NOVARTIS AG
Form 6-K
February 09, 2010
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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 or 15d-16 OF
THE SECURITIES EXCHANGE ACT OF 1934

Report on Form 6-K dated February 9 2010

(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: x Form 40-F: o

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

Yes: o **No**: x

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes: o **No**: x

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: o **No**: x

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GROUP REVIEW

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 OVERVIEW

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

We offer a portfolio focused on broad areas of healthcare to best meet these needs: innovative prescription medicines, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, and consumer health products.

FINANCIAL HIGHLIGHTS

KEY FIGURES

(In USD millions, unless indicated otherwise)

	2009	2008
Net sales	**44 267**	41 459
Operating income	**9 982**	8 964
Return on net sales (%)	**22.5**	21.6
Net income	**8 454**	8 163
Basic earnings per share (1) (USD)	**3.70**	3.59
Core (2)		
Operating income	**11 437**	10 319
Return on core net sales (%) (3)	**25.8**	25.0
Net income	**10 267**	9 501
Basic earnings per share (1) (USD)	**4.50**	4.18
Research & Development	**7 469**	7 217
As a % of net sales	**16.9**	17.4
Number of associates (FTE) (4)	**99 834**	96 717
Return on average equity (%)	**15.7**	16.5
Free cash flow	**5 505**	4 301

SHARE INFORMATION

	2009	2008
Share price at year-end (CHF)	**56.50**	52.70
ADS price at year-end (USD)	**54.43**	49.76
Dividend (6) (CHF)	**2.10**	2.00
Payout ratio of net income from continuing operations (%)	**55**	48

NET SALES, OPERATING INCOME, NET INCOME, CORE OPERATING INCOME AND CORE NET INCOME (5)

(Index: 2004 = 100%)

2009 NET SALES BY REGION

(% and in USD millions)

(1) 2009 average number of shares outstanding: 2 267.9 million (2008: 2 265.5 million)

(2) Core results for operating income, net income and earnings per share (EPS) eliminate the impact of acquisition-related factors and other significant exceptional items. These adjustments are explained in detail on page 151.

(3) In 2008 based on core sales of USD 41 305 million

(4) Full-time equivalent positions at year-end

(5) To ease comparability, net sales, operating income and net income for the years 2004 to 2007 exclude the Consumer Health Division Nutrition operations divested in 2007.

(6) Dividend payment for 2009: Proposal to 2010 Annual General Meeting

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NEWS IN 2009

PERFORMANCE	Another year of record results as momentum from recently launched products drives growth across broad healthcare portfolio. Net sales rise 7% (+11% in local currencies), led by Pharmaceuticals and Vaccines and Diagnostics. Core operating income advances 11% to USD 11.4 billion on the solid business expansion and operational improvements while absorbing an adverse currency impact. Core operating income margin improves to 25.8% of net sales. Core net income up 8% to USD 10.3 billon, while core EPS grows at same pace to USD 4.50.
NEW PRODUCTS	More than 30 major regulatory approvals in the US, Europe and Japan rejuvenate the portfolio. Approvals include the new medicines *Afinitor*, *Ilaris*, *Onbrez Breezhaler* and *Valturna*. Other approvals include the first-ever biosimilars in Japan and Canada; vaccines against Japanese encephalitis and the influenza A (H1N1) pandemic virus; and the *Prevacid24HR* over-the-counter medicine.
PIPELINE	Novartis is advancing 145 pharmaceutical projects (Phase I trials to registration). Pipeline highlights include US and European regulatory submissions for FTY720 (multiple sclerosis). Our focus is on medicines and vaccines offering potential best-in-class status and health benefits.
RESEARCH	By exploring mechanisms of disease, teams at the Novartis Institutes for BioMedical Research are seeking to discover novel therapies. Biologics account for an increasing proportion of the exploratory pipeline.
PORTFOLIO	Strengthening our focused portfolio to meet evolving healthcare needs, Novartis commits to invest more than USD 1 billion in China to create the country s leading pharmaceutical R&D institute and expand offering of vaccines. Sandoz acquires EBEWE Pharma s specialty generics business, gaining a new growth platform and improving access to oncology medicines.
CORPORATE CITIZENSHIP	Engaging with society to improve healthcare is integral to how Novartis operates and important to our success. Access-to-medicine programs for those in need reach 79.5 million patients in 2009. Contributions of USD 1.5 billion represent 3% of net sales.
DIVIDEND	Proposal for 5% increase in 2009 dividend to CHF 2.10 per share (2008: CHF 2.00 per share), with a dividend yield of 3.7%.
ALCON	Novartis announces in January 2010 its intention to gain full ownership of Alcon Inc., a global leader in eye care, through completion of the April 2008 agreement with Nestlé S.A. to acquire its 77% majority stake in Alcon, and subsequently a proposed direct merger of Alcon into Novartis in the interests of all stakeholders.

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Daniel Vasella, M.D.

DEAR SHAREHOLDER

I am pleased to report record results for 2009, both in sales and in profits, despite the global economic crisis that shaped the year.

Our Pharmaceuticals Division delivered an outstanding performance during the past year. This achievement was possible through new product growth and rejuvenation of our portfolio - both of which clearly bring value to patients and shareholders. Consumer Health and Sandoz, our generics division, showed solid growth, accelerating in the fourth quarter. The Vaccines and Diagnostics Division exceeded its targets thanks to the rapid rise in demand for influenza A (H1N1) pandemic vaccines.

The specific results were as follows:

• Net sales rose by 11% in local currencies (+7% in US dollars) to USD 44.3 billion.

• Operating income grew 11% to USD 10.0 billion.

• Net income climbed 4% to USD 8.5 billion, negatively influenced by currency effects, financing costs for Alcon and exceptional costs of USD 189 million from associated companies; excluding acquisition-related and significant one-off factors, net income rose 8% to USD 10.3 billion.

• Free cash flow before dividends showed dynamic growth and reached a level of USD 9.4 billion (+24%).

The **Pharmaceuticals** Division increased its net sales 12% in local currencies (+8% in US dollars) to USD 28.5 billion. This growth rate is twice the market, illustrating that we remain one of the strongest-growing companies in the industry. Oncology in particular posted outstanding growth rates: we have increased our global market share to 11% from 7.7% in 2001, and moved from fifth to second position in this competitive field. Operating income grew ahead of net sales despite increasing investments in research and development, and negative external factors, such as price-cutting measures and adverse exchange rates.

I am also pleased that we successfully rejuvenated our product portfolio. Two factors contributed to this accomplishment: the global launches of new products - *Lucentis*, *Exforge*, *Exjade*, *Exelon* Patch, *Reclast/Aclasta*, *Tekturna/Rasilez* - and our leukemia treatment *Tasigna*, which showed clear superiority to *Gleevec/Glivec* in comparative studies. New products accounted for 16% of total sales, a significant increase from 10% the previous year. We obtained regulatory approval for a number of important products in 2009 - in particular for the cancer medicine *Afinitor*, which shows considerable potential, and the biological therapy *Ilaris*.

The **Vaccines and Diagnostics** Division increased sales by 39% in local currencies (+38% in US dollars) to USD 2.4 billion, and operating income reached USD 372 million. These record results are largely due to the rapid development of several innovative influenza vaccines, in particular for protection against the influenza A (H1N1) virus. To date, nearly 50 million people have been infected, requiring exceptional efforts on a global scale to contain the pandemic. All vaccine production sites have been operating at maximum capacity since the summer, thanks to unprecedented support from hundreds of Novartis associates from other divisions. By the end of the year, approximately 116 million doses were delivered. To strengthen this division, we aim to discover and develop innovative vaccines to complement our influenza vaccines, which serve a cyclical public health need. One such innovative product is *Menveo*, a vaccine for meningococcal meningitis that is currently pending regulatory approval.

The generics division **Sandoz** achieved solid underlying growth (USD 7.5 billion, +5% in local currencies) in key markets thanks to new product launches and increased marketing initiatives. Operating income remained nearly stable (-1%) at USD 1.1 billion. As in past years, the business experienced an annual price erosion of about 7% and was further impacted by adverse exchange rates. Despite increases in efficiency and productivity, the impact of these factors could not be entirely neutralized. Falling sales had an impact in Eastern European countries against the backdrop of the global economic crisis. However, this was more than offset by new product launches and a significant increase in net sales from biosimilars, especially in the US.

The **Consumer Health** Division felt the impact of the global recession particularly in the first half of 2009. Nevertheless, the division posted a solid result: net sales grew 5% in local currencies to USD 5.8 billion, while operating income fell slightly by 3% to

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USD 1.0 billion. In the OTC Business Unit, we invested significantly in the largest-ever launch campaign for *Prevacid24HR*, our proton pump inhibitor. The *Prevacid24HR* launch was one of the biggest prescription-to-OTC switches in recent years, sales exceeded USD 100 million in the few weeks following its November launch. CIBA Vision achieved stronger growth than any competitor in the contact lens and lens care industry. New product expansion helped accelerate solid growth in local currencies. Animal Health also grew faster than the global market.

We achieved strong 2009 results in a global market that will remain challenging for the foreseeable future. We must continue to focus all our efforts and engagement - even more in this environment - on adding value for patients, and, ultimately, for our company. This focus shields us from erratic, ill-considered action on one hand and from clinging defensively to the status quo on the other - both would weaken Novartis in the long term. Since Novartis was founded in 1996 we have experienced a rapid acceleration in economic globalization and information flow, increasing the complexity of managing multinational companies.

In light of these developments, we will only remain successful if we continue to navigate the rapidly changing environment with diligence, foresight and reflection, and venture to seize strategic opportunities, which are always accompanied by risk.

Our strategy, based on the concept of diversification within the healthcare sector, has again proven to be the right approach in the past year. The fact that more and more companies are starting to imitate our strategy of focused diversification does not guarantee long-term success - but does indicate that we recognized the signs of the times at a very early stage.

We have systematically transformed Novartis into a company focused clearly on growth areas of the healthcare market. Businesses in chemicals, nutrition and agribusiness, as well as beverages and medical nutrition, were spun off or sold. Other companies were added to our portfolio, including the generics manufacturers Hexal and Eon Labs, as well as the vaccines producer Chiron, where we successfully increased our holding to 100% in 2006 and have since nearly tripled sales.

Our strong yet adaptable corporate culture enabled the successful integration of these and other companies. Since the founding of Novartis, we have shaped our culture by proactively facing inevitable change with confidence in the future, without ever giving up our fundamental beliefs. Intensive training and continuing education of our associates established a corporate culture based on performance and results, integrity and cultural openness.

I firmly believe that our recently proposed merger with Alcon can result in a successful integration of the two companies. Ultimately, we aim not only to acquire the majority stake in Alcon from Nestlé, as agreed in April 2008, but also to integrate Alcon fully as a new and largely independent division via a direct merger into Novartis. This would immediately make Novartis a world leader in eye care. With our complementary product portfolios and synergies in research and development, Alcon and Novartis constitute an excellent strategic fit. Given the growing medical needs of the aging world population, ophthalmology is an area of dynamic growth.

Last year we also substantially strengthened our generics division Sandoz with the acquisition of EBEWE Pharma s specialty generics business, which specializes in injectable cancer medicines.

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In addition, our Vaccines and Diagnostics Division announced plans to acquire an 85% stake in the Chinese vaccines manufacturer Zhejiang Tianyuan. This company is a leading privately owned producer of vaccines with a large range of competitive products in China and an interesting pipeline in the field of viral and bacterial diseases.

As a global company, our strategic investments are influenced by the fundamental eastward shift in the world economy. Twenty years ago, the equilibrium shifted from Europe to the US; today, we are experiencing a shift toward Asia. China, for example, has long been interesting not only as a highly dynamic market, but also as a promising research hub. That is why last fall we decided to increase our investment and the number of associates at our research center in Shanghai from 160 to nearly 1 000.

China is the most important market of the future. By 2013, sales in the pharmaceutical industry could nearly triple from their current level of USD 25 billion to more than USD 70 billion. This would make China, in only a few years, the third-largest pharmaceutical market after the US and Japan.

We are currently witnessing the dawn of a new era. Globalization no longer implies westernization. A company that acknowledges that Asia will shape our society and economy in the future has the potential to base its actions on the ramifications of this shift. Projects in China are typically approached systematically, strategically and with a long-term horizon - in contrast to the West, where politics, economics and financial analysis are often short-term and characterized by a hasty response to risks and opportunities. I hope that we in the West succeed in returning to the values we once embraced, such as trust in the future and belief in progress.

Robust growth drivers will remain a distinguishing characteristic of the healthcare sector in the future. There are several contributing factors:

• Demographic changes are increasing the demand for medical care. Co- and multi-morbidity are a feature of advanced age and, without effective medicines and adequate medical care, have a huge impact on quality of life.

• Chronic diseases are more common not only because of aging societies, but also because of lifestyle changes. In China there are almost 400 million smokers. In the US alone, the direct and indirect cost of obesity amounts to almost USD 500 billion annually - not including the cost of secondary diseases such as diabetes.

• The strong and stable growth of emerging markets, despite the financial crisis, is evident in the increased demand for medicines and treatments. Experience in 2009 again confirmed that demand for the best possible healthcare is outpacing economic growth in emerging markets. In the seven leading emerging markets acknowledged by IMS (Brazil, China, India, Mexico, Russia, South Korea and Turkey), the growth forecast for 2010 is between 12% and 14% and is likely to accelerate further in the years to come.

• Scientific and technological advances are creating new ways to better develop novel medicines that fight diseases we cannot treat today.

At the same time, there are several opposing forces: ever stricter regulatory authorities, financially restrictive payors increasingly aware of their power, and governments around the world trying to reduce healthcare system costs. Price-cutting is often used to reduce costs in the healthcare system; however, cutting prices across the board does not take into account the overall goal of improving productivity and quality in healthcare, which can only be achieved through transparency and the comparison of various treatment methods.

Our company can meet these challenges with confidence, because our aim is to discover and develop more innovative vaccines and medicines for patients. New and better medicines will continue to be appreciated by society and financially rewarded. Nevertheless, we should be aware that we must constantly adapt our business model to changing market demands to maintain our level of growth in the years to come.

Without better prevention and treatment, the cost of the most prevalent diseases in society - including diabetes, cancer and hypertension - will triple by the middle of the next decade, totaling billions annually for each disease area in the US alone.

