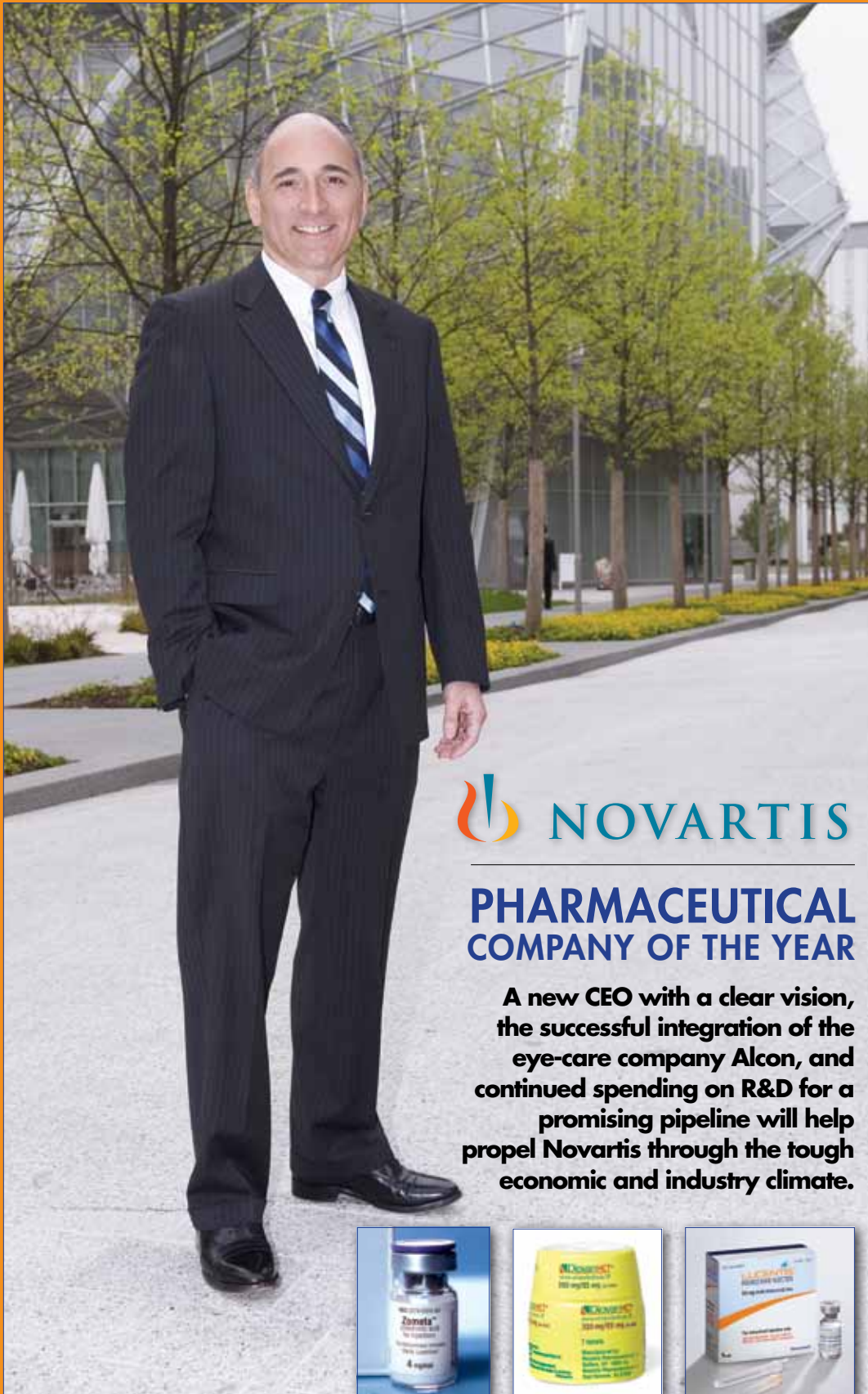


MedAdNews

THE MAGAZINE OF PHARMACEUTICAL BUSINESS AND MARKETING • MEDADNEWS.COM • SEPTEMBER 2011 • VOLUME 30 NUMBER 9



PHARMACEUTICAL COMPANY OF THE YEAR

A new CEO with a clear vision, the successful integration of the eye-care company Alcon, and continued spending on R&D for a promising pipeline will help propel Novartis through the tough economic and industry climate.



25TH ANNUAL REPORT

TOP 50 PHARMA COMPANIES

- Abbott Laboratories
- Actelion Pharmaceuticals Ltd.
- Allergan Inc.
- Amgen Inc.
- Astellas Pharma Inc.
- AstraZeneca Plc.
- Baxter International Inc.
- Bayer AG
- Biogen Idec Inc.
- Boehringer Ingelheim GmbH
- Bristol-Myers Squibb Co.
- Celgene Corp.
- Cephalon Inc.
- Chugai Pharmaceutical Co.
- CSL Ltd.
- Daiichi Sankyo Co.
- Dainippon Sumitomo Pharma Co.
- Eisai Co.
- Endo Pharmaceuticals Holdings Inc.
- Forest Laboratories Inc.
- Gilead Sciences Inc.
- GlaxoSmithKline Plc.
- Hospira Inc.
- Johnson & Johnson
- Kyowa Hakko Kirin Co.
- Lilly and Co., Eli
- Lundbeck AS, H.
- Merck & Co.
- Merck KGaA
- Mitsubishi Tanabe Pharma Corp.
- Mylan Inc.
- Novartis AG
- Novo Nordisk AS
- Nycomed Group
- Ono Pharmaceutical Co.
- Otsuka Holdings Co.
- Pfizer Inc.
- Ranbaxy Laboratories Ltd.
- F. Hoffmann-La Roche Ltd.
- Sanofi SA
- Shionogi & Co.
- Shire Plc.
- Stada Arzneimittel AG
- Taisho Pharmaceutical Co.
- Takeda Pharmaceutical Co.
- Teijin Ltd.
- Teva Pharmaceutical Industries Ltd.
- UCB SA
- Warner Chilcott Plc.
- Watson Pharmaceuticals Inc.

