reported compostable waste in the Infant & Baby Business Unit. Halogenated VOC emission was underestimated at one of our sites in India. The HSE investments and expenses of the previous years were converted from CHF into USD at a fixed rate. To allow comparisons of the 2003 data, the figures reported in previous years have been adjusted to include only data of sites still operated by Novartis. We have corrected this data in the HSE Data 2003 Overview Table in this report (p. 72).

The reporting and management processes as well as HSE data are part of the Corporate Citizenship assurance process. This is described in the assurance report (p. 81-82). In gathering these data, we take account of the impact of activities on our premises, together with major flows of material across our boundaries. We do not currently measure third-party impact from the manufacture of purchased goods, energy production or transportation.

Due to the many intangibles in healthcare value assessment of pharmaceutical products and the regulatory impact on many aspects of a pharmaceutical product's life cycle, we have not implemented a systematic, life-cycle-assessment management process for Novartis.

## 2003 Data

Divisional split based on 2003

	Consumer Health																Novartis Group <sup>(6)</sup>				
	Pharmaceuticals		NIBR		Sandoz <sup>(4)</sup>		OTC		Animal Health <sup>(5)</sup>		Medical Nutrition		Infant & Baby		CIBA Vision		% Change	2003	2002	2001	2000
	2003	2002	2003	2002	2003	2002	2003	2002	2003	2002	2003	2002	2003	2002	2003	2002	2003/2002				
<b>Employees</b>																					
HSE Personnel [number of employees working at least 50% for HSE]	202	201	2.0	1.0	111	76.9	2.3	2.0	25.3	23.5	4.0	5.75	40.0	41.0	25.2	24.1	6	414	389	449	396
<b>Finance</b>																					
HSE investments [USD millions]	76.9	26.3	0.90	0.14	6.77	8.00	0.35	0.28	0.58	0.46	0.83	0.60	0.21	1.44	0.57	0.57	128	87.7	38.5	31.5	36.3
HSE expenses [USD millions]	95.7	99.9	4.98	6.11	43.8	29.5	1.34	4.03	2.13	2.75	2.01	1.68	1.27	4.99	6.65	7.80	3	164	159	155	158
<b>Production</b>																					
Total production [1000 t = metric tons]	25.4	26.3			109	101	15.8	20.2	3.05	3.25	120	111	327	323	14.6	17.8	2	643	630	573	590
<b>Resources</b>																					
Water consumption [million cubic meters]	17.5	18.2	0.71	0.74	71.8	62.8	0.49	0.39	0.82	0.46	0.72	0.88	4.45	4.48	0.64	0.73	9	97.2	88.8	86.7	84.9
Energy consumption [million GJ]	5.13	6.00	0.52	0.45	6.27	5.10	0.32	0.31	0.18	0.14	0.26	0.31	2.07	2.17	0.75	0.83	1	15.6	15.4	14.5	13.8
<b>Health/safety</b>																					
Lost-time accident rate [accidents per 200 000 hours]	0.64	0.72	0.70	0.55	0.99	0.92	0.39	0.67	0.72	0.57	0.04	1.19	0.26	0.34	0.42	0.69	-15	0.60	0.71	0.71	0.88

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Consumer Health

Novartis Group<sup>(6)</sup>

worked]																						
Lost work																						
day rate [lost																						
days per 200																						
000 hours																						
worked]	<b>12.3</b>	15.4	<b>4.94</b>	2.12	<b>16.5</b>	7.50	<b>4.57</b>	14.7	<b>2.77</b>	7.60	<b>0.39</b>	7.72	<b>8.44</b>	8.95	<b>11.7</b>	10.7		-17	<b>11.0</b>	13.2	11.1	13.6

**Water emissions<sup>(1)</sup>**

Effluent discharge [million cubic meters]	<b>3.69</b>	4.07	<b>0.18</b>	0.19	<b>16.6</b>	11.7	<b>0.13</b>	0.24	<b>0.60</b>	0.11	<b>0.59</b>	0.78	<b>3.18</b>	3.32	<b>0.61</b>	0.68		21	<b>25.7</b>	21.2	20.4	19.2
Suspended solids[t]	<b>204</b>	247	<b>5.40</b>	7.50	<b>187</b>	184	<b>11.4</b>	10.7	<b>3.36</b>	6.81		2.30	<b>45.3</b>	19.1	<b>6.89</b>	4.09		-4	<b>487</b>	508	609	592
Chemical oxygen demand COD [1000 t]	<b>0.43</b>	0.42			<b>3.66</b>	3.06	<b>0.06</b>	0.05	<b>0.01</b>	0.01	<b>0.00</b>	0.03	<b>0.09</b>	0.06	<b>0.14</b>	0.09		19	<b>4.55</b>	3.83	3.96	3.82
Nitrogen [t]	<b>86.3</b>	122			<b>550</b>	303	<b>1.84</b>	1.22	<b>0.00</b>	0.00		0.17	<b>5.21</b>	5.80		0.24		49	<b>644</b>	432	401	504
Phosphate [t]	<b>21.1</b>	54.8			<b>17.2</b>	18.4	<b>4.11</b>	0.32	<b>0.00</b>	0.00			<b>12.0</b>	8.41	<b>2.61</b>	2.84		-33	<b>57.0</b>	84.7	61.3	96.9
Soluble salts [1000 t]	<b>7.69</b>	11.1			<b>14.9</b>	12.1	<b>0.50</b>	0.37	<b>0.00</b>	0.00		0.00	<b>0.01</b>	0.02	<b>0.15</b>	0.30		-2	<b>23.4</b>	23.9	20.2	20.8
Sum of heavy metals [t]	<b>0.06</b>	0.18			<b>0.15</b>	0.00												16	<b>0.21</b>	0.18	0.46	0.32

**Air emissions**

Carbon dioxide[t] <sup>(2)</sup>	<b>170</b>	212	<b>4.63</b>	1.09	<b>157</b>	119	<b>10.8</b>	10.8	<b>6.05</b>	4.97	<b>7.47</b>	13.6	<b>95.6</b>	89.0	<b>12.7</b>	6.93		2	<b>469</b>	462	435	440
Sulphur dioxide[t] <sup>(2)</sup>	<b>33.6</b>	41.0	<b>0.21</b>	0.01	<b>150</b>	121	<b>0.20</b>	0.08	<b>32.3</b>	35.3	<b>0.11</b>	0.30	<b>3.92</b>	3.70	<b>0.52</b>	0.32		9	<b>222</b>	203	393	273
Nitrogen oxide[t] <sup>(2)</sup>	<b>171</b>	197	<b>3.17</b>	0.59	<b>107</b>	95.4	<b>9.32</b>	7.95	<b>7.66</b>	7.11	<b>5.17</b>	9.57	<b>76.1</b>	71.4	<b>8.87</b>	5.81		-2	<b>392</b>	398	384	388
Particulates [t] <sup>2</sup>	<b>8.66</b>	10.8	<b>0.14</b>	0.01	<b>6.08</b>	3.65	<b>0.52</b>	0.46	<b>5.65</b>	6.12	<b>0.29</b>	0.53	<b>15.8</b>	15.1	<b>0.44</b>	0.16		2	<b>37.7</b>	37.0	35.9	62.4
Hydrochloric acid [t]	<b>0.41</b>	1.84			<b>2.18</b>	3.08	<b>0.00</b>	0.00	<b>0.01</b>	0.01	<b>0.00</b>			0.00				-37	<b>3.10</b>	4.93	4.39	4.87
Ammonia [t]	<b>0.01</b>	0.01			<b>0.08</b>	0.00	<b>0.01</b>	0.01	<b>0.02</b>	0.02	<b>0.00</b>		<b>0.47</b>	0.47				15	<b>0.58</b>	0.50	0.50	1.12
Volatile organic compounds (VOC) halogenated [t]	<b>13.1</b>	21.8			<b>326</b>	382	<b>0.02</b>	0.02		17.2	<b>0.00</b>				<b>18.8</b>			-13	<b>367</b>	421	759	436
Volatile organic compounds (VOC) non-halogenated [t]	<b>270</b>	227			<b>1200</b>	1050	<b>18.7</b>	17.2	<b>5.63</b>	0.90	<b>0.00</b>		<b>0.23</b>	0.43	<b>23.3</b>	18.8		16	<b>1530</b>	1320	1110	849

**Waste<sup>(3)</sup>**

Non-hazardous waste generated	<b>79.8</b>	51.6	<b>1.34</b>	1.63	<b>14.1</b>	12.4	<b>2.83</b>	3.68	<b>0.73</b>	0.76	<b>4.30</b>	6.99	<b>80.0</b>	66.8	<b>5.49</b>	6.14		25	<b>194</b>	155	131	135
Recycled	<b>64.9</b>	10.5	<b>0.66</b>	0.47	<b>7.27</b>	6.16	<b>1.18</b>	1.40	<b>0.16</b>	0.18	<b>3.32</b>	5.66	<b>70.8</b>	38.4	<b>1.75</b>	1.61		125	<b>154</b>	68.5	90.9	70.5
Treated	<b>4.91</b>	34.9	<b>0.57</b>	1.07	<b>0.63</b>	0.67	<b>1.25</b>	1.53	<b>0.08</b>	0.04	<b>0.99</b>	1.30	<b>0.09</b>	0.05	<b>0.07</b>	0.45		(78)	<b>8.68</b>	40.0	11.6	11.5
Disposed of	<b>10.1</b>	6.24	<b>0.10</b>	0.11	<b>5.79</b>	5.53	<b>0.91</b>	0.94	<b>0.70</b>	0.54		0.03	<b>10.5</b>	28.1	<b>3.47</b>	4.07		-30	<b>32.6</b>	46.4	25.4	54.1
<b>Hazardous waste generated</b>	<b>55.3</b>	53.1	<b>0.41</b>	0.27	<b>39.1</b>	17.9	<b>0.17</b>	0.27	<b>0.61</b>	0.52	<b>0.03</b>	0.09	<b>0.02</b>	0.03	<b>0.21</b>	0.21		33	<b>96.0</b>	72.3	62.3	51.2
Recycled	<b>12.8</b>	12.2	<b>0.01</b>	0.00	<b>10.4</b>	5.35	<b>0.00</b>	0.00	<b>0.00</b>	0.01	<b>0.00</b>	0.01	<b>0.01</b>	0.01	<b>0.01</b>	0.00		32	<b>23.3</b>	17.6	18.2	13.1



