NOVO NORDISK A S Form 6-K February 05, 2014

#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER** 

Pursuant to Rule 13a-16 or 15d-16 of the Securities Exchange Act of 1934

#### **FEBRUARY 5, 2014**

## **NOVO NORDISK A/S**

(Exact name of Registrant as specified in its charter)

Novo Allé DK- 2880, Bagsvaerd

Denmark

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F

Form 20-F [X] Form 40-F [ ]

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes [ ] No [X]

If Yes is marked, indicate below the file number assigned to the registrant in connection with Rule 12g-32(b):82-\_\_\_

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This Annual Report is published in both a Danish and an English version. In the event of any discrepancies, the Danish version shall prevail.

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# Letter from the **Chairman**

Last year, at Novo Nordisk S Annual General Meeting in March, I was named Chairman of the Board of Directors of which I have been a member since 2005. I feel honoured by and proud of this appointment, and will do my best to live up to the responsibilities that come with it.

As a board member I[ve followed Novo Nordisk]s development during a very difficult period for the pharmaceutical industry. It has been an exciting journey: in terms of both financial value creation for our shareholders and positive impact on people with diabetes, Novo Nordisk has delivered outstanding results.

I and the other members of Novo Nordisk is Board are confident that Novo Nordisk will continue to do very well despite having been through a year that, frankly, will be remembered for a number of negative events: a Warning Letter from the US Food and Drug Administration (FDA), a delay for Tresiba<sup>®</sup> (insulin degludec) in the US, a safety scare around the class of products to which Victoza<sup>®</sup> belongs, and a major product recall.

Our Chief Executive Officer, Lars Rebien Sørensen, will give you more details and share his reflections on these events on the following pages. What is important for me to say is that the Board has followed up meticulously on each and every one of these events to ensure that management has responded appropriately to them to minimise the negative effects and the risk of reoccurrence. And we firmly believe that it has.

The Board has also reviewed the company[s long-term strategy and outlook as we do every year. Is it realistic? Is it ambitious? Does the company have the skills and resources to execute it? And if so, does it provide Novo Nordisk with the competitive advantages needed to be successful in a very competitive industry? We believe it does.

We⊓ve also evaluated the strength of the company∏s executive leadership and senior management and reviewed the succession preparedness for key positions. Together with the executive team we∏ve assessed the company∏s organisational strengths and weaknesses. Whenever wenve identified issues that could become a significant obstacle to meeting the company∏s long-term goals, we ve agreed on a plan of action.

We re confident that in Lars Rebien Sørensen and his Executive Management team we have the leadership needed to execute Novo Nordisk s strategy and execute it well. It has been a pleasure to see how two new members of Executive Management have been smoothly integrated into the team, and how the company s

bench of senior vice presidents has been expanded with new members, several of them from our large and very successful affiliate in the US.

The Board is also pleased to announce the promotion of Chief Operating Officer Kåre Schultz to president. This is a reflection of the importance and complexity of his organisation and his successful management hereof. In this role, Kåre will work closely with Lars on planning Executive Management meetings and board meetings, and assume a more outward-facing role.

Despite the challenges Novo Nordisk faced in 2013, it met the sales and profit targets we communicated at the beginning of the year. Sales grew by 12% and operating profit by 15%, both measured in local currencies. Furthermore, we made significant progress on the key development projects, which bodes well for future growth and for the company s ability to achieve its long-term targets.

Against this background, at the Annual General Meeting on 20 March 2014 the Board of Directors will propose a 25% increase in dividend to 4.50 Danish kroner per share of 0.20 krone. The Board of Directors has furthermore decided to initiate a new share repurchase programme of up to 15 billion kroner.

I d also like to highlight two important decisions that the Board has made regarding corporate governance. We established a Nomination Committee to enhance the process for nominating

Chairman of the Board of Directors Göran Ando at the Novo Nordisk R&D Summit in November 2013.

members to the Board, and set new targets for the diversity of the Board as regards gender and nationality. For more information on this, please see p 47.

On behalf of the Board of Directors, I[d like to express my appreciation for the leadership shown by Lars Rebien Sørensen and his management team, and the hard work and dedication of the entire Novo Nordisk organisation.

> **Göran Ando** Chairman of the Board of Directors

# Letter from the **CEO**

2013 was both a good year and a tough year for Novo Nordisk.

Let me start with the tough part. As I mentioned in my letter in last year s Annual Report, we began the year with the unsettling fact of having received a Warning Letter from the US Food and Drug Administration (FDA), following an inspection of one of our insulin-filling plants in Denmark.

Unrelated to this, in February we received a Complete Response Letter from the FDA in which the agency requested additional cardiovascular safety data before it could complete its review of the New Drug Application for Tresiba<sup>®</sup> (insulin degludec). Tresiba<sup>®</sup> is our new-generation basal insulin with an ultra-long duration of action of more than 42 hours.

President and Chief Executive Officer Lars Rebien Sørensen at the Novo Nordisk Capital Markets Day in December 2013. To make matters worse, a debate emerged in March in which some scientists questioned whether the incretin class of diabetes medications [] the class to which our very successful product Victoza<sup>®</sup> belongs [] had an increased risk of side effects in the pancreas. Although the authorities later concluded that the data currently available don[]t confirm the concerns, the debate did create anxiety among some patients using these products.

In October, we had to recall a number of batches of NovoMix<sup>®</sup> insulin in some European countries as our analysis had shown that a small percentage of the products in these batches didn\_t meet the specifications for insulin strength.

Not the kind of events we d hoped for in our 90th anniversary year d or in any other year for that matter. For Novo Nordisk s employees, who take immense pride in the safety and efficacy of our products, such events are downright painful.

They are, however, also a good opportunity for learning and reflection, and we have learned from these events and are still learning. To mention just two examples: we[]re improving our measures to ensure compliance with the latest and ever-evolving standards for good manufacturing practice, and we[]re collecting more data than ever regarding cardiovascular safety to rule out that our products are associated with unacceptable risks.

I wish I could say that events such as the ones I[ve described will never happen again, but I[m not naive. Bad things happen, even to good companies; however, I firmly believe we[re coming out of these events wiser and stronger.

Allow me to turn to the brighter part of my account of 2013. I[m glad to report that our strategic products are doing well in the market. Tresiba<sup>®</sup> was launched in Japan as the first country in February 2013 and by the end of the year had claimed 8.6%

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of the segment for long-acting insulin (basal insulin) measured in value. Several other countries launched Tresiba<sup>®</sup> during the year and in all countries where the product is competing on an equal footing with other insulin products, it[]s gaining significant market shares.

Our established key products did well, too: sales of our modern insulins grew 14%, Victoza<sup>®</sup> 27%, NovoSeven<sup>®</sup> 8% and Norditropin<sup>®</sup> 16%, all measured in local currencies. I think it is fair to say that this is a solid performance in a global pharmaceutical market characterised by all forms of cost-containment measures. To me it shows that there is a large and growing need for our products.

From a regional perspective, North America was again the main contributor to our growth, followed by International Operations and Region China. It s also in these regions we expect to see most of the growth in the coming years. Our sales growth, combined with continuous focus on the efficiency of our operations, resulted in operating profit growth of 7% reported and 15% in local currencies. Growth in net profit was 18% and measured on an earnings per share basis, the increase was 20% [] all in all a very robust financial performance in 2013.

Several products in our development pipeline passed important milestones in 2013:

The cardiovascular outcomes trial for Tresiba<sup>®</sup> designed to provide the data requested by the FDA was initiated in October.

IDegLira, a fixed combination of liraglutide and insulin degludec for the treatment of type 2 diabetes, was filed for regulatory review in the EU.

We started the phase 3a programme for the faster-acting formulation of insulin aspart.

A 3 mg dose of liraglutide, the active substance in Victoza<sup>®</sup>, was filed for regulatory review in both the US and the EU as a potential new obesity treatment.

Semaglutide, a once-weekly GLP-1 analogue, started phase 3 trials.

FDA approved our insulin injection pens FlexTouch <sup>®</sup> and NovoPen Echo<sup>®</sup> for use with certain insulin products.

Within haemophilia, turoctocog alfa, our new factor VIII product for people with haemophilia A, was approved in the US, the EU and Japan. Turoctocog alfa will be marketed under the brand name NovoEight<sup>®</sup> in most countries.

You[]II find more information about these and other significant product development milestones in the research and development section on p 10 and in articles in this Annual Report.

In 2014, we[]II maintain a high level of investment in research and development and in our growth markets and strategic products. We[]II have special focus on:

The continued roll-out of Tresiba ®

The first launches of Ryzodeg  $^{\circledast}$  [] a combination of Tresiba $^{\circledast}$  and our fast-acting insulin NovoRapid $^{\circledast}$  ] and NovoEight $^{\circledast}$ 

The regulatory reviews of IDegLira and liraglutide 3 mg

Further strengthening our systems and processes for ensuring compliance with all relevant regulatory standards

Implementing our strategy for global access to diabetes care targeted at people who currently don thave access to the necessary medical treatment and care.

As you II see from the article on the diabetes pandemic later in this Annual Report, the number of people with diabetes is growing at an alarming rate. The latest estimates are that by 2035 close to 600 million people will have diabetes and at some point most of them will require medical treatment. You can read more about this on pp 22[23.

At Novo Nordisk we have a critical role to play and are committed to playing our part in the fight against diabetes. We ve set ourselves the target that 40 million people will be using our products by 2020. We are, however, keenly

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aware that our products alone will not address all the challenges. That s why we re working with partners all over the world to identify and implement local solutions for improving diabetes care. You II find some examples of this in the article on p 26.

In the coming years we ll have special focus on how to address the diabetes challenge in the world is big cities. All over the world, people are migrating to big cities and, unfortunately, urbanisation and type 2 diabetes go hand in hand. Not much is known about how to change the situation, but we re determined to work with partners to find out.

In the face of the challenges that 2013 brought for Novo Nordisk, I[]ve taken great pleasure from the collaboration I[]ve had with my Executive Management team, our Senior Management Board and the Board of Directors, and from dealing with the challenges we have encountered. I look forward to an even closer collaboration with Kåre Schultz in his new role as president. I have worked with Kåre for almost 20 years and have enjoyed following his development as leader of increasingly larger and more complex organisations. His promotion is well-deserved recognition of his accomplishments and leadership potential.

Ind like to thank everyone in the Novo Nordisk organisation for their contributions to our results in 2013, the people who use our products for their confidence in us, our stakeholders and partners for their collaboration, and our shareholders for their continued support.

Lars Rebien Sørensen President and chief executive officer

PS: Please tell us what you think about our Annual Report. Does it meet your information needs? Is it comprehensible? You can help improve our reporting by answering six questions at novonordisk.com/annualreport/feedback.

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# Novo Nordisk at a glance

PRODUCTS ESTABLISHED IN MARKETED IN DENMARK 180 IN 1923 EMPLOYEES IN 75 COUNTRIES COUNTRIES Novo Nordisk Way

## **Novo Nordisk Way**

In 1923, our Danish founders began a journey to change diabetes.

Today, we are thousands of employees across the world with the passion, the skills and the commitment to continue this journey to prevent, treat and ultimately cure diabetes.

Our ambition is to strengthen our leadership in diabetes.

We aspire to change possibilities in haemophilia and other serious chronic conditions where we can make a difference.

Our key contribution is to discover and develop innovative biological medicines and make them accessible to patients throughout the world.

Growing our business and delivering competitive financial results is what allows us to help patients live better lives, offer an attractive return to our shareholders and contribute to our communities.

We never compromise on quality and business ethics.

Our business philosophy is one of balancing financial, social and environmental considerations [] we call it the Triple Bottom Line.

We are open and honest, ambitious and accountable, and treat everyone with respect.

We offer opportunities for our people to realise their potential.

Every day we must make difficult choices, always keeping in mind what is best for patients, our employees and our shareholders in the long run.

It s the Novo Nordisk Way.

## The Triple Bottom Line

83.6 DKK BILLION IN SALES (+7%) 25.2 DKK BILLION IN NET PROFIT (+18%) Financially responsible Patients Socially responsible Environmentally responsible 24.3 MILLION PATIENTS USE OUR DIABETES CARE PRODUCTS (+7%) 125 THOUSAND TONS CO<sub>2</sub> EMISSIONS (+2%) 38,436 EMPLOYEES WORLDWIDE (+11%) 2,685 THOUSAND M<sup>3</sup> WATER CONSUMPTION (+8%)

# **2013 progress on strategic focus areas**

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Expand leadership in diabetes care 30% GLOBAL VALUE MARKET SHARE (+2%) Establish presence in inflammation

Five compounds in clinical trials with three in phase 2. Expand leadership in growth disorders

Liraglutide 3 mg for obesity completed phase 3a and was submitted in the EU and the US. Pursue leadership in haemophilia

NovoEight® was approved in the US, the EU and Japan.

N9-GP successfully completed first phase 3a trial.

NovoThirteen® was approved in the US.

Establish presence in obesity NovoSeven® sales DKK BILLION Norditropin® sales DKK BILLION 2012 2013 2012 2013 8.9 9.3 5.7 6.1 (+4%) (+7%) 65.5

DKK BILLION IN SALES (+8%) 2.6 (+2%) 2.2 ( 19%) 38.2 10.9 (+10%) ( 4%) 11.6 (+23%) 27% GLOBAL VALUE MARKET SHARE (+1%)

Tresiba® was launched in eight countries.

DEVOTE, a cardiovascular outcomes trial designed to provide the data for Tresiba® requested by the FDA, was initiated.

IDegLira was filed for regulatory review in the EU.

Semaglutide, a once-weekly GLP-1 analogue, started phase 3a trials. Protein-related products Oral antidiabetic products Modern insulins Human insulins Victoza® 5

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# 2013 performance and 2014 outlook

2013 was a year of mixed fortunes for Novo Nordisk marked by steady progression towards long-term financial, social and environmental targets, whereas the Complete Response Letter for Tresiba<sup>®</sup> in the US was a disappointment.

# **Financial performance**

The results for 2013 are higher than expected in the outlook for the year in the *Annual Report 2012* and in line with the latest guidance provided in connection with the quarterly announcement in October 2013.\*

## Sales development

Sales increased by 12% measured in local currencies and by 7% in Danish kroner. North America was the main contributor with 66% share of growth measured in local currencies, followed by International Operations and Region China contributing 20% and 9% respectively. Sales growth was realised within both diabetes care and biopharmaceuticals, with the majority of growth originating from the modern insulins and Victoza<sup>®</sup>.

In the following sections, unless otherwise noted, market data are based on moving annual total (MAT) from November 2013 and November 2012 provided by the independent data provider IMS Health.

Please refer to the company announcement of 30 January 2014 for explanation of results compared with the latest \* expectations.

## Diabetes care sales development

Sales of diabetes care products increased by 12% measured in local currencies and by 8% in Danish kroner to DKK 65,456 million. Novo Nordisk is the world leader in diabetes care and now holds a global value market share of 27% compared with 26% at the same time the previous year.

#### Insulins and protein-

#### related products

Sales of insulins and protein-related products increased by 11% in local currencies and by 6% in Danish kroner to

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DKK 51,577 million. Measured in local currencies, sales growth was driven by North America, International Operations and Region China. Novo Nordisk is the global leader with 48% of the total insulin market and 46% of the market for modern insulins and new-generation insulins, both measured in volume.

The roll-out of Tresiba<sup>®</sup> (insulin degludec), the once-daily new-generation insulin with an ultra-long duration of action, continues to progress. Launch activities are proceeding as planned and feedback from patients and prescribers is encouraging. Tresiba<sup>®</sup> has been launched in eight countries with 20 more countries expected to launch during 2014. In the countries where Tresiba<sup>®</sup> is reimbursed on a similar level to insulin glargine, it has steadily grown its share of the basal insulin market. In these countries, Tresiba<sup>®</sup> now represents around 10% of the basal insulin

market measured in monthly value market share. In the markets where Tresiba<sup>®</sup> has been launched with restricted market access compared with insulin glargine, market penetration remains modest.

Sales of modern insulins increased by 14% in local currencies and by 10% in Danish kroner to DKK 38,153 million. North America accounted for two-thirds of the growth, followed by International Operations and Region China. Sales of modern insulins now constitute 78% of Novo Nordisk sales of insulin.

#### Victoza®

#### (GLP-1 therapy for type 2 diabetes)

Victoza<sup>®</sup> sales increased by 27% in local currencies and by 23% in Danish kroner to DKK 11,633 million, reflecting robust sales performance driven by North America, Europe and International Operations. Victoza<sup>®</sup> holds the global market share leadership in the GLP-1 segment with a 71% value market share compared with 68% in 2012. The GLP-1 segment\_]s value share of the total diabetes care market has increased to 6.9% compared with 5.9% in 2012.

#### NovoNorm<sup>®</sup>/Prandin<sup>®</sup>/PrandiMet<sup>®</sup>

#### (oral antidiabetic products)

Sales of oral antidiabetic products decreased by 16% in local currencies and by 19% in Danish kroner to DKK 2,246 million. The negative sales development reflects an impact from generic competition in the US and Europe as well as a changed inventory set-up in China.

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# Biopharmaceuticals sales development

Sales of biopharmaceutical products increased by 12% measured in local currencies and by 6% in Danish kroner to DKK 18,116 million. Sales growth was primarily driven by North America and International Operations.

#### NovoSeven®

#### (bleeding disorders therapy)

Sales of NovoSeven<sup>®</sup> increased by 8% in local currencies and by 4% in Danish kroner to DKK 9,256 million. The market for NovoSeven<sup>®</sup> remains volatile, and sales growth is primarily driven by North America and International Operations.

#### **Norditropin**<sup>®</sup>

#### (growth hormone therapy)

Sales of Norditropin<sup>®</sup> increased by 16% in local currencies and by 7% in Danish kroner to DKK 6,114 million. The sales growth is primarily driven by contractual wins, the support programmes that Novo Nordisk offers healthcare professionals and patients as well as the penetration of the prefilled FlexPro<sup>®</sup> device in North America and furthermore by growth in International Operations. Novo Nordisk is the leading company in the global growth hormone market with a 28% market share measured in volume.

#### **Other biopharmaceuticals**

Sales of other products within biopharmaceuticals, which predominantly consist of hormone replacement therapy-related (HRT) products, increased by 15% in local currencies and by 9% in Danish kroner to DKK 2,746 million. Sales growth is driven by North America and reflects a positive impact of pricing and non-recurring adjustments to the provisions for rebates.

# Development in costs and operating profit

The cost of goods sold grew 5% to DKK 14,140 million, resulting in a gross margin of 83.1% compared with 82.7% in 2012. This development primarily reflects an underlying improvement driven by favourable price development in North America and a positive net impact from product mix due to increased sales of modern insulins and Victoza<sup>®</sup>. The gross margin was negatively impacted by around 0.3 percentage point due to the depreciation of key invoicing currencies versus the Danish krone compared with prevailing exchange rates in 2012.

Total non-production-related costs increased by 11% in local currencies and by 8% in Danish kroner to DKK 38,621 million.

Sales and distribution costs increased by 13% in local currencies and by 9% in Danish kroner to DKK 23,380 million. The growth in costs is driven by the expansions of the sales forces and sales and marketing investments in the US, China and selected countries in International Operations as well as costs related to the launch of Tresiba<sup>®</sup>. The growth percentage for costs has also been impacted by changes to legal provisions in 2012 and 2013.

Research and development costs increased by 9% in local currencies and by 8% in Danish kroner to DKK 11,733 million. Within diabetes care, costs are primarily driven by development costs related to the initiation of the Tresiba<sup>®</sup> cardiovascular outcomes trial, and the ongoing phase 3a trials for both faster-acting insulin aspart and semaglutide, the once-weekly GLP-1 analogue. Within biopharmaceuticals, costs are primarily related to the continued progress of the portfolio of development projects within haemophilia and the phase 2 trial for anti-IL-20, a recombinant human monoclonal antibody, in rheumatoid arthritis.

Administrative costs increased by 9% in local currencies and by 6% in Danish kroner to DKK 3,508 million. The increase in costs is primarily driven by back-office infrastructure costs to support the expansions of the sales organisations in North America, China and selected countries in International Operations, non-recurring costs related to new offices in Denmark and the US as well as an impact from a cost refund in 2012 of a previously expensed fine related to an import licence for a major market in International Operations.

Licence income and other operating income constituted DKK 682 million compared with DKK 666 million in 2012.

Operating profit increased by 7% in Danish kroner to DKK 31,493 million. In local currencies, the growth was 15%.

## Net financials and tax

Net financials showed a net income of DKK 1,046 million compared with a net expense of DKK 1,663 million in 2012. As of 31 December 2013, foreign exchange hedging gains of around DKK 1,200 million have been deferred for recognition in the income statement in 2014.

In line with Novo Nordisk is treasury policy, the most significant foreign exchange risks for the Group have been hedged, primarily through foreign exchange forward contracts. The foreign exchange result was a net income of DKK 1,146 million compared with a net expense of DKK 1,529 million in 2012. This net income reflects gains on foreign exchange hedging involving especially the Japanese yen and the US dollar due to their depreciation versus the Danish krone compared with the prevailing exchange rates in 2012, which has been partly offset by losses on commercial balances, primarily related to non-hedged currencies.

The effective tax rate for 2013 was 22.6%.

#### CONTINUED []

#### 8 ACCOMPLISHMENTS AND RESULTS 2013

# Capital expenditure and free cash flow

Net capital expenditure for property, plant and equipment was DKK 3.2 billion compared with DKK 3.3 billion in 2012. Net capital expenditure was primarily related to new offices in Denmark, filling capacity in Denmark and Russia, additional GLP-1 manufacturing capacity, new diabetes research facilities in Denmark as well as device production facilities in the US and Denmark.

Free cash flow was DKK 22.4 billion compared with DKK 18.6 billion in 2012. The increase of 20% compared with 2012 reflects the growth in net profit of 18% and a lower impact from tax payments in 2013 compared with 2012 related to ongoing transfer pricing disputes, which was partly offset by earlier payment of rebate liabilities in the US.

# Outlook 2014

The current expectations for 2014 are summarised in the table below:

Expectations are as reported, if not otherwise stated

Expectations 30 January 2014

Sales growth in local currencies as reported	8[]11% Around 3.5 percentage points lower
<b>Operating profit growth</b> in local currencies as reported	Around 10% Around 5.5 percentage points lower
Net financials	Income of around DKK 750 million
Effective tax rate	Around 22%
Capital expenditure	Around DKK 4.0 billion
Depreciation, amortisation and impairment losses	Around DKK 2.9 billion
Free cash flow	Around DKK 26 billion

**Sales growth** for 2014 is expected to be 8[11% measured in local currencies. This reflects expectations of continued robust performance for the portfolio of modern insulins and Victoza<sup>®</sup> as well as a modest sales contribution from Tresiba<sup>®</sup>. These sales drivers are expected to be partly countered by an impact from a more challenging contract environment in the US, generic competition for Prandin<sup>®</sup> in the US during the first half of 2014, intensifying competition within both diabetes and biopharmaceuticals as well as the macroeconomic conditions in a number of markets in International Operations. Given the current level of exchange rates versus the Danish krone, the reported sales growth is now expected to be around 3.5 percentage points lower than growth measured in local currencies.

For 2014, **operating profit growth** is expected to be around 10% measured in local currencies. This reflects a significant increase in costs related to the continued progress of key development projects within diabetes and biopharmaceuticals. In addition, significant costs are expected in relation to sales force expansions and sales and marketing investments in the portfolio of modern insulins and Victoza<sup>®</sup> in the US, China and selected markets in International Operations as well as the launch of Tresiba<sup>®</sup> outside the US. Given the current level of exchange rates versus the Danish krone, the reported operating profit growth is now expected to be around 5.5 percentage points lower than growth measured in local currencies.

For 2014, Novo Nordisk expects a **net financial income** of around DKK 750 million. The current expectation primarily reflects gains associated with foreign exchange hedging contracts following the depreciation of the Japanese yen and the US dollar versus the Danish krone compared with the average prevailing exchange rates in 2013.

The effective tax rate for 2014 is expected to be around 22%.

**Capital expenditure** is expected to be around DKK 4.0 billion in 2014, primarily related to investments in additional GLP-1 manufacturing capacity, expansion of filling capacity, prefilled device production facilities, construction of new laboratory facilities as well as expansion of protein capacity within the CMC (Chemistry, Manufacturing and Control) organisation. **Depreciation, amortisation and impairment losses** are expected to be around DKK 2.9 billion. **Free cash flow** is expected to be around DKK 26 billion.

All of the above expectations are based on the assumption that the global economic environment will not significantly change business conditions for Novo Nordisk during 2014, and that currency exchange rates, especially the US dollar, will remain at the current level versus the Danish krone.

Novo Nordisk has hedged expected net cash flows in a number of invoicing currencies and, all other things being equal, movements in key invoicing currencies will impact Novo Nordisk s operating profit as outlined in the table below:

Key invoicing currencies	Annual impact on Novo Nordisk[]s operating profit of a 5% movement in currency	Hedging period (months)
USD	DKK 1,300 million	12
CNY	DKK 220 million	12*
JPY	DKK 145 million	14
GBP	DKK 85 million	12
CAD	DKK 60 million	10

\* USD used as proxy when hedging Novo Nordisk s CNY currency exposure.

The financial impact from foreign exchange hedging is included in [Net financials].

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# Long-term financial targets

Novo Nordisk introduced four long-term financial targets in 1996 to balance short- and long-term considerations, thereby ensuring a focus on shareholder value creation. The targets have subsequently been revised and updated on several occasions, most recently in connection with the release of the financial statement for 2012. The targets have been selected to ensure focus on growth, profitability, efficient use of capital and cash flow generation.

The targets are based on an assumption of a continuation of the current business environment. Significant changes to the business environment, including the structure of the US healthcare system, regulatory requirements, pricing and contracting environment, competitive environment, healthcare reforms and exchange rates, may significantly impact the time horizon for achieving the long-term targets or require them to be revised.

Long-term financial target	Result 2013	Target
Operating profit growth	7%	15%
Operating margin	38%	40%
Operating profit after tax to net operating assets	97%	125%
Cash to earnings	89%	
Cash to earnings (three-year average)	94%	90%

### **Forward-looking statements**

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 Form 20-F, both expected to be filed with the SEC in February 2014, 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 targets, plans, objectives or goals for future operations, including those related to Novo Nordisk<sup>1</sup>/<sub>2</sub>s products, product research, product development, product introductions and product approvals as well as cooperation in relation thereto

statements containing projections of or targets for revenues, costs, income (or loss), earnings per share, capital expenditures, dividends, capital structure, net financials and other financial measures

statements regarding future economic performance, future actions and outcome of contingencies such as legal proceedings

statements regarding the assumptions underlying or relating to such statements.

In this document, examples of forward-looking statements can be found under the heading [2013 performance and 2014 outlook] and elsewhere.

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, governmentmandated 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

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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 [Risks to be aware of] on pp 42[43.

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.

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# Research and development

## **Diabetes**

In 2013, Novo Nordisk made important advances in the pipeline of diabetes care products.

#### Insulin

In response to the Complete Response Letter on Tresiba<sup>®</sup> from the US Food and Drug Administration (FDA), Novo Nordisk initiated a cardiovascular outcomes trial (DEVOTE) in October. It is double-blind, uses insulin glargine as comparator and will include 7,500 type 2 diabetes patients who have existing or high risk of cardiovascular diseases. Novo Nordisk expects to have sufficient data to support an interim analysis within two to three years and to complete the study within four to six years from initiation. The data will also be used to support the resubmission of Ryzodeg<sup>®</sup>, the combination of Tresiba<sup>®</sup> and insulin aspart.

Mid-2013, Novo Nordisk filed IDegLira for regulatory review in the EU. IDegLira is a fixed combination of insulin degludec and liraglutide and Novo Nordisk is the first company to submit a product in this new class. The filing of IDegLira in the US is pending the outcome of the interim analysis planned for the DEVOTE trial.

In the prandial insulin segment Novo Nordisk began the phase 3a programme named onset<sup>®</sup> for the faster-acting formulation of insulin aspart. The improved formulation is intended to enable a faster onset of appearance of insulin in the bloodstream, thereby mimicking the insulin secretion of a healthy individual more closely than NovoRapid<sup>®</sup>.

#### Devices

In the US, the FDA approved FlexTouch<sup>®</sup> for delivery of NovoLog<sup>®</sup> (NovoRapid<sup>®</sup>) and Levemir<sup>®</sup>. FlexTouch<sup>®</sup> is a prefilled pen featuring a spring-loaded dosing action that allows users to administer insulin at the touch of a button [] regardless of dosage size. The pen has been launched in the EU and Japan.

Also for administering NovoLog<sup>®</sup>, the FDA approved NovoPen Echo<sup>®</sup>, a reusable pen, especially designed to meet the needs of children with diabetes. The pen has been launched in the EU.

#### GLP-1 (Glucagon-Like Peptide-1)

In the GLP-1 category, Novo Nordisk initiated phase 3a trials investigating the efficacy and safety of liraglutide as an adjunct therapy to insulin in people with

type 1 diabetes. This programme, named ADJUNCT, is expected to include 3,000 people with type 1 diabetes.

Novo Nordisk s once-weekly analogue semaglutide has now started three of six global phase 3a trials, one of which will collect cardiovascular outcomes and other long-term diabetes-related endpoints. In total, the SUSTAIN<sup>1</sup> programme is expected to include more than 8,000 people with type 2 diabetes.

Novo Nordisk also brought a tablet formulation of semaglutide, OG217SC, into phase 2 development. Pioneering the effort within oral diabetes proteins, Novo Nordisk now has seven oral formulations of insulin and GLP-1 analogues in the early pipeline (phase 1 and 2).

## Obesity

Novo Nordisk successfully completed the SCALE<sup> $\Box$ </sup> phase 3a programme, which confirmed the efficacy and safety of liraglutide 3 mg for the treatment of obesity. Liraglutide 3 mg was filed for regulatory review in the US and the EU in December.

## Haemophilia

Novo Nordisk continued its strong progress in the development of treatments for people with haemophilia and other rare bleeding disorders.

Turoctocog alfa, a recombinant coagulation factor VIII, was approved in the US, the EU and Japan. The product, which is now being marketed under the trade name NovoEight<sup>®</sup>, is indicated for use in adults and children with haemophilia A for control and prevention of bleeding, perioperative treatment as well as routine prevention of bleeding episodes. In January 2014, Germany was the first country to launch the product.

Also for people with haemophilia A, a long-acting coagulation factor, glycoPEGylated rFVIII, N8-GP, is being studied in phase 3a. In March a trial was started in children, which is a regulatory requirement.

Strong results were reported in phase 3a for N9-GP, a long-acting recombinant factor IX molecule for people with haemophilia B, with a safe and well-tolerated profile, no inhibitor development and improved quality of life. Also, during major surgical procedures a single preoperative dose of N9-GP prevented bleeding in all participants with a 100% success rate. The compound continues development in clinical trials in

children and during surgical procedures.

In December, the FDA approved recombinant coagulation factor XIII as Tretten<sup>®</sup> for use in routine prophylaxis of bleeding in patients with congenital FXIII A-subunit deficiency (approved as NovoThirteen<sup>®</sup> in the EU).

## Inflammation

Novo Nordisk aspires to improve the lives of people with autoimmune and chronic inflammatory diseases by developing anti-inflammatory compounds with new modes of action for rheumatoid arthritis, systemic lupus erythematosus (SLE), inflammatory bowel disease and psoriatic arthritis. In March, Novo Nordisk initiated a phase 2a trial with anti-IL-21 for severely active Crohn s disease.

Finally, anti-NKG2D was approved for further phase 2 development for Crohn s disease.

## **Growth hormone**

Novo Nordisk completed its phase 1 trials for the once-weekly growth hormone NN8640 in healthy volunteers and adults with growth hormone deficiency. In the trial, NN8640 appeared to have a safe and well-tolerated profile and no safety concerns were identified. The trial confirmed the data from a similar trial in healthy adults and supports the suitability of NN8640 for once-weekly dosing in adults with growth hormone deficiency.

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# Social performance

Social performance has three dimensions: improving access to medical treatment and quality of care for patients, offering a healthy and engaging working environment for employees, and providing assurance that responsible business practices are in place, with the aim of contributing to the communities in which the company operates.

## **Patients**

Novo Nordisk estimates that the company provides medical treatments for approximately 24.3 million people with diabetes worldwide, showing a 7% increase compared with 2012. The number is calculated based on the WHO is recommended daily doses for diabetes medicines. This growth is driven by sales of insulin and Victoza<sup>®</sup>.

Of the 382 million people living with diabetes it is estimated that just over half of them are diagnosed and many of those diagnosed do not receive medical treatment. Novo Nordisk global access to diabetes care strategy aims to provide better care for those who need it and currently do not have access to proper diabetes care. The long-term goal is to reach 40 million people in 2020 with diabetes care products and thereby enable more people with diabetes to live better lives.

In 2013, Novo Nordisk sold human insulin according to the company s differential pricing policy in 35 of the 49 Least Developed Countries (LDC), as defined by the UN. According to this policy, the price should not exceed 20% of the average prices in the western world. While the number of countries buying insulin in accordance with this policy has been stable for some years, the volume sold increased by 7%. In 2013 the LDC ceiling price for insulin treatment per patient per day was USD 0.22, while the average price of insulins that Novo Nordisk sold under this programme was USD 0.17. In other low- and middle-income countries, Novo Nordisk sells large volumes of insulin at equally low tender prices through government health programmes. In 2013, an estimated 5.2 million patients worldwide have been treated with insulin at or for less than the LDC ceiling price.

Donations through the World Diabetes Foundation amounted to DKK 64 million in 2013. The World Diabetes Foundation

is an independent non-profit organisation established in 2002 by Novo Nordisk to help expand access to diabetes care. The foundation invests in sustainable initiatives to build healthcare capacity with the aim of improving prevention and treatment of diabetes in developing countries. Read more on worlddiabetesfoundation.org.

Novo Nordisk also provides financial support to improve global access to haemophilia care. In 2013, the company donated DKK 19 million to the Novo Nordisk Haemophilia Foundation, established in 2005. The foundation supports projects and fellowships in developing and emerging economies. Initiatives focus on capacity-building, awareness, diagnosis and registries. Read more on nnhf.org.