TOP 50 PHARMA COMPANIES

Novartis AG

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Switzerland
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Website: novartis.com



BEST-SELLING RX PRODUCTS

PRODUCT	2010 SALES	2009 SALES
■ Diovan, Diovan HCT	\$6,053	\$6,013
■ Gleevec/ Glivec	\$4,265	\$3,944
■ Lucentis	\$1,533	\$1,232
■ Zometa	\$1,511	\$1,469
■ Femara	\$1,376	\$1,266
■ Sandostatin	\$1,291	\$1,155
■ Exelon, Exelon Patch	\$1,003	\$954
■ Exforge	\$904	\$671
■ Neoral, Sandimmun	\$871	\$919
■ Voltaren Group	\$791	\$797
■ Exjade	\$762	\$652
■ Comtan, Stalevo group	\$600	\$554
■ Reclast/ Aclasta	\$579	\$472

All sales are in millions of dollars.

For a complete listing of the company's product sales and pipeline, visit pharmalive.com/specialreports.

FINANCIAL PERFORMANCE

	2010	2009
■ Sales	\$50,624	\$44,267
■ Net income	\$9,969	\$8,454
■ EPS	\$4.28	\$3.70
■ R&D	\$8,080	\$7,469

	1H11	1H10
■ Sales	\$23,847	\$20,255
■ Net income	\$5,385	\$4,019
■ EPS	\$2.34	\$1.75
■ R&D	\$4,585	\$3,930

All figures are in millions of dollars except EPS.

PHARMACEUTICAL COMPANY OF THE YEAR

Full speed ahead

A new CEO with a clear vision, the successful integration of the eye-care company Alcon, and continued spending on R&D for a promising pipeline will help propel Novartis through the tough economic and industry climate; these strengths helped make Novartis *Med Ad News'* Company of the Year.

By **Christiane Truelove** chris.truelove@ubm.com

For many companies in 2010, the global financial crisis hit hard and the pain isn't over yet as the economic uncertainty continues. But despite the ongoing economic problems around the world and a change in leadership that could have been disruptive, Novartis, the *Med Ad News* Company of the Year, sailed through 2010 with record sales and profits, and the first half of 2011 is also looking strong.

"Our well-balanced business portfolio and long-term strategy focused on innovation once more have proved to be robust and appropriate for the future," says Daniel Vasella, M.D., chairman, who stepped down as CEO in February 2010. "The ability to repeatedly launch new and better products, and thus establish market positions, is decisive for the sustainability of our success. We demonstrated both of these core competencies last year. New and recently launched products were a key growth driver in 2010 and hold more promise for the future."

New CEO Joe Jimenez has continued Novartis' strategy and launched new initiatives to improve productivity, as well as continuing to sustain investment in R&D. "His nomination has proven to be right both in terms of timing and in terms of the division of labor between the chairman and the CEO," Dr. Vasella says.

At the time Mr. Jimenez's appointment was announced in January last year, some industry analysts initially expressed surprise, but most quickly warmed to the idea that he was the logical choice to succeed Dr. Vasella. Mr. Jimenez had joined Novartis' con-



"Since becoming CEO, I'd say my proudest achievement has been our work bringing innovative therapies to patients in need," says CEO Joseph Jimenez.



"The ability to repeatedly launch new and better products, and thus establish market positions, is decisive for the sustainability of our success," says Novartis Chairman Daniel Vasella.



Lucentis sales reached \$1.53 billion in 2010 and are predicted to be more than \$2 billion by 2015.

sumer unit in 2007, and became head of the pharmaceuticals division very soon after. He also had stints in the consumer packaged goods industry before coming to Novartis.

Mr. Jimenez readily counters his critics when it comes to his appointment and his background.

“As head of Novartis Pharmaceuticals, I gained a really clear picture of how the industry was changing and how we as a company wanted to move forward,” he says. “I also shared Dan Vasella’s long-term vision for Novartis to be the most successful healthcare company, with our commitment to innovation and a strategically diversified portfolio focused on healthcare.

“My experience in the consumer packaged goods industry provided

many insights which are relevant to the healthcare industry now. The CPG industry taught me to pay close attention to the external environment, anticipate customers’ changing needs, and act quickly to stay ahead of the market. These are all lessons I draw on today, especially with the rapidly-changing healthcare market. This is one reason why I felt it was so important to shift our business model. Since joining Novartis, I’ve adapted our approach to deliver more services, better meet customers’ changing needs, and focus on patient outcomes.”

(For more insights from Mr. Jimenez, please see the full Q&A on page 74.)

Mr. Jimenez can point to two accomplishments in his first year

as CEO: the approval of **Gilenya**, the first oral drug for multiple sclerosis; and the acquisition and integration of the eye-care company **Alcon** Inc.

Novartis fully acquired the eye care company Alcon from Nestle Corp. in April. The newly formed Alcon business became the second largest division of Novartis, taking advantage of its collective eye care product portfolio and expertise to accelerate growth and product innovation. The division had combined pro-forma sales of more than \$9.4 billion in 2010, and will be headquartered in Fort Worth, Tex., with operations in 75 countries.

Analysts at Jefferies and Co. say Alcon sales will offset the decline in H1N1 vaccine sales and health-care reform impacts in 2011.

Gilenya received FDA approval in September 2010 for the treatment of relapsing forms of multiple sclerosis and the prevention of flares. According to Jefferies and Co. analysts, because the drug is an oral one and has a superior efficacy and a better side effect profile than the standard injectable treatments, “This creates a significant opportunity in an \$11 billion market that is currently dominated by injectable products, the majority of which can cause flu-like side effects and injection site reactions, which in turn cause a number of patients to make the decision not to medicate.” These analysts predict peak sales of about \$3.5 billion.

According to Dr. Vasella, Novartis is less affected by patent expiries than most of its competitors due to several recently launched products with rapid sales growth. “In the

last year, 21 percent of net sales (excluding Alcon) was attributable to products launched since 2007,” he says. “Furthermore, we have one of the best pipelines in the industry, with some very promising products at advanced stages of development.

