

NOVARTIS AG
Form 6-K
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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

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35
4056 Basel
Switzerland

(Address of Principal Executive Offices)

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

Form 20-F: Form 40-F:

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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:**

OUR MISSION

We want to discover, develop and successfully market innovative products to prevent and cure diseases, to ease suffering and to enhance the quality of life.

We also want to provide a shareholder return that reflects outstanding performance and to adequately reward those who invest ideas and work in our company.

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GROUP

Novartis provides healthcare solutions that address the evolving needs of patients and societies worldwide.

Now focused solely on growth areas in healthcare, Novartis offers a diversified portfolio to best meet these needs innovative medicines, cost-saving generics, preventive vaccines and diagnostic tools, and consumer health products.

FINANCIAL HIGHLIGHTS**KEY FIGURES**

(In USD millions, unless indicated otherwise)	2007	2006
Total Group net sales	39 800	37 020
Continuing operations (1)		
- Net sales	38 072	34 393
- Operating income excluding environmental and restructuring charges (2)	7 815	7 642
- Return on net sales (2) (%)	20.5	22.2
- Operating income	6 781	7 642
- Net income	6 540	6 825
Net income Discontinued operations	5 428	377
Net income Total Group	11 968	7 202
Basic earnings per share (3)		
- Continuing operations (1)	2.81	2.90
- Total Group	5.15	3.06
R&D investments (1)	6 430	5 321
- As % of net sales (1)	16.9	15.5
Number of associates (FTE (1), (4))	98 200	94 241

SHARE INFORMATION

	2007	2006
Return on average equity (%)	26.4	19.3
Free cash flow (1)	3 761	4 045
Operating cash flow per share (1), (3) (USD)	3.97	3.54
ADS price at year-end (USD)	54.31	57.44
Share price at year-end (CHF)	62.10	70.25
Dividend payment (5) (CHF)	1.60	1.35
Payout ratio of net income from continuing operations (%)	49	38

(1) Excluding Consumer Health discontinued operations

(2) Excluding in 2007 USD 590 million of Corporate environmental and USD 444 million of Forward initiative restructuring charges

(3) Average number of shares outstanding in 2007: 2 317.5 million (2006: 2 345.2 million)

(4) Full-time equivalent positions

(5) Dividend payment for 2007 proposed to shareholders

Business Review

Overview

NEWS IN 2007

GROUP

Record results in 2007 underscore benefits of strategic healthcare portfolio. Total Group net sales rise 8% (+3% in local currencies) to USD 39.8 billion. Net income reaches USD 12.0 billion. Results include contributions from Medical Nutrition and Gerber until divestment and an after-tax divestment gain of USD 5.2 billion in net income.

Strong contributions particularly from Sandoz and Vaccines and Diagnostics in continuing operations focused solely on healthcare. Net sales rise 11% (+6% lc) to USD 38.1 billion. Operating income decline reflects US pharmaceuticals slowdown and significant charges of about USD 1 billion for environmental provision as well as Forward initiative to improve competitiveness.

PHARMACEUTICALS

Europe, Latin America and key emerging markets generate double-digit growth and many products strengthen leading positions. Net sales grow 6% (+2% lc) to USD 24.0 billion. However, US impacted by generic competition and *Zelnorm* suspension. Operating income decline reflects lost US contributions and significant charges as well as major investments in new products and pipeline.

VACCINES AND DIAGNOSTICS

Net sales advance to USD 1.5 billion. Key growth drivers are vaccines for TBE (tick-borne encephalitis), pediatric immunization and seasonal influenza as well as NAT (nucleic acid testing) blood testing products. Meningitis vaccines in development progressing toward regulatory submissions.

SANDOZ

Dynamic performance with net sales up 20% (+13% lc) to USD 7.2 billion, providing an incremental increase of USD 1 billion thanks mainly to the US and Eastern Europe. Difficult-to-make generics provide competitive advantage. Operating income advances much faster than net sales, supported by productivity gains.

CONSUMER HEALTH

Solid expansion as OTC and Animal Health deliver double-digit growth from focus on strategic brands, new products and geographic expansion. CIBA Vision grows on improved product availability.

PIPELINE

15 major regulatory approvals in the US and Europe for new pharmaceutical products. Highly respected pipeline with 140 projects in clinical development. Many have potential best-in-class status that would advance or create new treatment standards.

RESEARCH

Novartis Biologics formed to accelerate R&D in biologic therapies, which represent 25% of the Novartis pre-clinical research pipeline. Many projects advancing rapidly at Novartis Institutes for BioMedical Research.

CORPORATE CITIZENSHIP

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Novartis access-to-medicine programs for those in need reach 66 million patients in 2007 through contributions valued at USD 937 million.

DIVIDEND

Proposal for 19% increase in 2007 dividend to CHF 1.60 per share. Represents 49% payout ratio of net income from continuing operations.

Letter from Daniel Vasella

DEAR SHAREHOLDERS:

It gives me great pleasure in our twelfth business year, which has been the most exceptional in the history of Novartis, to report another set of record results despite a difficult environment for the Pharmaceuticals Division, which experienced disappointments as well as successes.

We took decisive steps in 2007 to focus Novartis solely on healthcare through the divestments of Medical Nutrition and Gerber, which led to net income advancing 66% to USD 12 billion. This includes the after-tax gain of USD 5.2 billion from the divestments.

The sale of these businesses, along with one-time charges of approximately USD 1 billion for environmental provisions and restructuring measures, makes it challenging to compare this performance with the previous year. Therefore I will focus on continuing operations:

- Net sales from continuing operations rose 11% (+6% in local currencies) to USD 38.1 billion
- Operating income from continuing operations rose 2% to USD 7.8 billion excluding these one-time factors
- Earnings per share (EPS) rose 68% to USD 5.15 for the Group, and were up 9% to USD 3.15 for continuing operations when also excluding these one-time factors

- Free cash flow from continuing operations reached USD 3.8 billion

All divisions contributed to another record level of net sales for the Group. However, the overall results were impacted by a weaker performance in the Pharmaceuticals Division, which stood in stark contrast to the dynamic growth of Vaccines and Diagnostics and Sandoz. Consumer Health also delivered substantially improved results.

While the Pharmaceuticals Division faced a challenging year, it is important to note the overall good results, even if these were less likely to make headlines than the setbacks. Europe, Latin America and the priority emerging growth markets all posted double-digit expansion in net sales, while the Oncology and Neuroscience franchises delivered strong double-digit growth. Many of the top ten selling medicines – above all *Gleevec/Glivec* for the treatment of chronic myeloid leukemia and the high blood pressure medicine *Diovan* – maintained leading positions in their therapeutic areas. In the US, by contrast, net sales declined sharply following the withdrawal of *Zelnorm* in March and the entry of generic competition, which to some extent was unforeseen, for *Lotrel*, *Lamisil*, *Trileptal* and *Famvir*. In 2006, these five products together generated annual net sales of approximately USD 3 billion in the US, so these setbacks represent a loss of more than 10% of global Pharmaceuticals Division net sales. Additional challenges included the ongoing delay in gaining US regulatory approval for the new diabetes medicine *Galvus* and a regulatory decision in the US not to approve *Prexige*.

At the same time, all of our other healthcare businesses delivered excellent results.

The **Vaccines and Diagnostics** Division enjoyed dynamic growth in 2007. Strong deliveries of influenza vaccines to the US, as well as vaccines for tick-borne encephalitis and for pediatric immunization, were the most important growth drivers. The pipeline made significant progress, particularly the development of potentially first-in-class vaccines for meningococcal meningitis, and

supported by a new strategic alliance with Intercell that provides exclusive access to several promising projects.

The generics Division **Sandoz** also reported dynamic growth, especially in the US. The successful launches of several new difficult-to-make generics, which provide Sandoz a competitive advantage, underpinned the strong expansion. Operating income improved much faster than net sales, benefiting from sustained increases in sales volumes and productivity initiatives.

The **Consumer Health** Division delivered a good performance, as both OTC (non-prescription medicines) and Animal Health achieved attractive growth thanks to a common focus on strategic brands and the launch of new products as well as expansion in Japan and emerging growth markets. CIBA Vision improved its net sales, and in particular operating income, following the resumption of deliveries in 2007 after some recent product shortages. Operating income for the Division improved and supported significant R&D investments and geographic expansion.

The overall good performance in a difficult environment confirms that we are on the right strategic path. The events of 2007 have made clear the advantages of our strategy centered on focused diversification. We are active in fast-growing areas of the healthcare market while reducing risks, such as over-dependence on government-regulated pricing for medicines or the actions of regulatory agencies.

Despite the current industry challenges, the healthcare sector's future continues to promise robust growth. The growing need for medical services and medicines is driven above all by the following factors:

- First and foremost is the **aging of the world's population**. The incidence of chronic and degenerative diseases, such as arthritis, high blood pressure, cancer and, of course, dementia, rises with age. An estimated 80% of people over age 80 suffer from at least one disease, and more than 60% have two or more conditions. The entry of the baby boomer generation into retirement—the first members reached the traditional retirement age in 2007—will further support this trend.
- Younger generations are also being impacted by **health-related changes in society**. Changes in dietary habits and an increasingly sedentary lifestyle are having an impact. The number of over-weight people is not only rising in the US but also in Europe and many developing countries. Negative health consequences linked to obesity are becoming increasingly visible, especially cardiovascular disease and diabetes. At the same time, environmental pollution is causing more cases of cancer and pulmonary disease.
- **Strong economic growth in emerging markets** with large populations, particularly China, India and Russia, has led to rapid expansion of the middle class and greater demands for better healthcare services.
- Finally, **new technological discoveries and trends** are continuously enabling the development of innovative medicines to address a range of diseases that previously could not be adequately treated.

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Although these developments reaffirm prospects for rising demand for healthcare and our products, a number of challenges exist:

- **Increased pressure on costs:** Political resistance to high-price medicines is likely to grow throughout the world as

the overall cost of healthcare keeps rising. Although doctors, pharmacies and hospitals will not be able to escape political pressures, the pharmaceuticals industry unduly suffers due to its status as the most visible and tangible participant in the healthcare system. This makes us an easy scapegoat for rising costs.

- **Erosion of patent rights:** Our industry has recently found itself confronted by aggressive behavior from certain generics manufacturers. Some have launched copies of medicines before the expiry of patents because they consider these patents to be contestable, and in many instances courts have not yet stepped in to stop them.

- **Growing mistrust:** The pharmaceuticals industry has faced for some time a conservative attitude from the US Food and Drug Administration (FDA), which appears to be a reaction to public criticism. This conservatism is reflected in the agency's demands for growing volumes of data aimed at guaranteeing an unparalleled degree of safety. In the long term, this approach will be detrimental to medical progress since it is simply not possible to provide medicines that are completely free of side effects in all patients. The benefits and risks of any treatment must in the end be weighed individually by the physician and patient.

A strategy ignoring these trends, which to some extent overlap and are at times contradictory, will fail sooner rather than later. We are convinced that our diversified portfolio – yet one focused on growth areas of healthcare – ideally positions Novartis for the future and reduces risks. We have been steadfast in pursuing this strategy in recent years, for example, by purchasing Chiron in 2006 as well as by divesting the remaining non-core nutrition businesses in 2007.

The most decisive factor remains our strength in innovation. Our overall performance in gaining new product approvals was positive. It goes without saying that the delays in approvals for *Galvus* have been particularly disappointing. It is important, nonetheless, to recognize the overall successes during the year. Novartis received six positive regulatory decisions in the US and nine in the EU (15 positive decisions out of a total of 17). These included approvals for *Rasilez/Tektura* and *Exforge* (high blood pressure), *Exelon Patch* (Alzheimer's disease) and *Aclasta/Reclast* (osteoporosis) in the US and Europe. In addition, *Lucentis* (wet age-related macular degeneration, a leading cause of blindness) and *Sebivo/Tyzeka* (hepatitis B) were both approved in Europe. In the third quarter, *Galvus* received European approval as a new oral treatment option for patients with type 2 diabetes. At the end of 2007, the US and EU both granted approvals for *Tasigna* as a new medicine for patients with chronic myeloid leukemia no longer responding to *Gleevec/Imatinib*.

Novartis is widely recognized as having one of the industry's most attractive development pipelines. Research and Development activities are focused in particular on cardiovascular and metabolic diseases, oncology and neurology as well as respiratory and infectious diseases. Our portfolio includes 140 projects in clinical development, more than ever before. Several late-stage projects are progressing on track toward regulatory submissions. These include **FTY720** (multiple sclerosis), **QAB149** (respiratory diseases), **RAD001** (cancer), **ACZ885** (Muckle-Wells syndrome) and **SOM230** (Cushing's disease).

Breakthroughs have also been achieved in Sandoz and Vaccines and Diagnostics: Thanks to improvements in innovation and productivity, Sandoz has strengthened its leading position in bringing difficult-to-make generics to the market. European approval was granted in 2007 for epoetin alfa – a further milestone following the US approval of the growth hormone *Omnitrope* in 2006 as the world's first follow-on version of a previously approved biotechnology drug. As an affordable, high-quality biogeneric, epoetin alfa could be used to provide benefits to approximately 250 000 patients in Europe.

In 2007, Vaccines and Diagnostics gained European approval for the new pandemic flu vaccine *Focetria*. Novartis also gained a leading position in cell-culture flu vaccines with the European approval of *Optaflu*, which utilizes new technologies representing the most important innovation in influenza vaccine manufacturing in more than 50 years.

Innovation is our core competency this comprises the development of novel medicines and the creation of new R&D strategies. Driven by the increasing number of therapeutic proteins discovered by our researchers, we established a new Biologics R&D unit in 2007 to unify our core capabilities in biologics within one group.

It takes courage during uncertain times to follow your own path and be true to your convictions, rather than just keeping an anxious eye on competition. Novartis has steadfast positions and stands by them. Our points of view often do not win popularity contests. The tendency toward group thinking has sometimes been confused with the practice of benchmarking. This approach can often lead to errors in judgment. In such a situation, one rarely has the courage to review a situation objectively, draw conclusions and also take responsibility.

One of the fundamental aspects of the Novartis culture is being true to our values, ensuring that we remain committed ultimately to the needs of patients while engaging in social and political debates. It is critical

to differentiate between legitimate discussions about healthcare costs and those that appear to address this issue but instead actually mask hostility toward innovation.

Pressure on healthcare prices is simply a reality that must be accepted. Given the demographic trends, one can appreciate the cost reduction efforts. But there is a limit, and crossing it endangers incentives needed to drive innovation. Going beyond this limit would have dramatic consequences, massively weakening long-term investments that have led to historical advances in medicine. Progress is only possible in an environment that values innovation. I personally feel the level of hostility toward innovation goes too far when industrialized countries take for granted that they have the healthiest populations in the history of mankind but at the same time demand breakthrough medicines with no side effects and offered at minimal prices.

Aging societies are precisely those that can neither support such ill-considered views toward innovation nor the political conditions that facilitate them. On the contrary, aging societies must embrace innovation. One of the most urgent challenges in many critical markets for Novartis is the cost of healthcare, coupled with overall care of the elderly. Concern for the healthcare needs of the elderly could be reasonably addressed through innovation, especially if one eventually wants to avoid rationing. One interesting example is the link between Alzheimer's disease and the rise in life expectancy. If an effective treatment is not found, the costs of treating and caring for these patients could quickly skyrocket to absolutely unaffordable levels. The annual costs of caring for the estimated five million people in the US with Alzheimer's disease already represents about USD 150 billion of the nation's healthcare budget. Consider the implications of estimates forecasting the number of patients will rise to an unimaginable 100 million in 2025.

One would surmise that society would encourage research into these types of diseases, creating more attractive rewards for those who make significant R&D investments. This might seem counter-intuitive at first, but from a long-term perspective it could be the only viable approach.

Another development eroding the vital culture of innovation is the increasing aversion to any conceivable risk. This reflects several societal trends, and manifests itself mainly in relation to our products. Let me be clear: No medicine exists today that is completely free of side effects in all patients. Of course, this poses a dilemma for those involved—doctors and patients. During my time as a physician working in hospitals, I was confronted every day by this dilemma. I still firmly believe that one of the core capabilities of physicians is to take responsibility for decisions that involve their patients. When regulatory agencies take over these responsibilities, as is increasingly the case in the US, then healthcare policies will move toward a patronizing system where physicians and the pharmaceuticals industry are viewed with distrust instead of as important partners. These developments oppose the consistent demand for industry and individuals to take more responsibility for their actions, coupled with a corresponding reduction in the role of governments. Strict control systems are appropriate and important—and opinions should not differ on this point. But excessive anxiety will slow the pace of medical progress over the long term, and lead to suffering that will impact our entire society.

A sustained commitment to social responsibility is a fundamental value of Novartis. Our actions in corporate citizenship

are too critical to be linked to business cycles. Last year, for example, our access-to-medicine programs reached 66 million patients worldwide, with contributions totaling USD 937 million and representing about 2.5% of annual net sales from continuing operations.

Important Novartis initiatives are focused on neglected diseases, especially malaria, leprosy, dengue fever and treatment-resistant tuberculosis. In 2007 in more than 40 African countries, Novartis provided 66 million treatments of the anti-malaria medicine *Coartem* below costs, which saved an estimated 200 000 lives, a majority of which were children. Moreover, annual production capacity has been ramped up to deliver 100 million treatments of *Coartem*.

I would also like to take an opportunity to provide an industry perspective as well: An impressive 1.3 billion health-related interventions ranging from medicines to vaccines and disease awareness campaigns worth billions of dollars were distributed between 2000 and 2006 in developing countries considered to be of little commercial interest.