## **Employees**

At the end of 2013, the total number of employees was 38,436, corresponding to 37,978 full-time positions, which is an 11% increase compared with 2012. This growth is driven by expansion of the sales and marketing organisation in the regions North America and International Operations as well as significant expansion in Denmark in the research and development organisation and in production.

Employee turnover decreased from 9.1% in 2012 to 8.1%, reflecting a continued positive trend. The average number covers some geographical variation.

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The consolidated score in the annual employee engagement survey, eVoice, was 4.4, measured on a scale of 1 to 5, with 5 being the best score. The survey measures the extent to which the organisation is working in accordance with the Novo Nordisk Way. The 2013 result is an improvement on the score of 4.3 in 2012, and indicates that despite continued growth, there is a strong culture and commitment to the company svalues. Read more about the long-term target on p 12.

# In terms of diversity, by the end of 2013 a total of 70% of the 33 senior management teams were composed of a diverse group, with members of both genders and different nationalities. This represents a continued and steady positive trend towards the ambition that by the end of 2014 all senior management teams must meet these diversity criteria or explain why this has not yet been achievable.

In 2013, the average frequency rate of occupational injuries was 3.5 per million working hours, compared with 3.6 in 2012. Uniform occupational health and safety management procedures are being rolled out in the global organisation.

### Assurance

Mandatory training in business ethics is a high priority. In 2013, 97% of all relevant employees completed and documented their training and passed the related tests. This is a slight decrease from 99% in 2012, which can be explained by a higher number of employees in scope of training and the introduction of tests with an explicit requirement that documentation of training must be provided in addition to passing the tests. Annual business ethics training is required for all employees, including new hires. Business ethics training is a key element in all onboarding programmes.

Adherence to the company s global standards for ethical behaviour must be observed and is monitored. Internal business ethics audits are conducted by means of on-site interviews and documentation reviews to assess compliance with legal requirements and internal procedures. During 2013, 45 business ethics reviews were conducted, compared with 48 in 2012.

During the year, the global facilitator team conducted 75 audits of units adherence to the Novo Nordisk Way, so-called facilitations, covering approximately 11,500 employees, ie around one-third of the entire workforce. A facilitation consists of document review and interviews with local management, employees and stakeholders to determine the level of adherence to corporate values and behaviours spelled out in the Novo Nordisk Way. A conclusive report, presented to the Board of Directors, identifies best practices that are shared internally, while findings of non-compliance are reported to local management, which must subsequently implement corrective actions. Timely closure, measured as an average over a three-year period during which the entire organisation is covered, is consistently high. By the end of 2013, 96% of actions were closed on time, and the conclusion is that there is a high level of compliance with the Novo Nordisk Way across the organisation.

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A total of 221 supplier audits were conducted to assess the level of compliance with Novo Nordisk standards for suppliers. These relate to quality as well as environment, labour, human rights and business ethics, in line with Novo Nordisk sourcing standards.

These audits are undertaken by Novo Nordisk is corporate quality organisation. The level of audit activity was on par with 2012. Of these, 25 audits in 2013 were focused on responsible sourcing criteria, compared with 45 in 2012. Only high-risk

suppliers, identified through a robust risk assessment, are selected for responsible sourcing audits. In 2013, one critical finding was identified regarding excessive overtime. This finding is being addressed.

Following the receipt in December 2012 of a Warning Letter from the US Food and Drug Administration (FDA), a re-inspection was carried out in August 2013. In January 2014 Novo Nordisk received confirmation from the agency that the violations had been addressed satisfactorily.

In 2013, Novo Nordisk had six instances

of product recalls from the market, which is the same level as the previous year. Among one of these, an internal quality control found that a small percentage (0.14%) of certain batches of the company s prefilled insulin product NovoMix<sup>®</sup> 30 did not meet the specifications for insulin strength. As a result 3 million products were recalled from wholesalers, pharmacies and patients in several European markets. The root cause was found to be a production error and has been resolved.

# Long-term social targets

# 2013 performance against long-term social targets

Novo Nordisk has chosen three long-term social targets to support long-term financial performance, balancing responsibility with profitability, with the aim of creating sustainable value for shareholders and other stakeholders. The social targets reflect aspirations expressed in the Novo Nordisk Way: helping people live better lives, working the Novo Nordisk Way and nurturing a diverse working environment. In 2013, progress was made against all three targets.

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# Environmental performance

Novo Nordisk $\Box$ s environmental performance is measured on three strategic dimensions: consumption of water, consumption of energy and CO<sub>2</sub> emissions from energy consumption.

## Water and energy

In 2013, 2,572,000 GJ energy and 2,685,000 m<sup>3</sup> water were consumed at production sites around the world. This equals an increase of 6% and 8% respectively, which is linked to the increased production volume output and new production capacity.

Around half of the water and 30% of the energy consumed at the company is 13 production sites is consumed at the production site in Kalundborg, Denmark. Optimisations achieved at this site therefore have a significant impact on the company is total resource consumption.

# CO<sub>2</sub> emissions

In 2013, CO<sub>2</sub> emissions from production amounted to a total of 125,000 tons. This equals a 2% increase compared with 2012, which is directly linked to the increased consumption of energy. The increase in CO<sub>2</sub> emissions is less than the increase in energy consumption, because part of the increase in energy consumption<sup>2</sup>happened at sites where the energy consumed is less CO<sub>2</sub>-intensive. At the same time, consumption decreased at sites with coal-based energy supply.

The company is target of a 10% absolute reduction in 10 years is expected to be met in 2014. Since 2005, 685 energy-saving projects have led to a total reduction in CO<sub>2</sub> emissions of 44,000 tons annually. Production sites that rely on coal-based energy supply will be in focus for further reductions. These sites are Kalundborg in Denmark and Tianjin in China.

## Waste

In 2013, Novo Nordisk generated 91,712 tons of waste, which is an increase of 11% compared with 2012. Of this, 81% is non-hazardous organic production waste in diabetes care.

The objective is to reduce environmental impact from waste. As a consequence, instead of setting traditional reduction targets measured by quantity, those areas where environmental impacts from waste can be reduced the most have been singled out for focused attention.

Since October 2011, the company is organic production waste has been used for energy recovery in biogas plants, whereas previously it was used for animal feed. As a consequence, organic production waste is now reported as waste, included in the total waste volume. Organic waste production is the type of waste that increases the most in line with growing production. The total waste volume excluding organic production waste is stable.

# Long-term environmental targets

# 2013 performance against long-term environmental targets

Novo Nordisk has chosen three long-term environmental targets to support long-term financial performance, balancing responsibility with profitability, with the aim of creating sustainable value for shareholders and other stakeholders. The environmental targets for consumption of energy and water and CO<sub>2</sub> emissions contribute to optimising production efficiency and reducing environmental impacts.

The consumption of energy and water for production is increasing due to continued growth in sales and, as a consequence, emissions of  $CO_2$  are increasing too.

Performance against the targets is as projected and the targets are expected to be met.

#### Long-term environmental targets update

The long-term environmental targets for consumption of energy and water were revised and updated in 2013 to ensure that they were aligned with new business priorities in response to the need for expansions of production capacity and an increased product portfolio.

The new targets remain ambitious and reflect the aspiration of continuous decoupling of environmental impacts from business growth, measured as increase in sales in local currencies. The targets have been set as a maximum 50% increase in energy and water consumption compared with business growth, measured as a three-year average. This will be particularly challenging in years of production expansion and running-in of new plants or production lines.

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# **Performance highlights**

DKK million	2009	2010	2011	2012	2013	2012[]2013
Financial performance						Change
Net sales	51,078	60,776	66,346	78,026	83,572	7%
Underlying sales growth in local currencies	11%	13%	11%	12%	12%	
Currency effect (local currency impact)	1%	6%	(2%)	6%	(5%)	
Net sales growth as reported	12%	19%	9%	18%	7%	
Depreciation, amortisation and impairment						
losses	2,551	2,467	2,737	2,693	2,799	4%
Operating profit	14,933	18,891	22,374	29,474	31,493	7%
Net financials	(945)	(605)	(449)	(1,663)	1,046	N/A
Profit before income taxes	13,988	18,286	21,925	27,811	32,539	17%
Net profit for the year	10,768	14,403	17,097	21,432	25,184	18%
Total assets	54,742	61,402	64,698	65,669	70,337	7%
Equity	35,734	36,965	37,448	40,632	42,569	5%
Capital expenditure, net	2,631	3,308	3,003	3,319	3,207	(3%)
Free cash flow <sup>1</sup>	12,332	17,013	18,112	18,645	22,358	20%
Financial ratios						
Percentage of sales						
Sales outside Denmark	99.2%	99.4%	99.3%	99.4%	99.4%	
Sales and distribution costs	30.2%	29.9%	28.6%	27.6%	28.0%	
Research and development costs	15.4%	15.8%	14.5%	14.0%	14.0%	
Administrative costs	5.4%	5.0%	4.9%	4.2%	4.2%	
Gross margin <sup>1</sup>	79.6%	80.8%	81.0%	82.7%	83.1%	
Net profit margin <sup>1</sup>	21.1%	23.7%	25.8%	27.5%	30.1%	
Effective tax rate <sup>1</sup>	23.0%	21.2%	22.0%	22.9%	22.6%	
Equity ratio <sup>1</sup>	65.3%	60.2%	57.9%	61.9%	60.5%	
Return on equity (ROE) <sup>1</sup>	31.3%	39.6%	46.0%	54.9%	60.5%	
Cash to earnings <sup>1</sup>	114.5%	118.1%	105.9%	87.0%	88.8%	
Payout ratio <sup>1</sup>	40.9%	39.6%	45.3%	45.3%	47.1%	
the second s						
Long-term financial targets			<b>aa</b> == <i>i</i>			Targets
Operating margin <sup>1</sup>	29.2%	31.1%	33.7%	37.8%	37.7%	40%
Operating profit growth	20.7%	26.5%	18.4%	31.7%	6.9%	15%

assets <sup>1</sup>	47.3%	63.6%	77.9%	99.0%	97.2%	125%
Cash to earnings, (three-year average)	111.5%	115.6%	112.8%	103.7%	93.9%	90%
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Diabetes care sales						
Oral antidiabetic products (OAD)						
Protein-related products						
Victoza®						
Human insulins						
Modern insulins (insulin analogues)						
Biopharmaceuticals sales Other products	Norditrop	in(R) Nov	voSeven(R)			
Sales by geographic region Japan & Kore	a Region	China Inte	ernational O	perations	Europe N	orth America

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Operating profit after tax to net operating

FORM 6-K

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	2009	2010	2011	2012	2013	2012[]2013
Social performance Least developed countries where Novo Nordisk sells insulin according to the						Change
differential pricing policy	36	33	36	35	35	
Donations (DKK million) <sup>2</sup>	83	84	81	84	83	(1%)
New patent families (first filings)	55	62	80	65	77	18%
Employees (total)	29,329	30,483	32,632	34,731	38,436	11%
Employee turnover	8.3%	9.1%	9.8%	9.1%	8.1%	
Relevant employees trained in business ethics	N/A	98%	99%	99%	97%	
Product recalls	2	5	5	5570 6	6	
Warning Letters and re-inspections	0	0	0	1	1	
Company reputation with external key stakeholders (scale 1 [7]	N/A	N/A	5.6	5.7	5.8	
Long-term social targets Patients reached with Novo Nordisk diabetes care products in millions						Targets
(estimate)	N/A	N/A	20.9	22.8	24.3	40 by 2020
Working the Novo Nordisk Way (scale $1 \square 5$ )	N/A	N/A	4.3	4.3	4.4	4.0
Diverse senior management teams	50%	54%	62%	66%	70%	100% by 20143
Environmental performance						Change
Energy consumption (1,000 GJ)	2,246	2,234	2,187	2,433	2,572	6%
Water consumption (1,000 m <sup>3</sup> )	2,149	2,047	2,136	2,475	2,685	8%
CO emissions from energy consumption	100	05	0.4	100	105	20/
(1,000  tons)	166 2,062	95	94	122	125	2%
Wastewater (1,000 m <sup>3</sup> )	2,062 26,362	1,935 25,627	2,036 41,376	2,272 82,802	2,457 91,712	8% 11%
Waste (tons)	20,302	23,027	41,370	02,002	91,712	1170
Long-term environmental						
targets						Targets
Energy consumption (vs prior year)	(11%)	(1%)	(2%)	11%	6%	6%4
Water consumption (vs prior year)	(20%)	(5%)	4%	16%	8%	6%4
CO <sub>2</sub> emissions from energy consumption (vs 2004 baseline)	(24%)	(56%)	(57%)	(44%)	(42%)	by 2014

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Share performance						Change
Basic earnings per share/ADR in DKK <sup>1,5</sup>	3.59	4.96	6.05	7.82	9.40	20%
Diluted earnings per share/ADR in DKK <sup>1, 5</sup> Total number of shares (millions) 31	3.56	4.92	6.00	7.77	9.35	20%
December⁵	3,100	3,000	2,900	2,800	2,750	(2%)
Net asset value per share, (Group) in DKK <sup>5</sup>	11.53	12.32	12.91	14.51	15.48	7%
Dividend per share in DKK <sup>5</sup>	1.50	2.00	2.80	3.60	4.50	25%
Total dividend (DKK million)	4,400	5,700	7,742	9,715	11,8666	22%

**1.** For definitions, please refer to p 93. **2.** Donations to the World Diabetes Foundation and the Novo Nordisk Haemophilia Foundation, which are working to increase healthcare capacity in developing countries. **3.** By the end of 2014 all senior management teams must comply with the target to be diverse in terms of both gender and nationality or explain why this has not yet been achievable. **4.** The 6% equals 50% of the business growth measured as the increase in sales in local currencies. For detailed target definition, please refer to p 13. **5.** As at 2 January 2014 a stock split of the company[]s trading unit was conducted. Comparative figures have been restated to reflect the change in trading unit from DKK 1 to DKK 0.20. **6.** Proposed dividend for the year (not yet declared).

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Employees (total) ... Japan & Korea ... Region China ... International Operations ... Europe\* ... North America Includes headquarter functions and Research and Development in Denmark.

... Waste\* ... Waste excl organic production waste for biogas

\* Before 2011, most of the non-hazardous organic production waste was used for animal feed and classified as a by-product. Since October 2011, all this waste has been sent for energy recovery in biogas plants and is therefore reported as waste.

Net cash distribution to shareholders ... Dividends ... Share repurchases

# Business strategy: Our focus is our strength

If Novo Nordisk s business strategy were to be described in one word, it would have to be focus.

Each year, a team of people from different parts of Novo Nordisk s global organisation is tasked by senior management to explore the business environment, analyse trends and come back and challenge Novo Nordisk strategy based on the findings.

Novo Nordisk s corporate strategy is the result of this process, which ends when the Board of Directors approves the updated strategy in June. In the following months, it is anchored in the annual business and organisation plans, balanced scorecards and performance targets.

The direction and the core elements of the strategy do not change fundamentally from year to year, but are adjusted whenever signals of change occur in Novo Nordisk substants environment. The adjustments ensure that Novo Nordisk is capable of meeting current and emerging challenges and opportunities.

The current business environment has plenty of both. It is characterised by slow economic growth and austerity measures in some parts of the world, and rapid economic growth and urbanisation with alarming implications for public health in others. In high-income countries with ageing populations, governments and private payers are reluctant to pay a premium for new, innovative therapies. Low- and middle-income countries fight a double burden of poverty and poor health, and access to care is inadequate and unevenly distributed. Many countries with largely publicly funded healthcare systems are putting in place market restrictions for new medications and in the US, pharmaceutical companies, including Novo Nordisk, are facing increasingly tough pricing negotiations with managed care organisations and pharmacy benefit managers.

Many pharmaceutical companies are seeing major products going off patent and are unable to bring out innovative products that can make up for the lost revenue. Some have chosen to cut research and development budgets and lay off thousands of employees. Some have added generic and over-the-counter medicines to their offering, while others have created a broader service offering around their core products. And all have realised that new products will only have a chance in the market if they address unmet medical needs and are accompanied by convincing data about their health-economic benefits.

Novo Nordisk has decided to continue making large investments in research and development, strategic products and growth markets. The decision is based on a firm belief that huge unmet medical needs remain to be addressed, not least within diabetes, a disease that is growing at an alarming rate all over the world. Read more on pp 22[23.

To meet the increasing demands for data about its products health-economic benefits, capabilities are being further strengthened within the company is market access functions. Moreover, Novo Nordisk is expanding its field force in countries where there are significant opportunities for market expansion. It is also exploring new ways of reaching people with unmet health needs. For example, pilot programmes in low-income countries such as Kenya and Bangladesh have helped improve access to products in rural areas.

#### A focused strategy

The three core elements of Novo Nordisk strategy have remained unchanged for years:

**First,** Novo Nordisk has a sharp focus on a few diseases and conditions where it can make a significant difference. As a result of this focus, the company has built strong positions within diabetes care, haemophilia and growth disorders, while creating a platform for entering into treatments for obesity and autoimmune inflammatory diseases.

Second, activities are leveraging the company s five core capabilities:

- Engineering, formulating, developing and delivering protein-based treatments
- Deep disease understanding
- Efficient large-scale production of proteins
- Planning and executing global launches of new products
- Building and maintaining a leading position in emerging markets.

**Third,** Novo Nordisk has a values-based management system formalised in the Novo Nordisk Way. Read more on p 4. A key element of the Novo Nordisk Way is the Triple Bottom Line business principle, which was written into the company s Articles of Association at the Annual General Meeting in 2004. It states that Novo Nordisk strives to conduct its activities in a financially, environmentally and socially responsible way.

This is the company that 24.3 million patients rely on for their daily medication, where more than 38,000 employees work and in which more than 130,000 investors have bought shares.

### The five strategic focus areas

#### 1. Expand leadership in diabetes

382 million people worldwide are living with diabetes and it is predicted that by 2035 close to 600 million people worldwide will have diabetes. Read more about the diabetes pandemic on pp 22[23.

The global market for diabetes care products amounts to approximately 238 billion Danish kroner, of which Novo Nordisk products account for about 27%. The market has been growing by around 11% annually in the last decade and is expected to experience continued solid growth driven by an increased prevalence of diabetes and the need for better treatments. Of this global market, insulin accounts for 52%, oral diabetes products for 41% and GLP-1 products for 7%.

In 1923 the first patients were treated with insulin from the company that is now Novo Nordisk, and diabetes care remains its largest and fastest-growing business area.

Diabetes care accounts for close to 78% of Novo Nordisk s total sales, most of which comes from insulin and GLP-1 products. In both areas Novo Nordisk is the global market leader in terms of volume.

Novo Nordisk is well positioned to address the unmet medical needs in diabetes.

#### The insulin portfolio

The insulin portfolio includes:

- Tresiba<sup>®</sup> (insulin degludec), a once-daily new-generation basal insulin analogue with an ultra-long duration of action and a flat and stable action profile that reduces the rate of low blood sugar (hypoglycaemia). Read more about Tresiba<sup>®</sup> on pp 24[25.
- Ryzodeg<sup>®</sup> (insulin degludec/insulin aspart), a soluble insulin combination of Tresiba<sup>®</sup> and NovoRapid<sup>®</sup> (insulin aspart) providing both basal and mealtime glucose control.
- NovoRapid<sup>®</sup> (marketed as NovoLog<sup>®</sup> in the US), the world s most widely used rapid-acting insulin for use at mealtimes.
- NovoMix <sup>®</sup> 70/50/30 (NovoLog<sup>®</sup> Mix 70/30 in the US), dual-release modern insulins that cover both mealtime and basal requirements. These insulins can be used either to initiate or intensify insulin therapy.
- Levemir <sup>®</sup> (insulin detemir), a soluble, long-acting modern insulin for once-daily use. It provides glucose control with a favourable weight profile.

The primary goal of Novo Nordisk[]s diabetes research is to discover new therapies that lower blood glucose while reducing the risk of low blood sugar. A recent result of this research is IDegLira, a fixed combination of insulin degludec and liraglutide (the active ingredient in Victoza<sup>®</sup>). IDegLira is under regulatory review in the EU. Read more about IDegLira on pp 24[25.

Novo Nordisk is also developing a new faster-acting formulation of insulin aspart to be taken at mealtimes and recently initiated an extensive phase 3a programme.

In addition to new and improved injectable insulins, Novo Nordisk is also developing formulations of insulin that can be taken as tablets.

#### GLP-1 (Glucagon-Like Peptide-1)

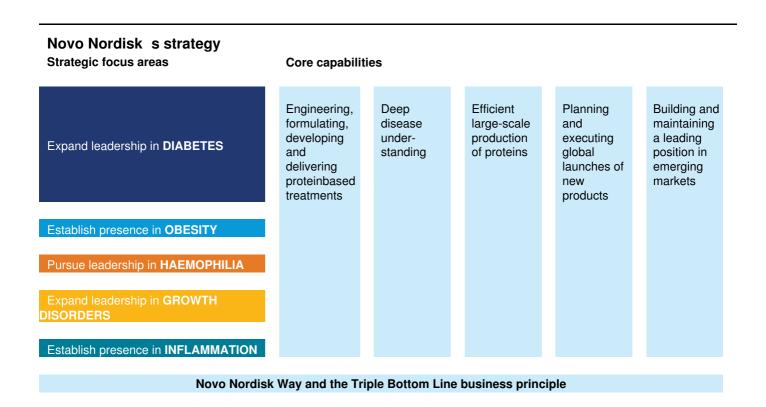
With the launch of Victoza<sup>®</sup> in 2009, Novo Nordisk entered the GLP-1 therapy segment. Victoza<sup>®</sup> is a human GLP-1 analogue with 97% similarity to the natural gut hormone. Victoza<sup>®</sup> is taken once daily and, like natural GLP-1, works by stimulating the beta cells in the pancreas to release insulin only when blood sugar levels are high.

GLP-1 therapy is a significant advance in the treatment of type 2 diabetes because it lowers glucose with only a very low risk of triggering low blood sugar.

Victoza<sup>®</sup> is approved for adults with type 2 diabetes who are unable to achieve blood glucose goals with lifestyle changes and tablet-based treatment (metformin, the most widely used tablet for type 2 diabetes). In less than two years, Victoza<sup>®</sup> became the leading GLP-1 treatment globally and has steadily expanded the market for GLP-1 treatment. The market is currently valued at around 16.4 billion kroner, of which Victoza<sup>®</sup> accounts for approximately 70%. Available in more than 80 markets, Victoza<sup>®</sup> is now used by approximately 800,000 people worldwide according to company estimates.

Based on the expertise Novo Nordisk has gained through the development of Victoza<sup>®</sup>, the company is now building a GLP-1 portfolio with the intention of providing an even broader range

#### CONTINUED []



of treatment options. Key projects include a once-weekly GLP-1 analogue, semaglutide, which in 2013 entered phase 3a development. Novo Nordisk is also developing formulations of GLP-1 that can be taken as tablets.

#### **Injection devices**

Novo Nordisk invented the market for insulin injection devices with the launch of the world s first insulin pen in 1985. Today, Novo Nordisk offers the world s most widely used durable and disposable devices for insulin and GLP-1, NovoPen® 4 and FlexPen®, and is currently introducing its latest innovations, NovoPen® 5 and FlexTouch®, in many markets. The development of injection devices is based on extensive studies of how patients experience their daily injections and what they want from their device. It is an area where Novo Nordisk can make a difference by developing devices that are simple, safe and user-friendly. Read more about devices on p 10.

### 2. Establish a

#### presence in obesity

According to the World Health Organization (WHO), obesity has reached pandemic proportions, with up to 1.4 billion adults (over 20 years old) being overweight. Of these, more than 200 million men and nearly 300 million women are clinically obese (ie BMI  $\geq$  30). Obesity is known to be a major risk factor in developing serious diseases such as type 2 diabetes and cardiovascular diseases.

Despite the growing prevalence of obesity globally, there are only a few pharmaceutical treatment options currently available and reimbursement for these medications is limited. The market for obesity products currently amounts to 2n3 billion kroner.

Novo Nordisk has been investigating the use of liraglutide in a 3 mg dose as a new once-daily treatment for some people with obesity, namely those with obesity-related medical conditions such as prediabetes, sleep apnoea, high blood pressure and lipid disorders. Liraglutide 3 mg is under regulatory review in the EU and the US. Read more about obesity on pp 28[29.

#### 3. Pursue leadership in haemophilia

Haemophilia is an inherited or acquired bleeding disorder that prevents blood from clotting. An estimated 420,000 people worldwide are living with severe or moderate haemophilia. The global haemophilia drug market is estimated at 53 billion kroner and has grown by more than 4% annually in recent years.

Novo Nordisk entered the haemophilia market in 1996 when it introduced NovoSeven® for the treatment of haemophilia patients who form antibodies against traditional treatments. The

company∏s ambition is to move from this niche into the main segments of the haemophilia A and B market and achieve a leadership position by developing improved treatment options for all patients. Read more about haemophilia on p 30.

## 4. Expand leadership

#### in growth disorders

Novo Nordisk has been active in the treatment of growth hormone deficiency for almost four decades. Growth hormone therapy is most frequently used in developed countries. Globally it is estimated that more than 2 million people are eligible for growth hormone therapy.

The market for growth disorder treatments is estimated at 16.4 billion kroner and has grown by more than 4% annually since 2009. Novo Nordisk is the leading provider of human growth hormone with a global market share of 30% measured by value.

Novo Nordisk strategy in growth hormone therapy is to expand leadership by providing innovative and convenient products and devices. Norditropin<sup>®</sup> (somatropin) is the only liquid growth hormone product with room temperature stability after first use that is available in a prefilled pen device. Novo Nordisk newest injection device for growth hormone is Norditropin<sup>®</sup> FlexPro<sup>®</sup>, which has an easy-touch dosing mechanism.

Novo Nordisk is also developing a long-acting growth hormone formulation, currently in phase 1 trials.

#### 5. Establish presence

#### in inflammation

Autoimmune inflammatory diseases, such as rheumatoid arthritis and Crohnns disease, result from the immune system attacking the body is own tissues and creating a chronic state of inflammation. Many people with autoimmune inflammatory diseases do not respond adequately to current treatments.

Novo Nordisk is using its expertise in designing therapeutic proteins and within chronic disease management care to develop new treatments, particularly for patients who are unresponsive to current treatments. Novo Nordisk has built a portfolio of first-in-class compounds with three projects being investigated in phase 2 clinical studies.

### The core capabilities

#### Engineering, formulating, developing

#### and delivering protein-based treatments

Novo Nordisk has dedicated research and development facilities in Denmark, China, the US and India. More than 7,000 employees are involved in research and development activities throughout the company, working in partnerships with external biotech and academic researchers.

Novo Nordisk s researchers have many years experience with formulation technology, protein engineering, expression and delivery, enabling the company to continuously improve the properties of therapeutic proteins such as insulin and GLP-1. Furthermore, since 1985, when Novo Nordisk launched the world s first insulin injection device [] NovoPen<sup>®</sup> [] the company has developed world-class expertise in designing and producing simple and convenient devices for injecting protein therapeutics.

#### Deep disease understanding

Novo Nordisk has a deep understanding of the unmet medical needs associated with chronic conditions. This, together with strong relationships and numerous collaborations with external researchers and clinicians, provides a solid foundation for the company research, development and marketing activities. One example is DAWN2<sup>II</sup> (Diabetes Attitudes, Wishes and Needs), a study conducted in 17 countries and including more than 15,000 people with diabetes, their family members and healthcare professionals. DAWN2<sup>D</sup>highlights opportunities for improving diabetes care, education and community support.

### Efficient large-scale

#### production of proteins

A high-quality, cost-effective global manufacturing infrastructure is a prerequisite for competing successfully in an increasingly competitive pharmaceutical market. It also enables Novo Nordisk to make treatments available at very low prices in developing countries. Novo Nordisk has a global production set-up with facilities strategically located in five countries across four continents:

- The production of active pharmaceutical ingredients is a highly specialised process and mainly takes place in Denmark, where Novo Nordisk has nine plants, including the largest insulin factory in the world.
- П The production of diabetes finished products takes place in five countries: Denmark, France, the US, Brazil and China, which all have the approval and ability to export to other markets.
- In addition, Novo Nordisk has a number of smaller manufacturing plants that support local demand in selected countries.
- All production facilities operate under one global quality management system with centrally deployed П standard operating procedures (SOPs) for all involved employees. This ensures a uniform and high quality standard for all products.

All manufacturing sites are held accountable for meeting ambitious targets for minimising their impact on the environment. Performance measures include energy and water consumption, CO<sub>2</sub> emissions and the amount of waste

generated during production processes. Read more about production on pp 36[37.

#### Planning and executing global launches of new products

Due to the high and increasing costs associated with developing, obtaining approval for and marketing a new medicine, most pharmaceuticals must be launched globally to optimise the return on investment. And, importantly, such launches must happen over a relatively short time so there is a reasonable period left before the product spatents expire. Through the launches of Victoza<sup>®</sup> in multiple markets over the past years, Novo Nordisk has refined this capability, which is now being utilised in connection with the launch of, for example, Tresiba<sup>®</sup>.

#### Building and maintaining a leading position in emerging markets

Many years of experience have helped Novo Nordisk understand the needs of new markets and forge partnerships with local stakeholders. The company[]s strategy has always been to establish a local organisation early [] as soon as there are signs of a market developing [] and to grow organically as the market develops. This has enabled Novo Nordisk to build long-term relations and a sustainable market presence, and is a key reason behind Novo Nordisk[]s success in rapidly developing markets such as China. Read more about Novo Nordisk[]s five regions on pp 31[]35.

## The Triple Bottom Line business principle

Novo Nordisk s strategy is underpinned by the Triple Bottom Line business principle, which ensures that financial, social and environmental impacts are considered when decisions are made. This requires systematic and respectful engagements with key stakeholders to stay attuned to their interests and expectations.

The aim is to ensure long-term profitability by mitigating risks and minimising negative impacts from business activities, and to enhance the positive contributions to society from the company global operations.

## Financially responsible: profitable for the long term

Doing business in a profitable and responsible way is the basis for the long-term viability of the company. Novo Nordisk uses four long-term financial targets to steer the business towards long-term sustainable growth. These targets help Executive Management balance growth in the short term with investments in longer-term growth such as new production facilities and research and development activities.

#### Socially responsible: promote healthy living [] and a healthy and engaging workplace

It is Novo Nordisk is mission to help people with diabetes, haemophilia and other chronic diseases live better lives. This is encapsulated in the company is corporate commitments of Changing Diabetes<sup>®</sup> and Changing Possibilities in Haemophilia<sup>®</sup>. As a research-based healthcare company, Novo Nordisk main contribution is to discover and develop innovative biological medicines and make them accessible to patients throughout the world.

With its deep disease understanding and patient focus, Novo Nordisk plays an active part in the fight against diabetes. The company is engaged in the prevention of diabetes through the promotion of healthy living, and is working to improve awareness, diagnosis and treatment of diabetes. Through these efforts, Novo Nordisk aims to reduce the human and financial burden of diabetes. Read more about Changing Diabetes<sup>®</sup> on pp 26[27.

Social responsibility is also about ensuring a healthy and engaging workplace for Novo Nordisk semployees. A healthy, inclusive and engaging working environment helps attract, motivate and retain the right people, and this is critical to sustain global growth and make positive contributions to society. Diversity of backgrounds and experience enriches the working environment. A diversity aspiration has been set for senior management teams. It drives strategic efforts to encourage recruitment and promotion of women and people from different nationalities

throughout the organisation. The people strategy offers global standards for equal opportunities, respect for the individual and a safe working environment. As a particular focus, the company promotes healthy lifestyles at work through its NovoHealth programme.

#### **Environmentally responsible:**

#### preserve nature s resources

Producing more with less is not just sound household management; it is a way to help preserve scarce natural resources and proactively address sustainability challenges throughout the value chain. As its business grows, Novo Nordisk seeks to reduce the consumption of natural resources and manufactured inputs across the value chain. In addition, there is also a focus on minimising outputs in the form of emissions such as CO<sub>2</sub> and waste. Read more about production on pp 36[]37.

#### Maximising the value of the Triple Bottom Line

The Triple Bottom Line business principle creates value for Novo Nordisk in three ways as it:

- makes the company more adaptive to changes in its business environment. This, in turn, mitigates risks and builds trust. Novo Nordisk proactively engages with stakeholders to address global and systemic challenges that could affect the company[]s success in the long term. One example is an active engagement in the development of a new set of global sustainable development goals under the auspices of the United Nations.
- 2. strengthens competitiveness. Changing Diabetes<sup>®</sup> is an example of how demonstrating social responsibility and systematic stakeholder engagements can effectively complement market strategies to drive revenue growth. Novo Nordisk has developed a method to demonstrate the business case, called the Blueprint for Change programme. Through a series of case studies, the programme documents how the company[]s approach to doing business in ways that are responsible and profitable creates shared value, ie benefits for both stakeholders and the business.
- 3. is an engine for innovation in collaboration with partners. One example is from the recent Blueprint for Change case study in Indonesia, one of the company[]s selected growth markets. The study showed how Novo Nordisk, by working with partners, can develop its business by reaching out more effectively to people with diabetes who currently do not have access to insulin treatment. The study has informed the strategy in Indonesia. Read more at novonordisk.com/sustainability.

