### 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 9, 2009** 

### **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 [ ]

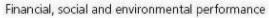
Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes [] No [X]

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

Sanofi Exhibit 2136.001 Mylan v. Sanofi IPR2018-01676









Sanofi Exhibit 2136.002 Mylan v. Sanofi IPR2018-01676



Sanofi Exhibit 2136.003 Mylan v. Sanofi IPR2018-01676

### Performance highlights 2008

		2008	2007	Change
Financial performance				
Sales total	DKK million	45,553	41,831	9%
Diabetes care	DKK million	33,356	30,478	9%
Of which modern insulins	DKK million	17,317	14,008	24%
Biopharmaceuticals	DKK million	12,197	11,353	7%
Gross profit	DKK million	35,444	32,038	11%
Gross margin	%	77.8	76.6	
Sales and distribution costs	% of sales	28.2	29.6	
Research and development costs	% of sales	17.2	20.4	
Research and development costs excl $AERx^{(e)} *$	% of sales	16.5	17.2	
Administration expenses	% of sales	5.8	6.0	
Operating profit	DKK million	12,373	8,942	38%
Operating profit excl AERx <sup>® *)</sup>	DKK million	12,698	10,267	24%
Net profit	DKK million	9,645	8,522	13%
Effective tax rate	%	24.0	22.3	
Capital expenditure	DKK million	1,754	2,268	(23%)
Free cash flow	DKK million	11,015	9,012	22%
Long-term financial targets				
Operating profit growth	%	38.4	(1.9)	
Operating profit growth excl AERx <sup>®</sup> *)	%	23.7	12.6	

Operating margin	%	27.2	21.4	
Operating margin excl AERx <sup>® *)</sup>	%	27.9	24.5	
Return on invested capital (ROIC)	%	37.4	27.2	
Cash to earnings (three-year average)	%	97.6	87.0	

### Non-financial performance

Employment impact worldwide	Number of jobs	88,500	81,600	8%
Water consumption	1,000m <sup>3</sup>	2,684	3,231	(17%)
Recycling percentage (waste)	%	51	38	
CO2 emissions	1,000 tons	215	236	(9%)
Employees	FTE	26,575	25,516	4%
Employee turnover rate	%	12.1	11.6	
Engaging culture (employee engagement)	Scale 1–5	4.2	4.1	
New patent families (first filing)	Number	71	116	(39%)

Dividend per share (proposed)	DKK	6.00	4.50	33%
Closing share price (B shares)	DKK	271	335	(19%)
Market capitalisation (B shares) **)	DKK billion	135	172	(22%)

\*\*) Excluding non-recurring costs related to discontinuation of all pulmonary diabetes projects.

\*\*) Novo Nordisk B shares (excluding treasury shares).
 See more financial and non-financial highlights on pp 16–17.

### About Novo Nordisk's annual reporting

Novo Nordisk is the world leader in diabetes care and has leading positions within haemostasis management, growth hormone therapy and hormone replacement therapy. The company also has an ambition to build a strong platform within inflammation.

With over 27,000 employees in 81 countries, Novo Nordisk manufactures and markets pharmaceutical products and services that make a significant difference to patients, the medical profession and society.

This is the fifth consecutive year of reporting on the company's financial and non-financial performance in one inclusive document, the *Annual Report*, covering the fiscal year 2008. The report discusses key challenges and strategic initiatives to develop the business in order to meet targets and sustain long-term value creation. It also explains Novo Nordisk's way of doing business as a values-based company guided by a vision.

The feature articles present company-driven activities in pursuit of the Novo Nordisk Vision and respond to concerns identified through interactions with shareholders, financial analysts and other stakeholders during the year.

External opinion leaders have been invited to contribute their perspectives on some of the key issues: the current economic climate, challenges in the healthcare industry and marketplace, new treatment paradigms for diabetes care and the interrelationship of the global climate change and a healthy future.

Designed to meet the information needs of shareholders, financial analysts and other corporate stakeholders, the report seeks to support business performance and enhance shareholder value by exploring the interactions between financial and non-financial objectives.

Novo Nordisk is in compliance with applicable corporate governance codes and follows current international standards for mandatory and voluntary reporting:

- International Financial Reporting Standards (IFRS).
- · AA1000 Assurance Standard (2003).
- US Sarbanes–Oxley Act requirements for documenting and reporting on the effectiveness of

internal controls for financial reporting. Novo Nordisk embarked in 2008 on a process of structuring the control environment for non-financial data with the aspiration to have full alignment with the control environment for financial data.

- The accountability standard, the AA1000 Framework.
- Global Reporting Initiative (GRI) G3 Sustainability Reporting Guidelines.
- UN Global Compact, Communication on Progress.

In the absence of global standards for inclusive reporting, the *Annual Report* is prepared in respect of current best practice for financial and non-financial reporting, respectively. This includes applying the principles of materiality, completeness and responsiveness.

Novo Nordisk has chosen to apply the term 'non-financial reporting' to performance on sustainability-driven issues. Hence, the *Annual Report* includes both financial statements and non-financial statements, while the narrative parts of the report present the company's performance from an inclusive perspective.

The accuracy, completeness and reliability of the company's reporting is verified through internal controls, assurance and independent audits.

The Annual Report 2008 includes the financial statements of the parent company, Novo Nordisk A/S (see pp 105–112), and is issued in February 2009 for approval by shareholders at the Annual General Meeting on 18 March 2009. It is subsequently filed with the Danish Commerce and Companies Agency. In addition, a Form 20-F Report for 2008 is filed with the United States Securities and Exchange Commission in February 2009.

These two public filings contain references and links to information posted on the Company's website; such information is not incorporated by reference into the public filings.

Additional reporting online provides more background, context and data. Many sections of this report reference additional online information and an index on p 116 provides links to online content at annualreport2008.novonordisk.com.



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Charlotte Lucas Østerlund expresses the full effect of living with diabetes at the 2008 meeting of the European Association for the Study of Diabetes in Rome.

Sanofi Exhibit 2136.008 Mylan v. Sanofi IPR2018-01676



Fifteen Novo Nordisk employees marked World Diabetes Day in Denmark by running a marathon from the company's headquarters, past several company sites, to the Changing Diabetes<sup>®</sup> Village in the centre of Copenhagen, Denmark.

### Welcome to Novo Nordisk

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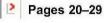
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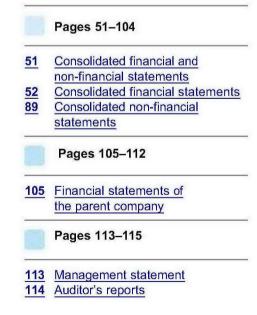
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Welcome to Novo Nordisk Our focus is our strength

## Our focus is our strength

The year 2008 is likely to be remembered by many as the year when, like a flash of lightning, a severe economic crisis brought an end to the belief in uninterrupted growth. The globalisation we have witnessed in recent years, which has had many positive effects, suddenly showed another face: no nation, no company and no individual is unaffected by the economic downturn. Businesses, large and small, are in crisis. Some that were considered icons in their industries no longer exist.

