



changing diabetes

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## Novo Nordisk's Capital Markets Day

Analysts and  
investors get  
an inside look  
at Novo Nordisk



**13%** sales increase in the first nine months (local currencies)

**25%** increase in underlying operating profit (local currencies)

**15%** reported operating profit

**29%** increase in sales of modern insulins (local currencies)

We are pleased with the way our business has developed during the first nine months of 2008. When measured in local currencies, operating profit was up by more than 25% and sales were up by 13%. This development is driven by continued solid performance across products and in all key markets. Novo Nordisk sustains its leadership position in the diabetes market, and despite the current economic turmoil we see no significant changes in the underlying market dynamics. Conversely, the performance during the first nine months of 2008 in combination with the appreciation of key invoicing currencies; US dollars, Japanese yen and British pounds, allows us to raise our guidance for full-year 2008 operating profit growth by 10 percentage points from previously between 22% and 25% to now 32% to 35%.



Lars Rebién Sørensen  
President and CEO, Novo Nordisk

## Next-generation insulins

Novo Nordisk has completed phase 2 trials and achieved clinical proof of concept with a new generation of insulins, NN5401 and NN1250. NN1250 is a long-acting insulin analogue and NN5401 is a neutral, soluble dual-acting insulin analogue. Both have a potential duration of more than 24 hours. Novo Nordisk intends to initiate phase 3 clinical development in the second half of 2009.



# Analysts and investors get Novo Nordisk update

On 26 September, Novo Nordisk invited professional analysts and investors to its third Capital Markets Day in Denmark.

More than 100 people had accepted this invitation, and came to the NovoPen®4-factory in Hillerød, part of which had been transformed into a conference facility. They came to get a full update on the business and future of Novo Nordisk from top management.

Novo Nordisk's Capital Markets Day meeting coincided with a US financial crisis well on its way to spreading across the globe. So Novo Nordisk had a comforting message for the audience:

In an industry full of expiring patents and relatively thin R&D pipelines, Novo Nordisk is different. It's a company that will remain a key player in diabetes, haemophilia with inhibitors and growth hormone, with limited exposure to patent expirations. And it has projects in new areas – obesity, general haemophilia, inflammation – in the portfolio as well.

This sets Novo Nordisk apart from many

other companies right now. And analysts know that.

"It's one of the stocks we advise our customers to go into, because it has strong defensive qualities," said Henrik Simonsen, an analyst with SEB Enskilda. ('Defensive qualities' means the stock is less dependent on market trends, ed.)

### R&D, operations and more

During the day, Novo Nordisk executives offered insights into the company's strategy, with a focus on R&D, production, sales and marketing.

They began with Novo Nordisk's next offering in the diabetes market, liraglutide, which is currently under regulatory review in the US as well as the EU. Investors, analysts and journalists saw headline results from a study (LEAD™ 6) comparing liraglutide with Eli Lilly's competitor product, Byetta®. There was also an update on the trials testing liraglutide as a treatment for obesity.

Next came the next-generation insulins

that are now completing phase 2 trials. Followed by a wave of news from Novo Nordisk's biopharm area, which covers NovoSeven® and new factor VIIa analogues (for treatment of people with haemophilia with inhibitors), and also new products in development for people with haemophilia A and B. There was information about a well-known product – Novo Nordisk's growth hormone product Norditropin® – and a new therapy area, inflammation.

And when the topic turned to operations, Novo Nordisk executives explained how the company plans to sell and market new and existing products, and stay competitive in a globalising world. The focus in these presentations was on the current solid performance in the US and large opportunities in the Asian markets where the majority of the expected increase in the number of people with diabetes is expected to come from.

Halfway through the day, participants

could see Novo Nordisk production for themselves during a tour of a Hillerød factory where two of the company's devices for injection of insulin – FlexPen® and InnoLet® – are produced.

The purpose of showing the investors and analysts the filling site was to illustrate how Novo Nordisk has been able to improve the production efficiency significantly in the last years.

