

# TOP 10 BIOPHARMA

**O** Novo Nordisk  
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 www.novonordisk.com

<b>HEADCOUNT</b>	26,000+
<b>YEAR ESTABLISHED</b>	1989
<b>BIOPHARMA REVENUES</b>	\$7,696 +18%/+8%*
<b>ROYALTY REVENUES</b>	\$0
<b>TOTAL REVENUES</b>	\$7,696 +18%/+8%*
<b>NET INCOME</b>	\$1,568 +44%/+32%*
<b>R&amp;D BUDGET</b>	\$1,571 +48%/+35%*

\* Change based on local currency (DKK)

## DRUGS APPROVED/LAUNCHED

Drug	Indication
levemir	type 1 and 2 diabetes (EU, Japan)
liraglutide	type 2 diabetes
novorapid	treatment of diabetes in elderly and people with renal or hepatic impairment (EU)
prandimet	type 2 diabetes

## DRUGS CANCELLED

Drug	Indication
small-molecule projects were discontinued and existing projects were divested in 2007	
novoseven line extension	trauma bleeding in emergencies
AERx	inhaled insulin (with partner Aradigm)

## DRUGS PENDING APPROVAL

Drug	Indication
activelle low dose	hormone replacement therapy
novoseven	hemophilia patients with inhibitors room-temperature-stable
novonorm + metformin fixed combo	type 2 diabetes
novomix 50 and 70	type 1 and 2 diabetes

## DRUGS IN PHASE IIB AND BEYOND

Drug	Indication
norditropin	chronic dialysis
vagifem	hormone replacement therapy
liraglutide	type 2 diabetes

## EARLY RESEARCH PROJECTS

Drug	Indication
long-acting growth hormone	growth disorder
rFXIII	elective surgery, cardiac surgery
subcutaneously administered rFVIIa	hemophilia patients with inhibitors
rFVIIa	hemostatic agent
long-acting analogue nn9535	type 2 diabetes

## DRUGS COMING OFF PATENT

Drug	Indication
NovoSeven	diabetes (2010)

## KEY PERSONNEL

Lars Rebien Sorensen  
*president and chief executive officer*

Mads Krogsgaard Thomsen  
*executive vice president and chief science officer*

## TOP SELLING DRUGS

Drug	Indication	\$	(+/- %)
Modern Insulins / Insulin Analogs	diabetes	\$2,577	41%
Insulin and Related	diabetes	\$2,313	-9%
Novoseven	hemostasis management	\$1,079	14%
growth hormone therapy	HGH deficiency	\$646	16%

Account for 86% of total pharma sales, down from 90% in 2006.

**N**OVO NORDISK STARTED OUT THE YEAR with a new ideology, halting small molecule development to focus R&D on its therapeutic proteins. This led to disappointment when its final studies investigating rFVIIa for the treatment of intracerebral hemorrhage failed to show sufficient benefits for patients. On the bright side, diabetes drug Liraglutide was recently filed in both the U.S. and the EU after several successful Phase III studies. The drug is also being investigated as a preventive for obesity-related health risks.

After deciding to focus on its growing pipeline of protein-based drugs, the company discontinued divested all existing

preclinical and clinical small-molecule projects. The company's biopharmaceutical ambitions include developing the next-generation successors to NovoSeven and creating new treatments for hemophilia, growth deficiency, hormone replacement and inflammation. To support these ambitions, the company opened a new pilot plant in Hillerod, Denmark, for the development and production of new biopharmaceuticals based on proteins cultured in mammalian cells.

The company's globalization efforts to expand its global supply chain, aimed at supporting the continued roll-out of Levemir and the rest of its portfolio of modern insulins,

## TOP 10 BIOPHARMA: Novo Nordisk

included a \$200 million investment to expand its facility in Brazil, which opened in April and is the largest insulin plant in Latin America; doubling its insulin filling capacity at its manufacturing facility in Clayton, NC; and expanding its network into China for R&D activities there. The company also added 700 new hires to its U.S. diabetes sales force during the past year. The diabetes market has the highest expected future growth rates in the pharmaceutical industry and NN controls more than half the worldwide insulin market. And, with its Liraglutide drug expected to hit the market in 2009 — with

Reasons for Exubera's failure were attributed to the clumsiness of the device used to administer the powdered insulin and because the drug had a tendency to slightly impair lung function.

### Pipeline Progress

One the diabetes front, drug approvals for additional indications include: Levemir, Novorapid and PrandiMet. Levemir was approved in the EU and Japan for use in type 1 and type 2 diabetes including combination treatment with other antidia-

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the potential to be approved to combat another growing epidemic, obesity — the company is expected to continue to see strong growth.

### A No-Go for Inhaled Insulin

In January 2008, following Pfizer's 2007 surrender on its inhaled insulin Exubera last year, citing lower-than-expected sales, NN discontinued all development of its AERx product, meant to deliver inhaled insulin droplets, which the company anticipated bringing to market by 2009 or 2010. NN also noted that its decision was not related to safety concerns. Pfizer later released a warning about a potential link of Exubera to lung cancer, but it's a different formulation.

According to the company, this was by no means devastating. In an interview last November with *Dow Jones*, Martin Soeters, president of Novo Nordisk's U.S. unit, said the company thought that its AERx iDMS inhaled insulin product would be a niche product, not a blockbuster as many thought it would be for Pfizer. He added that, "Inhaled insulin might not be appropriate for use over multiple decades, but rather for short-term users such as the elderly or women who have pregnancy-related diabetes." The financial impact for NN in 2007 for the cost of discontinuing development and manufacturing activities for the AERx system, was \$262 million, nowhere near the \$2.8 billion hit Pfizer took (plus opportunity costs).

betics. Also, recent data shows that the Levemir weight benefit continues after two years, a major plus for the drug. Novorapid was approved for treatment of diabetes in the elderly and in people with renal or hepatic impairment. Lastly, PrandiMet recently gained U.S. approval to improve glycemic control in adults with type 2 diabetes who are already treated with a meglitinide (such as Prandin) and metformin or who have inadequate glycemic control using either of these treatments.

Finally, after the last of five Phase III studies confirming the drugs efficacy, Liraglutide was filed in the U.S. and EU for the treatment type 2 diabetes. A recent study also showed that significant weight loss was sustained in obese people treated with the drug for one year.

NN recently discontinued the Phase III trial of NovoSeven for the treatment of bleeding in patients with severe trauma citing the analysis predicted a low likelihood of obtaining a positive trial outcome with the planned study population.

In the early-stage pipeline, a Phase I trial of NN7128, a long-acting version of NovoSeven, drew to a close after demonstrating safety and a pharmacokinetic profile. Also, NN licensed global rights to potential new hemostasis therapy for thrombin-activable factor X, supporting its ambition to expand its hemophilia and hemostasis portfolio. The company plans to explore the protein's potential as a new treatment option for hemophilia and other critical bleeding conditions. ■—KB

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