Against such a backdrop it is with great humility, but also with pride and satisfaction, that we can report on a year that has been very positive for Novo Nordisk, demonstrating the results of our focused business approach. We increased sales by 12% (mea sured in local currencies) and our reported operating profit by 38%. Our investment in research and development resulted in a strengthened pipeline of new products. And we continued to optimise processes and globalise our sales and production activities, which makes our organisation even better prepared for challenges in coming years.

One of the reasons why Novo Nordisk came through 2008 in better shape than many other companies is that we produce lifesaving medicines. Our customers, particularly people with chronic conditions, require treatment during recessions as well as periods of economic prosperity. But a great deal of our success is attributable to our more than 27,000 Novo Nordisk colleagues who have once again delivered excellent results. With doctors and patients, in the laboratories, in production, in administration and throughout our value chain, there has been a focus on achieving results for all stakeholders both in the short and long term.

### Innovation boosts competitiveness

Innovation in our pipeline is the source of long-term competitiveness in our industry, and in this area 2008 was very eventful.

Not everything has worked out as planned. In early 2008, we discontinued our attempts to develop inhalable insulin. Later in the year we had to reconcile ourselves to the fact that the effect of NovoSeven<sup>®</sup> for treatment of acute bleeds in trauma could not

Liraglutide has the potential to improve the treatment of type 2 dia betes. Even though requirements for approval of new medicines have become increasingly challenging, we are cautiously optimistic about the final outcome of regulatory assessment. We currently anticipate regulatory approval in the US and some European countries in 2009, followed by Japan and a number of other countries in 2010.

We know that even the best insulins available in the market today are not perfect. Phase 2 results for the company's new generation of insulins have demonstrated that long-acting insulins and insulins with a combined short- and long-acting effect can be further improved. If preliminary results are confirmed by additional trials, this new generation of insulins has the potential to offer better treatment for people with diabetes and to strengthen Novo Nordisk's competitive position.

In 2008, we decided to focus our biopharmaceutical research efforts in haemostasis, growth disorders and inflammation. Research in inflammation will be conducted by our Danish research organisation and a newly established research centre for inflammation in Seattle, US. Collaboration with a number of biotech companies also plays a significant role in our ability to bring new products to market in this area.

In 2008, Novo Nordisk made two significant breakthroughs that may have great impact on future diabetes treatment.

#### International expansion supports growth

In the diabetes market we have maintained our position as the world leader with a market share of more than 50% by volume. Demand for our products has increased and we see a continuing transition from traditional human insulin to modern insulins. Novo Nordisk won market share for modern insulins in 2008 and remains the only company with a full portfolio of short-acting,

Sanofi Exhibit 2136.011 Mylan v. Sanofi IPR2018-01676 be proven in controlled clinical trials within the foreseeable future. We also decided to discontinue trials to investigate the benefits of growth hormone therapy for dialysis patients because of the difficulty in recruiting trial participants.

However, 2008 will mostly be remembered as the year in which Novo Nordisk made two significant breakthroughs that may have great impact on future diabetes treatment. The development of liraglutide for the treatment of type 2 diabetes was finalised and regulatory approval was sought in the US, Europe, Japan and many other countries. In addition, a new generation of insulins for both type 1 and type 2 diabetes showed promising results in phase 2 trials.

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mixed and long-acting insulins. To expand our competitive position and brand awareness, not least among general practitioners, we have expanded our sales organisation in several key markets.

In November, we laid the foundation stone for a major expansion of our production site in Tianjin, China, which will create 500 new jobs. The new insulin formulation and filling plant is one of the largest investments in the history of Novo Nordisk and our biggest single investment outside Denmark. The second-largest single investment, the production site in Montes Claros, Brazil, became fully operational in 2008 and today provides insulin to a number of markets.

### Welcome to Novo Nordisk Our focus is our strength



Sten Scheibye, chairman of the Board of Directors, and Lars Rebien Sørensen, president and chief executive officer.

#### Managing responsibly

Many readers of this *Annual Report* will know that Novo Nordisk is managed using the Triple Bottom Line business principle. We assess our performance from three perspectives: financial, social and environmental. As we see it, a business can only be sustainable in the long term if it meets stakeholders' expectations in relation to all three aspects.

In this report we provide examples of how we conduct our activities in ways that are socially and environmentally responsible. We think a couple of them deserve particular mention.

In November, we announced a new programme to offer diabetes treatment, including free insulin, to 10,000 children in some of the world's poorest countries. This is part of a five-year programme called 'Changing the Future for Children with Diabetes', which begins in 2009. In addition to making free insulin available to a particularly vulnerable population of people with diabetes, the project will also build long-term solutions for distribution of insulin and sustainable diabetes treatment in the world's poorest countries.

We are well on our way to achieving the ambitious target for CO2 reduction we set for ourselves in 2006 and, as a result of our efforts, the majority of our future electricity supplies will be generated from wind. Just as the financial crisis is global, so is climate change, and everyone must take responsibility for addressing it. We will leave it to the scientists to debate to what life-saving medicines. The increasing prevalence of chronic disease is already a major financial burden with treatment costs putting pressure on healthcare budgets, even in wealthy countries. It will be a huge challenge to finance public health systems in the future in a way that makes it attractive to bring new and improved medicines to market and at the same time secure equal access to care.

It is well known that new medicines are needed to improve the treatment of many diseases, but it is also evident that public healthcare providers and insurance companies are subjecting the costs versus the benefits of new medicines to increased scrutiny. At the same time, increasing requirements to document potential long-term side effects make bringing new treatments to market even more costly. These challenges impact the outlook for the entire industry.

At Novo Nordisk we are, however, optimistic about the future. With our focus on diabetes care and biopharmaceutical niche products, we believe that we are uniquely placed. We also believe our unique market position justifies further investment in our research and development and in expanding our international organisation and global supply through controlled growth and with continued focus on financial results.

We would like to take this opportunity to thank our customers, shareholders and partners for their trust in Novo Nordisk during 2008. We also thank everyone at Novo Nordisk for their great efforts, creativity and engagement, which is the heart of our

> Sanofi Exhibit 2136.013 Mylan v. Sanofi IPR2018-01676

extent climate change is human-induced or caused by natural developments that are not related to human activity. There are, however, many reasons, including financial, for managing a business in a way that minimises environmental impact, and we will retain our focus on this in coming years.

### **Challenges ahead**

The pharmaceutical industry today is faced with a number of challenges that have certainly not diminished with the current global recession.

We believe that the current economic downturn will impair societies' and individuals' ability to pay for healthcare, including organisation and the foundation of the strong results presented in this report.

Lan R Spunson

Lars Rebien Sørensen

President and chief executive officer

Sky Seluibur

Sten Scheibye

Chairman of the Board of Directors

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Welcome to Novo Nordisk Managing in the current economic climate

# Managing in the current economic climate

### Interview with Novo Nordisk's CFO, Jesper Brandgaard

### In your opinion, what impact will the current economic downturn have on the pharmaceutical industry?

We have to recognise that this crisis is not only global, it is severe, and it is likely to be of significant duration. There are profound implications for wealth and growth throughout the world. Even in a sector less impacted by short-term economic swings, such as the pharmaceutical sector, there is a clear correlation between long-term economic growth at the societal level and growth opportunities for companies.

