

# Management report and discussion

Novo Nordisk is very pleased with the strong financial results that have been achieved in 2005. This has been a year of continued strong demand for Novo Nordisk's key strategic products: the insulin analogues and NovoSeven®. There has also been solid growth in the sales of products within Novo Nordisk's other therapeutic areas.

During 2005, the company continued to realise efficiency gains in its production. In combination with the strong growth in sales this has enabled Novo Nordisk to further expand the diabetes care sales force in the important North American market as well as in key markets in Europe. Furthermore, additional funds have been allocated to research and development to ensure the best possible foundation for moving key projects forward in clinical development.

## Business performance and discussion

Reported sales in 2005 of DKK 33,760 million correspond to a sales growth of 16% as compared with sales in 2004 of DKK 29,031 million, with the key drivers of growth being:

- ▶ Sales of insulin analogues increasing by 62% supported by the continued roll-out of Levemir® and NovoMix® in Europe and International Operations
- ▶ Sales of NovoSeven® increasing by 16% reflecting growth within all regions and with North America as the primary contributor to growth
- ▶ Sales in North America increasing by 27%
- ▶ Sales in International Operations increasing by 25%
- ▶ Sales measured in local currencies increasing by 15%.

Operating profit increased by 16% to DKK 8,088 million from DKK 6,980 million in 2004,

thereby exceeding the expectations for operating profit as communicated in January 2005. Measured in local currencies and excluding the impact from non-recurring items operating profit increased by around 20% – thereby exceeding the long-term financial target of 15%, which formed the basis for the operating profit growth expectations for 2005.

The operating margin for 2005 was realised at 24.0%, unchanged relative to the previous year. The unchanged operating margin mainly reflects efficiency gains in production and administrative areas countered by a lower level of non-recurring income. The impact in 2005 from development in foreign exchange rates on operating margin is negligible.

Net financials amounted to an income of DKK 146 million for 2005, as compared to an expected income of DKK 100 million at the beginning of 2005.

The effective tax rate decreased to 28.8%, from 32.8% in 2004. This is lower than expected in January 2005 but is mainly the result of a reduction in the Danish corporation tax from 30% to 28%, effective for the full income year of 2005 onwards, and a non-recurring reduction due to the tax-exempt status of non-recurring income from Ferrosan A/S and ZymoGenetics, Inc.

Net profit increased by 17% to DKK 5,864 million, as compared to the 2004 level of DKK 5,013 million. Earnings per share (diluted) thereby increased from DKK 14.83 to DKK 17.83 in 2005, corresponding to a growth of 20%.

The total net capital expenditure for property, plant and equipment was realised at DKK 3.7 billion – in line with expectations for the year when including the acquisition of tangible assets of approximately DKK 300 million from Aradigm Corporation related to the AERx® iDMS project.

Return on invested capital (ROIC) was 24.7%, an increase from 21.5% in 2004. This is mainly due to operating profits, less taxes, increasing at a higher rate than the average invested capital combined with a positive impact from the non-recurring impact on the effective tax rate. Adjusted for the impact of the effective tax rate from non-recurring items, ROIC was realised at 23.9% in 2005.

The cash to earnings ratio for 2005 was 82%, slightly down from 85% in 2004. The free cash flow for 2005 was expected to be more than DKK 2 billion, but was realised at a significantly higher level of DKK 4.8 billion, reflecting primarily the higher realised net profit for 2005, an increase in trade payables and a positive impact from the sale of shares in Ferrosan A/S.

## Long-term financial targets

Following the demerger of Novozymes towards the end of 2000, Novo Nordisk communicated four long-term financial targets in early 2001. Focusing on growth, profitability, financial return and generation of cash, the four targets have served to balance short- and long-term considerations, thereby ensuring a

Ratio	Previous target	Result 2005	Three-year average 2003–2005	New target
Operating margin	25%	24.0%	24.2%	25%
Growth in operating profit	15%	15.9%	11.0%	15%
Return on invested capital (ROIC)	25%	24.7% <sup>1)</sup>	21.6%	30%
Cash to earnings (three-year average)	60%	82.4% <sup>2)</sup>	82.4%	70%

<sup>1)</sup> Excluding the non-recurring reductions in 2005 in the effective tax rate, ROIC would have been 23.9%

<sup>2)</sup> The cash to earnings ratio is 82.4% both for the year 2005 and as an average for the period 2003–2005

focus on shareholder value creation.

By 2005, Novo Nordisk was approaching the achievement of the long-term financial targets. The four ratios are still considered the best way to ensure value creation; however, the current targets are no longer providing sufficient guidance on the targeted financial performance on a five-year horizon. Following a review, the targets for the four ratios have been reassessed and the updated targets are illustrated below.

The updated targets are guiding the financial development of Novo Nordisk given the current scope of business activities. Individually, and on a combined basis, these four financial targets are considered to be competitive compared to the overall performance of the pharmaceutical industry.

The target for operating margin remains at 25%, as further productivity improvements in production and administrative areas are expected to be re-invested in research and development activities.

The targeted growth in operating profit remains at 15% on average. The target allows for a deviation in an individual year if necessi-

tated by business opportunities or market conditions.

The target for return on invested capital (ROIC) measured post tax is raised from 25% to 30%. The increased target reflects the expectation of continued lower growth in invested capital compared to operating profit as well as a recurring lower effective tax rate, partly due to the lowering of the Danish corporate tax rate from 30% to 28% effective for the year 2005 onwards.

The targeted cash to earnings ratio is raised from 60% to 70% reflecting the improved cash conversion ability in the last three years. As previously, this target will be pursued as an average over a three-year period. Performance measured by this ratio may be impacted in individual years by significant in-licensing activities or other major investments.