Despite heated health policy controversies - where the pharmaceutical sector sometimes serves as the ideal scapegoat - I remain optimistic. I firmly believe society recognizes the value of medical progress and that the majority understands and accepts that incentives and investments make innovation possible.

Against the backdrop of cost pressure and inherent skepticism facing the pharmaceutical sector, innovation is more important than ever. Novartis is in a strong position. Our consistent investments in research and development, made regardless of business cycle pressures, are paying off: Novartis has one of the most competitive pipelines in the pharmaceutical industry with 145 projects in development. Sixty of these are new molecular entities. Since the turn of the millennium we

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have received more Food and Drug Administration approvals than our competitors, outperforming them year after year.

In 2009, our company received more than 30 positive decisions from regulatory authorities in the US, EU and Japan, including a record number of six approvals in Japan for *Rasilez*, *Tasigna*, *Xolair*, *Co-Dio, Lucentis* and *Clozaril*. Furthermore, in January 2010, *Equa* (local brand name for *Galvus*), *Exforge* and *Afinitor* were approved in Japan, the world s second-largest pharmaceutical market. Additional approvals include *Afinitor* (cancer) in the US and EU; *Ilaris* (CAPS), *Extavia* (multiple sclerosis), and combination products *Valturna*, *Exforge* HCT and *Rasilez* (all hypertension), in the US. Regulatory authorities are currently reviewing QAB149 for the treatment of chronic obstructive pulmonary disease, the highly innovative medicine FTY720 for treatment of multiple sclerosis and the novel vaccine *Menveo*.

Even in a difficult global economic environment we continue to extend our engagement in the area of corporate social responsibility. The current global economic situation is a litmus test for the social responsibility of companies: Who is taking action and who is merely talking? Since the founding of Novartis, we have always viewed social responsibility as an integral part of our corporate strategy and acted accordingly. In 2009 we spent about USD 1.5 billion (which is again 3% of our net sales) on programs aimed at providing patients in need with access to our medicines, and on research to discover new vaccines and medicines for developing countries.

I would like to emphasize that our primary purpose as a pharmaceutical company is to discover and develop effective medicines and successfully bring them to market. By doing this, we make an indispensable contribution to help alleviate suffering, improve patients quality of life and even save lives; we also make a major contribution toward lowering the direct and indirect cost of disease. It is the responsibility of governments, on the other hand, to provide for the welfare of their citizens including a functioning healthcare system. For this reason, we remain convinced that any access solution can only have a sustainable impact when governments, international organizations, local aid groups and the private sector collaborate - managing the complexity would be overwhelming for any one stakeholder.

Our engagement in malaria provides an example. We supply our malaria treatment Coartem to affected countries without profit, in cooperation with the World Health Organization (WHO), the United Nations Children s Fund (UNICEF), state health authorities and private aid organizations. To date, Novartis has supplied 300 million Coartem treatments, helping to save the lives of about 750 000 people suffering from malaria.

Since 2000 we have also supplied leprosy patients worldwide with the medicines they need free of charge in partnership with the WHO. Through the end of 2009, these donations, totaling USD 60 million, have cured more than 4.5 million patients.

The successful campaign against leprosy is a public health milestone. In the last two decades, more than 14 million people have been cured, resulting in a 95% decrease in leprosy cases worldwide. Novartis has played a crucial part in ensuring that this terrible disease, which has been the scourge of humankind for centuries, could be eradicated in the near future. Only three countries - Brazil, Timor-Leste and Nepal - have more than one in 10 000 people with leprosy.

Our associates are gratified by our contributions in the fight against leprosy and malaria, and of course, as our shareholders, you too can take pride in these achievements. These

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successes are acknowledged by the WHO, as well as many nongovernmental organizations that do not always view us favorably. These stakeholders also recognize our commitment to researching new medicines and vaccines for diseases common in developing countries, which is the goal of our nonprofit research institutes in Siena, Italy, and Singapore.

We also recognize our responsibility in environmental issues. In 2005 we were among the first signatories of the Kyoto Protocol, which established binding targets for reductions in CO_2 emissions. In environmental protection, Novartis pursues a dual strategy: On one hand, we consistently strive to improve energy efficiency - for example, five Novartis sites have used solar energy systems since last year - on the other hand, we take advantage of voluntary CO_2 offsetting - for example, by planting more than three million trees in northeast Argentina.

We regularly and critically assess our strategy, to ensure it remains relevant for the future. In the same manner, we must constantly review our organizational processes and improve their effectiveness and efficiency. Given the difficult market environment and rising research and development costs, it is essential that we continue to work as efficiently and productively as possible. This also means simplifying processes and creating leaner and flatter structures, so that we can work more quickly, in less complicated ways. Avoiding unnecessary costs enables us to invest more in research and to cope with pricing pressures. We initiated Project Forward two years ago with these objectives in mind. The program s goal was to implement productivity improvements and achieve savings of USD 1.6 billion within three years. After just two years, the project has already exceeded this target by 46%.

In the new, post-crisis reality, governments and the public have rightly raised the ethical bar for good corporate governance. At Novartis we have always been convinced that integrity and transparency are indispensable for a sustainable and successful business. Our Code of Conduct, which our associates must learn and apply in their daily work, builds on these values. We also decided last year to include long-term objectives in the employment contracts of our associates, and systematically implement clawback provisions for bonuses. In concrete terms, this means that action may be taken to reclaim bonuses if it later emerges that the bonuses were paid out based on false information or dishonest management. Setting clear boundaries should prevent our financial incentive programs from abuse.

Last year, the Board of Directors formed a new committee to ensure that risks in the company are properly analyzed and evaluated, and respective processes are followed.

In addition, the Board of Directors has decided to propose at the upcoming Annual General Meeting that you, our shareholders, may consultatively vote on our Compensation System in the future. This vote should take place before every significant change to the Compensation System, but at least every three years. We continue to believe that a vote on individual compensation does not increase the likelihood of achieving business objectives. Decisions on compensation are a key strategic management tool of the Board of Directors, and are based on clearly defined objectives and performance criteria, which are confidential for competitive reasons. For many years, Novartis has voluntarily exceeded the legally required disclosure level in reporting individual compensation of the Executive Committee.

Appointing outstanding leaders to positions of great responsibility is crucial to the sustainable success of our company. The timely planning of CEO succession was initiated in 2008 with the creation of a transitory COO position. Completing this process the Board of Directors accepted my request to hand over my CEO responsibilities and has decided to appoint Joe Jimenez as the new CEO effective February 1. I felt it was timely after 14 years that I concentrate on the duties of Chairman of the Board, and will henceforth focus on the strategic priorities of Novartis and the tasks which lie within the area of accountability of the Board. Joe Jimenez will be fully in charge of all aspects of the operational business.

At Novartis, the question of whether the functions of CEO and Chairman should be separated or not, will continue to be answered in a flexible manner, according to the company s strategic requirements. This will be decided in the future in the best interest of shareholders and will not be rigidly prejudged for formalistic reasons.

I felt that this was the right moment for a transition, as our full pipeline and the acquisition of Alcon marks a new growth phase. Our business portfolio has been transformed to exclusively focus on healthcare, our pipeline is highly valued, and our research organization is productive and greatly respected. Our leadership team is competent and motivated. Due to all these factors, today, Novartis is one of the most admired companies in the healthcare industry.

Over the last several years, Joe Jimenez has led our Pharmaceuticals business, our most important division, back to the road of success. In this process, he has distinguished himself as an excellent leader with a focus on clear objectives and impressive implementation skills. It is not just his energy, his self-discipline and his engagement that makes him an ideal appointment as CEO. At least as important is his poised composure, as well as his sense of humor, which is also a great asset in this job.

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Furthermore, Joe s international experience in several business sectors will allow him to move easily in different cultures and take on the responsibilities of a global leader implementing the Novartis strategy.

Joe Jimenez embodies two of the most important values in our corporate culture: a consistent focus on performance and a sense of responsibility towards patients and society. These two values have already shaped our predecessor companies Sandoz and Ciba-Geigy. Marc Moret never lost himself in theoretical reflection, but instead pursued his goals with energy and great determination, against all kinds of bureaucratic resistance which lurk in all big organizations. Alex Krauer was one of the first corporate leaders who understood that credibility and a holistic view are indispensable requirements for success in business. I owe a lot to my predecessors. It is with this in mind that I wish Joe Jimenez all the best as he assumes the responsibilities of his new position!

The Board appointed David Epstein as the new Head of our Pharmaceutical Division. Due to his great skills and sustained sense of continuity, David has led our oncology business to a thriving success.

In these times of leadership change, our finance department is not an exception. On February 1, 2010, Jon Symonds will take over as Chief Financial Officer (CFO) from Raymund Breu, who has reached the mandatory retirement age of 65. Since September 1, Jon Symonds has served as Deputy CFO of the Group and designated successor to Mr. Breu. Previously, Mr. Symonds was Managing Director, Investment Banking, with Goldman Sachs. Mr. Symonds experience in the pharmaceutical industry goes back many years. He was CFO with AstraZeneca for eight years and, prior to that, Finance Director at Zeneca.

I extend my heartfelt thanks to Raymund Breu for his outstanding contributions as CFO and for his exceptional achievements in management during his 35 years in the service of our company. He played a crucial role in the founding of Novartis and has been an invaluable partner for me and my colleagues. Novartis owes a great deal to his expertise and his sound judgment. I would also like to thank our COO, Joerg Reinhardt, who for many years successfully led our product development before he took over the responsibility for our vaccines and diagnostics business. He has now decided to leave our company to pursue new opportunities.

As shareholders you are obviously interested in the development of the value of our company. Our total shareholder return since the founding of Novartis amounts to 9% annually, including continuously increasing dividends and business divestments. Our total shareholder return surpasses not only that of the global market, but also the pharmaceutical industry index and share price performance of important competitors. This shows that we remain in demand as a safe stock with attractive long-term performance.

In 2010, we expect net sales to grow at a midsingle-digit percentage rate in local currencies and for further improvement in the Group s operating income margin.

Most critically, the Pharmaceuticals Division is equipped to manage the period of increasing generic competition for our best-selling product, *Diovan*. It is gratifying to note that the rest of our cardiovascular portfolio - including the innovative medicine *Tekturna/ Rasilez* and combination products - is growing dynamically, allowing us to most likely maintain our leading position in this therapeutic area. In addition, our broad product portfolio beyond pharmaceuticals offers further growth opportunities - not least in the field of eye care. But above all, at the start of this new decade, Novartis has a pipeline that is more promising than ever before in our corporate history.

I would like to thank all our associates for their ongoing engagement, commitment to Novartis, and determination in this challenging environment. I am especially pleased that our associates, in ever-changing conditions, have remained fully engaged and undeterred in contributing to a successful year. We should not take this for granted; it deserves our utmost respect.

Finally, I thank you, our shareholders, for the trust you continue to place in our company. I am pleased to propose an increase in the dividend to CHF 2.10 (+5%) at the next Annual General Meeting.

Sincerely,

/s/ Daniel Vasella
Daniel Vasella, M.D.
Chairman and Chief Executive Officer

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HEALTHCARE PORTFOLIO

Innovation is flourishing, bringing new effective treatments to patients. There are significant challenges, however, and the healthcare environment is undergoing unprecedented change.

The world s population is aging. Better healthcare treatments are needed, also prompting payors to manage costs aggressively. Advancing science and technology are enabling new drug discovery while increasing the cost of innovation. Economic growth in emerging countries is providing better healthcare access, but the poorest still lack basic medicines. Changing lifestyles are leading to higher prevalence of chronic and degenerative diseases.

Our strategy is to provide healthcare solutions that address the evolving needs of patients and societies worldwide.

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EXCELLENT HEALTHCARE PORTFOLIO

Novartis has a well-positioned portfolio focused on broad areas of healthcare, and is the only company to have leadership positions in all of them.

PATIENT-CENTRIC PORTFOLIO

PHARMACEUTICALS

Novartis creates innovative patent-protected pharmaceuticals that save lives and enhance outcomes for patients and healthcare providers. Our medicines are concentrated in therapeutic areas that include cardiovascular, oncology, neuroscience and ophthalmics, respiratory and auto-inflammatory diseases.

SANDOZ

Sandoz is a global leader in generic pharmaceuticals, providing affordable, high-quality medicines that improve access for patients and healthcare systems worldwide. Beyond supplying traditional off-patent medicines, Sandoz stands out for developing and producing differentiated generics and biosimilars.

VACCINES AND DIAGNOSTICS

Novartis vaccines and diagnostic tools help prevent the spread of life-threatening bacterial and viral diseases. In 2009, we were a leader in the fight against the influenza A (H1N1) virus as well as seasonal flu, meningitis and other diseases. Our screening diagnostics help safeguard national blood supplies and ensure patient safety.

CONSUMER HEALTH

Novartis creates and markets a range of innovative products for empowered consumers. OTC (over-the-counter) treatments enable self-medication for common illnesses and conditions. Animal Health provides a range of products to care for pets and livestock. CIBA Vision provides contact lenses and lens care products.

LONG-TERM STRATEGIC INITIATIVES TO CREATE SUSTAINABLE GROWTH

Selectively strengthen portfolio Our businesses have excellent growth prospects. We constantly evaluate internal and external opportunities to improve their competitiveness and better position Novartis for success.

Step up innovation Focusing on unmet medical need inspires us to connect science with customer insights to develop new products. Novartis is reaping the benefits of long-term investments in innovation, achieving more than 30 major regulatory approvals in 2009.

Expand in high-growth markets We are growing in the developed markets of North America, Europe and Japan. At the same time, we are investing to capture attractive growth opportunities in the top emerging markets of Brazil, China, Russia, India, South Korea and Turkey.

Improve organizational efficiency Productivity is an ongoing process. We continuously seek to deliver the highest-quality results even faster, while also freeing up resources for investments in innovation and business expansion.

Sustain our performance-oriented culture We are proud of our inspiring and challenging work environment. We reward those who invest their talent and ideas to create value for patients and customers.