We believe the pharmaceutical sector will first see an impact in economies that are largely dependent on exporting either goods or raw materials. Oil price volatility is, of course, important in this regard. Societies such as Russia, Algeria and Venezuela may experience an impact on their ability to procure advanced pharmaceutical products.

In many countries, notably in Europe, pressure to reduce the growth of public spending for pharmaceutical products will increase, with more substitution of generic products. There will also be greater emphasis on health economics to make sure that products paid for by society are achieving the desired health outcomes.

With the new administration in Washington, there is a high likelihood that 2009 will bring price reform in government-funded healthcare programmes such as Medicaid and Medicare. We have said that there has are likely to face higher co-payments. Everything else being equal, it will be increasingly difficult to obtain reimbursement for new, advanced treatments.

### How do you see the financial crisis impacting the structure of the industry?

There is still a profound need for large pharmaceutical companies to acquire innovation. These companies are gene rating significant positive cash flows but are challenged by lack of innovation and regulatory hurdles. At the same time, small biopharm companies that do not yet have products on the market will have increasing difficulty accessing long-term venture capital. These firms are likely to either look for opportunities to partner with larger fi rms or put themselves up for sale. In this environment, we expect to see consolidation in the industry.

We have not changed direction; we have stayed the course, and we believe this will now present us with new opportunities.

### How was Novo Nordisk impacted by market volatility in 2008?

While Novo Nordisk has continued to

of the Novo Group companies, including Novo Nordisk. Beyond the Foundation, we have experienced changes in the holdings of other large investors, notably US investors repatriating funds.

We have also seen a number of Danish pension institutions reducing their holdings in Novo Nordisk in order to maintain portfolio diversification. The challenge in the Danish stock exchange environment is that the relative performance of Novo Nordisk compared with other companies listed on NASDAQ OMX Copenhagen increased Novo Nordisk's weighting on the exchange dramatically during 2008.

So we have seen the shareholdings of some of the company's largest investors reduced. At the same time, we have seen solid support from new European and US investors, as well as from retail investors in Denmark.

These changes have not impacted the way the company interacts with the equity market, but have highlighted the need to be very transparent.

### How does Novo Nordisk manage its balance sheet, and have there been recent changes in direction?

Historically, Novo Nordisk, like most pharmaceutical and large-cap biopharm firms, has had a balance sheet with little debt. In fact, Novo Nordisk has operated with slightly positive net financial assets on its balance sheet. This is an advantage because having access to cash can now provide us with interesting

> Sanofi Exhibit 2136.015 Mylan v. Sanofi IPR2018-01676

been an advantage for the industry from the migration of patients from Medicaid to the Medicare Part D programme and we did not think this was sustainable. The details of a potential pricing reform remain to be seen, but we do anticipate changes in some of the schemes funded by the federal government, including Medicare Part D.

In the private health insurance market in the US, we are also looking at a scenario where funds are getting tighter. Patients

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have strong sales and cash flow and has not experienced any liquidity issues, recent market turmoil has had a bigger impact on the composition of Novo Nordisk's shareholder base than we originally anticipated.

Novo Nordisk's largest shareholder continues to be The Novo Nordisk Foundation through the Novo A/S holding company. The Foundation has bylaws stating that its primary objective is to be a stable owner investment possibilities. We have not changed direction; we have stayed the course, and we believe this will now present us with new opportunities.

In terms of cash returned to shareholders, Novo Nordisk has adhered to its dividend policy of gradually increasing the payout ratio to a level around the pharma industry average, which is now approximately 40%.

### Welcome to Novo Nordisk Managing in the current economic climate

### What impact did exchange rate fluctuations have on the company in 2008?

One obvious example of the impact that currency developments had on Novo Nordisk in 2008 was the impact on sales growth. In 2008, Novo Nordisk achieved sales growth of 12% when adjusted for the impact of currencies. However, in reported terms sales growth was 9% due to negative exchange rate impact compared to the Danish kroner of approximately 3%, or more than 1 billion kroner.

For a company with global operations like Novo Nordisk, extreme volatility requires that we be ever more transparent in our disclosures. In the longer term, it also requires that we continue to make investments globally that help to balance our long-term currency exposure.

A good example of this is the 400 million US dollar investment the company committed to make in China in 2008 for a new production facility. Beyond the attractiveness of the project in a growing market, the investment will help provide Novo

Jesper Brandgaard, chief financial officer.

Nordisk with a better balance between the company's income base and cost base. In addition, the more assets the company has in China, the easier it becomes to attract local talent.

### Are there lessons that Novo Nordisk has learned from previous economic downturns that apply to the current situation?

Previous downturns we've seen in recent years have been confined to specific regions, such as the Asian currency crisis in the late 1990s. The current downturn is likely to turn into a global recession with wide-ranging implications, some of which will be difficult to predict.

Cautious spending behaviour combined with a willingness to invest in markets with long-term growth prospects will continue to be the cornerstones of Novo Nordisk's strategy. In the longer term, this approach, along with a commitment to managing responsibly, has proven to be integral to the sustainable business model that the company is pursuing.



Fareed Zakaria Editor, Newsweek International

Novo Nordisk invited Fareed Zakaria to provide his perspective on the global economy.

# A problem of growth

I would argue that the current economic crisis is a problem of growth, created by 124 countries growing simultaneously and by the fact that you have a single world economy in which everyone is participating, so Chinese savings can fuel US consumption and vice versa.

The most important real world effect we have to worry about is countries turning inward. The possibility of turning away from the single, global market, away from the idea that we can create a greater degree of global prosperity and raise standards of living.

The challenge for a company like Novo Nordisk is to explore



whether it can play a role in trying to keep the Western world open.

The challenge for a company like Novo Nordisk is to explore whether it can play a role in trying to keep the Western world open. This is a path most corporations have steered away from because they don't want to get politically involved.

Dr Fareed Zakaria is editor of Newsweek International, host of CNN's Fareed Zakaria GPS, and co-host of PostGlobal, an online discussion of international issues.

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Welcome to Novo Nordisk Novo Nordisk at a glance

### Novo Nordisk at a glance

Novo Nordisk is a focused healthcare company and a world leader in diabetes care. Key market figures for the diabetes care business are provided here and on p 10.

In its other business segment, biopharmaceuticals, Novo Nordisk has a leading position within the therapeutic areas of haemostasis management, growth hormone therapy and hormone replacement therapy. The company reports biopharmaceutical sales globally and by therapy area. See pp 10–11 for more information.

### **North America**

Sales: 33% of total sales.

Insulin/modern insulin volume share: 42% of the total market; 33% of the segment. **International Operations** 

Sales: 19% of total sales.

Insulin/modern insulin volume share: 57% of the total market; 57% of the segment.

#### Europe

Sales: 38% of total sales.

Insulin/modern insulin volume share: 55% of the total market; 51% of the segment.