### Sales development by segments

Sales in 2005 increased by 16% in Danish kroner and by 15% measured in local currencies. Sales growth was realised both within dia-

betes care and biopharmaceuticals – primarily driven by the portfolio of insulin analogues as well as NovoSeven®. Furthermore, sales of growth hormone therapy products contributed to growth.

Sales growth was realised in all regions. The main growth driver was North America, constituting 28% of total sales, followed by International Operations with 18% of total sales.

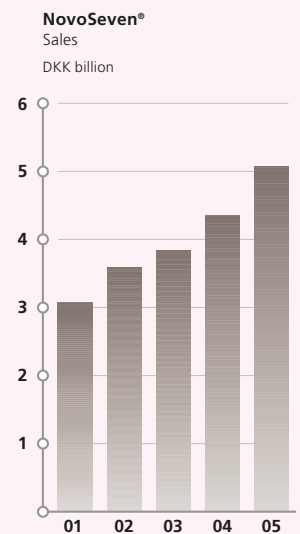
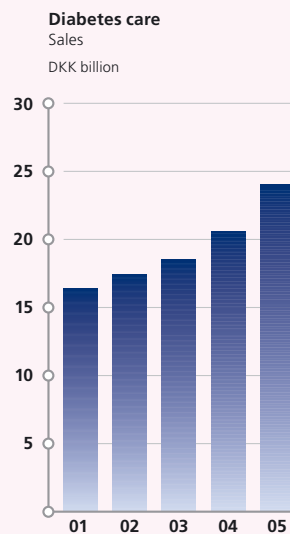
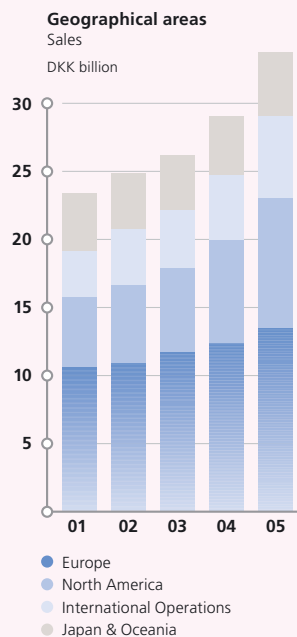
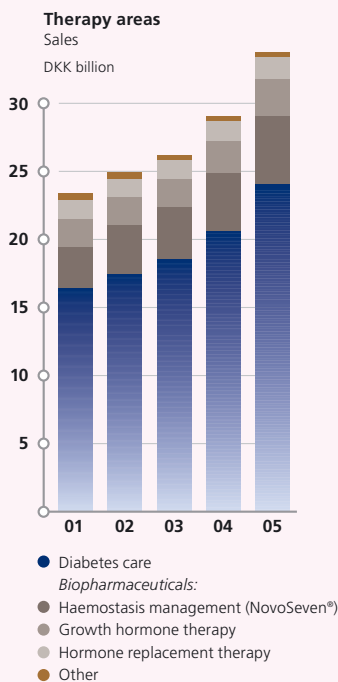
The growth of 16% in sales for 2005 exceeded the around 10% growth expectations outlined in January 2005 as a result of improved currency exchange rates as well as a stronger underlying sales performance.

### Diabetes care

Sales of diabetes care products increased by 17% in Danish kroner to DKK 24,012 million compared to 2004 and by 16% in local currencies.

### Insulin analogues, human insulin and insulin-related products

Sales of insulin analogues, human insulin and insulin-related products increased by 18% measured in Danish kroner to DKK 22,304



million and by 17% in local currencies. All regions contributed to growth measured in local currencies as well as in Danish kroner, with North America and International Operations having the highest growth rates.

Novo Nordisk continues to consolidate its global leadership position within the insulin segment: the company's total insulin market share worldwide is 51% and the analogue market share is 34%, both measured in volume. The similar market shares in 2004 were 50% and 28%, respectively.

Sales of insulin analogues increased by 62% in Danish kroner to DKK 7,298 million in 2005 and by 61% in local currencies. Insulin analogues constituted around 62% of the overall sales growth for Novo Nordisk in 2005, measured in local currencies, as compared to 55% in 2004.

### North America

Sales in North America increased by 40% in Danish kroner and by 39% in local currencies in 2005, reflecting solid sales performance for the insulin analogues NovoLog® and NovoLog® Mix 70/30. Novo Nordisk now holds 38% of the total US insulin market and 23% of the analogue market, both measured in volume. The similar market shares in 2004 were 34% and 18%, respectively. The human insulin products also contributed to the sales increase in 2005 due to higher volumes and higher average sales prices.

Novo Nordisk has in the final quarter of 2005 expanded its US diabetes care sales force by adding around 400 individuals, thereby bringing the total sales force to 1,200. The company is thereby well positioned to launch Levemir® in the US market, which is expected to take place during the second quarter of 2006.

### Europe

Insulin sales in Europe increased by 8% in Danish kroner and by 7% in local currencies, primarily reflecting progress for the portfolio of insulin analogues, including Levemir®. Novo Nordisk continues to consolidate the leadership position in the insulin analogue market, holding 43% of the market, measured in volume.

### International Operations

Sales in International Operations increased by 27% in Danish kroner and by 23% in local

currencies. The primary growth drivers in 2005 were sales in China, Russia and Brazil. China accounted for close to 20% of total insulin sales in International Operations and 25% of the increase in insulin sales during 2005. Novo Nordisk holds close to 60% of the Chinese insulin market, measured in volume.

Whereas insulin sales in International Operations remain dominated by human insulin products, the portfolio of insulin analogue products continues to add to the overall sales growth in the region, with Turkey and Russia as the largest growth drivers. Novo Nordisk remains the overall insulin market leader within the International Operations region and also holds the leadership position within insulin analogues.

