

# Share

Quarterly update for investors from Novo Nordisk **May 2009**



changing diabetes®

**Victoza® well received in the EU, negotiations continue in the US**

**Improving the life of 10,000 children with diabetes in Africa**

**FVIII-project in phase 3 is important step towards broad portfolio for haemophilia**



**18%**

sales increase in the first quarter of 2009

**35%**

increase in operating profit

**24%**

increase in net profit

**31%**

increase in sales of modern insulins

For Novo Nordisk, the first quarter of 2009 mirrors the end of 2008, with solid sales growth for Novo Nordisk's strategic products.

This quarter the North American region was the largest in terms of sales. A testament to both the successful outcome of Novo Nordisk's increasing efforts in this market, but also pointing to the challenging competitive situation in the European markets.

After six years in the reverse, currency trends have turned to Novo Nordisk's benefit, as the US dollar and the Japanese yen have strengthened compared to the Danish krone. Currencies, in combination with further efficiency gains at our production sites, are the main drivers behind the boost to Novo Nordisk's operating profit.



Lars Rebien Sørensen  
President and CEO, Novo Nordisk

# Victoza® debated at meetings in EU and USA

In April 2009, two groups of experts passed judgement on Victoza®, Novo Nordisk's once-daily human GLP-1 analogue.

The European regulatory authorities' Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion for the approval of Victoza® on 23 April.

The committee evaluates new drug candidates in Europe. Following a positive opinion, the European Commission normally issues a formal marketing approval within approximately two months.

The positive opinion for Victoza® covers the use of Victoza® for treat-

ment of type 2 diabetes in combination with one or more widely used tablet products (OADs) when the tablets alone don't give sufficient blood sugar control at the highest allowed doses.

"We are very pleased with the positive opinion from the CHMP, which gives us confidence that Victoza® will soon become available to many



people with type 2 diabetes in Europe,” says Mads Krosgaard Thomsen, executive vice president and chief science officer of Novo Nordisk.

### Discussions with the FDA continue

In the US, liraglutide was reviewed by a US Food and Drug Administration (FDA) Advisory Committee on 2 April. FDA advisory committees are panels of independent experts who advise the FDA as they consider regulatory decisions. The FDA is not bound by the committee’s recommendation, but it takes its advice into consideration when reviewing new drug applications.

The Advisory Committee voted on questions related to the risk profile of liraglutide.

While a majority of Advisory Committee members supported that appropriate evidence of cardiovascular safety had been provided, the Advisory Committee was split on the FDA question related to whether the available data on C-cell tumours permitted approvability. The European regulatory authorities, on the other hand, were satisfied with the documentation provided by Novo Nordisk.

Following the meeting, Novo Nordisk will be discussing next steps with the FDA to resolve the issues raised at the Advisory Committee meeting. US approval of liraglutide, and the timing thereof, will depend on the completion of the FDA’s review of the application. ■

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## Site Chartres expands

With an investment of several million euros a new filling line for Penfill® will be added to Novo Nordisk’s factory in Chartres, France. The filling line will open in 2011 according to plans. When the filling line is running, it is estimated to significantly expand capacity with the existing manning. The last time the factory was expanded was in 2003 to 2005, when a new FlexPen® assembly area was installed.

Site Chartres began operations in 1961 and is Novo Nordisk’s oldest production site outside Denmark. It is the second-largest production facility outside of Denmark after Brazil. Chartres has 630 employees.

## Changing Diabetes® Barometer website launched

The Changing Diabetes® Barometer website, launched in April 2009, contains a wealth of facts, figures and success stories with a powerful message for change.

The website is the latest effort in the Changing Diabetes® Barometer initiative, established by Novo Nordisk in 2007 as Novo Nordisk’s response to the challenge of really measuring the depth and breadth of diabetes.