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HEALTHCARE PORTFOLIO OVERVIEW

NET SALES BY DIVISION
(Index: 2004 = 100%; Vaccines and Diagnostics since 2006 acquisition)

CORE (1) OPERATING INCOME BY DIVISION
(Index: 2004 = 100%; Vaccines and Diagnostics since 2006 acquisition)

2009 NET SALES BY DIVISION
(% and in USD millions)

2009 CORE (1) OPERATING INCOME BY DIVISION
(% and in USD millions)

2009 NET SALES BY REGION

(% and in USD millions)

(1) Core operating income eliminates the impact of acquisition-related factors and other significant exceptional items. These adjustments are explained in detail on page 151.

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EMERGING MARKETS

The Novartis Pharmaceuticals Division achieved robust growth during 2009 in six key emerging markets - China, Russia, Turkey, South Korea, Brazil and India. This dynamic performance reflected aggressive investments to step up research and development, as well as marketing and sales, in these emerging countries. An increasing number of collaborations with institutions in China and other key emerging countries is enabling Novartis to share both experience in drug discovery and the Group s world-leading development technology platform.

In November 2009, Daniel Vasella, M.D., Chairman and Chief Executive Officer of Novartis, announced plans to invest USD 1 billion over the next five years to step up research and development activities in China and significantly expand the existing China Novartis Institutes for BioMedical Research (CNIBR) in Shanghai.

We are confident that our expanded investment in research and development will result in innovative therapies for patients in China and other countries, nurtured by the growing scientific excellence in China, Dr. Vasella said. The Shanghai center was founded in 2006, and specializes in basic research and development of new drugs to treat diseases that are highly prevalent in China, including infectious causes of cancer and liver diseases.

CNIBR is expected to become the largest comprehensive research and development center in China, with a staff of about 1 000 people, an increase from 160 people today. The institute will extend its collaborations with institutions in China, sharing both the drug development experience and the development technology platform of Novartis.

Novartis has invested more than USD 250 million in a new global technical center in Changshu, China, focused on technical research, development and manufacture of active pharmaceutical ingredients. The center is expected to be a critical part of the Novartis global production and supply chain network.

YOUNGER PORTFOLIO

In addition, Novartis agreed to pay the equivalent of USD 125 million for 85% of Zhejiang Tianyuan Bio-Pharmaceutical Co., a privately owned Chinese vaccines company that has grown dynamically in recent years. The acquisition is part of a strategic initiative by Novartis to enhance the prevention of diseases and build a leading vaccines business in China. Tianyuan offers a range of marketed vaccine products and focuses research and development activities on viral and bacterial diseases.

Novartis broke ground on a new vaccines plant in Brazil late last year, yet another example of continued investment in global vaccines infrastructure and pipeline. The new plant, located in Pernambuco state, represents an investment of up to USD 500 million and is expected to be fully operational by the end of 2014.

In 2009, Dr. Vasella also concluded an agreement with the government of South Korea, broadening the program of clinical trials to be conducted locally by Novartis as well as venture capital investments in the country s fledgling biotechnology industry. We are no longer just a drug company in South Korea. We are an investor committed to innovation and the long-term development of a national biotechnology industry, said Peter Jager, Head of the Novartis Country Organization in South Korea.

The flurry of activity underscores dynamic growth by Novartis in six key emerging

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markets: Brazil, China, India, Russia, South Korea and Turkey. Net sales in these six countries rose 19%, to USD 2.6 billion, in 2009, representing about 8.9% of net sales by the flagship Pharmaceuticals Division. As a result of aggressive investments in these markets, that proportion is expected to double, to more than 20% of the division s net sales, by 2012.

In emerging countries, just as in developed markets, Novartis benefits from a younger product portfolio than rival pharmaceutical companies. Growth in emerging markets is driven by innovative medicines that provide value for patients and payors compared with older, mature products facing competition from generics.

We definitely have a younger portfolio in emerging markets, said Joe Jimenez, Head of the Pharmaceuticals Division and member of the Executive Committee of Novartis. For example, *Galvus* is already successful in some key emerging markets and Novartis is rolling out other new products launched in recent years.

In the long run, the pharmaceutical industry is about innovation, Mr. Jimenez added. Our research and development investment is at the high end of the industry, and we expect that to continue, to create a best-in-class pipeline over the next five years. We are not backing off that commitment to innovation one bit and that goes for our emerging-market strategy as well.

A common thread underlying Novartis strategy in emerging markets is expansion of local sales forces. These are open markets where the physician has a high level of autonomy to prescribe, Mr. Jimenez added. So you are going to see us invest in additional sales representatives in those countries.

While Novartis has extensive local manufacturing in Turkey and Brazil - as well as fledgling production facilities in China - broadening local production in emerging markets is another strategic priority. We re looking for ways to move production to China, South Korea and Russia to lower our cost structure further, Mr. Jimenez said.

At the same time, the Consumer Health Division also sees potential for significant growth in China, which is the world s second largest market for veterinary products. Novartis Animal Health has posted compound annual net sales growth approaching 20% in China over the past five years. That success has been based on a strategy focusing primarily on pig production. Key customer groups include both the most modern, integrated pig production companies in China, as well as specialized household farms, usually run by individual families, that comprise by far the biggest share of the market.

Expansion of the sales force has helped the Animal Health organization in China almost double sales over the past four years, and steadily increase market penetration of *Denagard*, an anti-infective from Novartis used by pig farmers. In the next phase of expansion, Novartis Animal Health is expected to step up ongoing efforts to broaden the product portfolio available to Chinese customers, and to expand sales force optimization programs.

MANAGING VOLATILITY

According to IMS Health, a consulting firm specializing in the pharmaceutical industry, the top seven emerging markets worldwide are expected to grow at an average rate of between 13% and 16% in the next five years.(1) That forecast is in sharp contrast to the historically sluggish average annual growth of 4% to 7% projected for worldwide pharmaceutical sales in the same period.

China stands in a class by itself. IMS Health forecasts that average annual growth of China s pharmaceutical market will exceed 20% over the next five years. Net sales growth in China for the Novartis Pharmaceuticals Division accelerated sharply, to more than 30% in 2009, from 15% two years earlier.

The other priority emerging markets comprise a heterogeneous group, subject to volatile shifts in economic conditions and healthcare policies. In Turkey, for example, the rate of net sales growth accelerated in 2009 to 19%, from 7% in 2007, enabling Novartis to gain market share. But a severe program of cost-containment measures in Turkey, triggered by the economic recession, is expected to cause a steep decline of both the overall pharmaceutical market as well as net sales by Novartis in 2010.

South Korea s economy also declined during 2009 but is expected to return to growth this year. The overall pharmaceutical market is expected to expand at high-single-digit rates but Novartis expects sales growth to exceed 20% in 2010.

Clearly, managing volatility is a critical success factor in emerging countries. To capture opportunities and handle risks, you have to be extremely flexible and quick because conditions can change virtually overnight, said Guldem Berkman, Head of the Novartis Country Organization in Turkey.

CHINA: HEALTHCARE REFORM

China is unique both in terms of the sheer potential of its pharmaceutical market and the exceptional rate of growth likely to be sustained over many years. Given the level of industrialization and urbanization in China today, there is still a long way to go, said Emmanuel Puginier, M.D., Chairman Greater China Region for Novartis.

A primary objective of the sweeping healthcare reform program announced by the Chinese government is to increase coverage, particularly in rural areas. The government s goal is to have 90% of China s population covered by health insurance by 2011. At the same time, China plans to strengthen and expand the primary care system by building or refurbishing tens of

(1) The seven emerging countries tracked by IMS Health are Brazil, China, India, Mexico, Russia, South Korea and Turkey.

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thousands of community health centers around the country.

Shoring up primary care is a priority because too many patients currently access China s healthcare system through large university hospitals, leading to bottlenecks and care that is unnecessarily expensive. The government believes a progressive shift of focus from university hospitals to community health centers will help to alleviate bottlenecks. But this isn t something that can be done overnight. It will be complex to implement, and a series of pilot programs in different provinces over the next three to five years will test how best to implement the government s high-level vision for health-care, Dr. Puginier cautioned.

There is a difference between China and other emerging countries in the sophistication of policymaking and discipline of execution, he added. Strategic investment by the government in education and infrastructure puts China in a completely different league. And the greater visibility and predictability allow us to deploy a strategy with a longer time horizon and greater confidence that investments will yield the expected return.

NEW OPPORTUNITIES

Novartis is working with these pilot programs to take advantage of new opportunities in China. The Novartis sales force has grown rapidly - driven in part by geographical expansion as health insurance coverage improves for China s inland provinces. A customer-centric commercial model will help Novartis target the unique needs of community health centers.

The Novartis portfolio has also widened as a result of recent reimbursement decisions by health authorities. In November 2009, the Ministry of Human Resources and Social Security released the first update of the National Reimbursement Drug List since 2004. Several Novartis medicines including *Aclasta*, *Comtan*, *Exelon*, *Myfortic*, *Sebivo* and *Trileptal* were granted reimbursement. This was a very important milestone that will fuel our growth until the next update of the reimbursement list, expected in 2012, Dr. Puginier said.

Meanwhile buildup of the primary care network in China, including new community health centers, will engender entire classes of new customers best served by key account teams. Key account management is an increasingly important global trend. Cross-functional key account teams from Novartis - reinforced with specialist medical and health economic expertise - offer a convenient, single point of contact for senior executives, medical directors and procurement specialists at payor organizations who wield increasing influence over the medicines patients ultimately receive.

It s interesting to see that the global capabilities we are developing for more mature markets are also relevant for China in the context of healthcare reform, Dr. Puginier mused.

Clinical development is another function heading for an overhaul. Development activities by Novartis in China traditionally have been dominated by studies needed to meet specific Chinese regulatory requirements after global development of a new medicine was already completed. As a result, new Novartis medicines have received approval in China up to six years later than initial approval in the United States or Europe.

That is changing, and China is rapidly becoming an integral part of global development programs. When we think about the profile of a new compound, we need to ensure that we incorporate input from China - from patients, the medical community and key customers - with similar input from the United States, Europe and Japan, Dr. Puginier said. Starting from Phase II,

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there will be a cohort of patients from China in all future global development activities so that we no longer need to do China-specific studies at the very tail end of the process.

TURKEY: DEMOGRAPHICS AND HEALTHCARE REFORM

Positive demographic trends and steady expansion of state health insurance coverage have fueled sustained, double-digit growth of pharmaceutical sales in Turkey in recent years. Since 2004, the number of people covered under government health-care insurance has increased to 60 million from 43 million. The improved coverage has been particularly significant in rural areas. Access to physicians and hospitals has also broadened for people covered under state health insurance, a break with the past when access to major hospitals was tightly restricted.

Novartis has expanded its General Medicines field force beyond urban centers to rural regions. At the same time, additional Novartis medicines have reached the market, despite increasingly stringent standards for regulatory approval and reimbursement. During the past two years, *Exforge*, *Xolair* and *Tobi* were approved and received reimbursement, and *Lucentis* was launched in January 2009, said Ms. Berkman, the Novartis Country Head in Turkey.

That period of steady growth will be interrupted in 2010. Cost containment measures imposed by the Turkish government are expected to diminish the overall market by USD 2.5 billion, leading to a projected decline of nearly 20% for the Turkish pharmaceutical market in 2010. The measures clearly will delay launches of new medicines and also could exacerbate unemployment already running at a rate of 15%, said Ms. Berkman, who has played a key role in negotiations with the government as co-chair of Turkey s national pharmaceutical industry association.

SOUTH KOREA: INCREASING VISIBILITY

In South Korea, aggressive investment programs and savvy partnerships in marketing, as well as research and development, underpinned a rapid acceleration of net sales growth in 2009. At the same time, however, market access is a major challenge in South Korea.

Harsh pricing and reimbursement regulations introduced in 2007 have slowed approvals of medicines by international companies to a trickle. Novartis has received approvals for *Exforge*, *Galvus*, *Exelon* Patch and *Lucentis* since the new rules took effect. *Sebivo*, a treatment for hepatitis B, was rejected twice by South Korean authorities but was finally approved, much delayed, in November 2009. Reimbursement applications are pending for *Xolair*, *Aclasta* and *Rasilez*, and discussions with the government are ongoing.

In addition to adding new sales representatives, Mr. Jager has stepped up investment in prelaunch activities for the new medicines to accelerate uptake following launch. When you introduce three to five new products in the same year the risk is that you dilute the investment behind each brand, he said.

Moreover, Novartis has established integrated account teams that represent a single, integrated interface with major customers. Key account management not only increases the visibility of Novartis, Mr. Jager added. We are achieving faster product listings, and see better return on our investments as a result of improved alignment of commercial and medical activities across business units and divisions. In the end, it s all about maximizing customer focus and becoming more patient-centric as an organization.

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PHARMACEUTICALS OVERVIEW

KEY FIGURES

(In USD millions, unless indicated otherwise)

	2009	2008
Net sales	**28 538**	26 331
Operating income	**8 392**	7 579
Return on net sales (%)	**29.4**	28.8
Core operating income (1)	**9 068**	8 249
Return on core net sales (%) (2)	**31.8**	31.5
Research & Development	**5 840**	5 716
As % of net sales	**20.5**	21.7
Free cash flow	**9 170**	7 679
Net operating assets	**14 519**	14 812
Additions to property, plant & equipment (3)	**922**	1 115
Number of associates (FTE) (4) at year-end	**56 310**	53 632

(1) Core operating income eliminates the impact of acquisition-related factors and other significant exceptional items. These adjustments are explained in detail on page 151.
(2) In 2008 based on core sales of USD 26 227 million
(3) Excluding impact of business combinations
(4) Full-time equivalent positions at year-end

PORTFOLIO REJUVENATION

(% and total net sales in USD millions)

NEWS IN 2009

Dynamic underlying performance as the rapid growth of recently launched products transforms the portfolio and underpins double-digit expansion in all regions and therapeutic franchises.

Net sales rise 8% (+12% in local currencies) to USD 28.5 billion. Europe, the largest region, delivers solid performance, with improved results achieved in Japan, Latin America and Canada. The US returns to solid growth on the strength of new product launches.

Core operating income grows 10% to USD 9.1 billion on volume growth and productivity gains that support product launches and geographic expansion. Investments in R&D pipeline include the start of 14 Phase III trials in 2009. Core operating income margin improves to 31.8% of net sales from 31.5% in 2008.