### Japan & Oceania

Sales in Japan & Oceania increased by 10% in Danish kroner and by 11% in local currencies, primarily reflecting higher sales of NovoRapid® and NovoRapid® 30 Mix, assisted by the ongoing switch from durable to prefilled devices. In Japan, Novo Nordisk holds close to 60% and in Australia close to 70% of the insulin analogue market, measured by volume.

### Oral antidiabetic products

Sales of oral antidiabetic products increased by 4% in Danish kroner to DKK 1,708 million and by 3% in local currencies, compared to 2004. While the sales development was positive both in Europe and International Operations, this was partly offset by slightly lower sales in the US market, compared to 2004, reflecting a lower market share for Prandin®.

### Biopharmaceuticals

Sales of biopharmaceutical products increased by 15% in Danish kroner to DKK 9,748 million and by 14% in local currencies compared to 2004.

#### *NovoSeven®*

Sales of NovoSeven® increased by 16% in Danish kroner to DKK 5,064 million and by 16% in local currencies compared to 2004. All regions contributed to the increase in sales, with North America as the main contributor to growth.

The sales growth of NovoSeven® was influenced by several factors during 2005. Due to

the high penetration within spontaneous bleeds in congenital inhibitor patients, the predominant part of the growth within the inhibitor segment was generated by treatment of acquired haemophilia patients and usage of NovoSeven® in connection with elective surgery. Treatment of spontaneous bleeds for congenital inhibitor patients remains the largest area of use. In addition, sales are perceived to have been positively affected by increased investigational use of NovoSeven®.

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

Sales of growth hormone therapy products increased by 20% in Danish kroner to DKK 2,781 million and by 20% in local currencies, and all regions contributed to the sales increase compared to 2004, with North America and Europe having the highest growth rates. The NordiFlex® prefilled ready-to-use delivery device was the main reason for the increase in sales.

#### *Other products*

Sales of other products within biopharmaceuticals, which predominantly consist of hormone replacement therapy (HRT) products, increased by 4% in Danish kroner to DKK 1,903 million and by 4% in local currencies compared to last year. The main sales increase occurred in the US market, while sales in Europe were slightly above the levels realised in 2004.

### Costs, licence fees and other operating income

The cost of goods sold increased by 14% to DKK 9,177 million, representing a gross margin of 72.8%, compared to 72.3% in 2004. The improvement mainly reflects an improved product mix and increased production efficiency.

Total non-production-related costs increased by 16% to DKK 16,898 million. The increase in non-production-related costs in particular reflects increased sales and distribution costs, which increased in line with the growth in sales. This was mainly due to the increase in the US diabetes care sales force during the fourth quarter of 2005 as well as costs related to the continued roll-out of Levemir® in the European market, including expansion of sales forces in key markets.

Total costs related to depreciation, amorti-

sation and impairment losses in 2005 were DKK 1,930 million compared to DKK 1,892 million in 2004. The costs for 2005 include DKK 171 million in impairment charges, primarily related to fixed assets, compared to DKK 326 million in 2004.

In 2005, Novo Nordisk expensed costs in relation to share-based incentive programmes for senior management and other senior employees amounting to DKK 83 million. The comparable expense for 2004 was DKK 104 million. In addition, costs amounting to DKK 140 million in connection with the previously announced general employee share programme were expensed during the fourth quarter of 2005.

Licence fees and other operating income in 2005 were DKK 403 million, compared to DKK 575 million in 2004, reflecting a lower level of non-recurring income in 2005.

### Net financials and tax

Net financials showed an income of DKK 146 million in 2005 compared to an income of DKK 477 million in 2004.

The result from associated companies was an income of DKK 319 million compared to an expense of DKK 117 million in 2004, primarily reflecting Novo Nordisk's share of the net loss in ZymoGenetics, Inc being more than offset by total non-recurring gains during 2005 of approximately DKK 450 million from sales of shares in Ferrosan A/S and an offering of new shares in ZymoGenetics, Inc.

The foreign exchange result was a loss of DKK 40 million compared to a gain of DKK 533 million in 2004. The loss on foreign exchange in 2005 reflects losses from foreign exchange hedging activities due to the higher level in 2005 of especially US dollars versus Danish kroner compared to 2004. In accordance with IFRS, an unrealised loss of DKK 345 million was deferred by the end of December 2005 for profit and loss recognition in 2006 and 2007 when the hedged operational cash flows occur.

Novo Nordisk has as per 26 January 2006 hedged expected net cash flows in US dollars, Japanese yen and British pounds for 13, 12 and 10 months respectively. In accordance with IFRS, the financial impact from foreign

exchange contracts will be included in 'Net financials' as the underlying operational cash flows materialise.

The effective tax rate for 2005 was 28.8%, a decrease from 32.8% in 2004, equivalent to a total tax expense of DKK 2.4 billion in 2005. The lower effective tax rate for 2005 is a result of several factors, including the reduction of the Danish corporate income tax rate from 30% to 28%, effective for the entire 2005, and a beneficial impact from the re-evaluation of the company's deferred tax liabilities, as well as the tax-exempt status of the non-recurring gains from associated companies as mentioned above.

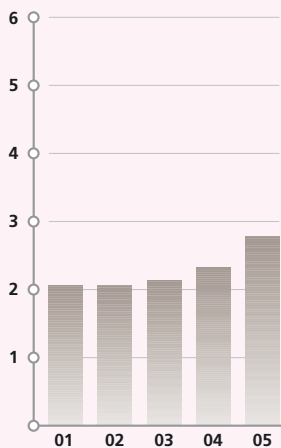
### Capital expenditure and free cash flow

Net capital expenditure for property, plant and equipment for 2005 was realised at DKK 3.7 billion, compared to DKK 3.0 billion for 2004. The main investment projects in 2005 were the expansion of purification and filling capacity for insulin products.

