

03 | Novo Nordisk

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HEADCOUNT	22,590
YEAR ESTABLISHED	1989
BIOPHARMA REVENUES	\$6,526 +16%
TOTAL REVENUES	\$6,526 +16%
NET INCOME	\$1,087 +11%
R&D BUDGET	\$1,064 +25%

DRUGS APPROVED/LAUNCHED

Drug	Indication
novorapid	insulin in pregnancy (EU)
novomix 30	type 2 diabetes - once and twice-daily dosing (EU)
levemir	type 1 and type 2 diabetes - in combination with oral antidiabetic drugs (EU)

DRUGS PENDING APPROVAL

Drug	Indication
levemir	type 1 and 2 diabetes (Japan)
novomix	type 1 and 2 diabetes (U.S.)
activalle	hormone replacement therapy (EU)

DRUGS IN PHASE IIB AND BEYOND

Drug	Indication
liraglutide (NN2211)	type 2 diabetes
AERx iDMS	type 1 and 2 diabetes
novonorm/metformin fixed combo	type 2 diabetes
novoseven	trauma, hemophilia patients with inhibitors
vagifem	hormone replacement therapy
norditropin	in dialysis patients

EARLY RESEARCH PROJECTS

Drug	Indication
il-21	colorectal cancer
nn344	type 1 and 2 diabetes
nn5401	type 1 and 2 diabetes
rFXIII	cardiac surgery
rFVIIa analogue	hemostatic agent
anti-kir	acute myeloid leukemia, cancer

TOP SELLING DRUGS

Drug	Indication	\$	(+/- %)
Insulin and related	diabetes	\$2,536	1%
modern insulins / insulin analogs	diabetes	\$1,823	49%
novoseven	hemostasis management	\$949	12%
growth hormone therapy	HGH deficiency	\$557	20%

Account for 90% of total biopharma sales, up from 89% in 2005.

KEY PERSONNEL

Lars Rebien Sørensen
president, chief executive officer

NOVO NORDISK MADE IT ONTO the Top 20 Pharma list last year, but the company made me revise its classification going into this edition of the Top Companies ranks. From the outset, I was undecided about NN because its key products were insulin, insulin analogues, and a recombinant factor for hemophilia. Sounds more biopharma than pharma, right?

Then the company made its January 2007 announcement that it was ceasing all small molecule R&D and focus exclusively on large molecule therapies. As Mads Krogsgaard Thomsen, NN's chief science officer and executive vice president, put it, "Our core competences lie within therapeutic proteins, and it is within this area that we can make the greatest difference in terms of patient outcomes and company growth. Therefore, it is a logical move to focus all our R&D efforts on this area."

That settled it. Novo Nordisk is now officially a biopharma company, as Contract Pharma defines them. To help seal the deal, Novo even sold off its ownership in cancer diagnostics firm Dako.

Of course, with that change of focus, Novo had to begin outlicensing its small molecules and firing some of its staff that was working in that part of the business. In February

2007, Novo announced that TransTech Pharma would license the company's glucokinase activator (GKA) program. TransTech had been partnering with Novo in the development of GKA since 2001, so the deal became a no-brainer after Novo opted to cut small molecules out of R&D. Novo will receive development milestones and commercial royalties, as applicable.

Novo's bread-and-butter remains the injectable diabetes market. The company posted \$1.8 billion in sales in 2006, and its "modern insulin" segment posted a 49% gain for the year. Novo doesn't break out sales within that group, but the company did get U.S. approval of one product, long-acting insulin Levemir, last year. Recently, Novo announced results of a clinical trial showing that Levemir can treat diabetes without weight gain. Levemir received approval in Europe in March 2007 for use with oral diabetes drugs.

In addition, the company's GLP-1 analog, Liraglutide, showed surprisingly good results in five Phase III studies, compared to Sanofi-Aventis' Lantus, leading Novo to predict that it would file for approval next year. The trials showed that NN's analog offered better glucose control than Lantus, and patients

in the Liraglutide group ended up with an average weight more than 7.5 lbs. lighter than the Lantus group. NN has another four trials with Liraglutide to wrap up.

After the Avandia scare, we may see insulin analogues take a greater chunk of the diabetes care market, as doctors elect to move toward easier-to-dose modern insulin products like those marketed by Novo. According to a Bloomberg article in June 2007, Novo controls 45% of the injectable insulin market, thanks in part to its prefilled pen injectors.

In November 2006, Novo announced that it would increase its U.S. diabetes sales force from 1,200 to 1,900. In June 2007, Novo opened its \$100 million expansion in Clayton, NC. The site will double the U.S. filling production for FlexPen, the company's prefilled insulin pen.

The U.S. isn't the only market Novo's trying to boost. In March 2007, the company announced a partnership with the Chinese Academy of Science to establish a joint research foundation. The company built an R&D center in Beijing in 2002; this collaboration will involve \$2 million in funding for research in "diabetes and biopharmaceuticals."

Said Mr. Thomsen, "This cooperation illustrates the great attention Novo Nordisk pays to China as well as our long-term commitment to help in further developing the Chinese health-care system."

NovoEight,Nine,Ten?

At present, NN's late-stage biopharma pipeline consists of a number of new applications for NovoSeven, its recombinant coagulation factor. Given that NovoSeven posted nearly \$1 billion in 2006 sales, I can understand why the company's looking to expand its uses. Novo is pursuing indications in a number of surgical settings, to treat intraoperative and postoperative bleeding.

In February 2007, NN announced that it was going to pass on submitting an SNDA for NovoSeven in the intracerebral hemorrhage indication. The company conducted an extensive Phase III study in ICH, and determined that, even

though NovoSeven significantly reduced intracerebral bleeding, that didn't seem to affect 90-day mortality and severe disability outcomes, which were the primary endpoint of the trial.

In June 2007, the company reported that it was entering Phase I trials with Neose Technologies to test a long-acting version of NovoSeven.

Novo's biopharma unit also includes its hormone products, including HRT and growth hormone treatments. In June 2007, the FDA approved a new indication for growth hormone Norditropin: treatment of short stature in children who suffer from Noonan syndrome, which affects fewer than 20,000 people.

In June 2007, NN opened a new biopharma pilot facility at its site in Hillerod. The 3,500-sq.-m. plant cost approximately \$63 million, is geared to mammalian cell-cultured proteins and will begin by producing several investigational cancer antibodies. "This new pilot plant underlines Novo Nordisk's strong commitment to biopharmaceuticals, both within existing areas such as hemostasis, and new areas such as inflammation and cancer. It will significantly increase our capacity for producing investigational compounds for clinical trials," said Mr. Thomsen.

In April 2007, NN opened a new insulin facility in Brazil, its largest outside of Denmark. The company spent \$200 million on the site, a sum it contends is the largest single facility investment in the Brazilian pharmaceutical industry. Almost 95% of the site's production — 3ml Penfill insulin cartridges — will be exported to other markets. The company approved another \$50 million for a facility in Brazil for a FlexPen facility, which is expected to open in 2009.

NN is certainly in an interesting position, with an established franchise in a growing field, and a yen to get into other portions of the biopharmaceutical market. I'm interested to see how Novo grows in the bio-segment in the years ahead. It's already in a tremendous position in diabetes treatment. ■