Recently launched products (USD 4.7 billion, +81% lc) provide 16% of net sales, up from 10% in 2008. Key growth drivers among products launched since 2007 include *Lucentis*, *Exforge*, *Exjade*, *Exelon* Patch, *Reclast/Aclasta*, *Tekturna/Rasilez*, *Afinitor* and *Ilaris*.

Oncology (USD 9.0 billion, +14% lc) is the largest therapeutic franchise with 32% of net sales and four top-selling products, led by *Gleevec/Glivec* (USD 3.9 billion). Cardiovascular and Metabolism (USD 8.8 billion, +9% lc) builds on global leadership of *Diovan* (USD 6.0 billion) and momentum of new high blood pressure medicines *Exforge* and *Tekturna/Rasilez*.

Development pipeline achieves many positive regulatory decisions. *Afinitor* gains US and European approvals for kidney cancer, trials are underway in other cancers. *Onbrez Breezhaler* (chronic obstructive pulmonary disease) is approved in Europe and quickly launched in Germany. Other approvals include *Ilaris* (CAPS) and high blood pressure combination therapies *Valturna*, *Exforge* HCT and *Tekturna* HCT. FTY720 (multiple sclerosis) is submitted for US and European regulatory approvals.

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PIPELINE

Novartis is consistently rated as having one of the industry s most respected pipelines with 145 projects in clinical development. Several of these pharmaceutical projects, which include potential uses of new molecular entities as well as additional indications or new formulations for marketed products, are for potentially best-in-class medicines that would advance treatment standards.

The following table provides an overview of selected pharmaceutical projects.

Project/compound	Common name	Mechanism of action
ABF656	albinterferon alfa 2-b	Interferon alpha-type activity (direct antiviral and immunomodulatory)
ACZ885	canakinumab	Anti-interleukin-1ß monoclonal antibody
AEB071	sotrastaurin	Protein kinase C inhibitor
AFQ056		Metabotropic glutamate receptor 5 antagonist
AGO178	agomelatine	MT1/MT2(4) agonist and 5-HT2c(5) antagonist
AIN457		Anti-interleukin-17 monoclonal antibody
ASA404	vadimezan	Tumor vascular disrupting agent
Certican/Zortress	everolimus	Growth-factor-induced cell proliferation inhibitor
Diovan/Starlix NAVIGATOR	valsartan, nateglinide	Angiotensin II receptor antagonist and insulin secretagogue
EPO906	patupilone	Microtubule depolymerization inhibitor
FTY720	fingolimod	Sphingosine-1-phosphate receptor modulator
LBH589	panobinostat	Histone deacetylase inhibitor
LCI699		Aldosterone synthase inhibitor
LCZ696		Dual angiotensin II receptor antagonist and neutral endopeptidase inhibitor
Lucentis	ranibizumab	Anti-VEGF(6) monoclonal antibody fragment
Mycograb	efungumab	Antibody fragment vs. fungal HSP90(7)
NIC002		Nicotine Qbeta therapeutic vaccine
NVA237	glycopyrronium bromide	Long-acting muscarinic antagonist
PKC412	midostaurin	Signal transduction inhibitor
PRT128	elinogrel	P2Y12 inhibitor
PTK796		Inhibition of bacterial protein synthesis
PTZ601		Inhibition of bacterial cell wall synthesis
QAB149	indacaterol	Long-acting beta-2 agonist
QAX028		Long-acting muscarinic antagonist

(1) Refers to planned submission date for lead indication only

(2) Refers to current phase for lead indication only

(3) US submission done by Human Genome Sciences, Inc. (HGS)

(4) Melatonin receptor subtypes 1 and 2

(5) Serotonin receptor subtype 2c

(6) Vascular endothelial growth factor

(7) Heat shock protein 90

continued on next page

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Project/compound	Indication	Therapeutic area	Formulation	Planned submission dates (1)	Current phase (2)
ABF656	Chronic hepatitis C	Immunology and Infectious Diseases	Injection	Submitted EU, US (3)	Registration
ACZ885	Refractory gout (lead indication), systemic onset juvenile idiopathic arthritis, type 2 diabetes	Immunology and Infectious Diseases, Cardiovascular and Metabolism	Injection	2010	III
AEB071	Prevention of organ rejection	Immunology and Infectious Diseases	Oral	≥2013	II
AFQ056	L-dopa induced dyskinesia in Parkinson s disease	Neuroscience and Ophthalmics	Oral	2012	II
AGO178	Major depressive disorder	Neuroscience and Ophthalmics	Oro-dispersible	2012	III
AIN457	Uveitis (lead indication), psoriasis, rheumatoid arthritis	Neuroscience and Ophthalmics, Immunology and Infectious Diseases	Subcutaneous, Intravenous injection	2011	III
ASA404	Non-small cell lung cancer	Oncology	Intravenous infusion	2011	III
Certican/Zortress	Prevention of organ rejection	Immunology and Infectious Diseases	Oral	Submitted US (approved EU)	Registration
Diovan/Starlix NAVIGATOR	Prevention of new-onset type 2 diabetes, cardiovascular morbidity and mortality	Cardiovascular and Metabolism	Oral	2010	III
EPO906	Ovarian cancer	Oncology	Intravenous infusion	2010	III
FTY720	Multiple sclerosis	Neuroscience and Ophthalmics	Oral	Submitted US, EU	Registration
LBH589	Hodgkin s lymphoma (lead indication), multiple myeloma	Oncology	Oral	2010	II
LCI699	Heart failure	Cardiovascular and Metabolism	Intravenous infusion	≥2013	II
LCZ696	Heart failure	Cardiovascular and Metabolism	Oral	≥2013	III
Lucentis	Diabetic macular edema (lead indication), Retinal vein occlusion	Neuroscience and Ophthalmics	Intravitreal injection	Submitted EU	Registration
Mycograb	Invasive candidiasis	Immunology and Infectious Diseases	Intravenous infusion	≥2013	III
NIC002	Smoking cessation	Respiratory	Injection	≥2013	II
NVA237	Chronic obstructive pulmonary disease	Respiratory	Inhalation	2011	III
PKC412	Aggressive systemic mastocytosis (lead indication), acute myeloid leukemia	Oncology	Oral	2011	II
PRT128			IV, Oral	≥2013	II

	Acute coronary syndrome /Chronic coronary heart disease	Cardiovascular and Metabolism			
PTK796	Complicated skin and subcutaneous tissue infections	Immunology and Infectious Diseases	IV, Oral	2012	III
PTZ601	Staphylococcal skin and subcutaneous tissue infections /hospital-acquired bacterial infections such as pneumonia	Immunology and Infectious Diseases	Intravenous infusion	2012	II
QAB149	Chronic obstructive pulmonary disease	Respiratory	Inhalation	Submitted US (approved EU)	Registration
QAX028	Chronic obstructive pulmonary disease	Respiratory	Inhalation	≥2013	II

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GLOSSARY

Project /Compound Novartis brand name for marketed products (*in italics*) or project reference code (combination of three letters and three numbers) for compounds, that are individual molecular entities.

Common name The official International Non-proprietary Name (INN) for an individual molecular entity as designated by the World Health Organization (WHO).

Indication A disease or condition for which a compound or marketed product is in development and studied as a potential therapy.

Mechanism of action Specific biochemical interaction through which a drug substance produces its pharmacological effect.

Formulation The way in which a medicine is administered, such as via tablet, injection, skin patch, infusion or device.

Phase I First stage of testing in humans, which includes Proof-of- Concept trials conducted on a small group of homogenous patients to provide early insight into efficacy, safety and toxicity of a molecule in a given indication

Phase II Following successful Proof-of-Concept results, confirmatory trials are performed in larger patient groups to further assess the efficacy and safety of how well a compound works, including at various doses and in various indications.

Phase III Final clinical trials before regulatory submissions to test a compound against a placebo or another medicine to determine definitive efficacy and safety in patients.

Submitted Comprehensive data provided to various regulatory agencies for marketing approval.

Project/compound	Common name	Mechanism of action
QMF149	indacaterol, mometasone furoate	Long acting beta-2 agonist and corticosteroid
QTI571 *(Glivec)*	imatinib	Signal transduction inhibitor
QVA149	indacaterol, glycopyrronium bromide	Long-acting beta-2 agonist and long-acting muscarinic antagonist
RAD001 (*Afinitor*)	everolimus	mTOR (8) inhibitor

SBR759		Calcium-free polymeric iron (III)-based phosphate binder
SMC021	salmon calcitonin	Regulator of calcium homeostasis, inhibition of osteoclast activity
SOM230	pasireotide	Somatostatin analogue
Tasigna	nilotinib	Signal transduction inhibitor
Tekturna SPC (9)	aliskiren, amlodipine, hydrochlorothiazide	Direct renin inhibitor, calcium channel blocker and diuretic
Tekturna ASPIRE HIGHER trials	aliskiren	Direct renin inhibitor
TKI258	dovitinib lactate	VEGFR1-3, FGFR 1-3, PDGFR and angiogenesis RTK inhibitor
Xolair	omalizumab	Anti-IgE monoclonal antibody
Valturna/Rasival SPC	aliskiren, valsartan	Direct renin inhibitor and angiotensin II recpetor antagonist
Zometa	zoledronic acid	Osteoclast inhibitor

(8) Mammalian target of rapamycin protein

(9) Single-pill combination

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Project/compound	Indication	Therapeutic area	Formulation	Planned submission dates (1)	Current phase (2)
QMF149	Asthma, chronic obstructive pulmonary disease	Respiratory	Inhalation	≥2013	II
QTI571 *(Glivec)*	Pulmonary arterial hypertension	Respiratory	Oral	2011	III
QVA149	Chronic obstructive pulmonary disease	Respiratory	Inhalation	2012	II
RAD001 (*Afinitor*)	Neuroendocrine tumors (NET) (lead indication), Tuberous sclerosis complex, breast cancer, gastric cancer, Diffuse large B cell lymphoma	Oncology	Oral	2010	III
SBR759	Hyperphosphatemia	Immunology and Infectious Diseases	Powder for Oral suspension	2011	II
SMC021	Osteoarthritis (lead indication), osteoporosis	Immunology and Infectious Diseases	Oral	2011	III
SOM230	Cushing s disease (lead indication), acromegaly, refractory/resistant carcinoid syndrome	Oncology	Injection	2010	III
Tasigna	Newly diagnosed chronic myeloid leukemia (lead indication), First line metastatic gastrointestinal stromal tumor, Metastatic melanoma with c-KIT mutation	Oncology	Oral	Submitted US, EU	Registration
Tekturna SPC (9)	Hypertension	Cardiovascular and Metabolism	Tablet	2010	III
Tekturna ASPIRE HIGHER trials	Renal and cardiovascular events	Cardiovascular and Metabolism	Oral	2010	III
TKI258	Renal cell carcinoma	Oncology	Oral	2012	II
Xolair	Allergic asthma in patients age 6-12	Respiratory	Lyophilised powder for reconstitution as subcutaneous injection	Submitted US (approved EU)	Registration
Valturna/Rasival SPC	Hypertension	Cardiovascular and Metabolism	Tablet	Submitted EU (approved US)	Registration
Zometa	Adjuvant breast cancer	Oncology	Intravenous infusion	Submitted US, EU	Registration

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PHARMACEUTICALS

Rejuvenation of the Pharmaceuticals Division s product portfolio accelerated during 2009. Medicines launched since 2007 generated net sales of USD 4.7 billion, 16% of the division s total net sales. Recently launched products - and innovative medicines approved during 2009 - are expanding options for patients in therapeutic areas in which Novartis already is an industry leader, as well as targeting other diseases with unmet medical need. Moreover, the division s strong, late-stage development pipeline benefited from positive regulatory decisions, underpinning prospects for continued growth.

Recently launched products are transforming the Pharmaceuticals Division and positioning Novartis as one of the industry s fastest growing companies.

Buoyant net sales of medicines launched since 2007 accelerated the ongoing portfolio rejuvenation, accounting for a strong and growing percentage of the division s growth. In 2009, all key therapeutic areas and regions expanded at double-digit rates.

The Pharmaceuticals Division s development pipeline realized excellent progress, with 25 regulatory approvals in the United States, European Union and Japan. Currently 145 projects are in clinical development.

Net sales in the top six emerging markets rose dynamically, with only limited signs to date of adverse impact from global economic conditions. These six markets - Brazil, China, India, Russia, South Korea and Turkey - represented a growing share of the Pharmaceuticals Division s net sales during 2009. (See Emerging Markets story, page 18.)

A rise in the division s operating income reflected dynamic business expansion and productivity gains that enabled significant investments to further bolster growth. Cost reductions not only help to improve profit margins but also ensure that we can continue to invest in research and development, as well as emerging growth markets, while showing good operating income progression, said Joe Jimenez, Head of the Pharmaceuticals Division and member of the Executive Committee of Novartis.

The fundamentals are strong, with multiple growth drivers, not one silver bullet, Mr. Jimenez added. These results underscore our solid foundation and robust growth as we approach a period during which we will lose sales due to the loss of patent protection on *Diovan* and other significant products.

RECENT LAUNCHES

Recently launched medicines fueled strong net sales growth by the Cardiovascular and Metabolism therapeutic franchise. *Tekturna/ Rasilez*, the first new class of high blood pressure medicine in more than a decade, is growing consistently.

Regulatory authorities in the United States and European Union have also approved single-pill combinations including aliskiren, the common name for *Tekturna/Rasilez*.

Galvus and *Eucreas*, oral treatments for type 2 diabetes, have been expanding rapidly in many European, Latin American and Asia-Pacific markets. Launched in 2008, *Galvus* is approved in 69 countries. *Eucreas*, a single-pill combination with the oral antidiabetes medicine metformin, is available in 50 countries.

Net sales rose at Novartis Oncology, the largest therapeutic franchise, fueled by double-digit growth of *Gleevec/Glivec*, a pioneering targeted treatment for chronic myeloid leukemia (CML) and other types of tumors. Expanding the CML franchise,

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Novartis has launched *Tasigna*, a therapy for patients who are resistant or intolerant to prior treatment including *Gleevec/Glivec*. The Oncology Business Unit was further strengthened by approvals in the United States and European Union of *Afinitor*, for use in treatment of patients with advanced renal cell carcinoma whose disease progressed on or after treatment with VEGF-targeted therapy.(1)

Other successful products include *Lucentis*, a biologic eye therapy that delivered robust performances in France, the United Kingdom, Australia and Japan. Approved in more than 80 countries, *Lucentis* is the only treatment proven to maintain and improve vision in patients with the wet form of age-related macular degeneration, a leading cause of blindness in people over 50. (Genentech holds the US rights to *Lucentis*.)