Free cash flow for 2005 was realised at DKK

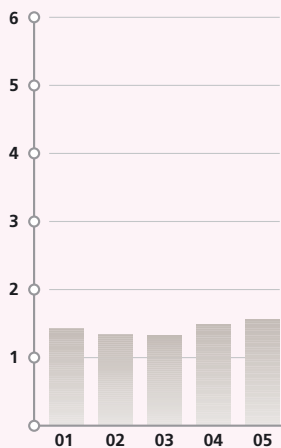
#### Growth hormone therapy

Sales  
DKK billion



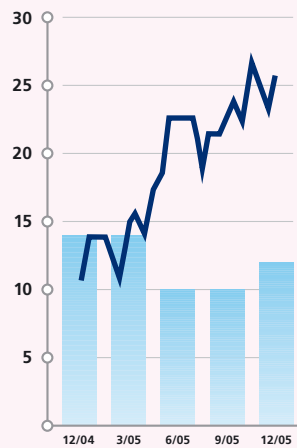
#### Hormone replacement therapy

Sales  
DKK billion



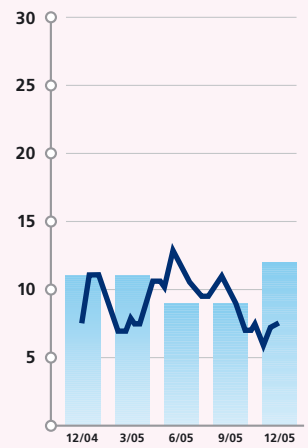
#### US dollars

Currency  
Months



#### Japanese yen

Currency  
Months



● Cover (left)  
● Rate (right)

● Cover (left)  
● Rate (right)

4.8 billion compared to DKK 4.3 billion for 2004.

Novo Nordisk's financial resources at the end of 2005 were DKK 11.4 billion compared to DKK 10.2 billion in 2004. Included in the financial resources are undrawn committed credit facilities of approximately DKK 7.5 billion.

### Non-financial performance

In managing its business with a Triple Bottom Line approach, the corporate Balanced Scorecard reflects financial as well as non-financial goals that are subsequently cascaded as appropriate to line management. Moreover, the performance-based incentive programme for Executive Management and the Senior Management Board is based on long-term value creation, following achievement of pre-defined overall business-related targets (see management's remuneration p 83).

#### Performance indicators

A set of top-level indicators help track the company's performance in terms of economic, environmental and social responsibility. They relate to areas of strategic importance: direct and indirect economic impacts; direct and indirect environmental impacts; and internal (people) and external (patients and society) social impacts. See performance data and comments in the consolidated non-financial statements on pp 92–97.

In addition, Novo Nordisk reports in accordance with the Global Reporting Initiative's 2002 Sustainability Reporting Guidelines and the principles of the Global Compact (see p 40).

#### Defining materiality

Ongoing interactions with stakeholders, trend-spotting, business monitoring and the integrated systematic risk management process are tools to identify the issues that are material to Novo Nordisk's business. As a result of these processes Novo Nordisk frames its strategic response and defines its targets. The company regularly reviews its key priorities to ensure that they reflect current agendas and reports on progress.

### Economic impacts

#### *Job creation*

In 2005, Novo Nordisk created 1,735 new positions globally and had 22,007 full-time positions, measured as full-time equivalents (FTE). This is an increase of 8% from 2004. These jobs translate into 52,200 indirect jobs globally, primarily in the supply chain from production needs, but also as a result of employees' private consumption.

#### *Economic contribution in Denmark*

Novo Nordisk's sales in 2005 accounted for 2.2% of the Danish GDP. The company's economic contribution to overall economic wealth for the Danish society through the value added was 1.3% of gross value added (GVA), and 4.8% of Danish exports compared to 3.9% in 2004.

### Environmental impacts

#### *Eco-efficiency*

In 2005, Novo Nordisk continued to improve eco-efficiency, a measure for the ability to produce more pharmaceutical products with less use of water and energy. In the period 2001–2005 the average annual realised improvements were 8% for water and 14% for energy as measured by EPI indices. Hence, the five-year targets of improvements of the water and energy use efficiency at 5% and 4% per annum respectively were achieved.

#### *Climate change*

At the end of 2005, Novo Nordisk finalised a climate strategy that sets an ambitious target for reducing its CO<sub>2</sub> emissions by 10% in the period 2004–2014 as compared with 2004. In the absence of reduction initiatives, the company's emissions would increase by 67% in line with production growth. The target has been defined in an agreement with the WWF, which makes Novo Nordisk the 10th company in the world to become a member of the Climate Savers programme. The significant CO<sub>2</sub> reductions will be achieved through a broad range of measures including improved energy efficiency, fuel switching and conversion to renewable sources.

#### *Compliance*

In 2005, Novo Nordisk continued to be challenged on compliance. The number of breaches

of regulatory limit values increased to 174 from 74 in 2004. The number of accidental releases increased from 29 in 2004 to 83 in 2005.

The registered breaches and accidental releases are evaluated to be minor incidents with no or only minor impact on the external environment. Out of 174 breaches of regulatory limits 164 (94%) are related to pH and temperature in waste water, which are monitored through continuous measurements. The number of breaches is largely due to the fact that at several production sites there have been challenges in managing pH levels in the wastewater in spite of the fact that the company has invested up to DKK 10 million per neutralisation system at some sites.

A total of 50 out of the 83 accidental releases (60%) were related to accidental releases of cooling agents such as HCFCs and HFCs. In 2005, a campaign set focus on accidental releases from these types of facilities. There was one accidental release of GMOs at the site in Montes Claros. There will be a continued focus on compliance and preventive measures to help curb the curve.

In 2006, a three-stringed approach will be taken to ensure increased focus on compliance: first, a revision of approvals in close cooperation with authorities, second, education, and third, focused exchange of experiences.