Using data collected from more than 70 countries, it covers topics such as the cost and quality of diabetes care, enabling users to compare the situation in locations around the world. This provides important inspiration for payers, politicians, healthcare professionals and patients around the world on which approaches and measures are more effective when dealing with the diabetes pandemic.

See the website here: [www.changingdiabetes-barometer.com](http://www.changingdiabetes-barometer.com).

# 18%

sales increase in the first quarter of 2009

# 2.6

percentage points improvement in gross margin

# 35%

increase in operating profit

# 24%

increase in net profit

## Performance in the first quarter of 2009

Novo Nordisk increased sales by 18% in the first quarter of 2009.

Operating profit increased by 35% supported by continued gross margin improvement.

- Sales in Danish kroner increased by 18% and by 11% in local currencies.
  - Sales of modern insulins increased by 31% (25% in local currencies).
  - Sales of NovoSeven® increased by 25% (18% in local currencies).
  - Sales of Norditropin® increased by 18% (9% in local currencies).
  - Sales in North America increased by 31% (16% in local currencies).
  - Sales in International Operations increased by 20% (16% in local currencies).
- Gross margin improved by 2.6 percentage points to 79.9% in the first three months of 2009, primarily reflecting continued productivity improvements and a positive currency impact of around 1.0 percentage points.
- Reported operating profit increased by 35% to DKK 3,810 million. Adjusted for the impact from currencies and non-recurring costs in 2008 related to the discontinuation of all pulmonary diabetes projects, underlying operating profit increased by around 15%.
  - Net profit increased by 24% to DKK 2,699 million. Earnings per share (diluted) increased by 27% to DKK 4.41.
  - In Europe, the Committee for Medicinal Products for Human Use (CHMP) under the European Medicines Agency (EMA) adopted a positive opinion for Victoza® (liraglutide) and Novo Nordisk expects to receive the European Marketing Authorisation from the European Commission within approximately two months.
  - In the US, following the Advisory Committee meeting on 2 April, Novo Nordisk is working with the United States Food and Drug Administration (FDA) as it completes the review of the liraglutide application.
  - For 2009, operating profit measured in local currencies is now expected to grow by at least 10% and reported operating profit growth to be around 8 percentage points higher.

Lars Rebieen Sørensen, president and CEO, said: "We are satisfied with the financial performance during the first quarter of 2009 which is driven by solid sales growth for the modern insulins and gross margin improvements. Following the positive opinion in Europe for Victoza®, we now

look forward to launching Victoza® in the first European markets this summer.”

## DIABETES CARE

Sales of diabetes care products increased by 17% measured in Danish kroner to DKK 9,169 million and by 11% in local currencies compared to the first three months of 2008.

### **Modern insulins, human insulins and insulin-related products**

In the first three months of 2009, sales of modern insulins, human insulins and insulin-related products increased by 18% in Danish kroner to DKK 8,478 million and by 12% measured in local currencies compared with the same period last year. All regions contributed to growth measured in local currencies, with North America and International Operations having the highest growth rates. Novo Nordisk continues to be the global leader with 52% of the total insulin market and 45% of the modern insulin market, both measured by volume.

The sales growth is driven by the portfolio of modern insulins exhibiting a steady sales growth globally. Sales of modern insulins increased by 31% in Danish kroner to DKK 4,990 million and by 25% in local currencies compared with the first three months of 2008. All regions realised solid growth rates, with North America accounting for more than half of the growth followed by Europe and In-

ternational Operations. Sales of modern insulins now constitute 62% of Novo Nordisk's sales of insulin.

## BIOPHARMACEUTICALS

In the first three months of 2009, sales of biopharmaceutical products increased by 20% measured in Danish kroner to DKK 3,329 million and by 13% measured in local currencies compared to the first three months of 2008.

### **NovoSeven®**

Sales of NovoSeven® increased by 25% in Danish kroner to DKK 1,805 million and by 18% in local currencies compared with the first three months of 2008. Sales growth for NovoSeven® was primarily realised in Europe and International Operations and is positively impacted by timing of sales in these regions. The sales growth for NovoSeven® primarily reflected increased sales within the congenital bleeding disorder segments. Treatment of spontaneous bleeds for congenital inhibitor patients remains the largest area of use.