Attracting the best talent from around the world is critical for a global company like Novartis, ensuring that associates feel respected and are recognized for their contributions. Ensuring equal opportunities, fairness and mutual respect are a sine qua non in a world that, in business terms, is growing ever closer together. Our Diversity & Inclusion Advisory Council (DIAC), comprised of nine external experts with different cultural, ethnic and social backgrounds, supports the objective of building teams that are both diverse and talented. The DIAC will further strengthen our competitiveness by reinforcing the importance of an inclusive environment not only among our associates but also in interaction with patients and other interest groups. I have been personally following the progress of the DIAC members, and I am deeply impressed by their engagement and contributions.

Novartis has long been committed to the principles of sustainability, encompassing more than just environmental protection and long before this issue found its way to the forefront as one of the first signatories of the UN Global Compact. A key aspect of our corporate culture is ensuring appropriate use of energy and other resources. Three years ago, Novartis made a voluntary commitment to reduce its greenhouse-gas emissions to levels mandated by the Kyoto Protocol. The improvements in energy efficiency have already exceeded expectations. Sustainability is a prominent feature of the Novartis Campus at our headquarters in Basel. A key objective is to use renewable energy on the Campus and eliminate CO₂ emissions in the medium term. The changing composition of the worldwide vehicle fleet is also contributing to these objectives: A 10% reduction in CO₂ emissions is expected by 2010 through the replacement of older vehicles with new ones utilizing hybrid technology or diesel motors with micro-particle filters.

I am particularly pleased that our commitment to sustainability of all forms was acknowledged in 2007 with the selection of Novartis as a sustainability leader in the Dow Jones Sustainability Index, a worldwide rating of companies according to economic, environmental and social factors.

This engagement in corporate responsibility and actually the success story of Novartis would not have been possible without a consistent focus on performance and results. As a global company, we have consistently considered challenging periods as opportunities to review how we work and to pursue improvements. The initiatives announced in the second half of 2007 involve innovation, efficiency and leadership. Beyond the creation of the new Biologics unit, two other initiatives will help us more quickly achieve our objectives:

- Project Step-up is designed to improve the effectiveness of drug development: We want to strengthen our project teams, integrate decision-making under the leadership of experienced colleagues at the franchise level and simplify development processes.

- A Group-wide initiative called *Forward* is underway to simplify our structures, accelerate and decentralize decision-making processes, and redesign the way Novartis operates, while at the same time providing productivity gains. Although the results of internal surveys show Novartis performs in almost all aspects better than comparable companies, they also show many associates feel the organization is too complex and could benefit from simplification. Given these perspectives, we have taken this opportunity both to streamline our organization and to redefine the way we work.

Coping with change is never easy, especially when jobs are affected. However, it would be fatal if we were to ignore significant industry changes taking place. Only by taking a proactive approach can we improve our competitiveness.

Last year, some leadership changes were also made to broaden experience at the top management level and to provide fresh impetus to our business. Switching positions, Joseph Jimenez became Head of the Pharmaceuticals Division and Thomas Ebeling took over as Head of the Consumer Health Division.

As a shareholder, you are naturally interested in the performance of our company. Since its creation in 1996, Novartis has provided on average a total annual return of 9.9% to shareholders, more than the returns of most large pharmaceutical companies. Our earnings per share have risen approximately 80% during the last five years, while the annual dividend payout has risen on average 11% during the same period. Unfortunately, these improvements have not been reflected in the share price, and this is not something to gloss over. At the same time, our fundamentals remain strong and are reflected in the twelfth consecutive year of record results achieved in 2007 despite significant challenges.

Indeed, the pharmaceuticals industry has suffered from a period of overall devaluation in market capitalization. The industry's price/earnings ratios only a few years ago ranged from between 25 to 30, but many have since collapsed to between 10 and 15. This broad devaluation indicates that financial markets have viewed pharmaceutical stocks with suspicion for some time, based on reasons already discussed. However, I believe the emphasis is far too much on challenges than on opportunities. In turbulent times, investors have often turned to the pharmaceuticals sector; a downturn in the economy will offer pharmaceutical stocks an opportunity to again be seen as valuable investments.

We are now preparing for a new growth cycle. The results in the first half of 2008 will be negatively impacted by a weak performance in the Pharmaceuticals Division, particularly in the US. This period will be used to further improve productivity and efficiency.

Thanks to new product launches and the strength of our flagship products *Diovan* and *Gleevec/Glivec*, a new growth cycle in Pharmaceuticals is also expected to emerge in the second half of 2008.

Cautious optimism seems appropriate for 2008: One must remember that the industry is facing a more volatile phase than experienced in the past. I am confident that I speak for all Novartis associates in saying we all are well aware that greater efforts will be needed for success as compared to the past.

Even when considering the challenges and setbacks, we look to the future with confidence. My conviction that 2008 will be a successful year is based on our long-term strategy, well-acknowledged innovation capabilities, operational excellence and the courage to act independently.

In times like these, marked by uncertain dynamics and fundamental changes, I would like to thank our associates, whose outstanding performances have once again helped Novartis achieve a record performance in a very challenging environment. These particularly valuable efforts are anchored in our shared purpose of improving the lives of patients.

In closing, I would like to once again express my appreciation to you, our shareholders, for the trust you continue to place in Novartis.

Sincerely,

Daniel Vasella, M.D.

Chairman and Chief Executive Officer

PHARMACEUTICALS

Strong performances in Europe, Latin America and key emerging markets lead to net sales rising 6% (+2% in local currencies) to USD 24.0 billion. However, US net sales decline 8% after entry of generic competition for *Lotrel*, *Lamisil*, *Trileptal* and *Famvir* as well as suspension of *Zelnorm*.

Many top ten products are leaders in their therapeutic categories. *Diovan* becomes the world's No. 1 branded high blood pressure medicine as net sales reach USD 5 billion for the first time in 2007. *Gleevec/Glivec* reinforces leadership in helping patients with certain forms of cancer as net sales reach USD 3 billion for the first time.

Operating income decline reflects lost contributions in the US, major investments in late-stage development compounds, new product launches and restructuring charges for the Forward initiative to improve competitiveness. Excluding these restructuring charges, operating income falls 5%.

15 major regulatory approvals during 2007 in the US and European Union. Many new medicines have the potential to set new treatment standards. Success reflects productivity from one of the industry's most respected pipelines. 140 projects in clinical development.

Recently approved products being rolled out around the world: *Exforge* and *Tekturna/Rasilez* (high blood pressure), *Lucentis* (age-related blindness), *Exelon Patch* (Alzheimer's disease), *Tasigna* (cancer), *Aclasta/Reclast* (osteoporosis), *Exjade* (iron overload) and *Xolair* (asthma).

Progress in late-stage pipeline. Potential for several new submissions between 2008 and 2010. FTY720 (multiple sclerosis), RAD001 (cancer) and QAB149 (chronic obstructive pulmonary disease) all complete enrollment in key Phase III trials.

Novartis Biologics created in 2007 as a dedicated unit. Objective to optimize research and development of biologic medicines by unifying and expanding expertise. Biologics represent 25% of pre-clinical research pipeline and are an increasing priority.

PHARMACEUTICALS

KEY FIGURES	2007	2006
(In USD millions, unless indicated otherwise)		
Net sales	24 025	22 576
Operating income excluding restructuring charge (1)	6 393	6 703
Operating income	6 086	6 703
Research and development	5 088	4 265
Research and development as % of net sales	21.2	18.9
Free cash flow	6 292	6 501
Net operating assets	13 984	13 640
Additions to property, plant and equipment (2)	1 436	1 135
Number of associates (FTE (3)) at year-end	54 613	54 314

(1) Excluding USD 307 million of Forward initiative restructuring charge

(2) Excluding impact of business combinations

(3) Full-time equivalent positions

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The following table is an excerpt of Novartis Pharmaceuticals clinical pipeline that holds a broad stream of 140 future projects including both new molecular entities and additional indications or formulations for marketed products.

Glossary of terms:

Compound Molecular entity

Generic name International Non-proprietary Name (INN) designated by the World Health Organization (WHO)

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

Phase I First clinical trials in patients to determine safety, tolerability and usually proof of concept

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

Submission In registration

Therapeutic area	Project/compound	Generic name	Indication
Cardiovascular and Metabolism	<i>Galvus</i>	vildagliptin	Type 2 diabetes
	<i>Diovan/Starlix</i> NAVIGATOR	valsartan, nateglinide	Prevention of new-onset type 2 diabetes, cardiovascular morbidity and mortality
	<i>Lotrel</i> ACCOMPLISH	amlodipine, benazepril	High-risk hypertension
	<i>Tekturna</i> ALTITUDE	aliskiren	Type 2 diabetes
	Tekturna FDC (1)	aliskiren, valsartan	Hypertension
	Tekturna FDC (1)	aliskiren, hydrochlorothiazide	Hypertension
Oncology & Hematology	<i>Tasigna</i>	nilotinib	Gastrointestinal stromal tumor
	EPO906	patupilone	Ovarian cancer and other solid tumors

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	RAD001	everolimus	Renal cell cancer, pancreatic islet cell tumor, solid tumors
	SOM230	pasireotide	Acromegaly, GEP (6) tumors, Cushing's Disease
	PKC412	midostaurin	Acute myeloid leukemia
	LBQ707	gimatecan	Solid tumors
	LBH589		Cutaneous T-cell lymphoma, hematologic tumors
	ASA404		Non small cell lung cancer
Neuroscience & Ophthalmology	AGO178	agomelatine (7)	Depression
	FTY720	fingolimod	Multiple sclerosis
	SAB378		Central nervous system
Respiratory	<i>Xolair</i>	omalizumab	Allergic asthma
	QAB149	indacaterol	Chronic obstructive pulmonary disease
	MFF258	formoterol, mometasone	Asthma, chronic obstructive pulmonary disease
	NVA237	glycopyrronium bromide	Chronic obstructive pulmonary disease
	NIC002		Smoking cessation
	QAT370		Chronic obstructive pulmonary disease
	QMF149	indacaterol,	Asthma, chronic obstructive pulmonary disease
		mometasone	
	QVA149	indacaterol, glycopyrronium bromide	Chronic obstructive pulmonary disease
		TBM100	tobramycin
Immunology & Infectious Diseases	<i>Certican</i>	everolimus	Prevention of organ rejection
	<i>Mycograb</i>	efungumab	Severe fungal infections
	<i>Albuferon</i>	albumin interferon alpha 2-b	Chronic hepatitis C
	<i>Aurograb</i>		Severe Staphylococcus aureus infections
	AEB071		Prevention of organ rejection
	ACZ885		Muckle-Wells syndrome, rheumatoid arthritis, systemic onset juvenile idiopathic arthritis
	SBR759		Hyperphosphatemia
	SMC021	calcitonin	Osteoporosis, osteoarthritis
	TFP561	tifacogin	Severe community acquired pneumonia

-
- (1) Fixed dose combination
 - (2) Breakpoint cluster region-Abelson fusion protein
 - (3) Important receptor tyrosine kinase protein
 - (4) Platelet-derived growth factor receptor protein
 - (5) Mammalian target of rapamycin protein
 - (6) Gastroenteropancreatic
 - (7) Licensed from Servier; Novartis has rights in the US
 - (8) Heat shock protein 90

Mechanism of action	Formulation	Planned submission dates	Phase I	Phase II	Phase III	Submitted
Dipeptidyl peptidase 4 inhibitor	Oral	Submitted US (approved EU)	XXXXXXXXXXXXXXXXXXXXXXXXXXXX			
Angiotensin II receptor antagonist and insulin secretagogue	Oral	2010	XXXXXXXXXXXXXXXXXXXXXXXXXXXX			
Angiotensin I converting enzyme inhibitor and calcium channel blocker	Oral	2009	XXXXXXXXXXXXXXXXXXXXXXXXXXXX			
Renin inhibitor	Oral	≥2011	XXXXXXXXXXXXXXXXXXXXXXXXXXXX			
Renin inhibitor and angiotensin II receptor antagonist	Oral	2008	XXXXXXXXXXXXXXXXXXXXXXXXXXXX			
Renin inhibitor and diuretic	Oral	Submitted US, EU	XXXXXXXXXXXXXXXXXXXXXXXXXXXX			
Bcr-Abl (2), c-Kit (3) and PDGFR (4) inhibitor	Oral	2009	XXXXXXXXXXXXXXXXXXXXXXXXXXXX			
Microtubule depolymerization inhibitor	Infusion	2010	XXXXXXXXXXXXXXXXXXXXXXXXXXXX			
mTOR (5) inhibitor	Oral	2008	XXXXXXXXXXXXXXXXXXXXXXXXXXXX			
Somatostatin analogue	Injection	2009	XXXXXXXXXXXXXXXXXXXXXXXXXXXX			
Signal transduction inhibitor	Oral	≥2011	XXXXXXXXXXXXXXXXXXXX			
Topoisomerase I inhibitor	Oral	≥2011	XXXXXXXXXXXXXXXXXXXX			
Deacetylase inhibitor	Oral	2009	XXXXXXXXXXXXXXXXXXXX			
Vascular disrupting agent	Infusion	≥2011	XXXXXXXXXXXXXXXXXXXX			
Melatonin receptor agonist and 5-HT_{2C} antagonist	Oral	2008	XXXXXXXXXXXXXXXXXXXXXXXXXXXX			
Sphingosine-1-phosphate receptor modulator	Oral	2009	XXXXXXXXXXXXXXXXXXXXXXXXXXXX			
Cannabinoid receptor agonist	Oral	≥2011	XXXXXXXXXXXXXXXXXXXX			
Anti-IgE monoclonal antibody	Liquid formulation for injection	2008	XXXXXXXXXXXXXXXXXXXXXXXXXXXX			
Long-acting beta-2 agonist	Inhalation	2008	XXXXXXXXXXXXXXXXXXXXXXXXXXXX			
Long-acting beta-2 agonist and long-acting steroid	Inhalation	2009	XXXXXXXXXXXXXXXXXXXXXXXXXXXX			
Long-acting antimuscarinic	Inhalation	≥2011	XXXXXXXXXXXXXXXXXXXX			
Nicotine Qbeta therapeutic vaccine	Injection	≥2011	XXXXXXXXXXXXXXXXXXXX			
Long-acting antimuscarinic	Inhalation	≥2011	XXXXXXXXXXXXXXXXXXXX			
Long-acting beta-2 agonist and long-acting steroid	Inhalation	2010	XXXXXXXXXXXXXXXXXXXX			
Long-acting beta-2 agonist and long-acting antimuscarinic	Inhalation	≥2011	XXXXXXXXXXXXXXXXXXXX			
Aminoglycoside antibiotic	Dry powder for inhalation	2009	XXXXXXXXXXXXXXXXXXXXXXXXXXXX			
Growth-factor-induced cell proliferation inhibitor	Oral	Submitted US, (approved EU, Japan)	XXXXXXXXXXXXXXXXXXXXXXXXXXXX			
Anti-HSP90 (8) antibody	Infusion	2009	XXXXXXXXXXXXXXXXXXXXXXXXXXXX			
Long-acting interferon	Injection	2009	XXXXXXXXXXXXXXXXXXXXXXXXXXXX			
Anti-Staph. aureus antibody	Infusion	≥2011	XXXXXXXXXXXXXXXXXXXX			
Protein Kinase C inhibitor	Oral	≥2011	XXXXXXXXXXXXXXXXXXXX			
Anti-interleukin-1 b antibody	Injection	2009	XXXXXXXXXXXXXXXXXXXXXXXXXXXX			
Selective binding of phosphate (Fe(III) containing polymer)	Oral	2010	XXXXXXXXXXXXXXXXXXXX			
Regulator of calcium homeostasis	Oral	≥2011	XXXXXXXXXXXXXXXXXXXXXXXXXXXX			
	Infusion	2009	XXXXXXXXXXXXXXXXXXXXXXXXXXXX			

Recombinant tissue factor
pathway inhibitor

PHARMACEUTICALS

Increased life expectancy is one of the most remarkable achievements of the past century. Yet old age brings increased risk of chronic ill health, disability and loss of independence. During 2007, Novartis received major approvals for new medicines that are helping to transform treatment of many diseases that represent paramount public-health challenges for the aging society.

Before Midge Hatzman was diagnosed with osteoporosis in the late 1980s, she had a succession of fractures including her back, wrist, ankle and ribs.

Osteoporosis, a progressive bone-thinning disease, forced Mrs. Hatzman to give up skiing and tennis. At the age of 80, however, she still gardens and hikes in her home town, Ossining, New York. During the summer, she even visits the local swimming pool with her husband, Al.

In 2004, her physician recommended that she consider participating in a clinical trial of *Aclasta/Reclast*, a new, once-yearly treatment for osteoporosis developed by Novartis. Mrs. Hatzman liked the fact that a single 15-minute infusion would protect her for the whole year. It was a snap, she says.

Even more important, she hasn't had any new fractures during the three years she has remained on treatment with *Aclasta/Reclast*.

Mrs. Hatzman exemplifies the challenges that aging populations are posing for healthcare systems around the globe. Increased life expectancy is one of the most remarkable human achievements of the past century; average life expectancy at birth has increased by nearly 20 years worldwide since the mid-1950s, according to the World Health Organization (WHO).

Yet old age brings increased risk of chronic ill health, disability and loss of independence. Moreover, the cost of providing healthcare for an older American is three to five times greater than for someone younger than 65, according to the US Centers for Disease Control and Prevention. The nation's healthcare spending is projected to climb a further 25% as the population of Americans older than 65 doubles by the year 2030.

The WHO estimates that the population aged 60 and older will triple worldwide by 2050, with most of the increase occurring in developing countries. At the same time, the disease profile is changing with low-and middle-income countries moving rapidly from an era of infectious diseases to an era of chronic diseases associated with lifestyle and economic changes.

The risk of outbreaks a new influenza pandemic, for example will require constant vigilance, the WHO warned. But it is the looming epidemics of heart disease, stroke, cancer and other chronic diseases that for the foreseeable future will take the greatest toll in deaths and disability.