#### Good reviews

Investors and analysts asked many questions throughout the day, and crowded around Novo Nordisk executives during the breaks to learn more. Post-meeting evaluations showed they were very satisfied with what they had heard during the day.

"I will be excited to see what will be happening next year – with lira (liraglutide, ed) in particular but generally also with the company," said Peter Abelin, an investor with the Swedbank Robur. ■

## Next generation of FlexPen® launched

The Novo Nordisk launch took place at the annual EASD meeting (the European Association for the Study of Diabetes) in Rome in September.

The next generation of FlexPen® offers more benefits, all of them aimed at improving safety and simplicity for people with diabetes.

- New full-colour labels, colour-coded cartridges and new packaging material, which makes it easier to distinguish between different insulins.
- Lower dose force needed, which reduces the force needed to inject the



required dose by approximately 30%.

- Adding the new NovoTwist™ needle, which makes it easier and faster for patients to attach their needle to FlexPen®. The NovoTwist™ needle will be launched approximately six months after the launch of the next generation of FlexPen®.

The next generation of FlexPen® will be available for patients around the world from late November and onwards. ■

## AGM and shareholders' meeting 2009

Next year's Annual General Meeting will be held at Falkoner Center in Copenhagen on 18 March 2009 at 14.00. It will be conducted in English with simultaneous interpretation into Danish. AGM participants will, however, be able to ask questions in Danish and have these translated into English.

Coffee will be served after the AGM and participants will have the opportunity to meet the company's Board of Directors and members of Executive Management.

#### Shareholders' meeting in Danish

On the same day, at 17.00, an informal shareholders' information meeting will be held, also at the Falkoner Center. This meeting will be conducted in Danish only.

The meeting provides an opportunity to meet informally with the entire Executive Management team, hear about their areas of responsibility and ask questions. The company's chairman of the Board will present what was approved at the AGM earlier the same day.

After the meeting, Novo Nordisk will host a light dinner buffet.

Invitations for both meetings will be distributed in February 2009.

#### Electronic proxy voting

Voting by proxy via Novo Nordisk's website will be possible prior to the 2009 Annual General Meeting. The service will be open from 24 February to 13 March. Admission cards for the AGM and the shareholders' meeting can also be ordered via Novo Nordisk's website. Requests for admission cards must be submitted by 13 March the latest. ■

## RESULTS FOR THE FIRST NINE MONTHS

13%

increase in total  
diabetes care sales\*

12%

increase in biopharm  
sales\*

# Performance in the first nine months of 2008

Novo Nordisk increased operating profit by 15% in the first nine months.

Expectations for growth in full-year operating profit raised to 32–35%

- Novo Nordisk increased sales by 13% in local currencies and by 7% in Danish kroner due to a negative currency development.
  - Sales of modern insulins increased by 29% (22% in Danish kroner).
  - Sales of NovoSeven® increased by 14% (6% in Danish kroner).
  - Sales of Norditropin® increased by 13% (8% in Danish kroner).
  - Sales in North America increased by 18% (5% in Danish kroner).
  - Sales in International Operations increased by 21% (13% in Danish kroner).
- Gross margin improved by 1.2 percentage points in local currencies and by 0.3 percentage points in Danish kroner to 77.0% in the first nine months of 2008, reflecting continued productivity improvements and a negative currency impact of around 0.9 percentage points.
- Operating profit increased by 15% to DKK 8,999 million. Adjusted for the impact from currencies, underlying operating profit increased by more than 25%.
- Net profit decreased by 3% to DKK 7,315 million due to the non-recurring tax exempt income of DKK 1.4 billion recorded in the second quarter of 2007 from Novo Nordisk's divestment of Dako's business activities. Excluding the effect from the non-recurring income, net profit increased by 19%.
- For 2008, the expectation for reported operating profit growth is increased by around 10 percentage points to 32–35%, primarily reflecting a significant positive development in Novo Nordisk's key invoicing currencies as well as lower operational costs.
- Novo Nordisk has achieved clinical proof of concept with a new generation of insulins, NN5401 and NN1250, and intends to initiate phase 3 clinical development in the second half of 2009.