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	Consumer Health															Novartis Group <sup>(6)</sup>					
Treated	<b>39.2</b>	38.0	<b>0.41</b>	0.27	<b>26.3</b>	10.3	<b>0.25</b>	0.27	<b>0.60</b>	0.50	<b>0.02</b>	0.08	<b>0.03</b>	0.03	<b>0.20</b>	0.19	35	<b>67.0</b>	49.7	40.3	35.3
thereof incinerated	<b>38.3</b>	36.7	<b>0.40</b>	0.26	<b>24.7</b>	8.43	<b>0.25</b>	0.27	<b>0.59</b>	0.50	<b>0.00</b>	0.00	<b>0.02</b>	0.03	<b>0.16</b>	0.15	39	<b>64.4</b>	46.3	37.3	31.5
Landfill	<b>3.13</b>	2.59	<b>0.01</b>	0.00	<b>2.46</b>	2.06	<b>0.00</b>	0.00	<b>0.00</b>	0.01	<b>0.00</b>	0.00	<b>0.00</b>	0.00	<b>0.00</b>	0.00	25	<b>5.82</b>	4.66	3.51	2.86
Other disposal	<b>0.00</b>	0.01	<b>0.00</b>	0.00	<b>0.18</b>	0.14	<b>0.00</b>	0.00	<b>0.00</b>	0.00	<b>0.00</b>	0.00	<b>0.00</b>	0.01	<b>0.01</b>	0.00	16	<b>0.19</b>	0.16	0.07	0.10
Intermediate storage	<b>0.22</b>	0.29	<b>0.00</b>	0.00			<b>0.00</b>		<b>0.00</b>	0.00			<b>0.00</b>	0.00			(26)	<b>0.22</b>	0.30	0.28	0.22

Table shows absolute values with three significant digits, 0.00 signifies values below 0.005 not applicable.

- (1) To waste water treatment plant excluding cooling water.
- (2) Calculated based on energy breakdown.
- (3) Difference between generated and handled waste due to treatment of waste stored in previous years in 2003.
- (4) Including Lek.
- (5) Including newly acquired business NAVI (Novartis Animal Vaccines Inc.) based in the US, Canada and the UK.
- (6) Including corporate functions, Business Unit Nutrition & Santé (detailed data see Internet: [www.novartis.com/hse](http://www.novartis.com/hse)).

### Fines and compliance

In 2003, four fines, three in the US/Canada and one in Latin America, which resulted in fines of less than USD 25 000 in total, were reported as well as seven cases of non-compliance with government HSE regulations. Additionally, two spills occurred which were reported to all relevant authorities and dealt with appropriately.

72

## Global Reporting Initiative (GRI)

Initiated in 1997, the GRI's aim is the development of globally applicable guidelines for reporting on sustainable management. In 2004, we will provide a report in the GRI format on the Internet, which will include our HSE performance data.

### Air Emission

Our three-year CO<sub>2</sub> emission-reduction target was a 3% absolute reduction (based on 2000 emission levels) by 2003. To evaluate the reduction fairly, we have compared the sites that existed from 2000 to 2003. From the 2003 figures we subtracted the impact of sites that were newly acquired, and that of sites that have been sold or divested since 2000. The resulting, absolute CO<sub>2</sub>-emission reduction is 2.8%.

Without the integration of the 28 Lek sites, we would have achieved a CO<sub>2</sub> emission reduction of 5% compared with 2002. However, taking into account these new sites, emission increased by 2%.

Our SO<sub>2</sub> emission levels have fallen by 20% compared with levels in 2000. Nevertheless, compared with 2002, SO<sub>2</sub> emission increased by 9% due to the start-up of production at an Indian site using heavy oil. We will be switching to another fuel source over the coming year.

At other sites we have invested in new equipment to reduce SO<sub>2</sub> emission. At Wusi Farm in China, the plant management allocated USD 225 000 to the replacement of two charcoal boilers dating from 1994. The boilers, which generated steam for active ingredient production, solid formulation and product packing, originally produced 18% of Novartis Group's SO<sub>2</sub> emission with an energy consumption of only around 0.3% of the Group's total. The installation of the new oil-fired boilers was completed in October 2003, and will lead to a massive reduction in SO<sub>2</sub> emission during 2004.

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Halogenated VOC emission is down by 13% due to process improvements at the Sandoz production facilities at Turbhe, India (see also: [www.novartis.com](http://www.novartis.com)), as well as process modifications at the Pharmaceuticals production facility in Grimsby, UK.

Non-halogenated VOC emission has risen by 16%. This is largely a result of the fact that non-halogenated VOC emission has been used to replace halogenated VOC emission, which has a higher environmental impact.

### Waste

Hazardous waste has risen by 33% due to changes in the Pharmaceuticals and Sandoz production mix and an increase in production. Lek management has already demonstrated its commitment to waste reduction. The Menges site in Slovenia achieved a significant decrease in hazardous waste through the installation of a new column to distill used methanol. There is sufficient capacity to reduce hazardous waste solvents by 30 m<sup>3</sup> per month.

Non-hazardous waste has risen by 25% overall, partly due to the demolition of a pharmaceutical building in Basel, and partly due to production increases in the Infant & Baby Business Unit.

Our waste reduction strategy is to first prevent, then to reduce, recycle or safely dispose of waste, in that order.

### Resource Consumption: Energy and Water

Novartis overall energy usage increased by approximately 1%, mainly due to the integration of Lek, without which we would have seen a decrease of 3%. You can read about several of our energy saving projects on our website at [www.novartis.com/hse](http://www.novartis.com/hse).

73

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Water consumption increased by 9% due to the integration of Lek and a new Animal Health facility.

### Accidents

This year we further reduced the LTAR to 0.6 (LTAR 0.7 in 2002) through increased training and a large number of awareness campaigns, as well as technical improvements.

However, our ambitious target of 0.5 for 2006 will be challenging, since further reductions can only be achieved by implementing measures to improve behavioral safety. We are currently exploring the options open to us in this area.

We sincerely regret the occurrence of five fatalities this year. One of our sales representatives died in a car accident in Poland while traveling to a customer meeting. Another sales representative died in a car accident in Italy on his way home. The three remaining fatalities were not work-related but occurred during working hours on Novartis premises. We would like to extend our sincerest sympathy to the families and friends of the deceased.

## Human Resources

### Employees by Region and Business at December 31, 2003

	USA	Canada and Latin America	Europe	Africa/Asia/ Australia	Total
Pharmaceuticals (excluding Research)	10 654	4 326	19 312	7 665	41 957
Pharmaceuticals Research	602	0	2 011	70	2 683
Sandoz	1 133	748	8 793	2 244	12 918
OTC	875	297	1 937	811	3 920
Animal Health	504	282	844	563	2 193

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	USA	Canada and Latin America	Europe	Africa/Asia/ Australia	Total
Medical Nutrition	789	40	1 833	187	2 849
Infant & Baby	2 234	1 947	605	43	4 829
CIBA Vision	2 492	1 099	1 369	757	5 717
Corporate	551	35	806	83	1 475
<b>Total</b>	<b>19 834</b>	<b>8 774</b>	<b>37 510</b>	<b>12 423</b>	<b>78 541</b>

### Fulfilling Career Aims

The open-plan office on the seventh floor of the IK@N (Informatics and Knowledge Management) building in Cambridge, US is a busy place. According to Dmitri Mikhailov: "People have this positive energy here because we're building a new site from the bottom up. That's what makes it exciting." Dmitri joined the Novartis Institutes for BioMedical Research, Inc. (NIBRI),<sup>(1)</sup> the new US research headquarters, eight months ago. He is currently a member of the advanced computing group and is also responsible for the local high performance computing infrastructure. With a PhD in biophysics, specializing in computational structural biology and bioinformatics, he is ideally suited to this new environment that is leading the industry in its approach to advancing drug discovery by leveraging IT.

(1)

NIBRI a corporation that operates in, and only in, Cambridge Mass. The Novartis Institutes for BioMedical Research (NIBR) is a global research organization. NIBR consists of NIBRI in Cambridge and the drug discovery activities (but only those activities) of other Novartis Corporations in Basel, Horsham, Vienna, Tokyo and East Hanover.