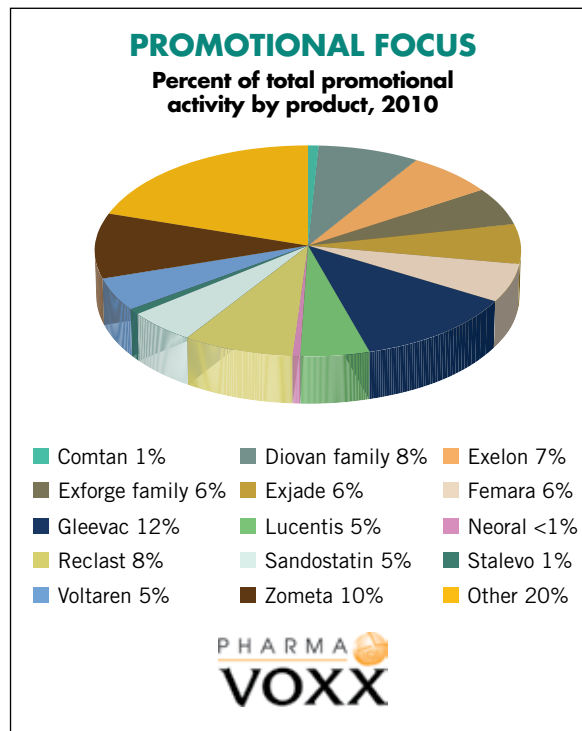
“Gilenya has impressive growth potential, and strong successor products are already on the market to replace Gleevec/Glivec and Diovan. We are confident of our ability to compensate for lost sales due to expiry of Diovan patents. Our broad portfolio with varied business cycles should deliver sustainable development compared with the industry. Therefore we have a good chance to more than compensate for the loss in sales, given of course a little luck.”

Gilenya is the first medicine in a new class called sphingosine 1-phosphate (S1P) receptor modulators. The drug is thought to work by reducing the immune system’s attack on the central nervous system by retaining selected subsets of lymphocytes, or white blood cells, in the lymph nodes. By preventing these blood cells from reaching the central nervous system, treatment with Gilenya diminishes inflammatory damage to the protective covering around nerve fibers.

Novartis acquired rights to fingolimod, the active chemical in Gilenya, from **Mitsubishi Tanabe Pharma Corp.** in 1997. The compound was initially developed for prevention of acute rejection after

renal transplantation. Novartis scientists explored other potential indications, including multiple sclerosis. Following tests in a series of preclinical models of multiple sclerosis, fingolimod completed a positive proof-of-concept study in 2005 and a formal development program began.

Elucidation of the S1P mechanism of action has progressed hand-in-hand with clinical testing of Gilenya. “It has been a par-



allel story, reconciling biological hypotheses with clinical observations,” says Pascale Burtin, M.D., global program head for Gilenya. “The biology of S1P receptors has progressed because Gilenya existed – the drug has been a pathfinder for in vitro and in vivo experiments.”

Jefferies and Co. analysts predict that Gilenya sales will reach \$2.5 billion by 2015.

■ Company and product performance

In 2010, Novartis’ net sales grew 14.4 percent to \$50.62 billion. Net income climbed 18 percent to almost \$10 billion, faster than operating income. Earnings per share were \$4.28, 58 cents more than in 2009.

The Pharmaceuticals Division achieved sales of \$30.56 billion in 2010, 7.1 percent more than in 2009. Sales of recently launched products were \$6.6 billion, accounting for 21 percent of the division’s sales, compared with 16 percent the previous year. Executives say this increase in sales for recently launched products enabled Novartis to grow significantly faster than the industry average. Pharmaceuticals Division sales comprised 60 percent of the company’s overall sales in 2010.

In the first half of 2011, Pharmaceuticals Division sales were \$16.04 billion, 8.1 percent more than in the same period in 2010. Europe remained the largest region in sales with \$5.9 billion, particularly benefiting from recently launched products, which generated 33 percent of net sales. The United States generated \$4.9 billion, 31 percent of total sales for the division. Japan’s performance of \$1.8 billion in sales improved versus the prior year due to new launches. Latin America and Canada, with \$1.5 billion, maintained solid growth rates. The top six emerging markets generated \$1.6 billion, led by double-digit growth from China and India.

Key growth drivers in the division included Lucentis, Exforge, Exelon Patch, Exjade, Reclast/Aclasta, Tekturna/Rasilez, Tasigna, Afinitor, Onbrez Breezhaler, Ilaris, and Gilenya. Pharmaceuticals sales growth was led by Oncology, with four top-selling products, including Gleevec/Glivec. The Exforge, Tekturna, and Galvus groups of products drove growth in the Cardiovascular and Metabolism franchise, building on the global leadership of Diovan. Neuroscience and Ophthalmics grew strongly, driven by Lucentis.

The company's leading pharmaceutical product in sales was the hypertension drug **Diovan/CoDiovan**. The drug generated \$6.05 billion in 2010, about the same as in 2009. During the first half of 2011, Diovan sales were \$2.92 billion, 2.5 percent less than in first-half 2010. Jefferies and Co. analysts predict sales of the drug will be \$1.94 billion by 2015, with the drop coming due to generic erosion.

The cancer treatment **Gleevec/Glivec** was the second best-selling Novartis drug in 2010, achieving sales of \$4.27 billion, 8.1 percent more than in 2009. The drug is a targeted therapy for Philadelphia chromosome-positive chronic myeloid leukemia, and is approved for the metastatic, unresectable, and adjuvant (post-surgery) treatment of gastrointestinal stromal tumors. Gleevec sales in the first half of 2011 were \$2.28 billion, 8.2 percent more than in the same period last year. Jefferies and Co. analysts believe that Gleevec sales will peak at \$4.66 billion by 2012, and fall to \$3.62 billion by 2015.

