

## 09 | Wyeth

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<b>HEADCOUNT</b>	50,060	
<b>YEAR ESTABLISHED</b>	1926	
<b>PHARMA REVENUES</b>	\$15,683	+10%
<b>TOTAL REVENUES</b>	\$20,351	+9%
<b>NET INCOME</b>	\$4,197	+15%
<b>R&amp;D BUDGET</b>	\$3,109	+13%

### DRUGS APPROVED/LAUNCHED

<i>Drug</i>	<i>Indication</i>
torisel	advanced kidney cancer
lybrel	continuous contraception
rapamune	immunosuppressant (dose)

### DRUGS PENDING APPROVAL

<i>Drug</i>	<i>Indication</i>
bazedoxifene	postmenopausal osteoporosis - prevention (approvable)
viviant	osteoporosis - prevention
pristiq	vasomotor symptoms of menopause
pristiq	major depressive disorder (approvable)
bifeprunox	schizophrenia
subcutaneous methyl naltrexone	opioid-induced constipation, I.V. postoperative ileus
HCV-796	hepatitis C

### DRUGS IN PHASE IIB AND BEYOND

<i>Drug</i>	<i>Indication</i>
lybrel	premenstrual dysphoric disorder
viviant	osteoporosis - treatment
aprela	postmenopausal osteoporosis, vasomotor symptoms of menopause
pristiq	fibromyalgia, neuropathic pain
bifeprunox	bipolar disorder
effexor XR	major depressive disorder (Japan)
protonix	gastroesophageal reflux disease (pediatric)
tygacil	community and hospital acquired pneumonia, resistant pathogens
13-valent pneumococcal conjugate vaccine	pneumococcal disease in infants and children 6 months to 2 years
rapamune	conversion in liver transplants
torisel	mantle cell lymphoma
aab-001	Alzheimer's disease (with Elan)

**I**N SOME RESPECTS, WYETH'S BEEN the model of competitiveness in the pharma industry. Unable to match the giant R&D and licensing budgets of its biggest competitors, Wyeth's worked at revamping its R&D structure and employing unique (for pharma) outsourcing models. The company filed four NDAs in the last year, its biologic sales would make it #3 in our Top Biopharma ranks, and it's the first U.S.-based company on this list to post double-digit revenue gains in 2006. Coincidence?

So, for a company whose top seller went generic last year, Wyeth doesn't seem to be in bad shape. Antidepressant Effexor lost its patent protection in August 2006, so the company will

### EARLY RESEARCH PROJECTS

<i>Drug</i>	<i>Indication</i>
ppm-201	type II diabetes
diaplasinin	atherothrombotic events
lxr-623	atherosclerosis
agg-523	osteoarthritis
ima-638	asthma
pla-695	asthma, osteoarthritis, rheumatoid arthritis
paz-417	Alzheimer's disease
slv-313	schizophrenia and bipolar disorder
inotuzumab ozogamicin	non-Hodgkin's lymphoma
mst-997	oncology
MnB rLP2086	meningococcal serotype B

### DRUGS COMING OFF PATENT

<i>Drug</i>	<i>Indication</i>
effexor/venlafaxine	antidepressant (2006, 2008)
zosyn	antibiotic (2007 ex-U.S.)

### TOP SELLING DRUGS

<i>Drug</i>	<i>Indication</i>	\$	(+/- %)
effexor	depression	\$3,722	8%
prevnar	pediatric vaccine	\$1,961	30%
protonix	GERD	\$1,795	7%
enbrel	rheumatoid arthritis	\$1,500	38%
	(outside N.A.)		
premarin	HRT	\$1,051	16%
zosyn/tazocin	antibiotic	\$972	9%
alliance revenues*		\$1,339	17%

Account for 79% of total pharma sales, up from 75% in 2005.

\* Alliance revenues include revenues from Amgen's sales of Enbrel, King Pharma's sales of Altace, and J&J's sales of the Cypher drug-eluting stent, for which Wyeth makes the API of the eluted drug.

need to find new revenue sources as it loses its grasp on the world's #1 selling antidepressant. The drug's XR version is protected in the U.S. until 2010, but a generic version of it was introduced in Canada early this year. Total Effexor family sales dropped 6% in 1Q2007 to \$891 million.

By the end of this year, it's possible that Wyeth will have a new #1 in pneumococcal vaccine Prevnar. It narrowly missed reaching the \$2 billion mark in 2006, but revenues of \$617 million in 1Q2007 (+43%) make it a good bet to close in on \$2.5 billion at the end of 4Q.