Exelon/Exelon Patch, a therapy for mild to moderate forms of Alzheimer s disease as well as mild to moderate dementia associated with Parkinson s disease, also grew strongly in 2009. More than half of net sales come from *Exelon* Patch, the novel skin patch launched in late 2007 and now available in more than 50 countries worldwide.

In Japan, the world s second-largest pharmaceuticals market, Novartis received approval for six new medicines during 2009, including *Rasilez* within the cardiovascular portfolio; *Tasigna* in oncology; *Lucentis;* and *Xolair*, a biologic treatment for severe persistent bronchial asthma. Regulatory applications are also pending for *Exforge* and *Galvus,* and approvals are expected to underpin momentum in the Japanese market.

These launches are really helping us to jump-start growth in Japan, Mr. Jimenez said.

(1) Vascular endothelial growth factor

DRIVING REJUVENATION

Medicines to treat cardiovascular disease and cancer epitomize the way innovation is driving rejuvenation of the Pharmaceuticals Division s portfolio.

Tekturna/Rasilez was approved during 2007 in both the United States and the European Union, and received approval from Japanese regulatory authorities in 2009 for treatment of high blood pressure, alone or in combination with other medicines. Regulatory agencies in the United States and the European Union also approved *Tekturna* HCT, a single-pill combination of aliskiren and the diuretic hydrochlorothiazide, one of the commonly used high blood pressure medications.

The US Food and Drug Administration, which had approved *Tekturna* HCT, broadened its indication last year to include initial therapy for patients likely to need multiple drugs to achieve their blood pressure goals. Other single pills with aliskiren are currently under development.

Novartis submitted the combination of aliskiren and amlodipine to regulatory authorities for approval in 2009. A calcium channel blocker, amlodipine is one of the world s leading high blood pressure medicines.

Combinations are important to help patients improve adherence to treatment of hypertension. Up to 65% of patients with high blood pressure do not have their condition under control and, if left untreated, hypertension increases the risk of stroke, heart attack and heart failure.

The majority of people with hypertension require more than one medication to control their blood pressure, said David Calhoun, M.D., Professor of Medicine, Vascular Biology and Hypertension Program, at the University of Alabama.

During 2009, the FDA also approved *Valturna*, a single-pill combination of aliskiren

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and valsartan, the active ingredient in *Diovan*. Along with the convenience of a single pill, *Valturna* offers significantly greater blood pressure reduction than either valsartan or aliskiren alone.

Further evidence of the commitment of Novartis to hypertension and *Tekturna/Rasilez* is the ASPIRE HIGHER clinical trial program, a cardio-renal outcomes program involving more than 35 000 patients in 14 clinical trials. The ASPIRE HIGHER program is studying the potential protective effects of direct renin inhibition in a variety of kidney and heart diseases, including diabetic kidney disease and heart failure.

STRIKING RESULTS

The development and launch of *Tasigna* represents an important advance for patients resistant or intolerant to *Gleevec/Glivec*. *Tasigna* drives home our commitment to develop compounds to fulfill unmet medical need by pursuing indications for patients with limited treatment options, said David Epstein, Head of Novartis Oncology and permanent attendee of the Executive Committee of Novartis.

Initial approvals of *Tasigna* were for treatment of patients with CML who failed to respond or were intolerant of *Gleevec/ Glivec*. Combined net sales of *Gleevec/Glivec* and *Tasigna* account for more than 90% of worldwide sales for treatments against CML.

Tasigna was designed to target Bcr-Abl more preferentially and potently than *Gleevec/Glivec*. Bcr-Abl is an aberrant protein, encoded by a defective gene, that drives uncontrolled proliferation of white blood cells, causing CML,

Results of the first key head-to-head comparison - a international study in newly diagnosed CML patients - showed *Tasigna* produced faster and deeper responses than *Gleevec/Glivec,* and was well tolerated. The results are striking, Mr. Epstein said.

We now know *Tasigna* reduces the level of Bcr-Abl faster and to a lower level than *Gleevec/Glivec* with profound implications for improving patients outcomes.

The study was the first to use molecular traces of key biomarkers specific to CML as a primary endpoint. Molecular monitoring enables clinicians to monitor residual disease that older methods cannot detect, Mr. Epstein added. A regulatory application for *Tasigna* was submitted to US authorities ahead of plan at the end of 2009.

The ability to identify biomarkers that can be used to select patients likely to respond to specific treatments represents an important step toward customized medicine. Another Phase III study with *Tasigna*, expected to begin in early 2010, will use a diagnostic test to select melanoma patients with a mutated form of the aberrant protein c-Kit who are considered most likely to respond to treatment. It s a form of cancer with huge unmet need, Mr. Epstein said.

The need to find surrogate endpoints and biomarkers has been well established in oncology, and Novartis has built a broad biomarker discovery program in recent years. We have biomarker discovery programs under way for the majority of medicines that we have in the clinic, Mr. Epstein said.

DEVELOPMENT MILESTONES

Important development milestones during 2009 included approval by regulators in the United States and the European Union of the anticancer medicine *Afinitor* (also known by the research number RAD001) as well as *Ilaris* (known by the research number ACZ885). *Ilaris* was approved for treatment of cryopyrin-associated periodic syndrome, or CAPS, a lifelong auto-inflammatory disease with debilitating symptoms and few treatment options.

RAD001 and ACZ885 exemplify another key Novartis strategy: exploring multiple disease indications. In addition to the initial approvals for treatment of patients with advanced renal cell carcinoma whose disease progressed on or after standard therapy, RAD001 is being studied in multiple cancer types, including neuroendocrine, breast and gastric carcinoma. Moreover, the active ingredient in *Afinitor*, known by the common name everolimus, was approved by the European Union in 2003 for the prevention of organ rejections in heart and kidney transplants, and is available in different dosage strengths outside the United States under the trademark *Certican*.

In the United States, everolimus is in registration for the prevention of organ rejection in kidney transplantation, under the brand name *Zortress*. The FDA issued a Complete Response letter in December 2009 requesting additional changes to proposed labeling and the proposed Risk Evaluations and Mitigations Strategies (REMS) for *Zortress*, as well as a safety update. But the FDA did not request additional clinical studies. Novartis will work with the FDA to address all additional issues to finalize FDA s review of the product. In 2008, Phase III development of everolimus was initiated worldwide for the prevention of organ rejection in liver transplantation.

ACZ885 is a fully human monoclonal antibody that blocks the action of the inflammatory protein interleukin-1 beta (IL-1 beta). Studies with ACZ885 are ongoing in other diseases in which IL-1 beta is believed to play an important role, from hard-to-treat gout, one of the most painful forms of arthritis, to systemic juvenile idiopathic arthritis (SJIA) and type 2 diabetes. Results from a Phase II study last year showed ACZ885 is significantly more effective than an injectable corticosteroid in reducing pain and preventing recurrent attacks, or flares, of chronic gout. Injectable corticosteroids have traditionally been given to

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hard-to-treat patients as a last resort against acute pain. Injectable corticosteroids are not appropriate for all patients, however.

Current treatments address symptoms of acute gout flares and do not achieve sustained suppression of inflammation or prevent recurrent flares. Phase III studies with ACZ885 in chronic gout began in both the United States and Europe during 2009. Phase III studies are also under way in SJIA, the most severe form of arthritis in children. ACZ885 has been designated as an orphan drug for treatment of SJIA in the United States, the European Union and Switzerland.

EMERGING RESPIRATORY PORTFOLIO

In December, the European Union approved *Onbrez Breezhaler*, a new once-daily maintenance bronchodilator treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD).

Also known by the research number QAB149, *Onbrez Breezhaler* is the first new inhaled compound for the treatment of COPD to be made available to EU patients in seven years. QAB149 was also filed with the FDA in late 2008. In October 2009, Novartis received a complete response letter in which the FDA requested additional information on the dosing proposed, which Novartis is working to address.

COPD is a progressive, life-threatening respiratory disease that impairs lung function, resulting in chronic breathlessness. COPD affects 210 million people worldwide and currently ranks 10th in overall disease burden, ahead of asthma and diabetes.

While incurable, COPD can be managed and improving airflow with the use of long-acting bronchodilators is central to symptomatic relief. Regulatory submissions by Novartis were supported by data from clinical studies involving more than 4 000 patients in 30 countries. Data on all evaluated doses of QAB149 show a good overall safety and tolerability profile. The most common adverse drug reactions - inflammation of the nasal passages, cough, upper respiratory tract infection and headache - were mild or moderate in the vast majority of cases and became less frequent when treatment was continued.

Improving the management of COPD is a priority focus for Novartis and *Onbrez Breezhaler* is the lead compound in an expected once-daily portfolio for treatment of this growing public health issue. Three other COPD treatments from Novartis are currently undergoing clinical testing as monotherapies - and as components in potential combination therapies.

TRANSFORMING TREATMENT OF MULTIPLE SCLEROSIS

Novartis also cleared key hurdles during 2009 for its emerging franchise in the treatment of multiple sclerosis. In August, the FDA approved *Extavia*, a new Novartis branded version of interferon beta-1b, the standard of care for relapsing forms of multiple sclerosis. Novartis gained approval for its own branded version of interferon beta-1b through agreements with Bayer Schering AG. Also available in Europe, *Extavia* is the

first in a new portfolio of medicines expected from Novartis to help patients manage this devastating disease.

Novartis also submitted regulatory applications in the United States and Europe for FTY720, a medicine with the potential to be the first multiple sclerosis treatment in a new class known as sphingosine 1-phosphate receptor modulators that act on inflammation and may have a direct beneficial effect on cells in the central nervous system.

Initial results from the two-year Phase III FREEDOMS study show that FTY720, known by the common name fingolimod, was significantly superior to placebo in reducing both relapses and disability progression in patients with relapsing-remitting multiple sclerosis. The results from FREEDOMS build

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on TRANSFORMS, a one-year Phase III study showing FTY720 at the 0.5 milligram dose reduced relapses by 52% compared with interferon beta-1a. FTY720 has a well-studied safety profile in clinical trials representing more than 5 300 patient years of exposure - including some patients now in their sixth year of treatment.

We are proud to have reached this critical milestone in the development of FTY720, a novel oral therapy that has the potential to transform the treatment of this ultimately disabling disease, said Trevor Mundel, M.D., Global Head of Development at the Pharmaceuticals Division.

The 0.5 milligram dose of FTY720 offers compelling efficacy on all relevant endpoints compared to both placebo and a standard of care, complemented by extensive safety data.

Multiple sclerosis is a chronic autoimmune disease in which the body s immune system attacks the myelin sheath, a protective tissue surrounding nerve fibers that carry electrical signals to the brain. Destruction of myelin causes problems with muscle control and strength, vision, balance sensation and mental function. Multiple sclerosis affects an estimated 2.5 million patients worldwide and is one of the leading causes of neurological disability in young adults.

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NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH

Nature is deeply conservative, and the same core signaling pathways are used time and time again across species in fundamental cellular processes as well as in the generation of organ systems. Defects in these signaling pathways are the underlying cause of disease, and scientists at the Novartis Institutes for BioMedical Research (NIBR) are racing to unravel pathways as a source of potential targets for drug discovery. Innovative technologies enable NIBR scientists to interrogate pathways in unprecedented ways, and new medicines such as the anticancer treatment *Afinitor* show how pathways are starting to yield to that approach.

Single proteins are the building blocks of life, assembled in core signaling pathways that regulate critical cellular functions and are conserved through evolution from fruit flies to humans in highly reproducible ways. Like the World Wide Web or other signaling networks, these are robust systems, but ones still vulnerable to attack at key nodes.

In the Novartis Institutes for BioMedical Research (NIBR), scientists are seeking ways to understand these pathways and their vulnerable nodes in great enough detail to provide new and proprietary targets for drugs. NIBR scientists have been successful in using this approach to discover treatments for disorders from cancer to degenerative diseases.

A shortage of validated targets remains a major challenge in drug discovery. Although the Human Genome Project was billed as a treasure trove of targets, reality has fallen short of expectations. The problem is that genes are not targets until they re related to a disease, said Mark C. Fishman, M.D., President of NIBR and member of the Executive Committee of Novartis. We don t yet know the function of the majority of human genes, or their role in disease. But we often do know which pathways are activated, especially in cancer.

NIBR s Developmental and Molecular Pathways platform (DMP) focuses on critical signaling pathways that play fundamental roles during embryonic development as well as later, in adult life. Our mission is to find new entry points in pathways that we can modulate to right the imbalance in a disease setting, said Jeffery Porter, Ph.D., Global Head of DMP.

The approval by regulatory agencies in the United States and the European Union of RAD001, also known by the common name everolimus, marks a breakthrough for the pathway-based research strategy. Approved in 2009 for treatment of patients with advanced renal cell carcinoma after failure of treatment with sunitinib or sorafenib, RAD001 works by inhibiting the protein mTOR. This protein is a master switch in cells that controls fundamental processes such as growth and proliferation.

Under the trademark *Certican*, everolimus has been approved as an immunosuppressant to prevent rejection of organ transplants in more than 40 countries outside the United States.(1)

It has taken decades, however, to unravel the complex connections between mTOR and cancer-related pathways. Novartis began parallel development of RAD001 in cancer in 2002.

Today RAD001 has found a place in the clinic for the treatment of patients with advanced renal cell carcinoma and mTOR has become a poster child, illustrating what

(1) For information about the everolimus transplantation regulatory status in the United States see page 31.

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we are trying to achieve on many levels, Dr. Porter said. We aspire to find more key nodes in fundamental signaling pathways like this one.

NEW FIELD OF MEDICINE

Developmental biology has been a critical influence in shaping the vision of drug discovery at NIBR. Dr. Fishman s career was influenced by pioneering experiments in the late 1970s that eventually earned Christiane Nuesslein-Volhard and Eric Wieschaus the 1995 Nobel Prize in medicine. They showed it is possible to understand complicated decisions of development in terms of the way single genes play out, Dr. Fishman explained.