> Sanofi Exhibit 2136.019 Mylan v. Sanofi IPR2018-01676

**Performance:** The number of people with diabetes in the US is now 24 million, according to the national Centers for Disease Control (CDC), and this is projected to exceed 30 million within 10 years. The rate of new cases of diabetes soared by about 90% in the past decade, according to the CDC, fuelled by growing obesity and sedentary lifestyles.

Novo Nordisk sees significant opportunities to improve care and treatment for people with diabetes in the US. To deliver on these opportunities, market access is crucial. More than 80% of the US population is currently covered by medical insurance. Novo Nordisk's products are eligible for reimbursement through 90% of managed care formularies, a key competitive advantage.

**Capacity-building:** 89,500 healthcare professionals have been trained or educated through Novo Nordisk's National Changing Diabetes<sup>®</sup> programmes.

Performance: Novo Nordisk's International Operations – covering South and Central America, the Middle East, Africa and Asia (excluding Japan & Oceania) – is a vast area representing 85% of the world's population and 80% of all people with diabetes.

Lack of access to adequate diabetes care is a continuing concern in these countries, although there are encouraging signs that diabetes is rising on the public health agenda. A growing middle class in emerging markets such as China and India are also better able to afford more advanced treatments. The dramatic rise in the number of people with diabetes in these markets is driven by several factors, including urbanisation, an ageing population, unhealthy eating habits and sedentary lifestyles.

Capacity-building: 151,500 healthcare professionals have been trained or educated through Novo Nordisk's National Changing Diabetes<sup>®</sup> programmes. Performance: Modern insulins are driving growth in the company's European operations. Levemir<sup>®</sup>, the company's basal insulin, is reinforcing Novo Nordisk's market leadership in the region.

Through its affiliates, Novo Nordisk is driving home the message that changing diabetes care begins with raising awareness and working with partners. In Italy, Novo Nordisk supported a meeting of about 200 diabetes experts, policymakers, patient representatives, industry and media to discuss how to stop the epidemic growth of diabetes. Marking its 50th anniversary, Novo Nordisk's affiliate in Germany held its second Camp D for young people with diabetes in 2008. Nearly 700 young people attended the four-day event, which focuses on enhancing quality of life for people with type 1 diabetes.

Capacity-building: 79,000 healthcare professionals have been trained or educated through Novo Nordisk's National Changing Diabetes<sup>®</sup> programmes.

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### Japan & Oceania

Sales: 10% of total sales.

Insulin/modern insulin volume share: 71% of the total market; 61% of the segment.

### Production sites

Bagsværd, Denmark Chartres, France Clayton, North Carolina, US Dely Brahim, Algeria Gentofte, Denmark Hillerød, Denmark Hijørring, Denmark Kalundborg, Denmark Koriyama, Japan Køge, Denmark Mexico City, Mexico Montes Claros, Brazil Måløv, Denmark Tianjin, China Værløse, Denmark

#### • R&D facilities

Bagsværd, Denmark Beijing, China Gentofte, Denmark Hillerød, Denmark Måløv, Denmark Seattle, Washington, US

Clinical development centres Beijing, China Princeton, New Jersey, US Tokyo, Japan Zurich, Switzerland

### • Regional and business area offices

Affiliates

Representative offices

### **Innovation and growth**

Novo Nordisk was created in 1989 from the merger of two companies founded in the 1920s that independently pioneered several breakthroughs in diabetes care. Both companies focused on treating the whole person and not just diabetes symptoms, and this approach continues to be a hallmark of Novo Nordisk's business.

The company has experienced significant growth in recent years, with total sales increasing by 119% since 2000. In the same period, the number of Novo Nordisk employees almost doubled to more than 27,000 in 81 countries. The milestones below highlight the company's recent innovations and growth.

**1996** NovoSeven<sup>®</sup> – for the treatment of haemophilia patients with inhibitor reaction – is launched.

**1998** Activelle<sup>®</sup> (Activella<sup>®</sup> in the US) – the first low-dose continuous-combined oral HRT for postmenopausal women – is introduced.

**1999** NovoRapid<sup>®</sup> (NovoLog<sup>®</sup> in the US) – the company's first modern insulin, a rapid-acting insulin analogue – is marketed. Modern insulins are designed

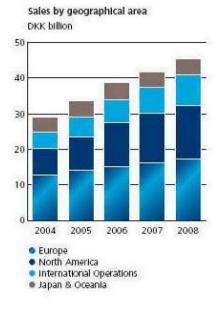
> Sanofi Exhibit 2136.021 Mylan v. Sanofi IPR2018-01676

**Performance:** Recognition of the need for better screening and earlier diagnosis of diabetes and other chronic diseases prompted a move by Japanese authorities in 2008 to establish a healthscreening programme for adults ages 40–74, or 45% of the population, which will include a check of HbA<sub>1c</sub> or blood

### glucose levels.

Levemir<sup>®</sup> is helping drive Novo Nordisk's longstanding market leadership in Japan, where it was introduced in 2007 and has had the fastest penetration among the company's major markets, owing to an aggressive and tightly focused launch, as well as its high acceptance among physicians and patients. While there has been increased competition, not least in the area of devices, Novo Nordisk's products and devices continue to hold a strong position in Japan.

Capacity-building: 60,000 healthcare professionals have been trained or educated through Novo Nordisk's National Changing Diabetes<sup>®</sup> programmes.



### to better mimic the normal insulin response to changes in blood sugar levels.

**2000** The company's enzymes business is spun off as a separate company, Novozymes A/S.

**2001** NovoRapid<sup>®</sup> FlexPen<sup>®</sup> is marketed. FlexPen<sup>®</sup> is a new prefilled pen, designed for easy and discreet use.

**2002** NovoMix<sup>®</sup> 30 – a dual-release modern insulin – is introduced.

**2003** Norditropin NordiFlex<sup>®</sup> – the world's first prefilled growth hormone pen – is launched.

**2004** Levemir<sup>®</sup> – a long-acting modern insulin – is launched.

**2007** In Montes Claros, Brazil, Novo Nordisk inaugurates its largest insulin production facility outside Denmark.

See more at novonordisk.com/about\_us/ history/milestones\_in\_nn\_history.asp.

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# Performance in 2008

## Novo Nordisk continued on a sustainable growth path in all its major business areas and delivered solid results in 2008.

Sales increased by 12% measured in local currencies and by 9% in Danish kroner. Modern insulins continued to be the main contributor to growth increasing by 28% in local currencies (24% in Danish kroner), and Earnings per share (diluted) increased by 16% to DKK 15.54.

### 2008 performance on long-term financial targets

Focusing on growth, profitability, financial return and generation of cash, the four long-term financial targets guide the company's financial development, aimed at ensuring a focus on shareholder value creation. These targets are operating profit growth, operating margin, return on invested capital and cash conversion. By 2008, Novo Nordisk reached the performance level stipulated in the four long-term financial targets which were outlined in 2006. The four ratios are still considered an appropriate way to ensure value creation, and several of the targets

> Sanofi Exhibit 2136.023 Mylan v. Sanofi IPR2018-01676

NovoSeven<sup>®</sup> and Norditropin<sup>®</sup> also continued to contribute to growth, increasing, respectively, by 14% in local currencies (9% in Danish kroner) and 12% in local currencies (10% in Danish kroner).

