

# TOP 20 PHARMA

**05 Merck & Co.**  
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<b>HEADCOUNT</b>	59,800
<b>YEAR ESTABLISHED</b>	1891
<b>PHARMA REVENUES*</b>	\$26,532 +10%
<b>TOTAL REVENUES</b>	\$26,791 +9%
<b>NET INCOME</b>	\$3,275 -26%
<b>R&amp;D BUDGET</b>	\$4,883 +2%

\* See note about revenues after Top Selling Drugs below

## DRUGS APPROVED/LAUNCHED

Drug	Indication
janumet	diabetes
isentress	HIV
emend	chemotherapy-induced nausea and vomiting for injection

## DRUGS CANCELLED

Drug	Indication
mk-0524A	atherosclerosis
claritin/singulair	seasonal allergic rhinitis (JV with Schering-Plough)

## DRUGS PENDING APPROVAL

Drug	Indication
gardasil	human papillomavirus vaccine in women aged 27 through 45 ("not approvable")
cordaptive	lipid-modification (NDA rejected by FDA)

## DRUGS IN PHASE IIB AND BEYOND

Drug	Indication
mk-0524B	atherosclerosis
mk-8669	cancer
mk-7418	heart failure
v270	hepatitis B vaccine
telcagepant	migraine
mk-0364	obesity
mk-0822	osteoporosis
mk-8141	cardiovascular
mk-0893	diabetes
v710	infectious disease
mk-0249	neurologic
sirna-027	ophthalmic
mk-0249	psychiatric disease
mk-2866	sarcopenia

## EARLY RESEARCH PROJECTS

Drug	Indication
v950	Alzheimer's disease
mk-1903	atherosclerosis
mk-0752	cancer
v930	cancer
mk-0448	cardiovascular
mk-0941	diabetes
mk-8122	infectious disease
v512	infectious disease

mk-8998	neurologic
mk-0140	ophthalmic
mk-0657	Parkinson's disease
mk-5757	psychiatric disease

## DRUGS COMING OFF PATENT

Drug	Indication
fosamax	osteoporosis (Feb. 2008)
trusopt	ophthalmic (Oct. 2008)

## KEY PERSONNEL

Richard T. Clark  
*chairman, president and chief executive officer*

Peter S. Kim, Ph.D.  
*executive vice president and president, Merck Research Laboratories*

David W. Anstice  
*executive vice president, Strategy Initiatives*

Willie A. Deese  
*executive vice president and president, Merck Manufacturing Division*

## TOP SELLING DRUGS

Drug	Indication	\$	(+/- %)
Singulair	asthma	\$4,266	19%
Cozaar/Hyzaar	hypertension	\$3,350	6%
Fosamax	postmenopausal osteoporosis	\$3,049	-3%
Zetia/Vytorin	cholesterol	\$2,593	34%
Gardasil	HPV vaccine	\$1,481	530%
ProQuad/MMRII/Varivax	children's vaccine	\$1,347	64%
Zocor	cholesterol	\$877	-69%
Trusopt	ophthalmic	\$787	13%
Primaxin	antibiotic	\$764	8%
Januvia	diabetes	\$668	1453%
Cancidas	antifungal	\$537	1%
Rotateq	rotavirus vaccine	\$525	222%

Account for 76% of total pharma sales, up from 74% in 2006.

\* Pharma revenues include \$2.6 billion in Zetia and Vytorin sales. This derives from a joint venture with Schering-Plough and are not counted as drug revenues by Merck. I have reported half of Vytorin/Zetia sales as Merck revenues to give a clearer idea of Merck's pharma performance. I also include \$3.8 billion in vaccines, which Merck does not count in its pharma unit.

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**H**ALF FULL OR HALF EMPTY? I keep looking over Merck's numbers and news, and still can't figure it out. On the one hand, the company looks like it's shrewdly navigated the self-laid minefield of Vioxx liability, striking a \$4.85 billion settlement that should take care of a vast majority of claims.

On the other hand, the company found itself facing a congressional investigation earlier this year in relation to Zetia and Vytorin, which it co-markets with Schering-Plough. If you haven't been following the story, the skinny is that a clinical study (ENHANCE) showed that Vytorin had no benefit in keeping arterial plaque from forming, but the companies didn't release the information for quite a while. Oh, and they maybesorta tried to change the endpoint of the trial without informing the lead investigator.

All things considered, Merck has weathered the ENHANCE storm better than SP has. That's because the two-year delay in reporting the trial results has raised some questions about share sales by SP executives, with the implication that the execs there knew bad results were coming and sold stock before the share price suffered. None of that was proved, but it still makes for a more salacious story than Merck's side of it.

### Up or Down?

Half full or half empty? On the one hand, the company's seeing great success from new products. DPP-4 inhibitor Januvia has run away with its new diabetes market, posting \$668 million in first-full-year sales and putting up \$272 million in 1Q08 sales while competitors have yet to receive FDA approval to enter the market. HPV vaccine Gardasil posted \$1.4 billion in first-full-year sales (up from \$235 million in partial-2006), while GSK's competitor Cervarix must wait for U.S. approval until at least

## THE LOWE DOWN

**M**ERCK IS PRESUMABLY BREATHING a bit easier, with most of the Vioxx disaster seemingly behind it. And they have some right to, considering that the whole episode looked fit to cripple the company a few years ago. But I wouldn't take off any shoes or loosen any shirt collars yet. The recent Cordaptive fiasco wasn't very inspiring: Merck is going to have to try to stop losing its projects so incredibly late in the process, after the serious long green has already been spent. But there are some advanced programs over there that have real possibilities for trouble (the CB-1 antagonist, for example), and the problem is, there's not much margin left for more trouble.

