

NOVARTIS AG  
Form 6-K  
February 08, 2008

## 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)

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### Novartis AG

(Name of Registrant)

Lichtstrasse 35  
4056 Basel  
Switzerland

(Address of Principal Executive Offices)

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

Form 20-F:  Form 40-F:

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

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-

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Yes:  **No:**

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## 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**

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

**SHARE INFORMATION**

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

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(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/Tekturna* 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 CO<sub>2</sub> emissions in the medium term. The changing composition of the worldwide vehicle fleet is also contributing to these objectives: A 10% reduction in CO<sub>2</sub> 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**

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

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(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><br>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><br>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 |
|--|----------------------------------|------------------------------------|------------------------------|----------|-----------|-----------|
| <b>Dipeptidyl peptidase 4 inhibitor</b>                                      | Oral                             | Submitted US (approved EU)         | XXXXXXXXXXXXXXXXXXXXXXXXXXXX |          |           |           |
| <b>Angiotensin II receptor antagonist and insulin secretagogue</b>           | Oral                             | 2010                               | XXXXXXXXXXXXXXXXXXXXXXXXXXXX |          |           |           |
| <b>Angiotensin I converting enzyme inhibitor and calcium channel blocker</b> | Oral                             | 2009                               | XXXXXXXXXXXXXXXXXXXXXXXXXXXX |          |           |           |
| <b>Renin inhibitor</b>   | 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         |          |           |           |
| <b>Melatonin receptor agonist and 5-HT<sub>2C</sub> antagonist</b>           | 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 |          |           |           |
| <b>Long-acting beta-2 agonist and long-acting steroid</b>                    | 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 warns. 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 is 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 cla