74

The work involved in building up the new site is demanding: "One of the things I found since joining NIBRI is that I have to wear multiple hats. My background is scientific but there has also been a lot of coordination and project management, so it was a steep learning curve for me. I work on a number of projects at the same time. This month, one of the things I'm doing is getting desktop PCs in the US linked up to the PC grid." In a ground-breaking project for the pharmaceutical industry, IK@N has already linked desktop PCs together, initially in Basel, in order to harness their surplus power for use in power-intensive computer simulation and modeling for drug discovery.

"One of the reasons I joined Novartis was to work more closely with scientists. I have a personal interest in life sciences and the projects here are very interdisciplinary. My experience is valued and my background allows me to give good feedback to scientists on how we can approach things.

"I see it as a very entrepreneurial place backed by a large organization. On a daily level it feels like I'm working in a small biotech where everyone knows everyone else and what they're working on, but on the other hand there is access to vast amounts of information and resources.

"When I first arrived, I was really impressed with how the company functioned globally from the IT perspective. You can just pick up your laptop computer and take it with you to another office and it looks and works the same way, even if the office is on the other side of the world just amazing. We have great technology here.

"When I look out of the window, I see the whole of Cambridge laid out in front of me. And on a good day I can just make out the Harvard campus. That's something else I appreciate our proximity to renowned universities like Harvard, MIT and Whitehead Institute. We have the chance to go to scientific seminars organized both by Novartis and external organizations, so it's a good opportunity to keep abreast of what's happening in science."

### 2003 Personnel Costs by Function and Region

Research USD millions	Development USD millions	Production & supply USD millions	Marketing & Sales USD millions	General & Administration USD millions	Total USD millions
--------------------------	-----------------------------	----------------------------------------	--------------------------------------	---------------------------------------------	-----------------------

USA	167	374	387	1 180	316	2 424
Canada and Latin America	1	16	75	186	57	335
Europe	230	417	761	954	640	3 002
Africa/Asia/Australia	10	57	42	322	60	491
<b>Total</b>	<b>408</b>	<b>864</b>	<b>1 265</b>	<b>2 642</b>	<b>1 073</b>	<b>6 252</b>

## Global Talent Management

We are a growing company and, for our continuing success, depend on a steady flow of top talent. As a performance-driven company, our associates must be highly qualified and motivated. Our efforts in Human Resources are directed towards recognizing and responding to our associates' needs. We have defined a broadly based range of programs instrumental in attracting, retaining and developing associates, to help them fulfill their career goals and potential.

### Attracting Top Talent

A key component for any company is the ability to attract talent, the search for which has become increasingly competitive. For top performers, the opportunity to grow and manage their career is an attractive proposition. In 2003, we have undertaken a number of new programs and initiatives that strengthen our ability to attract candidates.

75

To reach potential associates in a more targeted and cost-effective way, we have broadened our range of recruiting channels to include niche job-boards on the Internet. Employee-referral programs have also been particularly successful. In the US in 2003, approximately 60% of new recruits in the sales organization came via referrals from associates. In order to streamline executive searches, we have also reviewed and reduced the total number of search companies used, by 80%, to a small group that provides consistent quality. And when the global recruitment portal goes online later this year, all recruitment advertisements and information about working at Novartis will become available from a single source.

A coordinated approach to recruitment leads to a single profile, recognized by potential candidates around the world. In January 2003, we launched a global recruitment-brand that presents a consistent and distinctive identity in all our recruitment advertising on a global basis. By taking a unified approach to recruitment branding that embodies the opportunities to grow and develop offered by the company, we aim to position Novartis as an employer of choice.

In response to the growing wish among associates to have more say in managing their own careers, we are providing new associates with a structured set of tools and information that will give them more control over developing their future. The Pathways program uses defined competency profiles and sets clear performance-expectations within a consistent framework for individual development. This program builds a foundation of confidence for associates that they will be supported in developing their skill sets throughout their careers.

Our track record for innovation and our commitment to research has also drawn significant attention from the scientific community over the previous 12 months. Our global research headquarters in Cambridge, US, the Novartis Institutes for BioMedical Research (NIBR),<sup>(2)</sup> which opened in 2002, has already established a reputation for cutting-edge science and reflects well on the entire organization.

(2)

See note 1, page 69.

## Employees by Function and Region

Research	Development	Production & Supply	Marketing & Sales	General & Administration	Total
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	Research	Development	Production & Supply	Marketing & Sales	General & Administration	Total
USA	1 089	2 374	5 013	9 292	2 066	19 834
Canada and Latin America	9	293	2 937	4 620	915	8 774
Europe	2 352	4 552	12 404	13 161	5 041	37 510
Africa/Asia/Australia	127	778	2 307	7 943	1 268	12 423
<b>Total</b>	<b>3 577</b>	<b>7 997</b>	<b>22 661</b>	<b>35 016</b>	<b>9 290</b>	<b>78 541</b>

### Retaining Associates

A large part of our lives is spent at work and many factors beyond job responsibilities determine whether associates will commit themselves to the company. We undertake many individual and ongoing activities and programs to cultivate a sense of belonging and contributing to the company, from which loyalty to, and pride in the company can grow.

Joining a new organization is typically marked by an initial sense of disorientation. The new Global Orientation program, known as GO!, was introduced in 2003 to provide new associates with the necessary support, tools, resources and an interactive platform to help them start contributing productively from the first day. The six-month program has been launched in more than ten countries and in ten languages to date. It is structured to accompany associates through orientation with their job, team, department, the business and the organization as a whole.

### 2003 Leadership Survey Results<sup>(1)</sup>

To monitor overall satisfaction and the organizational climate, we run regular surveys at regional, country and divisional level. Recent results indicate that our performance management system and leadership development initiatives have been well-received and that our objectives and strategy are clear. Our leadership style is seen as having become more participative, persuasive and motivating, bringing with it a higher perceived competitiveness of associates, product quality and product development. A sense of pride in working at Novartis is a strong and constant element that runs through all the survey results. In addition to surveys we have also introduced other innovative techniques for stimulating feedback and focusing on issues. In more than 80 meetings worldwide, each with between 50 and 100 participants, the Open Space meeting technique has shown how effectively associates can cooperate to raise and define issues as well as propose approaches for their resolution within a very limited period of time.

(1)

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Comparison Novartis vs. ISR Global Senior Management Norm.

External evaluation in 2003 also confirms that we are on the right path. Novartis Finland, Italy, Mexico and Spain were among the companies singled out as having created a great workplace environment by the research and management consultancy the Great Place to Work® Institute. The annual survey assesses the quality of the working environment based on factors that include mutual trust between employees and management, team spirit and the pride each employee feels in belonging to the company. Novartis was also highlighted by Science magazine as one of only two European companies that made it into the top ten in their annual survey of the best biotech and pharma employers. Criteria used in the survey included quality of research, financial strength and vision for the future. Novartis was placed in eighth position. In the annual survey carried out by Working Mother magazine, Novartis Pharmaceuticals in the US was included in its "100 Best Companies for Working Mothers". Among the criteria Working Mother focused on were how well companies provide their employees with specific benefits like flexible schedules and leave for new parents, as well as programs for women's advancement.

77

### Female Employees by Business

	Female employees %	Female management %
Pharmaceuticals	44	30
Research	41	25
Sandoz	41	20
OTC	50	30
Animal Health	43	44
Medical Nutrition	48	23
Infant & Baby	41	31
CIBA Vision	64	28
Corporate	58	19
<b>Group overall</b>	<b>46</b>	<b>29</b>

### Female Employees by Region

	Female employees %	Female management %
USA	48	35
Canada and Latin America	42	36
Europe	46	28
Africa/Asia/Australia	43	19
<b>Group overall</b>	<b>46</b>	<b>29</b>

78

### Local Community Involvement

As part of our commitment to local community and to promote involvement with associates' families, a Family Day was held in Basel and in New Jersey in 2003. In Basel, the Family Day was held in June and more than 18 000 people registered to participate, but fine weather, live

music, guided tours and other events attracted many more on the day. More than 14 000 associates around the world also took the opportunity to "give something back" to their local community by taking part in our annual Community Partnership Day.

## Developing Potential

We seek out and cultivate talent in order to ensure our ongoing performance and future success. Through our corporate learning institution we take a structured approach to identifying promising individuals. We have developed a portfolio of learning programs geared to developing strong functional skills and equipping managers for future leadership.

In November 2003, our corporate learning institution was accredited by the European Foundation for Management Development (EFMD). Novartis is the first pharmaceutical company to receive EFMD accreditation and was awarded the quality label because it has demonstrated that it meets international standards in the provision of learning programs for senior managers.

During 2003 more than 550 managers went through the annual Organization and Talent Review (OTR) process. OTR is a key development tool in identifying leadership potential. Following career discussions with associates, management teams assess performance and potential, succession, and development opportunities, such as moving talent into critical job openings or recommending learning programs. In 2004, the process will be expanded to more levels within the organization in order to identify and tap leadership potential at an earlier stage. Diversity will play an increasingly important role, to provide better identification of women candidates for key openings.

## Corporate Learning

By the end of this year, our Corporate Learning Institution will have executed more than 160 courses and improved the leadership skills of approximately 4 000 associates worldwide. Learning is carried out in groups as a classroom experience or individually and is backed by e-learning for intensive preparation and follow up. Our three-part leadership program is taught by a world-class faculty from Harvard Business School, INSEAD and Stanford University as well as internal senior management speakers.