Another seminal insight was that genes always acted in cascades, or pathways. Mutations in several different genes all led to a fruit fly without a wing, for example. Not only could you dissect development in terms of how single genes acted, you could get the same effect by hitting any of several components of a pathway, Dr. Fishman added.

Nature is deeply conservative, and the same fundamental pathways are used time and time again across species in fundamental cellular processes as well as in the generation of organ systems. Moreover, defects in those core signaling pathways are the underlying cause of disease. When I was given the opportunity to come to Novartis, a big part of what I set out to do was to invent a new field of medicine by developing therapeutics around these pathways, Dr. Fishman said.

A comprehensive account of that vision appeared in the scientific journal Nature, in a 2005 article co-authored by Dr. Fishman and Dr. Porter, a blueprint that defined the mission of the DMP group. We attempt to unravel pathways as a source of potential targets for drug discovery and to find pathway modulators new therapeutic entry points that we can exploit to correct a signaling imbalance, Dr. Porter said.

He compared initial stages of pathway mapping to analysis of a satellite photo. We first try to capture all components, and then zero in on key nodes and the ways that pathways are interwoven into networks, Dr. Porter said. To probe the function of potential targets, he added, We might introduce a mutant form of a key component; in effect, taking out a traffic light to see what happens.

Signaling pathways relay essential information about the external environment to a cell. They also transmit decisions about whether to grow or when to divide to key nodes that implement those decisions. There is a high degree of interdependence among pathways, and among components within the same pathway, however.

Backup systems and feedback loops normally compensate when the function of one target node is blocked, so it s really hard to turn a pathway completely off, Dr. Porter said. Sometimes, adjusting the strength of a signal up or down can be a more effective therapeutic approach.

I think of using medicines as dimmers as much as on-off switches, he added.

TRACKING mTOR

The mTOR pathway was one of the first Dr. Porter and his team studied. It took us awhile to appreciate all the places an mTOR inhibitor could be important, Dr. Porter said. Along with immunosuppression and treatment of cancer, RAD001 currently is in Phase III clinical trials for treatment of tuberous sclerosis, a genetic disorder in which tumors form in the brain and kidneys, leading to seizures and mental disabilities.

Normally mTOR is kept under tight control in the cell. But genetic mutations or other biological defects can jam the pathway in the on position, triggering uncontrolled growth and proliferation characteristic of cancer. In recent years, the mTOR program gradually converged with another NIBR

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program focusing on PI3 kinases, a large family of enzymes often linked with cancer.

Importantly, mTOR appears to be a node in the downstream branch of the PI3 kinase pathway. Novartis was the first major pharmaceutical company to develop medicines that target both the upstream and downstream branches of the pathway. Those programs reflect a central tenet of NIBR research: to attack multiple targets within a pathway believed to play a major role in a disease like cancer.

In a paper published last year in the scientific journal Cell, NIBR scientists reported breakthroughs in understanding yet another enigmatic branch of the mTOR pathway. Scientists have known for years that mTOR also is activated by nutrients yet the essential nodes in this nutrient branch of the pathway have remained elusive.

Curiously, while the PI3 kinase branch of the pathway has attracted growing interest in recent years, the nutrient branch of mTOR predates the PI3 kinase branch in evolutionary terms and has important implications for cancer research. Tumor metabolism potential differences in the way tumor cells take up and utilize nutrients versus normal cells is an area of intense research interest today, said Leon Murphy, Ph.D., head of the NIBR laboratory that worked on the nutrient branch of the mTOR pathway.

INTERROGATING THE Wnt PATHWAY

Another pathway of interest to NIBR is the so-called Wnt pathway. Wnt proteins are a large ancient family of signaling molecules and the pathway plays important roles in key developmental processes and possibly even self-renewal of embryonic stem cells and regeneration of many normal tissues. Deregulated activity of the Wnt pathway has been implicated in many cancers, making the pathway an attractive target for anticancer therapies. We ve known for 20 years that the Wnt pathway fires inappropriately in colon cancer because of the loss of a molecular brake on the system, Dr. Porter said.

Development of therapies, however, has been hampered by the limited number of druggable targets components in the Wnt pathway amenable to inhibition by traditional chemical drugs or biologic medicines. In search of new targets, Dr. Porter and his team have discovered more than 100 new proteins associated with the Wnt pathway. Not all of these will be therapeutic targets, but using modern tools we can begin to determine which ones might be critical for signaling, he added.

Two enzymes have emerged as promising targets, offering new avenues for potential therapies acting on the Wnt pathway. Normally, Wnt pathway activity is carefully controlled by cyclical fluctuations in a protein called beta catenin. When the pathway is dormant, beta catenin is held in check by a so-called destruction complex in the cell.

When the pathway is activated, however, the destruction complex is disabled, and levels of beta catenin rise, eventually activating genes that drive cell growth and proliferation. Mutations in a gene called APC also can activate the Wnt pathway, arresting the destruction complex and driving uncontrolled cell proliferation.

Using drugs that inhibit two enzymes known as tankyrase 1 and 2, NIBR scientists have mimicked the normal function of the destruction complex, restoring degradation of beta catenin and blocking the abnormal signaling through the Wnt pathway. Once control of beta catenin is lost, it becomes very important to look at backup systems, Dr. Porter said. By activating the backup system, it may be possible to bring things back into balance.

Initial experiments to inhibit the tankyrase enzymes were done with a so-called tool compound that can demonstrate the potential mechanism of action but lacks properties needed to win regulatory approval. Novartis scientists have optimized a portfolio of tankyrase inhibitors as potential development candidates. It s not limited to cancer, Dr. Porter added. There are other indications where even transient inhibition of the Wnt pathway could provide major benefits for patients.

The experiments that confirmed the role of tankyrase enzymes in the Wnt pathway epitomize the multidisciplinary approach adopted by the DMP group. We use a number of different technologies, the newest of which enable us to interrogate pathways in unprecedented ways, Dr. Porter said. And it s working. The pathways are starting to yield to our approach.

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VACCINES AND DIAGNOSTICS OVERVIEW

KEY FIGURES

(In USD millions, unless indicated otherwise)

	2009	2008
Net sales	**2 424**	1 759
Operating income	**372**	78
Return on net sales (%)	**15.3**	4.4
Core operating income (1)	**719**	309
Return on core net sales (%) (2)	**29.7**	18.1
Research & Development	**508**	360
As a % of net sales	**21.0**	20.5
Free cash flow	**-82**	-226
Net operating assets	**5 583**	4 984
Additions to property, plant & equipment (3)	**437**	435
Number of associates (FTE) (4) at year-end	**5 416**	4 774

(1) Core operating income eliminates the impact of acquisition-related factors and other significant exceptional items. These adjustments are explained in detail on page 151.

(2) In 2008 based on core sales of USD 1 709 million

(3) Excluding impact of business combinations

(4) Full-time equivalent positions at year-end

VACCINES DEVELOPMENT PIPELINE

(1) Neisseria meningitidis bacteria serogroups A, C, W-135 and Y

(2) H5N1 vaccine intended for use before a pandemic outbreak

(3) Neisseria meningitidis bacteria serogroup B

(4) Intercell opt-in candidate

(5) Influenza cell culture

(6) Group B Streptococcus

(7) Cytomegalovirus, collaboration with AlphaVax

NEWS IN 2009

Novartis helps to address public health threat with major investments to rapidly deliver influenza A (H1N1) pandemic vaccines. Strong growth in emerging markets and regulatory approvals for *Ixario* (Japanese encephalitis vaccine) help expand global presence.

Net sales rise 38% (+39% in local currencies) to USD 2.4 billion. A rapid response after the outbreak of the A (H1N1) pandemic in April 2009 enables the delivery of more than 100 million vaccine doses to governments around the world. Pediatric and rabies vaccines and emerging markets help offset price pressure on seasonal influenza vaccines and decline in tick-borne encephalitis vaccines. Core operating income rises to USD 719 million despite significant investments in A (H1N1) vaccines.

Pioneering innovation: Novartis becomes the first company to produce A (H1N1) vaccines with modern cell-culture biotechnology that complements 50-year-old egg-based production. Looking to the future, Novartis opens the first large-scale US-based manufacturing facility for influenza cell-culture vaccines and adjuvants.

Menveo, a novel vaccine to protect against deadly meningococcal disease, progresses toward European regulatory approval, which is anticipated in early 2010 for initial use in adolescents and adults. A US regulatory decision is also expected in the first half of 2010. Trials for use in infants, most at risk for this disease, are underway. Global MenB vaccine, against B serogroup, also continues in clinical trials.

Targeted geographic expansion as Novartis offers its first vaccine in Japan and announces plans to acquire a majority interest in Chinese vaccines supplier Zhejiang Tianyuan.

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VACCINES AND DIAGNOSTICS

Following the declaration of the first influenza pandemic of the 21st century, associates at the Novartis Vaccines and Diagnostics Division surmounted extraordinary challenges to develop and deliver tens of millions of doses of vaccine against the influenza A (H1N1) 2009 virus, as well as seasonal flu vaccine. The pandemic campaign underscored the commitment by Novartis to respond to a worldwide public health challenge.

The virus writes the rules, and this one, like all influenza viruses, can change the rules, without rhyme or reason, at any time, warned Margaret Chan, M.D., Director-General of the World Health Organization, as she declared a pandemic on June 11, 2009. Just the next day, Novartis announced the successful production of the first batch of influenza A (H1N1) vaccine, weeks ahead of expectations, achieving global media coverage and a massive boost to the company s reputation for innovation and leadership.

Earlier in 2009, an influenza virus with pandemic potential had been discovered in Mexico and the United States, sparking a global race to develop a vaccine. Novartis scientists had gone to work immediately, and within days had analyzed the lineage and heritage of the virus, confirming the unique combination of genes in the new strain, known officially as influenza A (H1N1) 2009 virus. Working around the clock, Novartis scientists combined the protective antigens of the pandemic strain with a standard manufacturing strain, to make the world s first potential attenuated vaccine strain in just 17 days.

These were the first of repeated breakthroughs achieved by the Novartis Vaccines and Diagnostics Division against the backdrop of rapid spread of the virus.

Celtura, a Novartis vaccine derived from the cell-based manufacturing technology, was one of the first pandemic vaccines to begin clinical trials. So-called pilot trials gave regulatory agencies and prospective customers the first preliminary readout from human testing, indicating *Celtura* elicited a protective immune response, even at very low doses, paving the way for a larger global vaccine supply than otherwise would have been possible.

Positive results of a study conducted at the University of Leicester (England) were published in the prestigious New England Journal of Medicine in early September. In an accompanying editorial, Kathleen Neuzil, M.D., director of the influenza project at the Program for Appropriate Technology in Health, called the upbeat data eagerly anticipated as governments, public health officials and other stakeholders respond to the first influenza pandemic in over 40 years. The authors and their collaborators are to be commended for their prompt execution of the trials and rapid sharing of the results.

FULLY ENGAGED

To deliver millions of doses of vaccine in the months that followed, Novartis associates surmounted extraordinary challenges. When the initial cases of swine flu in the United States and Mexico were reported in April, the Vaccines and Diagnostics Division s major manufacturing sites were engaged with production of seasonal influenza vaccine. As the seasonal campaign continued

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through the summer, supply chain specialists raced to procure raw materials and supplies for the coming round of pandemic vaccine production.

There were additional challenges. The Vaccines and Diagnostics Division had invested more than USD 2 billion since 2006 to upgrade and expand production capacity as well as to accelerate development of novel vaccines, including the cell-culture technology used to manufacture *Celtura*. Virtually all of that new capacity, however, was due to come on stream in 2010 or later. The pandemic forced a dramatic acceleration of that timetable to make production of the A (H1N1) pandemic vaccines possible.

Along with bricks and mortar, additional production staff had to be found, and human resources specialists worked tirelessly to this end. In addition to contract staff hired by the sites, other Novartis divisions loaned hundreds of experienced employees, including supervisors, to reinforce the A (H1N1) production effort. It was like bringing on a whole new factory in three months, said Matthew Stober, Global Head Technical Operations at the Vaccines and Diagnostics Division.

But it wasn t just a matter of finding people and telling them to show up, Mr. Stober added. Our Human Resources team did a great job in obtaining visas and work permits, arranging housing, and all kinds of other things that had to be done before those additional employees could walk in the door. Then we had to train them so they could do the job right the first time. Every drop of vaccine was like gold.

In early October, Novartis announced that it had completed delivery of 27 million doses of seasonal flu vaccine to the United States ahead of schedule. Parallel production of pandemic vaccine had been under way for weeks, and the first shipments of influenza A (H1N1) vaccine arrived in the United States on September 27, less than four months after the WHO declared the pandemic.

It is an extraordinary achievement to complete deliveries of seasonal influenza vaccine early, while working hard to produce large quantities of A (H1N1) pandemic vaccines at the same time, said Andrin Oswald, M.D., Head of the Vaccines and Diagnostics Division and permanent attendee of the Executive Committee of Novartis. This should help physicians and public health officials better prepare for the upcoming flu season and balance the needs for pandemic and seasonal vaccination.

UNIQUE PORTFOLIO

Uniquely for any manufacturer, Novartis developed three different A (H1N1) pandemic vaccines. An A (H1N1) vaccine produced in Liverpool, England, using traditional egg-based technology and the Novartis seasonal influenza vaccine *Fluvirin* platform, was earmarked for the United States.

Governments outside the United States were able to purchase *Focetria*, an egg-based vaccine manufactured in Siena, Italy, or *Celtura*, produced in Marburg, Germany. Both *Focetria* and *Celtura* contain *MF59*, a proprietary adjuvant, or additive that can enhance the ability of the immune system to elicit a protective immune response in those people being vaccinated. Adjuvanted vaccines like *Focetria* and *Celtura* require smaller doses of antigen and elicit an enhanced immune response, helping to stretch scarce vaccine supplies to meet global demand. The US government opted against using adjuvanted vaccines in its national vaccination program but placed orders worth USD 483 million with Novartis for a bulk supply of *MF59* for the national stockpile of pre-pandemic avian influenza vaccines.

This broad Novartis portfolio of pandemic vaccines reflected a longstanding commitment to influenza at a time when many rivals had abandoned the field. The genesis of cell-culture technology dated from the 1980s, but Novartis guided the process through a marathon of testing to win European Union approval for the cell-based seasonal flu vaccine *Optaflu* in June 2007.