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# Pipeline overview

### **Diabetes care**

Compound	Indication	Description	Phase 1	Phase 2	Phase 3	Filed/ regulatory approval
Diabetes						
<b>Tresiba</b> ® (insulin degludec) NN1250	Type 1 and 2 diabetes	A new-generation basal insulin with an ultra-long duration of action of more than 42 hours. Approved to offer patients reduced risk of hypoglycaemia and the possibility of adjusting the time of injection, when needed. Approved and launched in the EU, Japan and other markets. Additional data required by the US FDA are being generated for the planned resubmission.				
<b>Ryzodeg</b> ® (insulin degludec and insulin aspart) NN5401	Type 1 and 2 diabetes	A soluble co-formulation of Tresiba <sup>®</sup> , the new-generation basal insulin analogue with an ultra-long duration of action, and NovoRapid <sup>®</sup> (insulin aspart, marketed as NovoLog <sup>®</sup> in the US), a rapid-acting mealtime insulin. Approved to offer patients reduced risk of hypoglycaemia. Approved in the EU, Japan and other markets. Additional data required by the US FDA are being generated for the planned resubmission.				
IDegLira (a fixed combination of insulin degludec and liraglutide)	Type 2 diabetes	A combination of insulin degludec and liraglutide intended to offer the benefits of the two components in a single preparation. Under regulatory review in the				

NN9068		Edgar Filing. NOVO NORDISK A 3 - Form 6-K EU. Regulatory filing in the US is awaiting the additional data required by the FDA for Tresiba <sup>®</sup> .
Faster-acting insulin aspart NN1218	Type 1 and 2 diabetes including pump users	A new formulation of insulin aspart to accelerate onset of action.
<b>Semaglutide</b> NN9535	Type 2 diabetes	A once-weekly GLP-1 analogue intended to offer the clinical benefits of a GLP-1 analogue with less frequent injections.
<b>LATIN T1D</b> NN9211	Type 1 diabetes	Liraglutide, a once-daily human GLP-1 analogue, intended to offer clinical benefits as adjunct therapy to insulin.
<b>OG217SC</b> NN9924	Type 2 diabetes	A long-acting GLP-1 analogue intended to offer the clinical benefits of a GLP-1 analogue in a tablet.
<b>OG987GT</b> NN9926	Type 2 diabetes	A long-acting GLP-1 analogue intended to offer the clinical benefits of a GLP-1 analogue in a tablet.
<b>OG9875C</b> NN9927	Type 2 diabetes	A long-acting GLP-1 analogue intended to offer the clinical benefits of a GLP-1 analogue in a tablet.
<b>OG217GT</b> NN9928	Type 2 diabetes	A long-acting GLP-1 analogue intended to offer the clinical benefits of a GLP-1 analogue in a tablet.
<b>LAI287</b> NN1436	Type 1 and 2 diabetes	A long-acting basal insulin analogue with potential for once-weekly dosing.
<b>OI338GT</b> NN1953	Type 1 and 2 diabetes	A long-acting basal insulin analogue intended to offer the clinical benefits of a basal insulin analogue in a tablet.
<b>OI362GT</b> NN1954	Type 1 and 2 diabetes	A long-acting basal insulin analogue intended to offer the clinical benefits of a basal insulin analogue in a tablet.

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<b>OI287GT</b> NN1956	Type 1 and 2 diabetes	A long-acting basal insulin analogue intended to offer the clinical benefits of a basal insulin analogue in a tablet.	
Obesity			
<b>Liraglutide 3 mg</b> NN8022	Obesity	A once-daily human GLP-1 analogue for use as adjuvant to lifestyle changes intended to offer weight loss for people with severe obesity, including those at particular risk of developing diabetes. Under regulatory review in the US and the EU.	

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### **Biopharmaceuticals**

Compound	Indication	Description	Phase 1	Phase 2	Phase 3	Filed/ regulatory approval
Haemophi	lia					
<b>N8-GP</b> NN7088	Haemophilia A	A long-acting recombinant coagulation factor VIII derivative intended to offer prophylaxis and treatment of bleeds.				
<b>N9-GP</b> NN7999	Haemophilia B	A long-acting recombinant coagulation factor IX derivative intended to offer prophylaxis and treatment of bleeds.				
<b>Concizumab</b> NN7415	Haemophilia A, B and with inhibitors	A monoclonal antibody against Tissue Factor Pathway Inhibitor (TFPI) intended for bleeding prevention after subcutaneous administration.				
Growth dis	sorders					
NN8640	Growth disorders	A long-acting human growth hormone intended to offer less than once-daily injections.				
Inflammat	ion					
<b>Anti-IL-20</b> NN8226	Rheumatoid arthritis	A recombinant human monoclonal antibody with a novel mechanism of action. The drug is intended to improve treatment outcomes in patients who do not respond adequately to existing treatments.				

		Edgar Filing: NOVO NORDISK A S - Form 6-K
<b>Anti-IL-21</b> NN8828	Crohn]s disease	A recombinant human monoclonal antibody with a novel mechanism of action. The drug is intended to improve treatment outcomes in patients who do not respond adequately to existing treatments.
<b>Anti-NKG2D</b> NN8555	Crohn[]s disease	A recombinant human monoclonal antibody with a novel mechanism of action. The drug is intended to improve treatment outcomes in patients who do not respond adequately to existing treatments.
<b>Anti-C5aR</b> NN8210	Rheumatoid arthritis	A recombinant human monoclonal antibody with a novel mechanism of action. The drug is intended to improve treatment outcomes in patients who do not respond adequately to existing treatments.
<b>Anti-NKG2A</b> NN8765	Rheumatoid arthritis	A recombinant human monoclonal antibody with a novel mechanism of action. The drug is intended to improve treatment outcomes in patients who do not respond adequately to existing treatments.
<b>Anti-IL-21</b> NN8828	Systemic lupus erythematosus	A recombinant human monoclonal antibody with a novel mechanism of action. The drug is intended to improve treatment outcomes in patients who do not respond adequately to existing treatments.

#### Phase 1

Studies in a small group (usually 10[100) of healthy volunteers, and sometimes patients, to

#### Phase 2

Studies of various dose levels in a larger group of patients (usually 100[]1,000) to learn about the

#### Phase 3

Studies in large groups of patients (more than 8,000) comparing a new medication with a commonly

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investigate how the body handles, distributes and eliminates new medication and establish maximum tolerated dose. new medication s effect on the condition and its side effects. In phase 2, clinical trials are carried out to evaluate efficacy (and safety) in specified populations of patients. The outcome of phase 2 trials is clinical proof of concept and the selection of dose for evaluation in phase 3 trials.

used drug or placebo for both safety and efficacy. Phase 3a covers trials conducted after efficacy is demonstrated and prior to regulatory submission. Phase 3b covers clinical trials completed during and after regulatory submission. In small therapeutic areas such as haemophilia, regulatory guidelines may allow the design of single-arm therapeutic confirmatory trials or trials that compare against eg historical control instead of existing treatment or placebo.

Read more at novonordisk.com/investors and clinicaltrials.gov.

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# The one rule we have to **break**

382 million people in the world have diabetes today. Yet half of these people have not been diagnosed and, alarmingly, it]s assessed that only 6% of people with diabetes live a life free from diabetes-related complications.

iabetes is an insidious disease of pandemic proportions. Ban Ki-moon, the Secretary-General of the United Nations, has described diabetes as a tsunami in slow motion. According to the latest figures from the International Diabetes Federation (IDF), 382 million people in the world have diabetes today  $\square$  a number predicted to grow to close to 600 million by 2035.1\* 80% of the total number affected live in low- and middle-income countries, where the pandemic is gathering pace at alarming rates due to the lifestyle changes associated with economic growth and

urbanisation.

Just as worrying is the fact that only about half of these people have been appropriately diagnosed with diabetes. This is where the ∏Rule of Halves∏<sup>2</sup> begins. Of those who are diagnosed, only half receive treatment from a qualified healthcare professional and again just half of these people achieve their treatment targets. Unfortunately the Rule of Halves does not end there: only half of this already relatively small group actually achieve the desired outcome and live a life free from diabetes-related complications

The Rule of Halves estimates a global average. For some countries, eg Vietnam, Kenya and China,<sup>1</sup> diagnosis rates are even lower than 50%. For some, treatment may

\* All footnotes can be found on p 112.

be almost non-existent, while in other countries a key issue is that even those people who are diagnosed and treated do not reach their treatment targets and therefore have a high risk of developing complications.

Findings from a landmark study in the UK showed that reducing blood sugar levels by close to 1% may reduce diabetes-related deaths by more than 20% and reduce microvascular complications by nearly 40%.<sup>3</sup> Microvascular complications include diabetic retinopathy, which causes more than 12,000 cases of blindness annually in the US alone.4

#### **Cannot be ignored**

In human as well as financial terms, the burden of diabetes is high, being a factor in 5.1 million deaths and accounting for some 548 billion US dollars in health spending (11% of the total spend worldwide) in 2013 according to the IDF.<sup>1</sup>

&nbspWhat all countries have in common is that the diabetes pandemic cannot be ignored. And what⊓s important from both the human and economic perspective is that countries have a plan for how to address the Rule of Halves with a view to minimising both the personal strains and the financial burdens of diabetes. Novo Nordisk is working with governments and non-governmental organisations in many countries to help address these challenges. Read more about Changing Diabetes<sup>®</sup> on pp 26 27.

382 MILLION PEOPLE LIVE WITH DIABETES WORLDWIDE BY 2035 592 MILLION PEOPLE WILL LIVE WITH DIABETES

The International Diabetes Federation (IDF) estimates that there are currently 35 million people with diabetes living in the Middle East and North Africa. With a population of 9 million, Cairo is the largest city in this region and as in all other big cities, the number of people with diabetes is increasing.

The Rule of Halves According to the Rule of Halves\*, only around 6% of people with diabetes live a life free from diabetes-related complications.

Of the estimated 382 million people with diabetes About 50% are diagnosed\*\*

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Of whom about 50% receive care\*\* Achieve treatment targets Of whom about 50% achieve treatment targets\*\* Achieve desired outcomes Of whom about 50% achieve desired outcomes\*\*

\* Hart J.T., Rule of Halves: implications of increasing diagnosis and reducing dropout for future workload and prescribing costs in primary care, Br J Gen Pract 1992, March; 42(356):116-119, and W.C.S. Smith, A.J. Lee, I.K. Coombie, H. Tunstall-Pedoe, Control of blood pressure in Scotland: The rule of halves, BMJ, 300 (1990): 981-983. \*\* Actual rates of diagnosis, treatment, targets and outcomes vary in different countries.

### Potential complications of uncontrolled diabetes

#### What is diabetes?

Diabetes affects the way the body uses food for growth and energy. There are two main forms of diabetes: type 1 and type 2. Type 1 diabetes is a lifelong autoimmune disease that develops when the body produces an immune response against its own cells, destroying beta cells in the pancreas. As a result, the pancreas stops producing insulin, often 🛛 but not always 🗋 at a young age.

At least 90% of people with diabetes have type 2, which is caused by a combination of lifestyle and genetic factors. People with type 2 diabetes may still produce their own insulin, but the amount is insufficient and the insulin is not used effectively by the body.

Most of the long-term health complications associated with diabetes are due to persistently high blood glucose levels, which can cause damage to the kidneys, neurological system, cardiovascular system, retina or to the feet and legs through effects on both large and small blood vessels.

## How is diabetes treated?

People with type 1 diabetes need to start taking insulin as soon as they are diagnosed and must continue to do so for the rest of their lives.

People with type 2 diabetes need different treatments as the disease progresses. Initially, lifestyle changes, including diet and exercise, and an oral medicine such as metformin may be suffi cient. If treatment goals are not met, GLP-1 therapy or a basal insulin (long-acting insulin) may be added. If treatment targets are still not achieved, intensive insulin treatment may be necessary. This may include adding a rapid-acting insulin at mealtimes, in addition to a basal insulin. For insulin initiation, premixed insulin with dual release to cover both mealtime and basal requirements may be used.

In total, approximately 45[]50 million people worldwide are using insulin.

A significant challenge in managing diabetes with insulin is to maintain appro priate blood glucose levels, adjusting insulin dosing as necessary to balance the impact of food and exercise to avoid either high blood glucose levels (hyperglycaemia), which can lead to

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long-term complications such as blindness and amputations, or low blood glucose levels (hypoglycaemia), which can lead to seizures, unconsciousness or, in rare cases, death.

Stroke Strokes are up to four times as likely

Blindness Diabetes is a leading cause of blindness

Heart attack Heart attack is three times as likely and heart disease is up to four times as likely

Total kidney failure Total kidney failure is three times as likely

Amputation Diabetes is a leading cause of non-traumatic lower-limb amputations.

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Image of the insulin degludec molecule based on X-ray crystallography data. Insulin degludec is the active compound in Tresiba®.

he fear of low blood sugar (hypoglycaemia) means that many people with type 2 diabetes are not treating their condition intensively enough to reduce blood sugar to the recommended level. Adding to this problem is the inflexibility of when injections must be taken, which can lead many people to not take insulin as prescribed. These factors can result in people with diabetes being at risk of developing severe long-term complications.

#### When long is not long enough

A long-acting insulin is often

has been designed with this need in mind.

Establishing a routine for when to take insulin is important, but with a duration of action that lasts beyond 42 hours, once-daily Tresiba® provides flexibility when needed. []To be able to change the time you inject from day to day, if the situation requires, gives a remarkable sense of freedom for patients,[] points out Dr Alan Moses, global chief medical officer. []And with the significantly lower risk of hypoglycaemia during the night, Tresiba® is a good example of how, even after 90 years, we can still engineer better insulin treatments.[]

#### Greater than the sum of its parts

Not all people can control their diabetes with a basal insulin alone. As type 2 diabetes progresses, it may become necessary to add treatment(s) to tackle the spike in the blood sugar level that occurs after meals too. For these people, Novo Nordisk has developed IDegLira, a combination of Tresiba® and Victoza® (liraglutide), delivered in a single daily dose. Victoza®, a human GLP-1 analogue, stimulates insulin secretion and inhibits glucagon secretion in a blood glucose-dependent manner and has also been shown to reduce body weight.

In clinical trials, when IDegLira was administered once daily independently of meals, it provided improved overall glycaemic control compared with Tresiba® or Victoza<sup>®</sup> alone, with no weight change and a low rate of hypoglycaemia compared with Tresiba<sup>®</sup>. []If people aren[]t getting good control on a basal insulin, IDegLira may provide the opportunity of continuing on a single daily injection of a long-acting insulin, but with the addition of Victoza<sup>®</sup>. During clinical trials, this co-formulation has been shown to work better than Tresiba<sup>®</sup> or Victoza<sup>®</sup> separately,□ says Alan Moses.

Jakob Riis agrees: []IDegLira may provide a new opportunity for people with type 2 diabetes who are not adequately controlling their blood sugar levels. We believe this product will improve convenience for patients, but the development the first step into insulin treatment for a person with type 2 diabetes ☐ the idea is that such a □basal insulin should only need to be taken once a day, so it∏s a []manageable[] introduction to insulin injections. One challenge, however, is that the speed at which the insulin is absorbed in the body can vary significantly from day to day in the same person. This increases the risk of hypoglycaemia, particularly at night. Another challenge is that most basal insulins do not provide an adequate level of insulin in the blood for full 24-hour coverage.1 []From speaking with many doctors and people with diabetes, we knew there was a need for a basal insulin with an ultra-long duration of action,∏ says Jakob Riis, executive vice president of Marketing & Medical Affairs. Tresiba® (insulin degludec)

programme has also supported that the two active ingredients actually complement each other. In May 2013, Novo Nordisk submitted the regulatory filing for IDegLira in the EU.

#### Making Tresiba<sup>®</sup> available for patients

Tresiba<sup>®</sup> was approved in the EU in January 2013 and by the end of the year it had been launched in eight countries. In countries with broad market access, Tresiba<sup>®</sup> has quickly gained a significant share of the market for long-acting insulins.

In February 2013, Novo Nordisk received a Complete Response Letter from the US Food and Drug Administration (FDA) in which the agency requested additional cardiovascular safety data from a dedicated cardiovascular outcomes trial before the review of the New Drug Application can be completed. While Novo Nordisk remains confident about the cardiovascular safety of Tresiba® based on both its own interpretation of the data derived from the clinical development programme and reviews by the European and Japanese regulatory authorities, the company also recognises the importance of reassuring the FDA about the cardiovascular safety. Hence, in October 2013, a dedicated clinical trial, named DEVOTE, was initiated to rule out any excess cardiovascular risk.

DEVOTE is a double-blind trial, using insulin glargine as comparator, and is expected to include around 7,500 type 2 diabetes patients who have existing or high risk of cardiovascular disease. Novo Nordisk expects to have sufficient data to support a prespecified interim analysis within two to three years and to complete the study within four to six years from initiation. Thereby Novo Nordisk passed a significant milestone in the process of making Tresiba<sup>®</sup> available for people with diabetes in the US.

#### Tresiba<sup>®</sup> study results

Translating the results from clinical trial programmes into real advances in clinical practice can be challenging, especially since new medicines are often utilised in patients who are not responding well to available therapies. However, recent findings from Marc Evans, a clinician investigator in the UK, provide some important insights into how much value Tresiba<sup>®</sup> can bring to patients who are experiencing challenges with other insulins. Dr Evans studied 25 consecutive patients who were experiencing poor glucose control and frequent low blood sugar with either insulin glargine or Levemir<sup>®</sup> (insulin detemir). He found that when switched to Tresiba<sup>®</sup>, these patients improved their glucose control (in both type 1 and type 2 diabetes) and substantially reduced the frequency of low blood sugar episodes.<sup>2</sup>

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# Changing diabetes

## where it matters most

It has been almost a decade since Novo Nordisk launched Changing Diabetes<sup>®</sup>, its promise to people with diabetes to help them live a better life. Much has been achieved in this time, but a lot still needs to be done.

**N**ovo Nordisk s core responsibility to people with diabetes and to society is to deliver innovative, high-quality products. We have a very diverse insulin portfolio, from human insulins to modern insulin analogues, says Jakob Riis, executive vice president of Marketing & Medical Affairs. Our core focus is to drive innovation and develop even better products to help people achieve the best possible outcome of their treatment.

As a world leader in diabetes care, Novo Nordisk not only produces insulin, but also works to ensure that it reaches the hands of those who need treatment and care worldwide. []We strive to make insulin accessible for more people living at the base of the economic pyramid, and we]II continue to offer human insulin at very low prices in developing countries,]] explains Jakob Riis.

While delivering products will always remain Novo Nordisk[]s number one priority, the efforts to change diabetes go beyond medicine. []Our goal is to make a difference to patients, and we know that we can only get part of the way with our products. This is why our Changing Diabetes<sup>®</sup> activities are important,[] points out Jakob Riis.

[Access to health is a human right, and Changing Diabetes<sup>®</sup> is Novo Nordisk[]s response to the global diabetes challenge. A key element is our strategy for global access to diabetes care, which we renewed in 2013. It is global in scope and part of our business model. Basically, we will stop diabetes ruining people[]s lives,[] explains Charlotte Ersbøll, corporate vice president of Corporate Stakeholder Engagement. and local stakeholders to identify the most pressing health needs and ways in which we can achieve the biggest impact, explains Charlotte Ersbøll.

For countries where improving understanding of diabetes and its prevention is of the utmost importance, Novo Nordisk works to raise awareness, for example through activities on World Diabetes Day and by organising high-level national and international diabetes leadership forums with policymakers.

More urgent in some countries is the need to increase diagnosis of diabetes and improve access to healthcare. In these areas Novo Nordisk is working with local partners to develop screening programmes, build capacity by training healthcare professionals, and establish clinics and networks to strengthen the existing healthcare infrastructure.

#### Ambitious long-term target

[]Ten years ago diabetes was not recognised as having a direct impact on development,[] says Charlotte Ersbøll. []The world knew diabetes was increasing in high-income countries such as the US, but didn[]t understand the implications of the rising prevalence of diabetes in developing countries. Today non-communicable diseases, including diabetes, are recognised as the biggest killer globally and therefore increasingly important on the global health agenda.[]

Novo Nordisk has set a long-term global target of providing quality diabetes care products to 40 million people by 2020. It builds on the belief that the way in which the company addresses a global health issue  $\square$ We would like to see a world where everyone with diabetes is diagnosed, everyone who is diagnosed gets treated and everyone treated can live their life to the full, $\square$  she adds.

That is why Novo Nordisk is working around the world together with its partners to break the diabetes [Rule of Halves]. Read more on pp 22[23.

#### The challenge is global, the solutions local

The challenges of living with diabetes are different from country to country and person to person, so we partner with governments must be linked to its commercial offering; otherwise it is not sustainable in the long term. Today, Novo Nordisk provides diabetes care products to more than 24 million people.

[With our [40by20] long-term target we hope to make a significant contribution to the World Health Organization]s target of decreasing mortality from non-communicable diseases such as diabetes by 25% by 2025,] adds Charlotte Ersbøll.

Team Novo Nordisk has raced more than 9,500 km in 55 races since its launch in December 2012.

#### The World Diabetes Foundation

The World Diabetes Foundati was established by Novo Nor in 2002 as an independent tr with the vision of being a cat for change in developing countries. Since 2002, Novo Nordisk has donated around billion Danish kroner to the Foundation. The largest share (37%) is spent on strengthen healthcare systems and build healthcare capacity. As of October 2013, 7,138 clinics h been established or strengthened, 4.6 million pat had been treated and 221,93 healthcare professionals train

## Inspire people with diabetes through Team Novo Nordisk

Ultimately, diabetes shouldn t restrict the lives of children or adults no matter where they live, says Jakob Riis. This is why we support Team Novo Nordisk, the world s first all-diabetes pro-cycling team. The team smission is to educate, empower and inspire those affected by diabetes. We want people to say I manage my diabetes, it doesn t manage me I. In total, Team Novo Nordisk consists of more than 80 cyclists, triathletes and runners who all have diabetes.

Eliodoro Gonzales lives in Bolivia. He has type 1 diabetes and lost his legs due to diabetes complication.

Training apprentices in China.

#### Building healthcare capacity

Healthcare professionals who are capable of detecting and treating diabetes are needed to catch up with the accelerating growth in the prevalence of

### In most of Africa there is a lack of knowledge about diabetes.

#### Reaching the base of the pyramid

People who earn 1,500[]3,000 US dollars per year constitute more th billion people. With some disposable income, but difficulties in acces

diabetes. In China, Novo Nordisk, the government and local partners collaborate to increase quality diabetes care. As of October 2013, 2,076 apprentices have been trained and people across 830 counties have benefited from improved diagnosis and treatment. Another example is the new REACH programme in which Novo Nordisk-owned Steno Diabetes Center is scaling up its efforts by establishing an education centre in various countries in Asia. Once fully rolled out, the programme, which is funded by the Novo Nordisk Foundation, is expected to train more than 9,200 healthcare professionals globally each year.

Patsy Left Hand Bull is a tribal elder of the Lakota Sioux tribe in the Rosebud Reservation. healthcare services, they belong to the base of the global economic pyramid. Novo Nordisk has launched projects in Kenya, India and Nig to bring diabetes care to these people. Through public private partnerships, integrated solutions are pursued to supply insulin and diagnosis as well as quality treatment and care. One example is the establishment of [One-Stop-Shops] in Nigeria, where people with diabetes are offered guidance on how to manage their diabetes, bloc glucose testing and easy and fast access to insulin.

> Ranjith is enrolled in Changing Diabete Children progra in I

## Changing Diabetes<sup>®</sup> in Children

In some developing countries, the life expectancy for children with type 1 diabetes is less than one year. In 2010. Novo Nordisk committed 75 million Danish kroner over five years to provide free insulin and care to children as part of its Changing Diabetes<sup>®</sup> in Children programme. The programme is a collaboration with local partners including ministries of health and the World Diabetes Foundation. Since 2010, 93 clinics have been established and over 4,150 local healthcare professionals have received the proper training and education to treat children. More than 11,700 children in nine countries across Africa and Southeast Asia have been enrolled in the programme.

#### Supporting vulnerable populations

People living in vulnerable communities are often overlooked if they live in high-income countries, but they experience disproportionately high levels of diabetes compared with the rest of the population. Novo Nordisk recently helped the Rosebud Sioux tribe of South Dakota in the US improve diabetes care. The project includes a mobile health unit for travelling to remote areas of the reservation, a wellness centre and a programme to certify diabetes educators. 28 OUR BUSINESS



The increasing prevalence of obesity is no longer just an issue for high-income countries; the number of people who are overweight or obese is rising to record-breaking levels in low- and middle-income countries too. Without doubt, obesity is a growing threat to global health as it has many potentially life-threatening complications, not least type 2 diabetes. With liraglutide 3 mg, Novo Nordisk hopes to be able to offer a new treatment option for some people with obesity.

## According to the World Health

Organization, being overweight or obese is the fifth leading risk for deaths worldwide, and is linked to more deaths globally than being underweight. In the US, where more than 35% of adults, or some 100 million people, are obese,<sup>1</sup> the American Medical Association recently recognised obesity as a disease. In 2011, a US congress committee urged the US Food and Drug Administration (FDA) to take steps to support the development of new treatments for obesity. The US isn⊓t the only country sounding the alarm over the obesity epidemic. Worldwide there appears to be a new willingness to address obesity.

The problem isn⊓t necessarily obesity itself, it⊓s that obesity can have many serious □ even life-threatening [] health consequences. Known co-morbidities including heart disease, hypertension, type 2 diabetes, sleep apnoea and some types of cancer<sup>2</sup> reduce life expectancy for people with obesity by 5 10 years. With increased BMI<sup>6,7</sup> (see box on p 29) the risk of these complications increases and, as a consequence, obesity has a huge cost implication for healthcare systems.8

significant health benefits.9015 However, with most people not managing to achieve and maintain this level of weight loss with diet and exercise alone, other treatment options are necessary. □In the past, when medicines with an acceptable efficacy and safety profile were lacking and after diet and exercise had failed, doctors may have been reluctant to engage in dialogue with patients about obesity, says Heather Millage, corporate vice president and responsible for bringing liraglutide 3 mg to the market. □We hope obesity care will improve when more tools □ in particular liraglutide 3 mg □ are available for the treatment of this disease. Liraglutide 3 mg, Novo Nordisk□s once-daily GLP-1 therapy, has recently completed the fourth phase 3a trial as part of SCALE<sup>1</sup>, the clinical development programme for obesity treatment.

□Liraglutide is a fascinating molecule,□ points out Mads Krogsgaard Thomsen. □Back in 1997, our research scientists suggested it could be efficacious for the treatment of type 2 diabetes, as well as obesity. We□ve therefore been investigating this molecule for the last 15 years. If approved, it□II be the first and only product to treat obesity based on physiological regulation of appetite.□ liraglutide 3 mg during one year lost 10% of their body weight. And the majority of patients who had prediabetes at the beginning of the trial and who took liraglutide 3 mg reverted to a normal glucose level.□ In fact, the majority of people with obesity treated with liraglutide 3 mg in the largest trial in the development programme achieved a clinically relevant weight loss of 5%. In one of the trials that extended for 104 weeks, weight loss achieved after one year was maintained for two years.

Safety has been a key issue for obesity treatments, with several drugs being withdrawn due to safety concerns. However, a lot is already known about the safety profile of liraglutide. Under the brand name Victoza<sup>®</sup>, liraglutide has been on the market since 2009 in 1.2 mg and 1.8 mg doses for the treatment of type 2 diabetes.

## Stigmatisation of people with obesity

While liraglutide 3 mg looks promising for the treatment of obesity, and with early research ongoing into other approaches to treating obesity, there are still challenges ahead. One is that many doctors, based on past experience, are reluctant to

Yet, many people with obesity are unaware how it might affect their health. □Some people who are overweight or obese may never experience any health issues,∏ explains Mads Krogsgaard Thomsen, executive vice president and chief science officer. 
|For these people, obesity may be less of a health concern. What we re concerned about are the people who have a BMI of 35 or more and a significantly elevated risk of complications such as diabetes, prediabetes or sleep apnoea, or indeed may already have these co-morbidities. It⊓s our vision to offer a medical treatment to help these people specifically.□

## Moderate weight loss has significant health benefits

Lifestyle interventions, including a healthy diet and increased physical activity, should always be part of the treatment for people with obesity. It recognised that a moderate weight loss of 5 10% has

#### A natural hormone

Liraglutide 3 mg is 97% similar to human GLP-1, a gut hormone that produces the sensation of fullness and decreases hunger signals when eating. Thereby it reduces appetite and food intake. In addition, liraglutide 3 mg stimulates the release of insulin in response to glucose to maintain the right levels of glucose in the blood.

[GLP-1 is a natural hormone in the body, so with liraglutide 3 mg we[]re using one of the body[]s own mechanisms to tackle obesity,[] says Mads Krogsgaard Thomsen. []In clinical trials, four out of 10 patients who took

prescribe antiobesity medications due to concerns that the benefits don⊓t outweigh the risks of treatment. Another is that obesity medications aren⊓t widely reimbursed. The latter is to a large extent the result of a false assumption that all people with obesity can effectively lose weight just by changing their lifestyle □ exercise more and eat less. For most this has proven exceedingly difficult, if not impossible, despite many attempts. It is this group often stigmatised due to their weight and suffering from the complications of obesity [] that may benefit from treatment with an obesity medication in combination with lifestyle changes and diet.

□There are many myths and a lot of stigmas when it comes to the science of obesity and its treatment. We need to remove the stigma and raise awareness that safe and effective treatment options can improve lives. This is what Novo Nordisk has been doing successfully with type 2 diabetes and we think we can do it with obesity too,□ says Heather Millage.

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Maria Lopez is one of the 100 million obese people in the US. Her BMI is 33.

#### **Definition of obesity**

Obesity is defined as abnormal or excessive fat accumulation that may impair health for people with a BMI over 30. BMI provides the most convenient population-level measure of overweight and obesity currently available.<sup>16</sup> BMI itself, however, does not define health risk.

### The role of hormones in obesity

The understanding of the biological factors contributing to weight gain and obesity is rapidly evolving. There is increased focus on the role of hormones and new research clearly indicates that much more is involved in the progression from normal body weight to obesity than just a person s lifestyle and eating habits.<sup>17</sup>

The regulation of appetite and food intake is a complex process involving multiple

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hormones that transmit signals between the organs that receive the food (the intestines or gut) and the brain. After a meal, the gut responds to food by producing several hormones that tell the brain to increase the feeling of fullness while reducing feelings of hunger. One of these hormones is GLP-1, which has been found to play an important role in regulating appetite.<sup>18</sup>

As a GLP-1 analogue, liraglutide directly addresses some of the underlying biological mechanisms of obesity. Novo Nordisk is committed to research into and further exploration of the role of hormones in obesity and weight management, and the development of liraglutide is a first step in this process.

The number of adults with obesity has doubled since 1980 500 million 1980 2008 Worldwide rates of obesity have doubled since 1980, with m

Worldwide rates of obesity have doubled since 1980, with more than 500 million adults classified as obese in 2008 more than 10% of the world s adult population (World Health Organization s global estimates from 2008).

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# An **important factor** of life

For people living with haemophilia A or B, there hasn[t always been a great deal of choice when it comes to treatment. With NovoSeven®, Novo Nordisk helps about 5% of these people [] but with the launch of NovoEight®, the company will be able to help many more.

Novo Nordisk addressed a huge unmet medical need in 1996 when it launched the first ever recombinant treatment for people with haemophilia with inhibitors. Today NovoSeven<sup>®</sup> is still an important treatment option for the small part of the haemophilia community who have inhibitors.

Now, Novo Nordisk is offering another product for people in the haemophilia community by launching a recombinant factor VIII product (turoctocog alfa) for people with haemophilia A. [While there are already similar products available for this group of people, NovoEight<sup>®</sup> should not be underestimated,[] says Stephanie Seremetis, chief medical officer, Haemophilia.

□We□ve tried to improve on what is available and I think we ve achieved this. Novo Eight® is technically a different product from our competitors[]. We[]ve established a production process focusing on providing a new, highly purified and well-defined molecule and I believe this is important for both safety and efficacy. Of all licensed factor VIII products, NovoEight<sup>®</sup> has undergone the largest pre-approval programme ever carried out, which also includes a paediatric study. We therefore have a lot of data to document

#### **Building on confidence**

In the phase 3 trial, NovoEight<sup>®</sup> demonstrated good efficacy in preventing and treating bleeds and had no confirmed inhibitor development. NovoEight<sup>®</sup> has now been approved in the US, the EU and Japan for the treatment and prophylaxis of bleeding in patients with haemophilia A. In January 2014 Germany was the first country to launch NovoEight<sup>®</sup>, and Novo Nordisk expects to launch the product in more European countries and in Japan during the year. Launch in the US is expected after April 2015, awaiting the expiration of existing patents.

□NovoEight<sup>®</sup> is very important for us as a company as we want to be a true partner for people with haemophilia and take a leadership role in this market  $\square$  and we can $\square$ t do that without a treatment option for people with haemophilia A,□ explains Paul Huggins, corporate vice president and responsible for bringing NovoEight® to the market. 
Patients and doctors have grown to know and have confidence in NovoSeven<sup>®</sup>. We want to build on that confidence by providing another option for physicians that s based on advanced purification technology.□

### A paradigm shift in treatment

Novo Nordisk is also developing a long-acting recombinant factor VIII (N8-GP) and factor IX (N9-GP). The latter holds the promise of changing treatment

#### Image of the turoctocog alfa molecule based on X-ray crystallography data. Turoctocog alfa is the active compound in NovoEight®.

options for people with haemophilia B. [Our strong clinical trial results have shown that prophylactic treatment with N9-GP reduces the number of bleeding episodes per year to a very large extent,[] says Stephanie Seremetis.

Unfortunately, the expansion of manufacturing capacity for N9-GP didn[]t progress as fast as planned, and Novo Nordisk therefore had to shorten the duration of one of the clinical trials. This, understandably, caused much frustration among both patients in the trial and their doctors

In addition to developing products for the wider haemophilia community, Novo Nordisk remains committed to smaller patient groups [] as illustrated by the development and approval in major markets of NovoThirteen<sup>®</sup> for the treatment of a rare bleeding disorder caused by congenital factor XIII deficiency, which around 1,000 people suffer from worldwide. the safety and efficacy of our product.  $\hfill \square$ 

### Haemophilia

Haemophilia is an inherited or acquired bleeding disorder that prevents blood from clotting. People with haemophilia lack, either partially or completely, an essential clotting factor needed to form stable blood clots. Internal bleeding into the joints, muscles and other tissues can cause severe pain, joint damage and disability. The treatment for haemophilia involves intravenous administration of replacement clotting factors. Treatment may be administered when bleeding occurs or, increasingly, on a preventive basis (prophylactic treatment).

People with haemophilia A may have either a decreased ability or total inability to produce clotting factor VIII. Approximately 350,000 people have haemophilia A globally. However, the disease is severely under-diagnosed in developing countries.

People with haemophilia B have deficiencies in producing clotting factor IX. Haemophilia B is inherited in the same way as haemophilia A, but is five times less common (70,000 people worldwide).

