NOVO NORDISK A S Form 6-K February 06, 2013

#### 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, 2013

## **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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The Management review, as defined by the Danish Financial Statements Act (FSA), is found on pp 1 54 and 94. This Annual Report is published in both a Danish and an English language version. In the event of any discrepancies, the Danish version shall prevail.

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2012 was a very good year for Novo Nordisk. Both in terms of financial performance with reported sales up by 18% and net profit growth of 25% and progress in the company s research and development pipeline, which promises well for the future. And as you will see from this Annual Report in which we account for both financial, environmental and social performance the company also did well in many other respects in 2012.

The company s Management and all its employees around the world can be proud of these results, which are exceptional in the pharmaceutical world these days when financial constraints and austerity measures are creating an increasingly difficult environment for research-based pharmaceutical companies.

We are very aware that Novo Nordisk s results are created against a sad background, namely the continuing rise in the number of people with diabetes around the world. And despite advances in healthcare over the years, only a small fraction of the people being treated today are well treated.

As I said in last year s report: There has never been more need for a company like Novo Nordisk; a company that has dedicated most of its resources, skills and innovation power to improving diabetes care. And at the same time is making very good use of the skills it has built within diabetes in developing its biopharmaceutical business, not the least within haemophilia.

Every year, the Board of Directors reviews the company s long-term strategy and outlook. As described in the article on p 15, the strategy is characterised by a strong focus on a few diseases, five core capabilities and a deeply rooted values-based management system. The Board remains confident that these strategic choices provide a solid basis for a continued positive development for Novo Nordisk in the coming years.

We are also confident that with Lars Rebien Sørensen and his Executive Management team we have the leadership needed to execute the strategy and fulfil Novo Nordisk s potential. Together with Lars and his team, in January 2013 we decided to expand Executive Management with two executives, promoted from senior vice president positions within the company. This lifts the direct responsibility for critical functions such as marketing, business development and IT into Executive Management, while also broadening the group of senior managers.

In his letter on the following pages, Lars outlines some key events in 2013, and as you will see, it looks like yet another exciting year for Novo Nordisk. However, I must also remind you that for Novo Nordisk, as for any company of our size in the pharmaceutical industry, there is always the risk of something not going as we expected. In the article on p 41, you can read more about key risks of which you should be aware.

At the Annual General Meeting on 20 March 2013, the Board of Directors will propose a 29% increase in dividend to 18 Danish kroner per share. The Board of Directors has furthermore decided to initiate a new share repurchase programme of up to 14 billion kroner.

For me personally, 2012 was the last full year on the Board of Directors of which I have been a member since 2003 and had the privilege to chair since 2006. It has been an exciting journey, in the course of which Novo Nordisk has developed into a leading, global and highly respected company. Shareholder return has been high, and the company s strategic foundation has been strengthened, making it well prepared to address the challenges ahead.

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

> Sten Scheibye Chairman of the Board of Directors

In 1923, the first patients were treated with insulin from the company that is now Novo Nordisk. Today, 90 years later, insulin is still our main product. I think it is worth mentioning for several reasons: it says something about how focused this company has been for many years and still is. It also shows that insulin and other protein-based medicines protein therapeutics as they are also called are fundamentally different from traditional chemical medicines in that our clever researchers can always find ways to make them even better. Finally, my brief history lesson is a reminder to all of us who work in the company today many of whom are also shareholders in the company that although we have good reason to be proud of what we have achieved with Novo Nordisk in recent years, we owe a lot to our predecessors, who laid the foundation for what we are doing today.

Most annual reports these days talk about how the state of the global economy and the ensuing austerity measures put pressure on businesses. This report is no exception. We are often facing situations where governments are demanding price reductions that we consider unacceptable or implementing measures to limit new products access to the market. It puts us in a moral dilemma. On the one hand, we want to continue supplying our best products to customers around the world; on the other hand, we cannot sell our newest products at the old products prices. If we do that, we start to erode the whole innovation model that created the products in the first place. Then we deny all the 371 million people who have diabetes the possibility of future, better treatments and, ultimately, a cure for their disease.

In such difficult times, it is crucial that we industry, politicians and payers rethink the approach to managing diabetes and other chronic diseases, ensuring more sustainable healthcare solutions. That is why we support initiatives such as the European Diabetes Leadership Forum, which gathered more than 700 participants in Copenhagen in April 2012 to discuss and agree on ambitions, priorities and actions for improving diabetes care in Europe and OECD countries.

Despite the difficult economic climate, we were able to grow sales in 2012 by 12% measured in local currencies due to continued strong demand for some of our key products. As in 2011, the products behind most of this growth were our once-daily human GLP-1 analogue Victoza® (liraglutide) and two of our modern insulins, NovoRapid® (NovoLog® in the US) and Levemir®. From a regional perspective, North America was again the main contributor to our growth, followed by International Operations and Region China. As you will see from the article on p 32 about our different markets, it is 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 32% reported and 20% in local currencies

While on the subject of profit, I am aware of the public debate on how much or how little large, international companies pay in corporate taxes. Therefore, it is important for me to assure you that Novo Nordisk does pay its fair share. In 2012, our tax expense amounted to 6,379 million kroner, corresponding to an effective tax rate of 22.9%. We pay taxes where profits are earned, according to international transfer pricing rules, and being a good corporate citizen everywhere we do business is a company objective.

Several products in our development pipeline passed important milestones. However, almost all attention from investors and the media was on our new generation of insulins, Tresiba® (insulin degludec) and Ryzodeg® (a combination of insulin degludec and insulin aspart). Both products were approved in Japan in 2012 and in the EU in January 2013. In the US, Canada, Switzerland and other countries, the approval process is ongoing.

Despite all eyes being on Tresiba® and Ryzodeg®, I would like to mention a few other encouraging developments. One is the completion of the phase 3a programme for IDegLira, a fixed-ratio combination of liraglutide and insulin degludec for the treatment of patients with type 2 diabetes. We are planning regulatory filing for IDegLira in the EU mid-2013 and in the US during 2013 pending marketing authorisation for Tresiba®.

In December 2012, we selected for phase 3 development a new formulation of insulin aspart, called FIAsp, with a faster onset of appearance than NovoRapid® (NovoLog® in the US), which we hope will enable more flexible insulin administration in connection with meals, as well as improved blood sugar control after meals

Within the area of haemophilia, we filed turoctocog alfa for approval in the EU, US and other markets. Turoctocog alfa is a recombinant factor VIII product for treatment of the most widespread form of haemophilia, haemophilia A. Furthermore, we launched NovoThirteen®, a recombinant factor XIII product for treatment of a rare In 2013, we will have special focus on:

the launch of Tresiba® in the EU, Japan (pending price negotiations) and other markets where it has been approved

approval of Tresiba® and Ryzodeg® in the US and other countries, where the regulatory review process is ongoing

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regulatory filing for IDegLira in the EU mid-2013 and in the US during 2013 pending marketing authorisation of Tresiba®

completion of the phase 3 programme investigating the use of liraglutide for treatment of people with obesity and co-morbidities

initiation of the phase 3 studies for semaglutide, a once-weekly GLP-1 analogue for the treatment of type 2 diabetes; FIAsp; and liraglutide for type 1 diabetes as adjunct to insulin.

We will invest in both current products and our new-generation insulins. We will spend 14 15% of our sales on research and development of new, innovative products, which will address unmet medical needs and help secure Novo Nordisk s long-term development. In 2013 alone, we expect that more than 28,000 people will participate in Novo Nordisk-sponsored clinical trials. And, we will continue investing in advocacy and activities in support of people with diabetes and haemophilia.

All of these investments serve one purpose: To help patients live better lives. That is what drives us. We know there are millions of people with diabetes who could be living their lives in full if only they got the necessary medical treatment and care, and we are determined to contribute to closing that gap. We have set an ambition that by 2020 we will provide medical treatment to an estimated 40 million patients.

Last but not least, we will continue investing in the development of our people, with a strong focus on doing business the Novo Nordisk Way never compromising on quality and business ethics.

Personally, I look forward to having two new members joining my Executive Management team: Lars Fruergaard Jørgensen, responsible for IT, Quality & Corporate Development, and Jakob Riis, head of Marketing & Medical Affairs.

We have also promoted four corporate vice presidents in our US affiliate to senior vice presidents and members of the company s global Senior Management Board. The promotions reflect the increasing size, complexity and strategic importance of our business and development pipeline in the US. I look forward to working with the new senior vice presidents and to the increased diversity and stronger US representation they bring to our Senior Management Board. bleeding disorder, in the EU and Canada (where it is marketed as Tretten®). On the negative side, we had to discontinue vactreptacog alfa, an analogue of recombinant factor VIIa, due to safety concerns.

Another negative event, unrelated to our research and development pipeline, came in December, when we received a so-called Warning Letter from the US Food and Drug Administration (FDA), following an inspection of an aseptic filling facility in Bagsværd, Denmark, in March 2012. We immediately took action to address the concerns raised by the agency, learn from them, and prevent them from occurring again. We submitted our response to the Warning Letter on 28 December. At the time of writing this letter, we are still awaiting a response from the agency.

#### I would like to thank everyone in the Novo Nordisk

organisation for their contributions to our results in 2012, 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 a few questions at novonordisk.com/annualreport/feedback.

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# **Performance highlights**

DKK million	2008	2009	2010	2011	2012	2011 2012
Financial performance						Change
Sales	17017	04 474	00.004	00 705	04.004	010/
Modern insulins (insulin analogues)	17,317	21,471	26,601	28,765	34,821	21%
Human insulins	11,804	11,315	11,827	10,785	11,302	5%
Victoza®		87	2,317	5,991	9,495	58%
Protein-related products	1,844	1,977	2,214	2,309	2,511	9%
Oral antidiabetic products (OAD)	2,391	2,652	2,751	2,575	2,758	7%
Diabetes care total	33,356	37,502	45,710	50,425	60,887	21%
NovoSeven®	6,396	7,072	8,030	8,347	8,933	7%
Norditropin®	3,865	4,401	4,803	5,047	5,698	13%
Hormone replacement therapy	1,612	1,744	1,892	2,054	2,163	5%
Other products	324	359	341	473	345	(27%)
Biopharmaceuticals total	12,197	13,576	15,066	15,921	17,139	8%
Total sales by business segment	45,553	51,078	60,776	66,346	78,026	18%
North America	15,154	18,279	23,609	26,586	34,220	29%
Europe	17,219	17,540	18,664	19,168	19,707	3%
International Operations	6,353	6,835	8,335	9,367	11,080	18%
Japan & Korea	4,196	4,888	5,660	6,223	6,617	6%
Region China	2,631	3,536	4,508	5,002	6,402	28%
Total sales by geographical segment	45,553	51,078	60,776	66,346	78,026	18%
Underlying sales growth in local currencies	12%	11%	13%	11%	12%	
Currency effect (local currency impact)	(3%)	1%	6%	(2%)	6%	
Total sales growth as reported	9%	12%	19%	9%	18%	
	0.440	0 554	0.407	0 707	0.000	(00())
Depreciation, amortisation and impairment losses	2,442	2,551	2,467	2,737	2,693	(2%)

Operating profit Net financials Profit before income taxes Net profit for the year	12,373 322 12,695 9,645	14,933 (945) 13,988 10,768	18,891 (605) 18,286 14,403	22,374 (449) 21,925 17,097	29,474 (1,663) 27,811 21,432	32% 270% 27% 25%
Total assets	50,603	54,742	61,402	64,698	65,669	2%
Equity	32,979	35,734	36,965	37,448	40,632	9%
Capital expenditure, net	1,754	2,631	3,308	3,003	3,319	11%
Free cash flow <sup>1</sup>	11,015	12,332	17,013	18,112	18,645	3%
Financial ratios						
Percentage of sales						
Sales outside Denmark	99.2%	99.2%	99.4%	99.3%	99.4%	
Sales and distribution costs	28.2%	30.2%	29.9%	28.6%	27.6%	
Research and development costs	17.2%	15.4%	15.8%	14.5%	14.0%	
Administrative costs	5.8%	5.4%	5.0%	4.9%	4.2%	
Gross margin <sup>1</sup>	77.8%	79.6%	80.8%	81.0%	82.7%	
Net profit margin <sup>1</sup>	21.2%	21.1%	23.7%	25.8%	27.5%	
Effective tax rate <sup>1</sup>	24.0%	23.0%	21.2%	22.0%	22.9%	
Equity ratio <sup>1</sup>	65.2%	65.3%	60.2%	57.9%	61.9%	
Return on equity (ROE) <sup>1</sup>	29.6%	31.3%	39.6%	46.0%	54.9%	
Cash to earnings <sup>1</sup>	114.2%	114.5%	118.1%	105.9%	87.0%	
Payout ratio <sup>1</sup>	37.8%	40.9%	39.6%	45.3%	45.3%	
Payout ratio excl non-recurring events <sup>2</sup>	36.6%	40.9%	42.8%	45.3%	45.3%	
Long-term financial targets						Targets <sup>3</sup>
Operating profit margin <sup>1</sup>	27.2%	29.2%	31.1%	33.7%	37.8%	40%
Operating profit growth	38.4%	20.7%	26.5%	18.4%	31.7%	15%
Operating profit after tax to net operating assets <sup>1</sup>	37.4%	47.3%	63.6%	77.9%	99.0%	125%
Cash to earnings, (three-year average)	97.6%	111.5%	115.6%	112.8%	103.7%	90%

#### ACCOMPLISHMENTS AND RESULTS 2012 5

	2008	2009	2010	2011	2012	2011 2012
Social performance						Change
Patients:						
Least developed countries where Novo Nordisk sells						
insulin according to the differential pricing policy	32	36	33	36	35	(3%)
Healthcare professionals trained or educated						
in diabetes (1,000)	N/A	425	373	835	1,274	53%
People with diabetes trained (1,000)	N/A	416	494	626	836	34%
Donations (DKK million)	78	83	84	81	84	4%
New patent families (first filings)	71	55	62	80	65	(19%)
Employees:						
Employees (total)	27,068	29,329	30,483	32,632	34,731	6%
Employees (average FTEs)	26,069	27,985	29,423	31,499	33,061	5%
Employee turnover	12.1%	8.3%	9.1%	9.8%	9.1%	
Assurance:						
Relevant employees trained in business ethics	N/A	N/A	98%%	99%	99%	
Business ethics assurance activities	25	30	35	46	48	4%
Fulfilment of action points from facilitations						
of the Novo Nordisk Way	92%	93%	93%	93%	94%	
Product recalls	2	2	5	5	6	20%
Warning Letters and re-inspections	0	0	0	0	1	
Company reputation with external						
key stakeholders (scale 1 7)	N/A	N/A	N/A	5.6	5.7	2%
Long-term social targets						Targets
Patients reached with diabetes care						10
products (million) (estimate) <sup>4</sup>	N/A	N/A	N/A	21	23	40 million by 2020
Working the Novo Nordisk Way						
(employee assessment) (scale 1 5)	N/A	N/A	N/A	4.3	4.3	4.0
Diverse senior management teams <sup>5</sup>	43%	50%	54%	62%	66%	100% by 2014
Environmental performance						Change
Resources:						enange
Energy consumption (1,000 GJ)	2,533	2,246	2,234	2,187	2,433	11%
Water consumption (1,000 m3)	2,684	2,149	2,047	2,136	2,400	16%
Emissions and waste:						
$CO_2$ emissions from energy consumption (1,000 tons)	217	166	95	94	122	30%

Wastewater (1,000 m3) Waste (tons)	2,542 24,314	2,062 26,362	1,935 25,627	2,036 41,376	2,272 82,802	12% 100%
Long-term environmental targets Energy consumption						Targets
(change compared with prior year)	(9%)	(11%)	(1%)	(2%)	11%	3% annual <sup>6</sup> growth
Water consumption						Ū
(change compared with prior year)	(17%)	(20%)	(5%)	4%	16%	5% annual growth
CO <sub>2</sub> emissions from energy consumption						10% reduction
(change compared with 2004) <sup>7</sup>	(1%)	(24%)	(56%)	(57%)	(44%	by 2014
Share performance						Change
Basic earnings per share/ADR in DKK <sup>1</sup>	15.66	17.97	24.81	30.24	39.09	29%
Diluted earnings per share/ADR in DKK <sup>1</sup>	15.54	17.82	24.60	29.99	38.85	30%
Dividend per share in DKK	6.00	7.50	10.00	14.00	18.00	29%
Total dividend (DKK million)	3,650	4,400	5,700	7,742	9,7158	25%

1. For definitions, please refer to p 93.

2. Impact of Zymogenetics, Inc. share divestment, discontinuation of all pulmonary diabetes projects and impact of DAKO A/S share divestment.

3. The long-term financial targets were updated in February 2013. Please refer to p 10.

4. The accounting policy has been updated in line with WHO definition, and historical data have been restated accordingly. Please refer to p 97.

5. 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 is not achievable.

For target definition, please refer to p 14.

7. The accounting policy has been updated and historical data have been restated accordingly. The target remains unchanged. Please refer to p 102.

8. Proposed dividend for the year (not yet declared).

# 2012 performance and 2013 outlook

2012 was a positive year for Novo Nordisk with strong sales growth, robust performance against long-term financial and social targets and significant progress in the clinical development pipeline.

# Financial performance

The results for the year are higher than expected in the outlook in the *Annual Report 2011* and in line with the latest guidance provided in connection with the quarterly announcement in October 2012.1

## Sales development

Sales increased by 18% measured in Danish kroner and by 12% in local currencies in 2012 compared with 2011. North America was the main contributor with a 66% share of growth measured in local currencies. followed by International Operations and Region China, contributing 20% and 11% respectively. Sales growth was realised within both diabetes care and biopharma-ceuticals, with the majority of growth originating from the modern insulins and Victoza®. Sales growth in 2012 was negatively impacted by around 1.5 percentage points due to healthcare and pricing reforms in several European markets, the US, China and International Operations.

In the following sections, unless otherwise noted, market data is based on moving

annual total (MAT) from November 2012 and November 2011 provided by the independent data provider IMS Health.

# Diabetes care sales development

Sales of diabetes care products increased by 21% measured in Danish kroner to DKK 60,887 million and by 15% in local currencies. Novo Nordisk is the world leader in diabetes care and now holds a global value market share of 26% compared with 24% at the same time the year before.

# Modern insulins, human insulins and protein-related products

Sales of modern insulins, human insulins and protein-related products increased by 16% in Danish kroner to DKK 48,634 million and by 10% measured in local currencies, with North America, International Operations and Region China achieving the highest growth rates. Novo Nordisk is the global leader with 49% of the total insulin market and 46% of the modern insulin market, both measured in volume.

Sales of modern insulins increased by 21% in Danish kroner to DKK 34,821 million and by 15% in local currencies. North America accounted constitute more than 75% of Novo Nordisk s sales of insulin.

#### North America

Sales of modern insulins, human insulins and protein-related products in North America increased by 29% in Danish kroner and by 20% in local currencies. This reflects continued solid market penetration of the modern insulins, NovoLog®, Levemir®and NovoLog® Mix 70/30, and a modest growth in human insulin sales. 50% of Novo Nordisk s modern insulin volume in the US is used in the prefilled device FlexPen®.

#### Europe

Sales of modern insulins, human insulins and protein-related products in Europe were unchanged in Danish kroner but decreased by 1% in local currencies. Sales in Europe reflect continued progress for NovoRapid® and Levemir®, countered by declining human insulin sales. Sales growth in Europe is negatively impacted by a continued low insulin volume growth, below 3%, and by the implementation of pricing reforms in several European markets. Device penetration in Europe remains high with 96% of Novo Nordisk s insulin volume being used in devices, primarily NovoPen® and FlexPen®.

#### **International Operations**

Sales of modern insulins, human insulins and protein-related products in

for more than half of the growth, followed by International Operations and Region China. Sales of modern insulins now

International

1. Please refer to the company announcement dated 31 January 2013 for explanation of results compared to latest expectations.

#### ACCOMPLISHMENTS AND RESULTS 2012 7

Operations increased by 19% in Danish kroner and by 16% in local currencies. The growth is driven by all three modern insulins and a solid contribution from human insulins. Currently, 58% of Novo Nordisk s insulin volume in the major private markets is used in devices.

#### Japan & Korea

Sales of modern insulins, human insulins and protein-related products in Japan & Korea increased by 1% measured in Danish kroner but declined by 6% in local currencies. Sales development is impacted negatively by a continued volume decline in the Japanese insulin market and a challenging competitive environment. Device penetration in Japan remains high, with 98% of Novo Nordisk s insulin volume being used in devices, primarily the FlexPen®.

#### **Region China**

Sales of modern insulins, human insulins and protein-related products in Region China increased by 27% in Danish kroner and by 15% 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®.

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

Victoza® sales increased by 58% in Danish kroner to DKK 9,495 million and by 50% in local currencies, reflecting robust sales performance in all regions. The global roll-out is continuing, with 60 countries having launched Victoza® by the end of

#### **North America**

Sales of Victoza® in North America increased by 60% in Danish kroner and by 48% measured in local currencies. This reflects a continued expansion of the GLP-1 class, which represents 7.3% of the total US diabetes care market in value compared with 5.8% in 2011. Despite the launch of a competitive product, Victoza® continues to drive the US GLP-1 market expansion and is the GLP-1 market leader with a 62% value market share.

#### Europe

Sales in Europe increased by 50% in Danish kroner and by 48% measured in local currencies. Sales growth is primarily driven by France, the UK, Italy and Spain. In Europe, the GLP-1 class s share of the total diabetes care market in value has increased to 6.7% compared with 5.0% in 2011. Victoza® is the GLP-1 market leader with a value market share of 76%.

#### **International Operations**

Sales in International Operations increased by 90% in Danish kroner and by 98% measured in local currencies. This reflects continued strong performance, driven by Brazil and a number of Middle Eastern countries, and a modest comparator in 2011. The GLP-1 class is expanding in International Operations and represents 3.0% of the total diabetes care market by value compared with 1.2% in 2011. The significant expansion of the GLP-1 class is primarily driven by a strong uptake in Brazil. Victoza® is the GLP-1 market leader across International Operations with a value market share of 80%.

#### **Region China**

Victoza® was launched in China during the fourth quarter of 2011. Early market feedback is positive and hospital listings are developing satisfactorily. The GLP-1 class in China is not reimbursed and is relatively modest in size, but its share of the total diabetes care market by value has expanded to 0.5% compared with 0.2% in 2011. Victoza® holds a GLP-1 value market share of 44%.

# NovoNorm®/Prandin®/PrandiMet® (oral antidiabetic products)

Sales of oral antidiabetic products increased by 7% in Danish kroner to DKK 2,758 million and remained unchanged in local currencies. The sales development reflects sales growth in all regions except Europe, where generic competition is negatively impacting overall sales in several markets.

# Biopharmaceuticals sales development

Sales of biopharmaceutical products increased by 8% measured in Danish kroner to DKK 17,139 million and by 2% measured in local currencies, primarily driven by higher sales in the US and partly countered by lower sales in Europe.

#### NovoSeven® (bleeding disorders therapy)

Sales of NovoSeven® increased by 7% in Danish kroner to DKK 8,933 million and by 2% in local currencies. The market for NovoSeven® remains negatively impacted by stricter budgetary controls, an increased number of inhibitor patients participating in clinical trials and patients transferring to an alternative treatment regimen of immune tolerance therapy. The sales development reflects a strong performance in Japan countered by lower sales in Europe. December 2012. Victoza® holds the global market share leadership with a 68% value market share in the GLP-1 segment compared with 58% in 2011. The GLP-1 segment s value share of the total diabetes care market has increased to 6.0% compared with 4.5% in 2011.

#### Japan & Korea

Sales in Japan & Korea increased by 39% in Danish kroner and by 29% measured in local currencies. In Japan, the GLP-1 market is growing and represents 2.3% of the total diabetes care market by value compared with 1.6% in 2011. Victoza®is the leader in the Japanese GLP-1 class with a value market share of 77%.

#### CONTINUED

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# Norditropin® (growth hormone therapy)

Sales of Norditropin® increased by 13% measured in Danish kroner to DKK 5,698 million and by 8% measured in local currencies. The sales growth is primarily driven by North America and International Operations. Novo Nordisk is the leading company in the global growth hormone market, with a 24% market share measured by volume.

#### Other products

Sales of other products within biopharma-ceuticals decreased by 1% in Danish kroner to DKK 2,508 million and by 6% measured in local currencies. This development reflects a negative impact from the decline in the total glucagon market for diagnostic purposes in Japan as well as generic competition to Activella®, countered by continued sales growth for Vagifem® in the US.

# Development in costs and operating profit

The cost of goods sold grew by 7% to DKK 13,465 million, resulting in a gross margin of 82.7% compared with 81.0% in 2011. This development primarily reflects an underlying improvement of 1.0 percentage point 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®. The gross margin was positively impacted by around 0.7 percentage point from currencies as a result of the appreciation of primarily the US dollar versus the Danish krone compared with 2011.

Total non-production-related costs increased by 12% to DKK 35,753

Furthermore, costs increased due to sales and marketing investments in selected countries in International Operations as well as the Chinese sales force expansion in mid-2011. Growth in sales and distribution costs is being partly offset by a reversal of provisions for legal disputes that have been resolved during 2012.

Research and development costs increased by 13% to DKK 10,897 million and by 11% in local currencies. The cost increase is primarily driven by development costs related to the ongoing phase 3 trials for liraglutide in obesity and the phase 3a trials for IDegLira, a fixed-ratio combination of insulin degludec and liraglutide. Within biopharmaceuticals, costs are primarily related to the portfolio of development projects within haemophilia and the phase 2 trial for anti-IL-20, a recombinant human monoclonal antibody, in rheumatoid arthritis.

Administration costs increased by 2% to DKK 3,312 million and stayed flat in local currencies. The unchanged costs in local currencies reflect items of a non-recurring nature in 2011 and 2012, and an underlying increase of approximately 4%, primarily to support the expansion of the international sales organisation.

Licence fees and other operating income amounted to DKK 666 million compared with DKK 494 million in 2011. This development reflects a higher level of recurring royalty income.

Operating profit in 2012 increased by 32% to DKK 29,474 million. In local currencies, the growth was 20%.

## Net financials and tax

Net financials showed a net expense of

been hedged primarily through forward currency contracts. Reflecting the portfolio of foreign currency exchange hedging contracts, the foreign exchange result for 2012 was an expense of DKK 1,529 million compared with an expense of DKK 322 million in 2011. This development reflects losses on foreign exchange hedging, involving especially the US dollar due to its appreciation versus the Danish krone compared with the prevailing exchange rate level in 2011.

The effective tax rate for 2012 was 22.9%, amounting to DKK 6,379 million. Danish income tax amounted to DKK 3,527 million, and accounted for an estimated 11% of total Danish corporate tax contributions.

# Capital expenditure and free cash flow

Net capital expenditure for property, plant and equipment for 2012 was DKK 3.3 billion compared with DKK 3.0 billion in 2011. The main investment projects in 2012 were primarily related to filling capacity in Denmark, Russia and France as well as device production facilities in the US, China and Denmark.

Free cash flow for 2012 was DKK 18.6 billion compared with DKK 18.1 billion in 2011. The limited increase compared with 2011 reflects non-recurring tax payments in 2012 related to income tax disputes from prior years.

## Equity

Total equity was DKK 40,632 million at the end of 2012, equivalent to 61.9% of total assets, compared with 57.9% at the end of 2011. The increase in equity of DKK 3,184 million was primarily driven by the generated net profit of DKK 21,432 million, partly offset by dividend payments

million and by 8% in local currencies.

Sales and distribution costs increased by 13% to DKK 21,544 million and by 8% in local currencies. The cost increase is driven by the expansion of the US sales force and other costs to prepare for the global launch of Tresiba® (insulin degludec). DKK 1,663 million compared with a net expense of DKK 449 million in 2011. As of 31 December 2012, foreign exchange hedging gains of around DKK 850 million have been deferred for recognition in the Income statement in 2013.

In line with Novo Nordisk s treasury policy, the most significant foreign exchange risks for the Group have

of DKK 7,742 million and share repurchases in 2012 of DKK 11,896 million. Please refer to Statement of changes in equity at 31 December on p 59.

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# Outlook 2013

The current expectations for 2013 are summarised in the table below:

Expectations are as reported, if not otherwise stated	Expectations 31 January 2013
Sales growth in local currencies as reported	8 11% Around 4.5 percentage points lower
Operating profit growth in local currencies as reported	Around 10% Around 7 percentage points lower
Net financials	Income of around DKK 1,400 million
Effective tax rate	Around 23%
Capital expenditure	Around DKK 3.5 billion
Depreciation, amortisation and impairment losses	Around DKK 3.0 billion
Free cash flow	Around DKK 22 billion

Novo Nordisk expects sales growth in 2013 of 8 11% measured in local currencies. This reflects expectations for continued robust penetration for the portfolio of modern insulins, a continued steady Victoza® performance and a positive sales contribution from Tresiba®, primarily in the US, the EU and Japan. These sales drivers are partly expected to be countered by an impact from the challenging pricing environments in major markets, generic competition to oral antidiabetic products, intensifying competition within diabetes care as well as biopharmaceuticals and 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 4.5 percentage points lower than growth measured in local currencies.