The No. 3 drug in 2010 for Novartis was **Lucentis**, for the treatment of wet age-related macular degeneration. Sales for the year were \$1.53 billion, 24.4 percent more than in 2009. During the first half of 2011, Lucentis sales were \$985 million, 33 percent more than in the same period last year. Lucentis is the only approved medicine to significantly improve vision in patients with wet age-related macular degeneration, for which it is established as the standard of care, and for the treatment of visual impairment due to diabetic macular edema. In the second quarter of 2011, Lucentis was approved in the European Union and Switzerland for the treatment of visual impairment due to macular edema secondary to retinal vein occlusion and in Switzerland for the treatment of visual impairment due to diabetic macular edema. Lucentis is approved in more than 90 countries for the treatment of wet age-related macular degeneration, and in more than 30 countries for the treatment of visual impairment due to diabetic macular edema or macular edema secondary to retinal vein occlusion. Genentech holds the rights to Lucentis in the United States. Jefferies and Co. analysts predict Lucentis sales will be \$2.25 billion by 2015.

Zometa, to reduce or delay skeletal-related events in cancer patients with bone metastases, had sales of \$1.51 billion in 2010, almost 3 percent more than in 2009. Sales declined slightly to \$749 million in the first half of 2011, due to new competition in the second quarter of the year. By 2015, sales of Zometa will fall to

\$455 million because of generic competition, according to Jefferies and Co. analysts.

The breast cancer drug **Femara** was Novartis' fifth-best-selling drug in 2010, with sales of \$1.38 billion, 8.7 percent more than in 2009. Sales of the drug were \$595 million in first-half 2011, a 12.8 percent decline compared with the first half of 2010. Sales dropped because of multiple generic entries in the United States and other key markets, executives say. Jefferies and Co. analysts believe that Femara sales will decline to \$363 million by 2015.

Novartis' No. 6 drug in sales in 2010 was the acromegaly drug **Sandostatin**. The drug generated \$1.29 billion for the year, 11.8 percent more than in 2009. First-half 2011 sales were \$702 million, almost 13 percent more than in the same period last year. Sales continued to benefit from from the increasing use of Sandostatin LAR in key markets for the treatment of symptoms associated with neuroendocrine tumors. Jefferies analysts predict that Sandostatin sales will be \$814 million by 2015.

Exelon/Exelon Patch was the company's seventh-best-selling drug in 2010, generating slightly more than \$1 billion in sales, 5.1 percent more than in 2009. The Alzheimer's disease drug recorded sales of \$515 million in the first half of 2011, 2.4 percent more than in first-half 2010. Combined sales were affected by the entry of oral generic competition in the United States, despite continued conversion from oral to transdermal therapy.



Although the Diovan family reached \$6.05 billion in sales in 2010, the product faces generic erosion.

Exelon Patch, the transdermal form of the medicine, grew 13 percent and generated more than 75 percent of total Exelon sales in the second quarter, compared to less than 65 percent in the 2010 period. Novartis received approval for Exelon Patch in Japan in the second quarter for mild-to-moderate Alzheimer's disease, and filed an application in the European Union for Exelon Patch for the treatment of Parkinson's disease dementia. Exelon Patch is approved for the treatment of mild-to-moderate Alzheimer's disease dementia in more than 80 countries, including more than 20 countries where it is also approved for Parkinson's disease dementia. Exelon sales are expected to fall to \$481 million by 2015, according to Jefferies and Co.

The eighth-best-selling Novartis product in 2010 was the hypertension drug **Exforge**, with sales of \$904 million, 34.7 percent more than in 2009. First-half 2011 sales of Exforge were \$569 million, 32

percent more than in the same period last year. Growth was fueled by continued prescription demand in the European Union, the United States, and other key regions, as well as ongoing Exforge HCT launches in Europe, Asia, and Latin America. Exforge, a single-pill combination of Diovan and the calcium channel blocker amlodipine, has delivered sustained growth globally since its launch in 2007. Launches are ongoing in China and Japan, two key markets with particularly high usage of calcium channel blockers. Exforge HCT, the first modern triple hypertension medication that includes a diuretic in a single pill, is now available for patients in more than 35 countries, with additional launches expected over 2011 and 2012. Sales of Exforge are predicted to fall to \$509 million by 2015.

Novartis' No. 9 drug in sales in 2010 was **Neoral/Sandimmune**. The transplantation drug had sales of \$871 million for the year, 5.2 percent less than in 2009. The drug's sales in the first half of 2011 were \$441 million, 2.8 percent more than in first-half 2010. Jefferies analysts expect the drug's sales will be \$428 million in 2015.

The painkiller **Voltaren**, in its prescription form, had sales of \$791 million in 2010, making it Novartis' tenth-best-selling drug. Voltaren sales are predicted to decline to \$596 million by 2015.

Novartis' Vaccines and Diagnostics Division recorded sales of \$2.92 billion in 2010, 2.4 percent more than in 2009. The increase stemmed mainly from sales of influenza A (H1N1) pandemic vac-

cines, which totaled \$1.3 billion during the first half of the year. Sales from this division comprised 6 percent of total company sales in 2010. The division's sales in the first half of 2011 were \$670 million, compared with \$1.93 billion in first-half 2010. The primary driver behind this drop was \$1.3 billion of A (H1N1) pandemic flu vaccine sales in the first half of 2010 that were not repeated in the same period of 2011

The generics division Sandoz achieved a 13.7 percent increase in sales to \$8.52 billion in 2010, thanks to stronger growth in the United States, Canada, Italy, and emerging markets compared to the previous year. The division's growth rate in Central and Eastern Europe is four times faster than the market – and three times faster in Turkey, the Middle East, and Africa. Executives attribute Sandoz's excellent results to the first-to-market launches in the United



Gleevec reached sales of \$4.27 billion in 2010.

States of differentiated generic versions of complex products such as enoxaparin – the most successful product launch ever by Sandoz – tacrolimus, and lansoprazole.

Growth also was attributable to biosimilars, as sales rose 63 percent in constant currencies to \$185 million. “With patents expected to expire over the next five years on biologics with global sales of \$64 billion, the full strategic importance of our leading position in biosimilars will soon become apparent,” executives say. Sales of the Sandoz division were 17 percent of total company sales in 2010.