Around 3,500[]4,500 people with haemophilia worldwide have high-titre inhibitors.

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### Living with haemophilia

HERO (Haemophilia Experiences, Results and Opportunities) is an international study that aims to build an understanding of life with haemophilia, seen from the perspective of people with haemophilia, their families and their healthcare providers. Read more about the study, which is supported by Novo Nordisk[]s programme Changing Possibilities in Haemophilia<sup>®</sup>, at novonordisk.com/ hero.

# Novo Nordisk<u></u>s FIVE REGIONS

North America .. Europe .. International Operations .. Region China .. Japan & Korea

Novo Nordisk markets its products in more than 180 countries. Despite the differences in terms of economic development, political systems and healthcare infrastructure between these countries, Novo Nordisk subside business model is fundamentally the same all over the world.

**N**ovo Nordisk has employees in 75 countries. They share the common ambition to be the country[s leading pharmaceutical company within the selected disease areas, both in commercial terms and when it comes to making a positive change for patients. Key to achieving this ambition are biological pharmaceuticals with new, distinct properties that Novo Nordisk[s researchers have invented and developed. These products, for example NovoRapid<sup>®</sup>/ NovoLog<sup>®</sup>, Levemir<sup>®</sup> and Victoza<sup>®</sup>, are what make up the bulk of Novo Nordisk[s revenues in all of its five business regions.

In addition, Novo Nordisk offers [] and is committed to continue offering [] lower-priced products in the form of traditional human insulin in countries where there[]s still a significant demand for such products.

### **Creating value for customers**

Novo Nordisk markets its products the same way globally by sharing clinical knowledge about the products with doctors, so that they can make an informed choice about whether these products are right for their patients. At the same time, payers and administrators [] typically public health systems and private health plans [] are presented with evidence about the cost efficiency of the products, in order to make informed decisions about pricing and reimbursement.

Moreover, Novo Nordisk organises and supports education of healthcare professionals in managing diabetes, and engages in activities aimed at improving awareness, prevention and diagnosis of the disease.

### Organisation

Novo Nordisk is a firm believer in having wholly owned affiliates and expanding them organically as the market develops. While

other pharmaceutical companies may build a presence through the acquisition of local companies, joint ventures or rented sales forces, Novo Nordisk prefers to hire its own people and train them to become the best. This is also seen as the best way to convey and preserve a strong company culture.

### Competitors

In its all-important insulin market, Novo Nordisk s main competitors are the same all over the world: Eli Lilly and Sanofi. In addition, there are local competitors in some countries such as China and India. However, they are not innovation-based and primarily offer human insulin. So far, these companies haven It been able to gain significant market shares. In the biopharmaceuticals business, Novo Nordisk faces competition from a broader number of pharmaceutical companies, in some markets including producers of biosimilar medicines (products that are similar but not identical to an original medicine). So far, biosimilar competition hasn t had a dramatic impact on the business, which has continued to grow at a global level.

### **Regional differences**

What almost all countries have in common is that the incidence of diabetes is increasing and that they [] re battling with how to tackle the situation most effectively. The countries differ, however, when it comes to the level of spending on diabetes care and in their ability and willingness to fund further investments in improving care, including the use of the latest advances in medical treatment. The following pages provide a review of Novo Nordisk[]s business in the five regions.

### CONTINUED []

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### **North America**

The North American region consists of the US and Canada and is Novo Nordisk[]s largest in terms of sales, which isn[]t surprising given that the US is the world[]s largest pharmaceutical market. In 2012, total pharmaceutical sales in the US amounted to 327 billion US dollars, of which 6% was spent on products for treating diabetes.

Novo Nordisk has experienced tremendous arowth in the US in recent years. Since 2008, sales have more than doubled from 14 billion Danish kroner (3 billion dollars) to 37 billion kroner (7 billion dollars) in 2013. In the same period Novo Nordisk organisation in the US, including research and development and production, has grown from around 3,700 employees to more than 6,100. The main drivers of sales have been □ and continue to be  $\square$  the portfolio of modern insulins and Victoza<sup>®</sup>.

In 2013, sales of diabetes care products increased by 18% in local currencies in North America. This reflects continued market penetration by the modern insulins, especially Levemir<sup>®</sup>, modest growth of human insulin and a 31% growth in sales of Victoza<sup>®</sup>, measured in local currencies.

Sales of biopharmaceuticals □ NovoSeven<sup>®</sup> and Norditropin<sup>®</sup> being the main products [] grew by 16% in 2013. measured in local currencies. Norditropin® in particular did very well in 2013, which is due to both the very positive reception of the FlexPro<sup>®</sup> injection device and the very comprehensive support programmes that Novo Nordisk offers both healthcare professionals and patients.

# A complex healthcare system

The US healthcare system is complex as it involves multiple payers and intermediaries with complex interactions. Roughly half of all Americans are insured by their employers and one-third by the government through programmes such as Medicare and Medicaid, while around 15% are uninsured. The government figure is expected to increase significantly while the number of uninsured is expected to drop significantly in the coming years as a result of the Affordable Care Act, which is currently being implemented.

To manage the purchase and delivery of healthcare, employers and the government contract with intermediaries such as health plans and pharmacy benefit managers (PBMs). These are often referred to as [payers], but are in most

providers such as physician, hospital and pharmacy networks to provide the required service. They provide different levels of coverage based on the payers[] willingness to pay for selected services for their employees. A PBM is an intermediary that contracts with payers and health plans to manage the pharmacy benefit for a specific population. Typical services include claims processing, managing enrolee eligibility, contracting pharmacy networks and managing rebate contracts with pharmaceutical companies.

The health plans use various methods for managing the use and cost of pharmaceuticals. Among the most widely used interventions are generic substitution, quantity limits, prior authorisation (which means that a medication will only be covered under certain conditions and subject to individual approval by the health plan) and tightly controlled Preferred Drug Lists.

### **Growing pressures**

Competitive pressures are growing in the managed healthcare industry, driving both consolidation through mergers and acquisitions and increasingly tough rebate negotiations with pharmaceutical companies. Novo Nordisk experienced the effects of the latter in the second half of 2013 when it lost coverage for NovoLog<sup>®</sup> and Victoza<sup>®</sup> for 2014 with Express Scripts National Preferred Formulary covering 45 million people in the US. Despite such

cases managers of healthcare costs on behalf of payers. Health plans contract with pressures and increasing competition from other pharmaceutical companies, Novo Nordisk maintains a competitive presence on the US market. The company[]s key diabetes care products have broad market access and are capturing market shares. In fact, in 2013 Novo Nordisk[]s three modern insulins were the only products with a growing volume market share in the US in the modern insulin category.

### Growing market for diabetes products

Novo Nordisk holds around 29% of the total US market for diabetes care medications and 37% of the insulin market, measured in value. The insulin market is expected to continue growing in volume in the coming years due to the increasing number of people with diabetes, many of whom will require insulin treatment. Moreover, in the US, only around 41% of insulin volume is delivered in a pen system such as Novo Nordisk∏s FlexPen<sup>®</sup>, while it is more than 95% in Europe. This means there is still significant potential to upgrade treatment in the US. In 2014, Novo Nordisk expects to introduce its newest pen system, FlexTouch<sup>®</sup>, with certain insulin products.

Novo Nordisk is the market leader within GLP-1-based therapies in the US, where Victoza<sup>®</sup> has a value market share of around 67%. The market itself experienced decelerating growth in 2013 due to questions being raised about potential pancreatic side effects. Read more on pp To further strengthen the presence in the US, Novo Nordisk S US affiliate has expanded its field force several times in recent years. The latest expansion was announced in 2013 with the addition of more than 350 new representatives, who after an intensive period of training will be in the field by April 2014.

### Preparing for a new market

The US affiliate is preparing to enter a new market for the medical treatment of obesity with liraglutide 3 mg, which was filed for regulatory review with the US Food and Drug Administration (FDA) in December 2013. Read more about obesity on pp 28[29.

## Developments to look out for

In February 2013, the FDA requested more data on the cardiovascular safety profile of Tresiba® (insulin degludec) before it could complete its review of Novo Nordisk[]s application. In response, Novo Nordisk In Philadelphia, 65% of the adult inhabitants are estimated to be overweight, making it one of the most obese cities in the US. More than 10% of the inhabitants have diabetes.

initiated a cardiovascular outcomes trial involving 7,500 patients. Read more on pp 24[25.

Another event that may have an impact on the insulin market is Sanofi]s basal insulin product, insulin glargine, which will lose US patent protection in 2015. Eli Lilly has submitted a biosimilar version of insulin glargine for regulatory approval, and Sanofi itself is developing a stronger formulation of insulin glargine. How, and to what extent, such events will change the market dynamics is not possible to predict at this point in time.

In the GLP-1 area, several new products are likely to enter the market in the coming years.

### CONTINUED []

38[41. Victoza<sup>®</sup>, however, continues to expand its share of the GLP-1 market and has further consolidated this position with the support of a new nationwide TV campaign.

It[]s Novo Nordisk[]s ambition to sustain the strong performance, despite the dynamic business environment, by consolidating the diabetes market leadership position through the modern insulins and Victoza<sup>®</sup>.

Sales in North America

### Europe

Europe is Novo Nordisk⊓s second largest region in terms of sales. Sales growth has been modest in recent years [] in the low single-digit range. To a large extent, this is a result of the depressed economy in many European countries in the wake of the financial crisis. This has led governments to implement cost-cutting measures, both through price cuts on medicines and by limiting access to new medicines. Tresiba® has been affected by such measures in countries such as the UK and Denmark.

In 2013, Novo Nordisk sales of diabetes care products in Europe increased by 3% in local currencies. Sales of insulin and protein-related products were unchanged, reflecting the fact that declining human insulin sales were offset by the continued progress of Levemir<sup>®</sup> and NovoRapid<sup>®</sup>. Furthermore, sales were impacted by low volume growth of the insulin market, around 3%. However, the use of devices for insulin injections is very high, with 96% of Novo Nordisk s insulin volume being used in devices, primarily NovoPen<sup>®</sup> and FlexPen<sup>®</sup>.

Sales of Victoza<sup>®</sup> increased by 20% in local currencies. Sales growth was primarily driven by France, the UK, Spain and Italy. In Europe, the GLP-1 class share of the total diabetes care market in value increased to 8% compared with 7% in 2012. Victoza<sup>®</sup> is the GLP-1 market leader with a value market share of 78%.

# Tresiba<sup>®</sup> is important for future growth

There are no signs of a return to significantly higher sales rates in the coming years, with government cost-cutting measures expected to continue. Moreover, the diabetes market is well developed, diagnosis rates

### International Operations

With sales of 12 billion Danish kroner in 2013 and average annual sales growth of around 15% since 2009, International Operations is Novo Nordisk⊓s main contributor to growth after North America. Thinking of International Operations as one business region requires a stretch of the imagination, though. It encompasses 149 countries all over the world with more than 4.4 billion people 🛛 Latin America, Africa, the Middle East, the Gulf, most of Asia, and Australia. A region of extraordinary diversity, it covers some of the world⊓s poorest countries and some of the richest.

This means that Novo Nordisk must be able to meet demand for both standard therapy in the form of human insulin in vials at verv low prices and advanced modern insulin products in sophisticated pen systems, which are sold at prices similar to those seen in Europe and the US. Within many of the countries in International Operations, there is both a public and a private market. In most cases the public market only reimburses use of human insulin vials, while the private market is primarily modern insulin paid for by people who either have private insurance or can pay out of their own pockets.

What these countries have in common is that the incidence of diabetes is increasing, and many of them are enjoying economic growth above what is being seen in the Western world. This means they can afford to extend the reach and quality of their healthcare systems.

In 2013, Novo Nordisk[]s sales of diabetes care products in International Operations increased by 16% in local currencies, driven by all three modern insulins. Currently, 59% of Novo Nordisk[]s insulin volume in the major

### **Future growth**

Growth in International Operations will continue to be driven by the increasing number of people with diabetes in the region and the fact that more of them will have access to medical treatment as economies develop. Novo Nordisk□s key priorities are to increase the modern insulin penetration, launch Tresiba<sup>®</sup> in more countries (Mexico and India already launched this product in 2013), continue the roll-out of Victoza<sup>®</sup> and ensure that more people are treated with insulin sooner than is the case today.

To support growth, Novo Nordisk is expanding its organisation in many of the key growth markets and making significant investments in building healthcare capacity within diabetes.

### **Region China**

With sales of 7.2 billion Danish kroner in 2013 and average annual sales growth of around 19% since 2009, China has been a major contributor to Novo Nordisk growth in recent years. This is predicted to be the case in the coming years too, partly due to the rapidly increasing number of people with diabetes in China. According to the latest estimates from the International Diabetes Federation, more than 99 million people in China have diabetes today.

With China s economic growth comes urbanisation, with urbanisation come sedentary lifestyles and diabetes follows. This is the same pattern seen in other rapidly developing countries, but on a much larger scale in a country with an ageing population of 1.35 billion. On top of this, there is another challenge. Twenty years ago, very few doctors in China knew how to treat diabetes, and outside the bigger cities this is often still the case. Novo Nordisk established its are high, birth rates low and Novo Nordisk already has an insulin market share of 49% measured by volume. This means there are limits as to how much Novo Nordisk can grow in Europe.

The key growth driver in the coming years is expected to be Tresiba<sup>®</sup> as it becomes available to patients in more European countries. Moreover, Novo Nordisk will be launching NovoEight<sup>®</sup> for treating haemophilia A in the first European countries in 2014.

Sales in Europe Sales in International Operations Sales in Region China private markets is used in devices. Novo Nordisk s insulin volume market share is around 56%.

Victoza<sup>®</sup> is becoming an increasingly important product in International Operations. Sales grew by 31% measured in local currencies in 2013 and the product was marketed in 43 countries by the end of 2013. own affiliate in China in 1994 and, to this day, the company s main focus has therefore been to educate doctors and patients in proper diabetes care, including how to use insulin effectively and safely. While these initiatives primarily took place in the biggest cities at first, today they re being rolled out to smaller cities and rural areas.

In 2013, Novo Nordisk sales of diabetes care products in Region China increased by

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13% in local currencies. The sales growth was driven by all three modern insulins, while sales of human insulins only grew modestly. Currently, 97% of Novo Nordisk∏s insulin volume in China is used in devices, primarily the durable device NovoPen<sup>®</sup>. GLP-1 products are currently not reimbursed in China and this class of products is therefore relatively small. However, its share of the total diabetes care market in value expanded to 0.6% compared with 0.5% in 2012. Victoza<sup>®</sup> holds a GLP-1 value market share of 74%.

# Reforms to widen healthcare coverage

The Chinese government is implementing widespread reforms of the healthcare system with a view to extending both its reach and quality and, as in many other countries, several measures are being taken to limit spending on pharmaceuticals. One way to do this is by creating lists of essential pharmaceuticals that are purchased from potential companies in large quantities at low prices. Pharmaceuticals on this list are primarily older products that have gone off patent, such as human insulin.

However, there[]s also a growing market for newer and higher priced pharmaceuticals in China as both the health awareness and the purchasing power of many Chinese families are growing. They[]re willing to pay for [] or have private health insurance that covers [] newer and more innovative treatments.

Novo Nordisk s growth in the coming years is expected to primarily come from the portfolio of modern insulins, in part driven by the continuing expansion of the company s reach into an increasing number of county hospitals, and from Victoza<sup>®</sup>.

In 2013, Novo Nordisk∏s sales of diabetes care products in Japan & Korea decreased by 4% in local currencies. This sales development reflects a stagnant Japanese insulin volume market and the negative impact from a challenging competitive environment. A shift in recent vears from the use of premixed insulin products, where Novo Nordisk is the clear leader with NovoMix<sup>®</sup>, to basal insulin products, where Novo Nordisk is in fierce competition with Sanofi, has led to a loss of market share.

In 2013, there have been signs that this development is changing with the launch of Tresiba<sup>®</sup>. Japan was the first country to launch Tresiba<sup>®</sup> in 2013 with broad market access. Since its launch in March, Tresiba<sup>®</sup> has steadily expanded its share of the basal insulin market and now represents 8.6% of this market measured in monthly value market share.

In 2014, the focus in Japan & Korea will be on the further penetration of Tresiba<sup>®</sup>, the launch of Ryzodeg<sup>®</sup> (insulin degludec/insulin aspart) and the launch of NovoEight<sup>®</sup> (turoctocog alfa) for treating haemophilia A. However, growth rates are expected to remain modest due to price reductions and the overall low growth of the total insulin market.

### Japan & Korea

With a 52% market share measured in volume, Novo Nordisk is the clear insulin market leader in Japan. The use of devices remains high in Japan, with 98% of Novo Nordisk s insulin volume being used in devices, primarily FlexPen<sup>®</sup>. Sales in Japan & Korea Diabetes care Value market share by geographic region ... North America ... Europe ... International Operations ... Region China ... Japan & Korea Modern insulins Global value market share by brand in its respective insulin segment\* ... NovoMix(r) ... NovoRapid(r) ... Levemir(r) \* Levemir(r) in the long-acting segment, NovoRapid(r) in the rapid-acting segment and NovoMix(r) in the dual-release segment.

Key regional facts	North America	Europe	International Operations	Region China⁴	Japan & Korea
Population (million) <sup>1</sup>	349	538	4.408	1.351	178
GDP per capita (USD) <sup>1</sup>	51,796	33,242	4,499	6,091	39,925
Healthcare spend per capita (USD) <sup>1</sup>	8,310	3,575	292	278	3,566
Physicians per 1,000 people <sup>1</sup>	2.4	3.3	1.1	1.8	2.1
Number of people with diabetes (million) <sup>2</sup>	27	34	203	99	11
Diagnosis rate <sup>2</sup>	78%	64%	55%	46%	51%
Diabetes national prevalence <sup>2</sup>	11%	9%	8%	10%	8%
Novo Nordisk total sales (DKK billion)	39.0	20.1	12.0	7.2	5.3
Insulin value market share <sup>3</sup>	38%	47%	49%	57%	52%
Insulin volume market share <sup>3</sup>	41%	49%	56%	59%	49%

**1.** The World Bank. **2.** The 2013 data are based on the *IDF Diabetes Atlas*, 6th edition, 2013. Prevalence rates have been estimated lower in a number of countries compared with the 5th edition used in the *Novo Nordisk Annual Report 2012*. This reduction is due to changes in methodology and sources used by IDF for a given country and not to an improvement in diabetes prevalence. All studies from the same country show an increase in diabetes prevalence over a longer time period. **3.** IMS Health, IMS MIDAS Customized Insights, November 2013. **4.** Data from IMS Health, IDF and The World Bank include China only.

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The complexity of insulin production

More than 24 million people globally rely on Novo Nordisk s products to treat their diabetes. Around 10,000 employees are responsible for manufacturing high-quality products with low environmental impact.

nsulin production at Novo Nordisk starts in Kalundborg, a town of about 16,000 inhabitants 100 kilometres west of Copenhagen, Denmark. It is here that the company makes insulin crystals, the active ingredient our manufacturing strategy, and our unique capabilities enable us to produce large volumes of insulin at a competitive cost. While most other large-molecule pharmaceuticals are produced

in relatively small quantities,

to create the different types of Novo Nordisk insulin, for example Levemir<sup>®</sup> (insulin detemir) or Tresiba<sup>®</sup> (insulin degludec). In the filling process, glass Penfill<sup>®</sup> cartridges and vials are filled on high-speed lines. Once filled and inspected, some in its insulin products, through the processes of fermentation, recovery and purification. Site Kalundborg is Novo Nordisk[]s largest production site at 1,350,000 m<sup>2</sup> [] equivalent to 270 football pitches. In fact, it[]s the largest production site for insulin in the world, making around half of the world[]s insulin crystals.

# A complex production process

Insulin is a protein and thus a large and complex molecule. Manufacturing insulin is very different from manufacturing most other pharmaceuticals, which are based on small molecules. It requires large investments in biotechnology, sterile production facilities and an understanding of working with living cells [] in this case yeast [] to produce a uniform and pure product.

[In Kalundborg we]ve developed large-scale production expertise over many years,] says Henrik Wulff, senior vice president and head of Product Supply. [Centralised insulin crystal production is an important part of production of insulin is a high-volume undertaking. It is estimated that an entire Olympic-sized swimming pool could be filled with Novo Nordisk s insulin every year. Every second, every day, 21 Penfill<sup>®</sup> insulin cartridges are filled. And enough FlexPen<sup>®</sup> injection devices are produced each year to stretch more than once around the globe.

# Final production close to patients

While the production of insulin crystals is centralised in Denmark, the next steps in the manufacturing process are closer to the patients and major markets that need the company[]s products.

The largest production sites outside Denmark are in the US, Brazil, France, China and Japan. Working according to the same, global quality management system, these plants turn the insulin crystals into finished products. In the formulation process, freeze-dried insulin crystals are blended with other ingredients and water cartridges are mounted into injection devices, such as FlexPen<sup>®</sup> and FlexTouch<sup>®</sup>. Finally, the products are packed to fulfil customer orders and shipped to their destination after final quality control.

 $\square$ We place the production of finished products close to where the patients are, $\square$ explains Henrik Wulff. □This allows us to react fast to local changes and lowers any supply risk; our obligation to patients is to supply safe, high-quality products in compliance with regulatory requirements, in volumes that meet demand. To live up to this obligation, we have one quality management system that defines the global standards for compliance and product quality.

### **Continuous improvement**

Novo Nordisk shighly efficient production system is based on years of experience and learning from better practices. The company has continuously developed its

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### One g quality system

Novo No uses one approac ensure t quality c products matter v the worl are prod The com quality manage system I designed ensure t manufac processe its stand operatin procedu (SOPs) a in comp with internati standard as Good Manufac Practice 9001. In Product the com producti division, more that 15,000 9 All er working Product receive to ensur complia the qual manage system, including docume all produ lines consiste meet the predeter criteria, identify

address systemic problem how to h deviatio the stan Furth Novo No has two function charged ensuring manufac quality. Control indepen validates products manufac complia all proce while Qu Assuran monitors processe conduct accorda the com SOPs. Th final con before b of medic released markets

Ephrem Rudahunga works at site Kalundborg, the largest insulin production site in the world.

production through technology upgrades, skill-building and process optimisation. []The introduction and in-house development of cLEAN<sup>®</sup>, our version of the lean manufacturing principles, has had a very positive impact on the quality and performance of our processes and hence the production cost, Henrik Wulff says. In fact, the company s ambition to improve production performance has produced remarkable results, with cost of goods sold as a percentage of sales falling from 28% to 17% from 2003 to 2013.

long-term aspiration is to continuously decouple environmental impacts from business growth. Since 2004, Novo Nordisk has reduced the emissions of CO<sub>2</sub> by 42%. In response to the need for expansions of production capacity and an increased product portfolio, the long-term environmental targets for consumption of energy and water were revised and updated in 2013.

Energy-saving projects have resulted in savings of up to 144 million kWh, equivalent to the annual energy usage of more than 7,000 Danish households, and reductions in CO<sub>2</sub> emissions of 44,000 tons become more difficult to optimise our absolute footprint as we ve become so efficient. However, we remain committed to ensuring that our environmental impact grows more slowly than the company grows its sales, explains Henrik Wulff.

□Looking ahead, I□m confident that we□re well prepared to continue our strong performance within production. We□II expand our production facilities to increase output in line with market demands and continue supplying high-quality products that meet regulatory requirements. At the same

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#### **Energy savings**

Optimising process performance has also helped reduce Novo Nordisk[]s environmental impact significantly. The annually. [In the beginning, we could realise large improvements in our environmental impact, but now it has

time, we ll keep our focus on improving our existing processes so that we continue to live up to our financial, environmental and social commitments, he concludes.

## A Warning Letter with important learnings

An error that shouldn thave happened

In December 2012, Novo Nordisk received a Warning Letter from the US Food and Drug Administration (FDA) following an inspection of a production plant in Denmark. In the Warning Letter. the FDA cited two specific violations of its compliance standards. Novo Nordisk immediately took action to address the issues. A re-inspection was carried out in August 2013 and in January 2014, Novo Nordisk received confirmation from the agency that the violations had been addressed satisfactorily. The learnings from this case are being applied throughout the global Product Supply organisation and serve as a reminder of the importance of keeping up with ever-evolving compliance standards.

In October 2013, Novo Nordisk recalled certain batches of its prefilled insulin product NovoMix<sup>®</sup> 30 in several European countries. A quality control conducted by Novo Nordisk had shown that a small percentage (0.14%) of the 3 million products in these batches did not meet the specifications for insulin strength. This could lead to the patient[]s blood sugar level becoming higher or lower than expected. To protect patient safety Novo Nordisk recalled all products in the affected batches from wholesalers, pharmacies and patients. The root cause, a production error at one of Novo Nordisk[]s production facilities, has been identified and resolved.

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# A question of trust

As a business with shareholders to satisfy, the pharmaceutical industry must have a strong focus on financial performance. But the industry[]s greater purpose is to improve human health. At first glance these ambitions may appear conflicting [] is it therefore any wonder that the issue of trust is so often raised?

he

pharmaceutical industry is no stranger to critical media attention. Headlines often call into question the ethics and transparency of business practices that must balance financial and social responsibilities. It is easy to find people who don It trust pharmaceutical companies to put the interests of patients above profits.

Calling into question the transparency of clinical trial results, some critics are suggesting that negative data, or data that don[]t support the hypothesis being tested, have been buried. They have called for the disclosure of further data. Authorities have

clinical trial results of approved products public, explains Peter Kristensen, senior vice president of Global Development.

It is Novo Nordisk[]s policy that the results of all clinical studies are published, preferably in scientific journals and at scientific meetings. Tabulated data from Novo Nordisk[]s clinical trials of products approved in the US are available today on the website

clinicaltrials.gov. This is a registry and results database of publicly and privately supported clinical trials conducted around the world and is run by the U.S. National Institutes of Health. Since 2005, Novo Nordisk has published a synopsis of results from the company s clinical trials of approved marketed products, whether positive or negative. Today this information is publicly available at novonordisk-trials.com including information

and redacted to protect patient and site confidentiality [] as they are the complete descriptions of the trials presented in a standardised format and the actual material used for submission to regulatory authorities. []In this way, we hope to further reassure healthcare professionals and patients that what we communicate is an accurate reflection of what we have observed and thereby strengthen public confidence in the approved medical treatments,[] adds Peter Kristensen.

He stresses that Novo Nordisk will publish the CSRs after regulatory approval in the EU and in the US, so that the

from discontinued trial

novonordisk-trials.com

will also provide access

(CSRs) for all Novo

to Clinical Study Reports

Nordisk trials after 2006

product indications that

are approved in the EU

company has chosen to

publish CSRs [] without

 $\Box$  regardless of study

outcome [] involving

and the US. The

appendices

From 1 March 2014.

programmes.

also recently reviewed guidelines on the interaction between the pharmaceutical industry and healthcare professionals in order to address concerns about this relationship. The dilemma is obvious: On the one hand, doctors have expert knowledge based on their clinical experience, without which pharmaceutical companies can∏t develop new medical treatments. On the other hand, some may see payments made to healthcare professionals for this knowledge as an illegitimate means of encouraging them to prescribe certain medicines. So can patients be sure that doctors are making treatment decisions in the patients[] best interests?

### Data

### transparency

Novo Nordisk has a strong track record on clinical trial data transparency. For almost a decade, the company has systematically shared and published results and related data □ irrespective of trial outcome. []For the success of future clinical trials, and for our long-term

business, it is imperative that we build good and trustful relationships with doctors and patients. We rely on our collaboration with them, and take the concerns they may have very seriously. This is why today, we already go beyond regulatory requirements by making our

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decision-making process of the regulatory authorities is not made even more complex by a parallel public debate. In addition, prior to approval, Novo Nordisk regards the design of its trials, as well as the results obtained, as confidential information. []We have to protect competitive information. Otherwise investments in future treatments will be lost, which would be bad for patients and the industry alike,]] points out Peter Kristensen.

### Access to patient-level data

Taking transparency to a new level, public access to individual patient

research data from clinical trials has recently been proposed by the **European Medicines** Agency (EMA). Novo Nordisk agrees that there is value in making these data available: □We have a responsibility to patients to ensure that the data they contribute to clinical trials are leveraged as much as possible to advance scientific understanding. We believe that by sharing detailed clinical trial data with the research community, new knowledge may be created that could contribute to the development of new and improved treatments,□ Peter Kristensen highlights. []However, we have to be careful that patient confidentiality is not compromised and that competitive business information is not divulaed.⊓

Therefore, Novo Nordisk will make patient-level data for approved products from trials completed after 2001 available to researchers upon request. To ensure that the data are handled in a responsible way, the company will establish an independent governing body. This will include experts skilled in evaluating clinical data and will assess researchers∏ requests for data and make decisions based on an accountable and transparent process.

□Our business ethics strategy is there to safeguard the integrity of our relationships with all our stakeholders and we want to make sure our actions are transparent,∏ comments Lise Kingo, executive vice president and chief of staffs. She is also the chair of the Business Ethics Board. which is responsible for implementing the company∏s business ethics strategy. □We have focused on business ethics for a long time and we⊓re always looking for ways we can make improvements in this area. By way of example, Lise Kingo mentions that all relevant employees are trained in  $\square$  and then tested on  $\square$  the company<sub>□</sub>s standard operating procedures for interactions with and payments to healthcare professionals.

# Global reporting, global transparency

This past year national regulations for disclosure of payments and other transfers of value to healthcare professionals have come into force in the US and France. There is now, for example, a requirement to report any individual payments exceeding 10 US dollars or 10 euros in the US and France respectively. Furthermore, the European pharmaceutical industry trade organisation EFPIA has recently revised its codes

#### Integrity and transparency are the foundation for building trust

A company such as Novo Nordisk can⊓t develop new medicines without the guidance, knowledge and expertise of doctors, who understand the medical needs of the patients they see in their clinics. It is therefore reasonable that they are fairly compensated for the services they provide in this respect. However, relationships with doctors can create the potential for conflicts of interest as the doctors have a direct impact on a company∏s sales via their prescribing decisions. The issue of trust raises its head again.

of conduct for interactions between the pharmaceutical industry and healthcare professionals and patient organisations. The revised codes ban all gifts to healthcare professionals, enable each country to set a threshold for any hospitality provided to doctors and, as in the US and France, call for individual disclosure of any transfers of value.

Novo Nordisk fully supports the new regulations and codes of conduct, and has developed a system for reporting payments to individual healthcare professionals. [Ultimately, we want to have one system for all our affiliates to ensure the same reporting standard, not only in the US and

#### CONTINUED

A selection of books published in recent years with a critical perspective on the pharmaceutical industry.

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Europe, but throughout the world. We are therefore ready to roll out this system in each country once specific national requirements have been announced and taken into account, explains Lise Kingo. We hope that these new regulations and revised codes of conduct will enhance transparency and reassure external stakeholders of our commitment to ethical behaviour.

# Reaffirming results to build confidence

For good reason, product safety is one of the greatest concerns for patients and healthcare professionals and is an issue that Novo Nordisk takes very seriously, particularly as the company makes potentially lifesaving treatments for people who are, by nature of their medical condition, vulnerable. The company therefore continuously and actively monitors the safety profile of its products. Stringent protocols and systems are in place to ensure product safety, both during the development phases and after a product has been launched.

### Read more in the box on p 41.

However, new pharmaceuticals often come under the spotlight, particularly if they represent a new class of drug. A recent example is GLP-1-based diabetes therapies, a drug class to which Novo Nordisk[]s Victoza<sup>®</sup> belongs. The safety of this drug class was challenged early in 2013, when a study (which did not include Victoza<sup>®</sup>) suggested an increased risk of side effects on the pancreas. The FDA and EMA reacted by reviewing data on GLP-1-based therapies to see if a link between them and an increase in pancreatic side effects could be determined.

In July, the EMA concluded that currently available data did not confirm the concerns over an increased risk of pancreatic adverse events with these medicines. The FDA has not officially announced the conclusion of its review. However, in response to questions from the media, a spokesperson said that the FDA was in agreement with the EMA[]s conclusions.

Mads Krogsgaard Thomsen, executive vice president and chief science officer, Back to Contents

### Continuous safety surveillance process

All Novo Nordisk products [] whether in development or on the market [] have a dedicated cross-organisational safety committee, with experts anchored in Global Safety, which oversees the safety of the product. Preclinical data, clinical studies, post-marketing reports, publications, competitor information and databases are continuously reviewed to detect any safety concerns.

The benefit⊓risk profiles of Novo Nordisk-marketed products are described in the product label, as agreed with health authorities. New data are shared with authorities, either as an ongoing process via individual case safety reports or at regular intervals via periodic safety update reports. If necessary, product labels are updated based on new data. Furthermore, when possible, analysis of safety data is published in peer-reviewed iournals in collaboration with experts.

Senior Clinical Research Associate Sowmya Muralidhar from India liscusses a clinical trial with a doctor involved in the trial.

welcomed the EMA[s conclusion: [Novo Nordisk is committed to patient safety and continuously monitors

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[Ensuring the safety of our products remains our top priority. I believe our history ] and how we have years to come, Lise Kingo hopes that Novo Nordisk[]s approach to business ethics will demonstrate the

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for adverse events related to all of its medicines. Victoza<sup>®</sup> has more than 1.9 million patient years of use and a strong body of evidence to support its safety and efficacy based on both clinical trial and real-world practice data.∏

Karsten Lollike, corporate vice president and head of Global Product Safety, adds that Novo Nordisk continues to conduct studies to assess the effects of long-term use of Victoza<sup>®</sup> on the pancreas. This includes a review of databases and the cardiovascular outcomes trial LEADER<sup>®</sup>, to be completed in 2016, and other post-marketing studies. handled safety issues and concerns in the past [] proves our commitment is more than just words,[] explains Karsten Lollike. [I[]m really pleased that in a recent survey<sup>1</sup> Novo Nordisk was ranked number one in the industry by patients for having a good record in ensuring patient safety. I believe this shows that patients trust us.[]

#### An ongoing issue requires a long-term perspective

While it can be expected that the issue of trust and the pharmaceutical industry will continue to be discussed for many company∏s commitment to building trust with all its stakeholders: □We have clear priorities and the needs of patients come first  $\square$  this has been the case ever since the company was founded. We have a Triple Bottom Line approach that ensures all business decisions live up to our financial, social and environmental responsibilities. This long-term perspective is absolutely fundamental to the way we work and how we run our business, and I believe this is our firm foundation for being a credible and trustworthy company,∏ she concludes.