Seen as a strategic business initiative, Leading at the Frontline is our largest program and is taught in five languages. It targets newly entering or promoted managers from all Business Units and provides formal leadership training that is directly linked to the participants' business activities. Aimed at managers of managers, the Role of the Leader, launched in 2003, focuses on the flawless execution of our business strategy through outstanding leadership skills. Also launched in 2003 was the Business Leadership Program at the Harvard Business School for our most senior managers. Our leaders must be long term visionary thinkers who are able to develop operational processes and drive performance in line with our longer term strategy. This course helps managers better understand the global challenges facing the healthcare industry and evaluate alternative strategies to improve performance.

Individual development was further supported in 2003 with the introduction of two programs. More than 90 senior managers took part in the Accelerated Development Program which defines a detailed development plan to accelerate the participant's ability to take on increasingly challenging roles. The Senior Leaders Mentoring Program demonstrates the commitment of senior leaders to building future leadership. By dedicating their personal time, senior leaders support top performers in the creation of a personal development plan and the presentation of a new business idea.

79

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## Excellence in Marketing

Marketing is critical to our continuing success, particularly in preparing new launches, building up blockbusters and maintaining high market shares. Marketing Excellence Generation 2 (MEX-G2), launched in 2003, builds on the framework of the successful Marketing Excellence program that was designed to develop top-level marketing skills and strong global brands as well as an enthusiastic and competitive spirit. MEX-G2 further focuses on enhancing the ability of managers to generate big ideas and execute them flawlessly at the same time as driving an externally focused and constructively aggressive competitive approach. In its first year MEX-G2 attracted 141 participants.

Senior level non-marketing managers, primarily in research and development have also been targeted in a management program aimed at developing a strong marketing mindset. The Marketing Awareness Program focuses on the creation and delivery of customer value across the brand life-cycle. It builds understanding of customer orientation and marketing in order to foster cross-functional teamwork while building successful products.

## Outlook 2004

In order to compete optimally in the market place as an attractive employer, and as a productive, innovative and progressive company, we are focusing on increasing the diversity of our workforce. Diversity includes ethnicity, gender, culture, age and experience, as well as thinking and working style. We are approaching this undertaking on a global basis with the aim of building an inclusive, high-performance environment that values and leverages differences.

We receive many thousands of applications every month and try to respond to each of them. To improve our application processing ability, this year we are introducing a global application tracking system. The system will enable efficient electronic management of individual applications using an online database that is globally accessible.

We will continue to foster innovation throughout the company by living and building a performance driven culture and support it by seeking out and developing individual contributors that show high potential.

## **Assurance Report on the Novartis Group Corporate Citizenship Reporting**

### **To the Audit and Compliance Committee of Novartis AG:**

We have performed review procedures on the management and reporting processes for Corporate Citizenship ("CC") and Health, Safety and Environment ("HSE") for the year ended December 31, 2003. We have also performed review procedures on the HSE key figures "Health, Safety and Environment 2003 Data" on pages 64 and 65 and the CC key figures "Employees by Region and Business" found on page 69 and "Female Employees by Business" and "Female Employees by Region" which are found on page 72 of the Novartis Annual Report (the "Report") for the year ended December 31, 2003. Novartis management is responsible for the Report and for the development and maintenance of the internal reporting processes, data and key figures for CC and HSE. Our responsibility is to report on the internal reporting processes, data, and key figures for CC and HSE based on our review procedures.

The scope of our review procedures was to:

Observe the existence of internal management processes and controls which ensure the implementation of the CC Policy including the Code of Conduct across Novartis AG and its consolidated subsidiaries (the "Group");

Test the effectiveness of the internal reporting system used to collect CC and HSE information from Group subsidiaries;

Observe compliance with the Group internal HSE reporting guidelines at selected sites; and

Perform, on a sample basis, certain procedures on the 2003 CC and HSE key figures.

Our review procedures included:

Interviewing personnel responsible for CC management at Group level;

Visiting the Sandoz and OTC business unit global headquarters, selected regional, country and business unit headquarters in Austria, Egypt, Mexico, Poland, Singapore, Switzerland and the United States, and specific sites in Austria, Egypt, Indonesia, Mexico, Poland, Switzerland and the United Kingdom;

Interviewing the Organizational Unit Head, CC Executive, Compliance Officer, Human Resources Leader and others responsible for CC reporting and CC key figures, in the different headquarters where our visits took place;



Reading and performing tests on a sample basis of the relevant documentation including Group policies, management and reporting structures, documentation and systems in place to collect, analyze and aggregate reported CC and HSE key figures; and

Performing tests on a sample basis of evidence supporting selected HSE parameters with regard to the reported data aggregation from the selected sites to Group level.

81

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There are no generally accepted international standards for the preparation or assurance of corporate sustainability or corporate citizenship reports. We have therefore based our approach on emerging best practice and the underlying principles within the Proposed International Standards on Assurance Engagements (ISAE) 2000, issued March 2003, and standards promulgated by the Swiss profession. We planned and performed our assurance procedures to obtain a reasonable basis for our conclusions. However, we have not performed an audit according to International Standards on Auditing. Accordingly, we do not express such an opinion.

Our statement should be read in conjunction with the section "HSE Performance and Data Management" on page 63 of the Report which defines the scope of the reporting, the inherent limitations of accuracy and completeness for the HSE information, and the fact that CC management process is in its second year of operation.

Based on our review procedures we conclude that:

The Group level processes and controls intended to implement the CC policy are functioning as designed;

The Group level reporting system for the collection, analysis and aggregation of the reported HSE key figures is functioning as designed;

The Group level CC reporting provides an appropriate basis for the disclosure of CC information across the Group; and

Nothing has come to our attention to cause us to believe that the reported 2003 CC and HSE key figures from the sites and reporting units do not give a fair picture of the CC and HSE performance.

From our work, we have provided the following recommendations to the management, which have been agreed:

Novartis should consider efforts to tailor the CC reporting system to the scope and objectives of external reporting; and to ensure a more technologically robust tool;

Novartis should continue to focus on effectively implementing the CC initiative in its daily business operations and thus building on the strong CC awareness programs effectuated to date; and

Novartis should take advantage of the introduction and implementation of its new HSE reporting tool in 2004 to establish more formalized and effective control procedures for HSE data reporting at site level.

Dr. Thomas Scheiwiller  
Basel, January 20, 2004

Thomas Frei

82

## Corporate Governance

Novartis is fully committed to good corporate governance. Novartis' principles and rules on corporate governance are laid down in the Articles of Incorporation, the Regulations of the Board and the Charters of the Board Committees. The Board's Corporate Governance Committee reviews these principles and rules regularly in the light of prevailing best practices and forwards suggestions for improvement to the full Board for approval.

### Group Structure and Shareholders

Novartis AG, a holding company organized under Swiss law, owns directly or indirectly all companies worldwide belonging to the Novartis Group.

The Novartis Group is divided operationally into two divisions: Pharmaceuticals and Consumer Health. The Pharmaceuticals Division is organized into five Business Units: Primary Care, Oncology, Transplantation, Mature Products and Ophthalmics. The six Business Units of the Consumer Health Division are: Sandoz, Over-the-Counter self-medication (OTC), Animal Health, Medical Nutrition, Infant & Baby and CIBA Vision. The business operations of the Business Units are conducted through local Novartis Group companies. The most important Novartis subsidiaries and associated companies are listed in Note 31 to the Group's consolidated financial statements.

There are three Novartis subsidiaries whose shares are traded on public stock exchanges. These are Novartis India Limited, Novartis Pharma S.A.E. (an Egyptian company), and Novartis Pharma (Pakistan) Limited. 49% of the shares of Novartis India Limited are registered for trading and less than 5% of the other two companies are registered for trading. In comparison with the Group structure and in relation to the size of the business of each of these three companies, none are considered significant to the Group as a whole.

Each of these companies is majority owned, indirectly, by Novartis AG.

Additionally, Novartis holds significant investments in two large publicly listed companies:

Roche Holding AG, registered in Basel, Switzerland, and listed on the SWX Swiss Exchange (registered shares: Valor No 1203211/ISIN CH0012032113, symbol RO; non-voting equity securities: Valor No 12032048/ISIN CH0012032048, symbol: ROG; ADRs for non-voting equity securities are traded on the OTC market in the US, symbol: RHHBY) The market capitalization of Roche Holding AG on Dec. 31, 2003 was USD 90.6 billion, and

Chiron Corporation, with its registered head office in Emeryville, California, and listed on the NASDAQ (Valor No 918297/ISIN US1700401094, symbol: CHIR). The market capitalization of Chiron Corporation on Dec. 31, 2003 was USD 10.7 billion.

Further information on the size of each shareholding and the method of consolidation are given in Note 10 to the Novartis Group's consolidated financial statement.

Both Roche and Chiron are associated companies but are independently governed, managed and operated.

The other significant Group subsidiaries and associated companies as shown in Note 31 to the Novartis Group's financial statement are not publicly traded. In December 2002, Novartis AG acquired through a wholly-owned subsidiary in a public tender offer 99.07% of Lek d.d., Ljubljana, Slovenia, a company which at that time was publicly listed on the stock exchange in Ljubljana. In 2003 Novartis AG acquired the remaining 0.93% of the outstanding shares and delisted the shares of Lek d.d. from the Ljubljana stock exchange.

83

The largest registered Novartis shareholders are the Novartis Foundation for Employee Participation, registered in Basel, Switzerland (holding 3.3% of the share capital) and Emasan AG, registered in Basel, Switzerland (holding 3.1%). No other shareholder is registered as owner of more than 2% of the issued share capital and there are no cross-holdings equal to or higher than this amount.