First-half 2011 sales by Sandoz were \$4.84 billion, 21.8 percent more than in first-half 2010. Sales were driven by strong growth in U.S. retail generics and biosimilars, Western Europe, and emerging markets, including Latin America and Central and Eastern Europe, as well as continued strong results from biosimilars. Sales volumes expanded 25 percentage points due to new product launches, and the activity of Falcon, the U.S. generics activities of Alcon, contributed 3 additional percentage points, more than compensating for price erosion of 11 percentage points.

The Consumer Health Division increased net sales by 6.8 percent in 2010 to \$6.2 billion. Sales by the CIBA Vision business unit grew 6.4 percent in constant currencies, while Animal Health benefited from some of its top brands. OTC sales growth was driven by analgesics and **Prevacid24HR** for the treatment of heartburn. Prevacid24HR became the No. 2 brand for Novartis OTC in the

THE PATH OF ALCON

Alcon became officially integrated into Novartis in April 2011. Following the merger, Novartis and Alcon shifted gears from months of meticulous planning to building the global leader in eye care and fifth strategic growth platform for Novartis.

Alcon is the second biggest division within Novartis, after Pharmaceuticals. Kevin Buehler, former CEO of Alcon, heads the new division, reporting to Novartis CEO Joseph Jimenez.

“Novartis’ strategy is based on high-growth, science-based segments of health-care, and Alcon is a great fit with our portfolio,” Mr. Jimenez says. “Together, Novartis and Alcon will hold competitive positions in highly complementary product areas and create an even stronger global leader in the dynamic eye care sector. And in eye care, just as in other Novartis growth platforms, innovation is fundamental to success. Access to ophthalmology research programs at the Novartis Institutes for BioMedical Research will provide a powerful drug discovery engine for the new division.”

When the division’s new commercial model is implemented in the second half of 2011, Alcon will comprise three businesses: the Surgical business, which accounts for \$3.2 billion of the new division’s pro forma annual sales, based on Alcon’s global leadership in ophthalmic surgery and implanted intraocular lenses; the Pharmaceuticals business, which represents about \$3.5 billion of pro forma sales; and Vision Care, which provides \$2.7 billion of the division’s pro forma annual sales.

A broad portfolio of ophthalmic medicines from Alcon will be augmented by the addition of Novartis drugs used to treat eye diseases and vision conditions and the Pharmaceuticals business will also oversee the line of professionally driven over-the-counter brands in artificial tears and ocular vitamins.

Contact lenses will come from CIBA Vision, a Novartis business unit that has been the world’s second-biggest manufacturer of contact lenses, while Alcon’s consumer eye care products include **Opti-Free**, the leading global lens care brand.

In 2010, Alcon sales rose 9.2 percent in constant currency, driven by dynamic growth of medicines for treatment of glaucoma as well as advanced technology intraocular lenses used in cataract surgery. According to company leaders, Alcon offers eye care professionals the most

comprehensive portfolio of treatments to lower intraocular pressure stemming from glaucoma; worldwide sales of Alcon’s glaucoma franchise climbed 13.1 percent in 2010.

“Through this merger, we are forging the strengths of Alcon, CIBA Vision, and Novartis Ophthalmics into one eye care business that is poised to serve our customers with an unparalleled product portfolio,” Mr. Buehler says. “Alcon now benefits from increased scale, resources, and growth opportunities to achieve its vision of being the most trusted leader in eye care.”

Alcon also is recognized as the world leader in ophthalmic surgery. The most recent advancements in this platform are intraocular lenses that simultaneously correct for presbyopia, which affects all cataract patients, and astigmatism, which affects about one-third of these patients. Alcon has established the leading market position in each category, enabling surgeons to deliver greater visual function and improve lifestyle freedom for patients. Global sales of

AcrySof advanced technology intraocular lenses grew 19.7 percent in 2010.

The CIBA Vision business unit posted 6.4 percent sales growth in constant currencies in 2010, double the overall market segment growth for the year. That performance reflected the strength of the **AirOptix** and **Dailies** brands. **ClearCare**, CIBA Vision’s lens disinfectant solution, experienced its third year of double-digit growth.

This diversified portfolio, company leaders say, will allow the new Alcon Division to respond to changes occurring within eye care.

“We have a blend of differentiated pharmaceutical products, which contrasts with surgical devices and intraocular lenses that have a different reimbursement structure – as well as a lower risk profile in research and development,” Mr. Buehler says. “Vision care in many countries is a patient-pay segment, yet one that is heavily driven by eye care practitioners.

“While the mix of our products in Pharmaceuticals and Surgical tends to tilt toward the aging patient, contact lenses and lens care cover the full spectrum from kids to teens to adult presbyopes in middle age. Overall, it’s a very nice offset: one business might be challenged by market conditions at any given time but another might do quite well. It gives us diversity and balance for long-term growth.”

Q&A with Joseph Jimenez

In an exclusive interview with *Med Ad News*, Mr. Jimenez reflects on his first year as CEO, the practices that shaped the executive he has become, and how Novartis will continue to grow and succeed in an increasingly difficult industry.

Med Ad News: At the time of your succession to Dr. Daniel Vasella last year, you were seen as a surprising but logical choice by many analysts, though some at your company believe that your background in consumer marketing is not the ideal. How do you believe your transition has gone, and how would you refute your critics?

Joseph Jimenez: The transition to CEO was relatively seamless. As head of Novartis Pharmaceuticals, I gained a really clear picture of how the industry was changing and how we as a company wanted to move forward. I also shared Dan Vasella's long-term vision for Novartis to be the most successful healthcare company, with our commitment to innovation and a strategically diversified portfolio focused on healthcare.

My experience in the consumer packaged goods (CPG) industry provided many insights which are relevant to the healthcare industry now. The CPG industry taught me to pay close attention to the external environment, anticipate customers' changing needs, and act quickly to stay ahead of the market. These are all lessons I draw on today, especially with the rapidly-changing healthcare market. This is one reason why I felt it was so important to shift our business model. Since joining Novartis, I've adapted our approach to deliver more services, better meet customers' changing needs, and focus on patient outcomes.

Med Ad News: In taking stock of your first 100 days of leadership at the company, what do you point to as your accomplishments? What did you learn during that time to take you forward in decisions? What do you think still needs to be addressed?