### RISKS

to be aware of

Several developments in 2013 were reminders that there are, and always will be, risks associated with Novo Nordisk s business risks that all investors should be aware of.

### 8 February 2013: The US

Food and Drug Administration (FDA) informs Novo Nordisk that it cannot approve the New Drug Applications for Tresiba<sup>®</sup> (insulin degludec) and Ryzodeg<sup>®</sup> (insulin degludec/ insulin aspart) in their current form. This unexpected development meant that these two insulin products could not be launched in the US in 2013 as originally planned. Read more on pp 24[25.

**22 March 2013:** A study is published suggesting that GLP-1-based drugs for treating type 2 diabetes have an increased risk of pancreatic side effects. Although the authorities later concluded that currently available data did not confirm the concerns, the growth of this market segment was affected in some countries. Read more on pp 38[]41.

**23 October 2013:** Novo Nordisk announces a recall of 3 million NovoMix<sup>®</sup> insulin products in several European countries due to a production error. Situations leading to product recalls may pose a risk to patient safety, lead to disruption of supplies in the affected countries and tarnish Novo Nordisk[]s reputation. Read more on pp 36[]37.

Three examples of three different types of risk that

### **Market risks**

The principal market risks Novo Nordisk experiences are:

price pressure and reimbursement restrictions by payers

the launch of new products by established competitors

increased competition from producers of biosimilar medicines in key markets.

Europe, China and the US are all main markets for Novo Nordisk where payers  $\square$  both governments and private payers □ take measures to limit spending on medicines, typically by driving down prices, demanding higher rebates and/or restricting access to and reimbursement of products. This is unlikely to change in the foreseeable future. For Novo Nordisk, reimbursement restrictions pose a significant risk when launching a new product such as Tresiba<sup>®</sup>, the new-generation basal insulin with ultra-long duration of action. Despite the patient benefits and data supporting the health-economic benefits of the product, it is not always possible to obtain market access on what Novo Nordisk considers reasonable conditions. In some countries, the company may therefore not launch Tresiba<sup>®</sup> under the current conditions.

The launch of new products by established competitors is an inherent market risk. As mentioned on p 33 in the article about Novo Nordisk[]s five regions, new products are under way in both the insulin and GLP-1 segments, including a biosimilar version of the best-selling modern insulin product. How and to what extent such events will change the market dynamics is not possible to predict at present. In addition to these global risks, in some countries in the International Operations region political instability or war may pose a risk to Novo Nordisk[]s business for varying lengths of time.

# Delays or failure of pipeline products

Development of a new pharmaceutical product is an expensive undertaking that can take more than 10 years. It includes extensive non-clinical tests and clinical trials as well as an elaborate regulatory approval process, including approval of the production facilities. During the process, various hurdles may delay the development of a potential product candidate and add substantial expense. In some cases, significant obstacles could lead to the company eventually deciding to abandon the development of the potential product candidate.

In Novo Nordisk[]s experience, there is a less than 35% chance of a diabetes product candidate in phase 1 clinical trials ultimately being approved for marketing, while the chance of success is around 40% for products in phase 2 trials and rises to around 70% for products in phase 3 trials. However, there is significant uncertainty regarding the come with being a pharmaceutical company and investor in one. And there are more. This article covers the main types of risk that Novo Nordisk faces. For some specific risks, reference is made to articles elsewhere in the Annual Report and notes to the consolidated statements. timing and success of the

#### regulatory approval process, as illustrated by the aforementioned decision by the FDA regarding Tresiba<sup>®</sup> and Ryzodeg<sup>®</sup>.

### Supply disruptions

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Failure or breakdown in one of Novo Nordisk⊓s or the company
☐s key suppliers
☐ vital production facilities could adversely affect operations and potentially cause employee injuries or infrastructure damage. Fire prevention design, alarms and fire instructions, annual inspections, back-up facilities and safety inventories all aim to mitigate this risk. To spread this risk geographically and optimise costs and supply logistics, Novo Nordisk has established production sites in several countries. Read more on pp 36||37.

# Quality and product safety issues

Quality and product safety issues may arise if, for example, a production facility is not continuously in compliance, a product is not within specifications or if side effects that were not detected in clinical trials become apparent when a product is used for long periods of time. Novo Nordisk proactively manages such risks through its quality management system, a key priority of which is to safeguard product quality and minimise risks to patient safety and secure product quality. The quality management system aims to ensure that the company is in compliance with all

FORM 6-K

#### hedges expected future cash flows for selected key currencies. Read more about how Novo Nordisk manages this risk in notes 4.2 and 4.3 on pp 79[83.

In the course of conducting business globally, transfer pricing disputes with tax authorities may occur. Novo Nordisk policy is to pursue a competitive tax level, meaning at or below the average for the company[]s peer group, in a responsible way. This means paying relevant tax in jurisdictions where business activity generates profits. As a general rule, Novo Nordisk affiliates pay corporate taxes in the countries in which they operate.

To manage uncertainties regarding tax, Novo Nordisk has negotiated multi-year transfer pricing agreements with tax authorities in key markets. Read more about taxes paid by Novo Nordisk in 2013, in note 2.4 on pp 68[70.

# Information technology risks

Well-functioning IT systems are critical for Novo Nordisk∏s ability to operate effectively. Furthermore, they hold confidential information that if disclosed could have a severe impact on Novo Nordisk∏s competitive situation. An information security strategy is in place to mitigate the risk of intruders causing damage to systems and gaining access to critical data. Specific measures include awareness

AIC with a few observations, which have no material impact on Novo Nordisk<sup>1</sup>s business in China.

This example underlines the potential business ethics risks associated with being a pharmaceutical company. To minimise the risk of violating national and international regulations, over the past decade Novo Nordisk has strengthened its global and regional business ethics compliance programmes. Global governance, a business ethics policy and global business ethics procedures, together with elaborate training programmes and tests for employees, close monitoring of performance, reporting requirements and audits, all aim to mitigate business ethics risks.

In June 2011, Novo Nordisk settled two civil cases with the US Department of Justice regarding alleged improper marketing of NovoSeven<sup>®</sup>. As part of the settlement, Novo Nordisk□s US affiliate entered into a five-year Corporate Integrity Agreement with the Office of the Inspector General of the US Department of Health and Human Services. Under that agreement, the US affiliate has added additional reporting and other procedures to its already robust compliance programme.

Also in the US, Novo Nordisk is a defendant in product liability lawsuits related to hormone therapy products and Victoza<sup>®</sup>. Read more about these and other pending litigations against Novo Nordisk and investigations involving the company, in note 3.6 on pp 74[]76. regulatory requirements and it includes standard operating procedures, quality controls and release, quality audits, quality improvement plans and systematic senior management reviews. For information on Novo Nordisk[s product safety monitoring, authority inspection status and product recalls, read more on pp 36[]37 and 38[]41 and in note 4.2 on p 100.

#### **Financial risks**

Novo Nordisk s main financial risks relate to exchange rates and tax disputes.

Novo Nordisk∏s reporting currency and the functional currency of corporate operations is the Danish krone, which is closely linked to the European euro in a narrow range of ±2.25%. However, the majority of the company∏s sales are in US dollars, European euros, Chinese yuan, Japanese yen and British pounds. Exchange rate risk is therefore the company□s biggest financial risk and the risk has grown in importance as the size of international markets and the share of sales in different currencies have increased. To manage this risk, the company

campaigns, access controls, and intrusion detection and prevention systems.

## Business ethics and legal risks

Business ethics violations and patent and contract disputes are the main risks in this area.

The pharmaceutical industry is tightly regulated in many respects, including which promotional claims it can make about its products and how it can interact with doctors and other healthcare professionals.

In June 2013, news broke in China of a government investigation into the business practices of an international pharmaceutical company. At the same time the Chinese government announced industry-wide measures to crack down on illegal business activities. Subsequently, several companies, including Novo Nordisk, were visited by the authorities. In August, Novo Nordisk s facilities in Tianjin were visited by the local Administration for Industry and Commerce (AIC) and asked to provide information regarding the company∏s operations in Tianjin City. The investigation has been closed by the

Protection of intellectual property through patents is very important for promoting innovation and stimulating long-term economic growth and job creation. Novo Nordisk∏s business model is based on developing new, innovative products, and when the company makes significant new inventions it will typically seek to patent them. Intellectual property risks occur if, for example, a government does not recognise the validity of patents or is unable to uphold patent rights, or if a competitor infringes a Novo Nordisk patent or challenges its validity.

### Novo Nordisk[]s risk management policy

In Novo Nordisk we will proactively manage risk to ensure continued growth of our business and to protect our people, assets and reputation. This means that we will:

> utilise an effective and integrated risk management system while maintaining business flexibility

identify and assess material risks associated with our business

monitor, manage and mitigate risks.

For more information on Novo Nordisk[]s risk management process, please visit novonordisk.com/about\_us.

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# **Shares and capital structure**

Novo Nordisk has two classes of shares: A shares and B shares. All A shares are owned by Novo A/S [] a wholly owned subsidiary of the Novo Nordisk Foundation. Novo Nordisk[]s B shares are listed on NASDAQ OMX Copenhagen, and on the New York Stock Exchange as American Depository Receipts (ADRs). Through open and proactive communication, the company seeks to provide the basis for fair and efficient pricing of its B shares.

#### Share capital and ownership

Novo Nordisk is total share capital of DKK 550,000,000 is divided into an A share capital of nominally DKK 107,487,200 and a B share capital of nominally DKK 442,512,800, of which Novo Nordisk A/S and its wholly owned affiliates held nominal DKK 20,570,405 as treasury shares as of 31 December 2013.

To secure liquidity for both the Novo Nordisk B shares and American Depositary Receipts (ADRs) and bring price levels in line with market practice, especially for the ADRs, a stock split of the Novo Nordisk B shares and ADRs was implemented in January 2014. Following the five for one stock split, Novo Nordisk[]s A and B shares are calculated in units of DKK 0.20. The ratio of Novo Nordisk[]s B shares to ADRs remains one-to-one.

The company ☐s A shares are not listed and are held by Novo A/S, a Danish public limited liability company wholly owned by the Novo Nordisk Foundation. The Novo Nordisk Foundation has a dual objective: to provide a stable basis for commercial and research activities conducted by the companies within the Novo Group (of which Novo Nordisk is the largest), and to support scientific and humanitarian purposes. According to the Articles of Association of the Foundation, the A shares cannot be divested. As of 2013, Novo A/S also held nominal value DKK 32,762,800 of B share capital. Each A share carries 200 votes and each B share carries 20 votes. With 25.5% of the total share capital, Novo A/S controls 74% of the total number of votes, excluding Novo Nordisk[]s holding of treasury shares.

The B shares are issued to the bearer but may, on request, be registered in the holder s name in Novo Nordisk s register of shareholders. As Novo Nordisk S B shares are in bearer form, no complete record of all shareholders exists. Based on available sources of information about the company∏s shareholders as of 31 December 2013. it is estimated that shares were distributed as shown in the charts on this page. As of 31 December 2013, the free float of listed B shares was 87.9%, excluding the Novo A/S holding and Novo Nordisk s holding of treasury shares. For details on share capital, see note 4.1 on pp **78□79**.

### The capital structure

Novo Nordisk[]s Board of Directors and Executive Management consider that the current capital and share structure of Novo Nordisk serves the interests of the shareholders and the company well, as it provides strategic flexibility to pursue Novo Nordisk[]s vision and a good balance between long-term return in the short term. Novo Nordisk⊓s guiding principle is that any excess capital, after the funding of organic growth opportunities and potential acquisitions, is returned to investors. The company applies a pharmaceutical industry payout ratio to dividend payments complemented by share repurchase programmes. As decided at the 2013 Annual General Meeting, a reduction of the company s B share capital, corresponding to approximately 1.8% of the total share capital, was implemented in April 2013 by cancellation of treasury shares. This enabled Novo Nordisk to continue to buy back shares without exceeding the limit for a holding of treasury shares equivalent to 10% of the total share capital. During the 12-month period since the release of the financial results for 2012, Novo Nordisk repurchased shares worth DKK 14 billion. Since 2008, the share repurchase programme has primarily been conducted in accordance with the provisions of European Commission Regulation No 2273/2003 of 22 December 2003 (also known as the Safe Harbour Regulation). In this programme Novo Nordisk appoints financial institutions as lead managers to execute a part of its share repurchase programme independently and without influence from Novo Nordisk.

31 December

shareholder value creation and competitive shareholder

### Share repurchase programme for 1 February 2014 to 31 January 2015

For the next 12 months, Novo Nordisk has decided to implement a new share repurchase programme with an expected total repurchase value of B shares amounting to a cash value of up to DKK 15 billion. Novo Nordisk expects to implement the majority of the new share repurchase programme according to the Safe Harbour Regulation. At the 2014 Annual General Meeting, the Board of Directors will propose a further reduction of the company∏s B share capital, corresponding to approximately 3.6% of the total share capital, by cancellation of 20 million treasury shares. After implementation of the share capital reduction, Novo Nordisk⊓s share capital will amount to DKK 530,000,000 divided into an A share capital of DKK 107,487,200 and a B share capital of DKK 422,512,800, corresponding to 537,436,000 A shares and 2,112,564,000 B shares of DKK 0.20.

Breakdown of shareholders % of capital (% of votes)Novo A/S, Bagsværd, Denmark Novo Nordisk A/S Other 25.5 (74.0) 3.7 (0.0) 70.8 (26.0)

Geographic distribution of shareholders\* % of share capital (2012 % of share capital) Denmark North America UK and Ireland Other \* Calculated using shareholders registered home country. 41.1 (40.4) 31.9 (34.0) 12.8 (12.9) 14.2 (12.7)

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#### Share price performance

Novo Nordisk share price increased by 8.5% from its 2012 close of DKK 916.50 to its 31 December 2013 close of DKK 994.00 for B shares with a nominal value of DKK 1. Following the stock split, the comparable share prices for B shares with a nominal value of DKK 0.20 were DKK 183.30 and DKK 198.80 at the end of 2012 and 2013 respectively. In comparison, the MSCI Europe Health Care and MSCI US Health Care indexes increased by 20% and 36% respectively during 2013. The smaller increase in Novo Nordisk∏s share price compared with the two indexes is assumed to reflect a negative impact from the delay in the US regulatory process for Tresiba® (insulin degludec), which has only partly been offset by an expanded leadership position in the growing diabetes care market, coupled with a continued improvement in operating margin and encouraging outlook for the rest of the research and development product portfolio. Read more about financial performance on p 6 and about developments in the pipeline on pp 20[21. The total market value of Novo Nordisk s B shares, excluding treasury shares, was DKK 419 billion at the end of 2013.

#### **Payment of dividends**

As illustrated below Novo Nordisk has continuously increased both the payout ratio and the dividend paid over the last five years. The dividend for 2012 recorded in March 2013 was equal to DKK 3.60 per share of DKK 0.20. At the 2014 Annual General Meeting, the Board of Directors will propose a dividend for 2013 of DKK 4.50 per A and B share of DKK 0.20, as well as for ADRs. The dividend for 2013 represents an increase in the dividend per share of 25% (adjusted for stock split). Novo Nordisk does not pay a dividend on its holding of treasury shares. The proposed dividend corresponds to a payout ratio of 47.1%. For 2012, the payout ratio was 45.3%, whereas Novo Nordisk∏s peer group of comparable pharmaceuticals companies operated with a payout ratio of 47%. Shareholders enquiries concerning dividend payments and shareholder accounts should be addressed to Investor Service. Read more on the back cover.

## Communication with shareholders

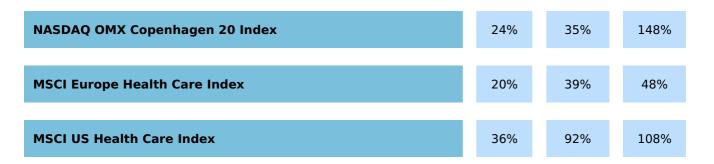
To keep investors updated on performance and the progress of clinical development programmes, Novo Nordisk hosts conference calls with Executive Management following key events and the release of financial results. Executive Management and Investor Relations also travel extensively to ensure that all investors with a major holding of Novo Nordisk shares can meet with the company on a regular basis and that a number of smaller investors and potential investors also have access to the company[]s Management and Investor Relations.

#### Analyst coverage

Novo Nordisk is currently covered by 34 sell-side analysts, including the major global investment banks that regularly produce research reports on Novo Nordisk. A list of analysts covering Novo Nordisk can be found at novonordisk.com/investors, where company announcements from 1995 onwards, financial, social and environmental results, a calendar of investor-relevant events, investor presentations, background information etc are also available.

# Novo Nordisk s share performance compared with benchmark indexes





Dividend payments and payout ratio Dividend per share for the year1 (left) Payout ratio2 (right) 1. Adjusted for the five for one stock split implemented as of 2 January 2014. 2. Dividend for the year as a percentage of net profit. 3. Proposed dividend for the financial year 2013. DKK

Price development and monthly turnover of Novo Nordisk s B shares on NASDAQ OMX Copenhagen 2013 Turnover of B shares (left) Novo Nordisk s B share closing prices (right) DKK billion DKK Total shareholder return Per cent

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# Corporate governance

In 2013, the Board of Directors established a Nomination Committee to enhathe process for nominating members to the Board of Directors. The Board of Directors also increased its diversity ambition and set new targets for 20

## **Governance structure**

#### Shareholders

Shareholders have ultimate authority over the company and exercise their rights to make decisions at general meetings in person, by proxy or by correspondence. Resolutions can generally be passed by a simple majority. However, resolutions to amend the Articles of Association require two-thirds of votes cast and capital represented, unless other adoption requirements are imposed by the Danish Companies Act. Novo Nordisk is not aware of the existence of any agreements with or between shareholders on the exercise of votes or control of the company.

At the annual general meeting, shareholders approve the annual report and any amendments to the company s Articles of Association. Shareholders also elect board members and the independent auditor.

Novo Nordisk[]s share capital is divided into A shares and B shares. Special rights attached to A shares include pre-emptive subscription rights in the event of an increase of the A share capital, pre-emptive purchase rights in the event of a sale of A shares and priority dividend if the dividend is below 0.5%. B shares take priority for dividends between 0.5% and 5% and for liquidation proceedings. Read more about shares and capital structure on pp 44[45.

#### **Board of Directors**

Novo Nordisk has a two-tier management structure consisting of the Board of Directors and Executive Management. The two bodies are separate and no one serves as a member of both. The Board of Directors determines the company is overall strategy and follows up on its implementation, supervises the performance, ensures adequate management and organisation, and as such actively contributes to developing the company as a focused, sustainable, global pharmaceutical company. The Board of Directors supervises Executive Management in its decisions and operations. The Board of Directors may also issue new shares or buy back shares in accordance with authorisations granted by the annual general meeting and recorded in the meeting minutes. For minutes from annual general meetings, see novonordisk.com/about us.

The Board of Directors has 11 members, seven of whom are elected by shareholders and four by employees in Denmark. Shareholder-elected board members serve a one-year term and may be re-elected. Members must retire at the first annual general meeting after reaching the age of 70. Four of the seven shareholder-elected board members are independent as defined by the Danish Corporate Governance Recommendations. Read more on pp

#### 52∏53.

A proposal for nomination of board members is presented by the newly established Nomination Committee to the Board of Directors, taking into account required competences as defined by the Board of Directors[] competence

profile and reflecting the result of a self-assessment process facilitated by internal or external consultants. The assessment process is based on written questionnaires and evaluates the Board of Directors composition and the skills of its members, including whether each board member and executive participates actively in board discussions and contributes with independent judgement.

To ensure that discussions include multiple perspectives representing the complex, global pharmaceutical environment, the Board of Directors aspires to be diverse in gender and nationality. Currently, one shareholder-elected board member is female and five of the seven shareholder-elected board members are non-Danes. In 2013, the Board of Directors increased its ambition and set out new targets with the aim that by 2017 it will consist of at least two shareholder-elected board members with Danish nationality and at least two shareholder-elected board members with a nationality other than Danish [] and at least two shareholder-elected board members of each gender. In accordance with section 99b of the Danish Financial Statements Act, Novo Nordisk discloses its mandatory diversity report at novonordisk.com/annualreport.

The self-assessment conducted in 2013 resulted in a continued focus on discussion of the current critical issues

and on management development and succession planning. In order to support continued fulfilment of the Novo Nordisk Way, criteria for board members include integrity, accountability, fairness, financial literacy, commitment and desire for innovation. Members are also expected to have experience of managing major companies that develop, manufacture and market products and services globally. The competence profile, which includes the nomination criteria, is available online at novonordisk.com/about us.

Under Danish law, Novo Nordisk semployees in Denmark are entitled to be represented by half of the total number of board members elected at the annual general meeting. In 2010, employees elected four board members from among themselves in three male and one female, all Danes. Board members elected by employees serve a four-year term and have the same rights, duties and responsibilities as shareholder-elected board members.

Novo Nordisk s Board of Directors met seven times during 2013.

#### Chairmanship

The annual general meeting directly elects the chairman and vice chairman of the Board of Directors. The Chairmanship carries out administrative tasks such as planning board meetings to ensure a balance between overall strategy-setting and financial and managerial supervision of the company. Other tasks include reviewing the fixed asset investment portfolio and recommending the remuneration of board members and Executive Management.

In practice, the Chairmanship has the role and responsibility of a remuneration committee, as the Board of Directors considers that each board member must have the opportunity to contribute actively to discussions and have access to all relevant information on remuneration.

In March 2013, the Annual General Meeting elected a new chairman, Göran Ando, and a new vice chairman, Jeppe Christiansen. See novonordisk.com/about us for a report on the Chairmanship s activities.

#### **Audit Committee**

The three members of the Audit Committee are elected by the Board of Directors among its members. Two members qualify as independent and have been designated as financial experts as defined by the US Securities and Exchange Commission (SEC). Under Danish law, two members qualify as financial experts and as independent. In 2013, an employee representative was elected as a member.

The Audit Committee assists the Board of Directors with oversight of the external auditors, the internal audit function, the procedure for handling complaints regarding accounting, internal accounting controls, auditing or financial reporting matters and business ethics matters (whistleblowing), financial, social and environmental reporting, business ethics compliance, post-completion reviews and post-investment reviews of investments, long-term incentive programmes, and in 2013 it was agreed that the Audit Committee also assists with oversight of IT security. In 2013, the Board of Directors re-elected Hannu Ryöppönen as chairman and Liz Hewitt as a member of the Audit Committee and, further, elected Stig Strøbæk as a new member. See novonordisk.com/about\_us for a report on the Audit Committee]s activities.

#### **Nomination Committee**

In 2013, the Board established a Nomination Committee consisting of four members to enhance the process for nominating members to the Board of Directors. Two members qualify as independent, while one member is an employee representative.

The Nomination Committee assists the Board with oversight of the competence profile and composition of the Board, nomination of members and committees, and other tasks on an ad hoc basis as specifically decided by the Board. In 2013, the Board of Directors elected Göran Ando as chairman and Bruno Angelici, Liz Hewitt and Anne Marie Kverneland as members of the Nomination Committee. See novonordisk.com\about\_us for a report on the Nomination Committee]s activities.

#### **Executive Management**

The Board of Directors has delegated responsibility for day-to-day management of Novo Nordisk to its Executive

## 

Management. In 2013, two new executives were appointed and Executive Management now consists of the president and chief executive officer plus six executives. They are responsible for overall conduct of the business and all operational matters, for organisation of the company as well as allocation of resources, determination and implementation of strategies and policies, direction-setting, and ensuring timely reporting and provision of information to the Board of Directors and Novo Nordisk stakeholders. Executive Management meets at least once a month and often more frequently. The Board of Directors appoints members of Executive Management and determines remuneration. The Chairmanship reviews the performance of the executives.

## Assurance

## **External audit**

The company is financial reporting and the internal controls over financial reporting processes are audited by an independent audit firm elected at the annual general meeting. The auditor acts in the interest of shareholders and expresses an audit opinion on the annual report as well as reporting any significant audit findings to the Audit Committee and the Board of Directors. As part of Novo Nordisk is commitment to its social and environmental responsibility, the company voluntarily includes an assurance report for social and environmental reporting in the annual report. The assurance provider reviews whether the social and environmental performance information covers aspects deemed to be material and verifies the internal control processes for the information reported.

### Internal audit

Novo Nordisk[]s internal audit function provides independent and objective

assurance, primarily within internal control of financial processes and business ethics.

To ensure that the internal financial audit function works independently of Executive Management, its charter, audit plan and budget are approved by the Audit Committee. The Audit Committee reviews the result of the audits and must approve the appointment, remuneration and dismissal of the head of the internal audit function.

Three other types of assurance activity [] quality audits, organisational audits and values audits, called facilitations [] help ensure that the company adheres to high-quality standards and operates in accordance with the Novo Nordisk Way.

## Compliance

Novo Nordisk[]s B shares are listed on NASDAQ OMX Copenhagen and on the New York Stock Exchange (NYSE) as American Depository Receipts (ADRs). The applicable corporate governance codes for each stock exchange and a review of Novo Nordisk[]s compliance are available at novonordisk.com/about\_us.

In accordance with section 107b of the Danish Financial Statements Act, Novo Nordisk discloses its mandatory corporate governance report at novonordisk. com/about us/corporate governance/ compliance.asp.

In 2013, new Danish corporate governance recommendations were introduced, and Novo Nordisk adheres to all but the following:

- The Board of Directors has not established a remuneration committee (but in practice the Chairmanship has such role).
- Current employment contracts for Executive Management allow in some instances for severance payments of more than 24 months fixed base salary plus pension contribution.

The majority of the Nomination Committee is members are not independent. It consists of two members who are not independent, including the Chairman, and two members who are independent. The reasons for deviating from the first two recommendations are given on pp 47 and 50. The reason for deviating from the third recommendation is that the Board of Directors finds that this composition of the Nomination Committee allows for both a representative of the majority shareholder as well as an employee representative to be on the Nomination Committee, while keeping it small.

Novo Nordisk complies with the corporate governance standards of NYSE applicable to foreign listed private issuers.

As a controlled company, Novo Nordisk is not obliged to comply with all standards established by NYSE. Furthermore, Novo Nordisk as a foreign private issuer is permitted to follow home country practice, which is the case in relation to independence requirements, audit committee, equity compensation plans, code of business conduct and ethics, and CEO certification.

The Novo Nordisk Way outlines the company s ambitions and the values that characterise the way Novo Nordisk does business and interacts with its stakeholders. Furthermore, it sets the direction for and applies to all employees in Novo Nordisk. Read more about the Novo Nordisk Way on p 4.

Novo Nordisk is part of the Novo Group and adheres to the Charter for Companies in the Novo Group, which is available online at novo.dk. However, all strategic and operational matters are solely decided by the Board of Directors and Executive Management of Novo Nordisk. Read more about the Novo Group on p 44.

## **Corporate governance codes and practices**

\* The Chairmanship is directly elected by the annual general meeting.

Compliance Governance structure Assurance

Danish and foreign laws and regulations Corporate governance standards Novo Nordisk Way Audit of financial data and review of social and environmental data (internal and external)Facilitation and organisational audit (internal) Quality audit and inspections (internal and external) Board of Directors Shareholders Executive Management Organisation Chairmanship\* Nomination Committee Audit Committee

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# Remuneration

At the Annual General Meeting in 2013, Novo Nordisk is shareholders approved that the maximum allocation for both the short- and long term incentive programmes for Executive Management was increased to 12 months base salary plus pension contribution. This was done to ensure flexibility for the Board of Directors in executive remuneration, as the benchmark had shown that elements of the executive remuneration were below market levels.

Remuneration of the Board of Directors and Executive Management is assessed on an annual basis against a benchmark of Nordic companies as well as European pharmaceutical companies that are similar to Novo Nordisk in size, complexity and market capitalisation. The results are presented to the Board of Directors by the chairman at its October meeting. The company strives for simplicity when composing the remuneration package, and its remuneration principles provide guidance for remuneration of the Board of Directors and Executive Management. These principles are available at novonordisk.com/about\_us/corporate\_governance/remuneration.asp.

#### Board of Directors remuneration

The remuneration of Novo Nordisk s Board of Directors comprises a fixed base fee, a multiplier of the fixed base fee for the Chairmanship and members of the company s Audit Committee and

Nomination Committee, fees for ad hoc tasks and a travel allowance.

At the December meeting, the Board of Directors agrees on recommendations for remuneration levels for the next financial year. In connection with the approval of the annual report, the Board of Directors endorses the actual remuneration for the past financial year and the recommendation on remuneration levels for the current financial year. These are then presented to the annual general meeting for approval.

#### **Travel and other expenses**

All board members who reside outside Denmark are paid a fixed travel allowance: 3,000 euros for Europe-based board members and 6,000 euros for board members based outside Europe. Otherwise, no travel allowance is paid to board members when attending board meetings outside Denmark. Expenses such as travel and accommodation in relation to board meetings as well as relevant continuing education are reimbursed. Novo Nordisk also pays social security taxes imposed by foreign authorities and bank transfer fees.

#### Variable remuneration

Board members are not offered stock options, warrants, restricted stock or participation in other incentive schemes.

#### **Executive Management** s remuneration

The remuneration of Novo Nordisk s Executive Management is proposed by the Chairmanship and approved by the Board

of Directors. Remuneration packages for executives comprise a fixed base salary, a cash-based incentive, a share-based incentive, a pension contribution and other benefits. The split between fixed and variable remuneration is intended to result in a reasonable part of the salary being linked to performance, while promoting sound, long-term business decisions to achieve the company[]s objectives. All incentives are subject to claw-back if

it is subsequently determined that payment was based on information that was manifestly misstated.

#### **Fixed base salary**

The fixed base salary is intended to attract and retain executives with the professional and personal competences required to drive the company s performance.

#### **Cash-based incentive**

The cash-based incentive is designed to incentivise individual performance and achievement of a number of predefined short-term functional and individual business targets linked to goals in the company s Balanced Scorecard. Short-term targets for the chief executive officer are fixed by the chairman of the Board of Directors, while the targets for the other members of Executive Management are fixed by the chief executive officer. The Chairmanship evaluates the degree of achievement for each member of Executive Management based on input from the chief executive officer.

## **Board of Directors**

In 2013, the base fee for members of the Board of Directors was DKK 500,000 (DKK 500,000 in 2012)

		2013				2012		
DKK million	Fixed base fee	Fee for ad hoc tasks and committee work	Travel allowance	Total	Fixed base fee	Fee for ad hoc tasks and committee work	Travel allowance	Total
Göran Ando <sup>3, 4</sup> (chairman of the Board and of the Nomination Committee)	1.4		0.1	1.5	1.0		0.1	1.1
Jeppe Christiansen <sup>1</sup> (vice chairman of the Board)	0.8			0.8				
Hannu Ryöppönen (chairman of the Audit Committee) Liz Hewitt <sup>1</sup>	0.5	0.5	0.1	1.1	0.5	0.4	0.1	1.0
(member of the Audit Committee and the Nomination Committee)	0.5	0.3	0.1	0.9	0.4	0.2	0.1	0.7
Stig Strøbæk (member of the Audit Committee) Bruno Angelici	0.5	0.2		0.7	0.5			0.5
(member of the Nomination Committee)	0.5	0.1	0.1	0.7	0.5		0.1	0.6
Henrik Gürtler	0.5			0.5	0.5			0.5

Total	7.2	1.3	0.7	<b>9.2</b> <sup>5</sup>	7.5	1.0	0.8	<b>9</b> .3 <sup>5</sup>
Jørgen Wedel <sup>2</sup>					0.1	0.1	0.1	0.3
Kurt Anker Nielsen²	0.1	0.1		0.2	0.5	0.3		0.8
Steen Scheibye <sup>2</sup>	0.4			0.4	1.5			1.5
Committee) Søren Thuesen Pedersen	0.5			0.5	0.5			0.5
Anne Marie Kverneland (member of the Nomination	0.5	0.1		0.6	0.5			0.5
Thomas Paul Koestler	0.5		0.3	0.8	0.5		0.3	0.8
Ulrik Hjulmand-Lassen	0.5			0.5	0.5			0.5

Liz Hewitt was first elected at the Annual General Meeting in March 2012, and Jeppe Christiansen was first elected at the

1. Annual General Meeting in March 2013.

2. Jørgen Wedel resigned as of March 2012. Steen Scheibye and Kurt Anker Nielsen resigned as of March 2013.

3. Novo Nordisk provides secretarial assistance to the chairman in Denmark and the UK.

As Göran Ando also holds the position of chairman of the Board, he has not received a fee as chairman of the Nomination 4. Committee.

In addition, social security taxes have been paid by Novo Nordisk amounting to less than DKK 1 million (less than DKK 1 5. million in 2012).

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In 2013, the Annual General Meeting approved that the maximum allocation per year cannot exceed 12 months base salary plus pension contribution, and in March the Board of Directors determined that the 2013 maximum would be up to 10 months.

#### **Share-based incentives**

The long-term share-based incentive programme is designed to promote the collective performance of Executive Management and align the interests of executives and shareholders. Share-based incentives are linked to both financial and non-financial targets.

The long-term incentive programme is based on a calculation of shareholder value creation compared with planned performance. In line with Novo Nordisk is long-term financial targets, the calculation of shareholder value creation is based on reported operating profit after tax reduced by a weighted average cost of capital-based return requirement on average invested capital. A proportion of the calculated shareholder value creation is allocated to a joint pool for the participants, who include Executive Management and other members of the Senior Management Board.

#### Pension

Pension contributions are paid to enable executives to build up an income for retirement.

#### **Other benefits**

Other benefits are added to ensure that overall remuneration is competitive and aligned with local practice. Such benefits are approved by the Board of Directors via delegation of powers to the Chairmanship. In addition, executives may participate in employee benefit programmes such as employee share purchase programmes.

#### Severance payment

Novo Nordisk may terminate employment by giving executives 12 months notice. Executives may terminate their employment by giving Novo Nordisk six months notice. In addition to the notice period, executives are entitled to a severance payment.