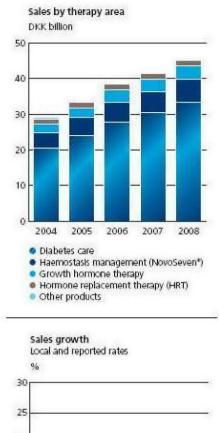
Sales growth was realised in all regions measured in local currencies. The main contributors to growth were North America and International Operations, which contributed 48% and 29%, respectively, of total sales growth. Europe contributed 21% and Japan & Oceania 2% of total sales growth in 2008, measured in local currencies.

The gross margin increased to 77.8% in 2008, up from 76.6% in 2007, reflecting an improvement of 1.2 percentage points, primarily driven by sustainable productivity improvements. Costs related to research and development decreased by 8%; however, when adjusted for non-recurring costs related to the closure of all pulmonary diabetes projects in 2007 and 2008, research and development costs increased by 4%. This reflects a sustained high level of investment in research and development activities supporting the future growth of the company.

Operating profit in 2008 increased by 38% to DKK 12,373 million compared to 2007.

Net profit increased by 13% to DKK 9,645 million. When adjusted for the non-recurring income from the divestment in 2007 of Dako A/S's business activities and the non-recurring costs related to the closure of all pulmonary diabetes projects, net profit increased by 22%.

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20 15 10 5 0 2004 2005 2006 2007 2008

In DKK as reported
 In local currencies

have consequently been increased. The revision is based on an assumption of a continuation of the current business environment and given the current scope of business activities and has been prepared assuming that currency exchange rates remain at current levels.

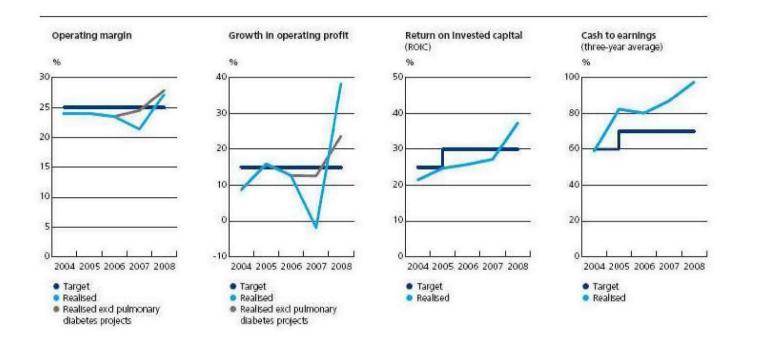
Operating profit growth was realised at 38%. However, adjusted for nonrecurring costs related to the closure of all pulmonary diabetes projects and a negative currency impact, the underlying operating profit increased by more than 25%. The long-term target is an average annual growth of 15%. The performance reflects solid underlying sales growth as well as an improved gross margin.

The *operating margin* for 2008 was realised at 27%, up from 24.5% in 2007 adjusted for non-recurring costs related

to the closure of AERx<sup>®</sup>, and exceeds the long-term target of 25%. The improvement in operating margin is driven by an improved gross margin.

The *return on invested capital* was 37%, significantly up compared to 2007 and now exceeding the long-term target of 30%. The improvement mainly reflects solid growth in operating profit as well as a lower level of invested capital primarily due to a reduction in the fixed asset base.

The *cash to earnings ratio* was realised at 114% in 2008 and at 98% for the last three years on average compared to the long-term target of 70%. The cashconversion ability will fluctuate in any given year, and therefore the long-term target measures the cash to earnings ratio over a three-year period.



### Long-term financial targets

Focusing on growth, profitability, financial return and generation of cash, 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 in 2001 and in 2006. By 2008, and despite a challenging currency exchange rate environment since the last update of the targets, Novo Nordisk has now reached the performance level stipulated in the four long-term financial targets and has consequently revised the target levels. The revision is based on an assumption of a continuation of the current business environment and given the current scope of business activities and has been prepared

assuming that currency exchange rates remain at current levels.

The target level for operating profit growth remains at 15% on average. The target still allows for deviations in individual years if necessitated by business opportunities, market conditions or exchange rate movements.

The target level for operating margin is increased from 25% to 30%. The key enabling factors are expected to be further productivity improvements in the manufacturing and administrative areas while at the same time ensuring investments for both research and development as well as sales and marketing. It should be noted that the achievement of the operating margin target may be influenced by significant changes in market conditions including regulatory developments, changes in pricing environment, healthcare reforms as well as exchange rate movements.

The target level for return on invested capital (ROIC) measured post tax is increased from 30% to 50%. The raised target reflects the expectation of continued lower growth in invested capital relative to operating profit as well as a stable effective tax rate.

The target level for the cash-to-earnings ratio is increased from 70% to 80%, reflecting improved cash conversion ability. As previously, this target will be pursued looking at the average over a three-year period. Performance on this ratio may be impacted in individual years by significant acquisitions, investments or licensing activities.

Ratio

Previous target

Result 2008

New targets

Sanofi Exhibit 2136.025 Mylan v. Sanofi IPR2018-01676

Growth in operating profit	15%	38.4%	15%
Operating margin	25%	27.2%	30%
Return on invested capital (ROIC)	30%	37.4%	50%
Cash to earnings (three-year average)	70%	97.6%	80%

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### **Diabetes care**

Novo Nordisk retained its position as global leader with 52% of the total insulin market and 44% of the modern insulin market, both measured by volume. The company is determined to sustain its leadership in diabetes care by leveraging the value of its full portfolio of modern insulins and delivery devices while developing new antidiabetic agents and a new generation of insulins to better address future needs for effective diabetes care. See pp 30–37.

#### Sales performance

Sales of diabetes care products increased by 13% measured in local currencies and by 9% in Danish kroner to DKK 33,356 million compared to last year.

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

Sales of modern insulins, human insulins and insulin-related products increased by 12% measured in local currencies and by 9% in Danish kroner to DKK 30,965 million. All regions contributed to growth, with North America and International Operations having the highest growth rates.

Sales of modern insulins increased by 28% in local currencies in 2008 and by 24% in Danish kroner to DKK 17,317

million. Sales of Levemir<sup>®</sup> increased by 55%, sales of NovoRapid<sup>®</sup> (NovoLog<sup>®</sup> in

the US) increased by 22% and sales of

NovoMix<sup>®</sup> (NovoLog<sup>®</sup> Mix 70/30 in the US) increased by 23%, all measured in local currencies. All regions realised solid growth rates, with North America

in Danish kroner. The sales development reflects sales growth for

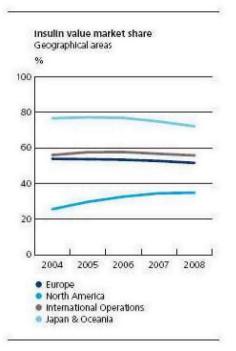
the modern insulins NovoRapid<sup>®</sup>,

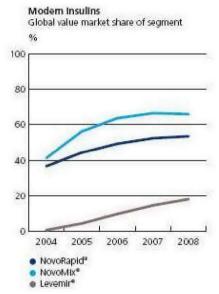
NovoRapid Mix<sup>®</sup> 30 and Levemir<sup>®</sup>. Novo Nordisk holds 72% of the total insulin market in Japan and 64% of the modern insulin market, both measured by volume.