For 2013, operating profit growth is expected to be around 10% measured in local currencies. This reflects significant costs related to the expected global launch of Tresiba®, the expanded US sales force, as well as sales and marketing investments in China and in a selected number of countries in International Operations. Given the current level of exchange rates versus the Danish krone, the reported operating profit growth is now expected to be around 7 percentage points lower than growth measured in local currencies.

For 2013, Novo Nordisk expects a net financial income of around DKK 1,400 million. The current expectation primarily reflects gains associated with currency hedging contracts following the depreciation of the US dollar and the Japanese yen versus the

Danish krone compared with the average prevailing exchange rates in 2012. The expectations for gains related to currency hedging contracts are more than offset by the expected significant negative net impact on reported operating profit from the depreciation of invoicing currencies versus the Danish krone, primarily reflecting depreciation of non-hedged emerging market currencies.

The effective tax rate for 2013 is expected to be around 23%.

Capital expenditure is expected to be around DKK 3.5 billion in 2013, primarily related to investments in filling capacity and prefilled device production facilities, and new office buildings in Denmark. Depreciation, amortisation and impairment losses are expected to be around DKK 3.0 billion. Free cash flow is expected to be around DKK 22 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 2013, and that currency exchange rates, especially for 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 975 million	12
JPY	DKK 200 million	13
CNY	DKK 110 million <sup>1</sup>	12
GBP	DKK 85 million	12
CAD	DKK 55 million	8

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

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

## Long-term financial targets

#### 2012 performance against 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 were subsequently revised and updated on several occasions. Novo Nordisk has now reached the performance level stipulated in the four long-term financial targets. The target levels have consequently been reviewed and two targets have been updated.

The targets have been revised 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 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 update

		The target level for operating profit growth remains at 15% on average. The target still allows for deviations
Long-term financial target update	Result 2012	in individ?average. The target still allows for deviations opportunities, market conditions or exchange rate movements.
Operating margin38%Operating profit after tax to net operating assets99%Cash to earnings87%Cash to earnings (three-year	32% 38% 99% 87% 104%	The target bevel for operating margin is increased from 35% to \$6%. This is expected to be enabled by continued robust sales growth coupled with gross margin expatibility from both pleative mix and pricing, as well as further productivity improvements in the manufacturing areas. For non-production-related activities, the poperating marging the ansion is expected to be supported by a modest development in administrative costs and scale advantages within
vard-looking statements		sales and marketing, whereas continued investment is envisioned for research and development activities, which are expected to grow in line with sales.

#### Forv

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 2013, 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 Delieve, expect, may, will, plan, strategy, prospect, foresee, estimate, project, anticipatenet energy atime assets a generation of the strategy of the similar meaning in connection discussion of future operating or financial performance identify forward Tooking sad a log to the top of the second s but are not limited to: continued robust operating profit growth combined

with a stable effective tax rate and relatively limited

statements of targets, plans, objectives or goals for future operations, in the apartal in the apartal ing a statements of targets, products, product research, product development, product introductions and product approvals as well as cooperation in relation thereto

> The target level for the cash-to-earnings ratio is maintained at 90%, as expected continued growth in

statements containing projections of or targets for revenues, costs, in the structure, net financials and other financial measures gradually impact working capital requirements. As previously, this target will be pursued looking at the

statements regarding future economic performance, future actions and practice retringences repended 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 2012 performance and 2013 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, government-mandated or market-driven price decreases for Novo Nordisk s products, introduction of competing products, reliance on information technology, Novo Nordisk s ability to successfully market current and new products, exposure to product liability and legal proceedings and investigations, changes in governmental laws and related interpretation thereof, including on reimbursement, intellectual property protection and regulatory controls on testing, approval, manufacturing and marketing, perceived or actual failure to adhere to ethical marketing practices, investments in and divestitures of domestic and foreign companies, unexpected growth in costs and expenses, failure to recruit and retain the right employees, and failure to maintain a culture of compliance.

Please also refer to the overview of risk factors in the Risk overview on p 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 progress

## **Diabetes care**

In 2012, Novo Nordisk made several advances in its marketed product portfolio. Following its approval for use in children aged 2 5 in the US, Levemir®became the modern long-acting basal insulin offering treatment to the widest range of patients in both the US and the EU. Furthermore, a new durable insulin pen for adults, NovoPen® 5, was launched in Europe, and NovoMet®, a fixed combination of metformin and repaglinide, was launched in China (marketed as PrandiMet® in the US).

The product label for Victoza® was expanded in both the EU and the US based on studies comparing Victoza®with exenatide and sitagliptin showing the superiority of Victoza® in blood sugar control and weight reduction. As part of a post-approval commitment given in the US and the EU with the objective of assessing the cardiovascular benefit risk profile of Victoza®, completion of enrolment of more than 9,000 patients globally was achieved. Also, positive results from a phase 1 trial exploring the efficacy and safety of liraglutide, the active ingredient in Victoza®, as adjunct therapy to insulin in people with type 1 diabetes, enabled the decision to be taken to progress this project into a phase 3 programme, ADJUNCT, commencing in the second half of 2013, with the intention of further expanding the Victoza® label.

Novo Nordisk also made significant progress in the clinical development pipeline in 2012. Within insulin, Novo Nordisk is pioneering innovation in all three segments: basal, combination and mealtime treatment. One major accomplishment was the approval of the two new-generation insulins Tresiba®(insulin degludec) and Ryzodeg® (insulin degludec/insulin with IDegLira, a fixed-ratio combination of Tresiba® and Victoza®, for treatment of patients with type 2 diabetes. The completed phase 3 clinical trial programme, DUAL , reconfirmed the competitive profiles of each of the components and documented that patients can benefit from the advantages of both compounds when combined into one product. Novo Nordisk is planning regulatory filing for IDegLira in the EU mid-2013 and in the US during 2013 pending marketing authorisation of Tresiba®.

Within GLP-1, semaglutide was selected as the company s once-weekly candidate and was approved to enter the global phase 3 development programme, SUSTAIN, starting in the first half of 2013, while liraglutide Depot was discontinued.

For both insulin and GLP-1, Novo Nordisk continued to explore oral formulations of these proteins in phase 1 studies. These products are primarily intended for the treatment of type 2 diabetes.

## **Biopharmaceuticals**

#### Haemophilia

Novo Nordisk made important headway in the continued development of solutions for people with haemophilia and other rare bleeding disorders. For the marketed product for haemophilia with inhibitors, NovoSeven®, marketing authorisations for a new administration system for intravenous infusion were obtained in both the EU and the US. The device reduces the number of steps that patients have to go through before they can commence dosing. Novo Nordisk also launched a new product, discontinue the phase 3 development of vatreptacog alfa, a fast-acting recombinant factor VIIa analogue for haemophilia patients with inhibitors, due to an unfavourable benefit risk profile. Finally, the phase 1 investigation of mAb2021 for all three haemophilia segments continued.

#### Inflammation

Novo Nordisk aspires to improve the lives of people with autoimmune and chronic inflammatory diseases by developing compounds with new modes of action for rheumatoid arthritis, lupus, inflammatory bowel disease and psoriatic arthritis. In 2012, for the first time ever, the company advanced an inflammation project, anti-IL-20 for rheumatoid arthritis, into phase 2b clinical development.

Further, phase 2a trials with anti-IL-21 for rheumatoid arthritis were initiated as was a phase 1 trial for lupus erythematosus. Novo Nordisk also started a phase 2a trial to investigate rFXIII (the active ingredient in NovoThirteen®) in ulcerative colitis, began a phase 1 trial with anti-C5aR-215 in rheumatoid arthritis and discontinued anti-NKG2D in rheumatoid arthritis and Crohn s disease due to insufficient efficacy.

## **Clinical trials**

The number of people in Novo Nordisk s clinical trials reflects the high level of activity in the pipeline. In 2012, a total of 23,018 people participated in Novo Nordisk-sponsored clinical trials.

aspart) in Japan and Mexico as well as in the EU in January 2013, alongside the FDA Advisory Committee s positive votes on the two products in the US. Further, phase 3b trials confirmed the efficacy and safety profile of the two compounds that had been demonstrated in the comprehensive BEGIN and BOOST studies. Finally, based on the successful completion of the phase 1 trial of the new faster-acting formulation of insulin aspart (NovoRapid®), FIAsp will initiate its phase 3 programme, onset®, in the second half of 2013.

Novo Nordisk is also at the forefront of the development of a new product class, the fixed combination of insulin and GLP-1,

NovoThirteen®in the EU, Tretten® in Canada, for the treatment of a rare congenital deficiency affecting approximately 900 people worldwide, and the regulatory file was re-submitted to the FDA in the US.

For the broader haemophilia indications, Novo Nordisk submitted regulatory applications for turoctocog alfa in the EU and the US, among others, for the prevention and treatment of bleeding in people with haemophilia A. For the same population, the company also initiated the phase 3 programme for its recombinant long-acting coagulation factor VIII project and completed recruitment for its recombinant long-acting coagulation factor IX offering, targeting the treatment of bleeds in people with haemophilia B, in phase 3. Novo Nordisk decided to

# 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, and providing assurance that responsible business practices are in place, with the aim of contributing to the communities in which the company operates.

## Patients

#### Access to care

Novo Nordisk estimates, based on the WHO standard data for daily insulin doses, that it provides medical treatments for approximately 23 million people with diabetes worldwide.

Of the 371 million people with diabetes, it is known that a large proportion is undiagnosed. About 80% of all people with diabetes live in lowand middle-income countries where provision of adequate healthcare is often absent or insufficient. Novo Nordisk s updated global access to diabetes care strategy aims at closing the gap between health needs and health care and the company has established a goal of reaching an estimated 40 million patients with medical treatment by 2020, Changing Diabetes®40by20 (see pp 13 and 39).

Through the dedicated programme Changing Diabetes® in Children, 9,710 children with type 1 diabetes in nine of the world s poorest countries are now receiving free insulin and care. In addition, about 2,000 healthcare professionals were trained and more than 70 clinics were established during 2012. The programme, which was

#### Capacity-building

Improved diagnosis and treatment of chronic conditions such as diabetes and haemophilia relies on healthcare professionals knowledge and disease understanding, as well as on the availability of treatment and access to care. Novo Nordisk therefore invests in building healthcare capacity such as diabetes clinics, and training and education of professional medical staff. During 2012, a total of 1,274,000 healthcare professionals attended face-to-face or online training programmes offered or sponsored by Novo Nordisk and 836,000 people with diabetes were trained in how to manage their condition.

Efforts to expand access to diabetes care include financial support through the World Diabetes Foundation, an independent nonprofit organisation established by Novo Nordisk in 2002. In 2012, the company donated DKK 64 million to the foundation, which invests in sustainable initiatives to build healthcare capacity that improve prevention and treatment of diabetes in developing countries. See note 5.4 on p 89 and worlddiabetesfoundation.org.

Novo Nordisk also seeks to improve global access to haemophilia care through financial support to the Novo Nordisk Haemophilia Foundation, established in 2005. In 2012, donations amounted to DKK 20 million for projects and fellowships in 48 developing and emerging economies. Initiatives focus on capacity-building, awareness, diagnosis and registries. See nnhf.org.

#### Pricing

Access to medicines is a key element of effective disease management and therefore a cornerstone in Novo Nordisk s global strategy for improved access to diabetes care. In 2012 the company s long-standing differential 11%, due to higher activity within early-stage discovery and development. This is partly countered by the elimination of the use of live animals for biological production control. The company works to continuously reduce, refine and replace the use of animals for testing.

## Employees

In 2012, the average number of full-time employees was 33,061, an increase of 5% compared with 2011. At the end of 2012, Novo Nordisk employed a total of 34,731 people, corresponding to 34,286 full-time positions. The growth in the number of employees is driven by the expansion of the sales and marketing organisation in the regions North America and International Operations as well as of the global Research and Development organisation. Employee turnover decreased from 9.8% in 2011 to 9.1%.

#### Working the Novo Nordisk Way

The annual employee survey, eVoice, measures the extent to which the organisation is working in accordance with the Novo Nordisk Way (see p 19). In 2012, as in 2011, the consolidated score was 4.3, measured on a scale of 1 to 5, with 5 being the best score. The high score indicates a strong culture and commitment to the company s values.

#### **Diversity**

Novo Nordisk seeks to attract and develop the best talent from all over the world and offers equal opportunities for career development and an inclusive, non-discriminating working environment. As the business globalises, it is imperative to nurture diversity at all levels. The company has chosen a strategic focus on gender

launched in 2008, has a goal to reach 10,000 children by 2014.

1. Includes headquarter functions and Research and Development in Denmark.

pricing policy, offering human insulin to the world s 49 poorest countries at prices not to exceed 20% of the average prices in the Western world, was accepted through government tenders or private market distributors in 35 of these countries.

This means that patients are getting insulin treatment at a maximum price of USD 0.2 per day. In other lowand middle-income countries, Novo Nordisk sells insulin at very low tender prices through government health programmes involving large volumes. As a result, an estimated 4.9 million patients have been treated with insulin for less than USD 0.2 a day in 2012. Such initiatives, however, will not suffice. To achieve the 40by20 target, more impact will need to be achieved by increasing the availability of all of Novo Nordisk s products, coupled with awareness-raising and early detection, training of healthcare professionals and support to patients, in partnership with local stakeholders.

#### **Animal testing**

The number of animals purchased for research went up to 73,601, which is an increase of

and nationality and has set an ambition that by the end of 2014 all senior management teams must comply with the target to have members of both genders and different nationalities or explain why this is not achievable. At the end of 2012, 66% of the 29 senior management teams met the diversity criteria, compared with 62% at the end of 2011.

#### Health and safety

Novo Nordisk will continuously improve the working environment and has three strategic focus areas: safety, ergonomics and well-being. In 2012, the average frequency rate of occupational injuries was 3.2 per million working hours, compared with 3.4 in 2011. Working from a zero-injury mindset, the long-term goal is to continually improve performance.

### Assurance

#### **Business ethics**

Each employee must understand their responsibilities in line with the company s

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values-based management system and policies for specific areas such as business ethics. Adherence to the company s global standards for ethical behaviour must be observed and monitored.

With more than 5,000 new employees being onboarded each year, training is a high priority. Training programmes address compliance requirements as well as emerging trends, such as changes in the regulatory environment. Annual business ethics training is required for all employees. In 2012, 99% of these completed the required training, in line with previous years performance.

Internal business ethics assurance activities are conducted using a risk-based approach, with on-site interviews and documentation reviews to assess compliance with Novo Nordisk s business ethics procedures. During 2012, 48 business ethics assurance activities were conducted, compared with 46 in 2011.

Any instances of suspected misconduct must be reported, whether related to specific areas such as business ethics or fraud or to other aspects of the Novo Nordisk Way. Employees can report to a manager or company legal counsel, or they can report anonymously through a compliance hotline monitored by the Audit Committee. The hotline is also open for calls from people outside of Novo Nordisk.

During 2012, 88 cases were reported through the compliance hotline, compared with 66 cases in 2011. Cases reported concerned potential instances of business ethics issues, fraud, violations of the Novo Nordisk Way, quality concerns and other issues. Disciplinary action was taken in all substantiated cases, none of which had any material impact for Novo Nordisk.

#### Values

Adherence to the Novo Nordisk Way, the company s values-based management system, is thoroughly reviewed through so-called facilitations, a systematic form of values audits conducted at organisational unit level. In 2012, the global facilitator team, consisting of senior people with deep understanding of the business and the business environment, conducted 61 facilitations, covering a total of almost 16,000 employees. Through close to 3,000 interviews with employees, local management and stakeholders the facilitators seek to determine the level of adherence to corporate values and behaviours. Best practice for how the Novo Nordisk Way translates into action is shared internally, while findings of non-compliance categorised as critical, major and minor

are reported to local management, which subsequently must implement corrective actions. In 2012, there were 166 findings overall.

#### Supplier audits

Novo Nordisk conducts audits of its suppliers to assess their level of compliance with the company s standards for suppliers. These relate to quality as well as environment, labour, human rights and business ethics, in line with Novo Nordisk s responsible sourcing policy. In 2012, a total of 219 audits were conducted, compared with 177 in 2011. These audits, carried out by Novo Nordisk s global quality organisation, found no critical non-conformities.

#### Quality

Quality and patient safety must never be compromised. Despite increasing volumes of production output, quality levels, measured as inspection findings, have been maintained. In 2012, 130 inspections of Novo Nordisk production facilities were concluded.

Novo Nordisk has received a Warning Letter dated 12 December 2012 from the US Food and Drug Administration (FDA) following a current Good Manufacturing Practice (cGMP) inspection of an aseptic filling facility in Bagsværd, Denmark. The facility inspection took place on 12 20 March 2012, and Novo Nordisk submitted its response to the inspection findings by the FDA in April 2012.

In the Warning Letter, the FDA cites two specific violations. Novo Nordisk takes the observed violations very seriously and is committed to taking the appropriate steps to address the concerns raised by the agency. The company submitted its response to the Warning Letter on 28 December. Novo Nordisk does not expect the Warning Letter to have an impact on products currently marketed in the US.

In 2012, Novo Nordisk had six instances of products recalled from the market, compared with five in 2011. None of the products recalled caused any harm to patients. Local health authorities were informed to ensure that appropriate information was provided to pharmacies, medical staff and patients.

## Long-term social targets

# 2012 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 patients live better lives, working the Novo Nordisk Way and nurturing a diverse working environment. In 2012 a new target was set to accelerate the reach to patients from the 2011 baseline of 21 million to 40 million people by 2020. Performance against the target for working the Novo Nordisk Way was exceeded. Performance against the long-term target for diversity is on track.

1. New long-term target. Data not available prior to 2011.

2. All senior management teams must comply with the target to be diverse in terms of gender and nationality or explain why this is not achievable.

# Environmental performance

As production and sales continue to grow, it becomes increasingly challenging to meet the company s long-term aspiration to keep minimising the total environmental impact. The environmental policy covers the entire value chain from molecule to patient. In addition to ensuring compliance and sound management practices in accordance with ISO 14001, efforts include process optimisations in production and innovation projects in partnership with suppliers, healthcare providers and local communities.

## Resources

Energy consumed for production at the company s 13 production sites in 2012 amounted to 2,433,000 GJ, while water consumption increased to 2,475,000 m3. This is directly linked to the increased production volume output. While all electricity supplies in Denmark are based on renewable energy, supplies of heating and steam for the company s largest production site in Kalundborg, Denmark, still rely on fossil fuels. Production increases at the Kalundborg site are therefore reflected as a negative trend in the total environmental performance, despite ongoing process optimisation, which has improved environmental impact. Around half of Novo Nordisk s direct environmental footprint derives from the production site in Kalundborg. A partnership initiative to secure supplies of district heating and steam based on biological waste modelled on the long-standing successful Symbiosis project will, if successful, result in a reduced carbon footprint from consumption of district heating and steam.

## **Emissions and waste**

CO<sub>2</sub> emissions related to production increased by 30% in 2012 compared with 2011. Most of the increase is due to the phase-in of a new filling plant in Tianjin, China. The remaining increase is a consequence of the larger production volume in Kalundborg. Since 2007, significant reductions have been achieved as a result of energy savings at all production sites and, in particular, the conversion to renewable energy for electricity supplies in Denmark. Initiatives to optimise resource utilisation, particularly in Kalundborg, partly counter the increasing need arising from production growth. Options for increasing the use of renewable energy in China, Denmark and the US are being explored.

Reducing waste is a key element of the company s environmental strategy. In 2012 the total volume of waste doubled to 82,802 tons from 41,376 tons in 2011, as a result of increased production volumes and a reclassification, effective since the end of 2011, of organic production waste (biomass). The majority of the waste, 58,193 tons, is biomass from the fermentation process in Kalundborg. The biomass was previously used for animal feed but is now recovered for biogas production. As a result, the recycling rate is high 84% in 2012 and only 5% and 1% respectively are disposed of as special waste and landfill.

## Long-term environmental targets

# 2012 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 are ambitious and reflect the aspiration to produce more with less and

annual increases in energy to 3% and average annual increases in water consumption to 5%, and to achieve an absolute reduction in CO<sub>2</sub> emissions of 10% by 2014, compared with the 2004 baseline. The CO<sub>2</sub> emissions target is expected to be achieved. Performance against the targets for energy and water consumption is as projected.

continuously reduce impacts on the environment: to curb average

1. From 2007 to 2011 the target was set as an accumulated reduction over four years from a 2007 baseline.

# Strategy is all about choice

# Novo Nordisk is the world s leading diabetes care company. While choices made in the past decade have played an important role in achieving this position, there is more to the story.

Today s Novo Nordisk is the result of many decisions taken during more than 90 years The most important, without which there would be no company, was made in 1922. During a visit to the United States, August Krogh, a Danish Nobel laureate, and his wife, Marie, a medical doctor who had diabetes, learned about the discovery of insulin in Canada. Marie urged August to meet Professor Macleod in Toronto who led the team of researchers behind the discovery. After the meeting, August and Marie returned to Copenhagen bringing with them a permission and a desire to start insulin production in Scandinavia. In March 1923, the first patient was treated with insulin produced in Denmark.

This was the beginning of what is now Novo Nordisk. Since then, many other important decisions and choices have been made. The direction and strategy for the company s further development are

laid out in a strategic framework, which forms the basis for the decisions and choices Management is making today. The framework forms a profile of Novo Nordisk with three distinct features:

First, Novo Nordisk has a sharp focus on a few diseases and conditions where it can make a significant difference. As a result, 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, the company has five distinctive core capabilities:

- Engineering, formulating, developing and delivering therapeutic proteins (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 (see p 19). 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 23 million patients rely on for their daily medication, where more than 34,000 employees work, and in which more than 130,000 investors have bought shares.

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#### Responding to a challenging business environment

In a world characterised by slowing economic growth and austerity measures, the research-based pharmaceutical companies business model is being challenged. Governments and private payers are struggling to meet the demands of ageing populations and are reluctant to pay a premium for new, innovative therapies. Furthermore, many companies are seeing major products going off patent and are unable to bring out innovative products that can make up for this lost revenue.

Pharmaceutical companies have responded to these challenges in various ways. Research and development budgets have been cut. Thousands of employees have been laid off. Some companies 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.

#### Strategy update

Novo Nordisk s strategy is updated and reviewed annually by the Board of Directors to ensure that the company identifies and responds to new business challenges and opportunities in a timely way. This is what led Novo Nordisk to direct its resources to therapeutic proteins and five strategic focus areas. While other options for broadening the company s business and research focus are being considered regularly as part of the annual strategy process, all indicators

show that the way in which Novo Nordisk can create most value for patients, shareholders and society at large is to remain focused on developing new, innovative therapeutic proteins within its current focus areas.

# The five strategic focus areas

#### Expand leadership in diabetes care

In 2012, more than 371 million people worldwide were living with diabetes and it is predicted that by 2030 more than 550 million people worldwide will have diabetes<sup>1</sup> (all footnotes can be found on p 112). Read more about the diabetes pandemic on pp 20 21.

The global market for diabetes care products amounts to approximately DKK 228 billion, of which Novo Nordisk products account for about 26%. The market has been growing by around 10% annually in recent years. Of this global market, insulin accounts for 49%, oral diabetes products for 45% and GLP-1 products for 6%.

Novo Nordisk s largest and fastest-growing business area is products for treating diabetes, accounting for close to 80% of total sales. Within this area, the company s focus is on insulin and GLP-1. In both areas Novo Nordisk is the global market leader by volume.

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

Around half of all insulin in the world comes from Novo Nordisk.

Novo Nordisk is the only company with a full portfolio of human insulins and modern insulins (also known as insulin analogues).

A new generation of insulins, Tresiba® (insulin degludec) and Ryzodeg® (insulin degludec/insulin aspart), is due to be launched in key markets in 2013.

Victoza® (liraglutide) has become the world's most prescribed GLP-1 product (Glucagon-Like Peptide 1) for treatment of adults with type 2 diabetes since its first launch in 2009.

Novo Nordisk makes the world's most widely used injection devices for insulin and GLP-1.

New promising treatments are under development, including a once-weekly GLP-1 analogue and a fixed-ratio combination of liraglutide and insulin degludec.

Finally, Novo Nordisk is involved in early-stage research with leading academic centres to find a cure for type 1 diabetes.

#### The insulin portfolio

Novo Nordisk's modern insulin portfolio includes:

NovoRapid® (NovoLog® in the US), the world's most widely used rapid-acting insulin for use at mealtimes. NovoRapid® is used by people with both type 1 and type 2 diabetes.

NovoMix® 70/50/30 (NovoLog® Mix 70/30 in the US) is a dual-release modern insulin that covers both mealtime and basal requirements. It can be used either to initiate or intensify insulin therapy and is primarily used by people with type 2

diabetes.

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Levemir® is a soluble, long-acting modern insulin for once-daily use for people with type 1 and 2 diabetes. Levemir® provides glucose control with a favourable weight profile.

The primary goal of the company's research in diabetes is to discover new therapies that safely and effectively lower blood glucose while reducing the risk of low blood sugar (hypoglycaemia). Tresiba® and Ryzodeg® are the latest outcomes of this effort:

Tresiba® is a once-daily basal insulin analogue with an ultra-long duration of action and a flat and stable action profile which reduces the rate of low blood sugar (hypoglycaemia). This also makes it possible to adjust insulin dosing time when needed. Ryzodeg® is a soluble insulin combination of Tresiba® and NovoRapid® (insulin aspart), providing both basal and mealtime glucose control. Insulin aspart is marketed under the brand name NovoLog® in the US. Read more about the challenges associated with insulin treatment on pp 24-25.

Novo Nordisk is also developing a faster-acting insulin to be taken at mealtimes, FIAsp, a new formulation of insulin aspart. The phase 1 proof-of-concept trials for a number of different formulations of insulin aspart have been completed and Novo Nordisk expects to initiate the phase 3a programme, onset®, towards the end of 2013.

In addition to new and improved injectable insulins, Novo Nordisk is developing formulations of insulin that can be taken orally as tablets. Encouraging progress has been made in 2012, but many technological challenges remain. Read more about the development of insulin in a tablet on pp 26-27.

#### GLP-1 (Glucagon-Like Peptide 1) a new class of diabetes treatments

With the launch of Victoza® in 2009, Novo Nordisk entered a new segment of the diabetes care market: GLP-1 therapies. Victoza® is a human GLP-1 analogue with 97% similarity to the natural gut hormone. Victoza® 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 major innovation in the treatment of type 2 diabetes because it lowers glucose with a very low risk of triggering low blood sugar (hypoglycaemia).

Victoza® is approved for adults with type 2 diabetes who are unable to achieve blood glucose goals with lifestyle changes and metformin, the most widely used tablet for type 2 diabetes). In less than two years Victoza® has become the leading GLP-1 treatment globally and has steadily expanded the market for GLP-1 treatment. The market is currently valued at approximately DKK 13.6 billion, of which Victoza® accounts for approximately 68%. Available in more than 60 markets, Victoza® is now used by approximately 700,000 people worldwide.

Furthermore, a clinical pharmacology trial investigating the use of liraglutide as adjunct therapy to insulin in people with type 1 diabetes, LATIN T1D (liraglutide as adjunct therapy to insulin in people with type 1 diabetes) has been completed. The phase 3 programme, ADJUNCT , which includes around 2,000 people with type 1 diabetes, will be initiated in the second half of 2013.

Based on the expertise Novo Nordisk has obtained through the development of Victoza®, the company is now building a GLP-1 portfolio with the intention of providing an even broader range of treatment options. Key projects include a once-weekly GLP-1 analogue, semaglutide, which has been approved for phase 3, and IDegLira, a fixed-ratio combination of liraglutide and insulin degludec, which offers the benefits of both compounds.

Novo Nordisk is also developing formulations of GLP-1 that can be taken as tablets.

#### **Injection devices**

Novo Nordisk offers the world s most widely used durable and disposable devices for insulin and GLP-1: NovoPen®4 and FlexPen®, and has recently introduced its latest innovations NovoPen® 5 and FlexTouch® in many markets. Read more about injection devices on p 28.

#### Establish 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 or obese. Of these, more than 200 million men and nearly 300 million women are clinically obese (ie BMI  $\ge$  30)? Obesity is known to be a major risk factor in developing serious diseases such as type 2 diabetes and cardiovascular disease.

Despite the growing prevalence of severe and morbid obesity globally, there are currently only a few medical treatment options, and reimbursement for these medications is limited. The market is currently valued at DKK 1.7 billion.

Novo Nordisk is investigating the use of once-daily liraglutide 3 mg as a new way of treating high-risk obese patients, namely those with obesity-related medical conditions such as prediabetes, sleep apnoea, high blood pressure and lipid. Results of the phase 2 trials and the first of four phase 3 trials have been reported. They suggest that liraglutide 3 mg may have a positive benefit risk profile.

Gaining regulatory approval for antiobesity medications is a major challenge. However, for the first time in more than a decade,

the US Food and Drug Administration has approved new obesity medications in 2012.

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#### Pursue leadership in haemophilia

Haemophilia is an inherited or acquired bleeding disorder that prevents blood from clotting. An estimated 400,000 people worldwide are living with severe or moderate haemophilia. The global haemophilia drug market is estimated at DKK 50 billion and has grown by around 8% 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 & B market and achieve leadership by developing improved treatment options for all patients. In October 2012, turoctocog alfa a recombinant factor VIII therapy was filed for approval in Europe and the US. Long-acting versions of recombinant factor VII and factor IX are in phase 3 development. Read more about activities within haemophilia on p 29.