Novartis AG has not concluded any shareholders' agreement or other agreement regarding voting or holding of its shares.

## Capital Structure

The share capital of Novartis AG is CHF 1 400 735 000, fully paid-in and divided into 2 801 470 000 registered shares of CHF 0.50 nominal value each. Novartis AG has neither authorized nor conditional capital. All shares have equal voting rights. Novartis has not issued participation certificates or non-voting equity securities (Genussscheine). After the repurchase program announced in 2001 was completed with a corresponding capital reduction approved by the General Meeting in 2002, Novartis announced on July 22, 2002, a further share repurchase program up to a total amount of CHF 4 billion using a second trading line on the SWX Swiss Exchange. At the Annual General Meeting on March 4, 2003 a resolution was passed to reduce the capital from CHF 1 412 075 000 to CHF 1 400 735 000 and to cancel the corresponding number of shares repurchased under the program. The repurchase program continued through 2003 and the Board will propose reducing Novartis AG's share capital by amounts corresponding to the nominal value of repurchased shares in 2003 (24 260 000 shares in 2003) at the forthcoming Annual General Meeting. Further information on the development of the share capital structure of Novartis AG during the last 2 years is presented in tabular form in Note 5 to the financial statements of Novartis AG.

## Convertible Bonds and Options

Novartis had no convertible bonds outstanding in 2003. In December 2001, Novartis sold a total of 55 million nine- and ten-year call options (Low Exercise Price Options, "LEPOs") and 55 million nine- and ten-year put options on Novartis shares to a third party. On June 26, 2003 Novartis redeemed these equity instruments.

Information about Novartis share options granted for executive and employee compensation is contained in the section on Compensation below and in Note 26 to the Group's consolidated financial statements.

## Shareholders' Rights

Each registered share entitles the holder to one vote at the General Meeting. There are no preferential voting shares. Shareholders also have the right to receive dividends, appoint a proxy, convene a General Meeting, place items on the agenda of a General Meeting and hold such other rights as defined in the Swiss Code of Obligations (SCO).

One or more shareholders whose combined shareholdings represent an aggregate nominal value of at least CHF 1 000 000 may demand that an item be included in the agenda of a General Meeting. Such a demand must be made in writing at the latest 45 days before the meeting and shall specify the items and the proposal of such a shareholder.

## Legitimization as Shareholder

Persons enrolled in the Novartis share register may exercise the membership rights of registered shares. Registration requires a declaration that the shareholder has acquired the shares in his own name and for his own account.

According to the Articles of Incorporation, no shareholder shall be registered to vote more than 2% of the issued share capital unless the Board has upon request granted an exemption. So far, such a request has never been denied. The Board may register nominees with the right to vote up to 0.5% of the issued share capital, and in excess of that limit if such nominees disclose particulars of the beneficial owners of these shares.

Groupings formed to circumvent this limitation are treated as one single person or nominee.

The statutory voting restrictions can be cancelled with a two-thirds majority of the shares represented at the General Meeting.

**Resolutions and Elections at General Meetings**

Shareholders registered at least 20 days prior to the General Meeting may vote their shares at the meeting.

Resolutions of the shareholders at General Meetings are approved with a simple majority of the shares represented at the meeting, except in the following matters which by law (SCO, Art. 704) and our Articles of Incorporation require the approval of two-thirds of all represented shares:

Alteration of the purpose of Novartis AG

Creation of shares with increased voting powers

Implementation or removal of restrictions regarding the transferability of shares

Authorized or conditional increase of the share capital

Increase of the share capital from equity or a contribution in kind, for the purpose of an acquisition of property and the grant of special rights

Restriction or suspension of rights of option to subscribe

Change in location of the registered office of Novartis AG

Dissolution of Novartis AG without liquidation

The Company has not adopted any decisions that differ from the rules applicable to it under the Swiss Stock Exchange Act (no opting-up or opting-out).

**The Board of Directors**

Members of the Board of Directors<sup>(1)</sup>

	Age	Director since	Term Expires
Dr. h.c. Daniel Vasella, MD	50	1996	2004
Prof. Helmut Sihler, JD, PhD	73	1996	2004
Hans-Joerg Rudloff	63	1996	2004
Dr. h.c. Birgit Breuel	66	1996	2005
Prof. Peter Burckhardt, MD	65	1996	2005
Prof. Srikant Datar, PhD	50	2003	2006
Walter G. Frehner	70	1996	2004
William W. George	61	1999	2006
Alexandre F. Jetzer	62	1996	2005
Pierre Landolt	56	1996	2005
Prof. Ulrich Lehner, PhD	57	2002	2005
Heini Lippuner	70	1996	2004

	Age	Director since	Term Expires
Dr.-Ing. Wendelin Wiedeking	51	2003	2006
Prof. Rolf M. Zinkernagel, MD	59	1999	2006

(1) See also the biographical information on pages 105 109

The average tenure of our Directors is six years and their average age is 61 years. Dr. Daniel Vasella is the only Executive Director. Alexandre F. Jetzer was a member of the Executive Committee until 1999 and supports Novartis' Government Relations under a consultancy agreement. On the basis of the independence criteria listed in the appendix to the Regulations of the Board and Committee Charters effective as of April 15, 2003 the Board has decided that with the exception of Dr. Daniel Vasella and Alexandre F. Jetzer, all Directors are independent and have no material dealings with Novartis AG or other companies of the Novartis Group outside their role as a Director<sup>(2)</sup>. No Director sits on the board of directors of other listed companies with which any Novartis Group company conducts a material amount of business.

(2) In his capacity as a Director, Prof. Rolf M. Zinkernagel, MD, represents the Board of Directors' interests on the Scientific Advisory Board of the Novartis Institute for Tropical Diseases (NITD). He is also a member of the Board of Directors of the Genomics Institute of the Novartis Research Foundation (GNF).

86

For the last seven years, Novartis has engaged the Harvard Business School (HBS), the employer of Prof. Srikant Datar, PhD, to train Novartis executives in financial and business matters. The compensation paid by Novartis for these programs is not material in comparison with the total revenues of Harvard Business School and, therefore, does not constitute a "material dealing" as defined under US Securities law or the Listing Standards of the New York Stock Exchange (NYSE). Prof. S. Datar was the person at HBS responsible for managing these Novartis programs. Prior to his nomination as Director, Prof. S. Datar relinquished his management responsibilities for these programs and since his nomination as Director has not been separately compensated. Therefore, under the definitions of Director independence in place at the time of his election as a Director, Prof. S. Datar was deemed by the Board to be an Independent Director. New NYSE rules published in 2003 and which will become effective in November 2004 provide for a three-year look-back period on compensation other than Board fees paid by an issuer to its directors. Under this new rule and its extended look-back period, as of November 2004 Prof. S. Datar, due to his professional engagement for Novartis AG prior to his nomination as Director, would not be considered "independent." As a consequence, and to avoid any doubt, in December 2003 Prof. S. Datar stepped down from the Audit and Compliance Committee which requires that all members are independent.

The specific term of office for a Director is determined by the General Meeting on the occasion of his or her election. Each year approximately one-third of all Directors are elected or re-elected. In principle, a Director is to retire after 12 years of service or the reaching of 70 years of age. Nonetheless, the shareholders may re-elect such Directors for additional terms of office. Dr. Daniel Vasella has been elected by the Board as its Chairman and also to serve as Chief Executive Officer. It is the view of the Board that this dual role ensures effective leadership and excellent communication between the shareholders, the Board and Management. The Board has appointed Prof. Helmut Sihler, JD, PhD, as Lead Director, whose responsibility it is to ensure an orderly process in evaluating the performance of the Chairman and CEO and to chair the Board's private sessions (i.e. the meetings of the non-executive Directors). In case of a crisis, he would assume leadership of the Independent Directors.

The Board appointed Prof. Helmut Sihler and Hans-Joerg Rudloff as its Vice Chairmen.

### **Role and Functioning of the Board**

The Board holds the ultimate decision-making authority of Novartis AG for all matters except those reserved by law (SCO, Art. 698) to the shareholders.

Decisions are taken by the Board as a whole, with the support of its four Committees described below (Chairman's Committee, Compensation Committee, Audit and Compliance Committee and Corporate Governance Committee). The primary functions of the Board are:

Strategic direction of Novartis

Organization of Novartis

Accounting matters, financial control and financial planning

Appointing and dismissing members of the Executive Committee and other key executives

Setting compensation: approving policies of certain fundamental importance to the functioning of the Group such as the Novartis Code of Ethical Conduct of CEO and Senior Financial Officers

Overall supervision of the business operations

Setting out matters to be presented at the General Meeting, including the Novartis AG financial statements and the Group's consolidated financial statements

87

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The Board has not concluded any contracts with third parties for the management of the Company but has delegated to the Executive Committee the coordination of day-to-day business operations of Group companies. The Executive Committee is headed by the Chief Executive Officer. The internal organizational structure and the definition of the areas of responsibility of the Board and the Executive Committee are set forth in the Board Regulations. The agenda for Board meetings is set by the Chairman. A Director may request that an item be included on the agenda. Board Members are provided with adequate materials to prepare for the items on the agenda in advance of Board meetings.