#### *Environmental management*

Global implementation of environmental management standards progresses on schedule. In 2005, an additional two of Novo Nordisk's production facilities achieved ISO 14001 certification. This is instrumental in focusing local management on pollution prevention and compliance.

#### *Sustainable supply chain management*

During 2005, a total of 340 suppliers, accounting for 20% of the total value of Novo Nordisk's purchases, were evaluated on their environmental and social performance. Of these, 87% reported a satisfactory performance, while 8% received a rating for poor environmental performance and 5% of suppliers received a rating for both poor environmental and social performance. Following implementation of corrective actions, Novo Nordisk has not yet had to withdraw from the relationship as a result of repeated poor performance.

As of 2005, the programme includes audits of suppliers, following similar processes as Novo Nordisk's regular quality audits. In 2005, 12 of 340 key suppliers were audited. These are mainly located in countries with high risk of violation of Novo Nordisk's requirements. The conclusions from the audits are a generally satisfying social and environmental performance. A close follow-up on non-satisfactory performance ensures that corrective actions are taken.

**Social impacts**

*People*

Living the values is a key performance parameter, as this is seen to impact business results. In 2005, there was a 100% fulfilment of action plans arising from facilitations which support a company-wide adherence to the Novo Nordisk Way of Management.

Employee satisfaction surveys underscore the internal support for the company's values-based approach. In the annual employee survey, the average of respondents' answers as to whether social and environmental issues are important for the future of the company were

on a par with 2004 4.2 (on a scale from 1 to 5, with 5 being the highest score). The average of respondents' answers as to whether their manager's behaviour is consistent with Novo Nordisk's values was 4.0, which is at the same level as in 2004.

In the same survey, employees were asked 'whether their work gives them an opportunity to use and develop their competences and skills'. The average of respondents' answers remained at a high level of 3.8. The average of respondents' answers to the question as to whether people from diverse backgrounds have equal opportunities increased from 3.8 to 3.9. This reflects the company's focus on equal opportunities and diversity management.

The rate of absence remained at 3.2, while the rate of employee turnover increased from 7.3 in 2004 to 8.0 in 2005.

While the health and safety initiatives in the organisation focus on prevention, additional measures will be made to prevent occupational injuries and improve the working environment, as there was a notable increase in the frequency of occupational injuries from 5.6 per million working hours in 2004 to 7.3 in

2005, which is not satisfactory. These figures cover the entire organisation; however, 70% of the injuries happen at production sites.

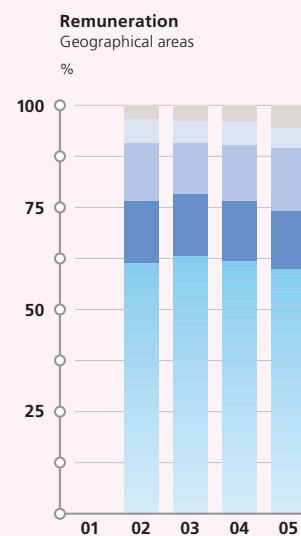
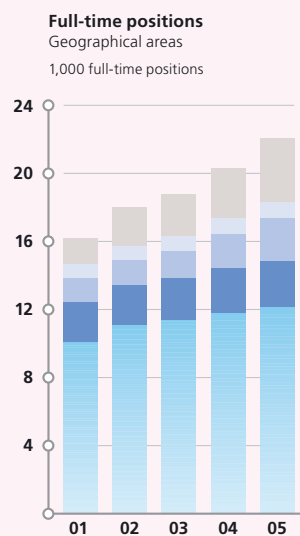
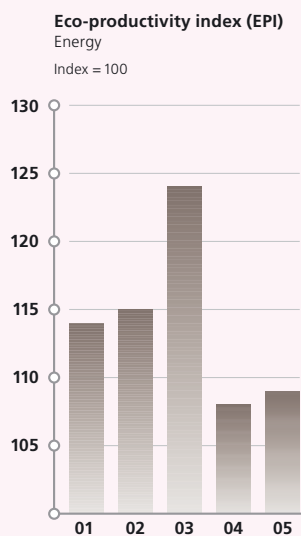
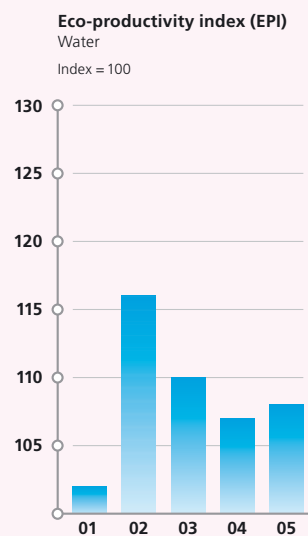
*Patients*

In 2005, Novo Nordisk provided insulin for 12–14 million people around the world. Of these, 6.5 million live in Europe, the US, Japan & Oceania; the remaining 5.5–7.5 million people live in the International Operations region. The range here is due to the fact that in the developing world two or three persons may share a daily dose of insulin.

During 2005, Novo Nordisk set off leading the fight against diabetes. With its mission of changing diabetes, concerted efforts focus on improved health management for people with diabetes and preventative measures for those at risk of acquiring it. The goal is to effectively curb the curve of the global diabetes pandemic.

Among the initiatives in 2005 was the Oxford Health Alliance that was established as an independent body to focus attention to prevention of chronic diseases.

Novo Nordisk's programmes to help provide global access to health continued in 2005. It is



estimated that the corporate and locally-driven programmes, most notably the National Diabetes Programme, reach out to at least 22 million people through awareness raising, education, diagnosis or treatment.