#### Expand leadership in growth disorders

Novo Nordisk has been active in the treatment of growth hormone insufficiency for almost four decades. The market for growth disorder treatments is estimated at DKK 18 billion and has grown by close to 6% annually in recent years. Novo Nordisk is the leading human growth hormone producer with a market share of 28% measured by value.

Novo Nordisk s strategy in growth hormone therapy is to expand leadership by providing innovative and convenient products and devices. Norditropin® is the only liquid, room temperature-stable growth hormone product available in a prefilled pen device, the ergonomic Norditropin® FlexPro® with an easy-touch dosing mechanism.

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

#### Establish presence in inflammation

Autoimmune inflammatory diseases, such as rheumatoid arthritis and Crohn s disease, result from the immune system attacking the body s 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 chronic disease management care to develop new treatments, particularly for patients who are unresponsive to current treatments. While most projects are still at an early stage of clinical development, three are 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. Around 6,000 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 of formulation technology, protein engineering, expression and delivery, which makes it possible for 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® the company has developed world-class expertise in designing and producing simple and convenient devices for injecting protein therapeutics. Read more about capabilities in research and development on pp 22 23.

#### 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 s research, development and marketing activities.

#### 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. This 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 different 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.

The production of diabetes finished products takes place in five strategic plants in Denmark, France, the US, Brazil and China, which all have the approval and the ability to export to other markets.

In addition, Novo Nordisk has a number of smaller manufacturing plants which support local demand in selected countries. All production facilities are operating under one global quality management system with centrally deployed standard

operating procedures 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,  $CO_2$  emissions and the amount of waste generated during production processes.

#### 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 s patents expire. Through the launches of Victoza® in multiple markets over the past years, Novo Nordisk has refined this capability within diabetes, which is being put to use in connection with the launches of Tresiba® in 2013.

#### 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 very early as soon as there are signs of a market developing and to grow the organisation organically as the market develops. This is a key reason behind Novo Nordisk s success in emerging markets such as China. Read more about Novo Nordisk s markets on pp 32 37.

### The Triple Bottom Line business principle

Novo Nordisk s sustainability strategy is based on the Triple Bottom Line business principle, which means the company sets goals, manages and accounts for

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performance on three dimensions: financial, social and environmental. The aim is to ensure long-term profitability by minimising any negative impacts from business activities and maximising the positive footprint from its global operations: improved health, employment, economic prosperity and social equity.

The Triple Bottom Line model (see p 18) illustrates the three dimensions with patient interests at the core, aiming to create long-term value by making balanced decisions. Value is created in three ways. Firstly, it makes Novo Nordisk more adaptive to changes in its business environment. This, in turn, helps protect the company s licence to operate and builds trust. Novo Nordisk proactively engages with stakeholders to address emerging challenges in the business environment. One example is the debate over access to health. Novo Nordisk has supported the advocacy for a UN Resolution on Diabetes and is partnering with multiple stakeholders to bring policies into action.

Secondly, the Triple Bottom Line business principle strengthens competitiveness. The company chose to invest in the conversion to renewable energy in Denmark in a strategic partnership with its energy supplier. With this move, Novo Nordisk has managed to continue to grow production and sales, and yet decrease carbon emissions significantly. This is a good example of how sustainability-driven decisions can drive operational excellence and reduce costs.

Finally, the Triple Bottom Line business principle can be an engine for business development. Through partnerships with stakeholders, Novo Nordisk can co-create innovative solutions that lead to new opportunities to grow the business. One example is a pilot project that makes human insulin available to low-income populations in Kenya at prices they can afford and with effective distribution via local communities.

#### Financially responsible: profitable for the long term

Doing business in a profitable and responsible way is the basis for delivering an attractive return on investment for shareholders and making a contribution to society. Novo Nordisk uses four financial targets to steer the business towards long-term profitable growth: operating profit growth, operating profit margin, operating profit after tax to net operating assets, and cash to earnings. These targets help Management balance growth in the short term with investments in longer-term growth such as research and development.

#### Socially responsible: patients first

As a research-based healthcare company, Novo Nordisk is focused on therapeutic innovations and improvements to medical

treatment for people with chronic diseases. Today, approximately 23 million people all over the world benefit from the treatments Novo Nordisk offers. The company also prioritises improving timely detection and prevention of diabetes and invests in strengthening healthcare infrastructure, awareness campaigns, education and support for lifestyle interventions.

In terms of societal value, Novo Nordisk generates wealth and contributes to socioeconomic development through sustainable business practices, investment and employment. As a pharmaceutical innovator, the company provides knowledge, research and development, and healthcare products. Outreach programmes such as Changing Diabetes® and Changing Possibilities in Haemophilia® improve awareness, diagnosis and treatment. Through these efforts, Novo Nordisk aims to bring down the human, societal and financial burden of diabetes. Read more about sustainable growth on pp 38 40.

Social responsibility is also about ensuring a healthy and engaging workplace for Novo Nordisk s employees. Novo Nordisk has global health and safety standards and policies to ensure respect for the rights of all employees. Through the workplace wellness programme, NovoHealth, the company also offers a healthy workplace and actively promotes healthy lifestyles.

As a global player, Novo Nordisk must also offer a diverse and inclusive working environment. Diversity in management teams and in functional units fosters innovative thinking, nurtures collaboration between people with different perspectives and drives performance. Novo Nordisk s Management has set an ambitious long-term aspiration that all senior management teams must be diverse in terms of gender and nationality.

#### Environmentally responsible: doing more with less

Producing more with less is not just sound household management; it is also a way to 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. There is also a focus on minimising outputs in the form of emissions such as CO<sub>2</sub> and waste. The ambition is to continue to produce more with less more products to serve more people, using less energy and water for

production, and leaving less waste.

## NOVO NORDISK WAY

The Novo Nordisk Way is a description of the ambitions and the values that characterise the company. It was developed for employees in Novo Nordisk, but has been shared with a broader audience. It sets the direction for all employees in Novo Nordisk and is a promise employees make to each other and to stakeholders outside the company.

#### **The 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.

## Diabetes an emergency in slow motion

Some emergencies happen in a split second. Others take decades to develop and in some cases you do not even realise what happened until you see it in the clear light of hindsight. Diabetes is an emergency developing in slow motion. Whenever the International Diabetes Federation (IDF) updates its figures on people affected by diabetes, the numbers just get bigger. The latest estimates, published in November 2012, say that today more than 371 million people have diabetes, diagnosed and undiagnosed, of which 80% live in low- and middle-income countries. And if current trends continue, IDF predicts that the number will rise to more than 550 million by 2030.

While diabetes care has improved greatly in recent decades, there are still millions of people dying from the disease annually 4.8 million in 2012 according to the IDF. Others are losing their eyesight or requiring amputations because of poorly controlled diabetes. Some because they do not have access to medicine or doctors who can tell them how to use it. Others because the treatment they receive is inadequate. Yet others maintain too high blood sugar because they fear the consequences of low blood sugar (hypoglycaemia), a common side effect of insulin treatment. 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%.1 Microvascular complications include diabetic retinopathy, which causes 10,000 cases of blindness annually in the US alone.<sup>2</sup>

Apart from the effect diabetes has on the person with diabetes, the disease is becoming a growing financial burden for society. It is estimated that diabetes caused at least 471 billion US dollars in healthcare expenditure in 2012.3

## The psychosocial aspects of diabetes

The physical, financial and emotional burden of diabetes across cultures and countries is carried by the entire family, not just by the person with diabetes. This is one of the initial results of Diabetes Attitudes, Wishes and Needs 2 (DAWN2) published in December 2012, which shows that:

63% of family members are anxious about the possibility that the person they live with will develop serious complications from the condition.

66% of family members of insulin- treated people with diabetes fear that their loved one will become hypoglycaemic during the night.

34% of family members report a negative financial impact on themselves due to the diabetes of their loved one.

#### What is diabetes?

Diabetes is a metabolic disorder affecting the way our bodies use digested food for growth and energy. Diabetes has two main forms: type 1 and type 2.

Type 1 diabetes is a lifelong autoimmune disease that develops when the body creates an immune reaction against its own cells, destroying beta cells in the pancreas. As a result, the pancreas stops producing insulin, often at a young age but this can happen at any time over a lifetime.

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 make their own insulin in the pancreas, but the insulin produced is insufficient and is not used effectively by the body.

Most of the long-term health complications associated with diabetes are due to persistent high blood glucose levels, which can cause damage to the kidneys, neurological system, cardiovascular system, the retina or to the feet and legs

through effects on both large and small blood vessels.

#### How is diabetes treated?

For type 1 diabetes, insulin is introduced at diagnosis and is required for the rest of the person s life.

Treatment guidelines for type 2 diabetes call for different approaches at different stages of the disease. The first step is lifestyle changes and initiation of tablet therapy (metformin) may be introduced. If treatment goals are not met, as a second step GLP-1 therapy, such as Victoza®, or basal insulin, such as long-acting Levemir®, may be added.

As a third step, treatment guidelines call for a transition to intensive insulin treatment to achieve and to maintain good glycaemic control. This may include adding a rapid-acting modern insulin at mealtimes, such as NovoRapid®(insulin aspart, marketed as NovoLog®in the US), in addition to a basal insulin. For insulin initiation, a modern premix insulin such as NovoMix® with dual release to cover both mealtime and basal requirements may also be used.

One challenge in managing diabetes with insulin is to maintain appropriate blood glucose levels, adjusting insulin dosing as necessary to balance the impact of food and exercise and to avoid low blood glucose levels (hypoglycaemia), which, if untreated, can lead to seizures or unconsciousness. In rare cases, low blood sugar can lead to permanent brain damage or death.

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## The protein powerhouse

## Novo Nordisk is highly focused on proteins. Some researchers at the company have spent their entire careers immersed in one specific protein.

For 90 years, Novo Nordisk has been researching proteins to treat what was originally an uncommon disease, but which today has reached pandemic proportions: diabetes.

Our dedication to discover and develop better and better therapeutic proteins to help people with diabetes is the red thread running through the company, explains Dr Mads Krogsgaard Thomsen, executive vice president and chief science officer at Novo Nordisk. Over many years we have developed a unique expertise, which helps us to make both incremental changes and leaps forward so that our medicines are getting more physiological and acting closer to what nature intended. This requires decades of perseverance. While other companies might stop looking for treatments for diabetes after launching one or two medicines, we are constantly searching for new ways to improve our medicines further.

#### Long-term focus

In fact there are very few, if any, companies with as great a focus on side chain protein backbones and engineering as Novo Nordisk. In the beginning we focused on purifying insulin. Thereafter we realised that insulin needed to work for longer, so we looked at how we could engineer this property into the product. With the advent of our human insulin range, diabetes treatment became safer and unlimited by slaughterhouse suppliers. Later, we developed our injection pens to make it easier for people to inject insulin. At the same time, we began to wonder how we could use protein technology to even more closely mimic the action profile of insulin found naturally in the body of someone who doesn t have diabetes, and this is what we re still working on today. We don t look five years into the future; we think in decades. And this long-term view has helped us to produce generation after generation of insulin to improve the lives of people with diabetes, says Mads Krogsgaard Thomsen.

#### Mimicking nature is not easy

Protein-based biological medicines therapeutic proteins are significantly different from traditional chemical drugs: while these small molecules usually block a target and therefore a process in the body around the clock, large protein molecules such as insulin seek to stimulate a process at the time it is needed. Mimicking nature in this way is not as easy as it perhaps sounds. In a person without diabetes, insulin is released from the pancreas

straight into the body s circulation, giving a characteristic action profile of peaks at meals and a steady basal level between meals and at night. But a person with diabetes who needs insulin injects this protein directly under the skin. This changed route of entry into the body results in a different action profile. To mimic nature as closely as possible Novo Nordisk s scientists therefore have to study a protein in great detail to work out which amino acids can and cannot be changed, in order to engineer particular properties into the molecule without changing its characteristics unfavourably. Side chain attachments to prolong the effect of the protein are also used to create the desired result. In this way Novo Nordisk has designed a full range of insulins, including Tresiba® (insulin degludec), the first once-daily basal insulin with an ultra-long duration of action, and the world s leading short-acting insulin NovoRapid®(NovoLog® in the US).

The company has also used its protein expertise to develop the leading human GLP-1 analogue, Victoza®, but research does not stop there. Current projects in development include a fixed-ratio combination of Tresiba® and Victoza®(IDegLira) and semaglutide, a once-weekly GLP-1 analogue for the treatment of type 2 diabetes. Further, Victoza® is being investigated for use in type 1 diabetes as an adjunct therapy to insulin. With 12 diabetes treatments in the pipeline, diabetes firmly remains Novo Nordisk s primary business. See the pipeline on pp 30 31 for more information.

We have been working with this disease since it was considered a niche area that only few seemed to care about, explains Mads Krogsgaard Thomsen. We have a unique competence platform of research and are only now beginning to understand how much more can be done for people with diabetes. And I think it s fair to say that our perseverance has paid off. You can see it in the number and quality of projects in our pipeline, the number of patents we re granted, publications in leading scientific journals, and the new medicines we have launched. What s also worth noting is that we use the same expertise, knowledge and technology to design proteins for haemophilia and growth hormone therapy.

#### Passion, pride and perseverance

To engineer a protein to such a level of perfection takes a network of scientists who understand that protein fully, including protein engineers,

pharmacologists, chemists and clinicians. But Novo Nordisk does not have much difficulty attracting and retaining the best people in these fields. Working here is lots of fun: we have a high level of expertise, we understand our area, our research and development budgets are growing and we treat people with respect. So scientists want to work here, says Mads Krogsgaard Thomsen, referencing the prestigious Science 2012 Top Employer survey in which Novo Nordisk ranked number 4, up from ninth place in 2011.

Our scientists have a profound insight into the protein on which they re working. For example the scientist who invented Tresiba® was working on this molecule for almost 30 years and is still invaluable in this area. All our scientists share the company s passion for proteins and our drive to constantly improve our medicines. This thrill is ignited when we see patients and doctors embrace our products. I think the bottom line is we re all proud of what we do.

#### What is it?

**Proteins** are large biological molecules consisting of one or more chains of amino acids in a specific sequence. Twenty different types of amino acids are commonly found in proteins and when combined in various ways they create millions of different proteins each with a specific function. Each cell in the human body contains thousands of different proteins, which together make the cell do its job. Some proteins are hormones that regulate various activities in the body.

**Insulin** is a hormone that is produced by the beta cells in the pancreas. It is needed for moving sugar (glucose) from the bloodstream into some cells in the body, for example muscle cells.

**GLP-1** (Glucagon-Like Peptide-1) is a natural gut hormone that helps regulate glucose metabolism by stimulating beta cells to secrete insulin and by reducing glucagon secretion. GLP-1 also has effects on food intake and it may play a role in protecting the beta cells, a key to slowing diabetes progression.

# Insulin treatment is a balancing act

Every day is a balancing act for people with diabetes who use insulin: too little insulin will make blood glucose levels rise, which can cause long-term complications such as blindness and amputations; too much insulin can result in dangerously low blood sugar levels, which can ultimately lead to coma and death.

The symptoms of low blood sugar (hypogly-caemia) are immediate, very unpleasant and something almost all people with diabetes try to avoid. Confusion, dizziness, trembling, a pounding heart and sweating are among the typical early symptoms. If left untreated, hypoglycaemia can lead to seizures or unconsciousness and, in rare cases, permanent brain damage or death.

So it is no surprise that many patients and doctors are reluctant to treat the blood sugar down to the levels recommended, for example by the American and European diabetes associations. They know that the closer the patient is to reaching the desired near-normal blood sugar level, the closer he or she also is to a state of hypoglycaemia. But maintaining blood sugar at higher-than-recommended levels comes at a price. Diabetes is a chronic disease, so while in the short term the side effects of high blood sugar may not have a great impact on quality of life, over time potentially irreversible damage is being done to the body.

## The problems of a progressive disease

According to Dr Alan Moses, Novo Nordisk s global chief medical officer, one barrier to effective blood sugar control is that most doctors have very little time for educating patients about their disease: Diabetes is complex, and different stages of the disease spectrum require different types of medications. But primary care physicians see many patients per day, perhaps over 100, so they have very little time to educate the patient about all the elements involved in good diabetes control, including medication, weight-appropriate diet, distribution of calories over the day, exercise and so on. There is therefore a tendency for the physician to prescribe the simplest treatment, even though it may not be appropriate or no longer match the stage of the disease. The next step in treatment is then not taken until the patient s blood glucose level increases to an unacceptable level. This is what some refer to as the treat to failure paradigm, which is sadly all too common.

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### Reducing the risk of hypoglycaemia

One way to reduce the risk of hypoglycaemia and thus allow for tighter blood sugar control is to develop engineered insulins that more closely mimic the way insulin acts in the body of a person without diabetes.

One of the challenges we re trying to overcome when developing new and improved insulin types is that insulin acts in a different way when injected compared with when it s secreted naturally into the bloodstream, says Alan Moses. It takes time for injected insulin to pass through the subcutaneous tissue into the blood vessels, and several factors, including the site of injection, play a role in how fast the insulin is absorbed in the body and which tissues it goes to first. This means that the insulin activity profile can vary significantly from day to day in the same individuals.

When Novo Nordisk launched human insulin in 1982 as the first company in the world, we thought that we had developed the perfect insulin, continues Alan Moses. I mean, it s 100% identical to the insulin produced in the body of a person who

doesn t have diabetes, so how could we do better? However, we came to realise that while human insulin is indeed the perfect insulin when secreted naturally from the pancreas, it s far from perfect when injected, for the reasons I mentioned before. That s what led us into the research and development of insulin analogues.

Insulin analogues are types of insulins that have been modified through genetic engineering to either act faster or slower than human insulin. Novo Nordisk s fast-acting insulin analogue NovoRapid®(NovoLog® in the US) was engineered to match the insulin peak seen in a person without diabetes following a meal. However, this type of insulin does not work long enough to provide an adequate basal level of insulin for full 24-hour coverage. Long-acting insulin analogues (basal insulin) were therefore developed to meet this need, but while they have been shown to reduce the risk of low blood sugar (hypoglycaemia) compared with human insulin, available insulin products are still associated with substantial variability of absorption, which can result in low blood sugar (hypoglycaemia) most worryingly at night. Furthermore, these insulins are

required to be injected at the same time every day. That is why Novo Nordisk decided to develop Tresiba® (insulin degludec).

The importance of good blood glucose control

People with diabetes should aim to keep their blood glucose (blood sugar) levels as near normal as possible, in other words in the range of that of someone without diabetes. The blood glucose target should be decided between the patient and his or her doctor.

Good blood glucose control is important as it has been shown to significantly reduce the risk of developing complications and prevents complications from getting worse.1,2 Regular blood glucose testing helps people with diabetes achieve their target blood glucose level. For more information read the article on diabetes on p 20.

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## Insulin in a tablet why is it so difficult?

## Many companies have tried, and failed, to develop insulin in tablet form. So what makes Novo Nordisk think it can do any better?

Many people ask why insulin and GLP-1 products such as Victoza® (liraglutide) are not made in tablet form. The short answer is that it is really difficult. Insulin and GLP-1 are amazing protein molecules, but if taken orally they would ordinarily be attacked by digestive enzymes in the gastrointestinal tract whose job it is to break down proteins, which is useful for food uptake but detrimental if the protein is a drug that needs to stay intact. And even if they were to somehow survive in the stomach, these large molecules would then have difficulty passing through the wall of the intestine and entering the bloodstream.

Oral insulin and GLP-1 that is insulin and GLP-1 in tablet form therefore have to be designed and engineered to overcome these challenges. But even if these barriers can be overcome, further challenges lie ahead as these proteins have to be absorbed by the body in the right quantities and stay in the blood for the right length of time regardless of whether the patient has an empty stomach, has just eaten or is suffering from diarrhoea. We have been working on oral insulin and GLP-1 for about five years. I can tell you that when we started, I thought this was nearly impossible and it is! says Dr Peter Kurtzhals, senior vice president and head of Diabetes Research at Novo Nordisk. But I ve been positively surprised and encouraged by the progress we ve made. Many other companies have tried to develop oral insulin but none have been able to

a tablet-based medication, for example metformin. What these medications have in common is that their active substance is a small molecule a chemical which is not broken down by enzymes in the gastrointestinal tract. However, for many people with type 2 diabetes the disease eventually progresses to a stage where insulin therapy is necessary to control the blood sugar. But insulin injections are daunting for many, and patients must be educated by healthcare professionals in order to administer insulin effectively and safely. Progression to insulin injections is therefore often delayed, with potential serious consequences for health in the long term.

Insulin in a tablet would enable patients to begin insulin therapy earlier and treat themselves more easily.

The simplicity and convenience of oral insulin would be amazing. While it takes time to learn how to inject insulin with a pen, everyone knows how to swallow a pill. This in turn could support greater compliance and lead to much better treatment outcomes to the benefit of patients, healthcare providers and society, highlights Peter Kurtzhals. He emphasises that insulin in tablets will probably not be able to replace injections entirely because it is likely to be used only in patients whose bodies can still produce some insulin.

#### Expert knowledge

For a company that is committed to changing diabetes, it is therefore

is built on our 90 years of experience with the insulin molecule and 20 years of experience with GLP-1. The scientists involved have been experts in the field for decades. This is a clear strength for engineering and designing the molecules for the oral route and is a major advantage over our competitors.

While Novo Nordisk is an expert in protein research, these oral preparations also require formulations that will enable the active ingredients to reach their targets in the body. Novo Nordisk has over the last five years built substantial oral formulation expertise and has entered into licensing and collaboration agreements with companies having technologies to facilitate oral absorption. It has been a learning curve for Novo Nordisk to establish technologies, animal models and exploratory clinical trials to support the development of oral insulin and GLP-1 formulations, says Peter Kurtzhals, and the company currently has two oral insulin and three oral GLP-1 formulations in phase 1 clinical trials

The journey ahead will not be easy. We re up against major barriers and we still don t know whether they can be overcome, reports Peter Kurtzhals. But if we look at the ideas we ve got and the progress we ve made I m optimistic that Novo Nordisk will be the first to turn oral insulin and GLP-1 into a reality. We are currently in phase 1 development so it is not unrealistic to think that if studies are successful, oral insulin and oral GLP-1 could be available in about 10 years. In the

show proof of concept but we are getting very close to this stage. I would say we are the leaders in this field at this point.

## Convenience leads to better outcomes

Currently, when people are diagnosed with type 2 diabetes they are often given

understandable that Novo Nordisk is investing so much time and money in developing oral insulin and GLP-1. And Peter Kurtzhals believes the company has the best people working on this task: The research and development team world of pharmaceutical research and development that s pretty close.

## **Simple injections**

The pursuit of simplicity for patients is the driver of Novo Nordisk s development of injection devices.

Novo Nordisk invented the market for insulin injection devices with the launch of the world s first insulin pen in 1985.

NovoPen<sup>®</sup> was designed and developed by a group of people who had a burning passion for this project and they had the persistence to see it through, explains Jesper Kløve, senior vice president for Device R&D at Novo Nordisk. Since then, Novo Nordisk has launched generation after generation of pen devices, the latest being NovoPen® 5 (pending approval in the US), which in July 2012 won the prestigious Red Dot Best of the Best Design Award . This was a huge accolade. To see our pen next to iconic products such as Apple s iPad and the redesigned Porsche 911 was

fantastic, says Jesper Kløve.

NovoPen® 5 is the successor to NovoPen® 4, the current global market leader among durable insulin injection pens. It aims to heighten the safety of insulin treatment by integrating an electronic module memory function into the pen that reminds the patient how much insulin has been taken and when. This helps the patient avoid missing an injection or mistakenly repeating a dose, which may have severe consequences.

#### Six million FlexPen® users

The largest category of insulin injection devices is prefilled pens in which Novo Nordisk s FlexPen® has been the global leader for many years. It is estimated that around 6 million people use FlexPen®every day to treat their diabetes. While patients using a durable pen have to load and replace insulin cartridges, prefilled pens already have the cartridge built in.

Novo Nordisk s latest innovation in prefilled insulin pens is FlexTouch®, which is designed to improve the experience of performing daily injections, explains Jesper Kløve. A few years ago, competition between insulin device manufacturers was about accurate dosing. We re beyond that point and are now focusing on how to reduce the force you need to apply to inject a dose. While other insulin pens require users to inject their insulin in the traditional way using the force of their thumb to push the button FlexTouch® has an easy-touch button which requires very little force to inject the insulin at any dose.

The technical platform of FlexTouch®(pending approval in the US) can be manufactured to deliver injections for insulin, GLP-1, combinations of insulin and GLP-1, or growth hormone treatments. In fact it is already being marketed under the brand name FlexPro® as a delivery device for Novo Nordisk s human growth hormone, Norditropin® (somatropin). Novo Nordisk has also made progress with its first device for haemophilia treatment. In October 2012, a new prefilled syringe for delivering NovoSeven® was approved by both the European Medicines Agency and the US Food and Drug Administration. It is designed to make life easier for NovoSeven® users by making the injection process less cumbersome.

## Responding to patients needs

"As with all our device developments, the market research for FlexTouch® and NovoPen® 5 started early on, explains Jesper Kløve. We sat down with patients and healthcare professionals in different countries to capture their initial feelings about the prototype. We then gave them time to test it to see how they got on.

Further insights into how patients feel about injections have been obtained from the DAWN2 study.

Supporting patients and healthcare professionals is very important to us. I think the injection device makes a huge difference. New patients have to deal with the knowledge that they have diabetes. Then they have to deal with learning how to inject. We can make a difference by making the device as simple and safe as possible to use for patients and for the doctors and nurses who teach the patients how to inject, says Jesper Kløve.

We seek to make our Scandinavian design heritage for simplicity inherent in all our devices, so that they are both aesthetically pleasing and user-friendly. Yes, we are the leaders in the device market but we know we can make more

improvements to create even simpler devices. In fact we re already working on the next-generation NovoPen®. OUR BUSINESS 29

## **Prevent bleedings**

Imagine having to give a 3-year-old an intravenous infusion several times a week which takes up to 40 minutes and can be very painful.

When we talk about the number of people with diabetes globally, we speak in the ballpark of hundreds of millions. But the scenario for haemophilia is very different. In fact, this is a small community of around 400,000 people globally, with just over 160,000 of them having haemophilia A or B.1,2 Of those diagnosed, only about 25% receive optimal treatment.<sup>3</sup>

It is, therefore, no wonder that employees at Novo Nordisk are passionate about the haemophilia treatments that the company has on the market and in its research and development pipeline. Haemophilia can be mild, moderate or severe, and the current treatments only manage to convert severe disease to moderate. This means that the patients bleed less, which is good, but I don t think there are any other diseases where it is considered optimal to treat someone only partially. So making a treatment better for example by needing fewer doses to achieve a good result, which means fewer intravenous injections can make a real difference, explains Dr Anne Prener, senior vice president, in charge of the haemophilia R&D portfolio at Novo Nordisk.

#### It started with NovoSeven®

15 20% of people with haemophilia will at some point develop an inhibitory antibody

to the product they are using to treat or prevent bleeding episodes. For about 3,500 patients worldwide, these inhibitors will eventually prevent the treatment from working.3 Novo Nordisk addressed a huge unmet medical need when it launched NovoSeven® (recombinant factor VIIa) in 1996 as a treatment for these people. It was the first recombinant treatment available, as at the time other coagulation factors were derived from blood plasma.

Novo Nordisk has been working within the field of haemophilia for more than 20 years. Like diabetes, haemophilia is a chronic disease, and the skills needed to develop new therapies are very similar. Our company has many years of experience in discovery, development, manufacturing and delivery of proteins, which gives us a big advantage, says Anne Prener.

## One project filed, two in phase 3, a fourth discontinued

Novo Nordisk s investments in haemophilia research have resulted in a broad range of haemophilia projects, including one filed for approval and two in phase 3 development for people with haemophilia A or B. This is our first step into haemophilia A and B on a broad basis, explains Anne Prener.

We hope that our recombinant factor VIII product will offer patients an extremely pure and consistent

## NovoThirteen® launched for rare bleeding disorder

In 2012, Novo Nordisk received approval in Europe and Canada to market a recombinant factor XIII product for the treatment of congenital factor XIII deficiency. It is a rare bleeding disorder with potentially life-threatening consequences if untreated. Factor XIII is the protein responsible for stabilising the formation of a blood clot. Without it, a clot will still develop but will remain unstable. Factor XIII deficiency affects men and women equally. It is estimated that about 900 people globally have the disease. Novo Nordisk s product is the first recombinant factor XIII product. It is marketed in Europe under the brand name NovoThirteen®and in Canada as Tretten®, and is under regulatory review in the US and in a number of additional countries.

product, while our long-acting versions of factor VIII and factor IX aim to reduce the number of injections

What is 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, which is called prophylactic treatment. People with haemophilia A may have either a decreased ability or total inability to produce clotting factor VIII. Those with haemophilia B have deficiencies in producing clotting factor IX. Around 3,500 people with haemophilia worldwide have high-titre inhibitors resistance (due t antibody formation) to their normal replacement treatment. Factor VIIa (NovoSeven®) was developed as a treatment for these people.

