

10 | Eli Lilly & Co.

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HEADCOUNT	41,500	
YEAR ESTABLISHED	1876	
PHARMA REVENUES	\$14,816	+8%
TOTAL REVENUES	\$15,691	+7%
NET INCOME	\$2,663	+34%
R&D BUDGET	\$3,129	+3%

DRUGS APPROVED/LAUNCHED

Drug	Indication
byetta	type 2 diabetes (EU)
gemzar	ovarian cancer

DRUGS PENDING APPROVAL

Drug	Indication
arxxant	diabetic retinopathy
evista	reduction of invasive breast cancer risk in postmenopausal women
cymbalta	generalized anxiety disorder

DRUGS IN PHASE IIB AND BEYOND

Drug	Indication
inhaled insulin	diabetes
arxofifene	osteoporosis, prevention of breast cancer
enzastaurin	glioblastoma multiforme
prasugrel	acute coronary syndrome
alimta	small cell lung cancer (SCLC)
pruvanserin	insomnia
ppar alpha agonist	atherosclerosis
survivin aso	solid tumors
gamma secretase inhibitor	Alzheimer's disease
asap	solid tumors

mGluR3 antagonist migraine
neri IV depression
mGlu2/3 prodrug schizophrenia
il-1 beta antibody rheumatoid arthritis
GLP-1 analog type 2 diabetes

EARLY RESEARCH PROJECTS

Drug	Indication
neri IV	ADHD

TOP SELLING DRUGS

Drug	Indication	\$	(+/- %)
zyprexa	schizophrenia	\$4,364	4%
gemzar	pancreatic cancer	\$1,408	5%
cymbalta	anxiety, depression	\$1,316	94%
	diabetic peripheral neuropathic pain		
humalog	diabetes	\$1,300	9%
evista	postmenopausal osteoporosis	\$1,045	1%
humulin	diabetes	\$925	-8%
alimta	cancer	\$612	32%
forteo	osteoporosis	\$594	53%
strattera	ADHD	\$579	5%

Account for 82% of total pharma sales, up from 79% in 2005.

ZYPREXA WAS A DOUBLE-EDGED SWORD for Lilly last year. While the antipsychotic racked up \$4.3 billion in sales — more than Lilly's next three top-sellers combined — the company faced a massive number of lawsuits over the product's risk of hyperglycemia and diabetes. In January 2007, the company settled more than 18,000 claims for around \$500 million. A previous settlement of 8,000 claims cost Lilly \$690 million. Just before this profile went to press, the company announced that it had settled another 950 claims, but didn't disclose the cost. Approximately 750 product liability claims remain. The company took plenty of heat in the New York Times and other newspapers for its Zyprexa sales practices.

Those claims aren't the only issues Lilly has with its biggest moneymaker. The company is also appealing a pair of rulings that opened the door for generic Zyprexa (olanzapine) in Canada and Germany. A December 2006 appeal upheld Lilly's U.S. patent on the product, which will remain in effect until 2011.

Despite all that, Zyprexa yielded \$1.1 billion in sales in 1Q2007, a 10% increase credited mainly to higher prices. Lilly realized its biggest sales growth from next-generation depres-

sion treatment Cymbalta, which nearly doubled in sales in 2006, blowing past the billion-dollar mark in its second full year. The drug continued to soar in 1Q2007, with sales up 89% to \$442 million. With a February 2007 FDA approval to treat generalized anxiety disorder, Cymbalta should continue its trek to top-dog status at Lilly in the years ahead, flanked by fast-growing Alimta and Forteo, up 44% and 21% in 1Q2007, respectively.

On the flipside of the coin, Lilly faced a major setback with Arxxant, its treatment for diabetic retinopathy. The FDA issued a dreaded "approvable" letter for Arxxant, requesting a three-year study's worth of data. The company is evaluating its next step with the drug, having already withdrawn its application in the EU. In addition, Symbyax — a combination of Prozac and Zyprexa — also received an "approvable" letter to expand its label to cover treatment-resistant depression; the company plans to have some sort of action on the letter by the end of 2007.

The next big clinical news from Lilly will be the completion of its Phase III head-to-head comparison of anticoagulant prasugrel with standard-of-care Plavix in patients with acute coronary syndrome undergoing percutaneous coronary interven-

tion (PCI). Lilly is co-developing prasugrel with Daiichi-Sankyo and plans to complete the trial soon, with an NDA filing by the end of the year. If approved, it could help Lilly put some space between itself and the next company on this list, Bristol-Myers Squibb (which co-markets Plavix).