Influenza vaccines have been produced in chicken eggs since the 1950s, but growing the virus in cell culture can offer more flexibility and speed compared with egg-based production. It s a switch from using tens of millions of eggs as small, individual fermenters to much larger artifical fermenters in which vaccine can be produced in a contained system, says Rino Rappuoli, Ph.D., Head Vaccines Research at the division.

We ll continue to live with egg-based vaccines for some time, but Novartis Vaccines is the only company that has approved, adjuvanted vaccines produced in cell culture.

Underscoring the strategic importance of cell-based production, Novartis and the US government are sharing the cost of a new factory under construction in Holly Springs, North Carolina. The Novartis Holly Springs facility was officially inaugurated in November 2009. If licensed in an emergency, the facility will be ready to respond to a pandemic as early as 2011. The plant is planned to be running at full-scale commercial production in 2013.

When fully operational, the Holly Springs site will be a key link in the US pandemic preparedness program, with potential capacity to produce 50 million doses of seasonal influenza vaccine each year and targeted capacity to produce 150 million doses of adjuvanted avian pandemic influenza vaccine within six months of declaration of a pandemic.

US government policy calls for establishing domestic capability to produce up to 600 million doses of avian pandemic vaccine within six months of a pandemic outbreak.

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The Vaccines and Diagnostics Division actually launched development of pandemic flu vaccines in 1997, the year that a highly virulent avian H5N1 strain first appeared in humans in Hong Kong. During the outbreak of avian flu in 1999, a field trial of the first H5N1 pandemic vaccine candidate in combination with *MF59* adjuvant elicited robust immune responses in people vaccinated. Lessons from that earlier development program gave Novartis a head start on the A (H1N1) program.

Our job is to be prepared for whatever the influenza virus is going to throw at us, and that s exactly what we have been doing, Dr. Rappuoli said. We have solutions for society to face the pandemic that we didn t have a few years ago and we are using them.

STEPPING FORWARD

Procurement was a formidable hurdle for the pandemic vaccine program. With several companies embarking on development of A (H1N1) vaccines, speed was critical, and management at the Vaccines and Diagnostics Division quickly approved significant investments. We had to do a whole lot of things at risk, recalled Mr. Stober. We had limited contracts and if no customers actually ordered vaccine, we would have been crushed commercially. But we felt we had to step forward to ensure the public was protected.

The division s procurement function scrambled to redesign the whole sourcing process for the coming six months at a point when there was no visibility in terms of the volumes that ultimately would be needed. Supply specialists faced three primary challenges: eggs, syringes and multidose vials.

The general rule of thumb in production is that one egg is needed to grow enough virus for each dose of vaccine. Hundreds of millions of doses required hundreds of millions of pathogen-free eggs, purchased from a limited number of qualified, audited farmers in Europe with facilities meeting stringent standards of quality and hygiene.

You can t double production by just pushing a button, said Gianluca Filacchione, Head of Procurement at Novartis Vaccines. To be sure, farmers were able to redirect some eggs being sold to retail food channels. But the division normally secured egg supplies well in advance to expand production. It takes more than a year for a new flock to reach the maturity necessary to produce the right number of eggs with the quality that we are asking for, added Mr. Filacchione. But in the first week after the outbreak of swine flu, we rolled the dice and locked down all the eggs we could find in the market.

Syringes posed another challenge. There is a small number of companies that manufacture syringes worldwide, and meetings with their senior executives revealed they needed at least a year to significantly ramp up production. The companies adopted a straightforward approach to customers: first come, first served. Timing was everything, and we got there first, Mr. Filacchione said.

Multidose vials hold enough vaccine for about 10 vaccinations and make it possible for companies to make more vaccine available than in single-dose syringes in a relatively short period of time. As governments and health authorities wrangled over the design of vials they preferred, Novartis hedged its bets by purchasing supplies of glass and reserving production capacity with vial producers. Mr. Filacchione also bought cardboard and capacity at printing firms for packaging. We wanted to make sure nothing would hold us up, he added.

That commitment rubbed off on some suppliers. One packaging firm promised to give priority treatment to orders from Novartis for pandemic vaccine packaging and slashed the normal delivery time from nine weeks to only two. Firms selling boxes,

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or eggs, or plastic bags for a chemical process don t have the same commitment to health as a pharmaceutical company, Mr. Filacchione observed. But when we reminded them why this project was so important, many of our suppliers responded to the challenge.

SHORT NOTICE

At the Liverpool site, 2009 was a pivotal year when production of *Fluvirin*, a seasonal influenza vaccine from Novartis, would move to a new, highly automated plant, replacing older manufacturing facilities. The transition was carefully planned to avoid disruptions in manufacture of seasonal flu vaccine.

Suddenly along came swine flu, said John Sullivan, Head of the Liverpool site. Novartis couldn t afford to lose production capacity so we continued operations at our old facility to fulfill the contract for A (H1N1) vaccine that we had received from the US government. At the same time, we accelerated operational readiness of the new facility by several months to be able to run both facilities as near to capacity as possible.

To underpin parallel production, it was necessary to bring in about 300 additional production workers, the equivalent of a complete new work force, Mr. Sullivan said. There was an additional stumbling block: limited capacity for pre-incubation, a process required to prepare eggs for production. We put together a plan for a second incubation center, representing a significant investment, on very short notice over a weekend, really, he added. My management team said typically they would need 10 months to get the new facility qualified and ready to go. Instead, we got the project done in five months.

At the same time, the management team was scrambling to prepare the new facility, known as Site 4, for regulatory inspections by the US Food and Drug Administration. A critical step in the approval process is a pre-approval inspection, conducted by four FDA inspectors over a 10-day period. Originally the pre-approval inspection for Site 4 had been scheduled for October, paving the way for final approval of the site shortly before year s end. Novartis suggested to the FDA that we move up the inspection to August, which meant bringing forward all of our readiness planning, Mr. Sullivan recalled.

It played havoc with other plans, but the team at Site 4 really stepped up to the challenge, and the inspection was very successful. The FDA granted final approval of Site 4 on October 9, 2009.

The Marburg, Germany, site pioneered cell-culture technology and was gradually increasing production capacity for *Optaflu*, a cell-based seasonal flu vaccine, as well as *Celtura*. The expansion program shifted into high gear in May. Two additional production lines for *Celtura* were brought on stream as well as a third production line for *MF59*.

EXPANDED SECONDARY MANUFACTURING

Following the initial bulk manufacturing process, vaccines proceed to secondary production and are filled in final dosage forms, syringes or multidose vials. In yet another challenge for the Vaccines and Diagnostics Division, however, capacity for secondary production of A (H1N1) vaccines fell far short of demand.

Seasonal influenza vaccines are trivalent, comprising three separate strains that are blended together before filling in a final dosage form. All A (H1N1) vaccines are monovalent, consisting of a single strain.

We needed three times as much secondary manufacturing capacity for A (H1N1) vaccines to match our bulk production, Mr. Stober said.

Sandoz, the generics division of Novartis, cleared a production line at a plant in Ljubljana, Slovenia, to fill *Celtura* in multidose vials. Third-party suppliers provided added filling capacity for *Focetria* and some of the A (H1N1) vaccine made in Liverpool.

There was a huge amount of regulatory work especially completion of process validation to gain approval for all these new secondary suppliers, Mr. Stober said. Bringing on a third party normally takes up to a year. We did it in less than half the usual time.

BOOSTING YIELDS

Every year, mutations in the influenza A and B virus strains circulating in humans transform key surface proteins enough to elude destruction by natural antibodies built up by people who have had influenza or have antibodies generated through vaccination. Vaccine producers try to keep pace by shuffling the strains in a vaccine as often as the virus itself changes.

That makes for hectic production cycles and close cooperation between vaccine manufacturers and health authorities. After analyzing circulating viral strains collected by dozens of specialized laboratories in its global surveillance network, the WHO recommends the strains to be included in seasonal flu vaccines for the coming year. Then a few government-sponsored labs incorporate those viral strains into fast-growing hybrid seed strains that are distributed to vaccine manufacturers globally.

Manufacturers of seasonal influenza vaccines turn the hybrid viral seed into working seed used to inoculate hundreds of millions of eggs. Growing the very small amounts of the raw material you get from the laboratories into an approved and qualified working seed takes several weeks and involves quite a lot of testing as well, Mr. Sullivan explained.

For production of A (H1N1) vaccine, the egg-based seed virus from the US Centers for Disease Control and Prevention reached manufacturers around mid-July. Once

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in production, however, it proved a big challenge. Initial yields languished at about a third of levels expected from a seasonal H1 strain, reducing the number of doses per egg and delaying vaccination programs planned by public health authorities worldwide.

To mitigate the impact, production of *Focetria* vaccine in Italy as well as the A (H1N1) vaccine from Liverpool changed quickly to different seed strains. When you make this strain change, there is a huge development program and lots of regulatory work that has to be done, Mr. Stober said. The key worry was the risk of a supply gap because of the time required to develop reagents and do calibration standards.

Following changes to the seed virus strains, production climbed steadily through the final months of last year. By late October, deliveries were under way in both the United States and Europe, and net sales of pandemic vaccines in 2009 reached USD 1 billion.

REAL-TIME DATA

Novartis initiated testing of its A (H1N1) pandemic vaccines under intense time pressure to ensure licensure as quickly as possible. We started 12 clinical trials in more than 9 000 people in all age groups within three months of the A (H1N1) virus being identified, said Ralf Clemens, M.D., Ph.D., Head Global Development at Novartis Vaccines. Further studies have been initiated since then and the entire A (H1N1) program will comprise 27 clinical trials and two observational studies including almost 75 000 people.

Studies progressed in close collaboration with health authorities. Dr. Clemens and his team held weekly meetings with officials from the FDA, the European Medicines Agency (EMEA), as well as regulators from Germany and Italy.

Novartis adopted some innovative features in the initial trials of A (H1N1) vaccines to provide regulators a rapid readout on efficacy of the new vaccines. The first pilot trial of *Celtura* was conducted at the University of Leicester. Results were relayed to regulators on both sides of the Atlantic prior to publication in the New England Journal of Medicine.

Cell-culture technology enabled us to produce and develop *Celtura* faster than egg-based vaccines, Dr. Clemens said. That s why we were first.

In Costa Rica, Novartis also conducted a pilot trial of the Liverpool-made vaccine involving more than 1 000 elderly people, adults and children. We were the first company to have data with a vaccine for the United States, Dr. Clemens added. Results were collected weekly, and the analysis shared immediately with FDA officials. It was unusual but it gave them real-time data that were helpful in their own internal decision making, Dr. Clemens said.

Earlier studies of a Novartis candidate vaccine against avian flu in 2007 provided a head start in development of the A (H1N1) pandemic vaccines. That study indicated that a pandemic and a seasonal vaccine could be administered simultaneously. We could see there was no interference, Dr. Clemens said. That observation looms large for plans to include A (H1N1) as a component of future seasonal influenza vaccine.

Following the pilot trial of *Celtura*, a pivotal trial was conducted in Germany, the Netherlands, Switzerland and Belgium. Results showed that *Celtura* generated a protective immune response after a single 3.75-microgram antigen dose in most age groups. That was a fraction of the 15-microgram dose required for unadjuvanted vaccines.

A pivotal study with *Focetria*, the adjuvanted egg-based pandemic vaccine, was conducted in the same centers as *Celtura*. There was such demand from people wanting to be vaccinated that we decided to simply keep the ball rolling with *Focetria*, Dr. Clemens said.

The FDA approved the A (H1N1) vaccine made in Liverpool in mid-September. Approval of *Focetria* by the EMEA followed in late September, and *Celtura* was approved by German regulatory authorities at the beginning of November. These approvals, however, were accompanied by significant requirements for post-marketing surveillance. In Europe we are planning for observational studies involving 45 000 volunteers who will be followed up on a monthly basis for any serious adverse event, Dr. Clemens said. This is a huge undertaking.

COLD CHAIN

Stringent logistical requirements for shipping pandemic vaccines around the world were equally daunting. All vaccines are sensitive biologic substances that progressively lose potency, but the loss of potency occurs faster when a vaccine is exposed to temperatures outside a recommended storage range. Any loss of potency is permanent and irreversible.

Temperature control is critical, said Stuart Dickson, Global Head Supply Chain at the Vaccines and Diagnostics Division. The vaccines must be kept between 2 degrees Celsius and 8 degrees Celsius at all times it s part of the quality of the product. That means we have to assure control in the distribution, and the receiving warehouse has to be quality approved, receive these goods quickly and have the technical skill to handle cold chain.

In Europe, temperature-controlled trucks have been the prime vehicle for distribution. The Liverpool-made A (H1N1) vaccine, however, was shipped from Liverpool to the United States by air in special containers. Distribution of seasonal influenza vaccines usually requires about 700 of these containers. For A (H1N1) pandemic vaccine, at least twice that number was needed.

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A lot of people have worked their hearts out supporting this endeavor, Mr. Dickson added. It s like a polar expedition. You know where you re trying to go, and you know that it s going to be tough. We re still in the middle of our journey and totally dedicated to succeed.

RETHINKING INFLUENZA

Last July, with preparations for production of pandemic vaccines in full swing, Novartis assembled a select group of influenza experts in Siena for a conference called Rethinking Influenza. Participants ranged from senior executives from the Vaccines and Diagnostics Division and prominent academics to public health officials at the epicenter of the pandemic, including Robin Robinson, Deputy Assistant Secretary for Preparedness and Response within the US Department of Health and Human Services, and Professor David Salisbury, Chair of the WHO s Strategic Advisory Group of Experts (SAGE), the principal advisory group to the WHO for vaccines and immunization.

In October, eight participants including Dr. Rappuoli of Novartis, Dr. Robinson and Dr. Salisbury summarized their deliberations in an article in the journal Science. Although the pandemic has the potential to cause a social and economic emergency, they wrote, It also provides an opportunity to rethink our approach to influenza virus disease, and to develop more effective vaccines and economically sustainable solutions for developing and developed countries.