Current employment contracts allow severance payments of up to 36 months[]

fixed base salary plus pension contribution in the event of a merger, acquisition or takeover of Novo Nordisk. If an executive semployment is terminated by Novo Nordisk for other reasons, the severance payment is three months fixed base salary plus pension contribution per year of employment as an executive, taking into account previous employment history. In no event will the severance payment be less than 12 months or more than 36 months fixed base salary plus pension contribution.

The existing employment contracts will not be changed. For the two executives who joined Executive Management in 2013 and for all future employment contracts for executives, the severance payment will be no more than 24 months fixed base salary plus pension contribution, which will bring Novo Nordisk into alignment with the Danish Corporate Governance Recommendations in the long term.

Non-financial targets are determined on the basis of an assessment of the objectives regarded as particularly important to the fulfilment of the company is long-term performance. These are typically related to reaching specific milestones within research and development, such as execution of trials, product approvals and product launches, or milestones within sustainability related to patients, environment, company reputation and

development of employees. The total number of non-financial targets varies, but is typically made up of 10[15 targets within five to six categories.

In 2013, the Annual General Meeting approved that the maximum allocation per year cannot exceed 12 months[] base salary plus pension contribution and in March the Board of Directors determined that the 2013 maximum for Executive Management would be nine months. If the financial target is met for economic profit, and at least 85% performance is reached on non-financial targets, the allocation to the joint pool would correspond to 4½ months[] base salary plus pension contribution for Executive Management.

This pool is then converted into Novo Nordisk B shares, which in any given year are locked up for three years before they are transferred to the participants. The shares in the joint pool are allocated to the participants prorated according to their base salary as per 1 April in any given year. If a participant resigns during the lock-up period, his or her shares will remain in the joint pool for the benefit of the other participants.

Further information on Novo Nordisk share-based incentives is available online at novonordisk.com/about\_us.

Remuneration	 ve Comments relating nent to Executive Management
Fixed fee/base salary	Accounts for $30$ ]55% of the total value of the remuneration package*
Fee for committee work	
Fee for ad hoc tasks	
Cash bonus	Up to 6[]10 months[] fixed base salary + pension contribution per year
Share-based incentive	Up to 9 months[] fixed base salary + pension contribution per year
Pensions	25 30% of fixed base salary and cash-based incentive
Travel and other expenses	
Benefits	Non-monetary benefits such as company car and phone
Severance payment	Up to 24 months[] fixed base salary + pension. The employment contracts entered into before 2008 exceed the 24-month limit, though will not exceed 36months[] fixed base salary plus pension contribution

## **Remuneration package components**

\* The interval 30[]55% states the span between []maximum performance[] and []on-target performance[].

# Delayed approval of Tresiba<sup>®</sup> in the US reduces share allocation in the 2013 incentive programme

While Novo Nordisk exceeded the planned financial performance in 2013, the company did not meet its target of having Tresiba® approved in the US due to the Complete Response Letter from the US Food and Drug Administration (FDA) in February. This event also entailed that the target for the submission of IDegLira for regulatory approval to the FDA could not be met. As a

consequence of these shortcomings, the allocation of shares under the long-term incentive programme was reduced. For 2013, Executive Management was allocated an amount equal to 4.75 months[] fixed base salary plus pension contribution per member compared with a potential maximum allocation of nine months.

## **Remuneration of the Executive Management and other members of the Senior Management Board**

	2013				2012							
DKK million	Fixed base salary	Cash bonus	Pension	Benefits	Share- based incentive	Total	Fixed base salary	Cash bonus	Pension	Benefits	Share- based incentive	Total
Executive Management Lars Rebien	10.1	5.1	3.8	0.3	П	19.3	8.4	2.9	2.8	0.3	П	14.4
Sørensen Jesper Brandgaard Lars	5.7	2.4	2.0	0.3		10.4	4.8	1.6	1.6	0.3		8.3
Fruergaard Jørgensen <sup>1</sup>	4.1	1.4	1.4	0.3		7.2						
Lise Kingo	5.1	1.9	1.8	0.3		9.1	4.3	1.1	1.4	0.3		7.1
Jakob Riis <sup>1</sup>	4.1	1.4	1.4	0.3		7.2						
Kåre Schultz	6.3	2.7	2.4	0.3		11.7	5.2	1.4	1.7	0.3		8.6
Mads Krogsgaard Thomsen	5.7	2.4	2.0	0.3		10.4	4.8	1.6	1.6	0.3		8.3
Executive Management in total	41.1	17.3	14.8	2.1		75.3	27.5	8.6	9.1	1.5		46.7
Other members of the Senior Management Board in total <sup>2</sup>	82.74	32.3	25.5	14.4		154.9	72.14	25.0	22.3	8.4		127.8
Share allocation <sup>3</sup>					51.5	51.5					73.1	73.1

- 1. Effective 31 January 2013, Novo Nordisk S Executive Management was expanded to include two new members, Jakob Riis and Lars Fruergaard Jørgensen.
- 2. The total remuneration for 2013 includes remuneration to 33 senior vice presidents (26 in 2012), five of whom have retired or left the company (none in 2012). The 2013 remuneration for the retired senior vice presidents is included in the table above, whereas severance payments of DKK 57.2 million are not included.
- 3. The joint pool of shares is locked up for three years before it is transferred to the participants employed at the end of the three-year period. The value is the cash amount of the share bonus granted in the year using the grant-date market value of Novo Nordisk B shares. Based on the split of participants at the establishment of the joint pool, approximately 40% of the pool will be allocated to the members of Executive Management and 60% to other members of the Senior Management Board (2012: 30% and 70%, respectively). In the lock-up period, the joint pool may potentially be reduced in the event of lower-than-planned value creation in subsequent years.
- 4. Including social security taxes paid amounting to DKK 2.0 million (DKK 1.5 million in 2012).

## Management[]s long-term incentive programme

The shares allocated to the joint pool for 2010 (842,880 shares) were released to the individual participants subsequent to the approval of the Annual Report 2013 by the Board of Directors and the announcement on 30 January 2014 of the full-year financial results for 2013. Based on the share price at the end of 2013, the value of the released shares is as follows:

Value as at 31 December 2013 of shares released on 30 January 2014	Number of shares	Market value <sup>1</sup> (DKK million)
Executive Management		
Lars Rebien Sørensen	74,985	14.9
Jesper Brandgaard	49,990	9.9
Lars Fruergaard Jørgensen	24,995	5.0
Lise Kingo	49,990	9.9
Jakob Riis	24,995	5.0
Kåre Schultz	49,990	9.9
Mads Krogsgaard Thomsen	49,990	9.9
Executive Management in total	324,935	64.5
Other members of the Senior Management Board in total <sup>2</sup>	392,970	78.1

1. The market value of the shares released in 2014 is based on the Novo Nordisk B share price of DKK 198.80 at the end of 2013.

2. In addition, 124,975 shares (market value: DKK 24.8 million) were released to retired members of the Senior Management Board.

Lars Rebien Sørensen serves as a board member of Danmarks Nationalbank, from which he received remuneration of DKK 22,232 in 2013 (DKK 22,012 in 2012), as a member of the Supervisory Board of Bertelsmann AG, from which he received remuneration of EUR 122,000 in 2013 (EUR 129,000 in 2012) and as a board member of Thermo Fisher Scientific Inc, from which he received remuneration of USD 314,786 in 2013 (USD 219,840 in 2012). Jesper Brandgaard serves as chairman of the Board of Directors of SimCorp A/S, from which he received remuneration of DKK 871,068 in 2013 (DKK 801,846 in 2012). Kåre Schultz serves as a board member of LEGO A/S, from which he received remuneration of DKK 350,000 in 2013 (DKK 300,000 in 2012). Kåre Schultz also serves as chairman of the Board of Directors of Royal Unibrew A/S, from which he received remuneration of DKK 625,000 in 2013 (DKK 625,000 in 2012). Mads Krogsgaard Thomsen serves as a board member of the University of Copenhagen, from which he received remuneration of DKK 79,800 in 2012). Lise Kingo serves as a board member of Grieg Star Group AS from April 2013, from which she received remuneration of NOK 225,000. Jakob Riis serves as a board member of ALK-Abelló A/S, from which he received remuneration of DKK 375,000 in 2013.

# **Board of Directors**

Göran Ando (chair)

Formerly CEO of Celltech Group plc, UK (retired). Member of the Board of Novo Nordisk A/S in 2005, vice chair since 2006, chair since 2013 and chair of the Nomination Committee since 2013.

#### Management duties:

Symphogen A/S, Denmark (chair), member of the boards of Novo A/S, Denmark, Molecular Partners AG, Switzerland, Archimedes Pharma Ltd., UK, and RAND Health, US. Senior advisor to Essex Woodlands Health Ventures Ltd., UK.

**Special competences:** Medical qualifications and extensive executive background within the international pharmaceutical industry.

**Education:** Specialism in general medicine (1978) and degree in medicine (1973), both from Linköping Medical University, Sweden.

## Jeppe Christiansen (vice chair)

Chief executive officer of Fondsmæglerselskabet Maj Invest A/S, Denmark. Vice chair of the Board of Novo Nordisk A/S since 2013.

**Management duties:** Member of the boards of Novo A/S, Haldor Topsøe A/S, KIRKBI A/S and Symphogen A/S, all in Denmark.

**Special competences:** Extensive background and experience within the financial sector, in particular in relation to financial and capital market issues, as well as insight into the investor perspective.

**Education:** MSc in Economics (1985) from the University of Copenhagen, Denmark.

## **Bruno Angelici**

Formerly executive vice president of AstraZeneca (retired). Member of the Board of Novo Nordisk A/S since 2011 and member of the Nomination Committee since 2013.

**Management duties:** Member of the boards of Smiths Group plc and Vectura Group plc, both in the UK, and Wolters Kluwer, the Netherlands. Member of the Global Advisory Board at Takeda Pharmaceutical Company Limited, Japan.

#### **Special competences:**

Extensive global experience with two companies in the fields of pharmaceuticals and medical devices, and in-depth knowledge of strategy, sales, marketing and governance of major companies.

**Education:** AMP (1993) from Harvard Business School and MBA (1978) from Kellogg School of Management at Northwestern University, both in the US. Law degree (1973) from Reims University and BA in Business Administration (1971) from École Supérieure de Commerce de Reims, both in France.

## Henrik Gürtler

President and CEO of Novo A/S, Denmark, since 2000. Formerly a member of Corporate Management of Novo Nordisk A/S with special responsibility for Corporate Staffs. Member of the Board of Novo Nordisk A/S since 2005.

Management duties:

## Liz Hewitt

Formerly Group Director Corporate Affairs of Smith & Nephew plc, UK (retired). Member of the Board of Novo Nordisk A/S since 2012, and member of the Audit Committee since 2012 and the Nomination Committee since 2013.

Management duties: Member of

## Ulrik Hjulmand-Lassen

Advanced IT quality advisor in the IT QA Office. Member of the Board of Novo Nordisk A/S since 2010.

**Education:** CISM (2011). Trained as an MCSA/IT Security (2009) and as an ISO 9001 lead auditor (2006). BSc (1985) from the Technical University of

Novozymes A/S (chair) and Copenhagen Airports A/S (chair), both in Denmark.

#### **Special competences:**

Knowledge of the Novo Group[]s business and its policies, and knowledge of the international biotech industry.

**Education:** MSc in Chemical Engineering (1976) from the Technical University of Denmark. the board, audit committee (chair), remuneration committee and nomination committee of Synergy Health plc and member of the board of Melrose Industries plc, both in the UK. External member of the audit committee of the House of Lords, UK.

**Special competences:** Extensive experience within the field of medical devices, significant financial knowledge and knowledge of how large international companies operate.

**Education:** BSc (Econ) (Hons) (1977) from University College London, UK, and FCA (UK Institute of Chartered Accountants) (1982). Denmark/DIA-E.

Name (male/female)	First elected	TermNationality	Born	Independence
Göran Ando (m)	2005	2014 Swedish	March 1949	Not independent <sup>2</sup>
Jeppe Christiansen (m)	2013	2014 Danish	November 1959	Not independent <sup>2</sup>
Bruno Angelici (m)	2011	2014 French	April 1947	Independent
Henrik Gürtler (m)	2005	2014 Danish	August 1953	Not independent <sup>2</sup>
Liz Hewitt (f)	2012	2014 British	November 1956	Independent <sup>4,5</sup>
Ulrik Hjulmand-Lassen <sup>3</sup> (m)	2010	2014 Danish	April 1962	Not independent

**1.** As designated by NASDAQ OMX Copenhagen in accordance with section 3.2.1 of *Recommendations on Corporate Governance* (2013). **2.** Member of Management or the Board of Novo A/S. **3.** Elected by employees of Novo Nordisk.

## **Thomas Paul Koestler**

Executive with Vatera Holdings LLC, US. Member of the Board of Novo Nordisk A/S since 2011. **Management duties:** Melinta Therapeutics Inc. (chair), US. Member of the boards of Momenta Pharmaceuticals Inc., ImmusanT Inc. and Arisaph Pharmaceuticals Inc., all in the US.

#### **Special competences:** Extensive R&D knowledge, both generally and within the field of regulatory affairs. Significant know-how about the pharmaceutical industry in general and how large international corporations operate. Additional knowledge of the US market. **Education:** PhD in Medicine & Pathology (1982) from the Roswell Park Memorial Institute and BSc in Biology (1975) from Daemen College, both in the US.

## Hannu Ryöppönen

Formerly CFO and deputy CEO of Stora Enso Oyj, Finland (retired). Member of the Board of Novo Nordisk A/S since 2009 and chair of the Audit Committee since 2012 (member since 2009). Management duties: Private equity funds Altor 2003 GP Limited (chair), Altor Fund II GP Limited (chair) and Altor III GP Limited (chair), all in Jersey, Channel Islands. BillerudKorsnäs AB (chair), Sweden. Member of the boards of Amer Sports Oyj, Finland, and the private equity fund Value Creation Investments Limited, Jersey, Channel Islands. Chair of the audit committee of Amer Sports Oyj, Finland.

**Special competences:** 

## **Anne Marie Kverneland**

Laboratory technician and full-time shop steward. Member of the Board of Novo Nordisk A/S since 2000 and member of the Nomination Committee since 2013.

**Education:** Degree in Medical Laboratory Technology (1980) from Copenhagen University Hospital, Denmark.

## Søren Thuesen Pedersen

External affairs director in Quality Intelligence. Member of the Board of Novo Nordisk A/S since 2006.

Management duties: Member of the board of the Novo Nordisk Foundation since 2002. Education: BSc in Chemical Engineering (1988) from the Engineering Academy of Denmark.

## Stig Strøbæk

Electrician and full-time shop steward. Member of the Board of Novo Nordisk A/S since 1998 and member of the Audit Committee since 2013. **Management duties:** Member of

the board of the Novo Nordisk Foundation since 1998. **Education:** Diploma as an electrician. Diploma in further training for board members (2003) from the Danish Employees[] Capital Pension Fund (LD). International executive background and thorough understanding of managing finance operations in global organisations, in particular in relation to accounting, financial and capital market issues, but also experience in private equity and mergers & acquisitions (M&A).

**Education:** BA in Business Administration (1976) from Hanken School of Economics, Helsinki, Finland.

Name (male/female)	First elected	<b>Term Nationality</b>	Born	Independence <sup>1</sup>
Thomas Paul Koestler (m)	2011	2014 American	June 1951	Independent
Anne Marie Kverneland <sup>3</sup> (f)	2000	2014 Danish	July 1956	Not independent
Søren Thuesen Pedersen <sup>3</sup> (m)	2006	2014 Danish	December 1964	Not independent
Hannu Ryöppönen (m)	2009	2014 Finnish	March 1952	Independent <sup>4,5</sup>
Stig Strøbæk <sup>3</sup> (m)	1998	2014 Danish	January 1964	Not independent

**4.** Mr Ryöppönen and Ms Hewitt qualify as independent Audit Committee members as defined by the US Securities and Exchange Commission (SEC). **5.** Mr Ryöppönen and Ms Hewitt qualify as independent Audit Committee members as defined under part 8 of the Danish Act on Approved Auditors and Audit Firms.

# **Executive Management**

## Lars Rebien Sørensen

President and chief executive officer\*

Lars Rebien Sørensen joined Novo Nordisk[]s Enzymes Marketing in 1982. Over the years, he has completed several overseas postings, including in the Middle East and the US. He was appointed a member of Corporate Management in May 1994, and in December 1994 was given special responsibility within Corporate Management for Health Care. He was appointed president and chief executive officer in November 2000.

Other management duties:

Member of the boards of Danmarks Nationalbank, Denmark, and Thermo Fisher Scientific Inc., US. Member of the Bertelsmann AG Supervisory Board, Germany. **Born:** October 1954.

## Kåre Schultz

Chief operating officer\*

Kåre Schultz joined Novo Nordisk in 1989 as an economist in Health Care, Economy & Planning. In November 2000, he was appointed executive vice president and chief of staffs. In March 2002, he took over the position of executive vice president and chief operating officer.

Other management duties:

Chair of the board of Royal Unibrew A/S and member of the board of LEGO A/S, both in Denmark.

Born: May 1961.

## Jesper Brandgaard

Chief financial officer

Jesper Brandgaard joined Novo Nordisk in 1999 as senior vice president of Corporate Finance. He was appointed executive vice president and chief financial officer in November 2000.

Other management duties: Chair of the boards of SimCorp A/S and NNIT A/S, both in Denmark. Born: October 1963.

## Lars Fruergaard Jørgensen

Chief information officer

Lars Fruergaard Jørgensen joined Novo Nordisk in 1991 as an economist in Health Care, Economy & Planning and has over the years completed overseas postings in the US and Japan. In 2004, he was appointed senior vice president for IT & Corporate Development. In January 2013, he was appointed executive vice president and chief information officer, assuming responsibility for IT, Quality & Corporate

Development.

### Other management duties:

Vice chair of the board of NNE Pharmaplan A/S and member of the board of NNIT A/S, both in Denmark.

Born: November 1966.

Mads Krogsgaard Thomsen

## Chief of staffs

Lise Kingo joined Novo Industry A/S in 1988 and worked over the years to build up the company[s Triple Bottom Line business principle. In 1999, she was appointed senior vice president, Stakeholder Relations. In 2002, she was appointed executive vice president and chief of staffs, assuming global responsibility for Corporate Relations. She is adjunct professor at the Medical Faculty, Vrije Universiteit, Amsterdam, the Netherlands.

#### Ansterdam, the Netherlands.

#### Other management duties: Chair of the board of Steno

Diabetes Center A/S, Denmark, and member of the board of Grieg Star Group AS, Norway. Chair of the Danish Council for Corporate Responsibility.

Born: August 1961.

Executive vice president of Marketing & Medical Affairs

Jakob Riis joined Novo Nordisk in 1996 as a health economist. From 2001 to 2005, he worked first in the US sales force and then as head of marketing in Japan. In 2005, he was appointed senior vice president for International Marketing. In January 2013, he was appointed executive vice president, assuming responsibility for Marketing & Medical Affairs.

**Other management duties:** Chair of the board of Copenhagen Institute of Interaction Design and member of the board and audit committee of ALK-Abelló A/S, both in Denmark.

Born: April 1966.

Chief science officer

Mads Krogsgaard Thomsen joined Novo Nordisk in 1991 as head of Growth Hormone Research. He was appointed executive vice president and chief science officer in November 2000. He is a member of the editorial boards of international journals. He has served as president of the National Academy of Technical Sciences (ATV), Denmark. He is adjunct professor of pharmacology at the Royal Veterinary and Agricultural University (now the Faculty of Health and Medical Sciences of the University of Copenhagen), Denmark.

Other management duties:

Member of the board of the University of Copenhagen, Denmark.

Born: December 1960.

\* Effective 30 January 2014, Kåre Schultz is appointed president and chief operating officer. Lars Rebien Sørensen continues as chief executive officer.

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# Consolidated financial, social and environmental statements 2013

### **Consolidated financial statements**

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## Consolidated environmental statement (supplementary information)

<u>101</u>	Statement of environmental performance
<u>102</u>	Notes to the Consolidated environmental statement

As Novo Nordisk[]s business continues to develop, the company remains committed to documenting its performance via its integrated reporting. The Consolidated financial, social and environmental statements are structured to increase focus on what drives the company[]s performance in accordance with the Triple Bottom Line business principle.

Within each of the financial, social and environmental statements, the notes are grouped into sections based on how Novo Nordisk views its business. Each of the statements includes an overview of the sections and notes, and each of the sections has an introduction explaining the link between how the company does business and how this is reflected in Novo Nordisk s financial, social and environmental statements. The disclosures in the notes are structured to provide full transparency on the disclosed amounts, describing the relevant accounting policy, key accounting estimates and numerical disclosure for each note

> Juan Jenny Li works as a chemistry professional in Novo Nordisk⊡s Research and Development Centre in Beijing.

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## **Income statement**

# and Statement of comprehensive income for the year ended 31 December

DKK million	Note	2013	201	.2 2	011	
Income statement						
Net sales Cost of goods sold	2.1, 2.2 2.2, 2.3	83,572 14,140	78,02 13,46		346 589	
Gross profit		69,432	64,56	51 53,	757	
Sales and distribution costs Research and development costs Administrative costs Licence income and other operating income, net	2.2, 2.3 2.2, 2.3 2.2, 2.3 2.2, 2.3, 5.6	23,380 11,733 3,508 682	21,54 10,89 3,31 66	97 9, .2 3,	004 628 245 494	
Operating profit		31,493	29,47	4 22,	374	
Financial income Financial expenses	4.7 4.7	1,702 656	12 1,78		514 963	
Profit before income taxes		32,539	27,81	.1 21,	925	
Income taxes	2.4	7,355	6,37	<b>'</b> 9 4,	828	
Net profit for the year		25,184	21,43	32 17,	097	
Earnings per share						
Basic earnings per share (DKK) <sup>1</sup> Diluted earnings per share (DKK) <sup>1</sup>	4.1 4.1	9.40 9.35	7.8 7.7		5.05 5.00	
DKK million		Ν	lote	2013	2012	2011
Statement of comprehensive income						
Net profit for the year				25,184	21,432	17,097

Total comprehensive income for the year		25,053	22,458	16,582
Other comprehensive income for the year, net of tax		(131)	1,026	(515)
Cash flow hedges, realisation of previously deferred (gains)/losses Cash flow hedges, deferred gains/(losses) incurred during the period Other items Tax on other comprehensive income, income/(expense)	2.4	(809) 1,195 75 (211)	1,182 849 35 (587)	658 (1,170) (20) 190
Items that will be reclassified subsequently to the Income statement when specific conditions are met: Exchange rate adjustments of investments in subsidiaries		(435)	(172)	(173)
Other comprehensive income: Items that will not be reclassified subsequently to the Income statement: Remeasurements of defined benefit plans	3.7	54	(281)	۵

1. Comparative figures have been restated to reflect the change in trading unit from DKK 1 to DKK 0.20.

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# **Balance sheet**

at 31 December

DKK million	Note	2013	2012
Assets			
Intangible assets Property, plant and equipment Deferred income tax assets Other financial assets	3.1 3.2 2.4 4.6	1,615 21,882 4,231 551	1,495 21,539 2,244 228
Total non-current assets		28,279	25,506
Inventories Trade receivables Tax receivables Other receivables and prepayments Marketable securities Derivative financial instruments Cash at bank and on hand	3.3 3.4 3.5 4.2, 4.6 4.3 4.2, 4.4	9,552 10,907 3,155 2,454 3,741 1,521 10,728	9,543 9,639 1,240 2,705 4,552 931 11,553
Total current assets		42,058	40,163
Total assets		70,337	65,669

## Equity and liabilities

Share capital Treasury shares Retained earnings Other reserves	4.1 4.1	550 (21) 41,137 903	560 (17) 39,001 1,088
Total equity		42,569	40,632
Deferred income tax liabilities Retirement benefit obligations Provisions	2.4 3.7 3.6	672 688 2,183	732 760 1,907
Total non-current liabilities		3,543	3,399
Current debt Trade payables Tax payables Other liabilities	4.6 4.6 3.8	215 4,092 2,222 9,386	500 3,859 593 8,982

Derivative financial instruments Provisions	4.3 3.6	□ 8,310	48 7,656
Total current liabilities		24,225	21,638
Total liabilities		27,768	25,037
Total equity and liabilities		70,337	65,669

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## **Statement of cash flows**

for the year ended 31 December

DKK million	Note	2013	2012	2011
Net profit for the year		25,184	21,432	17,097
Adjustment for non-cash items	5.3	10,738	11,253	9,117
Change in working capital	4.5	(265)	274	434
Interest received		131	207	332
Interest paid		(39)	(61)	(215)
Income taxes paid	2.4	(9,807)	(10,891)	(5,391)
Net cash generated from operating activities		25,942	22,214	21,374
Proceeds from sale of other financial assets		29		
Purchase of intangible assets and other financial assets	3.1, 4.6	(406)	(250)	(259)
Proceeds from sale of property, plant and equipment		31	53	70
Purchase of property, plant and equipment	3.2	(3,238)	(3,372)	(3,073)
Net sale/(purchase) of marketable securities		811	(501)	(197)
Net cash used in investing activities		(2,773)	(4,070)	(3,459)
Repayment of loans			(502)	(507)
Purchase of treasury shares, net	4.1	(13,924)	(11,896)	(10,595)
Dividends paid	4.1	(9,715)	(7,742)	(5,700)
Net cash used in financing activities		(23,639)	(20,140)	(16,802)
Net cash generated from activities		(470)	(1,996)	1,113
Net cash generated from activities		(470)	(1,990)	1,115
Cash and cash equivalents at the beginning of the year		11,053	13,057	11,960
Exchange gains/(losses) on cash and cash equivalents		(70)	(8)	(16)
Cash and cash equivalents at the end of the year	4.4	10,513	11,053	13,057
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## Statement of changes in equity at 31 December

				Other reserves				
DKK million	Share capital	Treasury shares	Retained earnings	Exchange rate adjust- ment	Cash flow hedges	Tax and other items	Total other reserves	Total
<b>2013</b> Balance at the beginning of the year	560	(17)	39,001	226	847	15	1,088	40,632
Net profit for the year Other comprehensive income for the year			25,184 54	(435)	386	(136)	(185)	25,184 (131)
Total comprehensive income for the year			25,238	(435)	386	(136)	(185)	25,053
Transactions with owners: Dividends (note 4.1) Share-based payments (note 5.1) Tax credit related to share option scheme Purchase of treasury shares (note 4.1) Sale of treasury shares (note 4.1) Reduction of the B share capital (note 4.1)	(10)	(15) 1 10	(9,715) 409 114 (13,974) 64					(9,715) 409 114 (13,989) 65 []
Balance at the end of the year	550	(21)	41,137	(209)	1,233	(121)	903	42,569
<b>2012</b> Balance at the beginning of the year Net profit for the year Other comprehensive income for the year	580	(24)	37,111 21,432 (281)	398 (172)	(1,184) 2,031	567 (552)	(219) 1,307	37,448 21,432 1,026
Total comprehensive income for the year <i>Transactions with owners:</i> Dividends (note 4.1)			21,151 (7,742) 308	(172)	2,031	(552)	1,307	22,458 (7,742) 308

Share-based payments (note 5.1) Tax credit related to share option scheme Purchase of treasury shares (note 4.1) Sale of treasury shares (note 4.1) Reduction of the B share capital (note 4.1)	(20)	(15) 2 20	56 (12,147) 264					56 (12,162) 266 []
Balance at the end of the year	560	(17)	39,001	226	847	15	1,088	40,632
<b>2011</b> Balance at the beginning of the year Net profit for the year Other comprehensive income for the year	600	(28)	36,097 17,097	571 (173)	(672) (512)	397 170	296 (515)	36,965 17,097 (515)
Total comprehensive income for the year			17,097	(173)	(512)	170	(515)	16,582
Transactions with owners: Dividends (note 4.1) Share-based payments (note 5.1) Purchase of treasury shares (note 4.1) Sale of treasury shares (note 4.1) Tax on sale of treasury shares Reduction of the B share capital (note 4.1)	(20)	(18) 2 20	(5,700) 319 (10,821) 242 (123)					(5,700) 319 (10,839) 244 (123) [
Balance at the end of the year	580	(24)	37,111	398	(1,184)	567	(219)	37,448

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## **Notes** Sections in the Consolidated financial statements

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Read this section to get an overview of the financial accounting policies in general and an overview of Management[]s key accounting estimates.

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## Section 2 Results for the year

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## **Section 5 Other disclosures**

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# **Section 1** Basis of preparation of the Consolidated financial statements

Novo Nordisk presents its Consolidated financial statements on the basis of the latest developments in international financial reporting and strives for early adoption of EU-endorsed IFRS accounting standards.

All entities in the Novo Nordisk Group follow the same Group accounting policies. This section gives a summary of the significant accounting policies, Management[]s key accounting estimates, new IFRS requirements and other accounting policies in general. A detailed description of accounting policies and key accounting estimates related to specific reported amounts is presented in each note to the relevant financial items.

# 1.1 Summary of significant accounting policies

The Consolidated financial statements included in this Annual Report have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB), in accordance with IFRS as endorsed by the European Union and also in accordance with additional Danish disclosure requirements for annual reports of listed companies.

### **Measurement basis**

The Consolidated financial statements have been prepared on the historical cost basis except for derivative financial instruments, equity investments and marketable securities measured at fair value.

The principal accounting policies set out below have been applied consistently in the preparation of the Consolidated financial statements for all the years presented.

### **Principal accounting policies**

Novo Nordisk s accounting policies are described in each of the individual notes to the Consolidated financial statements. Considering all the accounting policies applied, Management regards the following as the most significant accounting policies for the recognition and measurement of reported amounts:

Net sales and sales deductions (notes 2.1 and 3.6)

Revenue is only recognised when, in Management is judgement, the significant risks and rewards of ownership have been transferred and when the Group does not retain managerial involvement in or effective control over the goods sold. To arrive at net sales, rebates and discounts to retail customers, government agencies, wholesalers, health insurance companies and managed healthcare organisations are deducted from gross sales. These deductions include estimates of unsettled obligations, requiring the use of judgement when estimating the effect of these sales deductions on gross sales for a reporting period.

Research and development (note 3.1 and 3.2)

Internal research costs are fully charged to the consolidated income statement in the period in which they are incurred, consistent with industry practice. Novo Nordisk considers that regulatory and other uncertainties inherent in the development of new products preclude the capitalisation of internal development costs as an intangible asset until marketing approval from the regulatory authority in a relevant major market is obtained or highly probable. The same principles are applied to plant and equipment with no alternative use developed as part of a research and development project. However, plant and equipment with alternative use or used for general research and development purposes is capitalised and depreciated over its estimated useful life as

research and development costs.

For acquired in-process research and development projects, the probability effect is reflected in the cost of the asset, and the probability recognition criteria are therefore always considered satisfied. As the cost of acquired in-process research and development projects can often be measured reliably, these projects fulfil the capitalisation criteria as intangible assets upon acquisition. However, further internal development costs subsequent to acquisition are treated in the same way as other internal development costs.

#### Derivative financial instruments (note 4.3)

Novo Nordisk hedges commercial exposures, with foreign exchange risk being the principal financial risk for the Group. The overall objective of foreign exchange risk management is to limit the short-term negative impact on net profit and cash flow from exchange rate fluctuations, thereby increasing the predictability of the financial results. The purpose of hedge accounting is to match the impact of the hedged item and the hedging instrument in the Consolidated income statement. Management has chosen to classify the result of hedging activities as part of financial items. Thus, as the majority of Novo Nordisk sales are in EUR, USD, JPY, CNY, GBP and CAD, net sales will be impacted by exchange rate fluctuations whereas the impact of exchange rate fluctuations on Profit before income taxes depends on the results of the hedging activities and the development in non-hedged currencies.

In addition, the following other accounting policies are considered relevant to an understanding of the Consolidated financial statements:

- Income taxes (note 2.4)
- Property, plant and equipment including impairment (note 3.2)
- Inventories (note 3.3)
- Trade receivables and allowance for doubtful trade receivables (note 3.4)
- Provisions for legal disputes (note 3.6).

### Defining materiality

The Consolidated financial statements are a result of processing large numbers of transactions and aggregating those transactions into classes according to their nature or function. When aggregated, the transactions are presented in classes of similar items in the Consolidated financial statements. If a line item is not individually material, it is aggregated with other items of a similar nature in the Consolidated financial statements or in the notes.

There are substantial disclosure requirements throughout IFRS. Management provides specific disclosures required by IFRS unless the information is considered immaterial to the economic decision-making of the users of these financial statements or not applicable.

# 1.2 Summary of key accounting estimates

The use of reasonable estimates is an essential part of the preparation of the Consolidated financial statements. Given the uncertainties inherent in Novo Nordisk s business activities, Management must make certain estimates and judgements that affect the application of accounting policies and reported amounts of assets, liabilities, sales, costs, cash flows and related disclosures at the date(s) of the Consolidated financial statements.

Management bases its estimates on historical experience and various other assumptions that are held to be reasonable under the circumstances. The estimates and underlying assumptions are reviewed on an ongoing basis and, if necessary, changes are recognised in the period in which the estimate is revised. Management considers the carrying amounts recognised in relation to the key accounting estimates mentioned below to be reasonable and appropriate based on currently available information. However, the actual amounts may differ from the amounts estimated as more detailed information becomes available.

Management regards the following as the key accounting estimates and assumptions used in the preparation of the Consolidated financial statements:

- Sales deductions and provisions for sales rebates (notes 2.1 and 3.6)
- Indirect production costs (note 3.3)
- Allowance for doubtful trade receivables (note 3.4)
- Income taxes (note 2.4)
- Provisions for legal disputes (note 3.6).

Please refer to the specific notes for further information on the key accounting estimates and assumptions applied.

# 1.3 Changes in accounting policies and disclosures

### Early adoption of new or amended IFRSs

With effect from 1 January 2013, Novo Nordisk has implemented the new standards IFRS 10 [Consolidated Financial Statements], IFRS 11 [Joint Arrangements] and IFRS 12 [Disclosure of Interests in Other Entities]. These new standards have no material impact on the Consolidated financial statements in 2013, nor is a significant impact expected on future periods.