Lars Rebien Sørensen, president and CEO, said: "We are pleased with the way our business has developed during the first nine months. This allows us to raise guidance for full-year 2008 operating profit growth. Furthermore, our preliminary plans for 2009 indicate continued double-digit growth in both sales and operating profit."

### DIABETES CARE

Sales of diabetes care products increased by 13% measured in local currencies

and by 7% in Danish kroner to DKK 24,156 million compared to the first nine months of 2007.

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

Sales of modern insulins, human insulins and insulin-related products in the first nine months of 2008 increased by 13% measured in local currencies and by 7% in Danish kroner to DKK 22,367 million compared to 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 44% of the modern insulin market, both measured by volume.

Sales of modern insulins increased by 29% in local currencies and by 22% in Danish kroner to DKK 12,289 million. Sales of Levemir® increased by 61% in local currencies compared to the first nine months of 2007. All regions realised solid growth rates for the modern insulins, with North America and Europe as the primary contributors to growth. Sales of modern insulins now constitute 59% of Novo Nordisk's sales of insulin.

Sales of human insulin decreased by 4% in local currencies and by 8% in Danish kroner to DKK 8,711 million, mainly reflecting a continued robust conversion to modern insulins in all regions.

### BIOPHARMACEUTICALS

In the first nine months of 2008, sales of biopharmaceutical products increased by 12% measured in local currencies and by 5% measured in Danish kroner to DKK 8,814 million compared to the first nine months of 2007.

### NovoSeven®

Sales of NovoSeven® increased by 14% in local currencies and by 6% in Danish kroner to DKK 4,622 million compared to the first nine months of 2007. Sales growth for NovoSeven® was primarily realised in North America followed by International Operations and Europe. The sales growth for NovoSeven® primarily reflects increased sales in the congenital bleeding disorder indications, and treatment of spontaneous bleeds for congenital inhibitor patients remains the largest area of use. Sales of NovoSeven® in International Operations in the first nine months of 2008 were positively impacted by the timing

# 18%

increase in North American sales\*

# 21%

increase in International Operations sales\*

# 29%

increase in modern insulin sales\*

# 32-35%

Expected operating profit growth (reported) for the full year of 2008

\*in local currencies

of tender sales compared to the same period in 2007. Sales of NovoSeven® in the US were positively impacted by a minor inventory build-up in relation to the launch of room temperature-stable NovoSeven®.

### Norditropin®

Sales of Norditropin® (ie growth hormone in a liquid, ready-to-use formulation) increased by 13% measured in local currencies and by 8% measured in Danish kroner to DKK 2,805 million. Growth was realised in all regions, with North America as the primary contributor. Novo Nordisk continues to gain market share in the global growth hormone market and has the second-largest global market share of 24% measured by volume.

### Other products

Sales of other products within biopharmaceuticals, which predominantly consist of hormone replacement therapy (HRT)-related products, increased by 1% in local currencies and decreased by 5% in Danish kroner to DKK 1,387 million. This development reflects global sales growth for Vagifem®, a locally administered HRT product, offset by generic competition in the US to Activella®, a continuous-combined HRT product.

### OUTLOOK

Novo Nordisk still expects a sales growth for 2008 of 11–13% measured in local currencies whereas reported sales growth is now expected to be around

3 percentage points lower, given the current level of exchange rates.