Joseph Jimenez: Since becoming CEO, I'd say my proudest achievement has been

our work bringing innovative therapies to patients in need. I'm always touched when I hear stories of how our medicines have helped transform the lives of patients. For example, one multiple sclerosis patient thanked us for developing Gilenya, a breakthrough oral therapy for MS patients, saying we've "made things possible again" for her by providing treatment in a once-daily pill, and helping to prevent relapses.

However, there's always room for improvement. We've achieved a number of innovation milestones, but we still have a ways to go. I'm committed to sustaining our investment in R&D and following the science so we can continue to discover novel therapies and help patients live fuller lives.



Med Ad News: Please tell us a little more about Joe Jimenez, the person. What are the decisions, principles, and inspirations that enabled you to reach the top echelon of corporate management?

Joseph Jimenez: I've always been very goal-oriented. I learned a lot about hard work

and self-discipline from being a competitive swimmer when I was younger. As a teenager, I'd often spend 4 hours a day, 7 days a week, training in the pool. Swimming also helped instill in me a competitive mindset and strong desire to beat the competition.

I also learned early that working as a team toward shared goals and having challenging competition can bring out the best in teams. As CEO, I believe in listening and I like to speak with associates and leaders directly and solicit feedback.

I've been fortunate to have a lot of great mentors throughout my career. They've helped guide me and teach me to look at things differently. A great coach knows how to push people, but also when to back off. These lessons in leadership continue to have a profound impact on me.

Most importantly, I am inspired every day by the work we do at Novartis. Over the years, I've been able to meet many patients whose lives our products have touched, and it moves me to do my utmost with my colleagues to bring new medicines to market.

Med Ad News: Please describe a typical day for you. When does it start and end? Are you checking your BlackBerry or iPhone as soon as you wake up for the most recent headlines? What are your favorite sources of information? How many meetings a day are you involved in? Are you living in Basel now or splitting your time in the United States?

Joseph Jimenez: There really is no typical day for me. I travel a lot, and spend about half of my time visiting our teams in the countries. During these trips I also often get the chance to meet with patients, customers, and government officials, which gives me valuable insight. The other 50 percent of my time I am in Basel.

I have to admit, I am a BlackBerry enthusiast and do stay connected wherever I am. I check many different sources to get news so I gather diverse perspectives and opinions. Some of my favorite newspapers are the *Financial Times* and *The Wall Street Journal*. I also like to check out a few blogs like the WSJ.com Health Blog.

Med Ad News: What are the next steps forward for Novartis now, as the integration of Alcon into the company proceeds?

Joseph Jimenez: Alcon is now a fully integrated and operational division of Novartis. Over the last few months, we've implemented a new organizational structure in Alcon, streamlined decision-making, and combined our complementary product portfolios. Now, we're continuing to work on aligning our teams and leveraging synergies across our businesses. With our shared R&D activities and products that span a broad range of eye diseases, we expect to better meet patients' changing needs and the rising global demand for eye care. Alcon will be an engine of growth for us, as prevalence of eye disease rises and the elderly population grows.

Med Ad News: What do you believe is the future of innovative research at Novartis? What areas of the pipeline do you believe are particularly promising?

Joseph Jimenez: Innovation is what our industry is all about. At Novartis, we prioritize innovation, and will continue to invest heavily in R&D. Our research strategy follows the mechanism of disease pathways, grounded in science, not market potential. As a result, we are a leader in developing therapies for rare diseases and are better able to develop novel treatments for diseases with unmet needs. We have many promising areas in our pipeline, spanning specialty pharmaceuticals and novel therapies for rare diseases, vaccines and diagnostics, biosimilars and difficult-to-make generics.

One example of our commitment to research is our parallel development strategy for Afinitor (everolimus), which carries high risk and financial commitment. We simultaneously studied Afinitor's efficacy in multiple disease areas that we thought might share the mTOR pathway. And our strategy has been paying off. Afinitor has been approved to treat multiple diseases, including renal cell cancer, pancreatic neuroendocrine tumors, and a brain tumor known as SEGA that is associated with tuberous sclerosis. Afinitor has also shown potential in treating metastatic breast cancer, and we are currently studying its efficacy in breast, gastric, and liver cancers.

AFQ056 is another example of our leadership in rare diseases. AFQ056 has shown potential for Fragile X syndrome – a very rare disease that affects one in 5,000 children, but is the most common inherited cause of disabilities like mental retardation and autism.

Med Ad News: What do you believe is the future of the pharmaceutical industry? Do you see more diversification into "wellness" services, generics, biologics, and drug-device combos? What paths do you believe Novartis has to take and in what areas does the company need to prevail in order to succeed and continue to grow?

Joseph Jimenez: Yes, we're seeing a lot of pharma companies looking to diversify. However, at Novartis, we've been ahead of this trend and have pursued our strategy of focused diversification for quite some time. Our broad portfolio enables us to meet the healthcare demands of patients with diverse needs across geographies, and will continue to drive our growth. We focus on high-growth sectors of healthcare where there is high unmet need, including novel medicines, eye care, high-quality generics, vaccines and diagnostics, and consumer health.

As the industry continues to evolve, I think it's critical that we continue to invest in innovation, which is essential for our future growth, expand in key emerging markets where there is high unmet medical need, and focus our business model around improving patient outcomes, especially given today's cost-containment pressures.

Med Ad News: What are some of the harder decisions you have had to make so far, and what do you believe will be the hard choices you and other industry leaders will have to make in the future?

Joseph Jimenez: The market landscape is changing so quickly, I believe there will continue to be some tough choices to make in order to stay ahead of these shifts. Amidst the increased demand for healthcare, we're also facing greater pricing pressures and cost-containment efforts. A number of significant patents are expected to expire across the industry over the next few years. At Novartis, we are striving to remain a flexible, customer-focused organization and balance our resources effectively. A lot of our competitors are shrinking their R&D budgets and outsourcing innovation. I do not believe that is the best strategy, which is why we prioritize innovation and are keeping our R&D spend at the high end of the industry.