### **Growth hormone therapy (Norditropin®)**

Sales of Norditropin® (ie growth hormone in a liquid, ready-to-use formulation) increased by 18% measured in Danish kroner to DKK 1,034 million and by 9% measured in local currencies compared with the first three months of 2008. North America and Europe were the main contributors to growth measured in local currencies. Novo Nordisk →

**17%**  
increase in total  
diabetes care sales

**20%**  
increase in  
biopharm sales

**20%**  
Increase in  
International  
Operations sales

**31%**  
increase in North  
American sales

## Quarterly numbers for Novo Nordisk in 2008 og 2009

(Amounts in DKK million, except number of employees, earnings per share and number of shares outstanding)

	Q1 2009	Q4 2008	Q3 2008	Q2 2008	Q1 2008	% Change 2008–2009(Q1)
<b>Sales</b>	<b>12,498</b>	<b>12,583</b>	<b>11,246</b>	<b>11,110</b>	<b>10,614</b>	<b>18%</b>
Gross profit	9,990	10,047	8,640	8,556	8,201	22%
Sales and distribution costs	3,844	3,558	3,155	3,178	2,975	29%
Research and development costs	1,744	2,439	1,579	1,980	1,858	(6%)
– Hereof costs related to AERx®	-	-	50	(155)	(220)	
Administrative expenses	679	749	633	626	627	8%
Licence fees and other operating income (net)	87	73	51	74	88	(1%)
<b>Operating profit</b>	<b>3,810</b>	<b>3,374</b>	<b>3,324</b>	<b>2,846</b>	<b>2,829</b>	<b>35%</b>
<b>Operating profit (excl AERx®*)</b>	<b>3,810</b>	<b>3,374</b>	<b>3,274</b>	<b>3,001</b>	<b>3,049</b>	<b>25%</b>
Share of profit/(loss) in associated companies	(35)	4	(58)	(3)	(67)	(48)%
Financial income	142	(82)	306	429	474	(70)%
Financial expenses	412	226	66	21	368	12%
Profit before income taxes	3,505	3,070	3,506	3,251	2,868	22%
<b>Net profit</b>	<b>2,699</b>	<b>2,330</b>	<b>2,,664</b>	<b>2,471</b>	<b>2,180</b>	<b>24%</b>
Depreciation, amortisation and impairment losses	607	752	560	567	563	8%
Capital expenditure	413	764	448	328	214	93%
Cash flow from operating activities	4,148	3,204	3,673	2,916	3,070	35%
Free cash flow	3,626	2,421	3,210	2,589	2,795	30%
Equity	31,345	32,979	32,173	33,046	31,251	0%
Total assets	50,205	50,603	48,990	48,478	47,534	6%
Full-time employees at the end of the period	27,429	26,575	26,360	26,060	25,765	6%
Basic earnings per share (in DKK)	4.44	3.82	4.34	3.99	3.51	26%
Diluted earnings per share (in DKK)	4.41	3.80	4.30	3.96	3.48	27%
Average number of shares outstanding (million)	607.4	609.3	614.2	618.6	620.9	(2%)
Average number of shares outstanding incl dilutive effect of options 'in the money' (million)	612.7	614.4	618.6	623.5	626.3	(2%)

\*) Costs related to the discontinuation of all pulmonary diabetes projects.

→ remains the second-largest company in the global growth hormone market with 23% market share measured by volume.