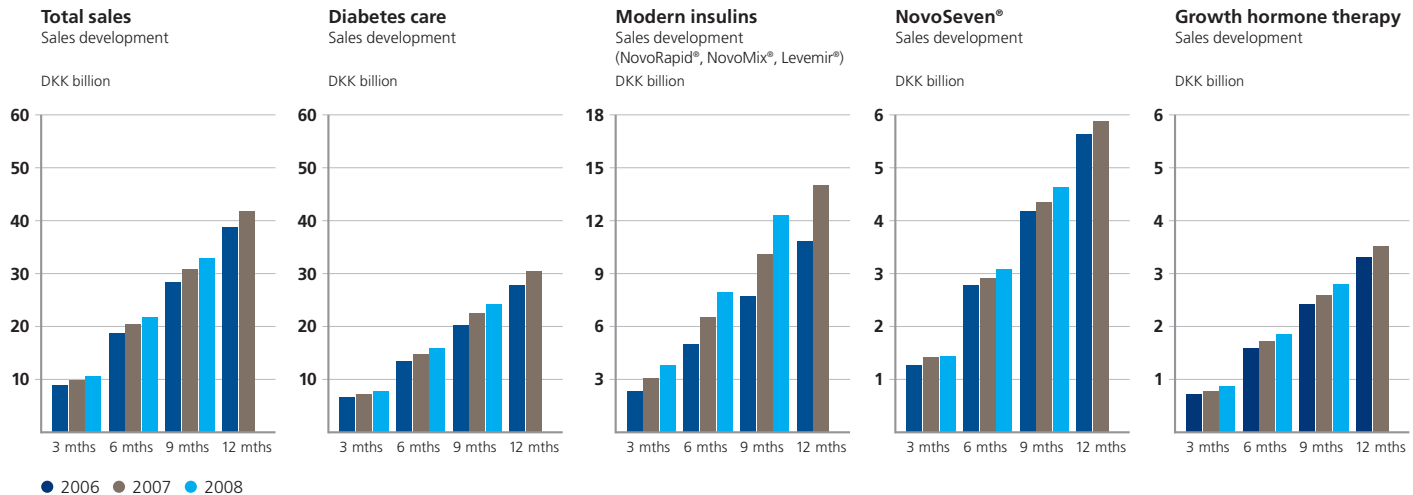
The expectation for growth in reported operating profit for 2008 is increased by around 10 percentage points to 32–35%. This primarily reflects a positive impact from the recent significant appreciation of Novo Nordisk's main invoicing currencies and lower operational costs, partly countered by costs related to the employee share programme as well as costs related to the discontinuation of the phase 3 study with Norditropin® in dialysis patients with low serum albumin. The forecast includes lowered non-recurring costs in relation to the discontinuation of all pulmonary diabetes projects (reduced from DKK 400 million to DKK 325 million).

Adjusted for the impact from currency and the non-recurring costs related to the discontinuation of all pulmonary diabetes projects in 2007 and 2008, the expectation for underlying operating profit is now increased to a growth of more than 25%.

For 2008, Novo Nordisk now expects a net financial income of DKK 350 million, reflecting the significant foreign exchange hedging gains in the first nine months of 2008, primarily related to the US dollar, partly being offset by the expected hedging losses in the fourth quarter of 2008 related to the recent significant appreciation of key invoicing currencies.

The expectation for the effective tax rate for 2008 is still 24%.

Capital expenditure is now expected to be around DKK 1.5 billion in 2008 whereas depreciations, amortisation and impairment losses are now expected to be around DKK 2.4 billion. Free cash flow is now expected to be around →



