06 Merck & Co.

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HEADCOUNT	60,000	
YEAR ESTABLISHED	1891	
PHARMA REVENUES	$23,425*	+4%
TOTAL REVENUES	$24,536	+6%
NET INCOME	$4,434	-4%
R&D BUDGET	$4,783	+24%

DRUGS APPROVED/LAUNCHED

Drug	*Indication*
zostavax	shingles
januvia	diabetes
zolinza	cancer (CTCL)
fosamax	osteoporosis - single, once-weekly tablet

DRUGS PENDING APPROVAL

Drug	*Indication*
emend for injection	chemotherapy-induced nausea and vomiting (approvable)
janumet	diabetes
isentress	HIV
arcoxia	osteoarthritis (not approvable)

DRUGS CANCELLED

Drug	*Indication*
gaboxadol	insomnia (with Lundbeck)

DRUGS IN PHASE IIB AND BEYOND

Drug	*Indication*
mk-0524B	atherosclerosis
mk-0524A	atherosclerosis
taranabant	obesity
mk-0974	migraine

EARLY RESEARCH PROJECTS

Drug	*Indication*
mk-0952	Alzheimer's disease
mk-6213	atherosclerosis
mk-0429	cancer
mk-0646	cancer
mk-0731	cancer
mk-0752	cancer
mk-0448	cardiovascular
mk-0941	diabetes
mk-0867	endocrine
mk-0994	glaucoma
mk-0608	infectous disease
mk-0454	insomnia
mk-0773	osteoporosis
mk-0657	Parkinson's disease
mk-2637	psychiatric disease

TOP SELLING DRUGS

Drug	*Indication*	*$*	*(+/- %)*
singulair	asthma	$3,579	20%
fosamax	postmenopausal osteoporosis	$3,163	4%
cozaar/hyzaar	hypertension	$3,134	3%
zocor	cholesterol	$2,803	-36%
zetia/vytorin*	cholesterol	$1,900	59%
primaxin	antibiotic	$705	-5%
trusopt	ophthalmic	$697	13%
proscar	benign prostatic hyperplasia	$619	-16%
vasotec	hypertension	$547	-12%
cancidas	antifungal	$530	-7%

Account for 75% of total pharma sales, down from 80% in 2005.

KEY PERSONNEL

Richard T. Clark
chairman, president, chief executive officer
Willie A. Deese
president, Merck Manufacturing Division

* Pharma revenues include $1.9 billion in sales of Vytorin/Zetia. Merck and Schering-Plough report this as equity income from a joint venture, not as drug revenues. In order to give a clearer idea of Merck's pharma business, I have reported the Vytorin/Zetia income as revenues.

I'M NOT EVEN GOING TO GET INTO recapping the status of Merck's Vioxx lawsuits, except to note that Merck may benefit from an April ruling in a Texas court. The company contends that a recently finalized FDA rule will invalidate 1,000 lawsuits pending in Texas. Meanwhile, several of the cases that went to trial are now in appeal and it remains to be seen if this Texas ruling will hold up and whether it will apply to other states' plaintiffs.

Merck continues its post-Vioxx march with its Plan to Win, unveiled in November 2005. To recap, the stated goals of the Plan are

- Advancing the product pipeline
- Using end-to-end lifecycle management to optimize the value of every product and therapeutic franchise
- Developing and executing an industry-leading commercial model

- Creating a lean and flexible cost-business model
- Creating a high-performance organization.

Merck chairman, president and chief executive officer Richard T. Clark contends that the company's making headway with the Plan, citing "capturing significant procurement savings; closing or selling excess facilities; achieving hundreds of millions of dollars in inventory reduction; making Merck a Six Sigma company; and implementing a new product-supply process," in a press statement.

I admit that I get a little agita anytime a company in an R&D-based industry talks about Six Sigma, so when Mr. Clark's letter to shareholders included mention of "deploying Lean/Six Sigma principles throughout Merck," it left me hoping that he meant "throughout manufacturing operations" and not "throughout all aspects, including discovery."

Filling Holes

If the sum total of Merck's Vioxx liabilities is fraught with uncertainty, at least there's some sort of measurement for the effect of patent expirations. For example, the generic changeover of Merck's Zocor left a $1.5 billion hole in 2006 revenues, dropping to $2.8 billion. With 1Q2007 revenues down 76% to $258 million, the company projects total 2007 Zocor revenues of $600 to $900 million. That means Merck needs to fill a $1.9 to $2.2 billion hole just to stay afloat. Top-seller Singulair is doing its level best, with sales up 25% to $1 billion in 1Q2007, but the high end of Merck's projections for Singulair is $4.2 billion, an increase slightly lower than $700 million.

Merck is working feverishly at making up for its Zocor shortfalls, gaining five new drug approvals in 2006, with more coming this year. The biggest PR splash came from the June 2006 approval of Gardasil, a vaccine to prevent Human Papilloma Virus infection, which are responsible for most cervical cancers.

Gardasil's approval meant Merck won the opening round in the HPV wars, especially since GlaxoSmithKline's Cervarix was denied fast-track status by the FDA (it was approved in Australia in May 2007). Given a sizeable head start, Merck chalked up $235 million in Gardasil sales in 2006, and another $365 million in 1Q2007.

The company has taken heat for funding legislative efforts to make HPV vaccinations mandatory, but at least the controversy has helped bring a new direction to debates about public policy and healthcare, instead of the standard "drugs should be free, totally safe and more effective" rants that plague us.