### Other products

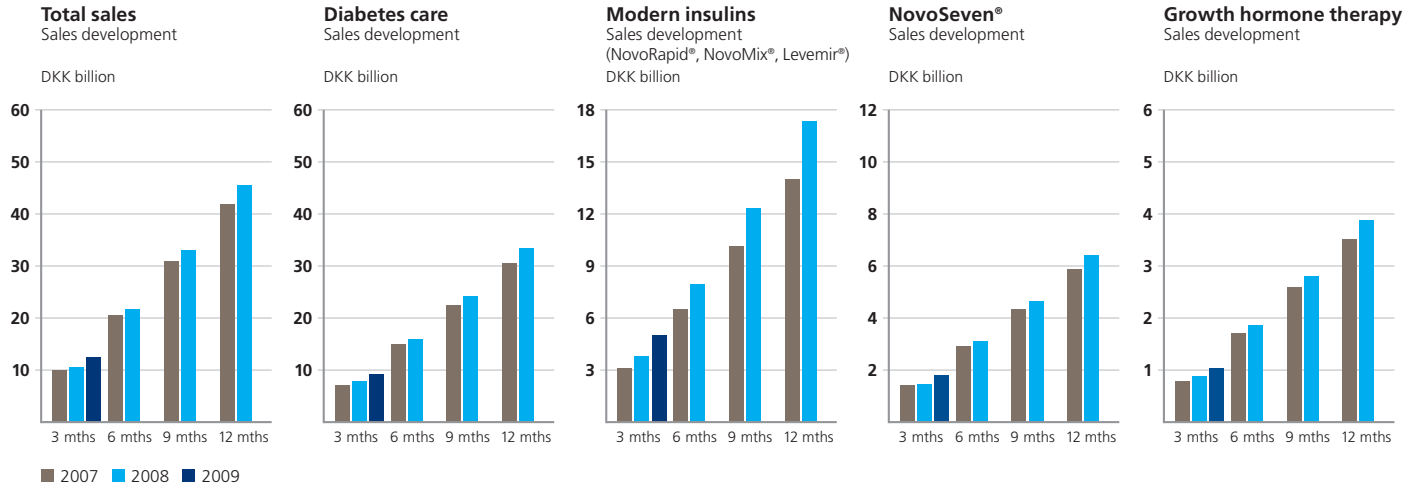
Sales of other products within biopharmaceuticals, which predominantly consist of hormone replacement therapy (HRT)-related products, increased by 8% in Danish kroner to DKK 490 million and by 3% in local currencies. This development primarily reflects continued sales progress for Vagifem®, a topical oestrogen product, partly due to a US price increase countered by generic competition in the US with Activella® (Activelle® outside the US), Novo Nordisk's continuous-combined HRT product. The low-dose version of Activelle® was launched

in Europe in April 2009 and has been available in the US since 2007.

### OUTLOOK 2009

Novo Nordisk still expects sales growth in 2009 at the level of 10% measured in local currencies. This is based on expectations of continued market penetration for Novo Nordisk's key strategic products within diabetes care and biopharmaceuticals as well as expectations of continued intense competition during 2009. Given the current level of exchange rates versus Danish kroner, the reported sales growth is now expected to be around 4.5 percentage points higher than the growth rate measured in local currencies.

For 2009, growth in operating profit is now expected to be at least



10% measured in local currencies. The increase reflects lower expected research and development costs for 2009 due to timing of phase 3 clinical trial programmes. Furthermore, the forecast is based on assumptions of a continued improvement of the gross margin and increased spending for sales and distribution relative to sales due to the increase in Novo Nordisk's global sales force. Given the current level of exchange rates versus Danish kroner, the reported operating profit growth is now expected to be around 8 percentage points higher than the growth rate measured in local currencies.

For 2009, Novo Nordisk now expects a net financial expense of DKK 1.5 billion. The current expectation reflects significant foreign exchange hedging losses, primarily related to the US dollar and the Japanese yen.

The effective tax rate for 2009 is now expected to be around 23%.

Capital expenditure is still expected to be around DKK 3 billion in 2009. Expectations for depreciations, amortisation and impairment losses of around DKK 2.6 billion are unchanged, and free cash flow is now expected to be around DKK 10 billion.