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Novartis is responding to these challenges with a broad portfolio of businesses addressing the needs of customers. Innovation remains the key to success.

There is no way around that; innovation is vital and will remain vital, says Daniel Vasella, M.D., Chairman and Chief Executive Officer of Novartis.

Innovation means breakthrough medicines that address unmet medical need and change the way medicine is practiced in diseases ranging from cancer to high blood pressure. Research and Development also delivers incremental innovation such as the once-yearly infusion of *Aclasta/Reclast*, to enhance adherence to treatment and improve outcomes.

Transforming Treatments

During 2007 Novartis received major approvals for a succession of new medicines that are helping to transform treatment of many diseases that represent paramount public-health challenges for the aging society.

Aclasta/Reclast was approved in the European Union (EU) and the US in 2007 as the first and only once-yearly medicine for postmenopausal osteoporosis. Osteoporosis is a long-term disease that causes bones to break more easily and affects more than 200 million people worldwide.

Novartis also launched *Exelon* Patch, the first transdermal skin patch for treatment of Alzheimer's disease. The new patch formulation maintains steady drug levels in the bloodstream, improving tolerability and allowing a higher proportion of patients to receive therapeutic doses of the well-established medication, *Exelon*.

Lucentis received approval in the EU as the first and only treatment proven in clinical trials to maintain and improve vision in patients with the wet form of age-related macular degeneration (AMD). A degenerative eye disease, wet AMD is a leading cause of severe vision loss in people older than 50 in the Western world. Currently there is no cure and treatment options are limited.

In addition, two new Novartis medicines were approved and launched for treatment of high blood pressure, a condition that affects a quarter of the world's adult population and causes more than 7 million deaths and an even greater number of debilitating events from cardiovascular disease every year. High blood pressure is the leading cause of death in the developed and developing world and the number-one modifiable risk factor.

Exforge, a single-pill treatment combining the power of the two most commonly prescribed branded hypertension medicines, was rolled out in both Europe and North America during 2007. *Rasilez/Tekturna*, a direct renin inhibitor, became the first new type of antihypertensive to reach patients in more than a decade, broadening a portfolio anchored by *Diovan*, now the world's best-selling branded antihypertensive medicine.

Aclasta - Improving Adherence

One out of every two women older than 50 suffers an osteoporotic fracture during her lifetime. Fractures are responsible for an estimated 500 000 hospitalizations in the US every year, costing the healthcare system more than USD 12 billion annually. Approximately 20% of women

older than 50 who suffer a hip fracture will die within one year.

Regulatory applications for *Aclasta/Reclast* were based on efficacy and safety data from the three-year Pivotal Fracture trial, involving more than 7 700 women. Results from the study showed that *Aclasta/Reclast* increases bone strength and reduces fractures in areas of the body typically affected by osteoporosis, such as the hip, spine, wrist and rib. *Aclasta/Reclast* is the only treatment approved to reduce fractures across all these key sites.

The active ingredient in *Aclasta/Reclast*, zoledronic acid, belongs to the chemical family known as bisphosphonates, the current standard of care. The once-yearly administration of *Aclasta/Reclast* gives physicians and payors an opportunity to address the problem of sub-optimal patient adherence to treatment with bisphosphonates taken weekly or monthly as tablets.

In an editorial about the Pivotal Fracture Trial in the New England Journal of Medicine (NEJM), Juliet Compston, M.D., University of Cambridge School of Clinical Medicine, wrote: Despite the availability of effective treatments for osteoporosis, poor adherence to drug regimes reduces the benefit and presents a major challenge for health professionals. Dr. Compston acknowledged that even a single infusion (of *Aclasta/Reclast*) appears to ensure efficacy for at least one year and probably longer. She concluded: Increased treatment choices for patients are to be welcomed and may provide one means of improving adherence and treatment outcomes in osteoporosis.

A separate study published by NEJM in 2007 confirmed the potential of *Aclasta/Reclast* to significantly improve treatment outcomes in the first-ever clinical study in patients with osteoporosis who already had suffered a hip fracture. Once-yearly infusions of *Aclasta/Reclast* resulted in a 35% reduction in new clinical fractures and a 28% reduction in death from any causes as compared with placebo.

The study involved more than 2 100 patients, between the ages of 50 and 98, who began treatment with *Aclasta/Reclast* within three months after hip-fracture repair and continued treatment for two years. An accompanying editorial in NEJM declared: The reduction in fracture incidence and death (for patients treated with *Aclasta/Reclast*) was striking and clearly establishes the need for pharmacologic intervention in patients who fracture a hip.

More than 300 000 hip fractures occur annually in the US, the majority related to osteoporosis and falls in older people. A third of hip-fracture patients die within two years of their injuries, and many of those who survive do not regain pre-fracture levels of mobility. They also endure loss of independence and deterioration in health-related quality of life, according to NEJM.

Still, few patients currently receive osteoporosis treatment following a hip fracture despite high risk of morbidity and mortality. Data from the Recurrent Fracture Trial have been submitted to regulatory authorities worldwide to broaden the treatment indication for *Aclasta/Reclast*.

For all the medical benefits demonstrated in clinical studies, once-yearly infusion represents a challenge for payors because of the one-time cost compared to oral daily, weekly or monthly treatments. Novartis has tried to assuage such concerns with innovative pricing models. In Germany, for example, Novartis has agreed to refund medication costs to health insurers in cases of treatment failure within a year of *Aclasta/Reclast* infusion. The money-back guarantee has accelerated reimbursement negotiations with German authorities.

Another program aimed to improve access to treatment encompasses a network of 130 Lighthouses, or mini-clinics, across Germany. Each clinic is fully equipped and has trained staff to deliver infusions for patients referred to the Light-house by their own physicians. For doctors who lack staff or infrastructure in their practices to offer infusions, the Lighthouse is a safe haven where they can feel confident their patients will receive optimal treatment with *Aclasta/Reclast*, says Emmanuel Puginier, M.D., Head of Marketing and Sales, General Medicines, at the Novartis Pharmaceuticals Division. It's another way we are building confidence with our stakeholders.

Lucentis – Important Advance in Treatment

John Blake is an avid golfer on links around his home in Birmingham, England, but he had difficulty following the flight of the ball after losing the central vision in his left eye. When Mr. Blake was diagnosed with the wet form of macular degeneration in the other eye two years ago, his

physician recommended treatment with Lucentis, a new medicine jointly developed by Novartis and Genentech Inc.

If you've gone blind in one eye you wonder if going to be the same in the other one, he muses. An independent life is everything to me and it makes you reflect how precious your eyes are.

Lucentis is administered as an intravitreal injection and Mr. Blake had to battle a fear of needles as well as the threat of losing his sight. I've got a phobia about injections so it did put a lot of fear into me but the fear of going blind was much more severe so I overcame that, he says. In the end the injection wasn't half as bad as I thought it would be.

His first *Lucentis* injection was successful. There was further improvement following a second and, after the third injection, my sight was quite good, Mr. Blake says. I can go and play anyone at golf, go fishing and drive a car. Everything has opened up again.

AMD is a disease caused by damage in the macula, the central part of the retina where light-sensitive cells send signals to the brain. The macula is responsible for straight-ahead central vision needed for activities ranging from driving to reading and identifying faces.

There are two forms of AMD. The dry form accounts for the vast majority of cases but the more severe wet form is responsible for up to 90% of cases of blindness from AMD, according to the US National Eye Institute.

There are an estimated 2.5 million wet-AMD patients living in EU member countries. More than half of those patients have not yet been diagnosed and, of those diagnosed, 40% are not receiving treatment.

The evolution of the disease and visual loss is very fast for wet AMD, says Professor Francesco Bandello, Chairman of the Department of Ophthalmology at the University of Udine, Italy. Moreover, the frequency of wet AMD is increasing because the number of older patients is increasing day by day.

By contrast to previous therapies that could only slow the decline in vision, treatment with *Lucentis* stabilizes vision in most patients treated and actually improves vision and vision-related quality of life in a significant number of people suffering from wet AMD. *Lucentis* is able to produce stabilization of visual function in 90% to 95% of our patients and we have about 30% of these patients who show some degree of improvement of visual function, Professor Bandello says. This is really a revolution compared to what we had before.

A therapeutic monoclonal antibody fragment, *Lucentis* was specifically designed to penetrate all the layers of the retina to reach the macula. The medicine binds to vascular endothelial growth factor (VEGF-A), a growth factor essential for the formation of new blood vessels. By binding to VEGF-A, *Lucentis* reduces abnormal vessel growth and leakage of fluid into the retina. This allows the retinal structure to return to normal.

The pivotal studies included in regulatory submissions for *Lucentis* show an unprecedented response rate among wet AMD patients. As Professor Bandello indicated, almost 95% of patients with *Lucentis* maintained their vision, defined as a loss in visual acuity (or clarity of vision) of less than 15 letters on the eye chart used in the study. About two out of three patients in the study treated with *Lucentis* gained some vision compared to baseline visual acuity measured at the beginning of the trial. That gain in vision has been sustained for two years with monthly treatments with *Lucentis*.

Adherence to treatment is important for wet AMD patients. *Lucentis* is given as a monthly injection for three months, followed by a maintenance phase in which patients are monitored monthly. *Lucentis* should be re-administered if a patient loses more than five letters of visual acuity. Novartis has developed self-monitoring tools for use by patients during the maintenance phase.

Lucentis was jointly developed by Novartis and Genentech Inc. Novartis holds exclusive commercial rights to *Lucentis* outside the US. Since the initial approval by Switzerland, more than 45 additional countries have approved *Lucentis*.

Even before the launch of *Lucentis*, Novartis was already at the forefront of treatment of AMD through *Visudyne*, a photodynamic therapy that combines intravenous injection of a drug and laser therapy to destroy abnormal blood vessels that cause AMD without harming healthy tissue. Expertise in the field helped Novartis to work closely with regulatory authorities to speed reimbursement discussions and make *Lucentis* available to patients as quickly as possible.

Switzerland and Canada granted the new medicine accelerated regulatory reviews and pre-license sales were allowed in Germany and France. Reimbursement discussions with French authorities were completed only five months after approval, about half the nine months usually required. In Australia, reimbursement talks took a mere four months versus the normal 12 months.

That's very important because treatment with *Lucentis* has to start fairly quickly after diagnosis, Dr. Puginier says. After onset of the disease, the optimum treatment window is six to 12 months.

Pioneering Patch

Petra Lauhoff-Spiegel is the main caregiver for her mother, who has been diagnosed with Alzheimer's disease. It's necessary for someone to be with her every day, Ms. Lauhoff-Spiegel says. I help her dress, tidy up the flat, do the laundry and prepare food. But I also provide the affection that a person in her situation needs.

Her mother's condition deteriorated gradually over several years, but eventually medication was prescribed to slow progression of the disease. Administering capsules can be very difficult. Sometimes I put the capsule into her hand along with a glass of something to drink but she lays the capsule down somewhere and just forgets about it, Ms. Lauhoff-Spiegel adds.

A few years ago, the family read about a clinical study sponsored by Novartis testing *Exelon Patch*, a unique new formulation in which medication was administered through a transdermal patch applied to the skin. After contacting St. Josef-Hospital in Bochum, Germany, her mother was enrolled into the study. Using the patch, Ms. Lauhoff-Spiegel says, her mother seems to have fewer side effects: The patch is easier to handle and once she has it on her shoulder, I know it will stay there and she will get the medication she needs.

Exelon Patch is the first and only transdermal treatment for Alzheimer's disease, a degenerative brain disorder affecting 18 million people worldwide and the third-leading cause of death in people older than 65 after cardiovascular disease and cancer.

Alzheimer's disease initially involves the parts of the brain that control thought, memory and language. Age is the most important known risk factor for Alzheimer's disease.

Approval of *Exelon Patch* by both the US and the EU in 2007 was based on results of the international IDEAL study involving almost 1 200 patients with mild-to-moderate Alzheimer's disease. The patch showed similar efficacy to the highest doses of *Exelon* capsules as well as significant improvement, compared to placebo, in memory and the ability to perform everyday activities. In addition, the IDEAL study demonstrated a sharp reduction in reported gastrointestinal side effects (nausea and vomiting) compared to the oral form of the medication.

The patch has been shown to increase compliance, reduce side effects and allow medication to be delivered through the skin into the bloodstream smoothly and continuously over 24 hours, helping to achieve

optimal dosing, says James Shannon, M.D., Global Head of Pharmaceutical Development at Novartis. All these benefits offer the potential for improved outcomes in patients.

Importantly, the patch was preferred by more than 70% of caregivers of participants in the IDEAL study. The patch, which is applied daily to the back, chest or upper arm of patients, was designed with compliance in mind. Caregivers said that transdermal delivery helped them follow treatment schedules and was easier to use than an oral medicine. I am pleased that the patch offers a new approach to treatment adds Mark Wortmann, Executive Director of Alzheimer's Disease International, an umbrella organization that offers support and advice to people with Alzheimer's disease and their caregivers.

Exelon was first approved in 1997 and is available in more than 70 countries to treat patients with mild-to-moderate Alzheimer's disease. Since 2006, *Exelon* in capsule form has been approved in the US and EU for the additional indication of Parkinson's disease dementia. In 2007, the US Food and Drug Administration approved *Exelon* Patch for treatment of Parkinson's disease dementia as well as Alzheimer's disease.

Comprehensive Blood Pressure Control

When Paul Bridge was diagnosed with high blood pressure during an annual check-up at the age of 52, it came as a surprise. I was quite active and swam very frequently, even competitively, but my doctor felt that my blood pressure just wasn't where it ought to be, given my lifestyle, Mr. Bridge recalls. He said we had time but that we should tackle it early.

The result was a journey of discovery between doctor and patient. Initially Mr. Bridge explored non-pharmaceutical treatment but it had no more than marginal effect, he says. The next step was to test different classes of antihypertensive medication. Eventually, he was prescribed *Co-Diovan*, a fixed combination of *Diovan* plus a diuretic. That was it, the key to getting my blood pressure down to the good values we were after, Mr. Bridge adds. And once I started with *Co-Diovan*, I stayed on it. My values have remained good and I have had no side effects.

The use of combination therapies is becoming increasingly common, reflecting US and EU treatment guidelines stating that a majority of patients with high blood pressure will require two or more anti hypertensive drugs to achieve effective control.

Yet Mr. Bridge, a retired banking executive who lives in Basel, Switzerland, is unusual in adhering to treatment and keeping his blood pressure under control during the past 10 years. Using a widely accepted definition of normal blood pressure, only about 30% of patients in the US achieve goal blood pressure, and the US does far better than other countries.

I understood early on that hypertension is a killer, Mr. Bridge says. But as lifestyle was not an issue in my case, I never regarded having to take medication for high blood pressure as a failure on my part. My swimming gives me an awareness of the state of my body and I have every interest in keeping it in as good shape as possible. *Co-Diovan* is one of the tools that modern medicine gives me to do that and I do indeed have the necessary self-discipline to make sure I keep it up.

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The risk of developing high blood pressure increases with age. About 60% of Americans older than 60 have high blood pressure, according to the Seventh Report of the Joint National Committee on the Detection, Evaluation and Treatment of High Blood Pressure.

Clinical studies have clearly demonstrated that effective treatment of high blood pressure reduces both coronary and renal events as well as strokes. Yet hypertension control rates are lowest among people

older than 60 in the US. According to a recent study in the Journal of the American Medical Association, the increase in hypertension prevalence in older Americans highlights the need for interventions that would target prevention.

High blood pressure makes the heart work harder and over time can damage blood vessels throughout the body. Atherosclerosis – deposition of fats in the arteries, caused in part by hypertension – can impede supply of blood to the heart muscle, leading to coronary heart disease and heart attack.

Long-term exposure to high pressure can lead to damage to the blood vessels of the kidney, allowing functional deterioration. This deterioration can lead to kidney failure, also commonly called end-stage renal disease.

Current treatment guidelines recommend a blood pressure goal of 140/90 mmHg in patients and more stringent goals for people with conditions such as diabetes or renal disease that increase the risk of organ damage. Despite the availability of multiple classes of blood pressure-lowering medicines, fewer than half of people with hypertension receive treatment and about 70% of people who are treated fail to achieve their recommended blood pressure goal. Importantly, a decrease of just 2 mmHg in systolic blood pressure is associated with a reduction in the risk of death from heart disease by 7%, and death from stroke by 10%.

Today, most treatment guidelines recognize that the majority of patients will require combinations with at least two anti-hypertensive drugs. In the US, Japan and major countries in Europe, more than 60% of patients treated for high blood pressure receive combination therapy.

Exforge, approved in both the US and EU last year, is a single-tablet combination of two of the worlds leading high blood pressure medicines, amlodipine and *Diovan*, flagship of the Novartis cardiovascular franchise. Delivering two agents in a single pill is expected to improve compliance with treatment.

Approval of *Exforge* was supported by an extensive clinical trial program involving more than 5 000 patients. Results show that *Exforge* can help up to nine out of 10 patients reach their treatment goal of systolic blood pressure under 140 mmHg. *Exforge* also works across all grades of high blood pressure and offers blood pressure reductions of over 40 mmHg in patients with higher baseline blood pressure.

By contrast to *Exforge*, which is a fixed combination of two established medicines, *Rasilez/Tekturna* is a direct renin inhibitor, a novel mechanism of action. The renin system is a key regulator of blood pressure and overactivity of the renin system is one of the principal causes of hypertension in a substantial proportion of patients. By directly inhibiting renin at the point of activation, *Rasilez/Tekturna* provides more complete control of the renin system than other antihypertensives that work further downstream.

With an elimination half-life of about 40 hours, *Rasilez/Tekturna* provides sustained and consistent blood pressure efficacy for 24 hours and beyond. This is an important treatment consideration because many high blood pressure medicines fail to work around the clock, especially during the early-morning hours when blood pressure often surges.