The Board recognizes the importance of being fully informed on material matters involving the Group and ensures that it has sufficient information to make appropriate decisions through several means:

By invitation, members of senior management attend Board meetings to report on areas of the business within their responsibility

Board Committees, in particular the Audit and Compliance Committee, regularly meet with management and outside consultants, including the Group's external auditors, to review the business, better understand all laws and policies impacting the Group and support the management in meeting the requirements and expectations of the stakeholders

Informal teleconferences between Directors and the Chairman and CEO or the Lead Director, as well as regular distribution of important information to the Directors

During 2003, the Board met seven times. Detailed information on each Director's attendance at full Board and Board Committee meetings is provided in the table below.

Once yearly, the Board reviews the performance of the Chairman and CEO and approves the objectives for the following year. The Board of Directors also performs a self-evaluation once a year.

The non-executive, Independent Directors met twice during 2003 in separate sessions chaired by the Lead Director.

88

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## Board Committees

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Detailed information on attendance at full Board and Board Committee meetings is as follows:

	Full Board	Chairman's Committee	Compensation Committee	Audit and Compliance Committee	Corporate Governance Committee
Number of meetings in 2003	7	8	3	8	2
Dr. h.c. Daniel Vasella, MD	7 <sup>(1)</sup>	8 <sup>(1)</sup>			
Prof. Helmut Sihler, JD, PhD	7	8	3 <sup>(1)</sup>	8 <sup>(1)</sup>	2
Hans-Joerg Rudloff	7	8	3		2
Dr. h.c. Birgit Breuel	7			7	
Prof. Peter Burckhardt, MD	7				
Prof. Srikant Datar, PhD <sup>(2)</sup>	5			5	
Walter G. Frehner	7			7	
William W. George	7	8	3		2 <sup>(1)</sup>
Alexandre F. Jetzer	7				
Pierre Landolt	7				
Prof. Ulrich Lehner, PhD	7			7	
Heini Lippuner	7	8			
Dr.-Ing. Wendelin Wiedeking <sup>(2)</sup>	4				
Prof. Rolf M. Zinkernagel, MD	7				2

(1) Chair

(2) Since March 4, 2003

### Role and Functioning of the Board Committees

Each Board Committee has a written Charter outlining its duties and responsibilities and a chair elected by the Board. The Board Committees meet regularly and consider meeting agendas determined by the Chair. Board Committee members are provided with adequate materials to prepare for the items on the agenda in advance of meetings.

#### The Chairman's Committee

The Chairman's Committee consists of the Chairman and Chief Executive Officer, the two Vice Chairmen, one of whom is the Lead Director, and such other members as are elected by the Board from time to time. In 2003, the Committee met eight times.

The Chairman's Committee reviews selected matters falling within the authority of the Board before the latter takes decisions on such matters and, in urgent cases, can take preliminary and necessary actions on behalf of the Board. The Chairman's Committee also interfaces with the Executive Committee, specifically deciding on financial investments and other matters delegated to the Committee by the Board of Directors.

### **The Compensation Committee**

The Compensation Committee is composed of three independent Directors. In 2003, it convened three times. The Compensation Committee reviews the compensation policies and programs of the Group, including share option programs and other incentive-based compensation before the full Board makes final decisions. It is responsible for reviewing and approving the compensation paid to members of the Executive Committee and other selected key executives, and for reviewing the performance of the Chairman and Chief Executive Officer. The Compensation Committee seeks outside expert advice from time to time to support its decisions and recommendations.

### **The Audit and Compliance Committee**

The Audit and Compliance Committee is composed of four members and in 2003 met eight times. The Board has determined that all the members of the Committee are independent, as defined by the rules of the New York Stock Exchange as well as by the independence criteria of Novartis (see appendix to the Regulations of the Board and Committee Charters), and that its chair, Prof. Helmut Sihler, JD, PhD is adequately qualified in financial management matters. The Audit and Compliance Committee has determined that Prof. Ulrich Lehner, PhD, is independent and possesses the required accounting and financial management expertise required under the rules of the NYSE. Therefore the Board of Directors has appointed him as the Audit and Compliance Committee's Financial Expert. Prof. S. Datar also was designated as a Financial Expert until he voluntarily stepped down from the Committee in December 2003. The Board has also reassured itself that other members of the Committee have sufficient experience and ability in finance and matters of compliance to enable them to adequately discharge their responsibilities.

The Committee's main duties are:

Evaluate and select the external auditors to be nominated for election at the Annual General Meeting

Review the terms of engagement of the external auditors and the scope of the external audit

Discuss with the external auditors the results of their audits, any unusual items or disclosures contained in the audits, and the matters required by US Statement on Auditing Services No. 61 (including, for example, the initial selection of, and changes in, significant accounting policies and the process utilized by management to formulate significant accounting estimates)

Review the scope of internal auditing and the adequacy of the organizational structure and qualifications of the internal auditing staff

Review with external auditors, internal auditors and the financial and accounting management of Novartis whether the accounting policies and financial controls are appropriate, adequate and effective

Meet with management and the external auditors to review the financial statements and annual report

Review risk control processes and procedures

Review all relationships between Group companies and external auditors

Review the processes and procedures for ensuring compliance with laws and internal regulations (such as the Novartis Code of Conduct)



Oversee Novartis' commitments as a subscriber to the UN's Global Compact initiative

90

### The Corporate Governance Committee

The Corporate Governance Committee is composed of four independent Directors and met twice in 2003. The Corporate Governance Committee develops corporate governance principles and recommends these to the Board for approval. Its duties include the regular review of the Articles of Incorporation with a view to reinforcing shareholder rights and of the composition and size of the Board and its committees. The Corporate Governance Committee conducts an annual evaluation of the Board as a whole and gives guidance to the Directors on how to avoid potential conflicts of interests.

### Further Corporate Governance Matters

#### Applicable Corporate Governance Standards

The standards on corporate governance implemented and applied at Novartis fully comply with the Directive on Information Relating to Corporate Governance published on July 1, 2002 by the SWX Swiss Exchange. Novartis is also in compliance with the corporate governance standards of the NYSE and applicable US law with two exceptions where Novartis continues to apply Swiss (home country) practices: (i) Swiss Law requires that the external auditors of Novartis be appointed by the General Assembly and not by the Audit and Compliance Committee and (ii) equity compensation plans are not voted at the General Meeting but are decided on by the Executive Committee or the respective committee of the local Novartis Group company. All such plans are established within the policies and programs approved by the Compensation Committee.

#### Documentation

The following documents describe the Corporate Governance Standards applied by Novartis and are available on the Novartis website: <http://www.novartis.com/investors/en/governance.shtml> or can be ordered in print from the Corporate Secretary Ingrid Duplain, JD.

Articles of Association

Regulations of the Board and Committee Charters, including the independence criteria for Board and Audit and Compliance Committee members

## Compensation

### Non-Executive Directors' Compensation

The Compensation Committee advises the Board of Directors on the compensation of non-executive Directors. Non-executive Directors receive an annual retainer in an amount that varies with the Board and Committee responsibilities of the Director. Directors are eligible to participate in certain of the equity programs which we offer to senior management and selected employees. Directors receive no additional fees for attending meetings. Directors can choose to receive the annual retainer in cash, shares, or a combination thereof. As of January 1, 2003, we no longer offer share options to Directors, or grant shares to Directors in acknowledgement of business performance. Directors are reimbursed for travel and other necessary business expenses incurred in the performance of their services.

91

### 2003 Directors' Compensation

Annual Cash Compensation (USD) <sup>(1)</sup>	Shares (number)
-----------------------------------------------------	--------------------

<b>Dr. h.c. Daniel Vasella, MD</b> Chairman's Committee (Chair)	(please refer to the table on page 97)	
<b>Prof. Helmut Sihler, JD, PhD</b> Vice Chairman, Lead Director Chairman's Committee (Member) Compensation Committee (Chair) Audit and Compliance Committee (Chair) Corporate Governance Committee (Member)	727 566	
<b>Hans-Joerg Rudloff</b> Vice Chairman Chairman's Committee (Member) Compensation Committee (Member) Corporate Governance Committee (Member)	18 795	11 874
<b>Dr. h.c. Birgit Breuel</b> Audit and Compliance Committee (Member)	336 402	
<b>Prof. Peter Burckhardt, MD</b>	99 145	4 391
<b>Prof. Srikant Datar, PhD<sup>(2)</sup></b> Audit and Compliance Committee (Member)	199 634	3 302
<b>Walter G. Frehner</b> Audit and Compliance Committee (Member)	336 402	
<b>William W. George</b> Chairman's Committee (Member) Compensation Committee (Member) Corporate Governance Committee (Chair)	246 060	4 069
<b>Alexandre F. Jetzer<sup>(3)</sup></b>	8 673	6 756
<b>Pierre Landolt</b>	79 707	4 965
<b>Prof. Ulrich Lehner, PhD</b> Audit and Compliance Committee (Member)	338 073	
<b>Heini Lippuner</b> Chairman's Committee (Member)	375 519	
<b>Dr.-Ing. Wendelin Wiedeking<sup>(4)</sup></b>	167 498	2 534
<b>Prof. Rolf M. Zinkernagel, MD<sup>(5)</sup></b> Corporate Governance Committee (Member)	210 647	7 738
<b>Total</b>	3 144 121	45 629

(1) Amounts have been converted from CHF to USD using the 2003 average exchange rate of CHF 1.35/USD.

(2)

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Prof. Srikant Datar, PhD, Professor for Accounting and Senior Associate Dean of the Harvard Business School was elected to the Board at the Annual General Meeting on March 4, 2003. Prof. Srikant Datar, PhD, stepped down from the Audit and Compliance Committee as of December 31, 2003.