#### 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. The first results from the study, which is supported by Novo Nordisk, were presented in July 2012. HERO is an initiative under the Changing Possibilities in Haemophilia® programme. It supports Novo Nordisk s strategic objective to achieve leadership in haemophilia by improving the efficacy of prevention and treatment of bleeding episodes for all haemophilia patients. Read more about HERO and Changing Possibilities in Haemophilia® at

novonordisk.com/about\_us/improving\_haemophilia/improving-haemophilia.asp.

needed when used proactively to prevent bleeds.

A third phase 3 project was discontinued in September 2012, when development of a fast-acting analogue of recombinant factor VIIa, vatreptacog alfa, was stopped due to safety concerns, as some patients in the phase 3 study developed antibodies to the product. Although all of these patients continued to respond well to treatment after having developed antibodies, there was still a potential risk that continued treatment would inhibit the effectiveness of the treatment over time. This would be an unacceptable situation as, in almost 20 years of use, no haemophilia A or B patients have developed inhibitory antibodies to NovoSeven®, says Anne Prener.

#### The dream

Our dream is to find treatments that can be administered subcutaneously, prevent bleeds and preserve joints, concludes Anne Prener. Imagine having to give a 3-year-old an intravenous infusion several times per week which takes up to 40 minutes and can be very painful; then you realise what a big difference these new products can make.

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## **Pipeline overview**

During 2012, Novo Nordisk made progress throughout the clinical development pipeline. This overview illustrates key development activities.

			Filed/ regulatory
Compound	Indication	Description	Phase 1 Phase 2 Phase 3 approval
Diabetes ca	re		
Diabetes			
Tresiba® (insulin degludec) NN1250	Type 1 and 2 diabetes	A new-generation basal insulin with ultra-long duration of action of more than 42 hours. Intended to offer a flexible treatment and a good safety profile. Approved in the EU and Japan and under regulatory review in the US and other major markets.	
Ryzodeg® (insulin degludec and insulin aspart) NN5401	Type 1 and 2 diabetes	A soluble fixed combination of Tresiba®, the new-generation basal insulin analogue with an ultra-long duration of action, and NovoRapid® (insulin aspart, marketed as NovoLog® in the US), a rapid-acting mealtime insulin. Approved in the EU and Japan and under regulatory review in the US and other major markets.	
IDegLira NN9068	Type 2 diabetes	A fixed-ratio combination of insulin degludec and liraglutide intended to offer the benefits of the two components in a single preparation.	
Semaglutide 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.	
FIAsp NN1218	Type 1 and 2 diabetes	A faster-acting formulation of insulin aspart (NovoRapid $^{(\!$	
LATIN T1D NN9211	Type 1 diabetes	Liraglutide, a once-daily human GLP-1 analogue, intended to offer clinical benefits as adjunct therapy to insulin.	
Ol338GT NN1953	Type 1 and 2 diabetes	A long-acting oral basal insulin analogue intended as a tablet treatment.	
OI362GT NN1954	Type 1 and 2	A long-acting oral basal insulin analogue intended as a tablet treatment.	

Filed/

	diabetes			
OG217SC NN9924	Type 2 diabetes	A long-acting oral GLP-1 analogue intended as a tablet treatment.		
OG987GT NN9926	Type 2 diabetes	A long-acting oral GLP-1 analogue intended as a tablet treatment.		
OG987SC NN9927	Type 2 diabetes	A long-acting oral GLP-1 analogue intended as a tablet treatment.		
LAI287 NN1436	Type 1 and 2 diabetes	A long-acting basal insulin analogue with potential for once-weekly dosing.		
Obesity				
Liraglutide 3 mg NN8022	Obesity	A once-daily human GLP-1 analogue. Intended, as adjuvant to lifestyle changes (including diet), to offer sustainable weight loss for people with severe obesity, including those at particular risk of developing diabetes.		
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#### Phase 1

Studies in a small group (usually 10 to 100) of healthy volunteers, and sometimes patients, to investigate how the body handles new medication and establish maximum tolerated dose.

#### Phase 2

Studies of various dose levels in a larger group of patients to learn about its 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.

#### Phase 3

Studies in large groups of patients worldwide comparing the new medication with a commonly used drug or placebo for both safety and efficacy in order to firmly establish its benefit risk relationship. Phase 3a covers trials conducted after efficacy of the medicine is demonstrated but prior to regulatory submission, whereas phase 3b covers clinical trials completed after regulatory submission.

Filed/

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

Compound	Indication	Description	Phase 1	Phase 2 Phase 3	regulatory 3 approval		
Biopharmaceuticals							
Haemophilia and other rare bleeding disorders							
NovoThirteen® (rFXIII) NN1841	Congenital FXIII deficiency	A recombinant coagulation factor XIII. Launched in the EU and Canada and approved in Switzerland. Submitted for marketing authorisation in the US and other larger markets.	1				
Turoctocog alfa NN7008	Haemophilia A	A recombinant coagulation factor VIII intended to prevent and treat bleeds. Submitted for marketing authorisation in the US, EU, Japan, Australia and Switzerland.					
N8-GP NN7088	Haemophilia A	A long-acting recombinant coagulation factor VIII derivative intended to offer prophylaxis and treatment of bleeds.					
N9-GP NN7999	Haemophilia B	A long-acting recombinant coagulation factor IX derivative intended to offer prophylaxis and treatment of bleeds.					
mAb2021 NN7415	Haemophilia A, B and withinhibitors	A monoclonal antibody against Tissue Factor Pathway Inhibitor (TFPI) intended for bleeding prevention.					
Growth disorders							

#### Growth disorders

NN8640

	Growth disorders	A long-acting human growth hormone intended to offer less frequent injections.
Inflammation		
Anti-IL-20NN8226	Rheumatoid arthritis	A recombinant human monoclonal antibody. The compound's novel mechanism of action is intended to improve treatment outcomes in patients who do not respond adequately to existing treatments. A phase 2b programme is ongoing.
Anti-IL-21 NN8828	Rheumatoid arthritis	A recombinant human monoclonal antibody. The compound snovel mechanism of action is intended to improve treatment outcomes in patients who do not respond adequately to existing treatments. A phase 2a programme is ongoing.
rFXIII NN8717	Ulcerative colitis	A recombinant coagulation factor XIII. The study is investigating the biological and clinical effect on mucosal healing in patients with mild to moderate active ulcerative colitis.
Anti-C5aR-151 NN8209	Rheumatoid arthritis	A recombinant humanised monoclonal antibody. The compound s novel mechanism of action is intended to improve treatment outcomes in patients who do not respond adequately to existing treatments.
Anti-C5aR-215 NN8210	Rheumatoid arthritis	A recombinant human monoclonal antibody. The compound's novel mechanism of action is intended to improve treatment outcomes in patients who do not respond adequately to existing treatments.
Anti-NKG2A NN8765	Rheumatoid arthritis	A recombinant human monoclonal antibody. The compound <b>s</b> novel mechanism of action is intended to improve treatment outcomes in patients who do not respond adequately to existing treatments.
Anti-IL-21 NN8828	Systemic lupus erythematosus	A recombinant human monoclonal antibody. The compound snovel mechanism of action is intended to improve treatment outcomes in patients who do not respond adequately to existing treatments.
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# Many markets one model

Novo Nordisk sells its products in more than 180 countries. Among them are the richest and poorest countries in the world, with healthcare systems ranging from well-developed to nonexistent. And yet, Novo Nordisk s basic business model and strategy is the same in all countries, says Kåre Schultz, Novo Nordisk s chief operating officer.

Novo Nordisk has its own wholly owned country organisations affiliates as they are called internally in 75 countries, organised in five regions, each reporting to a senior vice president: Europe, North America, International Operations, Region China and Japan & Korea. The reporting lines meet at Kåre Schultz s desk.

Novo Nordisk s business model and strategy is basically the same in all regions,

and based on a common ambition, which is to be the leading diabetes care company, both in commercial terms and when it comes to making a positive change for people with diabetes.

Our core offering to people with diabetes all over the world is sophisticated proteins biologic pharmaceuticals such as modern insulins to which our scientists have been able to give some distinct properties that can help better control the disease, says Kåre Schultz. We market and sell the products the same way globally, which is by sharing the clinical knowledge about our products with doctors, so they can make an informed choice about whether they are right for their patients. At the same time, we present the payers whether these are public health systems or private insurance

companies with evidence about the cost-efficiency of our products so they can make informed decisions about pricing and reimbursement. This is in essence our business model all over the world.

In many countries Novo Nordisk also engages in activities aimed at improving awareness about diabetes and training doctors in managing the disease. This work is much appreciated, especially in developing countries where diabetes has only recently become a serious problem and where there is not the knowledge or capacity to deal with the disease. I see this as a long-term investment, says Kåre Schultz. It can take many years to create a sustainable business in these countries, but once the economy allows for proper diabetes care for the population, doctors and health authorities will remember that

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Chief Operating Officer Kåre Schultz (far left) travels to meet management teams in key markets several times a year.

we were there for them when the going was tough. That s our experience.

#### Competitors

In the 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, but they primarily offer older-generation products and have not been able to gain significant market shares.

In the biopharmaceuticals business, Novo Nordisk faces competition in some markets from producers of biosimilar medicines (products that are similar, but not identical to an original medicine), for example human growth hormone. But so far it has not had a dramatic impact on the business.

#### CONTINUED

#### **North America**

The US is the world s largest market for pharmaceuticals, accounting for approximately 34% of global sales. It took Novo Nordisk many years and several failed attempts to establish a successful presence there. But this was achieved around 10 years ago when Novo Nordisk launched its first modern insulins (insulin analogues) and NovoSeven® (a haemophilia product) in the US. At the same time, major investments were made in building a strong organisation, which today totals more than 5,000 people.

Since then there has been no looking back. Today, North America is Novo Nordisk s largest and fastest growing region by far. In 2012, the region accounted for 66% of Novo Nordisk s total sales growth. And this picture will not change in the foreseeable future, predicts Kåre Schultz:

Diabetes is on the rise, and we have a range of great products on the market, even more promising products in our pipeline and an organisation that has proved it can meet our customers needs.

In his view there is still a major growth potential for Novo Nordisk s current modern insulins and Victoza® (liraglutide): Our insulin market share is still lower in the US than it is in many other countries, and I can t see why this should be the case, especially when we launch Tresiba®. Another thing to keep in mind is that in the US, only around 35% of insulin is delivered in pen systems, such as FlexPen®. In Europe, it s close to 100%. This means there s still a significant potential to upgrade treatment in the US.

In the GLP-1 market Victoza® is already the market leader. It is still a relatively small market but predicted to grow in the coming years, and Kåre Schultz believes there is a good chance Novo Nordisk will capture the lion s share of this growth, not only with Victoza® but also with IDegLira (a fixed-ratio combination of insulin degludec and liraglutide) and semaglutide (a once-weekly GLP-1 analogue) which Novo Nordisk hopes to bring to the market some years from now.

#### Prices

Novo Nordisk has experienced increasing pressure on prices in recent years when bidding for large contracts with managed care organisations and with the government, and Kåre Schultz predicts this will continue. I still think the US will remain the most attractive market in the world for a company such as ours, which is able to bring new and innovative products to the market.

Unlike many other countries, the US is willing to pay for innovation. This means that new products get a higher premium than elsewhere. But once they go off patent, a competitive market for generics ensures that prices drop to a fraction of what they were before. And since many blockbuster drugs have lost patent protection in recent years, the net effect is that the total spend on pharmaceuticals isn t growing.

When asked what apart from good products is the key to success in the US market, Kåre Schultz highlights the or individuals. Then there is Medicare Part D , the government-subsidised health insurance for the elderly, operated by the same managed care organisations, where prices are lower. And Medicaid, the government-funded health offering for people with a low income. These are just a few of the segments. The point is that each segment has its own way of working, which you must really understand and respond well to. I think it s fair to say that this is what we re doing now.

#### Europe

The sluggish economy in most European countries and the short-term cost containment measures that followed have made Europe a tough place for most pharmaceutical companies. In the largely publicly funded European healthcare systems, governments have been driving down prices, making it very challenging to obtain a price for new products that justifies the research and development costs. In addition, reimbursement restrictions often prevent innovative medicines from reaching patients. As a result, pharmaceutical companies have laid off thousands of employees in Europe in recent years. Novo Nordisk has been hit, too, with a total of 350 jobs cut in the European organisation in 2011 and 2012.

I don t agree with the argument that, in the current economic climate, European countries can t afford to pay for new and better products, says Kåre Schultz. To me, it s a matter of priority. The most

importance of having good people and a strong organisation. Furthermore, we learned the hard way 10 20 years ago that if you don t know every detail of how the US market functions, you don t have a chance, because it s extremely complex, he says. First you have to realise that it s not one market, it s a myriad of market segments. The largest segment, where prices are highest, is the managed care segment, which is financed through private health insurance paid by employers

worrying thing is that if nobody wants to pay a premium for innovation, then there II be no innovation, and Europe desperately needs innovative industries to drive future growth.

However, even in this difficult economic climate, Novo Nordisk managed to grow European sales by approximately 3% in 2012. Victoza® is the key growth driver in most European markets and it is likely to stay that way in the coming years. Longer term, Tresiba® (insulin degludec), which Novo Nordisk is launching in some European markets in 2013, will create additional growth, but it will take time for this product to penetrate the market as it does for all new insulin products.

#### Future growth rates

Kåre Schultz cannot see how Novo Nordisk can grow its business in Europe much more than it is doing right now. In the near term there are no signs that the European economies are improving, so more and even tougher measures to limit spending on drugs, especially new drugs, are to be expected. Furthermore, the diabetes market is well developed, the diagnosis rate is high, birth rates low, and Novo Nordisk has a high insulin market share of around 50% measured by volume. This means that there are limits to how much Novo Nordisk can expect to grow.

In recent years there has been much speculation about whether producers of biosimilar insulin (insulin which is similar but not identical to the original) would enter the European market on a large scale. So far this has not happened, and Kåre Schultz doubts it will. Insulin prices are already very low in many countries and I think the biosimilar insulin producers have concluded that it s an unattractive market to enter.

#### **International Operations**

Thinking of International Operations as a region requires a stretch of the imagination, says Kåre Schultz. We re talking about 149 countries all over the world with more than 4 billion people Latin America, Africa, Middle East, the Gulf, most of Asia and Australia. Here you will find some of the world s poorest countries and some of the world s richest it s a region of extraordinary diversity. This means we must be able to meet the demand for both standard therapy in the form of human insulin in vials at rock-bottom prices and advanced modern insulin products in sophisticated pen

systems, which are sold at prices similar to those seen in Europe and the US.

Even within many of the countries, there are diverse markets. Brazil, for example, has both a public tender market for human insulin vials, a mid-price market where Novo Nordisk delivers to the social security system and a private market for high-end products for people who either have private insurance or can pay out of pocket.

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

Indonesia and Brazil are two examples from different parts of the world. In both countries, people demand or expect that some of the economic growth is translated into better healthcare for them. And there s a political will to do so.

Kåre Schultz expects this development to continue: I can t see why not. With the increasing urbanisation and wealth in all these countries, diabetes rates will continue to increase. And most of the countries have good prospects for continued economic growth and will continue to invest in better healthcare, including diabetes care. Keep in mind that healthcare spend per capita in most countries in International Operations is only a fraction of what it is in Europe or Japan both in absolute terms and relative to GDP . (See table on p 37.)

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Novo Nordisk s experience is that when economies develop further, the healthcare systems offer treatment for more diseases and conditions. As a result, sales of NovoSeven® and Norditropin®(human growth hormone) are showing growth in many countries in International Operations. And Kåre Schultz believes that Victoza® will eventually become a big product in these countries. Sure, it will take years, because initially the product won t be reimbursed, so only people who can afford to pay for it themselves will be able to get it. But in many countries it will eventually be reimbursed or partly reimbursed by the healthcare system, and then I think we II see the same market penetration for Victoza® as we re currently seeing in Europe and North America.

#### **Growth opportunities**

Kåre Schultz sees the biggest business opportunities for Novo Nordisk in the countries and regions with large populations and high economic growth such as Brazil, Indonesia, India and some countries in the Middle East. But frankly, I see a growing market for years to come in most of the countries in International Operations; it s just a question of when, he says. In some cases it s happening now, in other countries it s just around the corner. In some African countries, it II take years for the market to grow, but it will happen eventually, I m sure.

In terms of organisation, Novo Nordisk s strategy is and has always been to establish an organisation very early as soon as there are signs of a market

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developing. The organisation is expanded gradually as the market develops. Vietnam and Peru are examples of countries where Novo Nordisk is building a bigger presence right now. And we do it organically, says Kåre Schultz.

Unlike many other international pharma companies, we re not believers in building a presence through acquisition of local companies. We prefer to hire our own people and train them to become the best.

#### Japan & Korea

Japan, the big brother in this two-country region, was for many years Novo Nordisk s largest market in terms of sales. Today, it is number two after the US, just ahead of China. But as in Europe, Japan s economy is in trouble; the population is ageing, and Novo Nordisk has a high insulin market share. Not the best conditions for growing a business, and Kåre Schultz admits it

will be difficult to achieve more than low single-digit growth in the coming years.

Nevertheless, despite market share losses in recent years, Novo Nordisk is the clear insulin market leader in Japan with a 55% market share measured in volume. It is also number one in the growth hormone market with Norditropin®, which is delivered in the new-generation pen system FlexPro®, and the company is doing well with NovoSeven® and Victoza®.

In the Japanese insulin market, competition is most intense in the long-acting (basal) insulin segment, where competitors have made inroads in recent years. Soon, Novo Nordisk expects to launch Tresiba®.

Kåre Schultz is confident that Tresiba®will help stabilise Novo Nordisk s position in the short term and, over time, grow the company s insulin market share in Japan: Tresiba® changes the competitive situation, he says. Studies have shown that, when compared with insulin glargine, Tresiba® gives the same level of blood glucose reduction with a significantly lower rate of hypoglycaemia during the night. In addition, we will make it available in FlexTouch®, our latest prefilled insulin pen, which is well suited for the very sophisticated Japanese market, where 98% of our insulin is delivered in pen systems.

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#### **Region China**

China became its own business region for Novo Nordisk in 2011, reflecting its large and growing strategic importance for the company: as a market for diabetes products, as an attractive production base and as a source of scientific innovation.

With more than 90 million people with diabetes, China has the dubious distinction of being the country with the most people affected by this disease. It has not always been that way, but with economic growth comes urbanisation, with urbanisation come sedentary lifestyles and then diabetes follows. This is the same pattern seen in other rapidly developing countries, but obviously on a much larger scale in a country with an aging population of 1.3 billion. On top of this, there is another problem: 20 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 own affiliate in China in 1994 and to this day, the company s main focus has therefore been to educate doctors and patients on proper diabetes care, including how to use insulin effectively and safely. A recent analysis demonstrated that between 2006 and 2010 Novo Nordisk and partners trained 55,000 doctors and 280,000 patients in China. Along the way, the company established itself as the market leader, today holding a 37% share of the diabetes market measured in value.

It is a high priority for the Chinese government to improve the quality and reach of the country s healthcare system.

As a result, many more people today have access to diabetes care, especially in the large cities. And the government s ambition is to make similar improvements in smaller cities and in rural areas, says Kåre Schultz, noting that, in China,

smaller cities often have more than a million inhabitants. But it takes time to make these improvements, because of the size of the country and because the healthcare system is a complex environment with many interests and decision-makers. In China, the central state government, the provinces, cities and counties all play a role. Understanding the structure of China s healthcare system is essential.

#### **Pressure on prices**

Many people with diabetes outside the large cities still do not have access to proper diabetes care. As this changes, the market for insulin and other diabetes products will become bigger. On the other hand, Novo Nordisk will also face and is already facing an increased pressure on prices as both the national and provincial governments try to limit spending on drugs. One way they have done this is by creating a list of essential drugs that are purchased from pharmaceutical companies in large quantities at very low prices by provincial governments.

Drugs on the Essential Drug Lists are primarily older products which have gone off patent, such as human insulin. But there will still be a growing market for newer and higher priced pharmaceuticals in China, predicts Kåre Schultz: The health awareness and purchasing power of many Chinese families is growing, and they re willing to pay for or have private health insurance that covers the newer and more innovative treatments. That s why I think that, over time, a treatment like Victoza®will become very big in China.

# Sustainable growth can it be done?

Entering into 2012, Novo Nordisk was cited by *Forbes* magazine as The most sustainable company on Earth . A prestigious position, hard-earned and tough to defend. What does it take to win? And is it possible at all to be a sustainable business?

Novo Nordisk s projected growth trajectory puts the company s sustainability aspirations to the stress test. How can it increase production while keeping environmental impacts down? How can it expand access to care where public healthcare s financial means are limited or healthcare services are inadequate? Novo Nordisk has given itself the challenge to demonstrate that sustainable growth is possible.

Sustainability in the world and in business is an imperative for survival and continued development. Climate change, scarcity of resources, population growth and uneven distribution of wealth are bound to have an impact on prospects for the future, explains Lise Kingo, executive vice president of Corporate Relations at Novo Nordisk. And she knows what she is talking about. For 20 years she has spearheaded the development of Novo Nordisk s Triple Bottom Line business principle, from what was initially an interesting idea to its current centre-stage position as a beacon for sustainable business practices.

Managing a business sustainably requires an ability to reconcile internal business interests with society s and external stakeholder priorities short term as well as long term. This is the way we grow our business while creating sustainable value for stakeholders. The Triple Bottom Line business principle is our way to ensure balanced decisions that take a broad perspective and consider both business and societal interests, says Lise Kingo.

#### Lean and green

Eco-productivity the ratio of environmental impacts relative to outputs gave some of the high scores that brought Novo Nordisk to the top of the Global 100 Index as The World s most sustainable company . The index is based on a rigorous benchmark analysis of leading global companies on a set of key performance indicators across all three bottom lines. It aims to recognise those global corporations that are most profitable and have been most proactive in managing environmental, social and corporate governance issues. On all counts, Novo Nordisk came out as the winner in 2012.

Over the past 10 years, Novo Nordisk has more than doubled sales and yet managed to decrease the use of energy and water as well as  $CO_2$  emissions. The goal is to continue to decouple growth in production and environmental impacts. The long-term target is to reduce, in absolute terms, production-related carbon emissions by 10% over a 10-year period until 2014. This goal has forced the organisation to think creatively, explore all opportunities for energy savings and develop a robust business case.

#### No trust, no business!

What few people know is that Novo Novo Nordisk s sustainability leadership is borne out of being confronted by challenges. Over the years, Novo Nordisk has learnt how to turn difficult issues such as genetic engineering, animal testing, clinical development and access to care into opportunities by listening and responding to stakeholders.

Treating people with respect is one of the essentials in the Novo Nordisk Way which also speaks to the importance of building and maintaining good relations with stakeholders. This is the foundation for earning their trust and respect. We want to be respected for putting patients first, leading in sustainability, being an outstanding workplace and having an excellent reputation, says Lise Kingo.

As Novo Nordisk continues to report solid growth rates in spite of the economic

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Novo Nordisk s largest production site in Kalundborg, Denmark, is an example of sustainable growth in practice.

slowdown, the company attracts more attention. Accountable and transparent performance management and reporting remains an important way to earn the trust of stakeholders. We need to walk the talk in everything we do, says Lise Kingo. There is growing regulatory scrutiny into pharmaceutical companies compliance with rules and regulations for clinical trials, patient safety, product quality and business ethics. And companies must be able to disclose how they and their suppliers live up to regulatory requirements.

That s why it s so crucial that every Novo Nordisk employee understands and embraces the values on which we build our business, including the Triple Bottom Line business principle.

#### Health for all

Access to care is a global issue. And pharmaceutical companies are expected to do their part in ensuring that people have access to affordable medicines and proper care. Novo Nordisk s global commitments to Changing Diabetes® and Changing Possibilities in Haemophilia® are the umbrellas for the company s efforts to improve access to care, complemented by donations to the World Diabetes Foundation and the Novo Nordisk Haemophilia Foundation.

In just one generation the prevalence of type 2 diabetes has risen to epidemic proportions, and the situation is becoming unsustainable. Today, 80% of all people living with diabetes live in low- and middleincome countries that account for only 20% of total global healthcare spending. Diabetes prevalence is growing most rapidly in SouthEast Asia and Africa, and is hitting young people at their most productive age, even children and adolescents.

In the face of such a daunting challenge, the response has to be bold. We have decided to accelerate our reach, in particular towards people with diabetes living in low- and middle-income countries, and have now set an ambitious long-term target Changing Diabetes® 40by20: by 2020, Novo Nordisk wants to provide medical treatment for an estimated 40 million people with diabetes worldwide. This is a doubling from the 2011 baseline.

Novo Nordisk has the broadest portfolio of diabetes care products, including human insulin and the most advanced modern treatments. This means that we can serve people with diabetes in most income groups, in rich and poor markets. With our products, global presence and strong partnerships we believe we can change diabetes sustainably.

We can only achieve this ambition if we pursue volume growth as well as value market shares, Lise Kingo stresses. China and International Operations will be central to achieving the new 40by20 ambition. We re focusing on eight strategic markets in International Operations with the biggest need our NextSix markets: Columbia, Egypt, Indonesia, Malaysia, Vietnam and Ukraine.

For the past 10 years we ve been working with our partners to overcome the barriers to access to diabetes care in the world s poorest countries, through our donations to the World Diabetes Foundation, our differential pricing policy, awareness-raising and education targeting healthcare professionals and patients. And we ve learnt a great deal. We have also realised that we must scale up to maximise our impact.

First of all we must ensure that our low-cost insulin products benefit the patients, Lise Kingo explains. Our pricing policy is a good offer, but it is not enough. Novo Nordisk is therefore piloting a new approach to building a business model at the base of the economic pyramid. In Kenya, Nigeria and India, the company is experimenting with new types of partnerships and distribution channels to ensure they reach people living in urban as well as rural areas. And by printing the retail price on the packaging, mark-ups and product diversion can be pre-empted.

Secondly, we need to improve healthcare capacity. In many low- and

and potential: Algeria, Argentina, Australia, Brazil, India, Mexico, Russia and Turkey. We will also scale up our efforts in the countries selected by Novo Nordisk as middle-income countries, there are too few trained diabetes physicians and nurses to cater for the growing number of people with diabetes, not least outside of the cities. On average a general practitioner will receive two days of diabetes training during a full medical curriculum. For many years, the Steno Diabetes Center has supported education

### CONTINUED

## 20 years in the business of sustainability

Twenty years ago Novo Nordisk hosted its first meeting with critical stakeholders at the table to learn how to meet their expectations without compromising business objectives. The book *20 years in the business of sustainability* tells the story of Novo Nordisk s journey, the lessons learnt and the challenges Novo Nordisk co-hosted an event that dealt with one of the new challenges: Next Generation Living the links between healthy living and sustainability. In this light we were particularly pleased to see that prevention, detection and treatment of non-communicable diseases, such as diabetes, were included in the outcome document as a priority for policymakers as part of the sustainability agenda. Just as importantly, business is now ahead in becoming a sustainable business.

One key learning has been how to engage with stakeholders to better understand their priorities, to learn with them, and to partner up on shaping common solutions to the big issues.

The book was prepared on the occasion of RIO+20, the UN Conference on Sustainable Development which took place in Rio de Janeiro in June 2012. Novo Nordisk representatives were among the more than 50,000 people attending, alongside world leaders who met to discuss and deal with the big global issues and point to a more sustainable future The future we want .

### invited to the table to help come up with

solutions to the global issues, and Novo Nordisk has been invited to team up with other global leaders in the UN process of defining a set of global sustainability goals. Partnerships will be the name of the game, and we are keen to play our part, says Lise Kingo.

The conference marked the 20th anniversary of the 1992 Earth Summit in Rio, which was a turning point that brought environmental issues onto the international political agenda. For Novo Nordisk, it also marked the start of the company s commitment to sustainable development.

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of healthcare professionals in China, Brazil and India. Now the time has come to scale up through a novel train-the-trainer concept so we can broaden our reach through education, Lise Kingo points out.

Finally, the company will put focus on the next generation. Lise Kingo explains: To truly break the curve, we need to target women and children. Ninety years after the discovery of insulin there are still children who die because of lack of access to diagnosis, treatment and care. We will continue to provide free insulin and support children with type 1 diabetes, their families and their caregivers through our Changing Diabetes in Children® programme. We also focus on diabetes during pregnancy, which in South-East Asia, for example, affects as many as 16 20% of all pregnant women. It can cause complications during pregnancy and birth, and both mother and child are at higher risk of developing type 2 diabetes later in life. We work to improve diagnosis, care and follow-up of women with gestational diabetes in Nicaragua. India and Colombia. Another project is looking at prevention of diabetes at its earliest stage, namely before a child is born, by improving health literacy among young couples in Malaysia getting ready to start a family .

The patient s own ability to manage their diabetes, with the support of the healthcare professional team, is critical for successful treatment. Our ability to improve outcomes and quality of life requires that we fully understand patients needs. In 2012 we completed the two largest global studies conducted to date looking into the psychosocial aspects of life with diabetes and haemophilia. People with diabetes and haemophilia, their families and caregivers have participated in the surveys. The next step is to translate these insights into new solutions for improved care and self-management in collaboration with global and local partners.

#### Engaged people drive performance

What engages people in Novo Nordisk is the conviction that the company is improving lives for people with diabetes, haemophilia and other chronic conditions. Being patient-centric begins in the lab and carries on through clinical development and the entire production and distribution chain, all the way until the products are in the hands of the patient.

