Perhaps no large pharmaceutical company is so well positioned to survive the approaching patient 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’ 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 Valturna, 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
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 Tasigna by the end of 2009. The company plans to file on INCB018424, an oral, selective Janus kinase inhibitor, for myelofibrosis in 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 Tasigna, 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 entry ticket was Diovan and Diovan HCT, but now with Exforge, which is fixed-dose combination, with Tekturna, which is a new class that we launched two years ago, as well as with Valturna, which is a combination of Valsartan and Tekturna, 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 Tekturna 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...
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 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 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.

Matthew Arnold