The article summarized swings in market conditions for seasonal influenza vaccines, from a low point around the year 2000 when major manufacturers abandoned the field, to a resurgence in 2003 through 2005 sparked by outbreaks of avian flu caused by H5N1, a potential pandemic virus. Between 2006 and 2008, global manufacturing capacity surged to 750 million doses per year from 400 million, and development of both adjuvants and cell-culture production technologies made major strides.

Those preparations left the world better prepared to face the A (H1N1) virus than any previous pandemic. But Dr. Rappuoli pointed to major problems that remained unsolved. We still don t have enough capacity to produce enough pandemic vaccine for developed countries, and certainly not for developing countries, he said at the conference. The present model for influenza vaccination is not sustainable to support pandemic preparedness.

In the Science article, the authors cited other lessons from the A (H1N1) outbreak. Until A (H1N1) the scientific community believed that a pandemic strain could only arise from a strain that had not previously been widely disseminated in humans, they noted. A (H1N1) showed, however, that human varieties may follow separate lines of evolution and generate potentially pandemic strains within an existing influenza strain. The authors called for epidemiological studies to include developing countries, humans, their livestock and wild animals to be able to map the diversity and circulation of the virus.

They emphasized that most knowledge of influenza virus is based on data accumulated in developed countries, leaving an incomplete and sometimes inaccurate view of virus spread and its global impacts. Improved influenza surveillance in developing countries is needed and it seems appropriate to add influenza to the vaccines recommended by the Expanded Program for Immunization, the authors said. The increase in vaccination would be based on excess manufacturing capacity for seasonal vaccines, and would encourage both international and local vaccine manufacturers to invest in additional capacity so as to sustain the surge capacity that is necessary in case of a pandemic.

Failure to act on those recommendations would be costly, Dr. Rappuoli had warned during the conference. If we don t change the game, we ll just go from one panic to the next, increasing capacity one day but shutting it down the next, he said. And that means never seeing global implementation of vaccination programs, so people will continue to die.

As Klaus Stohr, Ph.D., Global Head of Influenza Strategy Liaison at Novartis Vaccines and Diagnostics, added: Before joining Novartis, when I was leading the Global Influenza Program at the WHO including pandemic preparedness, we had gone some way to put the structures and processes in place to respond to a pandemic. Experience in 2009 has demonstrated that we need to prepare even better for the future. An effective response requires governments, vaccine manufacturers and other stakeholders to work closely together, in an uncertain environment, at top speed. Novartis has certainly played its full part in tackling this pandemic, and we can be proud of that.

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SANDOZ OVERVIEW

KEY FIGURES

(In USD millions, unless indicated otherwise)

	2009	2008
Net sales	**7 493**	7 557
Operating income	**1 071**	1 084
Return on net sales (%)	**14.3**	14.3
Core operating income (1)	**1 395**	1 421
Return on core net sales (%)	**18.6**	18.8
Research & Development	**613**	667
As a % of net sales	**8.2**	8.8
Free cash flow	**1 841**	1 066
Net operating assets	**15 151**	13 948
Additions to property, plant & equipment (2)	**282**	422
Number of associates (FTE) (3) at year-end	**23 423**	23 146

(1) Core operating income eliminates the impact of acquisition-related factors and other significant exceptional items. These adjustments are explained in detail on page 151.

(2) Excluding impact of business combinations

(3) Full-time equivalent positions at year-end

2009 NET SALES - ESTABLISHED VS. EMERGING/UNTAPPED MARKETS

(In %)

(1) 2009 Sandoz net sales growth in local currencies vs. 2008

NEWS IN 2009

Building a solid base for future growth as a global leader in generic pharmaceuticals: Steady improvement in 2009 led by turnaround in the US and contributions from all regions as well as important progress in differentiated generics.

Net sales slip 1% to USD 7.5 billion, but rise 5% in local currencies. German retail generics and biosimilars (+4% lc) solidify leadership position in a challenging market. US retail generics and biosimilars (+5%) helped by 25 new product launches, up from 17 in 2008. Sandoz continues to expand in Asia-Pacific, Russia and other markets with high growth potential.

Core operating income declines 2% to USD 1.4 billion. Improved underlying business expansion and benefits of productivity gains are more than offset by adverse currency impact. Core operating margin declines 0.2 percentage points to 18.6% of net sales.

Sandoz acquires EBEWE Pharma s specialty generics business for USD 1.3 billion in September, creating a new global growth platform in generic oncology injectables. EBEWE offers more than 15 marketed products and a strong pipeline with many potential near-term launches.

A pioneer in developing biosimilars, or generic biotechnology drugs, Sandoz is positioned to provide cost savings and improved access. Filgrastim, a third biosimilar, is launched in Europe, while somatropin becomes the first-ever biosimilar approved in Japan and Canada.

Serving areas with 90% of the world s population, Sandoz generates 40% of net sales from emerging and untapped generics markets. Targets for expansion include emerging markets and countries with low generic utilization, such as Japan and some European markets.

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SANDOZ

The acquisition of EBEWE Pharma GmbH, a specialist in generic oncology injectables, places Sandoz, the generics division of Novartis, among the top five global manufacturers in the expansive global market for injectable generics. Injectables underpin the Sandoz portfolio of differentiated generic products that are more difficult to develop, manufacture and market - but offer higher growth and profitability. Along with 15 marketed products, EBEWE brings Sandoz a deep development pipeline including more than 20 distinct molecules.

Sandoz, the generics division of Novartis, reinforced a key growth platform in 2009 by acquiring the specialty generic injectables business of EBEWE Pharma GmbH in a USD 1.3 billion transaction.

EBEWE, based in Unterach, Austria, specializes in generic oncology injectables. Together with existing businesses in retail generics, anti-infectives and biosimilars, the acquisition places Sandoz among the top five global manufacturers of injectable generics, a dynamic market with more than USD 10 billion in annual sales.

Biosimilars are follow-on versions of existing biologic medicines that have lost patent protection a promising market niche in which Sandoz is the pioneer and global leader.

Injectables underpin the Sandoz portfolio of differentiated generic products that are more difficult to develop, manufacture and market - but offer higher growth and profitability than more commoditized generics. This will greatly enhance our range of differentiated, affordable, high-quality generic medicines, said Jeff George, Head of Sandoz and permanent attendee of the Executive Committee of Novartis. Together with EBEWE, we will improve access to affordable cancer drugs for patients worldwide.

EBEWE brings Sandoz a portfolio of 15 marketed injectable anticancer products as well as a deep development pipeline including more than 20 distinct molecules. Launch opportunities are expected to sustain dynamic growth. Moreover, access to the global sales and marketing organization of Sandoz could fuel growth of EBEWE products in North America, Latin America and Japan, markets in which the firm has not traditionally had a strong presence.

Oncology is the biggest therapeutic area in the pharmaceutical industry today and the global market for cancer medicines is expected to grow at an annual rate of 12% to 15%, reaching USD 80 billion by 2012. According to IMS Health, a consulting firm specializing in the pharmaceuticals industry, up to 30 new anticancer agents are expected to be approved from 2008 to 2012. Generic manufacturers are also poised for growth; injectable oncology medicines with worldwide annual sales of USD 9 billion are set to lose patent protection by 2015.

BEYOND THE TRADITIONAL APPROACH

The purchase of EBEWE was a logical step, as Sandoz was the Austrian company s biggest single customer and links had become increasingly close in recent years. Hexal AG, the German generics giant acquired by Sandoz in 2005, had a longstanding relationship with EBEWE, and licensed marketing rights to oncology products as well as innovative packaging technology.

Sandoz built on that foundation as well as a growing commitment to the field of

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oncology, according to Friedrich Hillebrand, Ph.D., EBEWE s former Chief Executive Officer and Head of the new Oncology Injectables business at Sandoz . It became clear that if we ever decided to look for a potential partner to acquire EBEWE, Sandoz would be our first choice, Dr. Hillebrand said.

Following the acquisition, EBEWE was designated a new business center of excellence for oncology injectables within the Sandoz organization. Dr. Hillebrand has joined the Sandoz executive management committee. Sandoz has treated our employees very well, Dr. Hillebrand added. It has been the best outcome in all respects.

Like other generic manufacturers, EBEWE strives to claim coveted first-to-market positions by challenging patents on originator compounds. But EBEWE also goes beyond this traditional approach and offers customers additional features and benefits few rivals can match.

Anticancer medicines traditionally have been delivered to hospitals in vials or ampoules containing a lyophilized, or essentially freeze-dried, powder with a texture similar to instant coffee. This powder must be mixed with liquid by doctors or nurses immediately before administration. EBEWE, however, delivers the vast majority of its products in ready-to-use solutions - a safety bonus for healthcare professionals who administer the treatments. These substances are highly toxic and it is a competitive advantage to really understand how they are used in hospitals, Dr. Hillebrand said. We have focused on helping the entire delivery chain - from our factory to the patient.

One example of ready-to-use innovation is EBEWE s gemcitabine, a generic version of the blockbuster anticancer medication marketed by Eli Lilly & Co. under the brand name Gemzar®. While the originator medicine is available in a lyophilized form, EBEWE and Sandoz have jointly launched a more convenient, ready-to-use formulation in Europe.

Another innovative step by EBEWE is the development of specialized packaging techniques to increase safety in the transportation and handling of toxic anticancer medicines. The company s unique Onco-Safe system involves a polymer coating on individual vials and ampoules to prevent breakage and surface contamination.

We have to stay ahead of rival generics companies, Dr. Hillebrand said. But we try to avoid competing primarily on price. We want to talk to customers about other parts of the value chain and how our products can help address their needs.

SHARED DISTRIBUTION CHANNELS

Pooling sales and marketing acumen could provide significant benefits because injectable oncology products, anti-infectives and even biosimilars cater primarily to hospitals and often share distribution channels. Global reach helps you to build the kind of robust supply chain required in the unforgiving hospital environment, said Ernst Meijnders, Head of Anti-Infectives at Sandoz. And once the infrastructure is established, you want to ensure that you have a broad range of products.

As a leading global manufacturer of anti-infectives, Sandoz offers both the injectable formulations used inside the hospital to treat acute infections plus oral formulations - capsules and pills - that are more convenient for patients who continue treatment after being discharged. Traditionally, however, the Sandoz sales force hasn t focused on decision makers that EBEWE sales representatives see regularly on critical-care wards and in chemotherapy departments. Now that comes together around common customers as they are all heavily hospital-driven, Mr. George said.

Individual countries are at such different stages of evolution in treatment of cancer that it isn t yet possible to implement a uniform global marketing strategy, Dr. Hillebrand added. We tailor our approach country by country, according to market dynamics.

Moreover, despite the flood of new targeted anticancer medicines expected to reach the market in the next five years, Dr. Hillebrand insists affordable, generic versions of established chemotherapy regimens in broad use today will remain the foundation of treatment. These are the medicines we have in our existing portfolio, as well as our development pipeline, he said.

PIONEERING BIOSIMILARS

Injectable generics provide a bridge to biosimilars - large molecules in injectable dosage forms that in some cases also must be self-injected by patients. Sandoz is the only company to gain marketing authorization of three biosimilar products, and the division has a comprehensive biosimilar pipeline with numerous projects at various stages of development.

In regulatory breakthroughs in 2006, the recombinant human growth hormone *Omnitrope* became the first biosimilar product to receive regulatory approval in the United States and the European Union. During 2009, regulatory authorities in Japan and Canada granted approval of *Omnitrope* as the first biosimilar to reach patients in both countries.

Complementing *Omnitrope*, *Binocrit*, a biosimilar epoetin alfa used to regulate the formation of red blood cells, was approved by the European Union in 2007.

Breaking new ground again last year, Sandoz received approval from the European Union for a third biosimilar: *Zarzio*, known by the common name filgrastim and based on Neupogen® from Amgen Inc. *Zarzio* is indicated for treatment of neutropenia, a condition characterized by a lack of one of the most common types of infection-fighting

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white blood cells and often associated with chemotherapy or bone marrow transplants, as well as advanced HIV infections.

The biosimilar program at Sandoz is based on more than 25 years of experience in development and production of biologic medicines. Sandoz codeveloped and manufactured interferon alpha in the 1980s, and currently manufactures more than a dozen recombinant proteins on behalf of other companies in addition to the Novartis Pharmaceuticals Division and Vaccines and Diagnostics Division.

Like EBEWE, Sandoz also has developed delivery systems that enhance convenience for patients. *Omnitrope* was originally launched in a lyophilized form. But regulators in the United States and the European Union subsequently approved a new, more patient-friendly liquid pen form in which *Omnitrope* is marketed in a ready-to-use cartridge that can be loaded into the pen for injection.

Biopharmaceuticals offer real therapeutic hope to patients suffering from the most complex diseases of modern society, Mr. George said. Biosimilars, pioneered by Sandoz, increase access to these essential drugs, lowering treatment costs and saving money for patients and healthcare systems more broadly.

TIGHT COST CONTROL

While differentiated generic products generate a steadily increasing proportion of net sales, more commoditized generics still account for more than two-thirds of net sales at Sandoz. Commoditized generics are fiercely competitive, with annual price erosion of about 10%.

To offset that price erosion we have to recreate half our operating profit - well over USD 500 million per year - through a combination of increased volume, product introductions and cost reductions, Mr. George said.

Tight cost control is critical for success, but at times, Sandoz has faced challenges. Operating costs rose significantly faster than sales in 2008, which led Mr. George to initiate a broad operating improvement program known as Project Compete that reduced annual costs by more than USD 300 million in 2009. Of those savings, more than 80% were unrelated to employee head count. We re finding ways to become more efficient and continuously improve the way we work, Mr. George said.

In 2009, Sandoz management also completed a comprehensive remediation program at a production site in Wilson, North Carolina. In August 2008, Sandoz received a Warning Letter from the US Food and Drug Administration (FDA) regarding deviations from Good Manufacturing Practices (GMP) at the Wilson site. Sandoz subsequently initiated voluntary recalls of a number of products.

The remediation program at the Wilson site addressed specific validation and documentation issues cited by the FDA, and Mr. George replaced top management at the US unit of Sandoz as well as management at the North Carolina plant. A reinspection by FDA officials in August confirmed that issues identified in the Warning Letter had been resolved, the site was back in GMP compliance, and a stay on new

product approvals from the Wilson site was lifted.

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CONSUMER HEALTH OVERVIEW

KEY FIGURES

(In USD millions, unless indicated otherwise)

	2009	**2008**