For 2005, Novo Nordisk offered its best possible pricing scheme to all 50 Least Developed Countries as defined by the United Nations. Novo Nordisk operates in 35 of these countries, and during 2005, the company sold insulin in 32 of the LDCs at or below the maximum price at 20% of the average prices in the Western world.

### *Society*

In 2005, Novo Nordisk implemented a new global business ethics policy supported by a set of guidelines. The policy adheres to the principles of the UN Convention against Corruption and the Global Compact. Implementation measures include training, an advisory function and compliance audits.

Full disclosure of current clinical studies was completed within the deadlines requested by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the International Committee of Medical Journal Editors (ICMJE). Each of these bodies specifies a website at which clinical trial results must be registered. By the end of 2005, Novo Nordisk had 51 trials of compounds registered at the website required by the ICMJE and 73 trials for marketed compounds at the PhRMA site.

### *The value of knowledge*

People and talent development is one of the cornerstones in the People Strategy. This includes offers for continued education for all, talent pools and leadership training. In 2005, the annual spending for training, measured as average spend per employee, increased by 10% to 9,899 Danish kroner. The money spent per employee does not fully reflect investments in training, since on-the-job-training, internal seminars and other similar activities are not included.

## Research and development update

### Diabetes care

Levemir® was approved by the US Food and Drug Administration (FDA) in June 2005, and

Novo Nordisk is thereby the only company with a complete range of insulin analogues approved in the US, encompassing rapid-acting NovoLog®, premixed NovoLog® Mix 70/30 and now also the long-acting analogue, Levemir®. Novo Nordisk expects to launch Levemir® in the US market in the second quarter of 2006.

Levemir® was also filed for marketing approval in Japan. As is already the case in the US and Europe, Novo Nordisk expects, upon approval of the product, to be the first and only company with both rapid-acting, premixed and long-acting insulin analogues in Japan.

In Europe, the European Commission has extended the marketing authorisation for Levemir® to include treatment of diabetes in children and adolescents 6–17 years of age. Moreover, an extended authorisation has also been received in Europe for NovoRapid® to include treatment of diabetes in children 2–6 years of age. Also the US regulatory authorities (FDA) extended the marketing authorisation for both NovoLog® and Levemir® to include paediatric treatment.

A label expansion for NovoLog® Mix 70/30 in the US has been approved by the FDA. Key additions to the label include blood glucose control data showing that more patients on a NovoLog® Mix 70/30 regimen reach an HbA1c target of 7.0% compared to treatment with a basal insulin analogue. The label expansion is expected to support further market share gains for NovoLog® Mix 70/30 in the US market.

Novo Nordisk has received marketing authorisation from the European Commission for NovoMix® 50 and NovoMix® 70. For filing of NovoMix® 50 in Japan, additional data will be required for approval. Novo Nordisk is currently planning the initiation of the necessary additional clinical trials. For the US, Novo Nordisk filed an application in June with the FDA for a marketing authorisation for NovoLog® Mix 50/50 and NovoLog® Mix 30/70 (the US trade names for NovoMix® 50 and NovoMix® 70).

At the annual meeting of the European Association for the Study of Diabetes (EASD) in September 2005, Novo Nordisk launched the NovoPen® 4 durable pen device for insulin treatment of patients with diabetes. This is the fourth generation of the NovoPen® range of durable devices, and NovoPen® 4 offers patients a more convenient treatment option,

compared to other marketed products.

The phase 2b study with liraglutide was successfully completed in November 2005. The results from the 14-week study showed an improvement of long-term glycaemic control, as measured by haemoglobinA1c (HbA1c), of between 1.5 and 2 percentage points by treatment with liraglutide compared to placebo. Liraglutide was well tolerated and nausea was reported at a level of 5–10%. There were no cases of major or minor hypoglycaemia in spite of the impressive glycaemic control. Phase 3 studies with liraglutide including approximately 3,800 patients are still expected to start in February 2006.

### Biopharmaceuticals

In August 2005, the FDA approved the use of NovoSeven® in surgical procedures involving haemophilia patients with inhibitors against their existing factor VIII or factor IX treatment. Furthermore, the FDA has also approved the use of NovoSeven® in patients with factor VII deficiency, a rare hereditary haemorrhagic disease caused by the diminution or absence of this coagulation factor. Additionally, Novo Nordisk filed in December an application with the FDA for US marketing approval of NovoSeven® for treatment of bleeding episodes in patients with acquired haemophilia.

In October, Novo Nordisk filed in the EU for marketing approval of NovoSeven® in ICH, based on results of clinical phase 2 trials. Novo Nordisk has received preliminary feedback from EMEA, indicating a preference for receiving additional data. Based on this, and a higher than expected recruitment rate in the ongoing global phase 3 study, Novo Nordisk will withdraw the current file and resubmit an application following the completion of phase 3. The updated application will reflect the less restrictive inclusion criteria in the phase 3 trial. This trial, now expected to be completed by the end of 2006, is aimed at satisfying the needs of regulatory agencies for approval worldwide outside Japan. A phase 2 clinical study has been initiated in Japan, which is expected to include around 100 patients and to be completed during 2007.

The NovoSeven® phase 3 clinical study in trauma outside the US is continuing as planned. The study includes mortality as a primary study outcome and is expected to in-

clude around 1,500 patients.

In the US, the FDA has asked for additional data related to the feasibility of conducting a NovoSeven® phase 3 clinical study in trauma without a waiver of informed consent. Therefore, Novo Nordisk has decided to initiate a phase 3 study without a waiver of informed consent, with the same primary end-point as the non-US trial, in order to provide the required data to the FDA. Novo Nordisk expects this process to take at least one year, but the timeline will ultimately depend on how the FDA interprets preliminary patient enrolment data from the study conducted without a waiver of informed consent.

Novo Nordisk expects to finalise four ongoing phase 2 studies with NovoSeven® within traumatic brain injury, cardiac surgery, spinal surgery and upper gastro-intestinal bleeds, respectively, in the second half of 2006.

