

Ludwig Hantson,
CEO, US
pharmaceuticals



A Bountiful

Perhaps no large pharmaceutical company is so well positioned to survive the approaching patent cliff as Novartis. And it's no accident that the Swiss giant is in such good shape going into a period that for many of its peers will be a bloodbath.

Novartis faces the loss of US patent exclusivity on two huge drugs—\$2.4 billion Diovan, in 2012, and Femara, worth \$483 million, in 2011. But unlike many of its competitors, Novartis has a well-diversified business, with strong consumer and vaccines divisions, a strong pipeline and a wealth of newer products on the market to see it past those losses. The company boasts an oncology franchise that's the envy of the industry and leans less on the sort of aging mass-market blockbusters bedeviling many firms. In short, Novartis is right where a big drug company wants to be.

"We believe it is one of the better positioned pharmaceutical companies over an extended period of time," wrote Bernstein's Tim Anderson in a recent analyst's note maintaining an "overperform" rating for the company. Anderson cited "one of the best revenue/EPS growth profiles through 2015...partly due to the company's comparatively heavy diversification into other areas like consumer health, and also because certain important branded pharmaceutical products, like Gleevec, are likely to continue growing."

Then there's Novartis'

TOP BRANDS BY 2008 US SALES

**Diovan/
Co-Diovan:**
\$2.40B

**Gleevec/
Glivec:**
\$902M

Zometa:
\$666M

Femara:
\$483M

Sandostatin:
\$431M

Lotrel:
\$386M

Ritalin/Focalin:
\$347M

**Exelon/
Exelon Patch:**
\$279M

Exjade:
\$213M

Stalevo:
\$200M

remarkable R&D track record of late. There's an element of dumb luck in pharma R&D, but nine US approvals for the year to December, including three new innovative treatments, suggests sound design as well.

"We follow the science," says CEO, US pharmaceuticals, Ludwig Hantson. "We have a very strong pipeline, which you could say differentiates us from our competition. We look at unmet medical need, irrespective of the number of patients in a disease category. If we believe we can make a difference and address unmet medical need, we will do so."

In June, Novartis won FDA approval for Ilaris, a biologic for the treatment of a family of auto-immune disorders called cryopyrin-associated periodic syndrome, or CAPS, with a US patient population of around 300. "If you look at the way we developed it, it was a very targeted approach focusing on the mechanism of action," says Hantson. The company is looking at other possible indications including systemic juvenile idiopathic arthritis and type 2 diabetes.

Novartis got FDA's blessing for two innovative drugs in 2009: Afinitor, for renal cell carcinoma, in March; and Coartem, for malaria, in April. Extavia (AKA Betaseron) was approved in August for multiple sclerosis. The company's hypertension combo drugs Valtorna, Exforge HCT and Tekturna HCT got the green light, as did Novartis' H1N1 vaccine and OTC Prevacid formulation, Prevacid 24HR.

The company has another MS drug in its late-stage pipeline—FTY720 (fingolimod), an innovative oral compound for which Novartis was expected to file for FDA approval of a lower-dose formula by the end of 2009. Novartis looks to have a leg up

PHOTO: DAN DERRICO

Alpine Pipeline



Novartis received approval in 2009 for Afinitor, for renal cell carcinoma

on Merck, which has a similar drug in development but got hit with an FDA Refusal to File letter in November.

Novartis' vaccines division began shipping H1N1 vaccine in September and boasts two promising late-stage candidates for meningitis—Menveno and a meningitis B vaccine.

In oncology, Novartis expects to file SOM230 (pasireotide) for Cushing's disease in 2010, and planned to file for new indications for Zometa and Tassigna by the end of 2009. The company plans to file on INCB018424, an oral, selective Janus kinase inhibitor, for myelofibrosis in



The company launched a \$200 million marketing campaign for Prevacid 24HR, Prevacid's OTC counterpart. The ads focus on sufferers' "moment of decision" and were created by Deutsch

2011. Phase 3 trials for a potentially ground-breaking tumor-vascular disrupting agent, ASA404 (vadimezan) for non-small cell lung cancer, are ongoing, and several candidates will be entering phase 3 clinical trials in 2010, including LBH589 (panobinostat), for Hodgkin's lymphoma and multiple myeloma, and TKI258, for metastatic renal cell carcinoma.

Oncology is now Novartis' biggest category, worth around \$6.5 billion in global revenue for the first three quarters of 2009, though \$2.7 billion Gleevec is the sole blockbuster. It's a young and crowded franchise, though, with brand new drugs like Tassigna, Afinitor and Exjade along with more mature products like Femara, Zometa and Sandostatin.

Diovan loses US patent protection in 2012, but Novartis isn't ceding its heritage in cardiovascular. "I believe that we have a pipeline within hypertension," says Hantson. "Our

2008 GLOBAL SALES (BILLIONS)

Pharmaceuticals:
\$26.3 (+10%)

Sandoz:
\$7.6 (+1%)

Consumer Health:
\$5.8 (+4%)

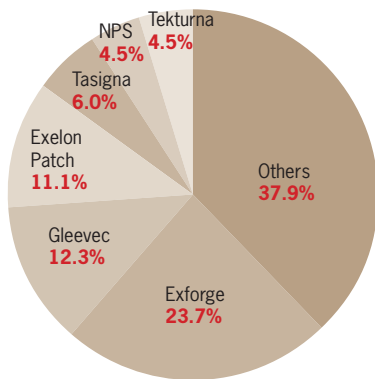
Vaccines and Diagnostics:
\$1.8 (+21%)

Total:
\$41.4 (+9%)

entry ticket was Diovan and Diovan HCT, but now with Exforge, which is fixed-dose combination, with Tekturta, which is a new class that we launched two years ago, as well as with Valturta, which is a combination of Valsartan and Tekturta, we believe that we have a portfolio within the disease area, so hypertension will continue to be critical."