Engaged people drive performance. Therefore, there has to be alignment between personal values and the values that define one s work life. People who choose to work with Novo Nordisk most often do so because they see opportunities to put their talent into play in ways that really make a difference in people s lives, says Lise Kingo, We call it life-changing careers.

As the company onboards more than 5,000 new people each year, it becomes increasingly important that people understand and live the Novo Nordisk Way.

Over the past decade we have been focused on nurturing a diverse and inclusive working environment. Diversity fosters motivation, competitiveness and innovation, says Lise Kingo, who does not hide the fact that she is keen to see Novo Nordisk as an even more diverse and inclusive workplace.

### **Documenting value creation**

The Triple Bottom Line business principle is a source of employee pride and external recognition that has helped safeguard the company s reputation and stakeholder will scale up our efforts to be a sustainable business, and through the Blueprint for Change programme we will document how these activities create value for our business, society and patients, says Lise Kingo.

The Blueprint for Change programme complements the integrated annual reporting in communicating value creation by conducting deep dive case studies from different corners of the business. Adding to the series of case studies on how the company is Changing Diabetes in different business environments China, US and Bangladesh the most recent study looks into business opportunities in Indonesia, one of Novo Nordisk s new strategic markets.

The case studies explore how to document value, measured in both financial and intangible value, and how to leverage and increase value for Novo Nordisk and its stakeholders. In Bangladesh, for example, a strategic partnership with a patient organisation resulted in more efficient distribution and use of Novo Nordisk s differential pricing policy, leading to better treatment offerings for the more than 8 million people in the country that have diabetes, and stronger relationships and increased sales for the company.

Our method has been taken up as an example of shared value thinking. This is an interesting and fresh perspective that we think will inspire other companies to embrace sustainability more strategically. It speaks in the language of business and offers a positive and simple way to go, says Lise Kingo. In our view, though, there is more to it than competitiveness. In our approach to business we strive to create long-term, sustainable value in a bigger picture perspective. For us, the patient s well-being is the ultimate goal.

confidence through challenging times. We

## 365 days a year

On World Diabetes Day Novo Nordisk employees around the world took part in activities to raise awareness about diabetes, how it can be effectively treated and how it can be prevented. This effort goes on throughout the year, as corporate programmes or local initiatives, and often with external partners. Novo Nordisk s Changing Diabetes® programmes address needs for improved access for proper care to people with diabetes throughout the world. Learn more at novonordisk. com/ about\_us/changing-diabetes/ CD\_programmes.asp.

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In the current economic landscape, tough decisions not to launch new products in some markets may lie ahead.

With every big opportunity comes a



FORM 6-K

Whenever investors and financial analysts get depressed about the future, stocks in pharmaceutical companies are in demand. The thinking is that the pharmaceutical industry is a safe haven in times of uncertainty. After all, people need medicine in both good and bad times. But if you think that the pharmaceutical industry is virtually risk free, think again. Or ask Jesper Brandgaard, Novo Nordisk's chief financial officer and chairman of the company's Risk Management Board.

"If you look at global economic development in a long-term perspective, it's understandable why many consider pharma stocks a relatively safe bet compared with other industries," says Jesper Brandgaard. "When they look outside of Europe and North America, they see many countries which are not only growing their economy despite all the financial turmoil in the world, but which are also spending a rising proportion of their gross domestic product on healthcare. This means that the global demand for medicine and the willingness and ability to pay for the newest and best treatments will be growing."

That is not to say that the pharmaceutical industry is immune to the economic problems of the world. Far from it, insists Jesper Brandgaard. "The contraction in the economy in Europe, for example, means that governments are finding new ways of curbing public spending including cutting the costs of medicines by forcing down prices and limiting patients' access to new products. And I can't see this changing in the foreseeable future. For us this poses a significant risk when launching a new product such as Tresiba® (insulin degludec), our new generation basal insulin with ultra-long duration of action. Despite the patient benefits and the data supporting the health economic benefits of the product, we will have to fight hard to obtain what we consider a fair price. We may even have to make the tough decision not to launch Tresiba® in some countries at all, if we can't agree on a price."

Jesper Brandgaard notes that with the arrival of Tresiba®, which is now approved in the EU and Japan, many countries will have three generations of Novo Nordisk insulin products on the market. The low-priced traditional human insulins, the mid-priced modern insulins, which provide additional benefits to patients, and Tresiba®, which provides even more benefits at a premium price: "It's important to know that the insulin market is a high-volume, low-price business compared with many other pharmaceuticals," says Jesper Brandgaard. "Daily treatment cost even with the best insulin products is modest. I realise that these are difficult economic times. but if governments don't want to pay a premium for the additional benefits of a new product like Tresiba®. I hope they will allow their citizens to do so. I'm convinced many people would be willing to pay the difference out of their own pocket if they had the option."

Jesper Brandgaard emphasises that Tresiba® and Ryzodeg® (insulin degludec/ insulin aspart) represent an opportunity to upgrade two-thirds of the global insulin market measured in value. As such these products represent Novo Nordisk's biggest growth opportunity in the coming years and therefore also the biggest risk, if the company is unable to launch them successfully.

#### CONTINUED

That s how it is: with every big opportunity comes a risk, says Jesper Brandgaard. I would be more worried if we were unable to continuously develop new opportunities if for some reason our researchers ran out of ideas for new and better products. Fortunately, I see no signs of this happening.

He points to pipeline products such as IDegLira, semaglutide and FIAsp as potential new opportunities for both patients with diabetes and Novo Nordisk (see pp 30 31 for details). Additionally, new haemophilia products are under way, as is the development of liraglutide for treating severe obesity. The business risks associated with the latter have changed over the past year, Jesper Brandgaard notes:

The regulatory risk has declined, while the commercialisation risk has increased. A couple of years ago, many thought that it would be all but impossible to obtain approval from the US Food and Drug Administration of new drugs for obesity. Nonetheless, in 2012, the agency approved two new products for this indication, which many see as a sign that the regulatory sentiment around obesity drugs is changing in light of the huge problems obesity is creating. But when we then look at how the first of these products has done after its launch, it is clear that approval doesn t equal immediate commercial success. The uptake of this product has so far been modest. I take it as a sign that the commercial risk associated with obesity products is higher than previously believed.

### Competition in the diabetes care market

With a global insulin market share of close to 50% and Victoza® (the once-daily

GLP-1 product) being the company s key growth driver in 2012, any new moves by competitors in the insulin and GLP-1 markets may pose new risks for Novo Nordisk. Jesper Brandgaard mentions a few developments to which he is paying particular attention:

The patents on insulin glargine, (Sanofi s long-acting insulin) expire in 2014 in the EU and in 2015 in the US. This means that the lion s share of the segment for long-acting modern insulins opens up for biosimilar producers. It is also worth noting that Lilly has a new long-acting insulin in phase 3 development which, if approved, would also compete with Tresiba® in this segment.

In the GLP-1 market, several companies are developing new products, but it is still too early to assess the potential commercial risks they may eventually pose to Victoza®.

Right now, we are closely watching exenatide, the GLP-1 product that Bristol Myers Squibb BMS and Astra Zeneca are now selling after BMS acquired Amylin, explains Jesper Brandgaard. I m very confident that the excellent profile of Victoza® will secure its leadership position, but BMS has paid a significant price for this Amylin product and are pushing hard with a big sales force to make it a success, so they will have some impact in the market, that s for sure.

### The threat of biosimilars?

In recent years there has been much speculation about how much of a risk biosimilar The regulatory hurdles of getting a complex molecule such as factor VIIa, the active molecule of NovoSeven®, approved in Europe, the US and Japan are high, so I don t see biosimilar producers as a major threat in these markets, says Jesper Brandgaard. Competition will primarily come from established producers such as Baxter and Bayer, who are developing their own versions of factor VIIa.

However, we will continue to improve our product through new formulations and better injection devices to ensure we have a competitive edge.

In the insulin market, biosimilar competition is not a new phenomenon for Novo Nordisk. For decades there have been and still are local insulin producers in some countries, but their attempts to grow internationally have so far failed.

The insulin market is very different from those for other biologic medicines, Jesper Brandgaard reiterates:

Insulin is a high-volume, low-price business, so it doesn t have the same appeal to biosimilar producers as other biologic medicines. Even when some of the modern insulins lose their patents it will be very difficult for biosimilar producers to achieve the economies of scale that established insulin producers have. Furthermore, to be successful a new producer with global ambitions must also be able to deliver the products in sophisticated pen systems. which further adds to the up-front investments needed and increases the total manufacturing costs.

products may pose to Novo Nordisk. In the human growth hormone market, the arrival of biosimilar products has led to price erosion in some markets. And after the patents for NovoSeven®

expired in many markets, biosimilar versions have been launched in Russia and Iran. For information on patent expiration of Novo Nordisk s main products, see p 99.

## **Risk overview**

Listed below are the main types of risks that Novo Nordisk faces. Many are an inherent part of being a pharmaceutical company. For some specific risks, reference is made to notes in the consolidated statements.

### Market risks

The principle market risks Novo Nordisk faces are:

- Negative effects on sales from pricing and reimbursement reforms enacted by governments. Europe, China and the US are all main markets for Novo Nordisk where such reforms are being implemented. New products from established competitors. Increased competition from
- producers of biosimilar medicines in key markets.

In addition, in some countries in the International Operations region (see pp 35-36), 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 production facilities. During the process obstacles may delay the development of a potential product candidate and add substantial expense. In some cases, it could lead to abandoning the potential product candidate altogether.

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 costs and supply logistics, Novo Nordisk has established production capacity on five continents.

#### Quality and safety issues

Quality and safety issues may arise if, for example, a production facility is not approved, a product is not produced according to specifications or if side effects, which 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 global quality system, a key priority of which is to minimise risks to patient safety and product quality. The quality management system aims to ensure that all regulatory requirements are in compliance and it includes standard operating procedures, quality audits, quality improvement plans and systematic senior management reviews.

For information on Novo Nordisk's product recalls from 2008 to 2012, see pp 13 and 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 hedges expected future cash flows for selected key

### Business ethics and legal risks

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

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The pharmaceutical industry is tightly regulated in many respects, including when it comes to the claims it may make about its products and how it may interact with doctors and other healthcare professionals. To minimise the risk of violation of such 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®. As part of the settlement, Novo Nordisk paid 25 million US dollars, but denied any wrongdoing. In addition to the financial settlement related to marketing practices in the US regarding NovoSeven®, as part of the agreement with the US Department of Justice, our 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, our US affiliate has added additional reporting and other procedures to its already robust compliance programme.

Protection of intellectual property in the form of patents is a very important tool for promoting innovation and stimulating long-term economic growth and job creation. Novo Nordisk's business model is based on chance of success is around 40% for products in phase 2 trials and rises to around 70% for products in phase 3 trials, although there remains significant uncertainty regarding the timing and success of the regulatory approval process.

### Supply disruptions

Failure or breakdown in one of the company's or its key suppliers' vital production facilities could adversely affect operations and could 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

### currencies. For more information on how the company manages this risk, see note 4.3 and 4.4 on pp 76-80.

In the course of conducting business globally, transfer pricing disputes with tax authorities may occur. Novo Nordisk's 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.

To manage uncertainties regarding tax, Novo Nordisk has negotiated multi-year agreements with tax authorities in key markets. For details on taxes paid by the company in 2012, see p 67. 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.

For information on Novo Nordisk's risk policy and risk management process, please visit novonordisk.com/ about\_us/corporate\_governance/risk\_ management.asp.

## 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 Novo Nordisk s B shares.

### Share capital and ownership

Novo Nordisk s total share capital of DKK 560,000,000 is divided into A share capital of nominally DKK 107,487,200 and B share capital of nominally DKK 452,512,800, of which Novo Nordisk A/S and its wholly owned affiliates held nominal DKK 17,416,676 as treasury shares as of 31 December 2012. The company s A shares are not listed and are held by Novo A/S, a Danish public limited liability company wholly owned

1. Calculated using shareholders registered home country.

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. More information on share capital is included in note 4.1 on pp 75 76. According to the Articles of Association of the Foundation, the A shares cannot be divested. As of 31 December 2012, Novo A/S also held nominal value DKK 35,312,800 of B share capital. Each A share (nominal value 1 Danish krone) carries 1,000 votes, and each B share (nominal value 1 Danish krone) carries 100 votes. With 25.5% of the total share capital, Novo A/S controls 73.5% of the total number of votes, excluding Novo Nordisk s stock of treasury shares.

Novo Nordisk s B shares are traded in units of DKK 1 and the ratio of Novo Nordisk s B shares to ADRs is 1:1. 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 official record of all shareholders exists. Based on available sources of information about the company s shareholders as of 31 December 2012, it is estimated that shares were distributed as shown in the charts on this page. As of 31 December 2012, the free float of listed B shares was 88.3%, which excludes the Novo A/S holding and treasury shares.

### The capital structure

Novo Nordisk s Board of Directors and Executive Management find 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

implemented in the previous 12-month period. 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. 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 14 billion. Novo Nordisk expects to implement the majority of the new share repurchase programme according to the Safe Harbour Regulation. At the 2013 Annual General

<sup>1.</sup> Dividend for the year as a percentage of net profit.

<sup>2.</sup> Adjusted for costs related to the

discontinuation of pulmonary diabetes projects.

Adjusted for impact from divestment of shares in ZymoGenetics.

<sup>4.</sup> Proposed dividend for the financial year 2012.

between long-term shareholder value creation and competitive shareholder 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 2012 Annual General Meeting, a reduction of the company s B share capital, corresponding to approximately 3.4% of the total share capital, was implemented in April 2012 by cancellation of treasury shares. This enables 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 2011, Novo Nordisk repurchased shares worth DKK 12 billion, in line with the share repurchase programme

Meeting, the Board of Directors will propose a further reduction of the company s B share capital, corresponding to approximately 1.8% of the total share capital, by cancellation of 10 million treasury shares. After implementation of the share capital reduction, Novo Nordisk s share capital will amount to DKK 550,000,000 divided into an A share capital of DKK 107,487,200 and a B share capital of DKK 442,512,800.

## 2013 restricted stock unit programme

2013 marks the 90th anniversary of the first diabetes patients being treated with insulin from the company that is now Novo Nordisk. To commemorate the occasion, employees in the company will be offered 20 restricted stock units. The programme includes all employees as of 1 January 2013, apart from employees in the separately operating affiliates NNE Pharmaplan and NNIT. A restricted stock unit gives the right to receive one Novo Nordisk B share free of charge on 1 April 2016 subject to continued employment and average sales growth of at least 5% per year measured in DKK in the period 2012 2015.

It is estimated that 474,000 shares will be needed for the programme. The costs of the programme approximately DKK 440 million will be amortised over the period 1 January 2013 to 1 April 2016. No dividends will be paid on the restricted stock units and the holders will have no voting rights until the restricted stock units are converted to shares in 2016.

### Share price performance

Novo Nordisk s share price increased by 39% from its 2011 close of DKK 660 to its 31 December 2012 close of DKK 916.50. The total market value of Novo Nordisk s B shares, excluding treasury shares, was DKK 399 billion at the end of 2012.

### Payment of dividends

As illustrated in the figure on p 44, Novo Nordisk has continuously increased both the payout ratio and the dividend paid over the last five years. The dividend for 2011 recorded in March 2012 was DKK 14 per share of 1 krone.

At the 2013 Annual General Meeting, the Board of Directors will propose a 29% increase in the dividend for 2012 to DKK 18 per A and B share of 1 krone, as well as for ADRs. Novo Nordisk does not pay a dividend on its holding of treasury shares. The proposed dividend corresponds to a payout ratio of 45.3%. For 2011, the payout ratio was also 45.3%.

Shareholders enquiries concerning dividend payments and shareholder accounts should be addressed to Investor Service (see 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 36 sell-side analysts, including the major

### Internet

Novo Nordisk s homepage for investors is novonordisk.com/investors. It includes information about Novo Nordisk s activities: company announcements from 1995 onwards, financial, social and environmental results, a calendar of investor-relevant events, investor presentations, background information and recent annual reports.

The company s share price development reflects a leading position in the growing diabetes care market, coupled with a continued improvement in operating margin and encouraging progress within research and development (see p 8 for further details on operating performance and pp 30 31 for further details on research and development pipeline developments).

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.

## **Corporate governance**

Corporate governance is the system by which companies are directed and controlled. For Novo Nordisk, this includes securities laws and corporate governance standards in both Denmark and the US, the two countries in which the company s shares are listed. The company s corporate governance also includes the internal values-based management system called the Novo Nordisk Way.

Novo Nordisk s B shares are listed on NASDAQ OMX Copenhagen, and on the New York Stock Exchange 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.

Novo Nordisk adheres to the majority of the Danish Corporate Governance Recommendations, with the following exceptions: The Board of Directors has not established a remuneration committee.

The Board of Directors has not established a nomination committee.

Current employment contracts for Novo Nordisk s Executive Management allow in some instances for severance payments of more than 24 months fixed base salary plus pension contribution.

The reasons for deviating from these recommendations are given on pp 48 and 51.

Novo Nordisk is a foreign listed private issuer and is in compliance with the corporate governance standards of the New York Stock Exchange applicable to foreign listed private issuers.

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. See p 19 for more information about the Novo Nordisk Way.

Novo Nordisk is part of the Novo Group (see p 44) 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.

## Governance structure Shareholders

Shareholders have ultimate authority over the company and exercise their right 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

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attached to A shares include pre-emptive subscription rights in the event of an increase of the A share capital, preemptive 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.

#### **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 s overall strategy on behalf of shareholders and 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 general meeting and recorded in the meeting minutes. For minutes from the annual general meeting, see novonordisk.com/about us.

The Board of Directors has 12 members, eight of whom are elected by shareholders at general meetings and four by employees in Denmark. Shareholder-elected board members serve a 1-year term and may be re-elected. Members must retire at the first general meeting after reaching the age of 70. Four of the eight shareholder-elected board members are independent as defined by the Danish Corporate Governance Recommendations. See p 53.

A proposal for nomination of board members is presented by the Chairmanship 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. The self-assessment and the Board of Directors competence profile are used in the nomination process.

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 eight shareholder-elected board members are non-Danes.

The self-assessment conducted in 2012

resulted in a further development of the strategy process and a continued focus on succession preparedness. 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 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 s employees in Denmark are entitled to be represented by half of the total number of board members elected at the general meeting. In 2010, employees elected four board members from among themselves three male and one female, all Danes. Board members elected by employees serve a 4-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 2012.

#### Chairmanship

The annual general meeting directly elects the chairman and vice chairman of the

### CONTINUED

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, recommending the remuneration of board members and Executive Management, and proposing candidates for election at a general meeting.

In practice, the Chairmanship has the roles and responsibilities of nomination and remuneration committees, and presents recommendations to the Board of Directors. The Board of Directors has not formally established separate committees, and as a result does not conform to the Danish Corporate Governance Recommendations. This is due to the fact that the Board of Directors finds that each board member must have the opportunity to contribute actively to discussions and have access to all relevant information on nomination and remuneration.

In March 2012, the annual general meeting re-elected Sten Scheibye as chairman and Göran Ando as vice chairman. See

novonordisk.com/about\_us for a report on the Chairmanship s activities.

### **Audit Committee**

The three members of Novo Nordisk s Audit Committee are elected by the Board of Directors from among its members. All members qualify as independent and have been designated as financial experts as defined by the US Securities and Exchange Commission (SEC). Under Danish law, all members qualify as financial experts and two of the

The Audit Committee assists the Board of Directors with oversight of the external auditors, the internal audit function, complaints regarding fraud or violations of business ethics, the financial, social and environmental reporting process, business ethics compliance and post-investment reviews, and in 2012 it was agreed that the Audit Committee also assists with oversight of long-term incentive programmes. In March 2012, the Board of Directors elected Hannu Ryöppönen as chairman and Kurt Anker Nielsen and Liz Hewitt as members of the Audit Committee. See novonordisk. com/about us for a report on the Audit Committee s activities.

### **Executive Management**

The Board of Directors has delegated responsibility for day-to-day management of Novo Nordisk to its Executive Management. Executive Management consists of the president & chief executive officer plus four executives. They are responsible 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 s 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 s financial reporting and the internal controls over financial

reporting processes are audited by an independent auditor 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 s 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, Group Internal Audit, reports to the company s Audit Committee. The 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 must approve the appointment, remuneration and dismissal of the head of the internal audit function.

Three other types of assurance activities 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. members also qualify as independent.

## Remuneration

Novo Nordisk aims to attract, retain and motivate talented individuals. The company s remuneration is therefore designed to be competitive. Remuneration rewards short- and long-term performance and is aligned with shareholder interests.

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 and complexity. The results are presented to Novo Nordisk s 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, 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

## **Board of Directors**

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 when attending board meetings in Denmark. No travel allowance is paid to board members when attending board meetings outside Denmark. The travel allowance is 3,000 euros for Europe-based board members and 6,000 euros for US-based board members. 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. The aggregate maximum amount that may be granted as an incentive for a given year is currently equal to 14 months fixed base salary plus pension contribution. 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 short-term achievements of individualised 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.

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In 2012, the base fee for members of the Board of Directors was DKK 500,000 (DKK 500,000 in 2011).

		2012				2011		
- 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
Sten Scheibye (chairman of the Board)	1.5			1.5	1.5			1.5
Göran Ando (vice chairman of the Board)	1.0		0.1	1.1	1.0	0.1	0.1	1.2
Hannu Ryöppönen (chairman of the Audit Committee)	0.5	0.4	0.1	1.0	0.5	0.3	0.1	0.9
Liz Hewitt <sup>1</sup> (member of the Audit Committee)	0.4	0.2	0.1	0.7				
Kurt Anker Nielsen (member of the Audit Committee)	0.5	0.3		0.8	0.5	0.5		1.0
Bruno Angelici <sup>1</sup>	0.5		0.1	0.6	0.4		0.1	0.5
Henrik Gürtler	0.5			0.5	0.5			0.5
Thomas Paul Koestler <sup>1</sup>	0.5		0.3	0.8	0.4		0.2	0.6
Anne Marie Kverneland	0.5			0.5	0.5			0.5
Ulrik Hjulmand-Lassen	0.5			0.5	0.5			0.5
Søren Thuesen Pedersen	0.5			0.5	0.5			0.5
Stig Strøbæk	0.5			0.5	0.5			0.5
Jørgen Wedel <sup>2</sup> Pamela J Kirby <sup>2</sup>	0.1	0.1	0.1	0.3	0.5 0.1	0.3	0.3	1.1 0.1
Total	7.5	1.0	0.8	9.33	7.4	1.2	0.8	9.433

1. Bruno Angelici and Thomas Paul Koestler were first elected at the Annual General Meeting in March 2011, and Liz Hewitt was first elected at the Annual General Meeting in March 2012.

2. Pamela J Kirby resigned as of March 2011. Jørgen Wedel resigned as of March 2012.

3. In addition social security taxes have been paid by Novo Nordisk amounting to less than DKK 1 million (less than DKK 1 million in 2011).

### 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 s 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.

Non-financial targets are determined on the basis of an assessment of the objectives regarded as particularly important to the fulfilment of the company s long-term performance. Non-financial targets are typically related to achievement of specific milestones within research and development, such as execution of trials, obtainment of product approvals and product launches, or within sustainability related to patients, environment, company reputation and development of employees. The total number of non-financial targets varies, but consists typically of 10-15 targets within 5 6 categories.

If the financial target is met for economic

profit, and at least 85% performance on sustainability targets and research and development targets respectively, then the allocation to the joint pool would correspond to four months base salary plus pension contribution for the Senior Management Board. The pool is capped at eight months base salary plus pension contribution.

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. 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 s share-based incentives is available online at novonordisk.com/about\_us.

### Pension

Pension contributions are paid to enable an opportunity for 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.

1. The interval 35 55% states the span between maximum performance and on-target performance .

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. severance payments of up to 36 months fixed base salary plus pension contributions in the event of a merger, acquisition or takeover of Novo Nordisk. If an executive s employment 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. For 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.

Current employment contracts allow

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

			20	12					20	11		
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												
Sørensen Jesper	8.4	2.9	2.8	0.3		14.4	7.3	3.1	2.7	0.3		13.4
Brandgaard	4.8	1.6	1.6	0.3		8.3	4.5	1.5	1.5	0.3		7.8
Lise Kingo	4.3	1.1	1.4	0.3		7.1	4.1	1.4	1.3	0.3		7.1
Kåre Schultz Mads Krogsgaard	5.2	1.4	1.7	0.3		8.6	4.9	1.7	1.7	0.3		8.6
Thomsen	4.8	1.6	1.6	0.3		8.3	4.5	1.9	1.5	0.3		8.2
Executive Management												
in total	27.5	8.6	9.1	1.5		46.7	25.3	9.6	8.7	1.5		45.1
Other members of the Senior Management Board in total <sup>1</sup>	72.13	25.0	22.3	8.4		127.8	70.83	26.3	22.4	10.8		130.3

Joint pool <sup>2</sup>	73.1	73.1	56.9	56.9

The total remuneration for 2012 includes remuneration to 26 senior vice presidents (26 in 2011) of which none has retired or left the company in 2012 (one in 2011). The 2011 remuneration for the retired senior vice president is included in the table above, whereas a cash settlement of DKK 5 million is not included.

The joint pool 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 time of establishment of the joint pool, approximately 30% of the pool will be allocated to the members of Executive Management and 70% to other members of the Senior Management Board (2011: 30% and 70% respectively). In the lock-up period, the joint

2. pool may potentially be reduced in the event of lower-than-planned value creation in subsequent years.

3. Including social security taxes paid amounting to DKK 1.5 million (DKK 1.7 million in 2011).

## Management s long-term incentive programme

The shares allocated to the joint pool for 2009 (177,066 shares) were released to the individual participants subsequent to the approval of the *Annual Report* 2012 by the Board of Directors and the announcement on 31 January 2013 of the full-year financial results for 2012. Based on the share price at the end of 2012, the value of the released shares is as follows:

Value as at 31 December 2012 of shares released on 31 January 2013	Number of shares	Market value <sup>1</sup> (DKK million)
Executive Management		
Lars Rebien Sørensen	15,764	14.5
Jesper Brandgaard	10,501	9.6
Lise Kingo	10,501	9.6
Kåre Schultz	10,501	9.6
Mads Krogsgaard Thomsen	10,501	9.6
Executive Management in total	57,768	52.9
Other members of the Senior Management Board in total <sup>2</sup>	105,848	97.0

1. The market value of the shares released in 2013 is based on the Novo Nordisk B share price of DKK 916.50 at the end of 2012.

2. In addition, 13,450 shares (market value: DKK 12.3 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 22,012 in 2012 (DKK 21,841 in 2011), as a board member of DONG Energy A/S until 18 April 2012, from which he received remuneration of DKK 87,500 in 2012 (DKK 175,000 in 2011), as a member of the Supervisory Board of Bertelsmann AG, from which he received remuneration of EUR 129,000 in 2012 (EUR 85,000 in 2011) and as board member of Thermo Fisher Scientific Inc, from which he received remuneration of USD 219,840 in 2012 (USD 58,022 in 2011; adjusted by USD 58,022 after final confirmation of 2011 remuneration). Jesper Brandgaard serves as chairman of the Board of Directors of SimCorp A/S, from which he received remuneration of DKK 801,846 in 2012 (DKK 753,455 in 2011). Kåre Schultz serves as a board member of LEGO A/S, from which he received remuneration of DKK 800,000 in 2012 (DKK 625,000 in 2011). Until January 2013, Mads Krogsgaard Thomsen served as a board member of Cellartis AB, from which he received remuneration of SEK 50,000 in 2011). Until January 2013, Mads Krogsgaard Thomsen served as a board member of Cellartis AB, from which he received remuneration of SEK 50,000 in 2012 (SEK 50,000 in 2011). As of 1 January 2012, Mr Thomsen also serves as a board member of Copenhagen University, from which he received remuneration of DKK 79,800 in 2012.

## **Board of Directors**

### Sten Scheibye (chair)

Formerly President and CEO of Coloplast A/S, Denmark (retired). Member of the Board of Novo Nordisk A/S in 2003, vice chairman in 2004 and chairman since 2006.

Management duties: Trade Council of Denmark (chair), the Danish Industry Foundation (chair), the Denmark-America Foundation (chair), the Danish Fulbright Commission (vice chair), member of the boards of the Novo Nordisk Foundation, Rambøll Gruppen A/S, Dades A/S, RM Rich. Müller A/S, the Rich. Müller Foundation, the Aase and Ejnar Danielsen Foundation and the Knud Højgaards Foundation, all in Denmark.

**Special competences:** Knowledge of the healthcare industry, particularly in relation to patients requiring chronic care, and managerial skills relating to international organisations.

**Education:** BComm (1983) from Copenhagen Business School, Denmark, PhD in Organic Chemistry (1981) and MSc in Chemistry and Physics (1978), both from the University of Aarhus, Denmark.

## Göran Ando (vice chair)

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

**Management duties:** Symphogen A/S, Denmark (chair), member of the boards of Novo A/S, Denmark, and Molecular Partners AG, Switzerland. Member of the Scientific Advisory

### **Bruno Angelici**

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

Management duties: Member of the boards of Smiths Group plc, 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: Novozymes A/S (chair), Copenhagen Airports A/S (chair) and COWI Holding A/S (chair), all in Denmark.