All of the above expectations are based on the assumption that the global economic downturn will not significantly change the business environment for Novo Nordisk during 2009. In addition, all of the above expectations are provided that currency exchange rates, especially the US dollar, remain at the current level versus the Danish krone for the rest of 2009. Novo Nordisk has hedged expected net cash flows in key invoicing currencies and, all other things being equal, movements in key invoicing currencies will impact Novo Nordisk's operating profit.

## RESEARCH AND DEVELOPMENT UPDATE

### Diabetes care

In Europe, the Committee for Medicinal Products for Human Use (CHMP) under the European Medicines Agency (EMA) on 23 April adopted a positive opinion for Victoza® for the treatment of type 2 diabetes. Victoza® is the first once-daily human Glucagon-Like Peptide-1 (GLP-1) analogue developed for the treatment of type 2 diabetes. The positive opinion for Victoza® covers the expected indications of: combination treatment with metformin or a sulphonylurea in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin or sulphonylurea and combination treatment with metformin and a sulphonylurea or metformin and a thiazolidinedione in patients with insufficient glycaemic control despite dual therapy. Novo Nordisk expects to receive the European Marketing Authorisation from the European Commission within approximately two months.

The regulatory process for liraglutide in Japan is progressing according to plans and a decision by the Japanese regulatory authorities is expected in 2010.

On 2 April and as previously communicated, the Endocrinologic and Metabolic Drug Advisory Committee of the United States Food and Drug Administration (FDA) discussed questions related to liraglutide, Novo Nordisk's once-daily human GLP-1 analogue which was filed for regulatory approval in the US in May 2008. The Advisory Committee voted on four questions related to the risk profile of liraglutide. A majority of Advisory Committee members supported that appropriate evidence of cardiovascular safety had been provided to rule out excess cardiovascular risk of liraglutide relative to comparators. Novo Nordisk has committed to do a large post-approval cardiovascular outcome study.

A majority of Advisory Committee members voted no to the question on whether the data available with the regulatory submission on thyroid C-cell tumours showed that this finding is not relevant to humans. However, the Advisory Committee was split on the FDA question related to whether the available data on C-cell tumours permitted approvability. Finally, the Advisory Committee unanimously dismissed any risk of papillary thyroid cancer related to liraglutide. Following the meeting, Novo Nordisk will be discussing next steps with the FDA to resolve the issues raised at the Advisory Committee meeting. US approval of liraglutide, and the timing thereof, will depend on the completion of the FDA's review of the application.

Novo Nordisk recently obtained two-year data from the liraglutide plus metformin combination study (LEAD™ 2). On a background of metformin therapy three different doses of liraglutide were compared to glimepiride treatment and placebo in people with type 2 diabetes. In total 880 people with diabetes completed the initial first six months of the study and 529 completed two years. People treated with liraglutide achieved statistically significant reductions in HbA<sub>1c</sub> compared to placebo after two years. Furthermore, significantly more people treated with the highest dose of liraglutide were below 7% HbA<sub>1c</sub>, the American Diabetes Association (ADA) target for good glycaemic control, compared to treatment with glimepiride. Finally, the favourable benefit to risk profile of liraglutide was confirmed in this study.

At the annual meeting of the American Diabetes Association (ADA) to be held in New Orleans on 5–9 June 2009, Novo Nordisk expects to present further detailed results from the global liraglutide clinical development programme.

Novo Nordisk very recently finalised a phase 2 study investigating

safety and efficacy of five doses of semaglutide (NN9535), a once-weekly human GLP-1 analogue, versus placebo and open-label liraglutide add-on therapy in people with type 2 diabetes. At study start, patients were treated with metformin or controlled with diet and exercise. The 12-week multi-centre, multinational, double-blind, placebo-controlled, randomised dose-finding trial, which included a little more than 400 patients, demonstrated that clinical efficacy and safety of semaglutide was broadly in line with liraglutide. Semaglutide was generally well tolerated and was not associated with an increase in injection site reactions, antibody formation or calcitonin levels. After more detailed analysis of the dose-response findings on efficacy and safety, Novo Nordisk will discuss the future plans for semaglutide development with regulatory authorities before initiation of phase 3 development.