Merck is also benefiting from its head-start with diabetes medicine Januvia. Its competitor in the DDP-4 inhibitor class, Novartis' Galvus, still awaits approval. In the meantime, Januvia hit $87 million in 1Q2007 sales, and stands to benefit from the "black box" warnings required by Avandia and Actos. One analyst estimated that the Avandia heart scare could add as much as $1 billion to Januvia's annual sales. As if that weren't enough, in April 2007, the FDA approved Janumet, a combo of Januvia and metformin.

Winning Partners

For more immediate assistance in filling that $2 billion hole left by Zocor, Merck is relying on a Zocor-related product: the Vytorin/Zetia joint venture with Schering-Plough. For accounting purposes, neither company declares sales from the venture as revenues, but for our semi-informal purposes, we'll continue to log Vytorin's as a near 50/50 split between the companies. In 2006, the venture yielded $3.8 billion in sales, up from $2.4 billion in 2005. The venture was up 47% in 1Q2007, yielding $1.2 billion in sales (half of which we'll cred-

THE LOWE DOWN

MERCK IS ONE OF THOSE IMPORTANT stories that's moving too slowly for spectators to get a handle on. Watching the progress of the Vioxx litigation is like trying to watch the movement of the hour hand on a clock. The appeals process makes the overall shape of things even harder to discern. Looking at the company's record so far, it's tempting to announce that they're winning, but the number of cases that have gone to trial versus the ridiculous number still waiting makes it impossible to say for sure.

You'd have to think that this is taking a toll inside the company. It's hard to remember now, but Merck used to seem as if they were immune to this sort of thing. Now that seems like a fish being immune to water, so thoroughly is the company immersed in Vioxx Litigation World. We have enough worry and uncertainty in this business already; an extra load can't be doing anyone any good.

One readout might be how well all their recent acquisitions are fitting in, but that sort of thing is impossible to work out from outside. And Merck's probably not through buying things, either. Watch their wallet this year.

—Derek Lowe

ACQUISITIONS

Target: Sirna Therapeutics
Price: $1.1 billion
Announced: October 2006
What they said: "We are excited about the opportunity to undertake the discovery and development of therapeutic siRNAs with Merck, a company that clearly recognizes the potential of this breakthrough technology"

—Barry Polisky, senior vice president of research, chief scientific officer, Sirna it to Merck, even if the company continues to book it as equity income from a joint venture).

In fact, the Merck/SP Vytorin partnership has been so successful that the companies have decided to develop a second product together. In March 2007, they announced plans to make a new combo drug, mixing Zetia and atorvastatin, also known as Lipitor. Of course, Lipitor's still under patent to Pfizer, but Merck contends that the development program is timed so that the new combination pill could be available around the time Lipitor's patent expires.

PATENT, SHMATENT

Last year, Abbott had to contend with threats of having an HIV medication shanghaied by Brazil's health ministry. This year, Merck was the target as Brazil issued a compulsory license for Stocrin/Sustiva, following negotiations that included a 30% price cut in Brazil. It was an interesting power play, because the government took the position that Brazil deserved drugs at as low a cost as Merck provides for dirt-poor third world countries, while also taking the position that Brazil is an up-and-coming world power. With the move, Brazil joined Thailand in the dubious distinction of violating international patents in order to cut its own healthcare costs. *—GYR*

Executive News

In last year's profile, we mentioned the April 2006 promotion of Peter Loescher to the top of Merck's marketing and sales pyramid. Thirteen months later, Mr. Loescher resigned from Merck to take the president and chief executive roles for German electronics company Siemens AG. At press time, Merck hadn't announced a successor to the role.

Also, with the retirement of longtime (17 years) chief financial officer Judy Lewent, Merck joined the parade of major companies that lost their CFOs in the past year. The *Wall Street Journal*'s Healthblog was the first place I saw it noted, but it's reached *Watchmen*-like proportions, with CFOs exiting Merck, Pfizer, Wyeth, Amgen and AstraZeneca.

Plan To Close

As part of its Plan to Win, Merck's restructuring initiative is rolling along. By the end of 2006, Merck had fired 4,800 of the 7,000 workers who are slated for layoffs. According to plan, the company closed two preclinical sites in Japan, and has sold or shut down three manufacturing facilities, with two more on the way. The remainder of firings and closings are scheduled to be complete in 2008.

Merck took almost $1 billion in restructuring charges in 2006, $142 million of which were employee-related. It expects to spend another $300 to $500 million in 2007. By the end of the process in 2008, Merck projects annual savings of $1.9 to $2.2 billion. Which just about balance out the Zocor revenues it expects to lose in 2007.

I should note that Merck's 10-K statement to the SEC refers to this as the "INITIAL phase of a global restructuring program designed to reduce the company's cost structure, increase efficiency and enhance competitiveness." There haven't been any announcements of Phase II in this process, so keep an eye out later this year or early in 2008.

Between its R&D-restructure and the 50 collaborations and three acquisitions Merck inked in 2006 (we covered GlycoFi and Abmaxis in last year's profile), the company is working to balance its cost-cutting measures with pipeline growth. It'll be interesting to see if they can maintain topline growth, especially now that one of their big options — acquiring Schering-Plough to control the Vytorin franchise — looks to be off the table. ■