

TOP 20 PHARMA



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HEADCOUNT	98,200	
(59,423 in Pharma, Vaccines & Diagnostics)		
YEAR ESTABLISHED	1996	
PHARMA REVENUES	\$25,477	+8%
TOTAL REVENUES	\$39,800	+8%
NET INCOME	\$11,968	+66%
R&D BUDGET	\$6,340	+18%

* Includes Pharmaceutical and Vaccines and Diagnostics business, but not Sandoz generic unit

DRUGS APPROVED/LAUNCHED

Drug	Indication
exforge	high blood pressure
tekturna/rasilez	high blood pressure
exelon patch	Alzheimer's disease
lucentis	age-related blindness
tasigna	cancer
aclasta/reclast	osteoporosis
extavia	multiple sclerosis
galvus	type 2 diabetes (EU)
optafly	influenza vaccine (EU)
focetria	influenza pandemic (EU)
sebivo	chronic hepatitis B (EU/China)

DRUGS CANCELLED

Drug	Indication
xbd173	generalized anxiety disorder
aae581	osteoporosis
prexige	musculoskeletal system

DRUGS PENDING APPROVAL

Drug	Indication
galvus	type 2 diabetes (U.S.)
tekturna FDC1	hypertension
certican	organ rejection

DRUGS IN PHASE IIB AND BEYOND

Drug	Indication
diovan/starlix	new-onset type 2 diabetes, cardiovascular morbidity and mortality
lotrel	high-risk hypertension
tekturna	type 2 diabetes
tasigna	gastrointestinal stromal tumor (GIST)
epo906	ovarian cancer and other solid tumors
rad001	renal cell cancer, pancreatic islet cell tumor, solid tumors
som230	acromegaly, GEP6 tumors, Cushing's disease

ago178	depression
fty720	multiple sclerosis
qab149	chronic obstructive pulmonary disease
mff258	asthma, COPD
tbm100	cystic fibrosis
mycograb	severe fungal infections
albuferon	chronic hepatitis C
acz885	Muckle-Wells syndrome, rheumatoid arthritis, systemic onset juvenile idiopathic arthritis
smc021	osteoporosis, osteoarthritis
tfp561	severe community acquired pneumonia
as1404	squamous non-small cell lung cancer

DRUGS COMING OFF PATENT

Drug	Indication
lamisil	antifungal (2007)
trileptal	antiepileptic (2007)
omnicef	antibiotic (2007)
lotrel	hypertension (2007)

TOP SELLING DRUGS

Drug	Indication	\$	(+/- %)
Diovan	hypertension	\$5,012	19%
Gleevec	chronic myeloid leukemia	\$3,050	19%
Zometa	bone metastasis	\$1,297	1%
Sandostatin group	acromegaly	\$1,027	12%
Neoral	immunosuppression	\$944	3%
Femara	breast cancer	\$937	30%
Lotrel	hypertension	\$748	-45%
Voltaren	inflammation/pain	\$747	8%
Trileptal	epilepsy	\$692	-4%
Lescol	cholesterol	\$665	-8%
Exelon	Alzheimer's disease	\$632	20%
Lamisil group	fungal infections	\$595	-39%

Account for 64% of total pharma sales, down from 66% in 2006.

LAST YEAR, NOVARTIS MADE a big jump on our charts, thanks to its acquisition of Chiron. This time, its growth was more modest, causing it to slide back one spot to #6. Of course, I'm still slicing off the sales numbers for Novartis' Sandoz division, since I remain unprepared to incorporate generics into my precious Top 20 report. (For the record,

Sandoz posted revenue growth of 20%, to \$7.2 billion, primarily due to growth in the U.S. and eastern Europe.)

In fact, Novartis' Vaccines and Diagnostics division, carved out of the Chiron buy, makes a bit of hash of my report. I'd prefer not to count diagnostic devices as pharma revenues, but Novartis doesn't itemize its V&D sales, so these

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are the results you're getting, extra revenues and all.

And boy, does Novartis need them. Generics and a product withdrawal took a bite out of Novartis' hide in 2007, shaving \$1.4 billion from 2006 sales. U.S. sales dropped 8%, thanks to the Zelnorm suspension and generic competition for Lotrel, Lamisil, Trileptal and Famvir. In 1Q08, pharma sales were up 6%, but only because of exchange rates. In local currencies, sales at the pharma unit were down 3%, as those generics continued to bottom out in the U.S.

That gave Novartis a taste of what's coming in September 2012, when current top seller Diovan, a \$5.0 billion hypertension treatment, loses patent protection in the U.S.

Novartis' preparations for D-Day have been extensive these past few years, including \$13 billion in acquisitions to build up its Sandoz division and \$5.7 billion to add vaccines and diagnostics expertise through Chiron. The company also shed its Medical Nutrition and Gerber units in 2007 for \$12 billion (after-tax gain of \$5.2 billion).

This year, the company took its diversification strategy to a new level in April 2008 with a potential \$39 billion, multi-year acquisition of Alcon, a maker of a range of eye care products. Novartis' initial purchase covered 25% of the company at \$11 billion, with an option to buy another 52% at \$28 billion between January 2010 and July 2011. Nestle, Alcon's owner, can compel Novartis to exercise the option, which makes it sound less "option"-like than I'm comfortable with.