## QUARTERLY NUMBERS FOR NOVO NORDISK IN 2008 AND 2007

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

	Q3 2008	Q2 2008	Q1 2008	Q4 2007	Q3 2007	Q2 2007	Q1 2007	% Change 2007–2008(Q3)
<b>Sales</b>	<b>11,246</b>	<b>11,110</b>	<b>10,614</b>	<b>10,946</b>	<b>10,504</b>	<b>10,563</b>	<b>9,818</b>	<b>7%</b>
<b>Gross profit</b>	<b>8,640</b>	<b>8,556</b>	<b>8,201</b>	<b>8,345</b>	<b>7,990</b>	<b>8,205</b>	<b>7,498</b>	<b>8%</b>
Sales and distribution costs	3,155	3,178	2,975	3,220	2,993	3,110	3,048	5%
Research and development costs	1,579	1,980	1,858	3,413	1,724	1,754	1,647	-8%
– Hereof costs related to discontinuation of all pulmonary projects*	50	(155)	(220)	(1,325)	-	-	-	-
Administrative expenses	633	626	627	677	623	594	614	2%
Licence fees and other operating income (net)	51	74	88	92	31	60	138	65%
<b>Operating profit</b>	<b>3,324</b>	<b>2,846</b>	<b>2,829</b>	<b>1,127</b>	<b>2,681</b>	<b>2,807</b>	<b>2,327</b>	<b>24%</b>
<b>Operating profit (excl AERx®)**</b>	<b>3,274</b>	<b>3,001</b>	<b>3,049</b>	<b>2,452</b>	<b>2,681</b>	<b>2,807</b>	<b>2,327</b>	<b>22%</b>
Share of profit/(loss) in associated companies	(58)	(3)	(67)	0	(57)	1,350	(60)	-
Financial income	306	429	474	375	322	297	309	-5%
Financial expenses	66	21	368	155	90	60	202	-27%
Profit before income taxes	3,506	3,251	2,868	1,347	2,856	4,394	2,374	23%
<b>Net profit</b>	<b>2,664</b>	<b>2,471</b>	<b>2,180</b>	<b>977</b>	<b>2,184</b>	<b>3,652</b>	<b>1,709</b>	<b>22%</b>
Depreciation, amortisation and impairment losses	560	567	563	1,396	586	516	509	-4%
Depreciation, amortisation, etc (excl AERx®)**	560	567	563	526	586	516	509	-4%
Capital expenditure	448	328	214	719	597	508	444	-25%
Cash flow from operating activities	3,673	2,916	3,070	2,498	3,500	1,438	2,551	5%
Free cash flow	3,210	2,589	2,795	3,198	2,888	826	2,100	11%
Equity	32,173	33,046	31,251	32,182	33,161	33,475	29,676	-3%
Total assets	48,990	48,478	47,534	47,731	48,423	48,300	44,742	1%
Full-time employees at the end of the period	26,360	26,060	25,765	25,516	25,206	24,729	24,045	5%
Basic earnings per share (in DKK)	4.34	3.99	3.51	1.56	3.46	5.75	2.69	25%
Diluted earnings per share (in DKK)	4.30	3.96	3.48	1.55	3.43	5.71	2.68	25%
Average number of shares outstanding (million)***	614.2	618.6	620.9	624.4	632.0	635.8	635.0	-3%
Average number of shares outstanding incl dilutive effect of options 'in the money' (million)***	618.6	623.5	626.3	629.6	636.4	640.2	639.4	-3%

\* Including costs related to the discontinuation of AERx® and all other pulmonary diabetes projects. \*\* Excluding costs related to the discontinuation of AERx® and all other pulmonary diabetes projects. \*\*\* For Q3 2008 the exact numbers of 'Average number of shares outstanding' and 'Average number of shares outstanding incl dilutive effect of options 'in the money' are 614,625,8885 and 618,666,332 respectively.

→ DKK 9.5 billion, primarily explained by higher operating profit expectations and the expected lower level of investments.

With regard to the financial outlook for 2009 it is Novo Nordisk's intention to provide detailed guidance on expectations in connection with the full-year release of financial results for 2008, scheduled for 29 January 2009. At

present, the preliminary plans for 2009 indicate both sales growth and operating profit growth at the level of 10% measured in local currencies. The reported sales growth for 2009 is expected to be around 8 percentage points higher and the reported operating profit growth is expected to be at least 15 percentage points higher due to an expected positive currency impact follow- →

→ ing the recent significant appreciation of Novo Nordisk's main invoicing currencies. These preliminary plans reflect expectations of a continued solid penetration of the portfolio of modern insulins as well as progress for the key products within biopharmaceuticals, but also an expectation of continued intense competition in both the diabetes care and biopharmaceuticals areas. The preliminary plans for growth in operating profit in 2009 also reflect a continued improvement of the gross margin as well as increased spending for sales and distribution relative to sales due to an expected high level of sales and marketing activities for primarily liraglutide and the modern insulins.