Moreover, poor compliance with anti-hypertensive therapy can lead to suboptimal blood pressure control and substantial increases in blood pressure can occur even after an occasional missed dose. Studies with *Rasilez/Tekturna* have shown that blood pressure reductions are maintained for four days even after the last dose.

Regulatory approval of *Rasilez/Tekturna* was based on data from more than 7 500 patients, generated in more than 40 clinical trials. Novartis also has begun an ambitious program of new studies, called ASPIRE HIGHER, to demonstrate whether more complete control of the renin system can provide organ-protection benefits beyond blood pressure lowering.

Initial studies in the ASPIRE HIGHER program, including heart-failure patients and people with type 2 diabetes with proteinuria (excessive amounts of protein in the urine) delivered positive results during 2007. Additional studies including patients with high blood pressure and left-ventricular hypertrophy, an enlargement of the left pumping chamber of the heart are due to report in 2008.

Another milestone in 2007 was the start of ALTITUDE, a large clinical-outcomes trial that will evaluate the efficacy of *Rasilez/Tekturna*, in addition to conventional therapy, in preventing cardiovascular and renal complications in patients with diabetic nephropathy who are at high risk of such events. ALTITUDE has a projected study population of more than 8000 patients and completion is anticipated by the year 2012.

Data from outcomes studies are viewed as the final proof of treatment by patients and physicians, and the gold standard of value-for-money by cost-conscious governments, insurers and other payors. Outcomes data generated through the *Diovan* megatrial program, involving more than 50 000 patients across the cardiovascular continuum, led to additional approvals for the indications of heart failure, and reduction of cardiovascular death in patients at high risk following a heart attack.

NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH

AIN457 was among a group of development compounds completing positive proof-of-concept trials in 2007. As a promising treatment for psoriasis and other autoimmune disorders, AIN457 underscores the growing emphasis on biologic therapies at the Novartis Institutes for BioMedical Research (NIBR) as well as intense collaboration between disease areas that is a distinctive feature of NIBR research strategy.

During 2005, tantalizing evidence of a link between Th-17 cells and patients suffering from psoriasis provided scientists at Novartis a key ingredient for transforming their own fundamental work into a medical advance.

Th-17 cells are specialized immune cells that help to protect the body against attack by certain microorganisms and fungi. Evidence had been mounting that Th-17 cells also appear to play a key role in several autoimmune diseases, ranging from rheumatoid arthritis to multiple sclerosis and dozens of other rare conditions.

The destruction of tissue characteristic of autoimmune diseases is caused by interleukin 17 (IL-17), a protein secreted by Th-17 cells. This meant that blocking Th-17 should abrogate ill effects in autoimmunity.

But how to confirm this hypothesis safely and quickly? Autoimmune diseases fluctuate in intensity, and many tissues affected are hard to check routinely to see if a drug is effective. That is one reason why the possibility that IL-17 was important in psoriasis, a skin disease, seemed such an exciting opportunity.

Moreover, Novartis scientists had created AIN457, a monoclonal antibody that inhibits IL-17. Monoclonal antibodies are laboratory-made versions of naturally occurring proteins that can locate and bind to substances in the body.

We decided immediately to examine AIN457 in psoriasis in patients, recalls Timothy Wright, M.D., Head of Exploratory Development at Novartis. That study exceeded expectations as a single infusion of AIN457 provided relief lasting for more than three months to a majority of patients taking part.

The successful Proof of Concept (PoC) with AIN457 in treatment of psoriasis is the first time that this IL-17/Th-17 mechanism has been proven in man. And as a result, we now have a strong position in the industry in this area, says Dhaval Patel, M.D., Head of Autoimmunity & Transplantation research at the Novartis Institutes for BioMedical Research (NIBR) site in Basel, Switzerland.

The AIN457 program says a lot about research and development at Novartis. First and foremost, it underscores the importance of being at the cutting edge of biology. Work at NIBR on AIN457 began as part of fundamental programs directed at a particular cell type, the lymphocyte, with suspected, but by no means certain, relationships to autoimmune diseases. The project took off in earnest as evidence of its medical importance accumulated.

AIN457 promises to be one of the first projects tackled by the new Biologics development unit formed during 2007 in response to the growing emphasis on monoclonal

antibodies and other biologic technologies at NIBR. Monoclonal antibodies now comprise 25% of NIBR's research portfolio, compared to only 4% of the portfolio a few years ago.

The Biologics program deserves a focused effort so we really can reap all the opportunities and benefits we have from this discovery effort," says Daniel Vasella, M.D., Chairman and Chief Executive Officer of Novartis.

The AIN457 program also underscores the integration between research and development—as well as across disease areas in each function—that has become a distinctive feature of research strategy at Novartis. Drug discovery at NIBR focuses on pathways, fundamental signaling networks that control many of the basic cellular functions of life. By identifying components of the core pathway, as well as other proteins that interact with the pathway and can modify its function, Novartis scientists seek to pinpoint key nodes that can be inhibited with a drug or biologic therapy, thus arresting the abnormal pathway function that underpins disease.

Approaches that integrate research across traditional disease-area boundaries are critical because a defective pathway may be involved in multiple diseases. At Novartis, sharing ideas as well as compounds to be tested among disease areas allows us to understand the biology, as well as the best patient population, for a given molecule as early as possible," Dr. Wright says.

As the AIN457 program demonstrates, availability of a medicine with a well-defined mechanism of action for testing in patients enables a company to confirm promising hypotheses much earlier than rivals. We are very responsive to emerging data and don't wait years to bring these treatments to patients," Dr. Wright adds. In fact, we can do so very nimbly—as in this case—branching off in mid-stream in a new direction that could end up being beneficial for patients and the company.

Orchestrating Immune Defenses

IL-17 was isolated in 1995 but Th-17 cells weren't identified as a subset of immune cells—and the source of IL-17—for another decade. Many details about the role of Th-17 cells are still under investigation today but their normal function appears to be orchestrating immune defenses against microbial invasion. As part of an elaborate signaling cascade, naïve T-cells differentiate into Th-17 cells that secrete IL-17 and that protein—known as a cytokine—recruits other immune-system cells to the scene of the attack.

The suspected role of Th-17 in rheumatoid arthritis stems from observations that levels of IL-17 are elevated in fluids taken from joints of patients afflicted with the condition. Moreover, studies in animals demonstrate that IL-17 acts in concert with other cytokines to enhance joint inflammation and destruction of cartilage and bone. Basically the picture that is emerging is that Th-17 cells are really the ones that cause the damage in the tissue," says Jan de Vries, Ph.D., Global Head of the Autoimmunity & Transplantation Disease Area at NIBR.

Clearly, Novartis scientists working in those early days in the area of rheumatoid arthritis under leadership of Brian Richardson, Dr. vet. med., Head of Arthritis and Bone Metabolism Research, were ahead of their time in picking IL-17 as a potential antibody target. Establishment of the new disease area Autoimmunity & Transplantation at NIBR in 2003—combined with the renewed interest in therapeutic monoclonal antibodies—was instrumental in enabling Dr. de Vries and his collaborators to move AIN457 forward quickly into testing.

Of course, the AIN457 program tapped deep pools of knowledge at NIBR, particularly a heritage of cytokine research dating back almost two decades. Franco Di Padova, M.D., the Senior Research Investigator at NIBR who led the team that generated AIN457, recalls that, at the outset of the program, it was barely possible to detect

low levels of IL-17 in blood and infected cells of patients. Subsequent progress was due to development of increasingly sophisticated and sensitive assays.

At first, IL-17 was considered a less-potent cytokine than tumor necrosis factor and IL-1, both established targets for drug discovery, Dr. Di Padova says. The AIN457 team broadened its understanding of IL-17 biology through a crucial collaboration with Professor Wim van den Berg, Head of Experimental Rheumatology at Radboud University Nijmegen Medical Centre in the Netherlands.

That's how it all started, says Dr. Di Padova. Professor van den Berg and others in the field were putting out threads of emerging biology and hints about the potential involvement of IL-17 in disease pathogenesis.

Working closely with Professor van den Berg helped the AIN457 team unravel the biology of IL-17 and steer through the explosion of research targeting the cytokine and Th-17 cells in recent years.

A Fully Integrated Biologics Company

Once AIN457 had been discovered, the program gained additional traction from an increasing strategic focus at NIBR on biologic treatments, and monoclonal antibodies in particular.

The 1984 Nobel Prize in Medicine was awarded to Georges Koehler and Cesar Milstein for their discovery of so-called hybridoma technique that allows unlimited production of monoclonal antibodies with predetermined specificity. The technology is now a pillar of modern biotechnology and according to the US industry group PhRMA, more than 150 monoclonal antibodies are currently in development as biotechnology medicines.

Both of the predecessor companies of Novartis were active in research targeting monoclonal antibodies. *Xolair*, the first monoclonal antibody to be approved for the treatment of asthma, was developed under an agreement between Novartis, Genentech Inc., and Tanox Inc. *Simulect* is a monoclonal antibody approved for the prevention of acute rejection episodes in recipients of kidney transplants. Under the leadership of Professor Mark Fishman, M.D., President of NIBR and member of the Executive Committee of Novartis, discovery and development of monoclonal antibodies and other biologics has become a strategic priority.

The push into biologics reflects limits on biological targets accessible to traditional small-molecule therapies. Ultimately what we want to do is to use the whole human genome for drug discovery, Dr. Fishman explains. Antibodies are able to hit parts of pathways inaccessible to low molecular-weight compounds, especially molecular targets that are secreted by cells or located on the cell surface.

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Yet even antibodies only touch about half the potential targets in the human genome, Dr. Fishman says. That is why Novartis has moved rapidly into another cutting-edge biologic technology, RNA interference (RNAi), a natural gene-silencing defense used by plants and animals against invading pathogens. Synthetic versions of RNAi could silence malfunctioning genes that cause disease.

There is no single answer in drug discovery. We need the entire armamentarium of potential therapeutics, Dr. Fishman adds. To that end, complementing our traditional strength in discovering chemicals as drugs, it's fair to say that Novartis now is also a full-fledged biologics company.

The growing output from NIBR promises to have a knock-on effect downstream in Pharmaceutical Development, prompting creation of the new Biologics development unit last year.

More and more, research at NIBR is focusing on targets that require us to go to biologics, but the development of biologics is different from small molecules, says James Shannon, M.D., Global Head of Pharmaceutical Development. Safety management is different in biologics and it is important to invest early, and to get the manufacturing process right early on. In addition, the intellectual property space relating to biologics is very complex and needs special focus.

The new Biologics development unit headed by Abbie Celniker, an executive with extensive experience in the US biotechnology industry will tackle those challenges. The Biologics unit will work closely with both NIBR and Development but also maintain key interfaces with marketing and production. The aim is to bring together all the talent we have in the Group relating to biologics and cultivate that entrepreneurial biotech culture, which is needed to really push the innovation of biotech products forward, Dr. Shannon adds.

Overarching Strategy

The success of AIN457 underscores the intimate and persistent interactions between research and development that set Novartis apart from many rivals. This teamwork is most apparent in the Exploratory Development function that serves as a bridge between research and later clinical development.

Working closely with NIBR scientists, Exploratory Development focuses on selection and effective profiling of drug candidates, and their transition to early stages of development. A distinctive feature of Early Development is the contribution of physician-scientists from the Translational Medicine group who complement the fundamental scientific discoveries by NIBR with clinical acumen needed to pinpoint both the diseases and patients most likely to benefit from a new treatment.

Proof-of-Concept studies (PoCs) are the cornerstone of the overarching strategy to bring more and better new medicines to

market in the shortest possible time. PoCs are small-scale Phase I clinical trials in well-defined diseases or targeted patient populations that allow a preclinical hypothesis about a mechanism of action to be tested and also provide a quick confirmation of potential therapeutic benefit to patients. Unsuccessful PoC studies help to eliminate compounds with toxicity or other liabilities early in the development process.

Once a successful PoC provides evidence that the medicine can help patients in these carefully targeted disease areas, Novartis R&D strategy expands that therapeutic benefit with parallel studies in additional diseases that share a common disease mechanism.

The clinicians in our Translational Medicine group are continuously part of a cross-functional research approach from the earliest stages of drug discovery. Often, uncommon but well-defined diseases are chosen for initial PoC studies, using biomarkers to provide clear, preliminary readouts about new Novartis medicines.

While each positive PoC represents a key milestone, success doesn't guarantee that the compound will make it to market. Discovery and testing of back-up compounds, based on the same mechanism of action, is another established feature of drug development at Novartis. This backup strategy provides alternative compounds if studies uncover side effects that rule out a lead compound as a candidate for further development.

The role of Translational Medicine physicians includes planning alternative development paths for a compound, working in what Dr. Wright calls a "tidal zone" where research and translational medicine interface. "It's where you see a lot of the action and intense interchange of ideas. And it's where these parallel indications pop out," he says.

The research component is identifying the biology and the indications for that particular molecule in humans. The development part is getting the medicine registered. No one can succeed alone; we have to cooperate to get through the research phase, into the clinic and ultimately into the market. And the counterculture here is that ideas are shared openly because we share the ultimate goal: to help patients.

The initial PoC study for AIN457 in late 2005 explored safety and efficacy through a careful dose escalation schedule in accordance with regulatory guidance. As an unplanned dividend, safety data on AIN457 obtained during the rheumatoid arthritis study was critical in gaining the green light from regulators to begin the parallel PoC in psoriasis.

For all the positive results to date, Dr. Wright cautions that it is still early in terms of exploring safety and efficacy of AIN457 in psoriasis in a clinical setting. Follow-up studies are planned to explore a broader range of dosage. "At week 12 we're still not seeing any evidence of flaring and some patients are still improving after the first dose," he adds. Psoriasis is a cyclical disease and episodes of flaring, or recurrences, appear repeatedly over time.

Patients in the initial study cohort of patients have been invited to extend the follow-up period to six months, rather than the four to six weeks initially planned.

VACCINES AND DIAGNOSTICS

Second year of strong growth in new Division created after Chiron acquisition in April 2006. Significant increase in vaccine deliveries underpins profitable growth ahead of schedule.

Net sales up 52% (+47% in local currencies) to USD 1.5 billion. Excellent performance driven by TBE (tick-borne encephalitis), pediatric and seasonal influenza vaccines as well as NAT (nucleic acid testing) blood testing products. On a comparable full-year basis, net sales rise 25% (including unaudited net sales from Chiron before April 2006 acquisition).

Strong business performance underpins improvement in operating income. Significant investments made in R&D, particularly for late-stage trials involving meningococcal meningitis vaccine candidates. The adjusted operating margin is 21.3% of net sales.

Novartis the second-largest manufacturer of influenza vaccines for the US. Developing a broad portfolio of vaccines against seasonal influenza and to protect people from an influenza pandemic. New cell-culture technology, approved in Europe in 2007, considered the most important production innovation for influenza vaccines in over 50 years.

Two meningococcal meningitis vaccine projects achieving key milestones. Results from Phase II trials show *Menveo* quadrivalent vaccine against four serogroups A, C, W135 and Y may protect infants as young as two months old. Highest attack rate for this potentially fatal bacterial disease seen in infants from three to 12 months of age. Existing vaccines have not worked in very young children.

Comprehensive Intercell alliance formed in 2007 to provide access to a promising vaccine development pipeline. Builds on collaboration for IC51 Japanese encephalitis vaccine.

Consistent growth through geographic expansion in diagnostics business. Dedicated to preventing the spread of infectious diseases through novel blood-screening tools. Important West Nile Virus assay test launched in the US in 2007.

VACCINES AND DIAGNOSTICS

KEY FIGURES	2007	2006 (1)
(In USD millions, unless indicated otherwise)		
Net sales	1 452	956
Operating income	72	-26
Research and development	295	148
Research and development as % of net sales	20.3	15.5
Free cash flow	-91	151
Net operating assets	4 801	4 536
Additions to property, plant & equipment (2)	287	113
Number of associates (FTE (3)) at year-end	4 810	3 395

(1) Chiron post-acquisition period: April 20 - December 31

(2) Excluding impact of business combinations

(3) Full-time equivalent positions

VACCINES AND DIAGNOSTICS

The meningitis franchise is a linchpin of dynamic growth ambitions in the Vaccines and Diagnostics Division. Two meningitis vaccines currently in development aim to set new standards for broad protection and extend coverage across all ages. At the same time, Novartis achieved significant advances with influenza vaccines last year, reinforcing its position as a global leader.

At an advanced stage of negotiations leading to the acquisition of Chiron Corp. two years ago, Novartis executives learned that future development of *Menveo*, a promising vaccine against bacterial meningitis, was in doubt.

At that time it was close to being stopped, recalls Joerg Reinhardt, Ph.D., Head of the new Vaccines and Diagnostics Division and member of the Executive Committee of Novartis. We were told there was no money to take the program forward.

Once Dr. Reinhardt took the helm at the new Division that encompasses most operations of the former Chiron, development of *Menveo* was accelerated. During 2007, more than 10 000 subjects were enrolled in clinical trials of the vaccine. This year, Novartis expects to submit an initial regulatory application for use of *Menveo* in people age 11 years or older. And in 2009, regulatory filings are planned for use of the vaccine in infants and young children, the group most vulnerable to meningococcal disease.

There are more than a dozen distinct classes of *Neisseria meningitidis* or meningococcus, the bacterium that causes most cases of bacterial meningitis. *Menveo* is a vaccine against the A, C, W and Y serogroups (MenACWY) but Novartis Vaccines is also developing a pioneering recombinant vaccine against all strains of serogroup B meningococcus (MenB).

If we're successful with *Menveo* and our recombinant MenB vaccine, we'll transform the field of meningitis, says Ralf Clemens, M.D., Head of Development at Novartis Vaccines.