### Liz Hewitt

Formerly Group Director Corporate Affairs for Smith & Nephew plc, UK (retired). Member of the board of Novo Nordisk A/S since 2012. Member of the Audit Committee of Novo Nordisk A/S since 2012.

**Management duties:** Member of the board and audit committee (chair) of Synergy Health plc, UK. External member of the audit committee of the House of Lords, UK.

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

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

### Ulrik Hjulmand-Lassen

Senior IT quality advisor in IT Governance. 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 Denmark/DIA-E.

### Thomas Paul Koestler

Executive with Vatera Holdings LLC, US. Member of the Board of Novo Nordisk A/S since 2011.

Board of Bausch & Lomb, US, and 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.

**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. Management duties: Member of the boards of Momenta Pharmaceuticals Inc., ImmusanT Inc., Arisaph Pharmaceuticals Inc., Rib-X Pharmaceuticals Inc., and Pearl Therapeutics Inc., all in the US. Chairman

of the Scientific Advisory Board of Bausch & Lomb, USA.

**Special competences:** Extensive R&D knowledge, both generally and within the field of regulatory affairs. Significant knowhow 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.

### Anne Marie Kverneland

Laboratory technician, currently working as a full-time shop steward. Member of the Board of Novo Nordisk A/S since 2000.

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

### Kurt Anker Nielsen

Formerly CFO and deputy CEO of Novo Nordisk A/S. CEO of Novo A/S, Denmark, from 2000 to 2003 (retired). Member of the Board of Novo Nordisk A/S since 2000. Member of the Audit Committee of Novo Nordisk A/S since 2004 (chair 2004 2012).

Management duties: Dalhoff Larsen & Horneman A/S (chair), Collstrop s

Mindelegat (chair), Novozymes A/S (vice chair), and member of the boards of the Novo Nordisk Foundation, Veloxis Pharmaceuticals A/S and Vestas Wind Systems A/S, all in Denmark. Chairman of the audit committees of Novozymes A/S, Veloxis Pharmaceuticals A/S and Vestas Wind Systems A/S, all in Denmark.

**Special competences:** In-depth knowledge of Novo Nordisk A/S and its businesses, working knowledge of the global pharmaceutical industry and experience in working with accounting, financial and capital market issues. **Education:** MSc in Commerce and

Business Administration (1972) from Copenhagen Business School, Denmark.

### Søren Thuesen Pedersen

Currently working as an 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.

### Hannu Ryöppönen

Formerly CFO and deputy CEO of Stora Enso Oyj, Finland (retired). Member of the Board of Novo Nordisk A/S since 2009. Chairman of the Audit Committee of Novo Nordisk A/S 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. Hakon Invest AB (chair), BillerudKorsnäs AB (chair), both in Sweden. Member of the board of Amer Sports Oyj, Finland, and the private equity fund Value Creation Investments Limited, Jersey, Channel Islands. Chairman of the audit committee of Amer Sports Oyj, Finland.

**Special competences:** International executive background and thorough understanding of managing finance operations in global organisations, in particular in relation to accounting, financial and capital markets 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.

### Stig Strøbæk

Electrician, currently working as a full-time shop steward. Member of the Board of Novo Nordisk A/S since 1998.

**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).

Name (male/female)	First elected	Term	Nationality	Date of birth	Independence1
Sten Scheibye (m)	2003	2013	Danish	October 1951	Not independent <sup>2</sup>

Göran Ando (m) Bruno Angelici (m) Henrik Gürtler (m) Liz Hewitt (f) Ulrik Hjulmand-Lassen <sup>3</sup> (m) Thomas Paul Koestler (m)	2005 2011 2005 2012 2010 2011	2013 2013 2013 2013 2013 2014 2013	Swedish French Danish British Danish American	March 1949 April 1947 August 1953 November 1956 April 1962 June 1951	Not independent <sup>2</sup> Independent Not independent <sup>2</sup> Independent <sup>4,5</sup> Not independent Independent
Anne Marie Kverneland <sup>3</sup> (f)	2000	2014	Danish	July 1956	Not independent
Kurt Anker Nielsen (m)	2000	2013	Danish	August 1945	Independent <sup>2,4</sup>
Søren Thuesen Pedersen <sup>3</sup> (m)	2006	2014	Danish	December 1964	Not independent
Hannu Ryöppönen (m)	2009	2013	Finnish	March 1952	Independent <sup>4,5</sup>
Stig Strøbæk <sup>3</sup> (m)	1998	2014	Danish	January 1964	Not independent

1. As designated by NASDAQ OMX Copenhagen in accordance with section 5.4.1 of Recommendations on Corporate Governance.

2. Member of Management or the Board of Novo A/S or the Novo Nordisk Foundation.

3. Elected by employees of Novo Nordisk.

 Mr Ryöppönen, Mr Nielsen 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

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. Mr Sørensen was appointed a member of Corporate Management in May 1994, and in December 1994 he 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.

**Education:** BSc in International Economics (1983) from Copenhagen Business School, Denmark, and MSc in Forestry (1981) from the Royal Veterinary and Agricultural University (now the Faculty of Science of the University of Copenhagen), Denmark. **Date of birth:** October 1954.

### 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: Chairman of the boards of SimCorp A/S and NNIT A/S, both in Denmark.

**Education:** MBA (1995) and MSc in Economics and Auditing (1990) from Copenhagen Business School, Denmark. **Date of birth:** October 1963.

### Lise Kingo

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 approach. In 1999, Ms Kingo was appointed senior vice president, Stakeholder Relations. In 2002, she was appointed executive vice president and chief of staffs in Novo Nordisk, assuming global responsibility for Corporate Relations. She is adjunct professor at the Medical Faculty, Vrije Universiteit, Amsterdam, the Netherlands.

**Other management duties:** Chairman of the board of Steno Diabetes Center A/S and chairman of the Danish Council on Corporate Social Responsibility, both in Denmark.

**Education:** MSc (Hons) in Responsibility and Business Practice (2000) from the University of Bath, UK, BCom in Marketing Economics (1991) from Copenhagen Business School, Denmark, and BA in Religions and Ancient Greek Art (1986) from the University of Aarhus, Denmark.

Date of birth: August 1961.

### 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: Chairman of the board of Royal Unibrew A/S and member of the board of LEGO A/S, both in Denmark. Education: MSc in Economics (1987) from the University of Copenhagen, Denmark. Date of birth: May 1961.

### Mads Krogsgaard Thomsen

Chief science officer

Mads Krogsgaard Thomsen joined Novo Nordisk in 1991. 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 is a former president of the National Academy of Technical Sciences (ATV), Denmark. Since 2000 he has served as 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.

**Education:** DSc (1991), PhD (1989) and DVM (1986) from the Royal Veterinary and Agricultural University (now the Faculty of Health and Medical Sciences of the University of Copenhagen), Denmark.

Date of birth: December 1960.

### New members of Executive Management

Effective 31 January 2013, Executive Management was expanded with two new members: Jakob Riis was appointed executive vice president with responsibility for Marketing & Medical Affairs, and Lars Fruergaard Jørgensen was appointed executive vice president with responsibility for IT, Quality & Corporate Development. Their biographies can be found on novonordisk.com/about\_us.

## Consolidated financial, social and environmental statements 2012

## Consolidated financial statements

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Shareholders meeting in Copenhagen, March 2012.

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

DKK million	No	te	2012	2011	2010	
Income statement						
Sales	2.1, 2	.2	78,026	66,346	60,776	
Cost of goods sold	2.2, 2	.3	13,465	12,589	11,680	
Gross profit			64,561	53,757	49,096	
Sales and distribution costs	2.2, 2	.3	21,544	19,004	18,195	
Research and development costs	2.2, 2	.3	10,897	9,628	9,602	
Administrative costs	2.2, 2	.3	3,312	3,245	3,065	
Licence fees and other operating income, ne	et 2.2, 5	.6	666	494	657	
Operating profit			29,474	22,374	18,891	
Financial income	4	.8	125	514	1,452	
Financial expenses	4	.8	1,788	963	2,057	
Profit before income taxes			27,811	21,925	18,286	
Income taxes	2	.4	6,379	4,828	3,883	
Net profit for the year			21,432	17,097	14,403	
Earnings per share						
Basic earnings per share (DKK)	4.1 39.0		30.24	24.81		
Diluted earnings per share (DKK)	4.1 38.8	5	29.99	24.60	_	
Statement of comprehensive income						
Net profit for the year					21,432	17,0
Other comprehensive income:						
Items that will not be reclassified subsequer Remeasurements on defined benefit plans	ntly to the Incom	ie sta	tement:	3.7	(281)	
Remeasurements on defined benefit plans				3.7	(281)	

14,403

Items that will be reclassified subsequently to the Income statement,				
when specific conditions are met:				
Exchange rate adjustments of investments in subsidiaries		(172)	(173)	300
Cash fiow hedges, realisation of previously deferred (gains)/losses		1,182	658	(422)
Cash fiow hedges, deferred gains/(losses) incurred during the period		849	(1,170)	(643)
Other items		35	(20)	4
Tax on other comprehensive income, income/(expense)	2.4	(587)	190	346
Other comprehensive income for the year, net of tax		1,026	(515)	(415)
Other comprehensive income for the year, net of tax		1,026	(515)	(415)
Other comprehensive income for the year, net of tax Total comprehensive income for the year		1,026 22,458	(515) 16,582	(415) 13,988

# Balance sheet at 31 December

DKK million	No	te	201	2	2011
Assets					
Intangible assets	3	.1	1,49	5	1,489
Property, plant and equipment	3	.2	21,53	9	20,931
Deferred income tax assets	2	.4	2,24	4	2,414
Other financial assets	4	.7	22	8	273
Total non-current assets			25,50	6	25,107
Inventories	3	.3	9,54	3	9,433
Trade receivables	3	.4	9,63	9	9,349
Tax receivables			1,24	0	883
Other receivables and prepayments	3	.5	2,70	2,705 2,3	
Marketable securities	4	.7	4,55	2	4,094
Derivative financial instruments	4	.4	93	1	48
Cash at bank and on hand	4	.5	11,55	3	13,408
Total current assets			40,16	3	39,591
Total assets			65,66	9	64,698
Equity and liabilities					
Share capital	4.1		560		580
Treasury shares	4.1		(17)		(24)
Retained earnings		;	39,001	;	37,111
Other reserves			1,088		(219)
Total equity			40,632		37,448
Loans	4.2				502
Deferred income tax liabilities	2.4		732		3,206
Retirement benefit obligations	3.7		760		439

Provisions	3.6	1,907	2,324
Total non-current liabilities		3,399	6,471
Current debt	4.2	500	351
Trade payables	4.7	3,859	3,291
Tax payables		593	1,171
Other liabilities	3.8	8,982	8,534
Derivative financial instruments	4.4	48	1,492
Provisions	3.6	7,656	5,940
Total current liabilities		21,638	20,779
Total liabilities		25,037	27,250
Total equity and liabilities		65,669	64,698

# Statement of cash flows for the year ended 31 December

DKK million	Note	2012	2011	2010
Net profit for the year		21,432	17,097	14,403
Adjustment for non-cash items	5.3	11,253	9,117	8,449
Change in working capital	4.6	274	434	297
Interest received		207	332	218
Interest paid		(61)	(215)	(252)
Income taxes paid	2.4	(10,891)	(5,391)	(3,436)
Net cash generated from operating activities		22,214	21,374	19,679
Proceeds from the divestment of ZymoGenetics, Inc.		()	<i>(</i> )	1,155
Purchase of intangible assets and other financial assets		(250)	(259)	(513)
Proceeds from sale of property, plant and equipment		53	70	68
Purchase of property, plant and equipment	3.2	(3,372)	(3,073)	(3,376)
Net purchase of marketable securities		(501)	(197)	(2,913)
Net cash used in investing activities		(4,070)	(3,459)	(5,579)
Repayment of loans	4.2	(502)	(507)	
Purchase of treasury shares, net	4.1	(11,896)	(10,595)	(8,820)
Dividends paid	4.1	(7,742)	(5,700)	(4,400)
Net cash used in financing activities		(20,140)	(16,802)	(13,220)
Net cash generated from activities		(1,996)	1,113	880
Cash and cash equivalents at the beginning of the year	4.5	13.057	11,960	11,034
Exchange gains/(losses) on cash and cash equivalents		(8)	(16)	46
Cash and cash equivalents at the end of the year	4.5	11,053	13,057	11,960
Additional information:1	A E	11 050	10.057	11.000
Cash and cash equivalents at the end of the year	4.5	11,053	13,057	11,960
Marketable securities at the end of the year	4.7	4,552	4,094	3,926

Undrawn committed credit facilities <sup>2</sup>	4,849	4,832	4,473
Financial resources at the end of the year	20,454	21,983	20,359
Net cash generated from operating activities	22,214	21,374	19,679
Net cash used in investing activities	(4,070)	(3,459)	(5,579)
Net purchase of marketable securities	501	197	2,913
Free cash fiow	18,645	18,112	17,013

 Additional non-IFRS measures. Please refer to p 93 for definitions.
 The undrawn committed credit facility is a EUR 650 million (EUR 650 million in 2011 and EUR 600 million in 2010) facility committed by a portfolio of international banks. The facility matures in 2016.

# Statement of changes in equity at 31 December

				Oth				
DKK million	Share capital	Treasury shares	Retained earnings	Exchange rate adjustment	Cash flow hedges	Tax and other items	Total other reserves	Total
2012 Delaura at the								
Balance at the beginning of the year	580	(24)	37,111	398	(1,184)	567	(219)	37,448
Net profit for the year Other comprehensive			21,432	(170)	0.001		4 007	21,432
income for the year <sup>1</sup>			(281)	(172)	2,031	(552)	1,307	1,026
Total comprehensive income for the year			21,151	(172)	2,031	(552)	1,307	22,458
Transactions with owners:								
Dividends (note 4.1) Share-based payments			(7,742)					(7,742)
(note 5.1) Tax credit related to share option scheme			308 56					308 56
Purchase of treasury shares (note 4.1)		(15)	(12,147)					(12,162)
Sale of treasury shares (note 4.1)		2	264					266
Reduction of the B share capital (note 4.1)	(20)	20						
Balance at the end of the year	560	(17)	39,001	226	847	15	1,088	40,632

				Oth	ner reserves			
DKK million	Share capital	Treasury shares	Retained earnings	Exchange rate adjustment	Cash fiow hedges	Tax and other items	Total other reserves	Total
2011	600	(28)	36,097	571	(672)	397	296	36,965

Balance at the
beginning of the year

Net profit for the year Other comprehensive income for the year <sup>1</sup>			17,097	(173)	(512)	170	(515)	17,097 (515)
Total comprehensive income for the year			17,097	(173)	(512)	170	(515)	16,582
Transactions with owners:								
Dividends (note 4.1)			(5,700)					(5,700)
Share-based payments (note 5.1)			319					319
Purchase of treasury shares (note 4.1)		(18)	(10,821)					(10,839)
Sale of treasury shares (note 4.1)		2	242					244
Tax on sale of treasury shares			(123)					(123)
Reduction of the B share capital (note 4.1)	(20)	20						
Balance at the end of the year	580	(24)	37,111	398	(1,184)	567	(219)	37,448

1. Please refer to Statement of comprehensive income p 56.

# **Notes**

As Novo Nordisk s business continues to develop, the company remains focused on simplifying and streamlining its integrated reporting. In 2012 Novo Nordisk has restructured the Consolidated financial, social and environmental statements 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 have been 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 refiected 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.

### Sections in the Consolidated financial statements

### Section 1 Basis of preparation

Introduces our financial accounting policies in general and an overview of Management s key accounting estimates.

- 1.1 Summary of significant accounting policies, p 61
- 1.2 Other accounting policies, p 62
- 1.3 Other general accounting policies, p 62

### Section 2 Results for the year

Comprises the notes related to the result for the year including operating segments, taxes and employee benefits.

- 2.1 Sales and sales rebates, p 63
- 2.2 Segment information, p 64
- 2.3 Employee costs, p 67
- 2.4 Income and deferred income taxes, p 67

### Section 3 Operating assets and liabilities

Relates to the assets that form the basis for the activities of Novo Nordisk, and the related liabilities.

- 3.1 Intangible assets, p 69
- 3.2 Property, plant and equipment, p 70
- 3.3 Inventories, p 71
- 3.4 Trade receivables, p 71
- 3.5 Other receivables and prepayments, p 72
- 3.6 Provisions, p 72
- 3.7 Retirement benefit obligations, p 73
- 3.8 Other liabilities, p 74

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# Section 4 Capital structure and financing items

Encompasses notes related to capital structure and financing items.

- 4.1 Share capital and earnings per share, p 75
- 4.2 Debt, p 76
- 4.3 Financial risk, p 76
- 4.4 Derivative financial instruments, p 78
- 4.5 Cash and cash equivalents, p 81
- 4.6 Change in working capital, p 81
- 4.7 Financial assets and liabilities, p 81
- $4.8\ Financial$  income and expenses, p 84

# Section 5 Other disclosures

Includes other statutory notes and notes of secondary importance from the perspective of the company.

- 5.1 Share-based payment schemes, p 85
- 5.2 Management s holdings of Novo Nordisk shares, p 87
- 5.3 Adjustments for non-cash items, p 88
- 5.4 Commitments and contingencies, p 89
- 5.5 Related party transactions, p 91
- 5.6 Licence fees and other operating income, p 91
- 5.7 Fee to statutory auditors, p 91

5.9 Financial definitions, p 93

5.8 Companies in the Novo Nordisk Group, p 92

# 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 the company strives for early adoption of EU endorsed IFRS accounting standards.

All affiliates in the Novo Nordisk Group follow the same Group accounting policies. This section describes the significant accounting policies and other accounting policies in general, including Management s key accounting estimates and the new IFRS requirements. 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), as well as in accordance with International Financial Reporting Standards (IFRS) as endorsed by the European Union.

Furthermore, the annual report has been prepared 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 the revaluation of available-for-sale financial assets such as derivative financial instruments measured at fair value through the income statement, and equity investments and marketable securities measured at fair value through other comprehensive income.

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 relation to the individual notes to the Consolidated financial statements. Considering all the accounting policies applied in the preparation of the Consolidated financial statements, Management regards the following as the most significant accounting policies for the recognition and measurement of reported amounts:

### Sales and sales rebates (notes 2.1 and 3.6)

Revenue is only recognised when, in Management s 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. Our gross sales are subject to various deductions that are composed primarily of rebates and discounts to retail customers, government agencies, wholesalers, health insurance companies and managed healthcare organisations. These deductions represent estimates of the related 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).

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 is obtained (highly probable) in a relevant major market.

Derivative financial instruments (note 4.4).

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 earnings 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 present the result of hedging activities as part of financial items. Thus, as the majority of Novo Nordisk s sales are in EUR, USD, JPY, CNY and GBP, Sales will be impacted by exchange rate fluctuations whereas the impact from exchange rate fluctuations on Profit before income taxes depends on the results of the hedging activities.

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

Income taxes (note 2.4) Intangible assets and Property, plant and equipment including impairment (notes 3.1 and 3.2) Inventories (note 3.3) Trade receivables and allowances for doubtful trade receivables (note 3.4) Provisions for legal disputes (note 3.6).

# Key accounting estimates

The use of reasonable estimates is an essential part of the preparation of consolidated financial statements. Given the uncertainties inherent in our 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 flow 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:

Rebates and sales discounts 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)

Deferred income tax assets and liabilities (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.

#### 1.2 Other accounting policies

#### Changes in accounting policies and disclosures

### Early adoption of new or amended IFRSs

IAS 19R Employee benefits was revised by IASB in June 2011 with an effective date on or after 1 January 2013 and endorsed by the EU in June 2012. Novo Nordisk has early adopted the amendment in 2012 and is thus not utilising the option to defer the recognition of actuarial gains and losses from defined benefit post-employment plans, known as the corridor approach, and is instead recognising all actuarial gains and losses in Other comprehensive income as these occur. Early adoption also involves immediate recognition of all past service costs, and replacing interest cost and expected return on plan assets with a net interest amount that is calculated by applying the discount rate used to discount to the net defined benefit obligation (asset).

As retrospective application of these changes would have only an immaterial impact on each previous financial year, Novo Nordisk has fully adopted the amendment in 2012 without restating previous years comparable amounts and disclosures. Thus, while the adoption has not had an initial impact on the Income statement in 2012, the implementation decreased Other comprehensive income and Equity by DKK 250 million, decreased Deferred income tax liabilities by DKK 31 million and increased Retirement benefit obligation by DKK 281 million.

Please refer to note 3.7 for a detailed description of the new accounting policy for retirement benefit obligations.

Furthermore, Novo Nordisk has early adopted the amendment to IAS 1 Presentation of financial statements , effective for annual periods beginning on or after 1 July 2012. The amendment requires items of Other comprehensive income, classified by nature, to be grouped into those that will be reclassified subsequently to the Income statement when specific conditions are met and those that will not.

### Adoption of new or amended IFRSs

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 1 January 2012, it has been assessed that the application of the new IFRSs has not had a material impact on the Consolidated financial statements in 2012 and Novo Nordisk 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 are the most significant:

IASB has issued IFRS 9 Financial Instruments , which is applicable for reporting periods starting on or after 1 January 2015. This 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. The new standards and the amendment have not yet been endorsed by the European Union. Novo Nordisk has assessed the impact of the standard and determined that it, in its current wording, will not have any significant impact on the Consolidated financial statements.

IASB has issued re-exposure drafts on IAS 18 Revenue and IAS 17 Leasing. The revised IAS 18 is expected to have only immaterial impact on the Consolidated financial statements. The change in lease accounting is expected to require capitalisation of the majority of the Group s lease contracts, which will have some impact on the Group s assets, liabilities and financial ratios, but no significant impact on net profit. However, the final impact may change depending on the final wording of the standards.

### 1.3 Other general accounting policies

# **Defining materiality**

Novo Nordisk s 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 statements or in the notes.

There are substantial disclosure requirements throughout IFRS. Novo Nordisk 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.

# **Principles of consolidation**

The Consolidated financial statements incorporate the financial statements of Novo Nordisk A/S and entities controlled by Novo Nordisk A/S.

Where necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies into line with Novo Nordisk 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 assets and liabilities, 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 income statements using average exchange rates, whereas balance sheet items are translated using the exchange rates prevailing 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. The above exchange rate adjustments are recognised in Other comprehensive income.

### Statement of cash flows

The Statement of cash flows is presented in accordance with the indirect method commencing with Net profit for the year.

# Section 2 Results for the year

This section comprises notes in relation to the results for the year, including disclosure on operating segments, and provides additional information related to two of Novo Nordisk s four long-term financial targets: Operating profit margin and Growth in operating profit.

Continued growth in the number of patients and innovative new products drive Novo Nordisk s growth in sales. Novo Nordisk expects growth in operating profit to be higher than sales growth, thereby increasing operating margin. This is expected to be enabled by gross margin expansion from both product mix and pricing as well as further productivity improvements in the manufacturing areas. For non-production related activities, the operating margin expansion is expected to be supported by a modest development in administrative costs and scale advantages within sales and marketing, whereas continued investment is envisioned for the research and development activities, which are expected to grow at least 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 2012 performance and 2013 outlook on p 6 gives a detailed description of the results for the year.

### 2.1 Sales and sales rebates

### Accounting policies

Revenue from goods sold is recognised when all the following conditions are met:

Novo Nordisk has transferred the significant risks and rewards of ownership of the goods to the buyer. Novo Nordisk retains neither continuing managerial involvement to the degree usually associated with ownership nor effective control over the goods sold.

The amount of revenue can be measured reliably.

It is probable that the economic benefits associated with the transaction will flow to the entity.

The costs incurred or to be incurred in respect of the transaction 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 reported as a reduction of revenue. 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.

### Key accounting estimates rebates and sales discounts

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. 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.

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 involves interpretation of relevant regulations that are subject to challenge or change in interpretative guidance by

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.

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. Since they are contractually agreed upon, 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 considers the sales performance of products subject to managed healthcare rebates and other contract discounts, and adjusts the provision periodically to reflect actual experience.

Wholesaler charge-backs relate to contractual arrangements existing between Novo Nordisk and indirect customers, mainly 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 one to three months of the liability being incurred.

In certain non-US countries, Novo Nordisk also provides rebates to governments and other entities mandated by laws or government regulations. Furthermore, Novo Nordisk enters into pay-for-performance arrangements with certain healthcare providers. Under these agreements, Novo Nordisk may be required to make refunds to the healthcare providers if anticipated treatment outcomes do not meet predefined targets. Potential refunds are estimated and recorded as a reduction of revenue at the time the related revenues are recorded.

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

### Gross-to-net sales reconciliation

DKK million	2012	2011	2010
Gross sales	103,948	84,386	75,811
US Medicaid and Medicare rebates US managed healthcare rebates US wholesaler charge-backs Non-US healthcare plans and programme rebates Sales returns and discounts	(7,519) (4,390) (8,196) (901) (4,916)	(5,075) (2,551) (5,894) (695) (3,825)	(4,124) (2,494) (4,994) (543) (2,880)
Total gross-to-net sales adjustments	(25,922)	(18,040)	(15,035)
Total net sales	78,026	66,346	60,776

#### 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 on a Group basis 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 fees and other operating income have 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.

#### **Business segments**

DKK million	2012	2011	2010	2012	2011	2010	2012	2011	2010
Segment sales	Di	abetes car	e	Bioph	armaceutio	cals		Total	
NovoRapid® / NovoLog®	15,693	12,804	11,900						
NovoMix® / NovoLog®Mix	9,342	8,278	7,821						
Levemir®	9,786	7,683	6,880						
Total modern insulins	34,821	28,765	26,601						
Human insulins	11,302	10,785	11,827						
Victoza®	9,495	5,991	2,317						
Protein-related products	2,511	2,309	2,214						
Oral antidiabetic products (OAD)	2,758	2,575	2,751						

Diabetes care total sales	60,887	50,425	45,710						
NovoSeven®				8,933	8,347	8,030			
Norditropin®				5,698	5,047	4,803			
Hormone replacement therapy				2,163	2,054	1,892			
Other products				345	473	341			
Biopharmaceuticals total sales				17,139	15,921	15,066			
Segment key figures									
Total sales	60,887	50,425	45,710	17,139	15,921	15,066	78,026	66,346	60,776
Change in DKK (%)	20.7%	10.3%	21.9%	7.7%	5.7%	11.0%	17.6%	9.2%	19.0%
Change in local currencies (%)	14.5%	12.6%	15.7%	2.4%	7.6%	5.4%	11.6%	11.4%	13.0%
Cost of goods sold	11,435	10,762	10,131	2,030	1,827	1,549	13,465	12,589	11,680
Sales and distribution costs	18,894	16,476	14,815	2,650	2,528	3,380	21,544	19,004	18,195
Research and development costs	7,322	6,402	6,744	3,575	3,226	2,858	10,897	9,628	9,602
Administrative costs	2,604	2,485	2,260	708	760	805	3,312	3,245	3,065
Licence fees and other operating									
income, net	464	285	342	202	209	315	666	494	657
Operating profit	21,096	14,585	12,102	8,378	7,789	6,789	29,474	22,374	18,891
Depreciation, amortisation and									
impairment losses included in costs	2,167	2,051	1,887	526	686	580	2,693	2,737	2,467
Additions to Intangible assets	ŕ		,				,	, i	,
and Property, plant and equipment	2,800	2,654	3,068	770	678	795	3,570	3,332	3,863
Assets allocated to business segments	36,030	34,853	34,947	9,119	8,998	7,906	45,149	43,851	42,853
Assets not allocated to business								00 c /=	10 - 16
segments <sup>1</sup>							20,520	20,847	18,549
Total assets							65,669	64,698	61,402

The part of total assets that has not been allocated to either of the two business segments includes Cash at bank and on hand,

1. Marketable securities, Derivative financial instruments and tax assets.

# 2.2 Segment information (continued)

# **Geographical segments**

Novo Nordisk operates in five geographical regions:

North America: the US and Canada

Europe: the EU, EFTA, Albania, Bosnia-Hercegovina, Croatia, 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, allowances 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 in relation to Novo Nordisk s activities in terms of geographical size and the operational business segments. Less than 1% of the total sales is realised in Denmark. Sales to external customers attributed to the US are collectively the most material to the company. 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.