(3)

In addition he was paid USD 129 456 for other consulting services.

(4)

Dr.-Ing. Wendelin Wiedeking, CEO of Porsche AG was elected to the Board at the Annual General Meeting on March 4, 2003.

(5)

Includes USD 185 705 for acting as the Board's delegate in the scientific advisory boards of the Genomics Institute of the Novartis Research Foundation (GNF) and the Novartis Institute for Tropical Diseases (NITD).

92

### Ownership of Novartis Shares and Share Options by the Non-Executive Directors

In December 2003 the Board of Directors adopted a share ownership guideline, under which non-executive Directors are required to own at least 5 000 Novartis shares within three years after joining the Board. The total number of Novartis shares owned as of December 31, 2003 by the non-executive Directors and persons closely linked to them was 297 040. "Persons closely linked to them" are (i) their spouse, (ii) their children below age 18, (iii) any legal entities that they own or otherwise control, or (iv) any legal or natural person who is acting as their fiduciary. No non-executive Director owned 1% or more of our outstanding shares. As of December 31, 2003, the individual ownership of Novartis shares by the non-executive Directors (including persons closely linked to them) was as follows:

Beneficial Owner	Number of Shares Owned Directly or Indirectly
Dr. h.c. Daniel Vasella, MD	(please refer to the table on page 98)
Prof. Dr. Helmut Sihler	34 304
Hans-Joerg Rudloff	97 954
Dr. h.c. Birgit Breuel	4 160
Prof. Dr. Peter Burckhardt	10 972
Prof. Srikant Datar, PhD	3 302
Walter G. Frehner	13 420
William W. George	35 000
Alexandre F. Jetzer	54 876
Pierre Landolt	200
Prof. Dr. Ulrich Lehner	120
Heini Lippuner	26 060
Dr.-Ing. Wendelin Wiedeking	3 534
Prof. Dr. Rolf M. Zinkernagel	13 138
<b>Total</b>	<b>297 040</b>

As of the same date, the non-executive Directors held a total of 365 421 Novartis share options. The number of share options granted and exercise prices have been adjusted to reflect the share split of 1:40 in 2001. Broken down by grant year since 1999 the number of options held are:

Grant Year	Options Held (number)	Conversion Rate	Exercise Price (CHF)	Term Life (years)
2002	125 541	1:1	62.0	9
2001	90 480	1:1	70.0	9
	10 000	1:1	62.6	10
2000	92 200	1:1	51.3	9
1999	17 200	1:1	68.4	9

## Compensation for Former Directors and Executives

In 2003, a total amount of USD 140 824 was paid to four former members of the Board and USD 2 350 630 to three former Executives.

93

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## Report of the Compensation Committee

### Executive Compensation Policy

Novartis' compensation programs are designed to attract, retain and motivate the high caliber executives, managers and associates who are critical to the success of the corporation. Globalization of labor markets for specialists and executives has led to a rapid convergence between US and European principles of compensation and a stronger focus on long-term, equity based forms of programs. Overall, the intention of the programs is to provide compensation opportunities that:

Are comparable to those provided by a selected group of industry-specific competitors

Support a performance oriented culture that allows high performers to achieve superior rewards; and

Align executives, management and associates to create sustainable shareholder value

Total individual compensation at target performance level is aimed at the median of comparable companies of our industries. Annual cash and equity incentive awards are based on both overall Group or affiliate company and individual performance. Long-term incentive awards include share options and other forms of equity participation. Executive compensation programs strongly encourage significant levels of share ownership and put a high portion of total compensation at risk, subject to individual and company performance and the appreciation of Novartis shareholder value. In addition, to further strengthen the Company's ownership philosophy, the Board of Directors established in 2003 share ownership guidelines under which the Executives are required to own a multiple of their base salary in Novartis shares.

### Compensation Programs Descriptions

The total compensation package for each executive consists of the three basic components discussed in more detail below. Target salary and incentive levels are set at the median of the peer group, based on available public data and the analysis of external compensation advisors. Actual compensation levels of individuals may in some instances surpass the median of the market, reflecting superior results. The Compensation Committee believes that this position is consistent with the performance of the Group and its evaluation of the external market.

**Salaries:** The 2003 salaries of the Executive Committee members are shown in the "Salary" column of the 2003 Summary Compensation Table on p. 112.

**Annual Incentive Awards:** Under the terms of the Novartis Annual Incentive Plan, awards are made each year based on the achievement of predetermined Group and individual performance objectives. Below a threshold level of performance, no awards may be granted under the plan.

**Long-Term Incentive Compensation:** Long-term incentive compensation, in the form of share options, performance-contingent shares, and restricted shares, comprises a major portion of the total compensation package for executives. In any given year, an executive may be offered share options, performance-contingent shares, and/or restricted shares. Long-term incentives are targeted at the median of the competitive market, with above-average and superior performance resulting in long-term compensation above the targeted amounts. Below a threshold level of performance, no awards may be granted under the plan. Share options are also granted to selected employees.

94

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### Share Options

(a)

*Novartis Share Option Plan*

Under the Novartis Share Option Plan, Directors (through 2002), executives and other selected employees of Group companies (collectively, the "Participants") may be granted options to purchase Novartis shares. These options are granted both in recognition of past performance and as an incentive for future contributions by the Participants. They allow the Participants to benefit as the price of the shares increases over time, and so provide a long-term incentive for improvements in our profitability and success. If a Participant voluntarily leaves Novartis, options not yet vested generally forfeit. The options under the Novartis Share Option Plan have an exercise period of seven years, which begins after the lapse of a two-year vesting period, and an exchange ratio of 1:1.

(b)

*Novartis US ADS Incentive Plan for US-based employees*

Introduced in 2001, the Novartis US American Depositary Shares (ADS) Incentive Plan grants options to US-based Directors (through 2002), officers and other selected employees thus replacing a Share Appreciation Rights Plan. Its terms and conditions are substantially equivalent to the Novartis Share Option Plan.

In order to further align the Novartis Share Option Plan and the US ADS Incentive Plan, as of 2004, (a) the vesting period for the Novartis Share Option Plan has been changed to a three-year vesting period, and (b) Novartis will introduce tradable stock options in ADS in the US.

**Share Plans:** We offer to certain executives a Long-Term Performance Plan, a Leveraged Share Savings Plan and a Restricted Share Plan. These plans are designed to foster long-term commitment of eligible employees by aligning their incentives with our performance.

(a)

*Long-Term Performance Plan*

Under the Long-Term Performance Plan, participants are awarded the right to earn Novartis shares. Actual payouts, if any, are determined with the help of a formula which measures, among other things, our performance using economic value added relative to predetermined strategic plan targets over a three-year period. Additional functional objectives may be considered in the evaluation of performance. If performance is below the threshold level of the predetermined targets, then no shares will be earned. To the extent the Group's performance exceeds the threshold performance level, participants are eligible to receive an increasing amount of Novartis shares, up to the maximum cap. Payout of shares is conditioned on the participant remaining in the employ of a Novartis affiliate at the time of payout.

(b)

*Leveraged Share Savings Plan*

There are two separate Leveraged Share Savings Plans.

Participants can choose to receive part or all of their Annual Incentive Award in shares. Shares awarded under this plan are blocked for five years after the grant date. After expiration of the blocking period, the respective shares are matched with an equal number of shares.

In 2001 the Board approved a new employee share ownership plan under which Swiss-based employees receive part of their income up to a specified amount in Novartis shares. After the expiration of a blocking period of three years the award is matched with half a share for each share held.

Generally, no matching shares will be granted if an employee voluntarily leaves Novartis prior to expiration of the blocking period.

(c)

*Restricted Share Plan*

Under the Restricted Share Plan, employees may be granted restricted share awards either as a result of a general grant or as a result of an award based on having met certain performance criteria. Shares granted under this Plan generally have a five-year vesting period. If a participant voluntarily leaves Novartis, shares not vested generally forfeit.

**Employee Benefits:** Employee benefits offered to executives are designed to be competitive and to provide a safety-net against the financial catastrophes that can result from disability or death, and to provide a reasonable level of retirement income based on years of service with Novartis.

### Evaluation of the Executive Committee Members' Performance

The Compensation Committee and the Board of Directors meet without the Chairman and CEO to evaluate his performance, and with the Chairman and CEO to evaluate the performance of other Executive Committee members. The bonuses and long-term incentives for 2002 and the base salaries for 2003 were discussed and approved at the meetings of the Compensation Committee held in January 2003. The decisions on compensation of Executive Committee members were mainly based on individual performance evaluations and also take into account current market conditions. In 2003, the Compensation Committee considered management's achievement of short and long-term goals, including revenue growth, economic value creation (operating and net income, earnings per share and economic value added) and ongoing efforts to optimize organizational effectiveness and productivity. The Compensation Committee also takes into consideration management's responses to the changes in the global marketplace and the strategic position of the Group. The performance measures were weighted subjectively by each member of the Compensation Committee.

### Summary

The Compensation Committee believes that the compensation practices and compensation philosophy of Novartis align executive and shareholder interests. We believe that the actions taken over the past year have allowed the Company to attract, retain and motivate the key talent Novartis needs to continue to compete and provide a strong return to shareholders.