Another move to shore up growth was the \$2.3 billion acquisition of ICOS, Lilly's development partner on Cialis. The buyout gives Lilly the full revenues to the erectile dysfunction drug, which totaled \$266 million (+19%) in 1Q2007. Cialis' worldwide sales — recognized as revenue from the Lilly ICOS joint venture — were \$971 million in 2006 (+30%). Meanwhile, Lilly's partnership with Amylin for Byetta (diabetes) is beginning to pay, netting Lilly \$219 million in sales for its full year. It may not reach early predictions of \$2.0 billion in sales by 2010, but Byetta appears to be carving out a significant niche in type 2 diabetes. In total, Lilly's diabetes treatments reached \$3.0 billion in 2006 sales.

Bio-Oriented

Lilly isn't resting on its laurels. Firmly in the "next" tier of major pharma, the company is looking at ways to streamline its operations even while it pursues near-double-digit sales growth. Lilly announced a new global manufacturing strategy in January 2007. The company ended construction of an insulin manufacturing site in Virginia, contending that a reduced rate of growth and improved production processes would allow existing facilities to meet the company's needs for the hor-

more. Lilly also offered voluntary exit to 250 out of 1,000 employees at its small molecule API facility in Tippecanoe Laboratories.

"Both of these decisions, along with the previously announced decision to close our manufacturing site in Basingstoke in the UK, are based on current capacity needs and an assessment of the future mix of products in our portfolio," said Scott Canute, Lilly's president of manufacturing operations, in January. In May 2007, Mr. Canute took a leave of absence from Lilly and his role was assumed by Dr. Frank Deane, who previously served as vice president, quality.

ACQUISITIONS

Target: ICOS

Price: \$2.3 billion

Announced: October 2006

What they said: "With full ownership of Cialis, we will be able to realize operational efficiencies in the development, marketing and selling of this important product."

—Sidney Taurel, chairman and chief executive officer, Lilly

Target: Hypnion

Price: \$315 million

Announced: March 2007

THE LOWE DOWN

YOUR TAKE ON ELI LILLY IS SORT OF a surrogate personality test. You can look at them and think "Hmm . . . stable company, always seems to have something in its pipeline, no big disasters in the last few years, not interested in mergers, stock trades at a premium — what's not to like?" Or, if you're a glass-half-empty sort, you might say "OK, Zyprexa's being attacked, too many of the other big sellers aren't even from the company's own labs, and the stock has been sitting there like a shelf fungus for years." So, who's right?

Well, disagreements are what make markets. I admire Lilly for remaining independent, and I have to say that the company has shown real persistence in some tough therapeutic areas. But the company's own research efforts haven't been paying off as much recently, or so it seems from outside. They've made up for some of that with some good inlicensing moves, but can that continue?

Some things are forever, though. Lilly's always going to be a force in diabetes, at least if they have anything to say about it. And some people are never going to consider working for them, because of the perception (fair or not) that they have to pay some of their people extra to live in Indianapolis.

—Derek Lowe

Along with the aforementioned closures and reductions, Lilly also announced expansions to its biomanufacturing capabilities. As part of its plan to launch an average of one new biologic each year beginning in 2010, Lilly is investing in bio-API capacity in its Kinsale, Ireland site and will boost its parenteral operations in Indianapolis. The company contends that biologics comprise approximately a third of its portfolio and pipeline.

Manufacturing only covers one aspect of Lilly's restructuring. The company is also immersed in a program it calls Sales Force of the Future, "[leaving] behind a system built around individual products and overlapping coverage of the same doctors," according to a letter to shareholders. Lilly is also rolling out a company-wide Six Sigma program, which it contends saved \$250 million in 2006 and will double that amount in 2007.

On the R&D side, Lilly has established new alliances in India and China in clinical data management, chemical screening, and other aspects of early stage development. According to a recent BusinessWeek article, the company had 35 clinical trials underway in China in 2006 and will enroll twice as many patients there in 2007.

Lilly has ambitious plans to grow its sales, expand its pipeline, and control its costs. Much is riding on the prasugrel trial, but the company looks poised to grow, with few immediate patent worries beyond the Zyprexa rulings. ■