Med Ad News: What will the Novartis of the future look like? What do you think the pharmaceutical industry of the future will look like?

Joseph Jimenez: Early on, we shifted our business model to focus on improving patient outcomes, rather than a transactional approach of selling pills. We focus on collaborating with stakeholders to deliver more services for the patient and help improve overall health, while lowering costs.

Med Ad News: You personally made announcements of the firings of middle managers because of various ethics violations. Why did you choose to come forward to make those comments?

Joseph Jimenez: At Novartis, ethics are integral to our culture. We strive for performance with integrity and are committed to acting responsibly and with transparency. We take our Code of Conduct very seriously and don't tolerate any misconduct. I have a personal commitment to showing our dedication to values and our reputation as an ethical company.

Med Ad News: Do you believe the situations that led those managers to commit those ethics violations have been addressed? Is there anything else you think still needs to happen to make employees more accountable for their actions?

Joseph Jimenez: Novartis is deeply committed to educating and training associates about our Code of Conduct to make sure it is as clear as possible. Prevention is the best way to stop unethical behavior. This is an effort that has to be sustained over the long term. Individuals can sometimes make poor choices, but we want to do everything possible to make sure ethical behavior is imbedded in our DNA.

Med Ad News: There is a buzz about layoffs within Novartis' sales force, particularly in oncology. How would you address concerns about this?

Joseph Jimenez: There is no doubt that our business model is changing. We have to adjust our organization to ensure we remain competitive, limiting bureaucracy and non-value-adding activities so we can sustain our R&D investment. Our pipeline gives us a strong outlook, driving our future growth and the success of Novartis.

United States, and Voltaren maintained its position in Germany as the country's largest self-medication brand. Consumer Health Division sales were 12 percent of company sales in 2010.

Although Alcon was not fully integrated into the company until April, Novartis accounted for \$2.43 billion in sales from that unit in 2010, 5 percent of the company's total sales for the year. In the first half of 2011, Novartis recorded pro-forma sales for Alcon of \$5.03 billion, 11.3 percent more than pro-forma sales in first-half 2010 (for more about Alcon, please see the story "The path of Alcon" on page 72).

"We achieved strong growth in 2010 despite a global political and economic situation shaped by considerable challenges and uncertainties," Dr. Vasella says. "Our strategy, which focuses consistently on growth areas of the healthcare market while paying careful attention to risks, has proved its value in this dynamic environment. Also in the future, based on this strategy of focused diversification, we expect our company to develop in a more stable way than several of our important competitors. Our acqui-

sition of global eye care leader Alcon is expected to soon provide an additional growth platform with considerable synergy potential. In view of our sustainable success, it is not surprising that our strategy is imitated today. In the long-term, success is reserved for those companies that can systematically focus on their core business, recognize the inevitable associated risks, and handle them rationally, with strategic vision."

■ Pipeline and future development

While other pharmaceutical companies are cutting back on R&D spending, Novartis continues to invest in its pipeline. In 2010, the company spent \$8.1 billion on R&D. This amount was 16 percent of net sales and 20 percent of pharmaceuticals sales.

"We have one of the strongest and most productive pipelines in the industry with 147 projects in clinical development, 63 of which are new molecular entities," Mr. Jimenez says. "Our research strat-

egy is centered on an understanding of the science of disease and unmet medical need. By understanding the molecular pathways that may be shared by various diseases, we are able to better search for novel therapies. The foundation of our success is our ability to develop new innovative treatments. Our industry-leading commitment to R&D enables us to continually expand our pipeline, leading to sustained growth. More importantly, we expect our R&D investments to allow us to achieve breakthroughs in crucial areas of unmet patient need."

Novartis' research strategy is driven by the Novartis Institutes for Biomedical Research, or NIBR, which is headed by Mark Fishman, M.D., Ph.D., as president. By mapping core signaling pathways that have been conserved by evolution, NIBR scientists are discovering novel targets for new medicines and expanding the development of new medicines to other diseases where the same mechanism is involved.

In second-quarter 2011, Novartis received four major approvals, made two major filings, and achieved significant results for new products and indications. In

Europe, **Rasilamlo**, a single-pill combination therapy for patients with



Femara sales reached \$1.38 billion in 2010, but are expected to decline quickly in the face of generic competition.

uncontrolled high blood pressure, was granted approval. Novartis also received EU approval for a new indication of Lucentis to treat visual impairment due to macular edema in patients suffering from retinal vein occlusion, a sudden-onset disease associated with debilitating vision loss.

In the United States, FDA granted approval for **Arcapta Neohaler**, containing indacaterol, a novel once-daily bronchodilator for chronic obstructive pulmonary disease. The agency also approved **Afinitor**, comprising everolimus, as the first new treatment in nearly three decades for patients with advanced neuroendocrine tumors of pancreatic origin, a highly aggressive cancer for which treatment options have been limited.

Additionally, indacaterol was approved in Japan under the brand name **Onbrez Inhalation Capsules**. Everolimus was approved in Switzerland under the name **Votubia** as a treatment for subependymal giant cell astrocytoma, a benign brain tumor associated with tuberous sclerosis, and received a positive opinion from the EMA's Committee for Medicinal Products for Human Use for approval in Europe.

Novartis filed an application in the Europe for an in-licensed Janus kinase inhibitor, **INC424**, to treat patients with myelofibrosis, a life-threatening blood cancer characterized by bone marrow failure and debilitating symptoms. In addition, FDA accepted an application to expand the indication of the meningococcal vaccine **Menveo** to include infants and toddlers

as young as 2 months, based on data from more than 6,000 children in this age group worldwide.

At the American Society of Clinical Oncology annual meeting in June, Novartis Oncology showcased 140 abstracts. Highlights included a Phase III study demonstrating that extending the post-surgical duration of Glivec treatment from one to three years can significantly improve survival in patients with gastrointestinal stromal tumors. In addition, the company presented data from two Phase III studies of **INC424** that show promise for patients with myelofibrosis, and presented a study of patients with chronic myeloid leukemia that shows patients on **Tasigna** are less likely to develop mutations than those taking Glivec.