### **Oral antidiabetic products**

### (NovoNorm<sup>®</sup>/Prandin<sup>®</sup>)

Sales of oral antidiabetic products increased by 16% in local currencies and by 11% in Danish kroner to DKK 2,391 million compared to 2007. This primarily reflects increased sales in International Operations and North America, mainly due to an increased market share in China and a higher average sales price in the US market.





and Europe as the primary contributors to growth. Sales of modern insulins contributed 77% of the overall growth in local currencies and now constitute 59% of Novo Nordisk's sales of insulins.

#### North America

Sales in North America increased by 21% in local currencies in 2008 and by 14% in Danish kroner, reflecting a solid penetration of the modern insulins Levemir<sup>®</sup>, NovoLog<sup>®</sup> and NovoLog<sup>®</sup> Mix 70/30. In the fourth quarter of 2008, US sales were positively impacted by a rebate reversal related to a federal healthcare programme. Novo Nordisk maintains its leadership position in the US insulin market with 41% of the total insulin market, both measured by volume. Currently, more than 37% of Novo Nordisk's modern insulin volume is

sold in FlexPen<sup>®</sup>.

#### Europe

Sales in Europe increased by 6% in local currencies and 5% measured in Danish kroner, reflecting continued progress for the portfolio of modern insulins. Novo Nordisk holds 55% of the total insulin market and 51% of the modern insulin market, both measured by volume, and is capturing the main share of growth in the modern insulin market.

### International Operations

Sales within International Operations increased by 18% in local currencies and by 14% in Danish kroner. The main contributor to growth in 2008 was sales of modern insulins, primarily in Turkey and China. Furthermore, sales of human insulins continue to add to overall growth in the region, driven by China.

#### Japan & Oceania

Sales in Japan & Oceania increased by 1% in local currencies and by 6% measured

### **Biopharmaceuticals**

Novo Nordisk continues to grow its biopharmaceuticals therapy areas by pursuing new indications for its existing product range and by exploring new potential proteins in other areas. See pp 38–41.

#### Sales performance

Sales of biopharmaceutical products increased by 11% measured in local currencies and by 7% measured in Danish kroner to DKK 12,197 million compared to last year.

### NovoSeven<sup>®</sup>

Sales of NovoSeven<sup>®</sup> increased by 14% in local currencies and by 9% in Danish kroner to DKK 6,396 million compared to last year. Sales growth for

NovoSeven<sup>®</sup> was primarily realised in North America and International Operations. The sales growth for

NovoSeven<sup>®</sup> during 2008 primarily reflected increased sales within the congenital bleeding disorder segments, where Novo Nordisk is the global leader, and was supported by the launch of

room temperature-stable NovoSeven<sup>®</sup> in the US as well as key markets in Europe. Treatment of spontaneous bleeds for congenital inhibitor patients remains the largest area of use. In the fourth quarter of 2008, sales of

NovoSeven<sup>®</sup> in the US were positively impacted by wholesaler stock building.

Sales of NovoSeven<sup>®</sup> in International Operations in 2008 were positively impacted by the timing of tender sales compared to 2007.

### Growth hormone therapy

### (Norditropin<sup>®</sup>)

Sales of Norditropin<sup>®</sup> (ie growth hormone in a liquid, ready-to-use formulation) increased by 12% measured in local currencies and by 10% measured in Danish kroner to DKK 3,865 million. North America and Europe were the main contributors to

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### Business results Performance in 2008

growth measured in local currencies. Novo Nordisk is the second-largest company in this market with 23% market share measured by volume.

### Other products

Sales of other products within biopharmaceuticals, which predominantly consist of hormone replacement therapy (HRT)-related products, increased by 1% in local currencies and decreased by 2% in Danish kroner to DKK 1,936 million. This development primarily reflects generic competition in the US

for Activella<sup>®</sup>, a continuous-combined HRT product, but also continued sales progress for Vagifem<sup>®</sup>, Novo Nordisk's topical oestrogen product.

### **Pipeline progress**

Novo Nordisk made significant progress in research and development in 2008. See pp 18–19 for a status on the current pipeline and progress during the year. Within biopharmaceuticals the key events for late-stage pipeline compounds in 2008 were:

 Novo Nordisk received marketing approval for a temperature-stable

version of NovoSeven<sup>®</sup> which is expected to deliver significant patient benefits including immediate access to treatment as well as fast and convenient administration when a bleeding episode occurs.

- A phase 3 study with recombinant FXIII in congenital FXIII deficiency was initiated.
- A phase 2 clinical study was initiated with a long-acting human growth hormone analogue designed for onceweekly treatment.
- Novo Nordisk decided to discontinue the phase 3 clinical study with Novo-Seven<sup>®</sup> for the treatment of bleeding in patients with severe trauma.

In 2008, costs amounting to DKK 171 million in connection with general employee share programmes were expensed. In 2008, Novo Nordisk expensed costs in relation to sharebased long-term incentive programmes for senior management and other senior employees (around 580 participants in total) amounting to DKK 160 million. The comparable expense for 2007 was DKK 121 million (around 525 participants in total).

Licence fees and other operating income were DKK 286 million in 2008 compared to DKK 321 million in 2007.

Operating profit in 2008 increased by 38% to DKK 12,373 million compared to 2007.

### Net financials and tax

Net financials showed a net income of DKK 322 million in 2008 compared to a net income of DKK 2,029 million in 2007.

Within diabetes care the key events for late-stage pipeline compounds during 2008 are summarised below:

- Novo Nordisk filed for regulatory approval of liraglutide for the treatment of type 2 diabetes in the US, Europe, Japan and many other countries. The applications contain documentation from an extensive clinical development programme designed to obtain the indication for use of liraglutide to treat type 2 diabetes as an adjunct to diet and exercise, both as monotherapy and in combination with commonly used antidiabetic medications.
- Novo Nordisk initiated the phase 3 programme with liraglutide for the treatment of severe obesity.
- Novo Nordisk finalised two phase 2 clinical studies with NN1250, a long-acting new generation of insulin with a potential duration of action of more than 24 hours, and two phase 2 clinical studies with NN5401, a neutral, soluble dual-acting, new generation of insulin, also with a potential duration of action of more than 24 hours.
- A phase 2 clinical study was initiated with the longer-acting human GLP-1 analogue, NN9535, designed for onceweekly treatment of type 2 diabetes.
- Novo Nordisk discontinued all pulmonary diabetes activities, including AERx<sup>®</sup>, in 2008 and decided to focus on injection-based delivery and alternative non-invasive approaches to delivery of insulin, GLP-1 and other therapeutic proteins.

 An update of the haemostasis strategy was presented including plans for continuing development of

potential successors to NovoSeven<sup>®</sup> as well as extending activities into general haemophilia.