### Adoption of new or amended IFRSs

IAS 19R [Employee benefits] effective for annual periods beginning on or after 1 July 2012 was early adopted in 2012. As retrospective application of these changes only had an immaterial impact on each previous financial year, Management fully adopted the revised standard in 2012 without restating previous years] comparative amounts and disclosures. Please refer to note 3.7 for a detailed description of the accounting policy for retirement benefit obligations.

Furthermore, amendment to IAS 1 [Presentation of financial statements], effective for annual periods beginning on or after 1 July 2012, was early adopted in 2012 with no material impact on the Consolidated financial statements. For a further description please refer to the Annual Report 2012.

Based on an assessment of new or amended and revised accounting standards and interpretations ([[IFRSs[]) issued by IASB and IFRSs endorsed by the European Union effective on or after 1 January 2013, it has been assessed that the application of these new IFRSs has not had a material impact on the Consolidated financial statements in 2013 and Management does not anticipate any significant impact on future periods from the adoption of these new IFRSs.

New or amended IFRSs that have been issued but have not yet come into effect and have not been early adopted In addition to the above, IASB has issued a number of new or amended and revised accounting standards and interpretations that have not yet come into effect. The following standards are in general expected to change current accounting regulation most significantly:

- IASB has issued IFRS 9 [Financial Instruments], which awaits final effective date and EU endorsement. IFRS 9 is part of the IASB]s project to replace IAS 39, and the new standard will substantially change the classification and measurement of financial instruments and hedging requirements. Novo Nordisk has assessed the impact of the standard and determined that it will not have any significant impact on the Consolidated financial statements in its current wording.
- □ IASB has issued re-exposure drafts on IAS 17 □Leasing□ and IAS 18 □Revenue□. The revised IAS 18 is expected to have only immaterial impact on the Consolidated financial statements. Depending on the wording of the final standard, the change in lease accounting is expected to require capitalisation of the majority of the Group□s operational lease contracts, representing less than 10% of total assets, with a minor impact on the Group□s assets, liabilities and financial ratios, and no significant impact on net profit.

# Changes in classification

With effect from 1 January 2013, Novo Nordisk has changed the classification of uncertain tax positions. Previously these were presented net as part of deferred tax liabilities. As of 2013 these are presented gross as part of deferred tax assets, tax receivables and tax payables. Refer to note 2.4 for further description.

# 1.4 General accounting policies

# **Principles of consolidation**

The Consolidated financial statements incorporate the financial statements of Novo Nordisk A/S and entities controlled by Novo Nordisk A/S. Control exists when Novo Nordisk own more than 50% of the voting rights or has the power to govern the entity in some other way.

Where necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies into line with Novo Nordisk group policies. All intra-Group transactions, balances, income and expenses are eliminated in full when consolidated.

# Translation of foreign currencies

### Functional and presentation currency

Items included in the financial statements of each of Novo Nordisk s entities are measured using the currency of the primary economic environment in which the entity operates (functional currency). The Consolidated financial statements are presented in Danish kroner (DKK), which is also the functional and presentation currency of the parent company.

### Translation of transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such trans actions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognised in the Income statement.

Translation differences on non-monetary items, such as financial assets classified as available for sale including equity investments, are recognised in Other comprehensive income.

### Translation of Group companies

Financial statements of foreign subsidiaries are translated into Danish kroner at the exchange rates prevailing at the end of the reporting period for balance sheet items, and at average exchange rates for income statement items.

All effects of exchange rate adjustment are recognised in the Income statement, with the exception of exchange rate adjustments of investments in subsidiaries arising from:

- the translation of foreign subsidiaries net assets at the beginning of the year at the exchange rates at the end of the reporting period
- the translation of foreign subsidiaries statement of comprehensive income from average exchange rates to exchange rates at the end of the reporting period
- the translation of non-current intra-Group receivables that are considered to be an addition to net investments in subsidiaries.

These specific exchange rate adjustments are recognised in Other comprehensive income.

# Section 2 Results for the year

This section comprises notes related to the results for the year, including sales and sales deductions, segment information, employee costs as well as details on income and deferred income taxes. Consequently the section provides additional information related to performance against two of Novo Nordisk four long-term financial targets: Operating profit margin and Growth in operating profit.

Continued growth in the number of patients, a global commercial presence and innovative products drive Novo Nordisk[]s growth in sales. Over the last five years, growth in operating profit has been higher than sales growth, resulting in an increasing operating margin. The gross margin expansion has primarily been driven by a positive product mix and a favourable pricing development. The operating margin expansion has also been supported by a modest development in administrative costs and economy of scale advantages within sales and marketing, whereas research and development costs have been growing in line with sales. Novo Nordisk continues to invest in innovation while contributing to society by paying corporate taxes in the countries where it operates. The Management review section []2013 performance and 2014 outlook[] on p 6 gives a detailed description of the results for the year.

# 2.1 Net sales and sales deductions

#### Accounting policies

Revenue from goods sold is recognised when Novo Nordisk has transferred the significant risks and rewards to the buyer, and the amount of revenue can be measured reliably.

Sales are measured at the fair value of the consideration received or receivable. When sales are recognised, Novo Nordisk also records estimates for a variety of sales deductions, including rebates, discounts, refunds,

incentives and product returns. Sales deductions are recognised as a reduction of gross sales to arrive at net sales. Where contracts contain customer acceptance provisions, Novo Nordisk recognises sales when the acceptance criteria are satisfied.

Revenue recognition for new product launches is based on specific facts and circumstances relating to those products, including estimated demand and acceptance rates for well-established products with similar market characteristics. Where shipments of new products are made on a sale or return basis, without sufficient historical experience for estimating sales returns, revenue is only recorded when there is evidence of consumption or when the right of return has expired.

### **Overall sales performance**

The sales performance for a five-year period is presented below in respect of business performance and geographical areas:

### **Financial performance**

### FORM 6-K

DKK million	2013	2012	2011	2010	2009
Net sales					
Modern insulins (insulin analogues)	38,153	34,821	28,765	26,601	21,471
Human insulins	10,869	11,302	10,785	11,827	11,315
Victoza®	11,633	9,495	5,991	2,317	87
Protein-related products	2,555	2,511	2,309	2,214	1,977
Oral antidiabetic products (OAD)	2,246	2,758	2,575	2,751	2,652
Diabetes care total	65,456	60,887	50,425	45,710	37,502
NovoSeven®	9,256	8,933	8,347	8,030	7,072
Norditropin®	6,114	5,698	5,047	4,803	4,401
Other biopharmaceuticals	2,746	2,508	2,527	2,233	2,103
Biopharmaceuticals total	18,116	17,139	15,921	15,066	13,576
Net sales by business segment	83,572	78,026	66,346	60,776	51,078
North America	39,024	34,220	26,586	23,609	18,279
Europe	20,063	19,707	19,168	18,664	17,540
International Operations	12,007	11,080	9,367	8,335	6,835
Japan & Korea	5,317	6,617	6,223	5,660	4,888
Region China	7,161	6,402	5,002	4,508	3,536
Net sales by geographical segment	83,572	78,026	66,346	60,776	51,078

# 2.1 Net sales and sales deductions (continued)

#### Key accounting estimates [] Sales deductions

Sales discounts and sales rebates are predominantly issued in Region North America. In this region, significant sales rebates are paid in connection with US public healthcare insurance programmes, namely Medicare and Medicaid, as well as rebates to managed healthcare plans. The most significant discounts are offered under contracts with institutions, mostly hospitals and government agencies. In addition, political pressure to contain healthcare costs has led several other countries to impose significant price reductions on pharmaceutical products. As such, concerted austerity measures have been implemented by governments in countries in Region Europe, while government-mandated price cuts have been introduced in Region China, Japan and major countries in Region International Operations.

#### US Medicaid and Medicare rebates

Medicaid and Medicare rebates have been calculated using a combination of historical experience, product and population growth, price increases, the impact of contracting strategies and specific terms in the individual agreements. For Medicaid, the calculation of rebates also involves interpretation of relevant regulations that are subject to changes in interpretative guidance from government authorities. Although accruals are made for Medicaid and Medicare rebates at the time sales are recorded, the actual rebates related to the specific sale will typically be invoiced to Novo Nordisk up to nine months later. Due to the time lag, the rebate adjustments to sales in any particular period may incorporate adjustments of accruals for prior periods.

#### US managed healthcare rebates

Rebates are offered to a number of managed healthcare plans. These rebate programmes allow the customer to receive a rebate after attaining certain performance parameters relating to formulary status and pre-established market share milestones relative to competitors. Rebates are estimated according to the specific terms in each agreement, historical experience, anticipated channel mix, product growth rates and market share information. Novo Nordisk adjusts the provision periodically to reflect actual sales performance.

#### US wholesaler charge-backs

Wholesaler charge-backs relate to contractual arrangements between Novo Nordisk and indirect customers in the US, whereby products are sold at contract prices lower than the list price originally charged to wholesalers. A wholesaler charge-back represents the difference between the invoice price to the wholesaler and the indirect customer s contract price. Provisions are calculated for estimated charge-backs using a combination of factors such as historical experience, current wholesaler inventory levels, contract terms and the value of claims received but not yet processed. Wholesaler charge-backs are generally settled within 10 to 30 days of the liability being incurred.

#### Discounts, sales returns and other rebates

Other discounts are provided to wholesalers, hospitals, pharmacies etc, and are usually linked to sales volume or provided as cash discounts. Sales returns are related to damaged or expired products. Accruals are calculated based on historical data, and recorded as a reduction in gross sales at the time the related sales are recorded.

Arrangements with certain healthcare providers may require Novo Nordisk to make refunds to the healthcare providers if anticipated treatment outcomes do not meet predefined targets.

### **Gross-to-net sales reconciliation**

DKK million	2013	2012	2011
-------------	------	------	------

Gross sales	115,906	103,948	84,386
US Medicaid and Medicare rebates US managed healthcare rebates US wholesaler charge-backs US discounts and sales returns Non-US rebates, discounts and sales returns	(9,959) (5,481) (10,126) (2,978) (3,790)	(7,519) (4,390) (8,196) (2,620) (3,197)	(5,075) (2,551) (5,894) (1,886) (2,634)
Total gross-to-net sales adjustments	(32,334)	(25,922)	(18,040)
Net sales	83,572	78,026	66,346

Provisions for sales rebates are adjusted to actual amounts as rebates and discounts are processed. Please refer to note 3.6 for further information on sales-related provisions.

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# 2.2 Segment information

#### **Accounting policies**

Operating segments are reported in a manner consistent with the internal reporting provided to Management and the Board of Directors.

#### **Business segments**

Novo Nordisk operates in two business segments based on therapies: Diabetes care and Biopharmaceuticals.

The Diabetes care business segment includes research, development, manufacturing and marketing of products within the areas of insulin, GLP-1 and related delivery systems, oral antidiabetic products (OAD) and obesity.

The Biopharmaceuticals business segment includes research, development, manufacturing and marketing of products within the areas of haemophilia, growth hormone therapy, hormone replacement therapy, inflammation therapy and other therapy areas.

Segment performance is evaluated on the basis of operating profit consistent with the Consolidated financial statements. Financial income and expenses and income taxes are managed at Group level and are not allocated to business segments.

There are no sales or other transactions between the business segments. Costs have been split between business segments according to a specific allocation with the addition of a minor number of corporate overhead costs allocated systematically between the segments. Licence income and other operating income has been allocated to the two segments based on the same principle. Segment assets comprise the assets that are applied directly to the activities of the segment, including intangible assets, property, plant and equipment, other financial assets, inventories, trade receivables, and other receivables and prepayments.

No single customer represents more than 10% of the total sales and no operating segments have been aggregated to form the reported business segments.

DKK million	2013	2012	2011	2013	2012	2011	2013	2012	2011
Segment sales	Dia	betes car	9	Biopha	armaceutio	als		Total	
- NovoRapid® / NovoLog® NovoMix® / NovoLog®	16,848	15,693	12,804						
Mix	9,759	9,342	8,278						
Levemir® Total modern insulins	11,546 38,153	9,786 34,821	7,683 28,765						
Human insulins	10,869	11,302	10,785						

# **Business segments**

		9							
Victoza®	11,633	9,495	5,991						
Protein-related	2,555	2,511	2,309						
products Oral antidiabetic									
products (OAD)	2,246	2,758	2,575						
Diabetes care total sales	65,456	60,887	50,425						
NovoSeven® Norditropin® Other products				9,256 6,114 2,746	8,933 5,698 2,508	8,347 5,047 2,527			
Biopharmaceuticals total sales	5			18,116	17,139	15,921			
Segment key figures									
Total net sales	65,456	60,887	50,425	18,116	17,139	15,921	83,572	78,026	66,346
Change in DKK (%) Change in local	7.5%	20.7%	10.3%	5.7%	7.7%	5.7%	7.1%	17.6%	9.2%
currencies (%)	12.0%	14.5%	12.6%	11.5%	2.4%	7.6%	11.9%	11.6%	11.4%
Cost of goods sold	11,909	11,435	10,762	2,231	2,030	1,827	14,140	13,465	12,589
Sales and distribution costs	20,584	18,894	16,476	2,796	2,650	2,528	23,380	21,544	19,004
Research and	7,786	7,322	6,402	3,947	3,575	3,226	11,733	10,897	9,628
development costs Administrative costs	2,767	2,604	2,485	741	708	760	3,508	3,312	3,245
Licence income and									
other operating income, net	510	464	285	172	202	209	682	666	494
Operating profit	22,920	21,096	14,585	8,573	8,378	7,789	31,493	29,474	22,374
Operating margin	35.0%	34.6%	28.9%	47.3%	48.9%	48.9%	37.7%	37.8%	33.7%
Depreciation, amortisation and impairment losses expensed Additions to	2,209	2,167	2,051	590	526	686	2,799	2,693	2,737
Intangible assets and Property, plant and equipment	2,651	2,800	2,654	990	770	678	3,641	3,570	3,332
Assets allocated to business segments Assets not allocated	36,436	36,030	34,853	10,525	9,119	8,998	46,961	45,149	43,851
to business segments <sup>1</sup>							23,376	20,520	20,847
Total assets							70,337	65,669	64,698

1. The part of total assets that remains unallocated to either of the two business segments includes Cash at bank and on hand, Marketable securities, Derivative financial instruments deferred tax assets and tax receivables.

# 2.2 Segment information (continued)

#### Information about geographical areas

Novo Nordisk operates in five geographical regions:

- North America: the US and Canada
- Europe: the EU, EFTA, Albania, Bosnia-Hercegovina, Macedonia, Serbia, Montenegro and Kosovo
- Japan & Korea: Japan and Korea
- Region China: China, Hong Kong and Taiwan
- International Operations: all other countries.

Sales are attributed to geographical regions according to the location of the customer. Allocation of property, plant and equipment, trade receivables, allowance for trade receivables and total assets are based on the location of the assets.

The country of domicile is Denmark, which is part of Region Europe. Denmark is immaterial to Novo Nordisk[]s activities in terms of geographical size and the operational business segments. More than 99.4% of total sales are realised outside Denmark. Sales to external customers attributed to the US are collectively the most material to the Group. The US is the only country where sales contribute more than 10% of total sales. Sales to the US represent more than 90% of sales in Region North America.

For patent expiry in key markets, please refer to note 2.5 in the social statements, where the various marketed products are listed.

# **Geographical areas**

DKK million	2013	2012	2011	2013	2012	2011
	North	America			Europe	
Sales by business segment: NovoRapid® / NovoLog® NovoMix® / NovoLog® Mix Levemir® Modern insulins (insulin analogues) Human insulins Victoza® Other diabetes care	9,953 2,694 6,823 19,470 1,976 7,537 1,590	9,033 2,488 5,290 16,811 1,959 5,930 1,998	6,934 2,088 3,711 12,733 1,762 3,716 1,705	3,819 2,450 2,909 9,178 2,427 2,896 885	3,707 2,544 2,833 9,084 2,642 2,427 965	3,464 2,623 2,577 8,664 3,032 1,620 1,210
Diabetes care total NovoSeven® Norditropin® Other biopharmaceuticals	30,573 4,459 2,273 1,719	26,698 4,397 1,721 1,404	19,916 3,951 1,394 1,325	15,386 2,294 1,729 654	15,118 2,206 1,741 642	14,526 2,310 1,705 627

Biopharmaceuticals total	8,451	7,522	6,670	4,677	4,589	4,642
Total sales by business and geographical segment	39,024	34,220	26,586	20,063	19,707	19,168
Underlying sales growth in local currencies <sup>1</sup> Currency effect (local currency impact)	17.8% (3.8%)	19.2% 9.5%	17.9% (5.3%)	2.5% (0.7%)	2.0% 0.8%	2.4% 0.3%
Total sales growth as reported	14.0%	28.7%	12.6%	1.8%	2.8%	2.7%
Property, plant and equipment Trade receivables Allowance for doubtful trade receivables Total assets	1,571 3,076 (20) 7,057	1,500 2,278 (18) 5,867	1,329 2,081 (22) 5,465	16,801 3,779 (245) 51,205	16,200 3,688 (239) 47,663	15,681 3,652 (333) 47,202

1. Additional non-IFRS measure; please refer to p 93 for definition.

# 2.2 Segment information (continued)

# Geographical areas

DKK million	2013	2012	2011	2013	2012	2011
	Interna	tional Opera	tions	Japan & Korea		
Sales by business segment: NovoRapid® / NovoLog® NovoMix® / NovoLog® Mix Levemir® Modern insulins (insulin analogues) Human insulins Victoza® Other diabetes care	1,639 1,875 1,290 4,804 2,954 741 692	1,408 1,708 1,106 4,222 3,073 613 632	1,100 1,482 942 3,524 2,581 322 583	951 789 288 2,028 490 331 471	1,175 1,028 386 2,589 768 455 493	1,057 970 363 2,390 960 327 430
Diabetes care total	9,191	8,540	7,010	3,320	4,305	4,107
NovoSeven® Norditropin® Other biopharmaceuticals	1,716 853 247	1,526 780 234	1,485 651 221	629 1,246 122	646 1,442 224	482 1,285 349
Biopharmaceuticals total	2,816	2,540	2,357	1,997	2,312	2,116
Total sales by business and geographical segment	12,007	11,080	9,367	5,317	6,617	6,223
Underlying sales growth in local currencies <sup>1</sup> Currency effect (local currency impact)	17.0% (8.6%)	16.2% 2.1%	17.1% (4.7%)	(0.1%) (19.5%)	(1.5%) 7.8%	5.1% 4.8%
Total sales growth as reported	8.4%	18.3%	12.4%	(19.6%)	6.3%	9.9%
Property, plant and equipment Trade receivables Allowance for doubtful trade receivables Total assets	1,292 2,196 (716) 5,945	1,508 2,177 (710) 6,660	1,672 2,052 (535) 6,419	140 269 (8) 1,022	174 335 (3) 989	207 377 (2) 1,388
DKK million	2013	2012	2011	2013	2012	2011
	Re	egion China		Total sum	of the five	regions
Sales by business segment: NovoRapid® / NovoLog® NovoMix® / NovoLog® Mix Levemir®	486 1,951 236	370 1,574 171	249 1,115 90	16,848 9,759 11,546	15,693 9,342 9,786	12,804 8,278 7,683

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Victoza®       128       70       6       11,633       9,495       5,9         Other diabetes care       1,163       1,181       956       4,801       5,269       4,8         Diabetes care total       6,986       6,226       4,866       65,456       60,887       50,4         NovoSeven®       158       158       119       9,256       8,933       8,3         Norditropin®       13       14       12       6,114       5,698       5,6         Other biopharmaceuticals       175       176       136       18,116       17,139       15,9	segment	7,101					
Victoza®       128       70       6       11,633       9,495       5,9         Other diabetes care       1,163       1,181       956       4,801       5,269       4,8         Diabetes care total       6,986       6,226       4,866       65,456       60,887       50,4         NovoSeven®       158       158       119       9,256       8,933       8,3         Norditropin®       13       14       12       6,114       5,698       5,0         Other biopharmaceuticals       175       176       136       18,116       17,139       15,9         Total sales by business and geographical       7,161       6,402       5,002       83,572       78,026       66,3	Underlying sales growth in local currencies <sup>1</sup>	12.7%	16.3%	11.7%	11.9%	11.6%	11.4%
Victoza® Other diabetes care       128 1,163       70 1,181       6 956       11,633 4,801       9,495 5,269       5,6 4,801         Diabetes care total       6,986       6,226       4,866       65,456       60,887       50,4         NovoSeven® Norditropin® Other biopharmaceuticals       158 4       158 13       158 14       119 12       9,256 6,114       8,933 5,698       8,3 5,0         Biopharmaceuticals total       175       176       136       18,116       17,139       15,9         Total sales by business and geographical       7,161       6,402       5,002       83,572       78,026       66,3	Underlying sales growth in local currencies <sup>1</sup> Currency effect (local currency impact)	12.7% (0.8%)	16.3% 11.7%	11.7% (0.7%)	11.9% (4.8%)	11.6% 6.0%	11.4% (2.2%)
Victoza® Other diabetes care       128 1,163       70 1,181       6 956       11,633 4,801       9,495 5,269       5,6 4,801         Diabetes care total       6,986       6,226       4,866       65,456       60,887       50,4         NovoSeven® Norditropin® Other biopharmaceuticals       158 4       158 13       158 14       119 12       9,256 6,114       8,933 5,698       8,3 5,0         Biopharmaceuticals total       175       176       136       18,116       17,139       15,9         Total sales by business and geographical       7,161       6,402       5,002       83,572       78,026       66,3							
Victoza®       128       70       6       11,633       9,495       5,9         Other diabetes care       1,163       1,181       956       4,801       5,269       4,8         Diabetes care total       6,986       6,226       4,866       65,456       60,887       50,4         NovoSeven®       158       158       119       9,256       8,933       8,2         Norditropin®       13       14       12       6,114       5,698       5,0         Other biopharmaceuticals       175       176       136       18,116       17,139       15,9		7,161	6,402	5,002	83,572	78,026	66,346
Victoza®       128       70       6       11,633       9,495       5,9         Other diabetes care       1,163       1,181       956       4,801       5,269       4,8         Diabetes care total       6,986       6,226       4,866       65,456       60,887       50,4         NovoSeven®       158       158       119       9,256       8,933       8,3         Norditropin®       13       14       12       6,114       5,698       5,0         Other biopharmaceuticals       4       4       5       2,746       2,508       2,5		7,161	6,402	5,002	83,572	78,026	66,346
Victoza® Other diabetes care       128 1,163       70 1,163       6 11,633       9,495 5,269       5,9 4,801         Diabetes care total       6,986       6,226       4,866       65,456       60,887       50,4         NovoSeven® Norditropin®       158       158       119       9,256       8,933       8,3	Biopharmaceuticals total	175	176	136	18,116	17,139	15,921
Victoza® Other diabetes care       128 1,163       70 1,163       6 11,633       9,495 5,269       5,9 4,801         Diabetes care total       6,986       6,226       4,866       65,456       60,887       50,4         NovoSeven® Norditropin®       158       158       119       9,256       8,933       8,3	Other biopharmaceuticals	4	4	5	2,746	2,508	2,527
Victoza®         128         70         6         11,633         9,495         5,9           Other diabetes care         1,163         1,181         956         4,801         5,269         4,8	Norditropin®	13	14	12	6,114	5,698	8,347 5,047
Victoza® 128 70 6 11,633 9,495 5,9	Diabetes care total	6,986	6,226	4,866	65,456	60,887	50,425
	Human insulins Victoza®	3,022 128	2,860 70	2,450 6	10,869 11,633	11,302 9,495	28,765 10,785 5,991 4,884

1. Additional non-IFRS measure; please refer to p 93 for definition.

# 2.3 Employee costs

#### Accounting policies

Wages, salaries, social security contributions, annual leave and sick leave, bonuses and non-monetary benefits are recognised in the year in which the associated services are rendered by employees of Novo Nordisk. Where Novo Nordisk provides long-term employee benefits, the costs are accrued to match the rendering of the services by the employees concerned.

# **Employee costs**

DKK million	2013	2012	2011
Wages and salaries Share-based payment costs (note 5.1) Pensions [] defined contribution plans Pensions [] retirement benefit	19,077 409 1,428	17,301 308 1,302	16,127 319 1,155
obligations (note 3.7) Other social security contributions Other employee costs	113 1,489 1,891	150 1,358 1,779	(2) 1,189 1,491
Total employee costs for the year	24,407	22,198	20,279
Employee costs included in property, plant and equipment <sup>1</sup>	(772)	(533)	(496)
Change in employee costs included in inventories	(29)	(70)	(37)
Total employee costs	23,606	21,595	19,746
Included in the Income statement.			
Included in the Income statement: Cost of goods sold Sales and distribution costs Research and development costs Administrative costs Licence income and other operating income, net	5,160 9,831 4,680 2,250 1,685	4,627 8,784 4,298 2,205 1,681	4,302 7,961 3,980 1,993 1,510
Total employee costs	23,606	21,595	19,746

1. This reflects annual gross employee costs included in property, plant and equipment, which subsequently will be included in depreciation and impairment losses.

Average number of full-time employees	36,144	33,061	31,499
Year-end number of full-time employees	37,978	34,286	32,136

# **Remuneration to Executive Management and Board of Directors**

DKK million	2013	2012	2011
Salary and cash-based incentive Pension Other benefits	58 15 2	37 9 1	35 9 1
Executive Management in total <sup>1</sup>	75	47	45
Fee to Board of Directors <sup>2</sup>	9	9	9

1. Excluding share-based payments, as these are allocated in the joint pool between Executive Management and other members of the Senior Management Board. Please refer to note 5.1 and [Remuneration], pp 49[51, for further information.

2. Excluding social security taxes paid amounting to less than DKK 1 million (less than DKK 1 million in 2012).

# 2.4 Income and deferred income taxes

Income taxes

# Accounting policies

The tax expense for the period comprises current and deferred tax and interest on tax cases ongoing or settled during the year, including adjustments to previous years and changes in provision for uncertain tax positions. Tax is recognised in the Income statement, except to the extent that it relates to items recognised in Other comprehensive income.

Following developments in ongoing tax disputes primarily related to transfer pricing cases, uncertain tax positions previously presented net as part of deferred tax liabilities are as of 2013 presented individually as part of deferred tax assets, tax receivables and tax payables. As retrospective application of this change in classification would have only an immaterial impact on comparative amounts, Novo Nordisk has applied the reclassification in 2013 without restating previous years] comparative amounts and disclosures. Had comparative amounts been restated for 2012, deferred tax liabilities would decrease by DKK 716 million, deferred tax assets increase by DKK 614 million, tax receivables increase by DKK 425 million and tax payables increase by DKK 1,755 million. In 2013 uncertain tax positions of DKK 1,705 million is presented as DKK 760 million in deferred tax assets, DKK 2,317 million in tax receivables and DKK 1,372 million in tax payables.

### Key accounting estimate [] Income taxes

Novo Nordisk is subject to income taxes around the world. Significant judgement is required in determining the worldwide accrual for income taxes, deferred income tax assets and liabilities, and provision for uncertain tax positions. Novo Nordisk recognises deferred income tax assets if it is probable that sufficient taxable income will be available in the future against which the temporary differences and unused tax losses can be utilised. Management has considered future taxable income in assessing whether deferred income tax assets should be recognised. In the course of conducting business globally, transfer pricing disputes with tax authorities may occur, and Management judgement is applied to assess the possible outcome of such disputes. Novo Nordisk believes that the provision made for uncertain tax positions not yet settled with local tax authorities is adequate. However, the actual obligation may deviate and is dependent on the result of litigations and settlements with the relevant tax authorities.

# 2.4 Income and deferred income taxes (continued)

# **Income taxes expensed**

DKK million	2013	2012	2011
Current tax on profit for the year Deferred tax on profit for the year	8,540 (682)	6,001 645	4,534 257
Tax on profit for the year Adjustments recognised for current tax of prior periods Adjustments recognised for deferred tax of prior periods	7,858 (74) (429)	6,646 4,042 (4,309)	4,791 277 (240)
Income taxes in the Income statement	7,355	6,379	4,828

Adjustments recognised for prior periods include adjustments caused by events that occurred in the current year related to current and deferred tax of prior periods. Such adjustments predominantly arise from tax payments on tax disputes related to transfer pricing and reversal of associated tax liability recognised in prior periods.

Computation of effective tax rate:

Statutory corporate income tax rate in Denmark Deviation in foreign subsidiaries[] tax rates compared with the Danish tax rate (net) Non-taxable income less non-tax- deductible expenses (net) Effect on deferred tax related to change in the Danish corporate tax rate Other	25.0% (2.0%) [ (0.3%) (0.1%)	25.0% (2.1%) 0.1% [] (0.1% <b>)</b>	25.0% (3.0%) (0.2%) 0.2%
Effective tax rate	22.6%	22.9%	22.0%
Tax on other comprehensive income for the year, (income)/expense	211	587	(190)

Tax on other comprehensive income for the year relates to tax on deferred (gains)/losses on cash flow hedges and internal profit in inventories. This is offset by DKK 48 million (DKK 12 million in 2012) recognised as current tax in Other comprehensive income in 2013.

# **Income taxes paid**

DKK million	2013	2012	2011
Income taxes paid in Denmark	7,363	7,895	2,825
Income taxes paid outside Denmark	2,444	2,996	2,566

	Total income taxes paid	9,807	10,891	5,391
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The income taxes of DKK 7,363 million paid in Denmark in 2013 (DKK 7,895 million in 2012) include adjustments arising from ongoing tax disputes primarily related to transfer pricing from prior periods.

# **Deferred income taxes**

#### Accounting policies

Deferred income taxes arise from temporary differences between the accounting and taxable values of the individual consolidated companies and from realisable tax-loss carry-forwards using the liability method. The tax value of tax-loss carry-forwards is included in deferred tax assets to the extent that the tax losses and other tax assets are expected to be utilised in future taxable income. The deferred income taxes are measured according to current tax rules and at the tax rates expected to be in force on elimination of the temporary differences. No provision is made for income taxes that would be payable upon the distribution of unremitted earnings unless a concrete distribution of earnings is planned.

# **Development in deferred income tax assets and liabilities**

DKK million	2013	2012
At the beginning of the year	1,512	(792)
Reclassification to Tax receivables/Tax payables Reclassification from Other liabilities (note 3.8)	1,330 []	(739)
Deferred tax on profit for the year Adjustment relating to previous years	682 429	(645) 4,309
Deferred tax on items recognised in Other comprehensive income Exchange rate adjustments	(259) (135)	(575) (46)
Total deferred tax assets/(liabilities), net	3,559	1,512

# 2.4 Income and deferred income taxes (continued)

Development in deferred income tax assets and liabilities

DKK million	Property, plant and equipment	Intangible assets	Inventories	Tax-loss carry <b>-</b> forward	Other	Offset within countries	Total
<b>2013</b> Net deferred tax asset/(liability) at 1 January	(997)	133	1,336	66	974		1,512
Reclassification to Tax receivables/Tax payables					1,330		1,330
Income/(charge) to the Income statement <sup>1</sup>	141	(44)	593	(7)	428		1,111
Income/(charge) to Other comprehensive income Exchange rate adjustment	3	(25)	(168) []	(5)	(91) (108)		(259) (135)
Net deferred tax asset/(liability) at 31 December	(853)	64	1,761	54	2,533		3,559
Classified as follows: Deferred tax asset at 31 December	109	378	2,637	54	3,567	(2,514)	4,231
Deferred tax liability at 31 December	(962)	(314)	(876)		(1,034)	2,514	(672)
<ol> <li>Including effect related to change in the Danish corporate tax rate.</li> </ol>							
2012							
Net deferred tax asset/(liab 1 January Reclassification from Other	(1,00	50) 24 <sup>,</sup>	4 1,599	87	(1,662) (739)	_	(792) (739)
liabilities Income/(charge) to the Inco statement	ome e	56 (10)	6) (185)	(17)	3,906		3,664
Income/(charge) to Other comprehensive income			(78)		(497)		(575)
Exchange rate adjustment		(3) (1	5) 🛛	(4)	(34)		(46)
Net deferred tax asset/(liab 31 December	ility) at (99	97) 13:	3 1,336	66	974		1,512

Classified as follows:

Deferred tax asset at 31 December	176	436	2,560	66	1,421	(2,415)	2,244
Deferred tax liability at 31 December	(1,173)	(303)	(1,224)		(447)	2,415	(732)

Further to the above, the tax value of the tax-loss carry-forward of DKK 182 million (DKK 208 million in 2012) has not been recognised in the Balance sheet due to the likelihood that the tax losses will not be realised in the future. None of the unrecognised tax-loss carry-forward expires within one year. DKK 8 million expires within two to five years and DKK 174 million after more than five years.

# Section 3 Operating assets and liabilities

This section presents details on the operating assets that form the basis for the activities of Novo Nordisk, and related liabilities. These net assets impact Novo Nordisk[]s long-term target for []Operating profit after tax to net operating assets (OPAT/NOA)[].

Novo Nordisk generates a relatively high OPAT/NOA due to a low level of acquired intangible assets and a stable operating asset base despite significant business growth. This is driven by Novo Nordisk[]s organic growth strategy with limited acquisition of rights or businesses, and reflects the fact that, in line with industry practice, Novo Nordisk does not capitalise internal development costs until regulatory approval is highly probable. The overall approach to managing operating assets is to retain assets for research, development and production activities under the company[]s own control, and generally to lease non-core assets related to administration and distribution. Furthermore, to maintain high quality in the company[]s products and the capability at all times to deliver products to customers, Novo Nordisk ensures that the total production capacity and inventory levels reflect this priority.

# $3.1 \frac{\text{Intangible}}{\text{assets}}$

### **Accounting policies**

Patents and licences, including acquired patents and licences for in-process research and development projects, are carried at historical cost less accumulated amortisation and any impairment loss. Amortisation is based on the straight-line method over the estimated useful life, which is the shorter of the legal duration and the economic useful life not exceeding 10 years. The amortisation of patents and licences begins, at the earliest, on production of pre-launch inventory or after regulatory approval has been obtained.