All of the above expectations are provided that currency exchange rates, especially the US dollar and related currencies, remain at the current level (USD 583, GBP 936, JPY 6.01 as of 29 October 2008) versus the Danish krone for the rest of 2008 and throughout 2009.

Novo Nordisk has hedged expected net cash flows in relation to US dollars, Japanese yen and British pounds for 15, 14 and 13 months respectively. The financial impact from foreign exchange hedging is included in 'Net financials'. Provided the currency exchange rates remain at the current level throughout 2009, it is expected that the significant positive impact on reported operating profit will be offset by a similar significant foreign exchange hedging loss.

## RESEARCH AND DEVELOPMENT UPDATE

### Diabetes care

Novo Nordisk is the only company with a new generation of insulins in full clinical development. The ambition is to further improve the treatment success rate, tolerability and convenience of insulin therapy for people with type 1 or type 2 diabetes. Novo Nordisk has made significant progress in this area and has recently finalised two phase 2 studies with NN1250, a long-acting insulin analogue with a potential duration of action of more than 24 hours, and two phase 2 studies with NN5401, a neutral, soluble dual-acting insulin analogue preparation also with a potential duration of action of more than 24 hours. NN1250 was investigated in both type 1 and type 2 diabetes, whereas NN5401 was investigated in type 2 diabetes alone. NN1250 was studied in trials where insulin glargine served as insulin comparator whereas NN5401 was studied in trials where NovoMix® 30 and insulin glargine served as insulin comparators. In total, around 700 patients were enrolled in the four treat-to-target studies and all patients were treated for 16 weeks.

The headline data from the four studies show promising proof-of-concept results for both of the new insulins in terms of safe and long-lasting blood glucose lowering. Between half and two-thirds of people with type 2 diabetes treated with NN5401 achieved HbA<sub>1c</sub> levels below 7% with no incidences of hypoglycaemia during the last four weeks of treatment. For people with type 2 diabetes treated with once-daily NN1250, around half achieved HbA<sub>1c</sub> levels below 7% without occurrence of hypoglycaemia in the last four weeks of treatment. In the type 2 diabetes trial three weekly injections of NN1250, every Monday, Wednesday and Friday, were also compared to once-daily basal insulin. The blood glucose control achieved

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## 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 2007* and Form 20-F both filed with the SEC in February 2008, 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', 'guidance', 'project', 'anticipate', 'can', 'intend' 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 (i) statements of plans, objectives or goals for future operations, including those related to Novo Nordisk's products, product research, product introductions and product approvals as well as cooperations in relation thereto, (ii) statements containing projections of revenues, income (or loss), earnings per share, capital expenditures, dividends, capital structure or other net financials, (iii) statements of future economic performance, future actions and outcome of contingencies such as legal proceedings, and (iv) statements of the assumptions underlying or relating to such statements.

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 in this document, could cause actual results to differ materially from those contained 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 development projects, 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 'Business strategy, opportunities and key risks' on pp 8–9 of the *Annual Report 2007* available on our website (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.

→ after three weekly NN1250 injections was found to be similar to that in the once-daily basal insulin arm, highlighting the very long action profile of NN1250.

Importantly, both insulins NN5401 and NN1250 appear to be safe and well tolerated. Based on the positive phase 2 data, Novo Nordisk will now start a dialogue with regulatory agencies regarding the design of the phase 3 programmes. Novo Nordisk plans to initiate phase 3 studies with both NN1250 and NN5401 in the second half of 2009.

At the annual meeting of the Canadian Diabetes Association in October, Novo Nordisk presented detailed results from the 26-week LEAD™ 6 phase 3b study in which the safety and efficacy of liraglutide, the once-daily human GLP-1 analogue, was compared to twice-daily exenatide in people with type 2 diabetes. As previously communicated, the study showed that patients treated with liraglutide achieved a statistically significantly better blood glucose control, compared to patients receiving exenatide treatment.