 Novo Nordisk decided to discontinue the phase 3 study with Norditropin<sup>®</sup> in dialysis patients with low serum albumin.

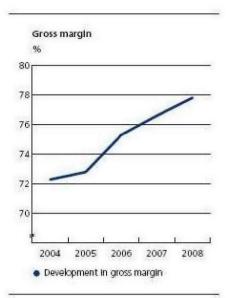
### **Operating performance**

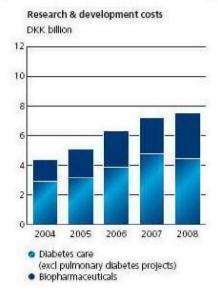
The cost of goods sold was DKK 10,109 million in 2008, representing a gross margin of 77.8% compared to 76.6% in 2007. This improvement reflects improved production efficiency and higher average prices in the US. The gross margin was negatively impacted by around 0.5 percentage points due to a negative currency development.

In 2008, total non-production-related costs amounted to DKK 23,357 million and were largely at the same level as in 2007. This development reflects lower costs related to research and development, primarily refl ecting the non-recurring costs related to the

discontinuation of AERx<sup>®</sup> in 2007, of DKK 1,325 million and non-recurring costs of DKK 325 million in 2008 related

to the discontinuation of AERx<sup>®</sup> and other pulmonary diabetes projects. Sales and distribution costs increased at a lower level than sales, primarily explained by a return of a deposit related to an antidumping case in Brazil countered by higher costs related to the expanded sales force in the US.





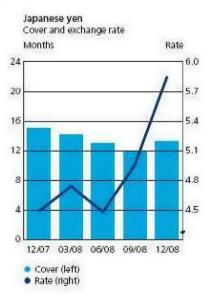
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Included in net financials is the result from associated companies with an expense of DKK 124 million, primarily related to Novo Nordisk's share of losses in ZymoGenetics, Inc of approximately DKK 192 million.

In 2007, the result from associated companies was an income of DKK 1,233 million, primarily related to the non-recurring





tax-exempt income of approximately DKK 1.5 billion from Novo Nordisk's divestment of the ownership of Dako's business activities.

The foreign exchange result was an income of DKK 159 million compared to an income of DKK 910 million in 2007. This development reflects gains on foreign exchange hedging activities, especially in US dollars, partly offset by losses on commercial balances in primarily non-hedged currencies. Foreign exchange hedging losses of DKK 864 million have been deferred for future income recognition, primarily in 2009.

The effective tax rate for 2008 was 24.0%, an increase from 22.3% in 2007, when the effective tax rate was positively impacted by the non-recurring taxexempt income from the divestment of Novo Nordisk's ownership of Dako A/S's business activities as well as from the non-recurring effect from the reevaluation of the company's deferred tax liabilities as a consequence of the reduction in the Danish corporation tax rate to 25%, introduced in 2007.

### Capital expenditure and free cash flow

Net capital expenditure for property, plant and equipment in 2008 was realised at DKK 1.8 billion compared to DKK 2.3 billion for 2007. The main investment projects in 2008 were

manufacturing expansion of FlexPen<sup>®</sup> assembly capacity as well as expansion of the purification and filling capacity for insulin products.

Free cash flow for 2008 was realised at DKK 11.0 billion compared to DKK 9.0 billion for 2007. Novo Nordisk's financial resources at the end of 2008 were DKK 17.2 billion, higher than the level at the end of 2007. Included in the financial resources are unutilised committed credit facilities of approximately DKK 7.5 billion.

#### **Proposed dividend**

At the Annual General Meeting on 18 March 2009, the Board of Directors will propose a 33% increase in dividend to DKK 6.00 per share of DKK 1, corresponding to a payout ratio of 37.8%, compared to 34.9% for the financial year 2007, when adjusted for the impact from the divestment of Dako's business activities and the AERx<sup>®</sup> discontinuation in 2007. No dividend will be paid on the company's holding of treasury B shares.

#### Share repurchase programme

During 2008, Novo Nordisk repurchased 15,579,207 B shares at an average price of DKK 303 per share, equal to a cash value of DKK 4.7 billion. The Board of Directors has approved an increase of DKK 1.0 billion in the ongoing DKK 17.5 billion share repurchase programme, bringing the total share repurchase programme to DKK 18.5 billion. Novo Nordisk still expects to finalise the share repurchase programme before the end of 2009. As a consequence Novo Nordisk expects to repurchase shares equal to a cash value of DKK 6 billion in 2009. In 2006 and 2007, Novo Nordisk repurchased B shares equal to a cash value of DKK 7.8 billion in total.

### Holding of treasury shares and reduction of share capital

As per 28 January 2009, Novo Nordisk A/S and its wholly-owned affiliates owned 25,721,095 of its own B shares, corresponding to 4.06% of the total share capital.

In order to maintain capital structure flexibility, the Board of Directors at the 2009 Annual General Meeting will also propose a reduction in the B share capital from DKK 526,512,800 to DKK 512,512,800 by cancelling 14,000,000 B shares of DKK 1 from the company's own holdings of B shares at a nominal value of DKK 14,000,000, equal to 2.2% of the total share capital. After implementation of the share capital reduction, the company's share capital

> Sanofi Exhibit 2136.031 Mylan v. Sanofi IPR2018-01676

### Equity

Total equity was DKK 32,979 million at the end of 2008, equal to 65.2% of total assets, compared to 67.4% at the end of 2007.

will amount to DKK 620,000,000 divided into an A share capital of DKK 107,487,200 and a B share capital of DKK 512,512,800.

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Sanofi Exhibit 2136.032 Mylan v. Sanofi IPR2018-01676

### Business results Performance in 2008

#### Legal issues

Novo Nordisk is party to a number of legal cases. See key legal issues and information on contingencies for pending litigations on pp 86–87.

### Long-term incentive programmes

Novo Nordisk's existing remuneration policy for executives aims to attract, retain and motivate members of the Board of Directors and Executive Management of Novo Nordisk. Remuneration levels are designed to be competitive and to align the interest of the executives with those of the shareholders.

### Long-term share-based incentive programme for senior management

As from 2004, members of Novo Nordisk's Executive Management (currently five) and the other members of the Senior Management Board (currently 24) have participated in a performancebased incentive programme where a proportion of the calculated shareholder value creation has been allocated to a joint pool for the participants. For members of Executive Management and the other members of the Senior Management Board the joint pool operates with a yearly maximum allocation per participant equal to eight months' fixed base salary plus pension contribution. Once the joint pool has been approved by the Board of Directors the total cash amount is converted into Novo Nordisk A/S B shares at market price. The shares in the joint pool are locked up for a three-year period before they potentially may be transferred to the participants.

will, according to the principles of the scheme, be transferred to 23 current and former members of senior management immediately after the announcement of the full-year 2008 financial results on 29 January 2009.

For 2008 and based on an assessment of the economic value generated in 2008, as well as the performance of the R&D portfolio and key sustainability projects, the Board of Directors on 28 January 2009 approved the establishment of a joint pool for the financial year 2008 by allocating a total of 171,492 Novo Nordisk B shares, corresponding to a cash value of DKK 55 million. This allocation amounts to eight months of fixed base salary and pension on average per participant. This amount was expensed in 2008.