In the HRT area, Novo Nordisk expects to file in February 2006 in Europe and the US for marketing approval of an ultra-low-dose version of Activelle® (Activella® in the US).

See also discussions of Novo Nordisk's research and development activities on pp 10–11 and 24–25 and the pipeline on pp 12–13.

## Equity

Total equity was DKK 27,634 million at the end of 2005, equal to 65.9% of total assets, compared to 70.8% at the end of 2004. The lower equity ratio reflects the accelerated completion of the DKK 5 billion share repurchase programme announced in April 2004 as well as unrealised losses on cash flow hedges, deferred as part of net equity for profit and loss recognition in 2006 and 2007.

### Proposed dividend and reduction of share capital

At the Annual General Meeting on 8 March 2006, the Board of Directors will propose a 25% increase in dividend to DKK 6.00 per share of DKK 2, corresponding to a pay-out ratio of 33.2%, compared to 31.8% for the financial year 2004. No dividend will be paid on the company's holding of treasury B shares.

In order to maintain capital structure flexibility the Board of Directors will also propose a reduction in the B share capital, by cancellation of nominally DKK 35.5 million (17,734,708

shares) of current treasury B shares, to DKK 566.4 million. This corresponds to a 5% reduction of the total share capital.

### Treasury shares and share repurchase programme

As per 27 January 2006, Novo Nordisk A/S and its wholly-owned affiliates owned 30,979,219 of its own B shares, corresponding to 8.73% of the total share capital. In 2005, a total of 852,647 B shares were disposed of to employees under the general employee share programme.

During 2005, Novo Nordisk purchased 9,657,118 B shares at a cash value of DKK 3 billion which, combined with the DKK 2 billion worth of B shares repurchased during 2004, completes the share repurchase programme of DKK 5 billion announced in April 2004.

The Board of Directors has approved the initiation of a new share repurchase programme of DKK 6 billion to be repurchased during 2006–2007. The objective is to align Novo Nordisk's capital structure to the expected positive development in free cash flow. The completion of the new programme will be subject to the shareholders' approval at the Annual General Meeting on 8 March 2006 of the proposed reduction of the company's share capital.

The repurchased shares will be kept as treasury shares and the value of the repurchased shares will, in accordance with Novo Nordisk's accounting policies, be written off against equity. A corresponding reduction will be made in 'number of shares outstanding' used in the calculation of Novo Nordisk's financial ratios.

## Corporate governance

### Long-term share-based incentive programme

As from 2004, Novo Nordisk's Executive Management and the Senior Management Board (26 in total) participate in a performance-based incentive programme where Novo Nordisk B shares are allocated annually to a bonus pool when certain predefined business-related targets have been achieved. The annual maximum allocation of shares to the bonus pool is capped at the equivalent of eight

months of salary on average per participant. The shares in the bonus pool are locked up for a three-year period before they are transferred to the executives at the expiry of the three-year lock-up period.

Based on an assessment of the economic value generated in 2005 as well as the performance of the R&D portfolio and key sustainability projects, the Board of Directors on 26 January 2006 approved the establishment of a bonus pool for 2005 by allocating a total of 116,013 Novo Nordisk B shares, corresponding to a cash value of DKK 35.5 million. This allocation amounts to seven months of salary on average per participant.

### Share option programme

The grant of share options to approximately 400 senior employees, excluding the members of Executive Management and the Senior Management Board, in accordance with Novo Nordisk's share option programme is subject to the achievement of shareholder value-based targets as determined by the Board of Directors. For 2005, targets were established for operating profit and return on invested capital, respectively, in addition to a number of non-financial targets for the performance of the R&D portfolio and key sustainability projects. These non-financial targets are identical to the targets included in the long-term share-based incentive programme for Executive Management and the Senior Management Board.

As the majority of the non-financial targets and both financial targets for 2005 were achieved, a total of 820,234 share options will be granted at an exercise price of DKK 306 per option. The options can be exercised in the period 31 January 2009–30 January 2014. The value of the share option programme is estimated to be DKK 47 million, based on the Black-Scholes model. The company's holding of its own shares will cover this commitment.

### Compliance with Sarbanes–Oxley requirements

In 2005, Novo Nordisk completed the process of becoming compliant with the Sarbanes–Oxley Act section 404 that requires detailed documentation of how financial reporting processes are designed and operating: the flow of information, and systems and controls sup-

porting the reporting processes. Novo Nordisk must ensure that there are no material weaknesses in the internal controls which could lead to a material misstatement in the company's financial reporting. Novo Nordisk will include a conclusion on the evaluation of the financial reporting processes and the auditors' evaluation hereof in the so-called Form 20-F filing to the US Securities and Exchange Commission, which is submitted in February 2006. Compliance with these requirements as a foreign registrant on the New York Stock Exchange (NYSE) is only required by the end of 2006 and, hence, Novo Nordisk's compliance with section 404 is achieved one year ahead of requirements.

### Legal issues

As of 26 January 2006, Novo Nordisk Inc, as the majority of hormone therapy product manufacturers in the US, is a defendant in product liability lawsuits related to hormone therapy products. These lawsuits currently involve a total of 37 individuals who allege to have used a Novo Nordisk hormone therapy product. These products (Activella® and Vagifem®) have been sold and marketed in the US since 2000. Until July 2003, the products were sold and marketed exclusively in the US by Pharmacia & Upjohn Company (now Pfizer Inc).

According to information received from Pfizer, an additional 13 individuals currently allege, in relation to similar lawsuits against Pfizer Inc, that they also have used a Novo Nordisk hormone therapy product. Currently, it is expected that the first trial may take place in the third or fourth quarter of 2006; however, Novo Nordisk is not expecting the claims to impact Novo Nordisk's financial outlook.