Novo Nordisk is preparing initiation of phase 3 programmes for the new generation of insulins, known as NN5401 and NN1250, in the second half of 2009 and good progress has been made with regulatory agencies around the world. The first phase 3 trials with NN1250 and NN5401 are expected to be initiated in the third and fourth quarters of 2009, respectively. Novo Nordisk expects to give a more detailed update on expected timelines and design of the phase 3 programmes in connection with the release of financial results for the first half of 2009 on 6 August 2009.

## **Biopharmaceuticals**

In April 2009, Novo Nordisk initiated a phase 3 trial of a recombinant factor VIII compound in patients with haemophilia A. The trial is conducted as a multi-centre, open-label, non-controlled trial and evaluates the efficacy and safety in both prevention and on-demand

treatment of haemophilia A bleeding episodes. A sub-trial investigates efficacy and safety of the recombinant factor VIII compound in patients undergoing major or minor elective surgery requiring factor VIII replenishment. Novo Nordisk expects to enrol a total of 140 patients in the phase 3 programme.

Novo Nordisk recently received approval from the Japanese Pharmaceuticals and Medical Devices Agency for an expansion of the Norditropin® label to include treatment of growth hormone deficiency in adults. Growth hormone deficiency in adults is an approved indication for Norditropin® in both Europe and the US.

As previously communicated, Novo Nordisk initiated a phase 3 study with recombinant FXIII in congenital factor XIII deficiency in August 2008. All 41 patients have now been recruited and entered into the one-year treatment period of this trial. ■

## Forward-looking statement

Novo Nordisk's reports filed with or furnished to the US Securities and Exchange Commission (SEC), including this document as well as the company's Annual Report 2008 and Form 20-F, both filed with the SEC in February 2009, and written information released, or oral statements made, to the public in the future by or on behalf of Novo Nordisk, may contain forward-looking statements. Words such as 'believe', 'expect', 'may', 'will', 'plan', 'strategy', 'prospect', 'foresee', 'estimate', 'project', 'anticipate', 'can', 'intend', 'target' and other words and terms of similar meaning in connection with any discussion of future operating or financial performance identify forward-looking statements. Examples of such forward-looking statements include, but are not limited to

- statements of plans, objectives or goals for future operations, including those related to Novo Nordisk's products, product research, product development, product introductions and product approvals as well as cooperations in relation thereto,
- statements containing projections of or targets for revenues, income (or loss), earnings per share, capital expenditures, dividends, capital structure or other net financials,
- statements of future economic performance, future actions and outcome of contingencies such as legal proceedings, and
- statements of the assumptions underlying or relating to such statements.

In this document, examples of forward-looking statements can be found under the headings 'Outlook 2009', 'Research and development update', 'Equity' and 'Legal issues update'.

These statements are based on current plans, estimates and projections. By their very nature, forward-looking statements involve inherent risks and uncertainties, both

general and specific. Novo Nordisk cautions that a number of important factors, including those described in this document, could cause actual results to differ materially from those contemplated in any forward-looking statements.

Factors that may affect future results include, but are not limited to, global as well as local political and economic conditions, including interest rate and currency exchange rate fluctuations, delay or failure of projects related to research and/or development, unplanned loss of patents, interruptions of supplies and production, product recall, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for Novo Nordisk's products, introduction of competing products, reliance on information technology, Novo Nordisk's ability to successfully market current and new products, exposure to product liability and legal proceedings and investigations, changes in governmental laws and related interpretation thereof, including on reimbursement, intellectual property protection and regulatory controls on testing, approval, manufacturing and marketing, perceived or actual failure to adhere to ethical marketing practices, investments in and divestitures of domestic and foreign companies, unexpected growth in costs and expenses, failure to recruit and retain the right employees and failure to maintain a culture of compliance.