Net sales growth in 2007 of 25% (on a comparable 2006 basis) has made the Vaccines and Diagnostics Division one of the fastest-growing vaccine manufacturers and helped it achieve profitability ahead of schedule. Moreover, the acquisition and turnaround of the Vaccines and Diagnostics Division underscores the strategic focus of Novartis on entering high-growth sectors of healthcare. The global market for vaccines and molecular diagnostics is expected to grow at solid, double-digit rates during the coming five years, significantly faster than demand for prescription medicines during the period.

Novartis Vaccines expects to do even better, according to Dr. Reinhardt. Over the next five years or so, we want to become one of the top three players in the vaccine market, Dr. Reinhardt says. Currently, Novartis ranks fifth among global vaccine manufacturers.

Meningitis

The meningitis-vaccine franchise is shaping up as a linchpin of the Division's ambitions. Meningococcal meningitis, a disease caused by the *Neisseria meningitidis* bacterium, strikes more than 500,000 infants, adolescents and young adults every year and kills 50,000 of them, according to the World Health Organization.

Sometimes meningococcal meningitis can lead to death only hours after the onset of symptoms, despite prompt treatment with antibiotics. A large proportion of people who survive an infection suffer long-lasting disability, including hearing loss, brain damage, renal failure or limb amputations. Outbreaks of meningococcal meningitis constitute a major public-health threat across sub-Saharan Africa but have also occurred in developed countries, ranging from Norway and New Zealand to the Normandy region of northern France.

Among the different serogroups, or distinct classes, of meningococcus that have been identified. Group A meningococcus (MenA) is the most common cause of epidemics in Africa. Group B and Group C predominate in Europe, and serogroups Y and W are becoming increasingly important in the US and the Middle East. MenB is the most lethal form of meningococcus in many countries.

One Novartis vaccine is already in use against a specific strain of MenB found only in New Zealand. Since the start of a nationwide vaccination program in 2004, the incidence of meningococcal meningitis in New Zealand has fallen by more than 80%.

Two other vaccines in development at Novartis – *Menveo* and the recombinant vaccine for MenB – aim to set a new standard for broad protection against serogroups as well as to extend protection across all ages, including infants and young children.

Menveo is a conjugate vaccine providing simultaneous protection against the A, C, W, and Y serogroups of meningococcus. Phase III studies in adolescents, adults and infants are ongoing, and it is expected that a regulatory submission will be made for *Menveo* in adolescents in 2008. Phase II data have shown good protection in this population, and Phase III data are expected to be released during the first half of 2008. A dossier for the use of *Menveo* in infants is planned for submission in 2009.

The recombinant MenB vaccine is a prototype for a new paradigm in vaccine discovery. After several decades of conventional vaccine research failed to deliver a vaccine against Group B meningococcus, Novartis scientists used a radically new approach to identify a set of protein antigens from the bacterium. Known as reverse vaccinology, this method makes use of genomic information on a range of different MenB sub-types, as well as recombinant methods, to identify and produce conserved, surface-accessible protein antigens.

The availability of pathogen genomes that can be mined using reverse vaccinology has increased the number of potential antigens by orders of magnitudes, says Rino Rappuoli, Ph.D., Head of Research for Novartis Vaccines. It allows us to develop novel vaccines by using the rules of the game that we know and have been successful with in the past. Every program where we are using reverse vaccinology is doing extremely well and we've only taken a handful of top candidates so far. The opportunity is huge.

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For the recombinant MenB program, a vaccine composed of three proteins and an outer membrane vesicle component was selected as the lead candidate. In a recent Phase II study, this vaccine has demonstrated that it protects infants from more than 70% of the known MenB strains, an enormous improvement over the best previous vaccines for which coverage was about 20%.

Phase III trials will begin this year; an estimated 5 000 subjects are expected to be enrolled in studies. If our initial data are

confirmed in Phase III trials, we will make the MenB vaccine the highest priority in our development program because of the unmet medical need, Dr. Clemens says.

Influenza

To achieve its ambitious goal of becoming a top-three player in vaccines, Dr. Reinhardt says Novartis Vaccines not only needs to gain global leadership of the meningitis business but also must maintain its leading position in influenza vaccines.

In keeping with this objective, the most significant advances for Novartis Vaccines last year came in the influenza market. The Division shipped 40 million doses of *Fluvirin* influenza vaccine to the US during last year's flu season, including the first shipments to healthcare providers in August. In addition, more than 30 million doses of influenza vaccines were produced for European markets in the 2007-2008 flu season.

Influenza vaccines in development also passed key regulatory milestones last year. Novartis received approval from European Union (EU) regulatory authorities for *Optaflu*, the first influenza vaccine produced using a proprietary cell-culture technology in place of the traditional production based on chicken eggs. Cell-culture manufacturing is the first major innovation in influenza vaccines in more than 50 years. The new technology enables flexible, faster start-up of vaccine manufacturing and a rapid response to potential pandemic influenza threats.

Optaflu, the cell-culture-based vaccine, will be rolled out in Europe this year and a regulatory application for the vaccine is also expected to be submitted to US authorities during 2008. Novartis has broken ground on a new USD 600 million cell-culturebased manufacturing facility in Holly Springs, North Carolina, where initial production is anticipated by 2011.

According to the WHO, seasonal influenza epidemics typically result in up to 500 000 deaths annually. Significant demand for flu vaccine is expected as countries such as Russia and China, where only 5% to 7% of the populations are vaccinated, move closer to US and EU vaccination rates of more than 25%. Demand in more developed markets for superior efficacy products will account for additional growth in the market.

In another major advance for preparations against a possible influenza pandemic, EU regulators approved *Focetria*, a new Novartis vaccine for use following the declaration of an influenza pandemic. *Focetria* contains the proprietary adjuvant *MF59*, which enhances the response of the immune system to the vaccine, improving efficacy and reducing the quantity of antigen needed to achieve protection.

Manufacture of *Focetria* would begin once a pandemic is declared by the WHO using the influenza strain that was actually causing widespread illness. Dr. Clemens notes that, based on experience from the 1918-1919 pandemic, "There will be a rapid spread of the disease within the first two months and if we wait for the true pandemic strain to be available, we'll be too late for many people."

In consequence, Novartis is developing *Aflunov*, a vaccine for H5N1 influenza that could be stockpiled or even used in advance of a pandemic: a so-called pre-pandemic vaccine. *Aflunov* became the first such vaccine submitted to EU regulatory authorities.

Aflunov is based on the currently circulating H5N1 influenza strain, and clinical data have demonstrated that it is protective for this strain as well as offering a degree of protection from other related strains. *Aflunov* also contains the *MF59* adjuvant, strengthening the immune response to the vaccine, and helping to provide a degree of cross-strain protection. Clinical studies in more than 4 000 people have demonstrated that *Aflunov* is as safe as *Fluad*, the adjuvanted seasonal-flu vaccine from Novartis that has been used to vaccinate more than 27 million people to date.

Global public-health advocates recognize avian influenza as a major worldwide health concern and we are ready to produce vaccines that will help protect people before and during an influenza pandemic, Dr. Reinhardt says.

SANDOZ

The world's second-largest generics company with leading positions in key markets, a broad product portfolio and expertise critical for success in providing difficult-to-make generics and biosimilars.

Going beyond traditional generics to offer higher-value, differentiated products that apply advanced technologies such as skin patches, inhalation devices and sustained-delivery dosage forms.

Dynamic performance as net sales expand 20% (+13% in local currencies) to USD 7.2 billion, led by the US and recent product launches as well as growth initiatives in Eastern Europe and emerging markets. 2007 growth represents incremental contribution of USD 1 billion in net sales.

Operating income grows faster than net sales, up 41% to USD 1.0 billion thanks to strong business expansion as well as operational improvements throughout Sandoz following 2005 acquisitions of Hexal and Eon Labs. Operating margin improves to 14.5% of net sales from 12.4% in 2006, but rises to 20.0% on an adjusted basis.

US accounts for 27% of net sales. Growth driven by a broad portfolio, demand for difficult-to-make generics with limited competition, including metoprolol succinate ER (Toprol-XL®) and cefdinir (Omnicef®), and the launch of authorized generics that include amlodipine/benazepril combination (*Lotrel*) and ondansetron (*Zofran*®).

Market-share gains in Eastern Europe reflect benefits of expanding presence in this fast-growing region. Germany sustains leadership under tough conditions. Double-digit growth in Latin America and key emerging markets.

Sandoz the leader in gaining US and European approvals for biosimilars, which are generic versions of previously approved biotechnology drugs. Biosimilars offer savings for patients and payors. European approval of epoetin alfa biosimilar in 2007 comes after landmark *Omnitrope* approval in 2006.

SANDOZ

KEY FIGURES (In USD millions unless indicated otherwise)	2007	2006
Net sales	7 169	5 959
Operating income	1 039	736
Research and development	563	477
Research and development as % of net sales	7.9	8.0
Free cash flow	1 112	876
Net operating assets	14 664	13 464
Additions to property, plant & equipment (1)	627	264
Number of associates (FTE (2)) at year-end	23 087	21 117

(1) Excluding impact of business combinations

(2) Full-time equivalent positions

SANDOZ

Sandoz, the generics Division of Novartis, is leading the industry in difficult-to-make generics based on specialized formulations ranging from transdermal patches and implants to extended-release tablets. This strategy is epitomized by biosimilars, follow-on versions of existing biologic medicines. Sandoz achieved a second regulatory milestone in its drive to bring high-quality, cost-effective biosimilars to patients with the European approval of a copy of epoetin alfa.

On May 7, 2007, the day after patent protection expired on the antibiotic cefdinir, Sandoz began shipping the first generic version to wholesalers and pharmacies across the United States.

Marketed under the brand name Omnicef®, cefdinir was one of the most widely prescribed cephalosporin antibiotics in the US. Once patent protection lapsed, it promised to be a prize addition to the broad antibiotic portfolio of Sandoz, the generics Division of Novartis and one of only a handful of companies worldwide with dedicated production of third-generation cephalosporins.

Yet beating rivals to market required a combination of deft development, legal acumen and a nimble trans-Atlantic supply chain. Only four days before the projected launch, the Sandoz Legal Department won a crucial judgement in a US District Court that could have blocked distribution of generic cefdinir. As soon as the court delivered its ruling, trucks loaded with generic cefdinir pulled out of the Sandoz cephalosporin facility in Kundl, Austria, and raced to a nearby airport where three jumbo jets were waiting to fly the cargo across the Atlantic.

To be successful, our products need to be on the market on Day One following patent expiry of the originator productsays Andreas Rummelt, Ph.D., Head of Sandoz and member of the Executive Committee of Novartis. I was particularly impressed that our cefdinir shipment cleared US customs and was released in only a few hours. That usually takes several days and at times can take more than a week, Dr. Rummelt adds. It was a great performance and shows the kind of commitment from our people I like to see.

As a global leader in the rapidly growing generics industry, Sandoz is a key pillar of the Novartis business portfolio that meets the evolving needs of patients and societies. Sandoz provides high-quality, affordable medicines in markets that encompass 90% of the world's population. And by replacing branded medicines after patent expiry, generics also spur innovation by freeing up funds payors redeploy to purchase innovative medicines.

During 2007 Sandoz net sales climbed 13% (in local currencies). Operating profit rose 41% and profit margins widened by two percentage points. The dynamic performance was driven by recent launches of difficult-to-make generics that more than offset continued pricing pressure in many markets. The US was the biggest growth driver last year but the Division's net sales also rose strongly due to initiatives in emerging growth markets and Eastern Europe.

Dynamic Launches

Sandoz is leading the way in difficult-to-make generics, products that are based on challenging active pharmaceutical ingredients or require specialized formulations and technologies, ranging from implants and extended-release tablets to transdermal patches and inhalation devices.

Along with cefdinir, key launches in the US included additional dosages of metoprolol succinate, a drug used to treat high blood pressure and heart failure. Sandoz is the first generics company to launch metoprolol succinate in a state-of-the art sustained-release formulation using a multiple-unit pellet system (MUPS).

The Sandoz version of ipratropium albuterol, a medicine used to treat respiratory disorders, earned a coveted period of market exclusivity following the US launch last year. It was an important strategic mile-stone for Sandoz because treatments for respiratory diseases represent a major growth initiative.

In Europe, Sandoz launched leuprorelin, a treatment for prostate cancer, in an implant formulation injected into the abdominal skin of patients. The implant offers patients and physicians cost savings and greater convenience compared to the originator product.

There isn't a single element that leads to hard-to-make products. It's usually a combination of things, says Bernhard Hampl, Ph.D., Head of Sandoz operations in the US. It's about getting the right products to market on time. Opportunities like these are what drive our business.

Crowning the difficult-to-make strategy are biosimilars, follow-on versions of existing medicines derived from living organisms that have been genetically modified to produce a desired protein. Last year, Sandoz became the first company to receive European Commission approval for a biosimilar epoetin alfa (EPO), another milestone in the company's efforts to bring high-quality, cost-effective biological medicines to patients. The Sandoz version of epoetin alfa was launched in Germany and the Netherlands during 2007 and will be rolled out in additional EU markets this year.

In a precedent-setting decision in April 2006, Sandoz became the first company to obtain European approval for a biosimilar medicine, the human growth hormone *Omnitrope*. Approval of *Omnitrope* in the US followed a month later. As more biopharmaceuticals lose patent protection in coming years, biosimilar products are expected to play a key role in the growth strategy of Sandoz.

Markets are so crowded today that generic versions of most blockbuster drugs become low-margin commodities, Dr. Rummelt says. Sandoz needs to make the products which not everyone else can make, where our resources and specialist technologies and capabilities set us apart from the competition.

Deep Pipeline

During 2007, Sandoz submitted regulatory applications for 92 different projects to authorities around the world. At the same time, the Development team has submitted supplementary regulatory applications in new markets for many existing products, part of a growth initiative prompted by the acquisition of Hexal and Eon Labs, says Gerhard Schaefer, Ph.D., Head of Global Product Development at Sandoz. We want to increase our business outside traditional core markets of Europe and the US by covering more and more countries with a potential for generics where we are not yet active, Dr. Schaefer adds.

The Sandoz development pipeline encompasses more than 750 projects, including a significant proportion of difficult-to-make products. Each new project completed by Sandoz Development represents a specific formulation, often available in multiple doses.

Development of difficult-to-make projects can take as long as seven years. Registration normally takes two years in the US but three years in Europe. Classical bioequivalence studies last about six months but some difficult-to-make products and biosimilars require Phase III clinical studies that last up to two years. Additional years are needed to develop the active pharmaceutical ingredient and specific formulations.

Project selection is a crucial competitive step. We look very early at potential future blockbusters, sometimes while pivotal clinical studies are ongoing, always aware of the risk that the originator may fail, Dr. Schaefer says. Even at this early stage, we focus on additional developments based on in-house technologies in order to create intellectual property that could make life more difficult for our main generic competitors.

A difficult-to-make product often starts with a complex active pharmaceutical ingredient. Traditionally, generic companies have sourced active pharmaceutical ingredients from third parties but in-house development offers an increasingly important competitive advantage for leading generic companies today.

Often we can create our own intellectual property by using more modern technologies in chemistry than ones available when the originator developed the molecules many years earlier. And the new technologies enable us to improve quality by reducing impurities, for example, Dr. Schaefer adds. Development projects involving more than 70 active pharmaceutical ingredients are currently underway at Sandoz.

Patch Prototype

The prototype difficult-to-make product for Sandoz was a generic version of fentanyl patch, an opioid analgesic marketed under the brand name Duragesic® and used for decades in the management of pain. By the time the basic patent expired in Germany two years ago, fentanyl had become the country's biggest-selling prescription medicine.

That commercial potential made fentanyl a major opportunity for generic manufacturers but the route of administration by transdermal patch posed a formidable hurdle. In addition, as expiry of the basic patent was approaching, the originator company introduced a new-generation matrix-patch formulation of fentanyl and managed to convert a large proportion of physicians and patients to the newer product.

Sandoz began its own patch project in the year 2000 and reached outside the pharmaceutical industry for novel technology. The inspiration was audio tape produced by German chemical giant BASF AG. We looked at both the material itself and the technology used to bring together different layers that comprise an audio tape, then adapted the technology and equipment to development of pharmaceutical patches, Dr. Schaefer says. It's a perfect example of what we mean by development: looking at technologies used in other fields and combining or adapting these ideas to new applications.

Sandoz conducted parallel development programs for both the reservoir-style patch originally used for fentanyl and the new matrix patch. Because we developed our own technology, both of our products avoided infringement of additional patents filed and granted to Johnson & Johnson, Dr. Schaefer says.

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The launches of the Sandoz fentanyl patches during 2005 were huge successes and it's just the beginning. There are clear advantages for patches, mainly in the form of better patient compliance, Dr. Schaefer says. Drugs delivered with patches sometimes help patients avoid side effects such as nausea and vomiting associated with tablet versions of the same medicine. And for patients unable to swallow or elderly patients who often are prescribed multiple

medications for chronic diseases or caregivers who supervise treatment a single patch applied weekly offers greater convenience than tablets that must be taken several times a day.

Sandoz has a broad-based program for additional patch products focusing on indications where patches aren't yet available, Dr. Schaefer says.

The Sandoz version of metoprolol succinate, launched in Germany in 2005, is the first MUPS product introduced to date by a generics manufacturer. The medicine was introduced in the US a year later and earned Sandoz a period of market exclusivity as the first to file for the lowest dosage strengths. Additional dosages of metoprolol succinate were introduced in the US during 2007. Along with a constant release profile, the MUPS formulation allows patients to disperse the tablet in a glass of water and still maintain the extended release dosage.

In Europe the Sandoz product is still the only MUPS version of metoprolol on the market and we have the full range of strengths in most countries, including Germany, Dr. Schaefer says. We will use this platform technology for other products, including cardiovascular treatments and other classes of medicines as well, he adds.