On top of that, no matter what the financial fallout, the company's reputation has taken a fearsome beating. When you consider the public esteem they were held in 20 years ago, it's downright tragic. But the company can still deliver winners like the Gardasil vaccine, and they still have resources, and they still have nerve: anyone who pays what they did for RNA interference does not lack for those. It's not going to be dull over there, that's for sure.

—Derek Lowe

mid-2009. Vaccine Rotateq may have dramatically reduced incidences of rotavirus gastroenteritis in children, according to the CDC. New HIV drug ISENTRESS is a first-in-class integrase inhibitor and may receive first-line treatment status soon.

On the other hand, projected \$2.0 billion heart drug Cordaptive received a "not approvable" notice from the FDA and won't reach the market till at least 2013, if ever. A

## ACQUISITION NEWS

**Target:** NovaCardia

**Price:** \$350 million

**Announced:** July 2007

**What they said:** "This acquisition gives Merck the possibility to expand its cardiovascular product pipeline into congestive heart failure, an area of important unmet medical need and significant burden to the healthcare system."

—Guy Eiferman, general manager of Merck's atherosclerosis and CV franchise

Claritin/Singulair combo product with Schering-Plough received the same status from the agency, leading to the withdrawal of its NDA. Gardasil was just rejected for treating its biggest patient group, women between 27 and 45. Another major project is pursuing the same path as Sanofi-Aventis' Acomplia, which the FDA wanted no part of.

Top-seller Singulair saw a 19% rise in 2007 sales, and a 10% increase in 1Q08, but Fosamax sales are crashing through the floor now that a U.S. generic is on the market (Feb. 08). Merck's Vytorin/Zetia revenues are poised to drop \$700 million in 2008, according to a company statement. I always take pains to disclose that Vytorin/Zetia sales are not counted as drug revenues by either Merck or SP but as equity income from a joint venture. So that \$700 million will not be missing from the company's reported revenues, but it will be missing from the bottom line.

The ineffectiveness of Zetia in preventing arterial plaque — even though it is proven to reduce LDL levels — throws into doubt Merck's plans for a combo of Zetia and generic Lipitor (atorvastatin), which could've been marketed like Vytorin on steroids.

The Cordaptive delay led the company to drop around 1,200 sales reps, but at least Merck hasn't executed a new massive restructuring in the past year. Instead, the company is sticking with its multi-year Plan To Win effort, which is supposed to save Merck between \$1.9 and \$2.2 billion annually, by the end of this year. Restructuring costs from Plan To Win dropped in 2007 from \$935.5 million to \$810.2 million, if I'm reading Merck's financial statements correctly. In the three years since it was implemented, the Plan To Win has reduced Merck's network by five manufacturing sites and two preclinical sites and led to 7,200 firings by the beginning of 2008.

(Honestly, I think "Plan To Win" is a silly name for any corporate initiative, much less one that involves shutting down

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plants and laying off workers. I always thought the point of capitalism is that you never “win,” but have to keep striving to stay ahead. I suppose Plan To Win it’s better than “Plan Not To Get Demolished,” but not by much.)

### A Small Hole in the [Redacted]

Merck’s vaccines R&D has been productive, but there have been some bumps in the road for operations. In April 2008, the FDA issued a warning letter to Merck’s big vaccine facility in West Point, PA, after the company failed to satisfy the agency’s concerns from an earlier Form 483. The site produces Liquid PedvaxHIB, Recombivax HB, ProQuad, Gardasil, Vaqta, and Comvax.

According to a *Philadelphia Inquirer* story by Karl Stark, John T. McCubbins, head of Global Vaccine Manufacturing and West Point Operations for Merck, contended that no contaminated vaccines were found and that Merck is addressing all of the FDA’s issues. The agency hasn’t threatened to shut down the plant nor has it called for any product recalls.

The text of the nine-page warning letter is available at [http://www.fda.gov/foi/warning\\_letters/s6756c.htm](http://www.fda.gov/foi/warning_letters/s6756c.htm) and it can be pretty scary. Its best line may be, “Your investigation into leaks discovered in the [redacted] during [redacted] recharge for lot [redacted] concluded that the leaks resulted from a small hole in the [redacted].”

On top of this, Merck announced in June 2008 that it would delay shipment of its shingles vaccine, Zostavax, after problems arose with a bulk ingredient lot in 2007. The company chose to focus on maintaining the supply of its pediatric chicken pox vaccine, which employs the same ingredient.

On the plus side, Merck is expanding its investment in a new vaccine facility in Durham, NC. Slated to manufacture Zostavax and several of its pediatric vaccines, the facility is a \$700 million investment for Merck and may employ more than 400 people when its final phase is complete in 2011.

### A Sieve?

Januvia has been an instant success for Merck, but the bulk of its growth is cur-

rently coming from vaccines, which have a tendency to stabilize, once they achieve market penetration. Meanwhile, the patent clock is running on its top two sellers, Cozaar/Hyzaar (2010) and Singulair (2012). With Zetia/Vytorin in precipitous decline, and Cordaptive off

the table, can Merck withstand those losses until its next round of Phase III gains a foothold in the market?

Which gets us back to my original question: Is Merck’s glass half full? Half empty? Or is it a sieve under a faulty faucet? ■