Internal development of computer software and other development costs related to major IT projects for internal use that are directly attributable to the design and testing of identifiable and unique software products controlled by Novo Nordisk are recognised as intangible assets if the recognition criteria are met, ie a significant business system where the expenditure leads to the creation of a durable asset. Amortisation is based on the straight-line method over the estimated useful life of 3[10 years. The amortisation begins when the asset is in the location and condition necessary for it to be capable of operating in the manner intended by Management.

#### Impairment of assets

Intangible assets with an indefinite useful life and intangible assets not yet available for use are not subject to amortisation but are tested annually for impairment irrespective of whether there is any indication that they may be impaired.

Assets that are subject to amortisation, such as intangible assets in use or with definite useful life, and other non-current assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. Factors considered material that could trigger an impairment test include the following:

- Development of a competing drug
- Changes in the legal framework covering patents, rights and licences
- Advances in medicine and/or technology that affect the medical treatments
- Lower-than-predicted sales
- Adverse impact on reputation and/or brand names
- Changes in the economic lives of similar assets
- Relationship with other intangible assets or property, plant and equipment

Changes or anticipated changes in participation rates or reimbursement policies.

If the carrying amount of intangible assets exceeds the recoverable amount based upon the existence of one or more of the above indicators of impairment, any impairment is measured based on discounted projected cash fl ows. Impairments are reviewed at each reporting date for possible reversal.

# **Intangible assets**

DKK million	2013	2012
Cost at the beginning of the year Additions during the year Disposals during the year Effect of exchange rate adjustment	2,712 403 [] (16)	2,538 198 (18) (6)
Cost at the end of the year	3,099	2,712
Amortisation and impairment losses at the beginning of the year Amortisation for the year Impairment losses for the year Amortisation and impairment losses reversed on disposals during the year Effect of exchange rate adjustment	1,217 166 113 [ (12)	1,049 160 32 (18) (6)
Amortisation and impairment losses at the end of the year	1,484	1,217
Carrying amount at the end of the year	1,615	1,495
Specified as: Patents and licences Internally developed software and software under development	810 805	762 733
Total	1,615	1,495

Intangible assets not yet in use amount to DKK 831 million (DKK 669 million in 2012), primarily patents and licences in relation to development projects.

In 2013, an impairment loss of DKK 113 million (DKK 32 million in 2012) related to patents has been recognised due to discontinuation of development projects. Impairment tests in 2013 and 2012 of assets not yet in use were based upon Management[]s projections and anticipated net present value of future cash flows from cash-generating units. Management has used a pre-tax discount rate (WACC) of 8% based on the risk inherent in the related activity[]s current business model and industry comparisons. Terminal values used are based on the expected life of products, forecasted life cycle and cash flow over that period, and the useful life of the underlying assets.

# **Amortisation and impairment losses**

Total amortisation and impairment losses	279	192	232
Licence income and other operating income, net	120	14	11
Sales and distribution costs Research and development costs	41 126	50 47	35 139
Cost of goods sold	97	81	47
DKK million	2013	2012	2011

# 3.2 Property, plant and equipment

#### Accounting policies

Property, plant and equipment is measured at historical cost less accumulated depreciation and any impairment loss. The cost of self-constructed assets includes costs directly and indirectly attributable to the construction of the assets. Subsequent cost is included in the asset s carrying amount or recognised as a separate asset only when it is probable that future economic benefits associated with the item will flow to Novo Nordisk and the cost of the item can be measured reliably. In general, constructions of major investments are self-financed and thus no interest on loans is capitalised as part of the cost. Depreciation is based on the straight-line method over the estimated useful lives of the assets:

#### Buildings: 12 50 years

- Plant and machinery: 5 [16 years
- Other equipment: 3 10 years
- Land: not depreciated.

The depreciation commences when the asset is available for use, ie when it is in the location and condition necessary for it to be capable of operating in the manner intended by Management.

The assets residual values and useful lives are reviewed and adjusted, if appropriate, at the end of each reporting period. An asset s carrying amount is written down to its recoverable amount if the asset s carrying amount is higher than its estimated recoverable amount (please refer to note 3.1 for a description of impairment of assets). Gains and losses on disposals are determined by comparing the proceeds with the carrying amount and are recognised in the Income statement.

<b>Property, plant and equipment</b>	Land and buildings	Plant and machinery	Other equipment	Payments on account and assets in course of construction	Total
2013					
Cost at the beginning of the year	15,345	18,022	3,359	5,878	42,604
Additions during the year	521	581	230	1,906	3,238
Disposals during the year	(195)	(655)	(259)		(1,109)
Transfer from/(to) other items	804	1,283	186	(2,273)	0
Effect of exchange rate adjustment	(291)	(267)	(59)	(79)	(696)
Cost at the end of the year	16,184	18,964	3,457	5,432	44,037
Depreciation and impairment losses at the	5,881	12,975	2,209		21,065
beginning of the year	688				
Depreciation for the year Impairment losses for the year	088 4	1,464 22	337 5		2,489 31
Depreciation and impairment losses reversed on	-		5		
disposals during the year	(192)	(643)	(243)		(1,078)

Effect of exchange rate adjustment	(114)	(204)	(34)		(352)
Depreciation and impairment losses at the end of the year	6,267	13,614	2,274		22,155
Carrying amount at the end of the year	9,917	5,350	1,183	5,432	21,882
2012					
Cost at the beginning of the year	14,600	17,845	3,080	4,815	40,340
Additions during the year	171	136	220	2,845	3,372
Disposals during the year	(287)	(350)	(111)		(748)
Transfer from/(to) other items	1,020	553	192	(1,765)	
Effect of exchange rate adjustment	(159)	(162)	(22)	(17)	(360)
Cost at the end of the year	15,345	18,022	3,359	5,878	42,604
Depreciation and impairment losses at the beginning of the year	5,525	11,888	1,996		19,409
Depreciation for the year	655	1,445	313		2,413
Impairment losses for the year	18	68	2		88
Depreciation and impairment losses reversed on	(263)	(315)	(91)	П	(669)
disposals during the year					
Effect of exchange rate adjustment	(54)	(111)	(11)		(176)
Depreciation and impairment losses at the end of the year	5,881	12,975	2,209		21,065
Carrying amount at the end of the year	9,464	5,047	1,150	5,878	21,539

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# 3.2 **Property, plant and equipment** (continued)

# **Depreciation and impairment losses**

DKK million	2013	2012	2011
Cost of goods sold Sales and distribution costs Research and development costs Administrative costs	1,984 37 340 59	1,909 46 416 53	1,833 60 494 58
Licence income and other operating income, net	100	77	60
Total depreciation and impairment losses	2,520	2,501	2,505

# 3.3 Inventories

### Accounting policies

Inventories are stated at the lower of cost and net realisable value. Cost is determined using the first-in, first-out method. Cost comprises direct production costs such as raw materials, consumables and labour as well as indirect production costs. Production costs for work in progress and finished goods include indirect production costs such as employee costs, depreciation, maintenance etc.

If the expected sales price less completion costs to execute sales (net realisable value) is lower than the carrying amount, a write-down is recognised for the amount by which the carrying amount exceeds its net realisable value.

Inventory manufactured prior to regulatory approval (pre-launch inventory) is capitalised but immediately provided for, until there is a high probability of regulatory approval of the product. Before that point, a provision is made against the carrying amount of inventory to its recoverable amount and recorded as research and development costs. At the point when a high probability of regulatory approval is obtained, the provision recorded is reversed, up to no more than the original cost.

# Key accounting estimate [] Indirect production costs

Indirect production costs account for more than 50% of the net inventory value reflecting a lengthy production process compared with low direct raw material cost. The production of both diabetes care and biopharma products is highly complex from fermentation to purification and formulation, including quality control of all production processes. Furthermore, the process is very sensitive to manufacturing conditions. These factors all influence the parameters for capitalisation of indirect production costs in Novo Nordisk and full cost of the products. Indirect production costs is measured using a standard cost method, which is reviewed regularly to ensure relevant measures of capacity utilisation, production lead time, cost base and other relevant factors. When calculating total inventory, Management must make certain judgements about cost of production and idle capacity when estimating indirect production costs for capitalisation. Changes in the parameters for calculation of indirect production costs could have an impact on the gross margin and the overall valuation of inventories.

# Inventories

DKK million	2013	2012
Raw materials	1,660	1,512
Work in progress	6,227	4,910
Finished goods	2,625	3,985
Total inventories (gross)	10,512	10,407
Inventory write-downs at year-end	960	864
Total inventories (net)	9,552	9,543
Carrying amount of inventory carried		
at net realisable value	0	0
Indirect production costs included in work		
in progress and finished goods (net)	4,834	4,894
Share of total inventories (net)	51%	51%
Movements in the inventory write-downs		
Inventory write-downs at the beginning of the year	864	815
Inventory write-downs during the year	465	845
Utilisation of inventory write-downs	(156)	(532)
Reversal of inventory write-downs	(213)	(264)
Inventory write-downs at the end of the year	960	864

# 3.4 Trade receivables

### **Accounting policies**

Trade receivables are recognised initially at fair value and subsequently measured at amortised cost using the effective interest method, less allowance for doubtful trade receivables.

The allowance is deducted from the carrying amount of Trade receivables and the amount of the loss is recognised in the Income statement under Sales and distribution costs. Subsequent recoveries of amounts previously written off are credited against Sales and distribution costs.

# Key accounting estimate [] Allowance for doubtful trade receivables

The customer base of Novo Nordisk comprises government agencies, wholesalers, retail pharmacies, managed care and other customers. Management makes allowance for doubtful trade receivables in anticipation of estimated losses resulting from the subsequent inability of customers to make required payments. If the financial circumstances of customers were to deteriorate, resulting in an impairment of their ability to make payments, an

additional allowance could be required in future periods. When evaluating the adequacy of the allowance for doubtful trade receivables, Management analyses trade receivables and examines historical bad debt, customer concentrations, customer creditworthiness and payment history, current economic trends and changes in customer payment terms. Please refer to note 4.2 for a general description of credit risk.

As a result of the generally troubled economic climate in Europe and the Eurozone countries, Novo Nordisk has increased its focus on the development in the outstanding trade receivables from this region. Payment history as well as current economic conditions and indicators are taken into account in the valuation of trade receivables. Furthermore, as a result of the significant increase in sales to countries within Region International Operations, and the fact that many of these countries have low credit ratings, the relative impact of Region International Operations on the allowance for doubtful trade receivables is increasing. Hence, Novo Nordisk continues to monitor the credit exposure related to this region.

Please refer to note 2.2 for a geographical split of trade receivables and allowance for doubtful trade receivables.

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# 3.4 Trade receivables (continued)

# **Trade receivables**

DKK million	2013	2012
Trade receivables (gross) Allowance for doubtful trade receivables	11,896 989	10,663 1,024
Trade receivables (net)	10,907	9,639
Trade receivables (net) are equal to an average credit period of 48 days (45 days in 2012).		
Age analysis of trade receivables Non-impaired trade receivables Not yet due Overdue by between 1 and 179 days Overdue by between 180 and 360 days Overdue by more than 360 days	9,985 844 78 0	8,950 629 60 0
Trade receivables with credit risk exposure	10,907	9,639
Allowance for doubtful trade receivables	989	1,024
Trade receivables (gross)	11,896	10,663
<b>Movement in allowance for</b> <b>doubtful trade receivables</b> Carrying amount at the beginning of the year Confirmed losses Reversal of allowance for confirmed losses Allowance for possible losses during the year Effect of exchange rate adjustment	1,024 (8) (10) 51 (68)	892 (35) (13) 189 (9)
Allowance at the end of the year	989	1,024

# 3.5 Other receivables and prepayments

### Accounting policies

Other receivables and prepayments is recognised initially at fair value and subsequently measured at amortised cost using the effective interest method. Other receivables comprise miscellaneous duties and work in progress for

third parties etc. Prepayments relate to ongoing research and development activities such as clinical trials and costs concerning subsequent financial years.

# **Other receivables and prepayments**

DKK million	2013	2012
Prepayments	1,110	1,033
Interest receivable	75	87
Amounts owed by related parties	141	184
Deposit	232	524
VAT receivable	197	185
Other receivables	699	692
Total other receivables and prepayments	2,454	2,705

# 3.6 Provisions and contingent liabilities

### **Accounting policies**

Provisions for sales rebates and discounts granted to government agencies, wholesalers, retail pharmacies, managed care and other customers are recorded at the time the related revenues are recorded or when the incentives are offered. Provisions are calculated based on the historical experience and the specific terms in the individual agreements.

Provisions for legal disputes are recognised where a legal or constructive obligation has been incurred as a result of past events and it is probable that there will be an outflow of resources that can be reliably estimated. In this case, Novo Nordisk arrives at an estimate on the basis of an evaluation of the most likely outcome. Disputes for which no reliable estimate can be made are disclosed as contingent liabilities.

Novo Nordisk issues credit notes for expired goods as a part of normal business. Where there is historical experience or a reasonably accurate estimate of expected future returns can otherwise be made, a provision for estimated product returns is recorded. The provision is measured at gross sales value.

Provisions are measured at the present value of the anticipated expenditure for settlement of the legal or constructive obligation using a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the obligation. The increase in the provision due to the passage of time is recognised as financial expense.

### Key accounting estimate [] Provisions for sales rebates

Novo Nordisk records provisions for expected sales rebates, wholesaler charge-backs and other rebates, including Medicaid and Medicare in the US.

Such estimates are based on analyses of existing contractual or legal obligations, historical trends and the Group[]s experience. Provisions are calculated on the basis of a percentage of sales for each product as defined by the contracts with the various customer groups.

Provisions for sales rebates are adjusted to actual amounts as rebates, discounts and returns are processed. Please refer to note 2.1 for further information on sales rebates and provisions.

Novo Nordisk considers the provisions established for sales rebates to be reasonable and appropriate based on currently available information. However, the actual amount of rebates and discounts may differ from the amounts estimated by Management as more detailed information becomes available.

#### Key accounting estimate [] Provisions for legal disputes

Provisions for legal disputes consist of various types of provision linked to ongoing legal disputes. Management makes judgements about provisions and contingencies, including the probability of pending and potential future litigation outcomes which, by their very nature, are dependent on inherently uncertain future events. When determining likely outcomes of litigations etc, Management considers the input of external counsels on each case, as well as known outcomes in case law.

Although Management believes that the total provisions for legal pro ceedings are adequate based upon currently available information, there can be no assurance that there will not be any changes in facts or matters or that any future lawsuits, claims, proceedings or investigations will not be material.

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# 3.6 Provisions and contingent liabilities (continued)

# **Provisions**

DKK million	Provisions for sales rebates	Provisions for legal disputes	Provisions for product returns	Other provisions <sup>1</sup>	2013 Total	2012 Total
At the beginning of the year Additional provisions, including increases to existing provisions Amount used during the year Adjustments, including unused amounts reversed during the year Effect of exchange rate adjustment	7,352 16,277 (15,069) (289) (321)	1,057 206 (3) (54) (55)	582 298 (335) 138 (2)	572 297 (86) (62) (10)	9,563 17,078 (15,493) (267) (388)	8,264 13,419 (11,255) (768) (97)
At the end of the year	7,950	1,151	681	711	10,493	9,563
Non-current liabilities Current liabilities	□ 7,950	1,151 []	409 272	623 88	2,183 8,310	1,907 7,656

1. Other provisions consist of various types of provisions, including employee benefits such as jubilee benefits, company-owned life insurance etc. Assets related to company-owned life insurance are presented as part of other financial assets.

# **Contingent liabilities**

Novo Nordisk is currently involved in pending litigations, claims and investigations arising out of the normal conduct of its business. While provisions that Management deems to be reasonable and appropriate have been made for probable losses, there are uncertainties connected with these estimates. Novo Nordisk does not expect the pending litigations, claims and investigations, individually and in the aggregate, to have a material impact on Novo Nordisk[]s fi nancial position, operating profit or cash flow in addition to the amounts accrued as provision for legal disputes.

# Pending litigation against Novo Nordisk

Along with a majority of the hormone therapy product manufacturers in the US, Novo Nordisk is a defendant in product liability lawsuits related to hormone therapy products. There are currently 2 cases against Novo Nordisk involving individuals who allege to have used a Novo Nordisk hormone therapy product. These products (Activella<sup>®</sup> and Vagifem<sup>®</sup>) 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, one individual (compared with 45 individuals in 2012) currently allege, in relation to similar lawsuits against Pfizer Inc., that they too have used a Novo Nordisk hormone therapy product. Novo Nordisk does not expect the pending claims to have a material impact on Novo Nordisk] s financial position, operating profit or cash flow.

In November 2006, Novo Nordisk A/S and the Italian affiliate Novo Nordisk Farmaceutici S.p.A. were sued by A. Menarini Industrie Farmaceutiche Riunite s.r.l. and Laboratori Guidotti S.p.A. ([Menarini]) in the Civil Court in Rome. Menarini claims that Novo Nordisk breached an alleged contract with Menarini for the sale and distribution of insulin and insulin analogues in the Italian market or, alternatively, has incurred a pre-contractual or extra-contractual liability arising from negotiations between the parties. Novo Nordisk disputes the claims made by Menarini. On 8 October 2013 a hearing was conducted for final conclusions. On 8 January 2014 the trial court dismissed the case against Novo Nordisk. Menarini has the right to appeal the decision of the trial court. Novo Nordisk does not expect the pending claim to have a material impact on Novo Nordisk[]s financial position, operating profit or cash flow.

In August 2013, a number of claims alleging pancreatic cancer and pancreatitis have been filed against various incretin-class manufactures in U.S. courts, including Novo Nordisk. Novo Nordisk is currently named in 34 product liability cases related to Victoza<sup>®</sup>, predominantly related to pancreatic cancer. On 26 August 2013, the request for centralisation of all federal pancreatic cancer cases has been granted, and a single multidistrict litigation (MDL) court is now presiding over all federal cases. Novo Nordisk does not expect the pending claims to have a material impact on Novo Nordisk<sup>[]</sup>s financial position, operating profit or cash flow.

Novo Nordisk, along with 93 other defendants, has been named in a lawsuit filed in 2009 in the United States by the Republic of Iraq. The lawsuit alleges damages related to the defendants participation in the United Nations defunct Oil for Food Program. Nordisk does not expect the pending claim to have a material impact on Novo Nordisk s financial position, operating profit or cash flow.

In addition to the above, the Novo Nordisk Group is engaged in certain litigation proceedings. In the opinion of Management, settlement or continuation of these proceedings is not expected to have a material effect on Novo Nordisk s financial position, operating profit or cash flow.

### Pending claims against Novo Nordisk and investigations involving Novo Nordisk

In February 2011, the office of the US Attorney for the District of Massachusetts served Novo Nordisk with a subpoena calling for the production of documents regarding potential civil and criminal offences relating to the company smarketing and promotional practices for the following products: NovoLog<sup>®</sup>, Levemir<sup>®</sup> and Victoza<sup>®</sup>. This matter is now being conducted by the US Attorney for the District of Columbia. Novo Nordisk is cooperating with the US Attorney in this investigation. Novo Nordisk does not expect the pending claims to have a material impact on Novo Nordisk is financial position, operating profit or cash flow.

In June 2005 Novo Nordisk filed a patent infringement lawsuit against Caraco Pharmaceutical Laboratories, Ltd. ([Caraco]), a generic pharmaceutical company, and its Indian parent, Sun Pharmaceutical Industries, Ltd., in the US District Court for the Eastern District of Michigan regarding Caraco] sabbreviated new drug application ([ANDA]) for a generic version of Prandin<sup>®</sup> (repaglinide). In January 2011, the District Court ruled that Novo Nordisk] s US Patent No. 6,677,358 (the [358 patent]), which is directed toward the use of repaglinide in combination with metformin for the treatment of type 2 diabetes, is invalid and unenforceable. Novo Nordisk immediately appealed this decision on the merits to the US Court of Appeals for the Federal Circuit. Following briefing and oral argument, the US Court of Appeals for the Federal Circuit reversed the District Court finding of patent unenforceability and affirmed the patent invalidity decision. Novo Nordisk] s request for rehearing *en banc* of the invalidity affirmance was denied on 18 September 2013.

# 3.6 Provisions and contingent liabilities (continued)

Novo Nordisk has been involved in patent infringement litigation with three additional ANDA applicants for generic versions of Prandin<sup>®</sup>: Paddock Laboratories, Aurobindo Pharma Ltd. and Sandoz Inc., and ANDA applicant Lupin Ltd. for PrandiMet<sup>®</sup>. Following the 18 September US Court of Appeals for the Federal Circuit denial of Novo Nordisk *n banc* request, the cases are concluding.

Also before the District Court for the Eastern District of Michigan is a consolidated class action where a putative class of direct purchasers of Prandin<sup>®</sup> asserts that Novo Nordisk has violated US antitrust laws in delaying the entry of generic versions of Prandin<sup>®</sup>.

Novo Nordisk does not expect the pending claims related to Prandin<sup>®</sup> to have a material impact on Novo Nordisk financial position, operating profit or cash flow.

In addition to the above, the Novo Nordisk Group is engaged in various ongoing tax audits and investigations. In the opinion of Management, these pending audits and investigations are not expected to have a material effect on Novo Nordisk s financial position, operating profit or cash flow.

# 3.7 Retirement benefit obligations

### **Accounting policies**

Novo Nordisk operates a number of defined contribution plans throughout the world. Novo Nordisk s contributions to the defined contribution plans are charged to the Income statement in the year to which they relate. In a few countries, Novo Nordisk still operates defined benefit plans. The costs for the year for defined benefit plans are determined using the projected unit credit method. This reflects services rendered by employees to the valuation dates and is based on actuarial assumptions primarily regarding discount rates used in determining the present value of benefits and projected rates of remuneration growth. Discount rates are based on the market yields of high-rated corporate bonds in the country concerned.

Actuarial gains and losses arising from experience adjustments and changes in actuarial assumptions are charged or credited to Other comprehensive income in the period in which they arise. Past service costs are recognised immediately in the Income statement.

Pension assets are only recognised to the extent that Novo Nordisk is able to derive future economic benefits such as refunds from the plan or reductions of future contributions.

The Group s defined benefit plans are pension plans and medical plans and are usually funded by payments from Group companies and by employees to funds independent of Novo Nordisk. Where a plan is unfunded, a liability for the retirement obligation is recognised in the Balance sheet. Costs recognised for post-employment benefits are included in Cost of goods sold, Sales and distribution costs, Research and development costs, and Administrative costs.

Other post-employment benefits mostly comprise post-retirement healthcare plans, principally in the US.

The net obligation recognised in the Balance sheet is reported as non-current liabilities.

# **Retirement benefit obligations**

DKK million	Germany	Switzerland	Japan	US	Other	2013 Total	2012 Total
At the beginning of the year	476	319	336	294	239	1,664	1,363
Current service costs	20	35	29	23	22	129	132
Settlements		(120)			(7)	(127)	
Interest costs	18	5	5	10	6	44	47
Remeasurement (gains)/losses	<sup>1</sup> 9	(17)	5	(23)	(7)	(33)	223
Plan participant contributions		11			5	16	19
etc Benefits paid	(4)	(15)	(14)	(6)	(13)	(52)	(80)
Exchange rate adjustment		(5)	(73)	(13)	(6)	(97)	(40)
At the end of the year	519	213	288	285	239	<b>1,544</b> 2	1,6642
assets At the beginning of the year Interest income Settlements	388 15 []	219 4 (90)	229 2 []		68 2 (2)	904 23 (92)	859 31
Remeasurement gains/(losses)			30		(1)	21	7
Employer contributions	21	28	24	6	10	89	93
Plan participant contributions etc	2	11			5	18	17
Benefits paid to employees	(4)	(15)	(14)	(6)	(13)	(52)	(80)
Exchange rate adjustment		(3)	(50)		(2)	(55)	(23)
At the end of the year	414	154	221		67	856	904
Net retirement benefit obligations at the end of the year	105	59	67	285	172	688	760

 Remeasurement relates primarily to change in financial assumptions.
 Present value of partly funded retirement benefit obligations amounts to DKK 1,115 million (DKK 1,229 million in 2012). Present value of unfunded retirement benefit obligations amounts to DKK 429 million (DKK 435 million in 2012).

# 3.7 Retirement benefit obligations (continued)

# Net retirement benefit obligations

DKK million	2013	2012
At the beginning of the year Costs recognised in the Income statement <sup>1</sup>	760 113	439 150
Remeasurements recognised in Other comprehensive income <sup>2</sup>	(54)	281
Exchange rate adjustment recognised in Other comprehensive income <sup>3</sup> Employer contributions	(42) (89)	(17) (93)
At the end of the year	688	760

1. Service costs, net interest, settlements and other.

2. 2012 includes effect of change in accounting policy amounting to DKK 65 million related to prior periods.

3. Exchange rate adjustments of investments in subsidiaries.

Please refer to note 5.4 for maturity analysis of net retirement benefit obligation.

Novo Nordisk does not expect the contributions over the next five years to differ significantly from current contributions.

# Weighted average asset allocation of funded retirement obligations

	DKK million	<b>2013</b> %	DKK million	2012 %
Coverage insurance <sup>1</sup>	584	68%	607	67%
Equities	78	9%	67	7%
Bonds	167	20%	214	24%
Cash at bank	17	2%	9	1%
Property	10	1%	7	1%
Total	856	100%	904	100%

1. Novo Nordisk s defined benefit plans in Germany and Switzerland are reimbursed by the international insurer Allianz regardless of the value of the plan assets. The risk related to the funding in these countries is therefore counterparty risk against Allianz.

# Assumptions used for valuation

2013	2012
Weighted	Weighted

	average	average
Discount rate Projected future remuneration increases Medical cost trend rate Inflation rate	3% 2% 4% 2%	3% 2% 3% 2%

Actuarial valuations are performed annually for all major defined benefit plans. Assumptions regarding future mortality are based on actuarial advice in accordance with published statistics and experience in each country.

Significant actuarial assumptions for the determination of the retirement benefit obligation are discount rate and expected future remuneration increases. The sensitivity analyses below have been determined based on reasonably likely changes in the assumptions occurring at the end of the period.

DKK million	1%-point increase	1%-point decrease
Discount rate	(216)	274
Future remuneration	62	(54)

The sensitivities above consider the single change shown with the other assumptions assumed to be unchanged. In practice, changes in one assumption may be accompanied by offsetting changes in another assumption (although this is not always the case).

# 3.8 Other liabilities

# **Other liabilities**

DKK million	2013	2012
Employee costs payable	3,962	3,748
Accruals	3,685	3,697
VAT and duties payable	761	703
R&D clinical trials	410	229
Other payables <sup>1</sup>	568	605
Total other liabilities	9,386	8,982

1. Primarily relates to royalty payments and deferred income.

# 78 CONSOLIDATED FINANCIAL STATEMENTSSection 4Capital structure and financing items

The notes in this section provide an insight into the capital structure, free cash flow and financing items. The free cash flow impacts Novo Nordisk[]s long-term target for []Cash to earnings[]. Further information on the company[]s capital structure can be found in []Shares and capital structure[] on pp 44[]45.

Novo Nordisk is capital structure is characterised by a substantial equity ratio. This reflects the long-term investment horizon that is generally applied in the pharmaceutical industry, where a development time of more than ten years is usual. The main financial risk is foreign exchange exposure, where Novo Nordisk aims to reduce the short-term impact from the movement in key currencies by hedging future cash flows.

# 4.1 Share capital, distribution to shareholders and earnings per share

**Share capital** 

DKK million	A share capital	B share capital	Total share capital
Development in share capital: 2009 2010 2011 2012	<b>107</b>	513 (20) (20) (20)	620 (20) (20) (20)
At the beginning of the year 2013	107 []	453 (10)	560 (10)
At the end of the year	107	443	550

With effect 2 January 2014 a stock split of the company s B shares was conducted changing the trading unit from DKK 1 to DKK 0.20. At the end of 2013, the share capital amounted to DKK 107 million in A share capital and DKK 443 million in B share capital (equal to 2,213 million B shares of DKK 0.20).

# **Treasury shares**

### **Accounting policies**

Treasury shares are deducted from the share capital at their nominal value of DKK 0.20 per share. Differences between this amount and the amount paid to acquire or received for disposing of treasury shares are deducted directly in equity.

**2013** 2012

	Market value DKK million	As % of share capital before cancellation	As % of share capital after cancellation	Number of B shares of DKK 0.20 (million)	Number of B shares of DKK 0.20 (million)
Holding at the beginning of the year Cancellation of treasury shares	15,962 (9,165)	3.1% (1.8%)		871 (50)	1221 (100)
Holding of treasury shares, adjusted for cancellation	6,797	1.3%	1.3%	37	22
Transfer regarding options and restricted stock units	(618)		(0.1%)	(3)	(4)
Purchase during the year	13,989		2.7%	73	73
Sale during the year Value adjustment	(65) 343		(0.2%)	(4) □	(4) □
Holding at the end of the year	20,446		3.7%	103	87

1. Comparative figures have been restated to reflect the change in trading unit from DKK 1 to DKK 0.20.

The purchase of treasury shares during the year relates to the remaining part of the 2012 share repurchase programme totalling DKK 1.0 billion and the DKK 14 billion share repurchase programme of Novo Nordisk B shares for 2013 of which DKK 1 billion remains at year-end. The programme ends on 28 January 2014. The purpose of the programmes is to reduce the company share capital. Transfer of treasury shares relates to exercised share options, long-term share-based incentive programme and employee share-savings programmes.

At year-end the holding of treasury shares amounts to 102,852,025 shares corresponding to DKK 21 million of the share capital (87,083,380 shares in 2012 or DKK 17 million of the share capital). At year-end 13.3 million shares of the holding of treasury B shares are regarded as hedges for the long-term share-based incentive programme and share options to employees.

# 4.1 Share capital, distribution to shareholders and earnings per share (continued)

Net cash distribution to shareholders

DKK million	2013	2012	2011
Dividends Share repurchases	9,715 13,924	7,742 11,896	5,700 10,595
Total	23,639	19,638	16,295

At the end of 2013, proposed dividends (not yet declared) of DKK 11,866 million (DKK 4.50 per share) are included in Retained earnings.

The declared dividend included in Retained earnings was DKK 9,715 million (DKK 3.60 per share) in 2012 and DKK 7,742 million (DKK 2.80 per share) in 2011. No dividend is declared on treasury shares.

# **Earnings per share**

### Accounting policies

Earnings per share is presented as both basic and diluted earnings per share. Basic earnings per share is calculated as net profit divided by the average number of shares outstanding. Diluted earnings per share is calculated as net profit divided by the sum of average number of shares outstanding, including the dilutive effect of outstanding share bonus pool and options [] in the money[]. The dilutive effect of share options [] in the money[] is calculated as the difference between the following:

1) the number of shares that would have been transferred assuming the exercise of the share options and share bonus pool.

2) the number of shares that could have been acquired at fair value with proceeds from the exercise of the share options.

The difference (the dilutive effect) is added to the denominator as an issue of shares for no consideration.

DKK million		2013	2012	2011
Net profit for the year		25,184	21,432	17,097
Average number of shares outstanding <sup>1</sup> Dilutive effect of outstanding share bonus pool and options Din the money <sup>1, 2</sup>	in 1,000 shares in 1,000 shares	2,679,362 14,263	2,741,690 16,650	2,827,165 23,495
Average number of shares outstanding, including dilutive effect of options []in the money[]	in 1,000 shares	2,693,625	2,758,340	2,850,660

Basic earnings per share <sup>1</sup>	DKK	9.40	7.82	6.05
Diluted earnings per share <sup>1</sup>	DKK	9.35	7.77	6.00

1. Comparative figures have been restated to reflect the change in trading unit from DKK 1 to DKK 0.20.

2. For further information on outstanding share bonus pool and options, refer to note 5.1.

# 4.2 Financial risks

Novo Nordisk has centralised management of the Group[]s financial risks. The overall objectives and policies for the company[]s financial risk management are outlined in an internal Treasury Policy, which is approved by the Board of Directors. The Treasury Policy consists of the Foreign Exchange Policy, the Investment Policy, the Financing Policy and the Policy regarding Credit Risk on Financial Counterparts, and includes a description of permitted financial instruments and risk limits.

Novo Nordisk only hedges commercial exposures and consequently does not enter into derivative transactions for trading or speculative purposes. Novo Nordisk uses a fully integrated Treasury Management System to manage all financial positions. All positions are marked-to-market based on real-time quotes, and risk is assessed using generally accepted standards.

# Foreign exchange risk

Foreign exchange risk is the principal financial risk for Novo Nordisk and as such has a significant impact on the Income statement, Other comprehensive income, the Balance sheet and the Statement of cash fl ows.

The overall objective of foreign exchange risk management is to reduce the short-term negative impact of exchange rate fluctuations on earnings and cash flow, thereby increasing the predictability of the financial results.

The majority of Novo Nordisk sales are in EUR, USD, JPY, CNY, GBP and CAD. Consequently, Novo Nordisk foreign exchange risk is most significant in USD, JPY, CNY, GBP and CAD, while the EUR exchange rate risk is regarded as low due to Denmark six fixed-rate policy towards EUR.

Novo Nordisk hedges existing assets and liabilities in key currencies as well as future expected cash flows up to a maximum of 24 months forward. During 2013, the hedging horizon varied between 8 and 14 months for USD, JPY, CNY, GBP and CAD. Currency hedging is based upon expectations of future exchange rates and mainly uses foreign exchange forwards and foreign exchange options matching the due dates of the hedged items. Expected cash flows are continually assessed using historical inflows, budgets and monthly sales forecasts. Hedge effectiveness is assessed on a regular basis.

# 4.2 Financial risk (continued) Key currencies

Exchange rate DKK per 100	USD	JPY	CNY	GBP	CAD
2013					
Average	562	5.77	91	878	545
Year-end	541	5.14	89	892	505
Year-end change	(4.4%)	(21.8%)	(2.2%)	(2.3%)	(11.2%)
2012					
Average	579	7.27	92	918	580
Year-end	566	6.57	91	913	569
Year-end change	(1.6%)	(11.5%)	0.0%	2.6%	1.1%

The financial contracts existing at the end of the year cover the expected future cash flow for the following number of months:

	2013	2012
USD JPY CNY <sup>1</sup> GBP	12 months 14 months 12 months 12 months	12 months 13 months 12 months