Implants are another platform technology being rolled out at Sandoz. Last year's launch of leuprorelin, a medicine used to treat advanced prostate cancer, culminated a six-year development program and represents the first implant formulation of an anticancer therapy from Sandoz.

Clinical studies demonstrated that the Sandoz implant version of leuprorelin has the same mode of action and achieves the same clinical results as the originator product. By contrast to micro-capsule or powder formulations that must be specially prepared by a physician before injection, the Sandoz leuprorelin comes ready to use. It also requires less of the active pharmaceutical ingredient, giving Sandoz a significant cost advantage over rivals.

Meanwhile, the launch of ipratropium albuterol in the US is the clearest sign yet of a strategic focus on medicines to treat respiratory disorders. Along with external collaborations, the expansion in the respiratory field will tap in-house technologies. We have a dedicated development center for respiratory products and a dedicated plant for production, Dr. Schaefer says.

Pioneering Biosimilars

Pioneering approvals of *Omnitrope* by the US and EU in 2006 as the first follow-on recombinant biotechnology medicine culminated a seven-year process that led through courts on both sides of the Atlantic. The case underscored the commitment of Sandoz to biosimilars, the epitome of difficult-to-produce products.

Sandoz brings unique acumen to the field with more than 25 years of experience in production of biologic medicines. The Kundl, Austria, site is one of the world's biggest development and manufacturing centers for microbially expressed recombinant proteins.

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During 2007, Sandoz built on the initial approvals by rolling out *Omnitrope* in additional countries. Along with geographic expansion, Sandoz introduced more sophisticated formulations of *Omnitrope*, including a new liquid formulation administered with a pen device. Pen devices have been popular delivery options for injectable biotechnology medicines for years, offering accurate dosing as well as convenience that allows use even away from home.

Acceptance of *Omnitrope* by physicians improved steadily during 2007, reflecting growing familiarity with the product. Doctors are switching more and more patients to *Omnitrope*, especially newly diagnosed patients, Dr. Schaefer says.

The European Union approved epoetin alfa (EPO) in August for treatment of patients with renal anemia, as well as those receiving chemotherapy. Sandoz launched the development project in the year 2000 in collaboration with Rentschler Biotechnologie GmbH, a German biotech firm.

In some respects, EPO was a more complex protein to develop than *Omnitrope* because it is produced in mammalian cells and undergoes glycosylation, the addition of certain sugar molecules that cause the protein to fold in a certain way. The regulatory process was also stringent for EPO: three Phase III clinical trials required for approval involved 593 patients and took two years to complete.

This is the beginning of a constant flow of follow-on products coming out of our biotechnology development, Dr. Schaefer adds. Sandoz scientists already are assessing second-generation, long-acting biotechnology products as possible projects. Another major focus will be follow-on versions of monoclonal antibodies that will begin losing basic patent protection in about five years. This is the future and as one of the major players in the field we clearly are looking into these opportunities, Dr. Schaefer says.

CONSUMER HEALTH

Focus on OTC (Over-The-Counter), Animal Health and CIBA Vision. The final divestments of nutrition businesses completed in 2007 with Medical Nutrition and Gerber sold for after-tax divestment gain of USD 5.2 billion.

Net sales from continuing operations rise 11% (+6% in local currencies) to USD 5.4 billion as OTC and Animal Health deliver double-digit expansion and grow faster than their respective markets. CIBA Vision advances on improved supplies of contact lens and lens-care products.

Thanks to solid performance, operating income improves and supports significant investments in R&D and marketing for product launches and geographic expansion, particularly Japan and emerging markets.

OTC expands thanks to continued focus on strategic brands including *Voltaren*, *Theraflu*, *Benefiber* and *Excedrin* and expansion in emerging markets, including Eastern Europe and Russia. Rapid growth in Japan following entry in 2007 into the world's second-largest OTC market. Maintains position as world's fourth-largest OTC company.

Animal Health, ranked No. 5 in its industry, benefits from solid performances in Europe, Asia-Pacific and Latin America. Sankyo Lifetech acquisition in Japan strengthens presence in companion-animal segment.

CIBA Vision successfully addresses production challenges for lens-care and contact lens products.

CONSUMER HEALTH CONTINUING OPERATIONS

KEY FIGURES (In USD millions unless indicated otherwise)	2007	2006
Net sales	5 426	4 902
Operating income excluding restructuring charge (1)	909	761
Operating income	812	761
Research and development	301	260
Research and development as % of net sales	5.5	5.3
Free cash flow	772	553
Net operating assets (2)	3 154	3 133
Additions to property, plant & equipment (3)	209	197
Number of associates (FTE (4)) at year-end	13 956	13 111

(1) Excluding USD 97 million of Forward initiative restructuring charge

(2) Excluding Consumer Health discontinued operations

(3) Excluding impact of business combinations

(4) Full-time equivalent positions

MARKET INFORMATION FOR CONSUMER HEALTH BUSINESSES

	OTC	Animal Health	CIBA Vision
Market Growth (1)	4.0%	4.5%	4.0%
Sales Growth (2)	6.4%	7.7%	3.1%
Market share (1)	3.7%	6.4%	21.8%
Rank	No. 4	No. 5	No. 2

(1) Source: Nicholas Hall, Internal Market Research

(2) 2007 Local currency growth vs. prior year

CONSUMER HEALTH

Veterinary reformulations of Novartis medicines discovered and developed for human patients enable the Consumer Health Division to generate additional value from research breakthroughs elsewhere in the Group. Such synergies fuel dynamic growth and make Consumer Health a key pillar in the Novartis strategy of focused diversification in healthcare.

Percorten was a pioneering treatment from Novartis for Addison's disease, an uncommon but potentially fatal disorder in which adrenal glands do not function properly and the body is unable to produce normal amounts of certain hormones.

Dogs suffer from a canine version of Addison's disease and the Animal Health Business Unit developed *Percorten-V*, a veterinary reformulation of the original medicine that enables thousands of pets to live long, active lives today.

Percorten-V is only one example of the broad portfolio of veterinary versions of Novartis medicines originally discovered and developed for human patients. Just as over-the-counter (OTC) adaptations of prescription-only originator medicines open new markets, human-to-veterinary switches enable the Novartis Consumer Health Division to generate development opportunities from breakthroughs made elsewhere in the Group.

The Consumer Health Division is a key pillar of the Novartis strategy of focused diversification in healthcare to address the evolving needs of patients and societies worldwide. The benefits of that strategy are becoming increasingly clear as new challenges slow growth of the flagship Pharmaceuticals Division.

Our strategy balances risks to some degree and takes advantage of fundamental trends in customer needs, says Daniel Vasella, M.D., Chairman and Chief Executive Officer of Novartis. Consumer Health, which traditionally had lower growth rates than pharmaceuticals, is now growing faster and has the potential to further expand dynamically.

And while pricing pressure on innovative pharmaceuticals continues to intensify in almost all markets around the world, Dr. Vasella adds, pressures are much less severe in the consumer brands. In fact, one has the opportunity to certainly compensate for inflation, sometimes even slightly more, he says.

In 2007, net sales at the Consumer Health Division climbed 6% (in local currencies) as both the OTC and Animal Health Business Units posted double-digit gains through a focus on strategic brands, new product launches and expansion in emerging markets and Japan. Net sales at CIBA Vision rose as deliveries of its contact-lens portfolio rebounded.

On the back of this solid performance, significant investments were made in research and development as well as marketing throughout the Division. For example, Animal Health stepped its up collaborations across the Group, from the Novartis Institutes for BioMedical Research (NIBR) and the new Vaccines and Diagnostics Division to Sandoz, the generics Division of Novartis.

The partnership with NIBR enables the Animal Health Business Unit to identify early-stage active compounds with potential for veterinary indications and has resulted in several new projects being added to the Animal Health development pipeline.

Animal Health and Novartis Vaccines are also joining forces to seek vaccine solutions for viral and bacterial targets. While vaccines traditionally have been a relatively small part of the total human pharmaceutical market, they represent a significantly greater proportion of global sales in animal health. Moreover, sales growth of veterinary vaccines continues to outpace other sectors of the animal health industry.

We seem to be able to move some of the new technologies into our industry more quickly than it is possible to adapt them to human health, says George Gunn, Head of Novartis Animal Health.

The Aqua Health business, which focuses on developing and marketing vaccines used in salmon farming, launched the first effective vaccine to prevent infectious haematopoietic necrosis (IHN), a viral disease spread by wild salmon among farm-raised Atlantic salmon, the mainstay of Canada's burgeoning aquaculture industry. Outbreaks of IHN have caused mortality rates of up to 80% and severe economic losses for fish farmers in British Columbia.

The *Apex-IHN* vaccine developed by Novartis uses plasmids, tiny spheres found naturally in bacteria, to stimulate production of pure viral protein, which in turn triggers an effective immune response in fish.

Yet another example of cutting-edge science emerging from labs at the Animal Health unit is discovery of amino acetonitrile derivatives as the first potential new class of livestock parasiticides in 25 years. Resistance to existing classes of parasiticides is a growing international problem that potentially threatens the viability of livestock farming.

Building Brands

While scientific innovation remains the foundation for success, the convergence of major industry trends today represents an inflection point in consumer health, says Thomas Ebeling, Head of the Consumer Health Division and member of the Executive Committee of Novartis. And this convergence creates massive opportunity for Novartis Consumer Health.

One key trend is privatization of healthcare as the public sector pushes more and more of the cost of care onto individuals. There is a shift away from visiting physicians for treatment of minor ailments like earache, for example. Nurse practitioners and pharmacists are taking a more active role in treating these minor ailments, Mr. Ebeling says.

Second, consumers today are becoming more aware and seek to take greater control of their health. It's clear that in the future there is going to be more self-choice about how people are medicated for non-acute conditions, Mr. Ebeling adds.

Finally, consolidation among retailers is spawning regional and global giants that want to capture a greater share of healthcare dollars. The trend is clearest in the US, where companies such as Wal-Mart Stores Inc., Walgreen Co. and CVS Caremark Corp. are looking for new growth vehicles and see opportunities in healthcare.

Amid these trends, building and owning brands are increasingly important. Optimal sales-force execution is also critical to success. Along with global retailers, Novartis Consumer Health targets small business, from eye-care practitioners and veterinarians to small pharmacies. And even as globalization advances, Novartis also needs to help these smaller customers grow their businesses.

Two success stories from 2007 exemplify the brand-building capability of Novartis. *Lamisil Once*, a novel OTC product

that cures athlete's foot with a single application, is adding incremental value to the prescription-only formulation of *Lamisil*, a blockbuster medicine for treatment of toe-nail fungus. The typical consumer of athlete's-foot medication is an active male, around the age of 35, who wants immediate relief and doesn't want to apply medication two times a day, several days a week. *Lamisil Once* offers a novel administration, combining the active ingredient with a thin polymer that attaches to the skin and holds the active ingredient against the infected area without washing off.

We found a high degree of tryer/rejectors in the athlete's-foot category, Mr. Ebeling says. The efficacy of *Lamisil Once* is attracting back users who had dropped out of the category, driving a high rate of repeat purchases and providing incremental sales.

The success of *Voltaren* shows how compelling advertising can rejuvenate an established brand. Net sales of non-prescription *Voltaren* surged 16.2% last year, eclipsing low single-digit growth for the topical analgesic segment worldwide. The consumer insight driving *Voltaren* is that many people personalize pain because it prevents them from doing simple things they enjoy, for example, a grandmother picking up and playing with a two-year-old grandchild. An advertising campaign called *The Joy of Movement* portrays people enjoying those small but important activities, without pain, after using *Voltaren*.

Salesforce Execution

In recent years, Novartis Consumer Health has established key account teams to cater to large, sophisticated and demanding retailers such as Wal-Mart, Walgreens and CVS Caremark. By pooling efforts of Consumer Health business units and drawing on cross-functional capabilities, key-account teams generate synergies and additional sales. Aggressive expansion by customers is creating opportunities for continued growth for Consumer Health and potentially other Novartis divisions as well.

For example, Wal-Mart challenged pharmacy rival Walgreens by announcing plans to open as many as 400 in-store health clinics in the next two to three years, with prospects of reaching 2,000 clinics by 2012. The health clinics, which lease space in Wal-Mart stores, will be managed by local or regional hospitals or other organizations independent of Wal-Mart. The giant retailer has expanded rapidly from a pilot program launched in 2005, and more than 75 clinics are currently operating in 12 states across the US. The clinics are staffed by certified nurse practitioners or physicians, and offer preventive and routine care for ailments such as allergies and sinus conditions.

Walgreens, the largest drugstore chain in the US, responded by moving beyond its traditional pharmacy business to acquire Take Care Health Systems, a leading operator of convenient-care clinics. With the acquisition, Walgreens expects to have more than 400 convenient-care clinics in its stores nationwide by the end of 2008.

Take Care Health's clinics also are staffed by certified nurse practitioners who treat patients 18 months and older for common illnesses, including ear and sinus infections and strep throat. They also provide vaccinations and physical examinations.

Hoping to leverage existing relationships, the Consumer Health Division is developing product offerings tailored to the needs of new in-store clinics.

Meanwhile, expansion combined with an increasing focus on productivity of the sales force at the Animal Health Business Unit has accelerated sales growth to 12% between 2004 and 2007, from only 4% during the preceding four-year period, 1999 to 2003.

The additional muscle in key markets throughout the world has enabled Novartis Animal Health to deepen its business relationships with existing veterinary customers, while improving coverage of new customer groups.

One successful example is *CLiK*, a preventive treatment for Blowfly Strike. Novartis almost doubled its UK market share last year as the percentage of British sheep farms using *CLiK* surged to 43% from 26% a year earlier. The main attraction for new customers is the longer protection offered by *CLiK* compared to rival products.

The expanded sales force also propelled growth of more than 20% last year for *Atopica*, the only non-steroidal treatment available for atopic dermatitis in dogs. *Atopica* provides increased comfort for pets with reduced risk of complications associated with long-term use of steroids in dogs.

CORPORATE CITIZENSHIP

Introduction

Corporate Citizenship at Novartis rests on four pillars: Commitments to Patients, to People and Communities, to the Environment, and to Ethical Business Conduct

Treatments worth USD 937 million are contributed through access-to-medicine programs in 2007, reaching 66 million patients in need

During 2007, Novartis and partners complete clinical trials of a new pediatric formulation for the antimalarial medicine *Coartem*, enhancing convenience of use and palatability for young children who are especially vulnerable to this disease

Novartis issues guidelines on interactions with patient advocacy groups and makes public a list of patient groups given support in the United States and Europe, underscoring commitment to transparency

Diversity & Inclusion Advisory Council plays an active role in building diverse and talented teams, reinforcing the importance of an inclusive environment

External carbon-offset projects, launched in support of voluntary commitment to reduce greenhouse-gas emissions to Kyoto protocol levels, will be submitted for registration under the UN Clean Development Mechanism

Novartis again achieves top-level positions in influential rankings:

- A sustainability leader in 2007 Dow Jones Sustainability Index, which tracks the global economic, environmental and social performance of companies
- Fifth consecutive year in Science magazine list as one of the top ten employers in biotechnology, biopharmaceuticals and pharmaceuticals
- Again one of the world's 25 most respected companies in annual Barron's survey

- The top-ranked major pharmaceutical company in a survey of the World's Most Ethical Companies by Ethisphere magazine

KEY PERFORMANCE INDICATORS

Indicator (1)	2007	2006	2005	2004	2003
Economic (2)					
Net sales in USD billions	38.1	34.4	29.4	25.7	22.7
Net income in USD billions (% of net sales)	6.5 (17)	6.8 (20)	5.8 (20)	5.4 (21)	4.7 (21)
Research and Development in USD billions (% of net sales)	6.4 (17)	5.3 (15)	4.8 (16)	4 (16)	3.6 (16)
Purchased goods and services (2), (3) in USD billions (% of net sales)	19.4 (51)	15.8 (46)	13.3 (45)	11.2 (44)	9.7 (43)
Personnel costs in USD billions (% of net sales)	9.9 (26)	8.7 (25)	7.5 (25)	6.5 (25)	5.9 (26)
Taxes in USD billions (% of income before taxes)	0.9 (13)	1.2 (15)	1.0 (14)	1.0 (16)	0.9 (16)
Dividends in USD billions (% of net income)	3.2 (49)	2.6 (38)	2.0 (35)	2.1 (39)	1.9 (40)
Cash returns to shareholders in USD billions (% of Group total net income)	4.7 (39)	0 (0)	0.5 (8)	1.7 (32)	0.9 (20)
Share price at year-end (CHF)	62.10	70.25	69.05	57.30	56.15
Patients					
Access to medicine (4): value in USD millions	937	755	696	570	371
Access to medicine (4): number of patients reached	65.7	33.6	6.5	4.25	2.76
People and Communities					
Number of full-time equivalent positions	98 200	100 735	90 924	81 392	78 541
Resignations, separations, hiring (% of associates)	9, 4, 17	8, 4, 19	8, 4, 16	7, 3, 15	
Women in management (5) (% of management)	35	31	28		
Lost-time accident rate [accidents per 200 000 hours worked] (2)	0.41	0.45	0.51	0.47	0.73
Environment (2), (6)					
Water use [million m3]	82.8	84.5	87.0	81.3	87.4
Energy [million GJ]	16.4	16.4	15.3	13.8	13.5
Emission CO ₂ /GHG, Scope 1: Combustion and processes [1000 t]	388	401	383	372	362
Emission into Air: halogenated and nonhalogenated VOCs [t]	2 080	1 744	1 905	1 316	1 675
Total Operational Waste [1000 t]	229	206	165	144	131
Ethical Business Conduct					
Number of associates trained on Code of Conduct (7) (e-learning courses)	16 697	14 574	33 000		
Managers completing certification on Code of Conduct	27 000	23 000	20 000		
Cases of misconduct reported	906	651	442(8)	410(9)	
Cases of misconduct substantiated	290	228	142(8)	204(9)	
Dismissals/resignations (related to misconduct)	168	130	78(8)	107(9)	
Number of suppliers	228 558				
Number of suppliers informed of Novartis Third Party Guidelines (Annual sales of more than USD 10 000)	61 715	42 200	39 000	30 000	
Number of suppliers to confirm key standards (10) (self-declaration)	1 377	8 600	5 500	4 600	

(1) Data reported in the Ethical Business Conduct (except Number of suppliers items) and Health, Safety and Environment sections (except Lost-time accident rate) include the entire Group; Data reported in Number of suppliers items excludes the Vaccines and Diagnostics Division

All items relate to continuing operations excluding Consumer Health Division divestments unless stated otherwise

(2) As included in the Group's Value Added Statement

- (3) See table on page 76 (Access-to-medicine table)
- (4) Management defined locally
- (5) Details see: www.novartis.com/hse
- (6) 2007 figure includes new associates and other associates not previously trained
- (7) From April to December 2005
- (8) From October 2003 to September 2004
- (9) In 2007 Novartis modified financial requirements for self-declarations by suppliers, focusing on suppliers with the highest business volumes and resulting in a significant decline in the number confirming key standards
- (10)

CORPORATE CITIZENSHIP

Corporate Citizenship at Novartis begins with the success of our core business. During 2007, medicines and vaccines from Novartis were used to treat and protect more than 800 million people worldwide. Innovation is the key to our ability to change lives and we strive to maintain ethical corporate standards and do business in a manner that is responsible and sustainable.