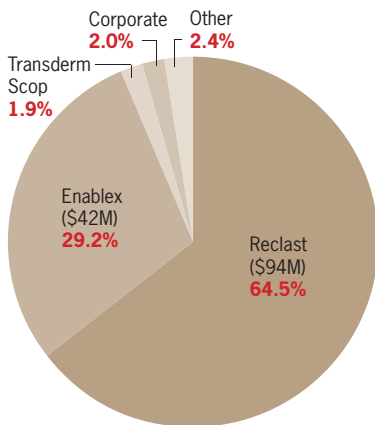
The franchise brought in \$5.4 billion globally for the first nine months of 2009, with Diovan still gaining and Exforge and Tekturta delivering more than seven percentage points of franchise net sales gains for the first half. "We know now hypertension isn't one disease area, that within hypertension you have different types of patients," says Hantson. "You have hypertensive patients with diabetes who respond differently from hypertensive African-Americans, different from patients who have mild stage one hypertension, different from those patients who





2008 JOURNAL AD SPEND

Novartis spent \$10.4 million on journal ads in 2008, according to SDI data, with nearly half of that going to Exforge, Gleevec and Exelon Patch. According to Perq/HCI's Journal Ad Review, the company placed sixth among top journal advertisers for the year. Source: SDI



2008 DTC AD SPEND BY BRAND

Novartis spent a scant \$145 million on consumer advertising in 2008, according to SDI—virtually all of that for the launches of osteoporosis drug Reclast and Enablex, for overactive bladder. For Diovan, the company's top-selling drug, Novartis spent only \$401,000. The hypertension treatment loses patent protection in 2012. Source: SDI's Direct-to-Consumer Audit

have severe stage two or complicated hypertension. We now know segmentation is critical. So, mass market will continue to be a big piece of our business, but the specialty side is going to grow faster, so it's got to be a bigger portion of our portfolio."

In October 2008, Novartis announced a realignment of its commercial model. Dubbed its "Customer Centric Initiative," the reorg replaced Novartis' nationally managed sales force with five regional units with cross-functional responsibility for primary care. The aim was to modernize the company's sales operation.

"The US market is no longer a homogenous market," says Hantson. "For example, the Northeast, where you have a very restricted market, is different from the South, in Florida, where you still have an open market and access is good. On top of this, if you think of the physician model, years ago, you were talking about solo physician practices being the majority. Solo practices moved into large or group practices and then into integrated healthcare systems. So, this is a simple way of segmenting the market. Instead of the top-down, one-size-fits-all type of model which is driven by headquarters, we put it upside down and made the customer central, we built strategies around that and we built teams around that. It's very much a regionalized, bottom-up type of approach, and it's a value proposition tailored toward the needs of and the insights that we get from the account. We believe that we can increase satisfaction and be more laser focused in the field."

It's also a recognition of the increasing power of consumers and payers in healthcare decision-making. "When you talk about innovation, it's not only innovation in the pipeline but it's also innovation in the way you do business," says Hantson. "The definition of our customer has changed over the years. We used to focus on regulatory authorities as well as on the physician, but we are now moving towards putting patients and payers more central."

As part of the realignment, which took effect January 1, 2009, the company cut 550 sales positions, but vowed

2009 HIGHLIGHTS

- Industry-leading number of US approvals, including cancer drug Afintor, hypertension combo therapy Valturta, H1N1 flu vaccines and Ilaris, a biologic for the treatment of auto-inflammatory disorders
- Advanced promising late-stage pipeline candidates for MS and meningitis, among others
- Launched Prevacid OTC switch along with Exjade and Exelon
- Implemented Customer Centric Initiative, a sweeping reorientation from a brand-focused commercial model to a more customer-centered approach, and cut 550 sales posts

- Fielded a tranche of newer drugs, including Lucentis, Exforge, Exjade, Exelon Patch, Reclast/Aclasta and Tekturta/Rasilez, that promise to absorb some of the blows from the imminent expirations of patents for Femara and Diovan

to do so "in a socially responsible manner," with half coming from unfilled vacancies. Most of those cuts were ultimately realized through attrition, says Hantson.

Novartis' efforts to fulfill the patient-centric part of its formula have borne very narrow and tactical but thoughtful efforts, like the social networks for CML and CAPS sufferers and caregivers (CML Earth and Caps Connect).

"On top of bringing a differentiated product to the market, we have to look at patient needs and see what we can do as an organization to give patients services," says Hantson.

DTC ad for Reclast, one of Novartis' newest drugs to hit the market

That's not to say that Novartis, the company that created Digger the Dermatophyte, is giving up on TV. Ads for Reclast, Enablex and Prevacid 24HR are up now.

"We have invested in traditional advertising and I do believe that DTC is an opportunity for us to help with disease awareness as well as product awareness," says Hantson. "Patients want to know what their disease is all about. They want to understand the symptoms and what they can do to manage the disease. Plus, they want to be involved in the treatment decisions, so for us on the commercial side, making sure that we listen to them and build their insights into our commercial plan is absolutely critical."

— Matthew Arnold