Alcon had sales of \$5.6 billion in 2007, with income of \$1.6 billion. The company has three business units — surgical care (\$2.5 billion in 2007 sales), prescription (\$2.3 billion) and consumer (\$800 million) — and 14,500 employees. In interviews after the acquisition announcement, chief executive officer Dr. Daniel Vasella contended that the areas it opens up for Novartis — surgical care, personal products — are less price-

sensitive than pharmaceuticals. (Like cancer treatment Gleevec, which can cost around \$8,500/month? But I digress. . .)

Eye care isn't new to Novartis. The company began co-marketing Visudyne, a treatment for age-related macular degeneration (wet AMD), in 2001 with QLT. In 2007, it gained EU approval for Lucentis, another wet AMD treatment, and managed to post \$393 million in non-U.S. sales. Genentech has U.S. rights, and sold \$815 million worth of the drug in 2007.

Since Alcon's portfolio doesn't encroach on the wet AMD business, Novartis is poised to build a powerhouse in eye care, especially since Alcon's main competitor, Bausch & Lomb, stumbled badly in recent years with quality issues.

ACQUISITION NEWS

Target: Alcon, Inc.

Price: \$11 billion for 25% stake, with \$28 billion option for additional 52% stake

Announced: April 2008

What they said: "This acquisition furthers our strategy of accessing high-growth segments of the healthcare market while balancing inherent risks. The strategic fit of Alcon and Novartis is excellent with our complementary product portfolios and R&D synergies. Eye care will continue to grow dynamically as there is a growing unmet medical need driven primarily by the world's aging population."

—Dr. Daniel Vasella, chairman and CEO of Novartis

Target: Protez Pharmaceuticals

Price: \$100 million, plus \$300 million in milestones

Announced: June 2008

What they said: "The addition of Protez and its pipeline, including PZ-601, to our existing initiatives will further strengthen our position in the specialty field of hospital infections while helping to address the public health challenges of increasing bacterial resistance and high mortality rates."

—Joe Jimenez, CEO of Novartis Pharma AG

THE LOWE DOWN

NOVARTIS HAS LOOKED SECURE for quite a while now, and we all know what that can mean in this industry, unfortunately. They spent an awful lot of money building up a whole new U.S. research arm in Cambridge a few years ago, with all sorts of talk about how this was going to be a completely different sort of place. That's odd, in retrospect, because all indications are that it's ended up as the same sort of place as everywhere else: once again, the search for the Perfect Pharma Research Structure seems to have come up short. Who'd have thought?

But even without perfection, their research has paid off better than the industry average. Their DPP-IV inhibitor for diabetes doesn't look like it's ever going to get a chance to make them a dime in the U.S., but they've got some good candidates in oncology. And the company has made a big push into vaccines, which could pay off quite well — just ask Merck.

—Derek Lowe

Eyes are the Prize

Novartis isn't just trying to buy its way past that 2012 Diovan date. Like any good pharma company, it's also working feverishly at getting new products approved and marketed. So it's gotta be driving Novartis crazy that it can't get diabetes drug Galvus on the U.S. market.

One of the company's biggest disappointments of late has to be Galvus' "approvable" status with the FDA. The agency asked for new safety studies that would likely lead to a 2010 resubmission. This leaves Novartis stalled in the DPP-4 market. As the previous profile shows, Merck's DPP-4 inhibitor Januvia hit \$668 million in 2007 sales, virtually from a standing position. Missing

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out on this market is a huge setback for Novartis.

Galvus has been approved in Europe, but Dr. Vasella remarked in January 2008 that Novartis may have to pass on the U.S. market entirely, if the FDA's trial requirements are too great. To capitalize on the drug's approval, Novartis also began marketing Galvus in the EU as a combo with metformin, under the brand name of Eucreas. No sales figures are available for Galvus yet.

Forward March!

Novartis' weak results led the company into a restructuring program that began in fall 2007. It began with disappointing 3Q07 numbers, which led to 1,260 layoffs in U.S. sales and marketing, but was followed by announcement of a comprehensive plan known as "Forward." The restructuring will "simplify organizational structures, accelerate and decentralize decision-making processes, redesign the way Novartis operates and provide productivity gains," according to the company's statement.

The plan is intended to shave \$1.6 billion from operating costs by 2010, at a cost of \$450 million and 2,500 firings. According to a *Wall Street Journal* report on Forward, the company also plans to review its use of CROs for clinical trials, "a huge expense for Novartis."

In comparison with its peers, this doesn't seem too extravagant a restructuring. The company contends that the second half of 2008 will signal a new growth cycle, as recent approvals gain acceptance in key markets and the losses to generics in the U.S. bottom out. Novartis appears to be framing the current slowdown as an opportunity to fine-tune, rather than an apocalyptic crisis. The *WSJ* piece also mentions that one of Dr. Vasella's key concepts is that there should be no more than six layers of employees in any division, after learning how bureaucracy-heavy his company has become.

While thinning the ranks and reorganizing management, the company also announced the establishment of Novartis Biologics, a unit intended to "accelerate and optimize the potential of R&D of innovative biologic medicines." Biologics make up 25% of the company's

preclinical pipeline and "are increasingly a priority in R&D activities." We'll see if this ends up being complicating the management structure, since it'd be easy to see these biologics crossing from the Pharmaceutical Division to the Vaccines & Diagnostics one.

Novartis has managed to get several new products off the ground, in hopes of ameliorating the loss of Diovan. The company also has a number of Phase III products that look promising, but this diversified company isn't taking anything for granted. ■