DKK million	2012	2011	2010	2012	2011	2010
	No	orth America	l		Europe	
Sales by business segment:						
NovoRapid® / NovoLog®	9,033	6,934	6,501	3,707	3,464	3,258
NovoMix® / NovoLog®Mix	2,488	2,088	2,099	2,544	2,623	2,562
Levemir®	5,290	3,711	3,229	2,833	2,577	2,410
Modern insulins (insulin analogues)	16,811	12,733	11,829	9,084	8,664	8,230
Human insulins	1,959	1,762	2,156	2,642	3,032	3,532
Victoza®	5,930	3,716	1,457	2,427	1,620	753
Other diabetes care	1,998	1,705	1,646	965	1,210	1,536
Diabetes care total	26,698	19,916	17,088	15,118	14,526	14,051
NovoSeven®	4,397	3,951	4,043	2,206	2,310	2,180
Norditropin®	1,721	1,394	1,320	1,741	1,705	1,823
Other biopharmaceuticals	1,404	1,325	1,158	642	627	610
Biopharmaceuticals total	7,522	6,670	6,521	4,589	4,642	4,613

# **Geographical segments**

Total sales by business and geographical segment	34,220	26,586	23,609	19,707	19,168	18,664
Underlying sales growth in local currencies <sup>1</sup>	19.2%	17.9%	22.4%	2.0%	2.4%	4.6%
Currency effect (local currency impact)	9.5%	(5.3%)	6.8%	0.8%	0.3%	1.8%
Total sales growth as reported	28.7%	12.6%	29.2%	2.8%	2.7%	6.4%
Property, plant and equipment	1,500	1,329	987	16,200	15,681	15,669
Trade receivables	2,278	2,081	1,689	3,688	3,652	3,437
Allowance for doubtful trade receivables	(18)	(22)	(19)	(239)	(333)	(200)
Total assets	5,867	5,465	3,680	47,663	47,202	46,654

1. Additional non-IFRS measure. Please refer to p 93 for definitions.

# 2.2 Segment information (continued)

# **Geographical segments**

DKK million	2012	2011	2010	2012	2011	2010
	International Operations Japan & Korea				l	
Sales by business segment:						
NovoRapid® / NovoLog®	1,408	1,100	965	1,175	1,057	987
NovoMix® / NovoLog®Mix	1,708	1,482	1,377	1,028	970	913
Levemir®	1,106	942	843	386	363	349
Modern insulins (insulin analogues)	4,222	3,524	3,185	2,589	2,390	2,249
Human insulins	3,073	2,581	2,588	768	960	1,101
Victoza®	613	322	37	455	327	70
Other diabetes care	632	583	553	493	430	394
Diabetes care total	8,540	7,010	6,363	4,305	4,107	3,814
NovoSeven®	1,526	1,485	1,245	646	482	461
Norditropin®	780	651	530	1,442	1,285	1,120
Other biopharmaceuticals	234	221	197	224	349	265
Biopharmaceuticals total	2,540	2,357	1,972	2,312	2,116	1,846
Total sales by business and geographical segment	11,080	9,367	8,335	6,617	6,223	5,660
Underlying sales growth in local currencies <sup>1</sup>	16.2%	17.1%	22.3%	(1.5%)	5.1%	3.3%
Currency effect (local currency impact)	2.1%	(4.7%)	(0.4%)	7.8%	4.8%	12.5%
Total sales growth as reported	18.3%	12.4%	21.9%	6.3%	9.9%	15.8%
Property, plant and equipment	1,508	1,672	1,929	174	207	213
Trade receivables	2,177	2,052	1,995	335	377	446
Allowance for doubtful trade receivables	(710)	(535)	(408)	(3)	(2)	0
Total assets	6,660	6,419	6,327	989	1,388	1,158
DKK million	2012	2011	2010	2012	2011	2010
	Re	egion China			Total	

070	0.40	400	45.000	10.004	44.000
					11,900
			· ·		7,821
		-			6,880
		,			26,601
2,860	2,450	2,450		10,785	11,827
70	6	0	9,495	5,991	2,317
1,181	956	836	5,269	4,884	4,965
6,226	4,866	4,394	60,887	50,425	45,710
158	119	101	8,933	8,347	8,030
14	12	10	5,698	5,047	4,803
4	5	3	2,508	2,527	2,233
176	136	114	17,139	15,921	15,066
6,402	5,002	4,508	78,026	66,346	60,776
16.3%	11.7%	19.9%	11.6%	11.4%	13.0%
11.7%	(0.7%)	7.6%	6.0%	(2.2%)	6.0%
28.0%	11.0%	27.5%	17.6%%	9.2%	19.0%
2,157	2,042	1,709	21,539	20,931	20,507
		-			
1,161	1,187	933	9,639	9,349	8,500
	1,187 0	933 0	9,639 (1,024)	9,349 (892)	8,500 (627)
	70 1,181 6,226 158 14 4 176 <b>6,402</b> 16.3% 11.7% <b>28.0%</b>	1,574       1,115         171       90         2,115       1,454         2,860       2,450         70       6         1,181       956         6,226       4,866         158       119         14       12         4       5         176       136         6,402       5,002         16.3%       11.7%         11.7%       (0.7%)         28.0%       11.0%	1,574       1,115       870         171       90       49         2,115       1,454       1,108         2,860       2,450       2,450         70       6       0         1,181       956       836         6,226       4,866       4,394         158       119       101         14       12       10         4       5       3         176       136       114         6,402       5,002       4,508         16.3%       11.7%       19.9%         11.7%       11.0%       27.5%	1,574       1,115       870       9,342         171       90       49       9,786         2,115       1,454       1,108       34,821         2,860       2,450       2,450       11,302         70       6       0       9,495         1,181       956       836       5,269         6,226       4,866       4,394       60,887         158       119       101       8,933         14       12       10       5,698         4       5       3       2,508         176       136       114       17,139         6,402       5,002       4,508       78,026         16.3%       11.7%       19.9%       11.6%         11.7%       27.5%       17.6%%	1,574       1,115       870       9,342       8,278         171       90       49       9,786       7,683         2,115       1,454       1,108       34,821       28,765         2,860       2,450       2,450       11,302       10,785         70       6       0       9,495       5,991         1,181       956       836       5,269       4,884         6,226       4,866       4,394       60,887       50,425         158       119       101       8,933       8,347         14       12       10       5,698       2,507         176       136       114       17,139       15,921         6,402       5,002       4,508       78,026       66,346         16.3%       11.7%       19.9%       11.6%       11.4%         11.7%       27.5%       17.6%%       9.2%

1. Additional non-IFRS measure. Please refer to p 93 for definitions.

# 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	2012	2011	2010
Wages and salaries	17,301	16,127	14,520
Share-based payment costs (note 5.1)	308	319	463
Pensions defined contribution plans	1,302	1,155	1,052
Pensions retirement benefit			
obligations (note 3.7)	150	(2)	210
Other social security contributions	1,358	1,189	1,067
Other employee costs	1,779	1,491	1,510
Total employee costs for the year	22,198	20,279	18,822
Employee costs included			
in property, plant and equipment <sup>1</sup>	(533)	(496)	(559)
Change in employee costs included in inventories	(70)	(07)	76
	(70)	(37)	76
Total employee costs expensed			
in the Income statement	21,595	19,746	18,339
Included in the Income statement:			
Cost of goods sold	4,627	4,302	4,006
Sales and distribution costs	8,784	7,961	7,240
Research and development costs	4,298	3,980	3,697
Administrative costs	2,205	1,993	2,059
Licence fees and other operating			
income, net	1,681	1,510	1,337
Total employee costs	21,595	19,746	18,339

1. This reflects annual gross employee costs included in property, plant and equipment, which subsequently will be included in depreciation of tangible fixed assets.

Average number of full-time employees	33,061	31,499	29,423
Year-end number of full-time employees	34,286	32,136	30,014

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

DKK million	2012	2011	2010
	07	05	
Salary and cash based incentive Pension	37 9	35 9	32 8
Other benefits	1	1	1
Executive Management in total1	47	45	41
Fee to Board of Directors <sup>2</sup>	9	9	7

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 on remuneration to the Board of Directors, Executive Management and other members of Senior Management Board.

2. Excluding social security taxes paid amounting to less than DKK 1 million (less than DKK 1 million in 2011).

## 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. Tax is recognised in the income statement, except to the extent that it relates to items recognised in other comprehensive income.

#### Income taxes expensed

DKK million	2012	2011	2010
Current tax on profit for the year Deferred tax on profit for the year	6,001 645	4,534 257	3,477 495
Tax on profit for the year Adjustments related to previous years	6,646	4,791	3,972
current tax Adjustments related to previous years	4,042	277	504
deferred tax	(4,309)	(240)	(593)
Income taxes in the			

Income statement	6,379	4,828	3,883
Computation of effective tax rate:			
Statutory corporate income tax rate			
in Denmark	25.0%	25.0%	25.0%
Deviation in foreign subsidiaries			
tax rates compared with the Danish	(0.40())	(0,00())	
tax rate (net) Non-taxable income less non-tax-	(2.1%)	(3.0%)	(2.5%)
deductible expenses (net)	0.1%	(0.2%)	(1.2%)
Other	(0.1%)	0.2%	(0.1%)
Effective tax rate	22.9%	22.0%	21.2%
Tax on other comprehensive income			
for the year, (income)/expense	587	(190)	(346)

Tax on other comprehensive income for the year relates to tax on deferred (gains)/losses on cash flow hedges and internal profit. In addition DKK 12 million has been recognised as current tax in other comprehensive income in 2012.

# Income taxes paid

Income taxes paid in Denmark	7,895	2,825	1,826
Income taxes paid outside Denmark	2,996	2,566	1,610
Total income taxes paid	10,891	5,391	3,436

The income taxes of DKK 7,895 million paid in Denmark in 2012 include adjustments arising from tax disputes primarily related to transfer pricing.

#### 2.4 Income and deferred income taxes (continued)

#### **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. Unremitted earnings are generally retained by subsidiaries for reinvestment, hence no provision is made for income taxes that would be payable upon the distribution of such earnings unless a concrete distribution of earnings is planned.

### Key accounting estimate deferred income tax assets and liabilities

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.

### Development in deferred income tax assets and liabilities

DKK million	2012	2011
At the beginning of the year	(792)	(1,018)
Reclassification from Other liabilities (note 3.8)	(739)	
Deferred tax on profit for the year	(645)	(257)
Adjustment relating to previous years	4,309	240
Deferred tax on items recognised in Other comprehensive income	(575)	190
Exchange rate adjustments	(46)	53
Total deferred tax assets/(liabilities), net	1,512	(792)

DKK million	Property, plant and equipment	Intangible assets	Inventories	Tax-loss carry- forward	Other	Offset within countries	Total
<b>2012</b> Net deferred tax asset/(liability) at 1 January	(1,060)	244	1,599	87	(1,662)		(792)
Reclassification from Other liabilities	66	(106)	(185)	(17)	(739) 3,906		(739) 3,664

Income/(charge) to the Income statement							
Income/(charge) to Other comprehensive income			(78)		(497)		(575)
Exchange rate adjustment	(3)	(5)		(4)	(34)		(46)
Net deferred tax asset/(liability) at 31 December	(997)	133	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)
2011							
Net deferred tax asset/(liability) at 1 January	(1,279)	545	1,431	113	(1,828)		(1,018)
Income/(charge) to the Income statement	227	(316)	127	(21)	(34)		(17)
Income/(charge) to Other comprehensive income			41		149		190
Exchange rate adjustment	(8)	15		(5)	51		53
Net deferred tax asset/(liability) at 31 December	(1,060)	244	1,599	87	(1,662)		(792)
Classified on follows:							
Classified as follows: Deferred tax asset at 31 December	173	550	2,880	87	980	(2,256)	2,414
Deferred tax disset at 31 December	(1,233)	(306)	(1,281)	07	(2,642)	2,256	(3,206)

Further to the above, the tax value of tax-loss carry-forward of DKK 208 million (DKK 221 in 2011) has not been recognised in the balance sheet due to the likelihood that the tax losses will not be realised in the future. Of the unrecognised tax-loss carry-forward, DKK 3 million expires within one year, DKK 11 million between two to five years and DKK 194 million after more than five years.

# **Section 3**

# **Operating assets and liabilities**

This section specifies 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 operates with 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 Intangible 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 calculated using the straight-line method to allocate the cost of patents and licences over their estimated useful lives. Estimated useful life is the shorter of the legal duration and the economic useful life. 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. The computer software has to be a significant business system and the expenditure must lead to the creation of a durable asset. Amortisation is calculated using the straight-line method over the estimated useful life of 3 10 years. The amortisation 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.

### Impairment of assets

Intangible assets with an indefinite useful life and intangible assets not yet available for use are not subject to amortisation and 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 or 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 flows. Impairments are reviewed at each reporting date for possible reversal.

## Intangible assets

DKK million	2012	2011
Cost at the beginning of the year	2,538	2,277
Additions during the year	198	259
Disposals during the year	(18)	(1)
Effect of exchange rate adjustment	(6)	3
Cost at the end of the year	2,712	2,538
Amortisation and impairment losses		
at the beginning of the year	1,049	819
Amortisation for the year	160	107
Impairment losses for the year	32	125
Amortisation and impairment losses reversed		
on disposals during the year	(18)	(1)
Effect of exchange rate adjustment	(6)	(1)
Amortisation and impairment losses		
at the end of the year	1,217	1,049
Carrying amount at the end of the year	1,495	1,489
Specified as:		
Patents and licenses	762	696
Internally developed software	532	518
Other intangible assets	201	275
Total	1,495	1,489

Hereof intangible assets not yet in use amount to DKK 669 million (DKK 980 million in 2011), primarily patents and licences in relation to development projects.

In 2012, an impairment loss of DKK 32 million (DKK 125 million in 2011) related to patents has been recognised due to discontinuation of development projects. Impairment tests in 2012 and 2011 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

DKK million	2012	2011	2010

Total amortisation and impairment losses	192	232	80
income, net	14	11	6
Research and development costs Licence fees and other operating	47	139	19
Sales and distribution costs	50	35	13
Cost of goods sold	81	47	42

#### 3.2 Property, plant and equipment

### Accounting policies

Property, plant and equipment is measured at historical cost less accu mulated depreciation and any impairment loss. The cost of self-constructed assets includes costs directly attributable to the construction of the assets. Subsequent cost is included in the asset s carrying amount or recognised as a separate asset, as appropriate, 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 material interest on loans is capitalised as part of the cost. Depreciation is provided under the straight-line method over the estimated useful lives of the assets as follows:

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.

Property, plant and equipment	Land and buildings	Plant and machinery	Other equipment	Payments on account and assets in course of construction	Total
0010					
2012 Cost at the beginning of the year	14 600	17,845	2 090	4,815	40.240
Cost at the beginning of the year	14,600 171	17,845	3,080 220	,	40,340
Additions during the year			-	2,845	3,372
Disposals during the year	(287)	(350)	(111)		(748)
Transfer from/(to) other items	1,020	553	192	(1,765)	(0.00)
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 disposals during the year	(263)	(315)	(91)		(669)
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
2011					
Cost at the beginning of the year	13,598	17,243	2,861	4,516	38,218
Additions during the year	312	262	293	2,206	3,073
Disposals during the year	(228)	(522)	(167)	,	(917
Transfer from/(to) other items	982	937	85	(2,004)	x ,
Effect of exchange rate adjustment	(64)	(75)	8	97	(34
Cost at the end of the year	14,600	17,845	3,080	4,815	40,340
Depreciation and impairment losses at the beginning of the year	5,048	10,806	1,857		17,711
Depreciation for the year	623	1,471	289		2,383
Impairment losses for the year	29	93			122
Depreciation and impairment losses reversed on disposals during the year	(165)	(462)	(157)		(784
Effect of exchange rate adjustment	(10)	(20)	7		(23
Depreciation and impairment losses at the end of the year	5,525	11,888	1,996		19,409
Carrying amount at the end of the year	9,075	5,957	1,084	4,815	20,931

## 3.2 Property, plant and equipment (continued)

## **Depreciation and impairment**

DKK million	2012	2011	2010
Cost of goods sold	1,909	1,833	1,790
Sales and distribution costs	46	60	47
Research and development costs	416	494	441
Administrative costs	53	58	56
Licence fees and other operating			
income, net	77	60	53
Total depreciation and			
impairment losses	2,501	2,505	2,387

## **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 (IPC). Production costs for work in progress and finished goods include IPC such as employee costs, depreciation, maintenance etc.

If the expected sales prices less completion costs to execute sales (net realisable value) are 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 is capitalised as an asset but 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 R&D 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

IPC are measured using a standard cost method, which is reviewed regularly to ensure relevant measures of utilisation, production lead time and other relevant factors. Changes in the parameters for calculation of IPC could have an impact on the gross margin and the overall valuation of inventories.

### **Inventories**

DKK million	2012	2011
Raw materials	1,512	1,432
Work in progress	4,910	5,035

Finished goods	3,985	3,781
Total inventories (gross) Inventory write-downs at year-end	10,407 864	10,248 815
Total inventories (net)	9,543	9,433
Indirect production costs included in work in progress and finished goods (net) Share of total inventories (net)	4,894 51%	5,125 54%
Movements in the inventory write-downs Inventory write-downs at the beginning of the year Inventory write-downs during the year Utilisation of inventory write-downs Reversal of inventory write-downs	815 845 (532) (264)	1,301 303 (500) (289)
Inventory write-downs at the end of the year	864	815

# 3.4 Trade receivables

### **Accounting policies**

Trade receivables are, if collection is expected within one year (or in the normal operating cycle of the business if longer), classified as Current assets. If not, they are presented as Non-current assets.

Trade receivables are recognised initially at fair value and subsequently measured at amortised cost using the effective interest method, less allowances for doubtful trade receivables.

The allowances are 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. When a trade receivable is uncollectible, it is written off against the allowance account for trade receivables. Subsequent recoveries of amounts previously written off are credited against Sales and distribution costs in the income statement.

# Key accounting estimate Allowance for doubtful trade receivables

Novo Nordisk maintains allowances 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, additional allowances 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, current economic trends and changes in customer payment terms. Please refer to note 4.3 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 allowances for doubtful trade receivables.

# 3.4 Trade receivables (continued)

# **Trade receivables**

DKK million	2012	2011
Trade receivables (gross)	10,663	10,241
Allowances at the end of the year	1,024	892
Trade receivables (net)	9,639	9,349
Trade receivables (net) are equal to an average credit period of 45 days (51 days in 2011).		
Age analysis of trade receivables		
Non-impaired trade receivables		
Not yet due	8,950	8,503
Overdue by between 1 and 179 days	629	712
Overdue by between 180 and 359 days	60	134
Overdue by more than 360 days	0	0
Trade receivables with credit risk exposure	9,639	9,349
Impaired trade receivables	1,024	892
Trade receivables (gross)	10,663	10,241
Movement in allowances for		
doubtful trade receivables		
Carrying amount at the beginning of the year	892	627
Confirmed losses	(35)	(66)
Reversal of allowances for confirmed losses	(13)	(18)
Allowances for possible losses during the year	189	361
Effect of exchange rate adjustment	(9)	(12)
Allowances at the end of the year	1,024	892

# 3.5 Other receivables and prepayments

# Accounting policies

Other receivables and prepayments are 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 are payments made to ongoing research and development activities and concerning subsequent financial years etc.

## Other receivables and prepayments

DKK million	2012	2011
Prepayments	1,033	935
Interest receivable	87	113
Amounts owed by related parties	184	88
Deposit	524	558
VAT receivable	185	122
Other receivables	692	560
Total other receivables and prepayments	2,705	2,376

## 3.6 Provisions

### 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. They are calculated on the basis of 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 interest expense.

### Key accounting estimate Provisions for sales rebates

Novo Nordisk records provisions and accruals for expected sales rebates, wholesaler charge-backs and other rebates, including Medicaid and Medicare in the US and similar rebates in other countries.

Such estimates are based on analyses of existing contractual or legal obligations, historical trends and the Group s experience. They 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 provision.

Novo Nordisk considers the provision 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

# FORM 6-K

Provisions for legal disputes consist of various types of provisions 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.

# 3.6 Provisions (continued)

Provisions						
	Provisions	Provisions	Provisions			
	for sales	for legal	for product	Other	2012	2011
DKK million	rebates	disputes <sup>1</sup>	returns	provisions <sup>2</sup>	Total	Total
At the beginning of the year	5,666	1,554	555	489	8,264	6,667
Additional provisions, including increases to existing provisions	12,912	41	263	203	13,419	10,511
Amount used during the year	(10,954)		(238)	(63)	(11,255)	(8,228)
Adjustments, including unused amounts reversed during the year	(187)	(513)		(68)	(768)	(782)
Effect of exchange rate adjustment	(85)	(25)	2	11	(97)	96
At the end of the year	7,352	1,057	582	572	9,563	8,264
Classified as follows:						
Non-current liabilities		1,057	349	501	1,907	2,324
Current liabilities	7,352		233	71	7,656	5,940

1. Please refer to note 5.4 for further information on commitments and contingencies.

2. Other provisions consist of various types of provision including employee benefits such as jubilee benefits etc.

### 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; these are primarily located in Japan, Germany, the US and Switzerland. 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 com prehensive 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.

Please refer to note 1.2 for a description of the changed accounting policy for retirement benefit obligations.

## **Retirement benefit obligations**

DKK million			2012	2011
	Pension plans	Medical benefits	Total	Total
At the beginning of the year	1,125	238	1,363	1,452
Current service costs	111	21	132	155
Interest costs	37	10	47	52
Remeasurement (gains)/losses1	188	35	223	(29)
Past service costs				(27)
Benefits paid	(75)	(5)	(80)	(75)
Curtailments <sup>2</sup>				(241)
Exchange rate adjustment	(36)	(4)	(40)	43
Other	20	(1)	19	33
At the end of the year	1,370	294	<b>1,664</b> 3	1,363 <sup>3</sup>

1. Remeasurement relates primarily to change in financial assumptions.

2. Curtailment relates to changes in defined benefit plans in Japan and the US in 2011.

3. Present value of partly funded retirement benefit obligations amounts to DKK 1,229 million (DKK 1,071 million in 2011). Present value of unfunded retirement benefit obligations amounts to DKK 435 million (DKK 292 million in 2011).

## Fair value of plan assets

2012	2011
859	766
31	28
7	(20)
93	128
(80)	(75)
(23)	20
17	12
904	859
	859 31 7 93 (80) (23) 17

# Net retirement benefit obligations at the end of the year (unfunded)<sup>1</sup>

760

1. Unrecognised remeasurements in 2011 amounted to DKK 65 million. Net retirement benefit obligation recognised in the Balance sheet in 2011 amounted to DKK 439 million.

The amount recognised in the Balance sheet is reported as non-current liabilities.

## 3.7 Retirement benefit obligations (continued)

## Net retirement benefit obligations

DKK million	2012	2011
At the beginning of the year	439	569
Costs recognised in the Income statement <sup>1</sup>	150	(25 <b>)</b>
Remeasurements recognised in		
Other comprehensive income <sup>2</sup>	281	
Exchange rate adjustment recognised in		
Other comprehensive income <sup>3</sup>	(17)	23
Employer contributions	(93)	(128)
At the end of the year	760	439

1. Costs in Income statement include service costs, net interests, curtailments and other.

2. Remeasurements charged to Other comprehensive income including effect of change in accounting policy in 2012 amounting to DKK 65 million.

3. Recognised in Other comprehensive income as part of 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

		2012		2011
	DKK million	%	DKK million	%
Coverage insurance <sup>1</sup>	607	67%	575	67%
Equities	67	7%	49	5%
Bonds	214	24%	152	18%
Cash at bank	9	1%	75	9%
Property	7	1%	8	1%
Total	904	100%	859	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

	2012	2011
Discount rate	3%	4%
Projected future remuneration increases	2%	2%
Medical cost trend rate	3%	3%
Inflation rate	2%	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.

	1%-point	1%-point	
DKK million	increase	decrease	
Discount rate	(237)	309	
Future remuneration	77	(57)	

#### 3.8 Other liabilities

#### **Other liabilities**

DKK million	2012	2011
Employee costs payable	3,748	3,369
Accruals	3,697	2,9921
VAT and duties payable	703	537
R&D clinical trials	229	211
Other payables <sup>2</sup>	605	1,425
Total other liabilities	8,982	8,534

1. Including reclassification to deferred income tax liabilities of DKK 739 million in 2012 (note 2.4).

2. Other payables primarily relates to royalty payments and deferred income.

# Section 4

# Capital structure and financing items

This section encompasses notes related to Novo Nordisk s capital structure and financing items. Further information on the company s capital structure can be found in Shares and capital structure on pp 44 45.

Novo Nordisk s guiding principle on capital structure is that excess cash flow after funding of organic growth opportunities, research and development, and potential licensing and acquisitions is returned to the company s shareholders. Novo Nordisk applies a pharmaceutical industry average payout ratio to dividend payments, complemented by share repurchase programmes. The main financial risk is foreign exchange exposure, where Novo Nordisk intends to reduce the short-term impact from the movement in key currencies by hedging future cash flows.

## 4.1 Share capital and earnings per share

#### **Share capital**

DKK million	A share capital	B share capital	Total share capital
Development in share capital: 2008 2009 2010 2011	107	527 (14) (20) (20)	634 (14) (20) (20)
At the beginning of the year 2012	107	473 (20)	580 (20)
At the end of the year	107	453	560

At the end of 2012, the share capital amounted to DKK 107 million in A share capital (equal to 107 million A shares of DKK 1) and DKK 453 million in B share capital (equal to 453 million B shares of DKK 1).

#### **Treasury shares**

#### Accounting policies

Treasury shares are deducted from the share capital at their nominal value of DKK 1 per share. Differences between this amount and the amount paid to acquire or received for disposing of, treasury shares are deducted from Retained earnings.

		2012	2011
		Number	Number
		of	of
As % of	As % of		
share	share capital after	B Shares of DKK 1	B Shares of DKK 1

	Market value DKK million	capital before cancellation	cancellation	(million)	(million)
Holding at the beginning of the year Cancellation of treasury shares	16,131 (13,200)	4.2% (3.4%		24 (20)	28 (20)
Holding of treasury shares, adjusted for cancellation Purchase during the year Sale during the year Value adjustment	2,931 12,162 (266) 1,135	0.8%	0.8% 2.6% (0.3%)	4 15 (2)	8 18 (2)
Holding at the end of the year	15,962		3.1%	17	24

The purchase of treasury shares during the year relates to the remaining part of the 2011 share repurchase programme totalling DKK 1.1 billion and the DKK 12 billion share repurchase programme of Novo Nordisk B shares for 2012 of which DKK 1 billion remains at year end. The programme ends at 29 January 2013. The purpose of the programmes is to reduce the company s share capital. Sale of treasury shares relates to exercised share options, long-term share-based incentive programme, employee share savings programmes and employee shares.

At year-end the holding of treasury shares amounts to 17,416,676 shares (24,440,186 shares in 2011). At year-end 3.5 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.

## Dividend

At the end of 2012, proposed dividends (not yet declared) of DKK 9,715 million (DKK 18.00 per share) are included in Retained earnings.

The declared dividend included in Retained earnings was DKK 7,742 million (DKK 14.00 per share) in 2011 and DKK 5,700 million (DKK 10.00 per share) in 2010. No dividend is declared on treasury shares.

#### 4.1 Share capital and earnings per share (continued)

#### **Earnings per share**

#### **Accounting policies**

Earnings per share (EPS) is presented as both basic earnings per share 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 share 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 could have been acquired at fair value with proceeds from the exercise of the share options

2) the number of shares that would have been issued assuming 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		2012	2011	2010
Net profit for the year		21,432	17,097	14,403
Average number of shares outstanding Dilutive effect of outstanding share bonus pool and options in the money 1	in 1,000 shares in 1,000 shares	548,338 3,330	565,433 4,699	580,438 5,039
Average number of shares outstanding, including dilutive effect of options in the money	in 1,000 shares	551,668	570,132	585,477
Basic earnings per share1 Diluted earnings per share1	DKK DKK	39.09 38.85	30.24 29.99	24.81 24.60

1. For further information on outstanding share bonus pool and options, refer to note 5.1.

#### 4.2 Debt

#### Accounting policies

Loans are recognised initially at fair value, net of transaction costs incurred. Loans are subsequently stated at amortised cost; any difference between the proceeds (net of transaction costs) and the redemption value is recognised in the Income statement over the period of the loans using the effective interest method. Loans are classified as Current debt unless Novo Nordisk has an unconditional right to defer settlement of the liability for at least 12 months after the end of the reporting period.

Debt

DKK million	2012	2011
Loans1 Current debt (bank overdrafts) Derivative financial instruments (note 4.4)	500 48	502 351 1,492
Total debt	548	2,345
The debt is denominated in the following currencies: DKK EUR USD JPY Other currencies	20 1 53 0 474	82 501 983 404 375
Total debt	548	2,345

1. A loan of DKK 502 million with maturity in 2022 has been repaid during 2012.

## 4.3 Financial risk

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 flows.

The majority of Novo Nordisk s sales are in EUR, USD, JPY, CNY and GBP. Consequently, Novo Nordisk s foreign exchange risk is most significant in USD, JPY, CNY and GBP, while the EUR exchange rate risk is regarded as low due to the Denmark s fixed-rate policy towards EUR.

The overall objective of foreign exchange risk management is to limit the short-term negative impact of exchange rate fluctuations on earnings and cash flow, thereby increasing the predictability of the financial results.

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 2012, the hedging horizon varied between 11 and 13 months for USD, JPY, CNY and GBP. 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.

## 4.3 Financial risk (continued)

#### **Key currencies**

Exchange rate DKK per 100	USD	JPY	CNY	GBP
2012				
Average	579	7.27	92	918
End of year	566	6.57	91	913
Year-end change	-1.6%	-11.5%	0.0%	2.6%
2011				
Average	536	6.73	83	859
End of year	575	7.42	91	890
Year-end change	2.5%	7.7%	7.1%	2.7%

The financial contracts existing at the end of the year cover the expected future cash flow for the following number of months:

	2012	2011
USD	12 months	12 months
JPY	13 months	12 months
CNY1	12 months	12 months
GBP	12 months	12 months

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

Foreign exchange sensitivity analysis:

A 5% increase/decrease in the following currencies will impact Novo Nordisk s operating profit as outlined in the table below:

DKK million	Estimated for 2013	2012
USD	975	775
JPY	200	170
CNY	110	100
GBP	85	75

A 5% increase/decrease in all other currencies versus EUR and DKK would affect the hedging instruments impact on Other comprehensive income and the Income statement as outlined in the table below:

5% increase in all	5% decrease in all
currencies against	currencies against

DKK million	DKK and EUR	DKK and EUR
<b>2012</b> Other comprehensive income	(1,313)	1,376
Income statement	(117)	106
Total	(1,430)	1,482
2011		
Other comprehensive income	(1,011)	1,026
Income statement	54	(38)
Total	(957)	988

The higher foreign exchange sensitivities in 2012, compared with 2011, are primarily a result of higher expected future cash flow.