Corporate Citizenship at Novartis begins with the success of our core business. The more successful we are in discovering, developing, manufacturing and marketing new medicines, the greater the benefits we can offer to patients, healthcare professionals, associates, shareholders and other key stakeholders.

Novartis provides a uniquely broad range of healthcare solutions that address the evolving needs of patients and societies worldwide. Our business portfolio includes innovative prescription medicines with improved efficacy and fewer side effects. Our vaccines and diagnostic tools offer protection against life-threatening diseases, including some newly emerging diseases that have triggered major international concern. Generic products that replace branded medicines after patent expiry free up funds for innovative medicines. And consumer health products, including OTC or self-medication brands, are readily available and enable healthy lifestyle choices.

During 2007, medicines and vaccines from Novartis were used to treat and protect more than 800 million people around the world, according to internal estimates. If all the patients reached by Novartis last year stood shoulder to shoulder, the line would circle the earth 10 times.

Medicine has made huge advances in recent decades due in large part to pharmaceuticals. Innovation is the key to this remarkable progress and scientists from Novartis have contributed breakthroughs that address unmet medical need and transform the lives of patients. These medicines include *Gleevec/Glivec*, the pioneering treatment for certain forms of cancer, and *Diovan*, the world's top-selling branded treatment for high blood pressure. To sustain that stellar record of innovation, Novartis invested USD 6.4 billion in research and development during 2007.

Adhering to Values

At the same time, Novartis believes that companies contribute to the positive development of societies by doing business in a responsible way and supporting ethical values and principles. We strive to operate in a manner that is economically, socially and environmentally sustainable, and responsible toward stakeholders. We actively take on societal challenges in areas in which we are competent, helping where most needed while also establishing and implementing transparent ethical corporate standards and policies.

Novartis was one of the first pharmaceutical companies to sign the United Nations Global Compact. It is an initiative in which signatories embrace, support and implement, in their sphere of influence,

principles for responsible corporate conduct within the areas of human rights, labor standards, environmental care and efforts to combat corruption.

Novartis associates are expected to uphold the ideals and values defined in our Code of Conduct. If we don't have a set of values and live by them the Group won't be successful, says Daniel Vasella, M.D., Chairman and Chief Executive Officer of Novartis.

Our efforts have been recognized by external observers. Novartis was selected as one of the sustainability leaders in the 2007 Dow Jones Sustainability Index, (DJSI), a global index tracking economic, environmental and social performance of companies. We are pleased to see that the DJSI recognizes our responsible business approach and the increasing engagement of Novartis in the area of sustainability, says Thomas Wellauer, Ph.D., Head of Corporate Affairs and member of the Executive Committee of Novartis.

Framework of Corporate Citizenship

Corporate Citizenship at Novartis is based on four pillars: Commitment to Patients, Commitment to People and Communities, Commitment to the Environment, and Commitment to Ethical Business Conduct.

Novartis associates strive to create value beyond business success in the world at large. When we operate in a way that is respectful of human rights, socially equitable and environmentally sustainable, we can better meet our economic responsibilities. Business success and social responsibility are mutually inclusive indeed, they depend on each other.

The hierarchy of corporate responsibilities at Novartis begins with essential, non-negotiable corporate duties: compliance with national laws and regulations, avoidance of deception or fraud, and protection of the environment and the health and safety of employees, customers and neighbors.

Enlightened companies have long recognized that acting in a responsible way means taking into account legitimacy as well as legality and sometimes doing more than the law requires. Legitimate corporate conduct is doing the right thing: for example, maintaining consistent global standards, regardless of legislation or regulation at the local level.

Finally, our hierarchy of corporate responsibilities includes philanthropy: pro bono research, community and neighborhood programs, volunteerism and donations.

We recognize that access to our medicines clearly favors people who live in affluent, developed societies. Millions of poor people are being left behind and diseases that are curable with modern medicines are still destroying lives. We want to be leaders and partners in finding and implementing solutions to help close the access gap.

To enhance access to treatment, Novartis has created innovative programs targeting diseases such as leprosy, malaria and tuberculosis, working with partners ranging from the World Health Organization to procurement agencies and nongovernmental organizations. In 2007, our access-to-medicine programs reached 65.7 million patients in need through contributions valued at USD 937 million.

Defending Innovation

Novartis faces an increasingly complex map of external stakeholders today and expectations of those stakeholders can be contradictory. In making decisions about how we are going to navigate, I think it is extremely important to follow the direction shown by our own inner compass, Dr. Vasella says. In adhering to our values we should recognize that sometimes we have to make unpopular decisions.

One example during 2007 was a legal dispute in India about patent protection for *Gleevec/Glivec*, our pioneering anticancer medicine. In 2006 an Indian patent court rejected an application from Novartis seeking a patent for *Glivec*, which already had been granted patent protection by almost 40 countries. Novartis appealed the patent court's ruling and separately challenged the constitutionality of a controversial section of the 2005 Indian Patents Act.

In August of last year an Indian High Court dismissed the petition from Novartis, challenging the constitutionality of the country's new patent law, and deferred to the World Trade Organization (WTO) to resolve a question about compliance under the international Trade-Related Aspects of Intellectual Property Rights agreement. In a related proceeding, the Intellectual Property Appellate Board in India is now reviewing the *Glivec* patent appeal.

Protection of intellectual-property rights is essential to encourage research and development. Only with effective patent laws can Novartis continue to bring therapeutic improvements to patients that ultimately result in better care.

The journey of *Glivec* through India's patent process, however, underscores the potential uncertainties of a country in transition. In India, Novartis faces a globalization dilemma that characterizes many emerging economic powers: two markets in a single country. Novartis recognizes that poor patients in India face many obstacles to access to medical care. Through the *Glivec* International Patient Assistance Program (*GIPAP*), Novartis provides *Glivec* free to more than 99% of patients prescribed the life-saving medicine in India, because they would not otherwise be able to afford treatment. To date, more than 8 000 Indian patients diagnosed with chronic myeloid leukemia or gastrointestinal stromal tumors have participated in the *GIPAP* program.

At the same time, Novartis seeks business opportunities with affluent urban consumers and the burgeoning middle class in India's dynamic economy. International trade agreements offer both rights and responsibilities to member countries. Ensuring

effective protection for intellectual property is among these responsibilities.

Incremental Innovation

In challenging a provision of India's new patent law, the primary objective for Novartis was to ensure protection for incremental innovation. Medical progress occurs through incremental innovation—innovation by steps—providing important value for patients in the form of enhanced efficacy or improved side-effect profiles.

One example is *Sandostatin LAR*, a Novartis medicine used to treat debilitating gastrointestinal tumors. Development of a long-acting formulation reduced the number of injections from more than a thousand per year to only 12, a huge benefit for patients. Development of *Exelon Patch*, the first and only transdermal treatment for Alzheimer's disease, has been shown to increase compliance, reduce side effects and allow medication to be delivered through the skin continuously for 24 hours, helping to achieve optimal dosing.

These types of advances are currently not acknowledged by India's patent law even though they meet WTO patentability standards and deliver significant value for patients. Novartis is concerned that hurdles to recognition of genuine innovation in the Indian patent law will hinder development of future medicines. We took on this case because we firmly believe it was the right thing to do for patients.

International nongovernmental organizations (NGOs), including Médecins sans Frontières and Oxfam, drew attention to the case by claiming that, if Novartis prevailed, India would no longer be able to supply much of the developing world with inexpensive medicines, including treatments for HIV/AIDS.

The basis of those arguments is false and misleading. Safeguards established under international-trade accords allow governments in developing countries to make exceptions to patent rights and to import pharmaceuticals produced under compulsory license in cases of a national emergency. Access to HIV/AIDS medications is not, and has never been, threatened by our case. Independent of the legal outcome, currently available generic drugs launched before 2005—including HIV/AIDS medicines and generic versions of *Glivec*—will continue to be available under a so-called grandfather clause in the Indian patent law.

We commend the progress India has made in recent years to advance intellectual-property rights. But more needs to be done to align this increasingly important industrial country with minimum international standards.

We are confident that dialogue about shortcomings in India's patent law will continue and ultimately lead to establishment of effective protection for incremental innovation. Novartis will continue to participate in this essential debate both in India and as it expands globally.

Despite the strident comments of some NGOs, I am convinced our efforts to gain clarity on India's commitment to meet minimum international intellectual-property standards will benefit India and its people, Dr. Vasella says. For a research-based company like Novartis, patents are non-negotiable.

CORPORATE CITIZENSHIP: TARGETS AND RESULTS FOR 2007 AND TARGETS FOR 2008

UN Global Compact

Targets 2007

Publish a case study about implementation of living wage-initiative at Novartis plus separate third-party supplier case study delayed in 2006. Continue active engagement in country networks. Start conceptual work on project about accountability of nongovernmental organizations (NGO).

Results 2007

Two case studies were published in 2007: Implementing the Living Wage Globally and Chain Reaction, the third-party supplier case. Both were communicated internally and externally. Novartis continued to participate in various Global Compact events, including those related to the still-emerging Swiss network. Two articles about the role of NGOs for the Global Compact's mission were published in academic journals.

Targets 2008

Publish a case study about Corporate Citizenship at Novartis. Continue to look for opportunities to support the United Nations Global Compact in shaping projects and opportunities for maximum impact.

Respect for Human Rights

Targets 2007

Evaluate pilot Human Rights Compliance Assessment and carry out compliance assessment in one new country. Participate in debate about corporate content of the Right to Health. Work closely with UN Representative on Business and Human Rights, as well as Special Rapporteur on the Right to Health.

Results 2007

Fulfilling the objective, the Human Rights Compliance Assessment was piloted in Taiwan in cooperation with the Danish Institute for Human Rights. Novartis Foundation for Sustainable Development co-hosted two conferences on business and human rights, one leading to the book Human Security & Business and the other providing state-of-the-art input to the work of the UN Representative on Business and Human Rights. Professor Klaus M. Leisinger was appointed a member of the Business and Human Rights Working Group of the Global Compact Board.

Targets 2008

Pilot a Human Rights Compliance Assessment in an additional country and develop a pharma-specific version of the assessment. Support the Business Leadership Initiative on Human Rights (BLIHR) in development of an online tool to help companies assess and address challenges related to human rights. Contribute to the new round of discussions about business and the right to health.

Transparent Reporting

Targets 2007

Achieve further progress in UN Global Compact reporting. Define structure and content of online Corporate Citizenship reporting. Publish Corporate Citizenship brochure.

Results 2007

The Global Compact Office recognized the Communication on Progress (CoP) for 2006 as a Notable CoP. A print version of Corporate Citizenship review was released in January 2007 and the online report, Citizenship@Novartis, launched in April 2007

Targets 2008

Release 2007 Communication on Progress. Continuously update Citizenship@Novartis.

Government Relations/Lobbying

Targets 2007

Establish integrated policy development across divisions. Improve professional, public-affairs skills through internal training.

Results 2007

Published Novartis perspective about key topics on Novartis.com to increase transparency. Integrated new Vaccines and Diagnostics Division into position development and yearly planning process. Conducted public-affairs training in all major regions. In 2007, Novartis spent USD 23 million in support of major international, American and European trade associations.

Targets 2008

Publish additional position papers about healthcare topics to maintain transparency with topics of interest to external stakeholders.

Financial Community

Targets 2007

Results 2007

Targets 2008

Edgar Filing: NOVARTIS AG - Form 6-K

Update online reporting using Global Reporting Initiative (GRI) format.

The online GRI report for 2006 was completed and received the in accordance check from the GRI.

Transition to the G3 Guidelines for the 2007 GRI report.

COMMITMENT TO PATIENTS

Access to our medicines clearly favors people who live in affluent, developed societies. To help close that access gap, Novartis has developed programs to enhance access and affordability of treatments for diseases that are curable with modern medicines, but still continue to destroy lives. Responsibility must be shared, however, and each sphere of society has a role to play.

Novartis endorses the right to health. Our most important contribution to patients is providing medicines to treat and prevent disease, ease suffering and improve quality of life.

Discovery and development of new medicines at Novartis benefit from an ongoing dialogue with patient groups. Many of us engage with patients or patient advocacy groups, says Professor Mark Fishman, M.D., President of the Novartis Institutes for Biomedical Research (NIBR) and member of the Executive Committee of Novartis. And we bring in patient-advocacy groups as soon as we start thinking about a project.

Under the leadership of Dr. Fishman, NIBR often tests new medicines in genetically well-defined diseases to provide the initial readout on safety and efficacy. Often these diseases are rare: ACZ885, a monoclonal antibody targeting interleukin-1-beta, was first tested in patients with Muckle-Wells syndrome, an inflammatory disorder that affects only a few hundred patients worldwide. Following the successful proof-of-concept study, ACZ885 has progressed steadily to an advanced stage of clinical testing as a treatment for Muckle-Wells syndrome.

Last year ACZ885 was designated an orphan medicinal product by the European Commission. That is a status, reserved for medicines used to treat rare diseases, that entitles the manufacturer to a period of market exclusivity. In all, nine Novartis medicines have been designated orphan products in Europe in the past five years.

Affordability and Access

Even the best medicines cannot help patients who do not adhere to treatment. According to a report by the World Health Organization, patient adherence to long-term therapy for chronic illnesses averages a mere 50% in developed countries and rates are even lower in developing countries. Non-adherence is a common problem in patients with high blood pressure; less than half of patients being treated take all of their prescribed medication.

Novartis has developed a broad array of programs aimed at enhancing affordability and access to treatment, as well as driving improved compliance.

In the US, more than 300 000 patients have enrolled in BP Success Zone, a patient-education program from Novartis to help people who have been prescribed *Diovan* reach the blood pressure goal set by their healthcare professional. The program includes a free-sample supply of *Diovan* plus a membership card good for discounts and other benefits. Novartis also offers to refund out-of-pocket costs for

patients who fail to control their blood pressure after taking the maximum recommended dose of *Diovan HCT* for at least 30 days.

In Brazil, Novartis has introduced a customer-service card known as Vale Mais Saude (VMS) that offers patients discounts on the price of Novartis medicines when they fill their prescriptions at selected pharmacies. The program also includes educational material and reminder calls to refill prescriptions. Currently, 40 000 physicians and more than 700 000 patients in Brazil are enrolled in the VMS program. Data collected to date indicate that people participating in the VMS program have an average duration of treatment more than double that of people not enrolled in the program.

Money-back guarantees as part of patient-support programs offer an incentive for patients who lack prescription-drug coverage or live in less-affluent countries that often require patients to pay for their own medicines. In the US, for example, Novartis introduced a patient starter kit for *Tyzeka*, a new treatment for hepatitis B infection. As part of the program, eligible self-paying patients who take *Tyzeka* for six consecutive months and have detectable virus in their blood at week 24 will be reimbursed for their entire out-of-pocket drug costs.

Moreover, the efficacy demonstrated in clinical studies of *Aclasta/Reclast*, along with the guaranteed compliance of once-yearly administration, has enabled Novartis to develop innovative pricing models for the medicine. A once-yearly infusion represents a challenge for payors because of the one-time cost of *Aclasta/Reclast*, compared to oral daily, weekly or monthly treatments.

In Germany, Novartis has agreed to refund medication costs to health insurers in cases of treatment failure within one year. The money-back guarantee has had an added benefit for Novartis, speeding reimbursement negotiations for *Aclasta/Reclast* with German authorities.

Novel commercial models are likely to become increasingly common amid intense pressure on pricing from governments, insurers and other healthcare payors. Payors obviously want fair value for their investment and if we offer them guaranteed value for their money, very often they will accept our prices, says Joseph Jimenez, Head of the Pharmaceuticals Division and member of the Executive Committee of Novartis.

I think you can offer an attractive proposition if you have differentiated products in a specialty category, he adds. We start to reflect on the payor's value proposition very early in our development process and the end point is reflected in our clinical and marketing plans. This will become an integral part of our marketing strategy.

Trusted Partner

Interaction with patient groups provides an important opportunity for the exchange of balanced, accurate and easy-to-understand scientific information about diseases and available treatments, as well as healthcare policies that affect patients. Novartis believes that it is important for patients to be able to communicate their views clearly and to build effective relationships with diverse stakeholders in the pursuit of superior access to healthcare. Stable links with patient groups enable Novartis to understand more intimately the needs of patients and how to best address such needs.