Also in the second quarter, two Phase III studies in patients with severe gouty arthritis showed that **ACZ885**, currently marketed as **Ilaris** for the rare disease cryopyrin-associated periodic syndrome, provides superior pain relief and reduces the risk of new attacks by up to 68 percent compared to the anti-inflammatory standard of care.

The development program for **ACZ885** suffered a setback in June, however, when an FDA advisory panel voted in favor of the overall efficacy but not the overall safety of the compound to treat gouty arthritis attacks in patients not obtaining adequate relief with non-steroidal anti-inflammatory drugs or colchicine. The committee members raised the potential for use in a narrower population of gouty arthritis patients, and Novartis is working with FDA

to identify the right patients who might benefit from this therapy.

ACZ885 is also in Phase III trials for systemic juvenile idiopathic arthritis, and Phase II for cardiovascular risk reduction, osteoarthritis, and COPD. Jefferies and Co. had targeted **Ilaris** sales for \$840 million by 2015, but after the advisory committee vote, was reconsidering the estimates.

In the respiratory area, two Phase III studies added to the growing body of evidence that indacaterol, marketed in the European Union as **Onbrez Breezhaler**, is an effective treatment for patients with chronic obstructive pulmonary disease. The studies showed that when used in conjunction with tiotropium, indacaterol produces a significantly greater improvement in lung function than tiotropium alone. Separately, a Phase III study showed that once-daily **NVA237** is superior to placebo and similar to tiotropium in improving lung function in patients with moderate-to-severe COPD. This data will be used to support Novartis' first regulatory submission for **NVA237**, which the company plans to file by the end of 2011.

In July, an interim analysis of a pivotal Phase III study showed that **Afinitor** in combination with exemestane significantly extended progression-free survival, or time without tumor growth, when compared to placebo plus exemestane in postmenopausal women with metastatic breast cancer whose disease has progressed, despite initial endocrine therapy. The study, **BOLERO-2** (Breast cancer trials of OraL EverOLimus-2), is

a Phase III, randomized, double-blind, placebo-controlled study of everolimus in combination with exemestane versus placebo plus exemestane in postmenopausal women with estrogen receptor-positive locally-advanced or metastatic breast cancer, whose disease has progressed, despite treatment with the nonsteroidal aromatase inhibitors letrozole or anastrozole. Novartis plans to make worldwide regulatory submissions in the second half of 2011.

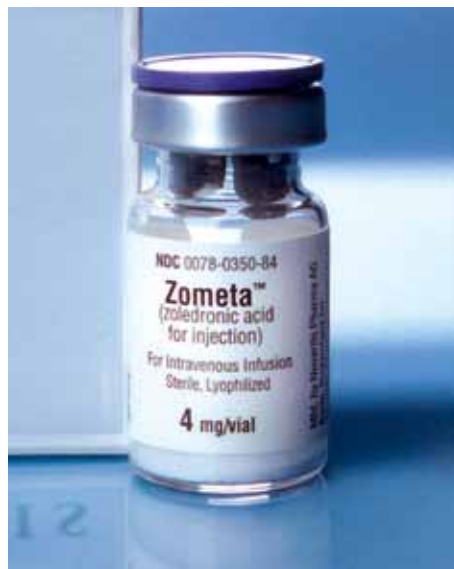
“Despite clinical progress in advanced breast cancer, most women are either initially resistant or develop resistance to endocrine therapy over time,” says Hervé Hoppenot, president, Novartis Oncology. “As a result, there is a significant need for new treatment options. Based on these study results, this combination has the potential to extend the time until chemotherapy is needed for these patients.”

Additionally, a Phase III trial of Afinitor in patients with tuberous sclerosis met the primary endpoint of reducing subependymal giant cell astrocytomas tumor size.

In September, Afinitor gained approval in the European Union for the treatment of patients with advanced pancreatic neuroendocrine tumors. The decision applies in all 27 European Union member states, plus Iceland and Norway. Additional regulatory submissions for everolimus in advanced NET are under way worldwide.

The approval was based on Phase III data from the largest clinical trial to date in advanced pancreatic neuroendocrine tumors. The RA-

DIANT-3 (RAD001 In Advanced Neuroendocrine Tumors) trial showed treatment with Afinitor more than doubled the time without tumor growth (median 4.6 to 11.0 months) and reduced the risk of cancer progression by 65 percent when compared with placebo in patients with advanced pancreatic neuroendocrine tumors. A consistent improvement in progression-free survival was seen with Afinitor in all patient subgroups, including patients who had not received prior chemotherapy.



Zometa sales were \$1.51 billion in 2010.

“Today’s approval of Afinitor means that thousands of advanced pancreatic NET patients across Europe will have a new targeted approach for the treatment of this aggressive cancer type for which few therapeutic options are available,” Mr. Hoppenot says. “We remain committed to the development of everolimus and to further researching the role of mTOR inhibition in multiple tumor types to address significant unmet med-

ical needs for patients.”

In Vaccines and Diagnostics, two pivotal studies of vaccine candidate **Bexsero** showed promise for protecting infants against meningococcal serogroup B, a deadly strain of meningococcal disease most dangerous for infants and young children.

To free up resources and ensure continued investment in R&D, Novartis is focused on improving efficiency and reducing costs across the entire business, partly by actively managing and prioritizing the portfolio. In the second quarter, Novartis sold the global rights to manufacture, market, and commercialize the psoriasis drug **Elidel** to **Meda** for \$420 million. This, as well as the discontinuation of the development program **PTK796**, reflects a strategy of prioritizing investments and focusing commercialization efforts on new product launches and core brands.

Novartis continues to look for ways to streamline its production capacity. During the second quarter of 2011, the company concluded the divestment of a Sandoz site in Jena, Germany, and announced the exit from a CIBA Vision production site in Cidra, Puerto Rico. Novartis recorded charges related to exits and inventory write-offs of \$44 million in the second quarter of 2011, and \$162 million cumulatively since the program began in the fourth quarter of 2010. These steps aim to help the company reduce excess capacity and enable the shift of strategic production to technology competence centers. ■ MEDADNEWS