Please also refer to the overview of risk factors in 'Managing Risks' on pp 24–25 of the Annual Report 2008 available on the company's website ([novonordisk.com](http://novonordisk.com)).

Unless required by law Novo Nordisk is under no duty and undertakes no obligation to update or revise any forward-looking statement after the distribution of this document, whether as a result of new information, future events or otherwise.

# FVIII haemophilia product in phase 3

The project marks an important milestone in Novo Nordisk's ambition to diversify its presence in the haemophilia market.

In April 2009, a drug candidate built on a third-generation factor VIII molecule developed by Novo Nordisk, entered phase 3 clinical trials. The trial is designed to have the same patients participate in both phase 1 and phase 3.

"This is our first step into treatment of the broader categories of haemophilia A and B, which makes it of strategic importance," says Peter Kristensen, senior vice

president of Global Development

Novo Nordisk's long-term goal for factor VIII is the development of a long-acting, preferably once-weekly product.

Factor VIII research is just one element of the complete haemophilia research effort in Novo Nordisk. Another goal is a long-acting, once-weekly version of factor IX which can be used for both prevention and on-demand treatment. A substance which might help reach this goal is in the pipeline and expected to enter phase 1 clinical trials later this year. ■

## What is haemophilia?

In people with haemophilia, the body's coagulation process does not work effectively, because they lack one of two specific proteins: factor VIII (haemophilia A, 250,000 persons worldwide) or factor IX (haemophilia B, 50,000 persons). Most can be treated with the coagulation factor they lack, but a small group of people (3,500 people) develop inhibitors that prevent treatment from working. Novo Nordisk make NovoSeven® to help this group of people.

## Two shareholders' events

On 18 March 2009, Novo Nordisk shareholders were invited to participate in two separate events in Copenhagen, Denmark. First order of the day was the Annual General Meeting, followed by the more informal Annual Shareholder Meeting.

At the Annual General Meeting shareholders elected a new member of the Board of Directors, Hannu Ryöppönen, replacing Kurt Briner, who had decided not to seek re-election.

The shareholder meeting attracted 1,400 participants who watched presentations by Novo Nordisk's Executive Management. Each of the members of this group described 2008's main events in their area of responsibility.

Hannu Ryöppönen is a Finnish citizen and served, until 1 April 2009, as deputy CEO in Stora Enso Oyj. Hannu Ryöppönen has an international executive background and thorough understanding of finance operations in global organisations.





# Project brings insulin and diabetes care to Africa's children

If a child in sub-Saharan Africa is diagnosed with type 1 diabetes, he or she has a life expectancy of one year. To this end, a project called 'Changing the future for children with diabetes' is being launched. The ultimate goal of the project is to change the lives of 10,000 children with diabetes in 10 of the world's poorest countries.

In 2009, activities will be initiated in five African countries. Apart from providing insulin, the five-year project aims to set up treatment centres where diagnosis, treatment, patient

education, patient registration and healthcare training can take place. It is funded by Novo Nordisk with additional funding provided by the World Diabetes Foundation for selected activities.

## Donations a new approach

Novo Nordisk has never previously given away insulin, offering it instead at greatly reduced prices to the least developed nations of the world. But more must be done to reach children with diabetes, who are particularly vul-

nerable in poor countries, where families are forced to make the choice between food for the whole family and insulin for a single child. It is estimated that some 38,000 African children aged 0–14 have type 1 diabetes.

The project is designed to become taken over by the governments of the countries involved in the project. To make that happen, the project aims to collaborate with as many local partners as possible. ■

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**Product names** Not all products mentioned in *Share* have been introduced worldwide. Trade names may vary from country to country. **Photos:** Jesper Westley, Novo Nordisk, m.fl.