In addition, Wyeth was rewarded for sticking with its hor-

mone replacement therapy franchise, which recovered from a serious health scare several years ago to post \$1.1 billion in 2006 sales. The company added to its women's health lineup with the May 2007 approval of Lybrel, a low-dose contraceptive. Lybrel made headlines for its ability to stop women's periods. To honor that, I'll end this paragraph period-free

## Pipe Up

As mentioned, the company's R&D pipeline has continued to yield results out of proportion to its expenditures. Wyeth's recent NDA filings cover oncology, depression, menopause, contraception, osteoporosis and schizophrenia, but the company's long-term sights are set on treatments for Alzheimer's disease. Menelas Pangalos, Ph.D., Wyeth's vice president of neuroscience research, remarked, "Our plan is to take as many shots on goal as possible using compounds or programs in multiple areas believed to be involved in the Alzheimer's disease process."

In May 2007, Wyeth and partner Elan entered Phase III trial of bapineuzumab, a MAb that binds to beta-amyloid plaques and clears them from neurons in the brain. The decision to push into Phase III was based on positive interim data from Phase II trial that won't be completed and analyzed till next year. Bapineuzumab has fast-track designation from the FDA.

## Spring Out

Last year, I wrote about Wyeth's "Project Springboard," a restructuring plan. The company didn't publicize much of the project, nor estimate the savings it would yield, but it seems to be continuing the plan. In its financial report, Wyeth commented, "Our ultimate goal from Project Springboard is to move beyond specific initiatives and create a culture where we continually look for new ways to become more productive in everything we do as a company." So Project Springboard is looking more like a continuous improvement strategy than a one-shot restructuring. The company incurred charges of \$219 million in 2006 as part of the project.

Part of this plan involved an expansion of its outsourcing agreement with Accenture, which originally contracted to handle clinical data operations. In July 2006, Wyeth entered a master services agreement with Accenture, covering "transactional processing and administrative support services over a broad range of areas, including information services, finance and accounting, human resources and procurement functions."

In January 2007, the company signed a deal with DHL to

## ACQUISITIONS

**Target:** Wyeth KK (joint venture in Japan with Takeda)

**Price:** not disclosed

**Announced:** April 2007

**What they said:** "Japan [is] one of the strongest markets for this important biotech product [Enbrel] for the treatment of rheumatoid arthritis."

—Robert Essner, chairman and chief executive officer, Wyeth

## THE LOWE DOWN

WYETH HAS PICKED SOME TOUGH areas to try to make a splash in over the years. Obesity has famously been one of them, a therapeutic area that's just littered with reasonable ideas that have fallen to pieces. It's been years, but the fen-phen crash's dented hubcaps have only recently stopped spinning and settled onto the asphalt. Not content with that delightful area, though, the company's making a push into Alzheimer's as well, which makes you wonder what's next.

The thing is, these strategies still make sense. These are tremendous underserved markets, and they're getting bigger all the time. (Problem is, they're underserved for some very good reasons). Wyeth's high-risk high-reward Alzheimer's push with Elan is probably the best way to get into such an area, because variations on existing therapies aren't going to do the job. But it doesn't help anyone's nerves over there, I'll bet.

They've got a reasonable lineup of other small-molecule drugs, though, ones which are only as risky as the usual run of things in our industry — you know, "very" as opposed to "wildly." That and their presence in biologicals give them, by recent standards, a rather stable outlook for the next few years. Who'd have guessed?

—Derek Lowe

handle global CTM distribution. "Our goal is for DHL to significantly streamline our clinical trials logistics operations, improve Wyeth's clinical trial logistical analysis and rationalization of related warehouse optimization, and encompass services provided to our research organization, as well as Wyeth's third party service providers," said Ira Spector, vice president, vice chief of operations clinical development operations, Wyeth Research.

Wyeth is also in the midst of a program to create Early Clinical Development Centers, building a global network of clinical sites to streamline the actual conduct of clinical trials. Look for an interview on that initiative in an upcoming issue of CONTRACT PHARMA.

Not every improvement goes according to plan. As part of its restructuring, Wyeth had planned to close a manufacturing site in Rouses Point, NY by the end of 2008. However, severe manufacturing problems at a facility in Puerto Rico led Wyeth to boost production at the Rouses Point site, and the company recently announced that the plant will remain open approximately one year longer than planned. In May 2007, the FDA gave the Puerto Rico site a positive re-classification.

Because of the economics of the industry, some contend that Wyeth's "next-tier" status makes it an obvious takeover target. I'm hoping it manages to retain its independence, so we can find out what happens in the next chapter of *Moneyball: Pharma Style*. ■