At its Capital Markets Day on 26 September, Novo Nordisk presented headline data from a 14-week extension of the LEAD™ 6 study. After an initial 26 weeks of treatment with either liraglutide or exenatide in the LEAD™ study, 376 patients with type 2 diabetes entered this 14-week non-randomised extension study where all patients received liraglutide. Patients from the initial liraglutide treatment arm continued previous treatment at an unchanged dose while patients from the initial exenatide treatment arm were switched to liraglutide 1.8 mg once daily, following a two-week dose escalation period. The study showed that patients who switched from exenatide to liraglutide experienced a reduction in HbA<sub>1c</sub> of 0.3 percentage points, a decrease in fasting plasma glucose of 0.9 mmol/l, a weight loss of approximately 1 kg as well as a reduction in systolic blood pressure of close to 4 mmHg – all differences being statistically significant. Furthermore, the tolerability profile of liraglutide was confirmed in the LEAD™ 6 extension.

As previously communicated, the phase 3 programme for liraglutide in obesity is expected to be initiated before the end of 2008 and will include 4,500–5,000 patients. One-year data from the study is expected in early 2011.

## BIOPHARMACEUTICALS

Novo Nordisk has decided to discontinue the phase 3 study with Norditropin® in dialysis patients with low serum albumin (LSAD) which was started in July 2007. The decision to discontinue the study is not due to safety concerns. The discontinuation is based on an analysis of the significant delay in recruitment of patients for the study which is expected to have a negative impact on the outcome of the study. The analysis shows that the study is not expected to be completed before 2012 or potentially later and that actions undertaken to accelerate patient recruitment have not been sufficiently successful. The primary endpoint in the study is mortality and the plan was to enrol around 2,500 patients.

Novo Nordisk regrets the inconvenience this may cause to patients, doctors and medical staff, and is grateful to all who took part in the study. Novo Nordisk will do its utmost to ensure a smooth trial closure for the involved patients and clinical centres. In the study, growth hormone or placebo treatment has been added in addition to existing treatment, not as a replacement for another treatment. Novo Nordisk expects to finalise the discontinuation of the study during the first half of 2009.

Novo Nordisk is finalising the analysis of results from the phase 3 trial with NovoSeven® for the treatment of bleeding in patients with severe trauma. As previously announced the trial was discontinued earlier this year based on the results of an analysis for fertility conducted by the independent Data Monitoring Committee. In total 541 patients with severe trauma completed the trial. The primary efficacy endpoint was 30-day mortality and the results show that there was no statistical difference between the mortality outcome for patients treated with NovoSeven® and placebo. As seen in previous trials with NovoSeven® in trauma, patients treated with NovoSeven® in this trial received statistically significantly fewer transfusions at 24 and 48 hours compared to placebo, thereby confirming its haemostatic effect. The safety profile of NovoSeven® was consistent with previous trials of NovoSeven® in critical bleeds. Novo Nordisk expects to publish detailed results from the phase 3 trial in peer-reviewed journals and at scientific conferences in 2009.

At the Capital Markets Day, Novo Nordisk provided an update of the haemostasis strategy including plans for extending activities into general haemophilia. This was underpinned by the announcement that phase 1 studies are expected to be initiated with a recombinant factor VIII compound and a long-acting recombinant factor IX compound during 2008 and 2009 respectively. Additionally, it was announced that the long-acting recombinant FVIIa derivative NN7128 has completed phase 1 and that a phase 2 study is expected to be initiated in 2009.

Within haemostasis Novo Nordisk also announced that the phase 3 study with recombinant FXIII in congenital factor XIII deficiency was initiated in August 2008. In addition, it was announced that a phase 2 study with recombinant factor XIII within prevention of bleeding in cardiac surgery is expected to be initiated in 2009.

Finally, at the Capital Markets Day, Novo Nordisk provided an update on the progress in the area of inflammation research and announced the progression of the first two projects, anti-IL-20 and anti-C5aR, to phase 1 clinical development. ■