### The Compensation Committee of the Board of Directors

Prof. Helmut Sihler, JD, PhD (Chairman)  
Hans-Joerg Rudloff  
William W. George

### Executive Compensation

In 2003, there were 20 Executive Committee members, Permanent Attendees to the Executive Committee and Business Unit Heads ("Executives"), including those who retired or terminated their employment in 2003. In total, the Executives received USD 10 781 000 in salaries and USD 4 025 000 in cash bonuses. The number of share options granted was 3 252 937 and the number of shares granted was 487 853. An additional USD 1 089 000 was set aside for their pension, retirement and similar benefits. Compensation represents all payments made in 2003; however, cash bonuses and long-term compensation are based on 2002 business performance. The following summary compensation table provides details on the 2003 compensation of the Executive Committee members.

96

### 2003 Summary Compensation Table

Name and Principal Position	Annual Compensation		Long-Term Compensation				Total Compensation (USD) <sup>(5)</sup>
	Salary (USD)	Cash Bonus (USD)	Restricted Share Awards (number) <sup>(1)</sup>	Unrestricted Share Awards (number) <sup>(2)</sup>	Share Options (number) <sup>(3)</sup>	All Other Compensation (USD) <sup>(4)</sup>	
Dr. h.c. Daniel Vasella, MD <sup>(6)</sup> Chairman & CEO	2 228 463		122 825	122 826	1 399 254	122 298	14 431 040
Urs Baerlocher, JD <sup>(6)</sup> Head of Legal & General Affairs	545 973		30 389	10 134	153 918	122 083	2 053 948

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	Annual Compensation		Long-Term Compensation				
Raymund Breu, PhD <sup>(6)</sup> Chief Financial Officer	699 490		23 030	13 818	419 777	117 804	3 104 301
Paul Choffat, JD <sup>(6)</sup> Head of Consumer Health	557 116	250 702	6 909	11 516	125 933	120 515	1 995 627
Thomas Ebeling <sup>(6)</sup> Head of Pharmaceuticals	742 821	854 244	10 000	15 354	429 105	521 015	4 538 453
Prof. Mark C. Fishman Head of Pharmaceuticals Research	850 000		5 745	6 023	133 648	34 781	2 374 579
Norman C. Walker <sup>(6),(7)</sup> Head of Human Resources	297 128	311 985		9 213	70 523	101 252	1 303 421

- (1) The Restricted Share Awards include shares granted under the Leveraged Share Savings Plan.
- (2) The Unrestricted Share Awards include shares granted under the Long-Term Performance Plan.
- (3) The share options granted provide the right to purchase one share per option. Share options granted under the Novartis Share Option Plan have a closing price at grant of CHF 48.85 per share and an exercise price of CHF 49.00 per share. The options have a cliff-vesting period of two years after the date of grant and will expire on February 3, 2012. The tradable share options have a tax value of CHF 4.94 per option, calculated based on the Black-Scholes Method. Share options granted under the US ADS Incentive Plan have a closing price at grant and an exercise price of USD 36.31 per share. The options have a cliff-vesting period of three years after the date of grant and will expire on February 1, 2013. The non-tradable share options have a value of USD 7.95 per option, calculated based on the Black-Scholes Method.
- (4) Amounts include, among others, payments made by Novartis to the Management Pension Fund, a defined contribution plan.
- (5) The total compensation amounts have been calculated using the taxable value or Black Scholes Value of the shares and share options granted. All amounts have been converted into USD using 2003 average rates (CHF 1.35/USD).
- (6) Compensation is paid in CHF.
- (7) Norman C. Walker left the company on August 31, 2003. Compensation shown includes payments made until then.

**Distribution of Share Options Granted to Employees**

Under the Novartis Share Option Plan and the Novartis US ADS Incentive Plan described above, a total number of 29.8 million share options with an exchange ratio of 1:1 were granted to 8 028 Participants in 2003. 11% of the overall number of share options were granted to the Executives.

As of December 31, 2003, a total number of 61.6 million share options were outstanding, providing the right to an equal number of shares, which corresponds to 2.2% of the nominal outstanding share capital of Novartis AG.

#### Ownership of Novartis Shares and Share Options by the Executives

The total number of Novartis shares owned as of December 31, 2003 by the Executives and persons closely linked to them was 940 117. "Persons closely linked to them" are (i) their spouse, (ii) their children below the age of 18, (iii) any legal entities that they own or otherwise control, and (iv) any legal or natural person who is acting as their fiduciary. No Executive owned 1% or more of our outstanding shares.

As of December 31, 2003, the individual ownership of Novartis shares of the Executive Committee members (including persons closely linked to them) was as follows:

Beneficial Owner	Number of shares owned Directly or Indirectly
Dr. h.c. Daniel Vasella, MD	401 469
Urs Baerlocher, JD	129 536
Raymund Breu, PhD	189 496
Paul Choffat, JD	7 659
Thomas Ebeling	54 522
Prof. Mark C. Fishman	5 745
<b>Total</b>	<b>788 427</b>

As of December 31, 2003, the 20 Executives held a total of 6 361 294 Novartis share options. The number of share options and exercise price were adjusted to reflect the share split of 1:40 in 2001. Broken down by grant year since 1999, the number of share options held are:

Grant Year	Options Held (number) <sup>(1)</sup>	Conversion Rate	Exercise Price (CHF)	Term Life (years)
2003	3 182 414	1:1	49.0	9
2002	2 124 250	1:1	62.0	9
2001	490 070	1:1	70.0	9
2000	430 200	1:1	51.3	9
1999	101 000	1:1	68.4	9



- (1) The number of share options held includes share options granted under the Novartis Share Option Plan and the US ADS Incentive Plan.

98

### Swiss Employee Benefit Plans

Base Salary (CHF)	Years of Service					
	15	20	25	30	35	40
100 000	17 076	22 764	28 464	34 152	39 840	45 528
140 000	26 076	34 764	43 464	52 152	60 840	69 528
180 000	35 076	46 764	58 464	70 152	81 840	93 528
220 000	44 076	58 764	73 464	88 152	102 840	117 528
over 220 000	44 076	58 764	73 464	88 152	102 840	117 528

- (a) Swiss Pension Fund

The Swiss Pension Fund is a defined benefit fund that provides retirement benefits and risk insurance (covering death or disability). The Swiss Pension Fund is funded by contributions from Group companies and the insured employees. The Swiss Pension Fund insures remuneration up to a maximum of CHF 220 000 per year. The maximum retirement pension is 60% of the insured remuneration after 40 years of contribution. The table above shows the annual pension benefit by Base Salary and Years of Service. In 2003 Novartis contributed CHF 11 700 for each of the Swiss-based Executive Committee members.

- (b) Swiss Management Pension Fund

The Swiss Management Pension Fund is a defined contribution plan and provides retirement benefits and risk insurance (covering death or disability) for components of remuneration not covered by the Swiss Pension Fund. Employees exceeding the maximum insurable remuneration of the Swiss Pension Fund are eligible for the Swiss Management Pension Fund. The benefits under the Swiss Management Pension Fund are granted in addition to those of the Swiss Pension Fund. The Swiss Management Pension Fund is funded through contributions by Novartis and the employee.

### US Based Employee Pension Plan

The Pension Plan for US based employees of Novartis Corporation (Pension Plan) is a funded, tax-qualified, noncontributory defined-benefit pension plan that covers certain employees of Novartis Corporation and its United States affiliates, including Prof. Mark C. Fishman. The Pension Plan provides for different pension formulas depending on which Novartis company is the employer of a particular employee. The pension formula in which Prof. Mark C. Fishman participates under the Pension Plan is a pension equity (PEP) formula. Benefits under the PEP formula are based upon an employee's highest average earnings for a five calendar-year period during the last ten calendar years of service with Novartis and the employee's accumulated PEP credits (expressed as a percentage of final average earnings, and ranging from 2% to 13% for each year of service based on the employee's attained age in a particular year), and are payable after retirement in the form of an annuity or a lump sum. The amount of annual earnings covered by the Pension Plan is generally equal to the employee's base salary and annual bonus. The amount of annual earnings that may be considered in calculating benefits under the Pension Plan is limited by law. For 2003, the annual limitation was USD 200 000.

Novartis Corporation and its United States affiliates also maintain various unfunded supplemental pension plans that each provide its employees with an amount substantially equal to the difference between the amount that would have been payable under the Pension Plan in the absence of legislation limiting pension benefits and the annual earnings that may be considered in calculating pension benefits under tax-qualified pension plans, and the amount actually payable under the Pension Plan.

#### **Personal Loans, Change of Control and Severance Agreements**

Under the provisions of the US Sarbanes-Oxley Act, enacted in July 2002, no new loans may be given to Executives. Loans granted prior to the act were repaid during 2003. As of December 31, 2003 no loans were outstanding. Under a change of control provision, four executives have provisions whereby their normal contractual severance of 36 months is extended by 24 months during the 12 months following a change of control. One executive has a provision whereby the normal contractual severance of 12 months is extended by 12 months during the 12 months following a change of control. Between January 1, 2003 and December 31, 2003, three Executives left the company; under the terms of the agreements with these Executives, USD 1 795 000 were paid as severance.

#### **Performance Graph**

This graph compares our total shareholder returns, the Morgan Stanley World Pharmaceuticals Index (MSWPI), and the Swiss Market Index (SMI). The graph assumes CHF 100 invested at Novartis per share closing price on December 31, 1995, in Novartis shares and each of the indices.

<b>Dec</b>	<b>Dec</b>	<b>Dec</b>	<b>Dec</b>	
<b>95</b>	<b>96</b>	<b>97</b>	<b>98</b>	<b>Dec</b>
				<b>99</b>