In September 2005, Novo Nordisk filed a patent infringement lawsuit against sanofi-aventis, Aventis Pharmaceuticals Inc, Aventis Pharma Deutschland GmbH, and Aventis Pharma AG alleging that the OptiClik® pen system marketed in the US by Aventis Pharmaceuticals infringes US patent No. 6582408. In the complaint, Novo Nordisk has asked for an injunction and monetary damages that have and will result from sale of the OptiClik® pen system. The lawsuit was filed in the US District Court for the district of Delaware. An initial

conference was held on 10 January 2006, at which time the court scheduled the trial for August 2007. The discovery phase will commence in early 2006.

In June 2005, Novo Nordisk filed a patent infringement lawsuit against Caraco Pharmaceutical Laboratories Ltd in response to their Abbreviated New Drug Application (ANDA) for repaglinide, the active ingredient in Prandin®. In their ANDA, Caraco requests approval to sell repaglinide following the 2009 expiration of a US patent relating to repaglinide, and provides Paragraph IV certification under the statutes of the Drug Competition and Patent Term Extension Restoration Act (Hatch-Waxman Act), alleging non-infringement and invalidity of a Novo Nordisk patent relating to the fixed combination or simultaneous administration of repaglinide with metformin, which expires in 2018. The discovery phase is expected to commence in early 2006.

Novo Nordisk Inc is currently a defendant in three separate cases filed in the US alleging that Novo Nordisk and a number of other pharmaceutical companies provided a false Average Wholesale Price for certain drugs covered by Medicaid. These cases have been brought by the State of Alabama, the State of Mississippi and Erie County, New York. Novo Nordisk was recently dismissed from 31 similar cases by counties in the State of New York.

In December 2005, the office of the US Attorney for the Eastern District of New York served Novo Nordisk with a subpoena calling for the production of documents relating to the company's US marketing and promotional practices. The company believes that the investigation is limited to its insulin products. The subpoena indicates that the documents are necessary for the investigation of potential criminal offences relating to healthcare benefit programmes. Novo Nordisk is cooperating with the US Attorney in this investigation.

For information on contingencies for pending litigation, see the financial statements, note 37 on p 89.

### Outlook 2006

Novo Nordisk expects at least 10% growth in sales measured in local currencies for 2006. This is based on expectations of a strong market for insulin products in general and the continued market penetration of Novo Nordisk's insulin analogue portfolio, combined with expectations of increasing NovoSeven® and Norditropin® SimpleXx® sales. Given the current level of exchange rates versus Danish kroner, the sales growth rate for 2006 measured in Danish kroner is expected to be slightly higher than the growth rate measured in local currencies.

For 2006, operating profit growth measured in local currencies and excluding the impact from non-recurring items is expected to grow by around 10%, reflecting the expected higher spending on sales and marketing activities, combined with an increased number of late-stage clinical development projects. Measured in Danish kroner the growth in operating profit is expected to be slightly more than 10%, reflecting a minor positive currency impact and the absence of non-recurring income in 2006.

Novo Nordisk expects a net financial expense of DKK 350 million in 2006, reflecting:

- a net financial expense of around DKK 150 million (excluding Novo Nordisk's share of profit & loss in associated companies), primarily related to deferred losses from foreign exchange hedging contracts, and
- a negative impact from losses in associated companies of around DKK 200 million, primarily reflecting Novo Nordisk's share of the expected loss in ZymoGenetics, Inc.

### Invoicing currency

USD  
JPY  
GBP  
USD-related<sup>\*)</sup>

Annual impact on Novo Nordisk's operating profit in 2006 of a 5% movement in currency

DKK 350 million  
DKK 150 million  
DKK 90 million  
DKK 100 million

<sup>\*)</sup>USD-related currencies include CNY, CAD, ARS, BRL, MXN, CLP, SGD, TWD and INR

Novo Nordisk expects the effective tax rate to be 30%, 1 percentage point higher than the tax rate realised for 2005. As previously stated, the tax rate for 2005 was positively impacted by the tax-exempt status of non-recurring gains related to associated companies as well as the positive impact from re-evaluation of deferred tax liabilities.

Novo Nordisk plans capital expenditures of around DKK 3 billion, primarily related to the construction of additional purification and filling capacity for insulin products. Depreciation, amortisation and impairment losses are expected to be around DKK 2.1 billion and the free cash flow to be around DKK 4 billion.

All of the above expectations are provided that currency exchange rates remain at the current level for 2006. All other things being equal, movements in key invoicing currencies will impact Novo Nordisk's operating profit in 2006 as illustrated on p 50.

With the results achieved and the investments made in 2005, the Board of Directors and Executive Management are confident that this provides a strong platform for 2006, which will enable Novo Nordisk to deliver solid financial performance and to continue to invest in the future.

### Forward-looking statement

The above sections contain forward-looking statements as the term is defined in the US Private Securities Litigation Reform Act of 1995. Forward-looking statements provide current expectations or forecasts of events such as new product introductions, product approvals and financial performance.

Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions. This may cause actual results to differ materially from expectations. Factors that may affect future results include interest rate and currency exchange rate fluctuations, delay or failure of development projects, production problems, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for Novo Nordisk's products, introduction of competing products, Novo Nordisk's ability to successfully market both new and existing products, exposure to product liability and other lawsuits, changes in reimbursement rules and governmental laws and related interpretation thereof, and unexpected growth in costs and expenses.

Risks and uncertainties are further described in reports filed by Novo Nordisk with the US Securities and Exchange Commission (SEC) including the company's Form 20-F, which was filed on 21 February 2005. Please also refer to pp 56–57. Novo Nordisk is under no duty to update any of the forward-looking statements or to conform such statements to actual results, unless required by law.