Patient groups seek financial support from a wide variety of sources and this funding sustains important activities enhancing the well-being of many people living with serious or debilitating medical conditions. Yet there is increasing public scrutiny of funding from industry and questions about whether such payments might compromise the independence of patient groups that receive them.

Both industry and patient groups have taken steps in recent years to ensure that interactions are fully transparent. In 2006, Novartis issued guidelines for interactions with patient groups worldwide to ensure all projects comply with the groups' own by-laws and self-regulatory codes, as well as local laws and regulations.

Funding receives special attention in the new guidelines. Financial support from Novartis to a patient group must be in the form of a grant, donation, support of an educational program or other type of arm's-length arrangement. Funding must be clearly documented by way of written agreements that set forth in detail all the rights and obligations of both parties.

Activities should be mutually beneficial and fall within the objectives of both organizations. For the long term, Novartis must not provide the majority of financial contributions to a patient group. And the guidelines call for particular attention when Novartis provides the only available treatment option for a specific disease or condition.

During 2007, Novartis posted on the company website the names of US and European patient groups that receive financial support. The initiative was part of a pilot program for public reporting of interactions with patient groups; this initial list of US and European patient groups will be updated annually. In addition, individual Novartis country organizations can list on national websites the names of patient organizations they support. For competitive reasons, Novartis does not disclose the amounts given to patient groups.

One recent example of mutually beneficial advocacy was the first audit of diabetes prevalence, costs and policies across the 25 European Union member states published two years ago. The audit was commissioned by the Federation of European Nurses in Diabetes (FEND) and the European arm of the International Diabetes Federation (IDF Europe), with financial support from Novartis.

FEND is a professional organization that promotes the delivery of evidence-based

based care for people with diabetes throughout Europe. FEND also is an active advocacy group with the aim of influencing European healthcare policy relevant to diabetes care and research. IDF Europe is an affiliate of the umbrella organization that calls itself the only global advocate for people with diabetes and their healthcare providers. IDF encompasses almost 200 diabetes organizations in 150 countries.

The Diabetes EU 25 report provided empirical evidence that EU member states were not addressing the diabetes pandemic effectively. For example, only 11 of 25 member countries had a national framework or plan for diabetes in place. Moreover, the report underscored severe inequalities in standards of diabetes prevention, diagnosis and control across Europe, and concluded: Patients are suffering needlessly as a result.

The audit served as the basis for policy recommendations that FEND and IDF Europe presented at an EU healthcare summit held during the Austrian presidency. One compelling reason for member-state governments to take action, according to FEND and IDF Europe, was to contain the threat of a dramatic rise in costs of diabetes from an estimated 50 billion euros per year at that time. Sharing best practices could help reduce inequalities across the EU 25, the report asserted. The Austrian EU Presidency went on to declare type 2 diabetes a key health priority and call for urgent targeted action to address growing incidence and prevalence of the disease, as well as the rapid rise in direct and indirect costs of diabetes across the EU. FEND and IDF Europe had an opportunity to raise the profile of diabetes further at a similar health summit focusing on chronic diseases in July 2007, under the Portuguese EU Presidency.

The EU 25 audit was a unique study of the status of diabetes in national health plans at that time. It highlighted those countries that have national plans and are implementing them, but also encouraged those countries that have not yet addressed diabetes as a priority to do so, says Anne-Marie Felton, President of FEND and a key architect of the audit. It isn't sufficient to just have national plans. They have to be implemented and mechanisms to monitor implementation are another integral part of any national plan, Ms. Felton adds.

The audit provided FEND and IDF Europe, as advocacy organizations, with a means of holding Ministries of Health and politicians to account in their decision-making and ensuring that diabetes remains a priority.

Importantly, the audit will be repeated during 2008 within the current 27 member states, as well as aspiring countries that plan to apply for EU membership. Underscoring its continued commitment to diabetes, Novartis will also be a major sponsor of the 2008 audit by providing an unrestricted educational grant. Our hope is that this will become an ongoing and dynamic document, Ms. Felton says.

There are still major gaps in data related to diabetes across the EU. From the audit, we saw an interesting discrepancy in data from different entities within the same country, she adds. And one by-product is that governments are more willing to talk to patient organizations today, and wish to appear in a better light in future audits.

Like representatives from other advocacy organizations, Ms. Felton welcomes clearer rules of engagement in interaction with Novartis. It's a delicate area because, on the one hand, none of us can do this on our own and we regard the pharmaceutical industry as a key stakeholder in prevention of diabetes and the fight against the complications of diabetes. But as an organization, FEND must be extremely careful to maintain our credibility and independence, and not fall within the control of industry.

Closing the Access Gap

Major initiatives by Novartis target neglected diseases, ranging from malaria and leprosy to drug-resistant tuberculosis (TB). We provide medicine at no profit, or sometimes free, to patients in the developing world. We also offer discounts and support programs to patients in industrialized countries without medical insurance or other financial resources.

Since the year 2000, Novartis has provided free treatment for all leprosy patients worldwide in a pioneering collaboration with the WHO. In another partnership, with the WHO and the United Nations Children's Fund, Novartis is providing the pioneering antimalarial medicine Coartem on a non-profit basis for public-sector use in developing countries.

Through the WHO, Novartis is providing fixed-combination tablets to treat 500 000 tuberculosis patients in the world's poorest countries with Directly Observed Therapy Short-Course, or DOTS. The DOTS approach requires TB patients to swallow their medicines in the presence of a health worker or community volunteer. The spread of drug-resistant TB is one of the world's most pressing public-health challenges and DOTS has emerged as the most effective form of treatment.

In addition to donations, Novartis is helping poor patients in the tropics benefit from the revolution in biomedical science and technology that underpins the Group's commercial research.

The Novartis Institute for Tropical Diseases (NITD) was founded in 2002 as a state-of-the-art research facility focusing on scourges such as dengue fever and drug-resistant tuberculosis that take a daunting toll among patients in the developing world. Any therapies discovered at NITD will be made available to poor patients without profit.

The Singapore-based research center was envisaged as a scientific catalyst, rejuvenating interest in neglected tropical disorders while at the same time transplanting the special skills needed to translate basic science into actual drugs.

Dengue fever and drug-resistant TB were chosen as the initial targets for research at NITD after discussions with physicians, public-health officials and industry experts underscored the urgency of scientific advances in treatment of those diseases. When we selected the first diseases for research, we wanted to choose disease areas where there was clear unmet medical need and insufficient resources allocated, says Professor Paul Herrling, Ph.D., Chairman of NITD and Head of Corporate Research at Novartis.

That urgency also was reflected in the challenging objectives Prof. Herrling set for drug-discovery programs. By the end of 2008, NITD expects that at least two new compounds discovered at the institute will begin clinical testing.

NITD expanded its research operations to include malaria in 2006 under a five-year, USD 20 million collaboration funded by the Wellcome Trust, the Singapore Economic Development Board and Medicines for Malaria Venture (MMV). The malaria project has two unprecedented objectives: development of a single-dose cure for *Plasmodium falciparum*, the most dangerous form of malaria, as well as a curative modality for *Plasmodium vivax*, the most frequent and widely distributed form of malaria.

Eliminating Leprosy

The 17th International Leprosy Congress in Hyderabad, India, will be a landmark in the battle against neglected diseases. As a result of decades of concerted international action, the burden of leprosy has been greatly reduced, and Novartis, through the efforts of the Novartis Foundation for Sustainable Development, has been at the forefront of this public-health breakthrough.

The face of leprosy has changed dramatically thanks to the development of multi-drug therapy (MDT), a curative treatment, and its increasing availability to patients free of charge. Two of the three drugs used in multi-drug therapy, the treatment recommended by the WHO, were developed in the research laboratories of Novartis.

The commitment by the Novartis Foundation to provide MDT free of charge was made at a critical juncture in the effort to eliminate leprosy. Availability of free treatment is the cornerstone of the leprosy-elimination strategy and MDT donations by the Novartis Foundation have led to the cure of about 4.5 million patients so far, according to WHO estimates.

In 2005, Novartis decided to extend the MDT donation for an additional five-year period, until the end of 2010. Adequate supplies of free, high-quality MDT will help to ensure that the remaining endemic countries reach the elimination target and that other countries sustain the impressive progress made so far. Continued availability of MDT will be crucial in maintaining high coverage of leprosy services in the coming years to interrupt transmission of the disease.

As well as introducing the concept of social marketing to leprosy treatment – using marketing techniques to enhance social ends – the Novartis Foundation has made a significant contribution to simplifying the provision of disability-prevention services in communities. Many of the approaches devised under the Foundation's Comprehensive Leprosy Care Project in India have now been incorporated into the disability-care packages of both the government and NGOs.

Support from Novartis and its Foundation has helped change the face of leprosy, from one of disfigurement and despair to the promise of cure, says Margaret Chan, M.D., Director General of the WHO.

The development of high-quality drugs, and the decision to make these drugs

available at no cost, are a model of corporate social responsibility. At least 4 million leprosy patients can thank this Foundation for their cure, and their freedom to live a normal and productive life. This is proof of the gains for sustainable development as we move toward a world that knows this ancient disease no more.

Battling Malaria

For almost a decade, Novartis has led a revolution in the treatment of malaria. The main battleground is Africa, where malaria kills more than a million people every year, mainly pregnant women and children younger than five years of age.

Malaria is more than an ordinary disease on this continent, says the Honorable Richard Nduhura, Uganda's Minister of State for Health. It has major implications on all essential aspects of our life, as individuals, as families, as communities and as a nation.

When Novartis joined the fight against malaria during the late 1990s, Africa was on the brink of a public-health disaster. Malaria parasites had developed resistance to the older antimalarial drugs, such as chloroquine, on which African countries relied for decades.

Working with partners in China, Novartis developed *Coartem*, the first of a new class of antimalarial medicines known as artemisinin-based combination therapy, or ACT. *Coartem* included a component used for centuries in traditional Chinese medicine to treat fever. A second antimalarial compound, working through a different mechanism of action, acts synergistically to eliminate remaining parasites that might have survived the initial assault.

To ensure broad access to *Coartem*, Novartis forged a partnership with the WHO to provide *Coartem* at no profit for use by public-health systems in developing countries. The exceptional efficacy of *Coartem*, combined with availability of international donor financing through the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria, pushed demand for the new drug higher than anyone could have imagined.

NOVARTIS ACCESS-TO-MEDICINE PROJECTS 2007

Project	Objective	Target region	Value (USD millions)	Patients
Malaria/WHO (1)	Provide <i>Coartem</i> at cost for public sector use	Africa, Asia, Latin America	190	64 800 000
Leprosy/WHO (2)	Eliminate leprosy by providing free medications to all patients worldwide with WHO, through 2010	Global	6	244 000
Tuberculosis (2)	Donation of fixed-dose combinations	Tanzania, Sri Lanka	3	112 000
Novartis Foundation for Sustainable Development(3)	Improve health and quality of life of poor people in developing countries through Think Tank, policy and project work	Developing countries	8	390 000
		Developing countries	12	

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Novartis Institute for Tropical Diseases (NITD)(3)	Discover novel treatments and prevention methods for major tropical diseases; NITD discoveries to be available in poor endemic countries without profit			
Patient Assistance Programs (PAP); excl. <i>Gleevec/Glivec</i> (2)	Assistance to patients experiencing financial hardship, without third-party insurance coverage for their medicines	US	113	106 000
<i>Gleevec</i> US PAP (2)	Within capability of Novartis, continue to ensure access for patients in the US who cannot afford the drug	US	56	3 000
<i>Glivec</i> Global PAP (2), (4)	Within capability of Novartis, continue to ensure access for patients outside the US who cannot afford the drug	Global (excluding US)	534	20 000
Together Rx Access	Discount program for the uninsured	US	1	12 000
Emergency relief & other product donations	Support to humanitarian organizations	Global	14	
Total			937	65.7 million

(1) During 2007, 64.8 million *Coartem* treatments reached patients based on a preliminary analysis of local distribution; Of these, 29 million treatments came from shipments completed in 2006, and 35.8 million from the total shipment of 66 million completed in 2007. The Value of the *Coartem* program in 2007 was calculated using the number of treatments shipped and the ex-factory price of *Coartem* to private-sector purchasers in malaria-endemic developing countries, minus payments to Novartis to cover costs under terms of the public-private partnership with WHO. These payments were received through WHO, UNICEF and other procurement agencies, acting on behalf of governments and other public sector institutions in developing countries eligible to receive *Coartem* at the not-for-profit price.

(2) Ex-factory price to private market

(3) Operating costs

(4) Inclusive Shared Contribution Model as described on page 77

During 2007, 66 million treatment courses of *Coartem* were delivered to more than 30 countries across Africa. About 70% of treatments delivered were for children who account for the vast majority of deaths from malaria.

Cumulative deliveries of *Coartem* under the not-for-profit partnership with the WHO reached 142 million treatments, helping to save an estimated 450 000 lives. Production capacity for *Coartem* if orders are placed in a timely manner is currently 100 million treatments per annum.

The Novartis Foundation has agreed to donate *Coartem* in support of the Millennium Villages Project, an initiative aiming to help impoverished communities in rural Africa achieve the United Nations Millennium Development Goals and halve poverty by 2015. Along with *Coartem* donations, the Foundation is providing financial support to Ilongangulu village in Tanzania for a transition from subsistence farming to self-sustaining commercial activity.

With some of the most populous countries in Africa now rolling out *Coartem*, malaria experts are upbeat about the potential impact on public health. We have the opportunity to use *Coartem* as an entry point for making the whole government healthcare sector work better, not only by managing sick patients, but also by streamlining distribution and maintaining supplies of drugs to ensure effective treatment at remote healthcare facilities, says Robert W. Snow, Professor of Tropical Public Health at the University of Oxford and one of the world's leading authorities on malaria.

During 2007, Novartis and partners completed clinical testing of a new dispersible formulation of *Coartem*, aiming to increase convenience of administration and improve palatability for young children. Dispersing *Coartem* in milk or water to drink promises to make dosing more reliable than the current practice of crushing adult tablets for use by children. And a new cherry flavor developed for the dispersible formulation masks the bitter taste that *Coartem* has in common with most other artemisinin-based antimalarial medicines.

Gleevec/Glivec Patient Assistance Programs

For the breakthrough anticancer therapy *Gleevec/Glivec*, Novartis maintains one of the most comprehensive patient-assistance programs yet implemented on a global scale in the field of cancer to help people who otherwise would not be able to afford treatment.

The *Glivec* International Patient Assistance Program (*GIPAP*) provides free *Gleevec/Glivec* as well as additional support to eligible patients in developing countries with minimal reimbursement capabilities. A separate patient-assistance program gives *Gleevec/Glivec* to patients in need in the US and Canada.

Eligible patients must be properly diagnosed with chronic myeloid leukemia (CML) or gastrointestinal stromal tumor (GIST); lack coverage by reimbursement or insurance; and have no other financial resources. *GIPAP* also provides information and referral assistance to patients, members of their families and caregivers.

GIPAP works through a global network of more than 900 qualified physicians. To date, more than 27 000 patients in more than 80 countries have received free treatment through *GIPAP*.

To ensure independence in evaluation and approval of eligible patients, the Max Foundation, a non-profit organization based in Seattle, Washington, serves as the main partner in the administration of *GIPAP*. In countries in which Novartis Oncology has no local representation, Novartis partners with Axios International, a consulting firm, to administer the *GIPAP* program.

Unlike traditional donation programs, *GIPAP* is based on a patient-direct model, facilitating delivery of *Gleevec/Glivec* to patients by their treating physician. Novartis has continued to explore new ways to maximize *Glivec* access by designing models built on public-private partnerships in which Novartis enlists governments and other third parties, including payors, as partners. Under shared-contribution models, Novartis is no longer the sole provider of therapy through a donation; rather, national healthcare systems or other payors assume portions of the cost of *Glivec* treatment.

COMMITMENT TO PATIENTS: TARGETS AND RESULTS FOR 2007 AND TARGETS FOR 2008

Stakeholder Engagement

Targets 2007

Increase transparency in collaborations with patient-advocacy groups. Expand systematic stakeholder-engagement process.

Results 2007

Implemented new Novartis guidelines for interactions with patient groups. Continued training of business teams about how to work with patient groups, using patient-group leaders as coaches. Published names of all patient groups supported by Novartis in Europe and the United States on Novartis.com.

Targets 2008

Embed concept of consulting with key patient groups in the development and marketing cycles of major brands and therapy areas. Increase involvement of Novartis in civil-society debate about access to medicines.

Access to medicine

Targets 2007

Expand partnerships for *Coartem* distribution beyond World Health Organization. Establish research collaboration in malaria with Wellcome Trust.

Results 2007

Proportion of *Coartem* sales supplied through alternative providers such as UNICEF, Crown Agents, Mission Pharma, Médecins Sans Frontières and direct deliveries to countries increased to 51% in 2007. Following a grant from the Wellcome Trust, Medicines for Malaria Venture and Singapore Economic Development Board, an NITD-led consortium initiated research to deliver lead compounds for a one-dose cure for *Plasmodium falciparum* and a curative modality for *Plasmodium vivax*.

Targets 2008

Launch pediatric dispersible formulation of *Coartem*. Facilitate data collection and publication of studies showing health impact of *Coartem* use.

**Novartis Institute for Tropical Diseases
(New target)**

Targets 2007

Results 2007

Targets 2008

Fully consolidate Institute's new ventures Eijkman Institute; Hasanuddin University Clinical Research Institute (NEHCRI); and malaria research while continuing the build-up of the pipeline in dengue fever, tuberculosis and malaria. Maintain vigorous teaching and training activity, as well as high international scientific presence in tropical diseases research and development.