The financial instruments included in the foreign exchange sensitivity analysis are the Group s Cash, Trade receivables and Trade payables, Current and non-current loans, Current and non-current financial investments, Foreign exchange forwards and Foreign exchange options hedging transaction exposure, Interest rate swaps and Cross-currency swaps.

Not included are anticipated currency transactions, investments and non-current assets.

#### Interest rate risk

In general, DKK and EUR interest rates declined in 2012. The Danish two-year interest rate was 0.53% at the end of 2012, down from 1.08% at the end of 2011. The three-month Cibor interest rate was 0.28% at the end of 2012, down from 1.00% at the end of 2011.

Changes in interest rates affect Novo Nordisk s financial instruments. At the end of 2012, a 1 percentage point increase in the interest rate level would, all else being equal, result in a decrease in the fair value of Novo Nordisk s financial instruments of DKK 20 million (a decrease in the fair value of DKK 17 million in 2011).

The financial instruments included in the sensitivity analysis consist of marketable securities, deposits, current and non-current loans, interest rate swaps and cross-currency swaps. Not included are foreign exchange forwards and foreign exchange options due to the limited effect that a parallel shift in interest rates in all currencies has on these instruments.

#### Liquidity risk

Novo Nordisk ensures availability of required liquidity through a combination of cash management, highly liquid investment portfolios and uncommitted as well as committed facilities. Novo Nordisk uses cash pools for optimisation and centralisation of cash management. For non-cash pool affiliates, surplus cash above the balance required for working capital management is deposited centrally.

#### **Credit risk**

Credit risk arises from the possibility that counterparties to transactions may default on their obligations, causing financial losses for the Group. Novo Nordisk considers its maximum credit risk on financial assets to be DKK 17,036 million (2011: DKK 17,550 million). In addition, Novo Nordisk considers its maximum credit risk on Trade receivables, Other receivables less prepayments and Other financial assets to be DKK 11,539 million (2011: DKK 11,024 million). Please refer to note 4.7 for details of the Group s total financial assets.

To manage credit risk on financial counterparties, Novo Nordisk only enters into derivative financial contracts and money market deposits with financial counterparties possessing a satisfactory long-term credit rating from both Standard and Poor s and Moody s. Furthermore, maximum credit lines defined for each counterparty diversify the overall counterparty risk. The credit risk on bonds is limited as investments are made in highly liquid bonds with solid credit ratings. The table below shows Novo Nordisk s credit

## exposure on cash, fixed-income marketable securities and financial derivatives.

Credit exposure on Cash at bank or on hand, Marketable securities and Derivative financial instruments (market value)

DKK million	Cash at bank or on hand	Marketable securities	Derivative financial instruments	Total
2012		4,544		4 5 4 4
AAA-range	6,930	4,544	466	4,544 7,396
AA-range A-range	4,011		180	4,191
BBB-range	4,011		285	4,191 754
Not rated or	409		203	7.54
below BBB-range	143	8		151
Total	11,553	4,552	931	17,036
2011				
AAA-range		4,083		4,083
AA-range	6,223		16	6,239
A-range BBB-range Not rated or	7,156		32	7,188
below BBB-range	29	11		40
Total	13,408	4,094	48	17,550

#### 4.3 Financial risk (continued)

Credit risk on Trade receivables and Other receivables and prepayments is less material as Novo Nordisk has no significant concentration of credit risk, with exposure being spread over a large number of counterparties and customers. However, due to the troubled economic climate in the Eurozone, the Group continues to focus on the development in the outstanding trade receivables from this region. Novo Nordisk also continues to monitor the credit exposure in Region International Operations due to the increasing sales and low credit ratings of many countries in this region.

Please refer to note 2.2 for split of allowance for trade receivables by geographical segment.

#### **Capital structure**

Novo Nordisk s capital structure is characterised by a substantial equity ratio. This is in line with the general capital structure of the pharmaceutical industry and reflects the inherent long-term investment horizons in an industry with typically more than 10 years development time for pharmaceutical products. Novo Nordisk s equity ratio, calculated as equity to total liabilities, was 61.9% at the end of the year (57.9% at the end of 2011).

#### 4.4 Derivative financial instruments

#### **Accounting policies**

The derivative financial instruments are used to manage the exposure to market risk. None of the derivatives are held for trading. However, not all derivatives are designated for hedge accounting.

Novo Nordisk uses forward exchange contracts and currency options to hedge forecast transactions and assets and liabilities. Currently, net investments in foreign subsidiaries are not hedged.

Upon initiation of the contract, Novo Nordisk designates each derivative financial contract that qualifies for hedge accounting as one of:

- hedges of the fair value of a recognised asset or liability or a firm commitment (fair value hedge)
- hedges of the fair value of a forecast financial transaction (cash flow hedge)
- hedges of a net investment in a foreign operation (net investment hedge).

All contracts are initially recognised at fair value and subsequently remeasured at their fair values based on current bid prices at the end of the reporting period.

Forward exchange contracts recognised as hedging assets or liabilities in foreign currencies are measured at fair value at the end of the reporting period. Value adjustments are recognised in the Income statement along with any value adjustments of the hedged asset or liability that is attributable to the hedged risk.

The value adjustments on forward exchange contracts designated as hedges of forecast transactions are recognised directly in Other comprehensive income, given hedge effectiveness. The cumulative value adjustment of these contracts is transferred from Other compre hensive income to the Income statement as a reclassification adjustment under Financial income or Financial expenses when the hedged transaction is recognised in the Income statement.

Currency swaps used to hedge net investments in subsidiaries are measured at fair value based on the difference between the swap exchange rate and the exchange rate at the end of the reporting period. The value adjustment is recognised in Other comprehensive income.

Furthermore, Novo Nordisk uses currency option hedges of forecast transactions. Currency options are initially recognised at cost, which equals fair value of considerations paid, and subsequently remeasured at their fair values at the end of the reporting period. The cumulative value adjustment of the currency options for which hedge accounting is applied, which is the intrinsic value of the options, is transferred from Other comprehensive income to the Income statement as a reclassification adjustment under Financial income or Financial expenses when the hedged transaction is recognised in the Income statement. Gains and losses on currency options that do not meet the criteria for hedge accounting are recognised directly in the Income statement under Financial income or Financial expenses.

The fair value of financial assets and liabilities is measured on the basis of quoted market prices of financial instruments traded in active markets. If an active market exists, fair value is based on the most recently observed market price at the end of the reporting period.

If a financial instrument is quoted in a market that is not active, Novo Nordisk bases its valuation on the most recent transaction price. Adjustment is made for subsequent changes in market conditions, for instance by including transactions in similar financial instruments that are assumed to be motivated by normal business considerations.

If an active market does not exist, the fair value of standard and simple financial instruments, such as foreign exchange forward contracts, interest rate swaps, currency swaps and unlisted bonds, is measured according to generally accepted valuation techniques. Market-based parameters are used to measure fair value.

When a hedging instrument expires or is sold, or when a hedge no longer meets the criteria for hedge accounting, any cumulative gain or loss existing in equity at that time remains in equity and is recognised when the forecast transaction is ultimately recognised in the Income statement. When a forecast transaction is no longer expected to occur, the cumulative gain or loss that was reported in equity is immediately transferred to the Income statement under Financial income or Financial expenses.

## 4.4 Derivative financial instruments (continued)

Hedging activities	2012			2011		
	Contract amount at	Positive fair value at	Negative fair value at	Contract amount at	Positive fair value at	Negative fair value at
DKK million	year-end	year-end	year-end	year-end	year-end	year-end
Forward contracts, cash flow hedges	25,639	732		18,906		1,256
Currency options, cash flow hedges	2,755	134		4,805	116	
Forward contracts, fair value hedges	2,521	95	48	2,534		176
Cross-currency swaps, net investment hedges1				166		56
Total currency-related instruments	30,915	961	48	26,411	116	1,488
Interest rate swaps, cash flow hedges				250		4
Total interest-related instruments				250		4
Total hedging activities	30,915	961	48	26,661	116	1,492
Total derivatives included in:						
Derivative financial instruments (current assets)		931			48	
Derivative financial instruments (current liabilities)			48			1,492
Equity, Other reserves		30			68	

1. No net investment hedge exist at year-end 2012. In 2011, the financial contract existing at the end of the year hedged 13% of the net investments in JPY.

## Presentation in the Income statement and Other comprehensive income

	2012		2011	
DKK million	Positive fair value at year-end	Negative fair value at year-end	Positive fair value at year-end	Negative fair value at year-end
Cash flow hedges for which hedge accounting is not applied	19		48	8

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Fair value hedges	95	48		176
Total fair value adjustments through the Income statement	114	48	48	184
Cash flow hedges for which hedge accounting is applied Net investment hedges (included in exchange rate adjustment)	847		68	1,252 56
Total fair value adjustments through Other comprehensive income	847		68	1,308
Total fair value adjustments	961	48	116	1,492
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## 4.4 Derivative financial instruments (continued)

## Hedging of forecast transactions (cash flow hedge)

		2012		2011			
DKK million	Contract amount at year-end	Positive fair value at year-end	Negative fair value at year-end	Contract amount at year-end	Positive fair value at year-end	Negative fair value at year-end	
Hedging of forecast transactions qualifying for hedge accounting USD JPY, GBP and other currencies	19,939 5,700	409 323		14,250 4,656		896 360	
Total forward contracts (forecasted cash flow)	25,639	732		18,906		1,256	
USD JPY	2,402 353	72 43		4,007 798	66 2		
Total currency options (forecasted cash flow)	2,755	115		4,805	68		
Total interest rate swaps (variable payments on debt instruments) EUR /EUR				250		(4)	
Total cash flow hedges for which hedge accounting is applied	28,394	847		23,961	68	1,252	
Other forecast transaction hedges for which hedge accounting is not applied Currency options and interest rate swaps for which hedge accounting is not applied		19			48	8	
Total contracts of forecast transactions	28,394	866		23,961	116	1,260	

## Hedging of assets and liabilities (fair value hedge)

2012			2011			
Contract	Positive	Negative	Contract	Positive	Negative	

DKK million	amount at year-end	fair value at year-end	fair value at year-end	amount at year-end	fair value at year-end	fair value at year-end
USD JPY GBP Other	698 444 365 1,014	95	30 18	478 731 376 949		81 72 7 16
Total forward contracts	2,521	95	48	2,534		176

The table above shows the fair value of fair value-hedging activities for 2012 and 2011 specified by hedging instrument and the major currencies. All changes in fair values are recognised in the Income statement, amounting to a net gain of DKK 47 million in 2012 (a net loss of DKK 176 million in 2011). As the hedges are highly effective, the net gain or loss on the hedged items is similar to the net loss or gain on the hedging instruments.

The financial contracts existing at the end of the year hedge the currency exposure on assets and liabilities in the Group s major currencies other than DKK and EUR, ie primarily assets and liabilities in USD, JPY and GBP. Other comprises AUD at DKK 475 million (DKK 399 million in 2011), CAD at DKK 138 million (DKK 170 million in 2011) and PLN at DKK 401 million (DKK 380 million in 2011).

#### 4.5 Cash and cash equivalents

#### **Accounting policies**

Cash and cash equivalents consist of cash and marketable securities with original maturity of less than three months offset by short-term bank loans. Financial resources consist of cash and cash equivalents, bonds with original term to maturity exceeding three months and undrawn committed credit facilities expiring after more than one year.

## Cash and cash equivalents

DKK million	2012	2011	2010
Cash at bank and on hand (note 4.3) Bank overdrafts (note 4.2)	11,553 (500)	13,408 (351)	12,017 (57)
Cash and cash equivalents at the end of the year	11,053	13,057	11,960

#### 4.6 Change in working capital

#### Accounting policies

Working capital is defined as current assets less current liabilities.

It measures how much in liquid assets Novo Nordisk has available for the business.

## Change in working capital

DKK million	2012	2011	2010
Trade receivables	(290)	(849)	(1,437)
Other receivables and prepayments Inventories Trade payables	(329) (110) 568	27 256 385	(441) 327 664
Other liabilities Exchange rate adjustments	448 (13)	580 35	1,141 43
Total change in working capital	274	434	297

#### 4.7 Financial assets and liabilities

#### **Accounting policies**

Novo Nordisk classifies its investments in the following categories:

#### Available-for-sale financial assets

## Loans and receivables

Financial assets at fair value through the Income statement (derivatives).

The classification depends on the purpose for which the investments were made. Management determines the classification of its investments on initial recognition and re-evaluates this at the end of every reporting period to the extent that such a classification is permitted and required.

## Recognition and measurement

Purchases and sales of investments are recognised on the settlement date. Investments are initially recognised at fair value.

Available-for-sale financial assets and financial assets at fair value are subsequently carried at fair value. Loans and receivables are carried at amortised cost using the effective interest method.

Fair value disclosures are made separately for each class of financial instruments at the end of the reporting period.

## Derecognition

Investments are derecognised when the rights to receive cash flows from the investments have expired or have been transferred, and Novo Nordisk has transferred substantially all risks and rewards of ownership.

## Available-for-sale financial assets

Available-for-sale financial assets consist of equity investments and marketable securities and are included in Other financial assets unless Management intends to dispose of the investment within 12 months of the end of the reporting period. If that is the case, the current part is included in Other receivables and prepayments.

Unrealised gains and losses arising from changes in the fair value of financial assets classified as available for sale are recognised in Other comprehensive income. When financial assets classified as available for sale are sold or impaired, the accumulated fair value adjustments are included in the Income statement.

The fair values of quoted investments (including bonds) are based on current bid prices at the end of the reporting period. Financial assets for which no active market exists are carried at fair value based on a valuation methodology or at cost if no reliable valuation model can be applied.

#### Loans and receivables

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. If collection is expected within one year (or in the normal operating cycle of the business if longer), they are classified as Current assets. If not, they are presented as Non-current assets.

Trade receivables and Other receivables are recognised initially at fair value and subsequently measured at amortised cost using the effective interest method, less provision for allowances. Provision for allowances is made for trade receivables when there is objective evidence that Novo Nordisk will not be able to collect all amounts due according to the original terms of the receivables.

The provision for allowances 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. When a trade receivable is uncollectible, it is written off against the allowance account for trade receivables. Subsequent recoveries of amounts previously written off are credited against Sales and distribution costs in the Income statement.

## 4.7 Financial assets and liabilities (continued)

Total financial assets at the end of the year by category	4,699	931	11,392	11,553	28,575
Cash at bank and on hand (note 4.5)				11,553	11,553
Derivative financial instruments (note 4.4)	-	931			931
Marketable securities (bonds) (note 4.3)1	4,552		(1,200)		4,552
less prepayments (note 3.5)			(1,033)		(1,033)
Trade receivables (note 3.4) Other receivables (note 3.5)			9,639 2,705		9,639 2,705
Other financial assets	147		81		228
2012					
DKK million	fair value	statement	receivables	equivalents	Total
	assets at	Income	and	and cash	
	financial	through the	Loans	Cash	
	for-sale	fair value			
	Available-	measured at			
		assets			
Financial assets and liabilities		Financial			

	Financial liabilities		Financial liabilities	
	measured at	Financial	measured at	
	fair value	liabilities	fair value	
	through the	measured at	through Other	
	Income	amortised	comprehensive	
DKK million	statement	cost	income	Total
Current debt (note 4.2)		500		500
Trade payables		3,859		3,859
Other liabilities (note 3.8)		8,982		8,982
less VAT and duties payable (note 3.8)		(703)		(703)
Derivative financial instruments (note 4.4)	48	. ,		48
Total financial liabilities at the end of the year by category	48	12,638		12,686

	Available-	measured at				
	for-sale	fair value				
	financial	through the	Loans	C	ash	
DKK million	assets at fair value	Income statement	and receivables	and c equivale		Total
2011						
Other financial assets	230		43			273
Trade receivables (note 3.4)			9,349			9,349
Other receivables (note 3.5) less prepayments (note 3.5)			2,376 (935)			2,376 (935)
Marketable securities (bonds) (note 4.3)1	4,094		(333)			4,094
Derivative financial instruments (note 4.4)	.,	48				48
Cash at bank and on hand (note 4.5)				13,4	408	13,408
Total financial assets at the end of the year by category	4,324	48	10,833	13,4	408 2	28,613
	Financia	I	Fina	ancial		
	liabilities	6	liab	ilities		
	measurec a	Financia	l measur	ed at		
	fair value	e liabilities	s fair v	value		
	through the		through (	Other		
	Income	e amortised	l comprehe	nsive		
DKK million	statemen	t cos	t ind	come	Total	
		_				
Loans (note 4.2)		502			502	
Current debt (note 4.2)		351			351	
Trade payables		3,291			3,291	
Other liabilities (note 3.8)		8,534			8,534	
less VAT and duties payable (note 3.8)		(537	,		(537)	
Derivative financial instruments (note 4.4)	184	Ļ	-	,308	1,492	

 Including Danish AAA-rated mortgage bonds issued by Danish credit institutions governed by the Danish Financial Supervisory Authority of DKK 4,544 million (DKK 4,083 million in 2011); refer to note 4.3. Redemption yield on the bond portfolio is 0.73%.
 For a description of the credit quality of financial assets such as Trade receivables, Cash at bank and on hand, Marketable securities, Current debt and Derivative financial instruments, refer to notes 4.3 and 4.4.

## 4.7 Financial assets and liabilities (continued)

## Maturity analysis

maturity analysis					
	Equity	Maturity	Maturity > 1 year	Maturity	
DKK million	investments	s < 1 year	< 5 years	> 5 years	Total
2012					
Other financial assets	147	,		81	228
Trade receivables (note 3.4)	147	9,639		01	9,639
Other receivables (note 3.5)		2,705			2,705
less prepayments (note 3.5)		(1,033)			(1,033)
Marketable securities (bonds) (note 4.3)		3,318	1,234		4,552
Derivative financial instruments (note 4.4)		845	86		931
Cash at bank and on hand (note 4.5)		11,553			11,553
Total assets at the end of the year by maturity	147	27,027	1,320	81	28,575
Current debt (note 4.2)		500			500
Trade payables		3,859			3,859
Other liabilities (note 3.8)		8,982			8,982
- less VAT and duties payable (note 3.8)		(703) 48			(703) 48
Derivative financial instruments (note 4.4)		40			40
Total liabilities at the end of the year by maturity		12,686			12,686
2011					
Other financial assets	230			43	273
Trade receivables (note 3.4)		9,349			9,349
Other receivables (note 3.5)		2,376			2,376
less prepayments (note 3.5) Marketable securities (bonds) (note 4.3)		(935) 2,311	1,783		(935) 4,094
Derivative financial instruments (note 4.4)		48	1,700		48
Cash at bank and on hand (note 4.5)		13,408			13,408
Total assets at the end of the year by maturity	230	26,557	1,783	43	28,613
Loope (pote 4.9)			106	206	502
Loans (note 4.2) Current debt (note 4.2)		351	196	306	502 351
Trade payables		3,291			3,291
Other liabilities (note 3.8)		8,534			8,534
less VAT and duties payable (note 3.8)		(537)	00		(537)
Derivative financial instruments (note 4.4)		1,400	92		1,492

Total liabilities at the end of the year by maturity	13,039	288	306	13,633

## Fair value measurement hierarchy

		Directly or		
	Active	indirectly	Not based on	
	market	observable	observable	
DKK million	data	market data	market data	Total
2012				
Total financial assets at fair value	4,625	931	74	5,630
Total financial liabilities at fair value		48		48
2011				
Total financial assets at fair value	4,153	48	1712	4,372
Total financial liabilities at fair value		1,492		1,492

2. Including reclassification of DKK 39 million regarding investment in associated company.

Financial assets and liabilities measured at fair value can be categorised using the fair value measurement hierarchy above. There have not been any transfers between the categories Active market data and Directly or indirectly observable market data during 2012 or 2011.

#### 4.8 Financial income and expenses

#### Accounting policies

The activity of the financial assets and liabilities and borrowings generates the financial income and expenses in Novo Nordisk. For 2012, Share of profit or loss of associated companies has been reclassified as part of financial income, disclosed as Income from other financial assets. The net financials in the Income statement are mainly related to foreign exchange elements and can be specified as follows:

#### **Financial income**

DKK million	2012	2011	2010
Interest income Foreign exchange gain (net) Foreign exchange gain on	124	274	235 86
derivatives (net) Income from other financial assets	1	240	61 1,070
Total financial income	125	514	1,452
Financial expenses			
DKK million	2012	2011	2010
Interest expenses	58	275	500
Foreign exchange loss (net) Forward contracts loss (net)1	161 39	256 1,276	2,049
Loss on currency options (net)	147	200	82
Loss on investments etc.	118	27	23
Other financial expenses	83	99	46
	00		
Cash flow hedge transferred from other comprehensive income (net)1	1,182	(1,170)	(643)

Comparative figures for 2011 and 2010 have been adjusted to align with the 2012 presentation. Total financial expenses are unchanged 1. for 2011 and 2010.

# Section 5

# **Other disclosures**

This section includes other statutory notes or notes that are of secondary importance for understanding the financial performance of Novo Nordisk. A list of subsidiaries in the Novo Nordisk Group is also included here.

## 5.1 Share-based payment schemes

## Accounting policies

#### Share-based compensation

Novo Nordisk operates equity-settled, share-based compensation plans. The fair value of the employee services received in exchange for the grant of the options or shares is recognised as an expense and allocated over the vesting period.

The total amount to be expensed over the vesting period is determined by reference to the fair value of the options or shares granted, excluding the impact of any non-market vesting conditions. The fair value is fixed at the grant date. Non-market vesting conditions are included in assumptions about the number of options or shares that are expected to vest. At the end of each reporting period, Novo Nordisk revises its estimates of the number of options or shares that are expected to vest. Novo Nordisk recognises the impact of the revision of the original estimates, if any, in the Income statement and in a corresponding adjustment to Equity (change in proceeds) over the remaining vesting period. Adjustments relating to prior years are included in the Income statement in the year of adjustment.

#### Share-based payment

DKK million	2012	2011	2010
Employee shares	50	96	241
Long-term share-based incentive programme (Senior Management Board) Long-term share-based incentive programme and share options	73	57	64
(Management group below Senior Management Board)1	185	166	158
Share-based payment expensed in the Income statement	308	319	463

1. Includes long-term share-based incentive programme for 2007 2012.

#### **Employee shares**

In 2010, a general employee share programme was implemented in Denmark with exercise in the same year. Outside Denmark the programme was structured as share options with the same initial benefit per employee as in Denmark. The cost of the programme outside Denmark is amortised over the period 2010 2013.

#### Long-term share-based incentive programme

For a description of the programme, please refer to Remuneration in Governance, leadership and shares , pp 49 51.

On 30 January 2013, the Board of Directors approved the establishment, for members of the Senior Management Board, of a joint pool for the financial year 2012 by allocating a total of 97,381 Novo Nordisk B shares. This allocation amounts on average to eight months fixed base salary plus pension contribution per participant, corresponding to a value at launch of the programme of DKK 73 million. This amount was expensed in 2012. The share price used for the conversion was the average share price (DKK 751) for Novo Nordisk B shares on NASDAQ OMX Copenhagen in the period 2 16 February 2012. Based on the split of participants when the joint pool was established, approximately 30% of the pool will be allocated to members of Executive Management and 70% to other members of the Senior Management Board.

The shares allocated to the joint pool for 2009 (177,066 shares), corresponding to a value at launch of the programme of DKK 54 million expensed in 2009, were released to the individual participants subsequent to the approval of the Annual Report 2012 by the Board of Directors and after the announcement of the 2012 full-year financial results on 31 January 2013.

For the management group below the Senior Management Board, a share-based incentive programme with similar performance criteria was introduced in 2007.

The shares allocated to the joint pool for 2009 (605,218 shares), corresponding to a value at launch of the programme of DKK 186 million amortised over the period 2009 2012, were released to the individual participants subsequent to the approval of the Annual Report 2012 by the Board of Directors and after the announcement of the 2012 full-year financial results on 31 January 2013. The number of shares to be transferred (541,321) is lower than the original number of shares allocated to the share pool as some participants had left the company before the release conditions of the programme were met.

The total number of shares in the joint pools relating to the years 2010, 2011 and 2012 is as follows:

2014 2015 2016
2014 2015 2016

#### 5.1 Share-based payment schemes (continued)

#### Share options

Each option gives the right to purchase one Novo Nordisk B share. All share options are hedged by treasury shares. No ordinary share options have been granted since 2006 as the long-term incentive programme from 2007 onwards has been share-based.

The options are exercisable three years after the issue date and will expire after eight years. The exercise price for options granted based on performance targets for the financial years 2000 2006 was equal to the market price of the Novo Nordisk B share at the time the plan was established. The options can only be settled in shares.

The internal rules for trading in Novo Nordisk securities by board members, executives and certain employees only permit trading in the 15-calendar-day period following each quarterly announcement.

#### Assumptions

The fair value of the Novo Nordisk B share options has been calculated using the Black-Scholes option-pricing model.

The expected volatility is calculated as one-year historical volatility (average of daily volatilities).

The assumptions used are shown in the table below:

	2012	2011	2010
Expected life of the option in years			
(average)	1	2	4
Expected volatility	21%	23%	21%
Expected dividend per share (in DKK) Risk-free interest rate	18.00	14.00	10.00
(based on Danish government bonds) Novo Nordisk B share price	0.00%	0.20%	2.00%
at the end of the year (in DKK)	916.50	660	629

		Average exercise price	Calculated fair value
Outstanding share options in Novo Nordisk	Share options	per option DKK	per option1 DKK
Outstanding at the end of 2010	3,436,894	110	498
Exercised in 2011 ordinary share option plans	(624,760)	74	

Exercised in 2011 employee share options Cancelled in 2011	(506,300) (126,500)		
Outstanding at the end of 2011	2,179,334	153	504
Exercised in 2012 ordinary share option plans Exercised in 2012 employee share options Cancelled in 2012 Employee share options NNIT	(835,094) (1,150) (63,750) 7,060	142	
Outstanding at the end of 2012	1,286,400	130	760

1. The fair value has been calculated using the Black-Scholes model with the parameters existing at year-end of the respective year.

## Management s share options

Total	101,325	44,650	56,675	41
Executive Management Other members of the Senior Management Board	101,325	44,650	56,675	41
Share options in Novo Nordisk	At the beginning of the year	Exercised during the year	At the end of the year	Fair value2 DKK million
	At the	Exercised		

2. The fair value has been calculated using the Black-Scholes model with the parameters existing at year-end of the respective year.

## 5.1 Share-based payment schemes (continued)

Exercisable and outstanding share options in Novo Nordisk	Issued share options	Exercised share options	Cancelled	Outstanding/ exercisable share options	Exercise price DKK	Exercise period
2004 Ordinary share option plan	1,618,832	(1,430,166)	(118,000)	70,666	134	31/1/08 30/1/13
2005 Ordinary share option plan	1,640,468	(1,178,875)	(159,368)	302,225	153	31/1/09 30/1/14
2006 Ordinary share option plan	2,229,084	(1,406,782)	(187,053)	635,249	175	31/1/10 30/1/15
Exercisable at the end of 2012	5,488,384	(4,015,823)	(464,421)	1,008,140		
2010 Employee share options Employee share options NNIT	273,000 7,060	(1,800)		271,200 7,060	0 0	1/12/13 1/12/14
Outstanding at the end of 20123	5,768,444	(4,017,623)	(464,421)	1,286,400		

3. All share options will vest if there is a change of control of Novo Nordisk A/S.

Average market price of Novo Nordisk B shares per trading period in 2012	Average market price DKK	Exercised share options
2 February 16 February	751	425,594
27 April 11 May	830	81,200
9 August 23 August	944	174,175
31 October 14 November	909	155,275
Total exercised options		836,244

## 5.2 Management s holdings of Novo Nordisk shares

The internal rules for trading in Novo Nordisk securities by board members, executives and certain employees only permit trading in the 15-calendar-day period following each quarterly announcement.

	At the beginning of the year	Additions during the year	Sold/transferred during the year	At the end of the year	Market value1 DKK million
Sten Scheibye Göran Ando Bruno Angelici Henrik Gürtler	800 1,600 500	500		800 2,100 500	0.7 1.9 0.5

Liz Hewitt		400		400	0.4
Ulrik Hjulmand-Lassen	1,057	24		1,081	1.0
Thomas Paul Koestler	1,600			1,600	1.5
Anne Marie Kverneland	2,475	24	(54)	2,445	2.2
Kurt Anker Nielsen	81,704		(3,300)	78,404	71.8
Søren Thuesen Pedersen	324	24	(25)	323	0.3
Hannu Ryöppönen	2,250			2,250	2.1
Stig Strøbæk	390			390	0.4
Board of Directors in total	92,700	972	(3,379)	90,293	82.8