As the long-term share-based incentive programme is evaluated by the Board of Directors to have worked successfully in 2008, it is planned to continue in 2009 with an unchanged structure.

Long-term share-based incentive programme for corporate vice presidents and vice presidents As from 2007, a number of key employees below top-level management also participate in a share-based programme with similar performance criteria as the programme for the members of Executive Management and the other members of the Senior Management Board. The share-based incentive programme for key employees will, as is the case for the programme for Executive Management and the other members of the Senior Management Board, be based on an annual calculation of shareholder value creation

performance of the R&D portfolio and key sustainability projects, the Board of Directors on 28 January 2009 approved the establishment of a pool for 2008 by allocating a total of 570,390 Novo Nordisk B shares, corresponding to a cash value of DKK 181 million. This allocation amounts to four months of fixed base salary on average per participant. The number of participants for 2008 is approximately 550. The cash value of the allocation will be amortised over four years.

### Compliance with Sarbanes– Oxley requirements

In 2008, Novo Nordisk was, as was the case in 2007, compliant with the US Sarbanes–Oxley Act section 404 that requires detailed documentation of how financial reporting processes, systems and controls are designed and operating. Management's conclusion and the external auditor's certification of the 2008 compliance are included in the Form 20-F, which Novo Nordisk as a listed company on the New York Stock Exchange is required to file with the US Securites and Exchange Commission (SEC). Form 20-F is expected to be filed in February 2009.

### Non-financial performance

Managing direct and indirect economic, environmental and social impacts in areas of strategic importance serves a dual purpose: to reduce risks and to strengthen competitiveness. Novo Nordisk's Triple Bottom Line approach aims to deliver long-term value to the business and benefits to society. See performance highlights on p 17 and the

> Sanofi Exhibit 2136.033 Mylan v. Sanofi IPR2018-01676

For 2005, 232,026 shares were allocated to the joint pool and the market value of the scheme, corresponding to DKK 35.5 million, was expensed in 2005. The number of shares in the 2005 joint pool has not been reduced as the financial performance in the subsequent years (2006–2008) reached specified threshold levels. Hence, the original number of shares allocated to the joint pool compared to the planned performance for the year. The pool will operate with a maximum contribution per participant equal to four months' fixed base salary. The shares in the pool are also locked up for a three-year period before they potentially may be transferred to the participants.

Based on an assessment of the economic value generated in 2008 as well as the

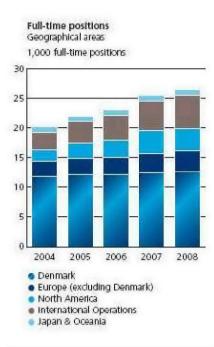
consolidated non-financial statements on pp 89–99.

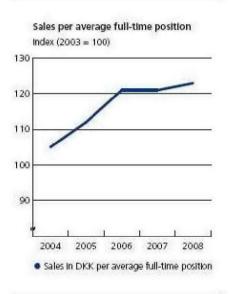
### Economics

In 2008, Novo Nordisk created 1,059 new positions worldwide and had 26,575 full-time positions, measured as full-time equivalents (FTE) at the end of the year. This is an increase of 4% compared to 2007 and reflects the company's continued expansion, particularly in sales and

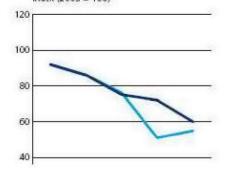
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### Business results Performance in 2008





Environmental impacts compared to sales index (2003 = 100)



marketing functions and geographically in International Operations. Via the multiplier effect, the increase translates into 61,925 indirect jobs in the global supply chain.

Sales per employee was DKK 1.7 million, up from DKK 1.6 million in 2007, indicating an ability to maintain high productivity while expanding the workforce.

#### Environment

Novo Nordisk strives to reduce resource consumption and waste production. The aim is to decouple production growth and environmental impacts.

The company's ambitious long-term target to achieve a 10% absolute reduction in  $CO_2$  emissions from

production by 2014 as compared with 2004 levels is on track. In 2008, CO<sub>2</sub>

emissions fell for the first time from 236,000 tons in 2007 to 215,000 tons. It is expected that the curve will break significantly at the end of 2009 when supplies of wind energy for the Danish production facilities can begin.

Measured by volume, the consumption of water and energy decreased by 17% and 9%, respectively, while waste volumes increased by 16%. The Eco Intensity Ratios (EIR) showed improved performance in both diabetes care and biopharmaceuticals, and for both water and energy, and on track with the targets for a 10% reduction by 2010 compared with 2005. A set of new longterm targets for environmental performance will be implemented as of 2009. See pp 28–29.

A continued preventative focus on compliance with environmental regulation is beginning to show results. In 2008, the number of accidental releases decreased by 13% to a total of 91. However, in the same period, the number of breaches of regulatory limit values increased by 27% from 22 in 2007 to 28. In 2008, a new diversity strategy was implemented, setting a five-year goal for all senior management teams to be diverse in terms of gender and nationality. See p 27.

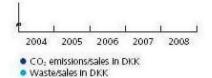
The level of employee engagement is measured by the average answers of 10 equally weighted questions in the annual survey, eVoice. In 2008, the consolidated score (on a scale of 1–5, with 5 being highest) was 4.2, increasing by 0.1 from 2007 and well above the long-term target of 4.0. This is underscored by a continued high closure rate at 99% of all action points arising from facilitations.

In 2008, the annual spending on training, measured as average spent per employee remained high, amounting to DKK 13,192, which was a slight increase of 0.5%. This level reflects the company's strategic priority on talent and leadership development, and on lifelong learning offered to all employees.

Changing Diabetes<sup>®</sup>, Novo Nordisk's global campaign to improve prevention, detection and care, effectively put diabetes on the public and political agendas. In the second year of marking the UN-observed World Diabetes Day, 14 November, Novo Nordisk succeeded in engaging more than 300,000 people in events in 56 countries. The company's global advocacy to raise awareness of and spur action on diabetes supports the implementation of the UN Resolution on diabetes, adopted in December 2006, in recognition of diabetes as a major global health challenge and in respect of the human right to proper care. See pp 34-37.

Novo Nordisk's strategy to improve access to diabetes care is a long-term leadership strategy to promote on-time insulin and provide sustainable diabetes care for all who need it. It focuses on giving people with diabetes priority, driving health outcomes and breaking the curve of the diabetes pandemic. See pp 30–33.

> Sanofi Exhibit 2136.035 Mylan v. Sanofi IPR2018-01676



During 2008, 13 prescreening audits and 19 regular audits of suppliers' environmental and social performance were conducted. These resulted in four critical findings and termination of relationship with one supplier.

#### Social

Attraction and retention of talented people is a key precondition for Novo Nordisk's ability to develop and grow its business. In 2008, employee turnover increased to 12.1% from 11.6%. A global employer-branding campaign was launched in 2008. In 2008, the company launched an ambitious five-year programme to supply free insulin and care for children with type 1 diabetes in the world's poorest countries. The programme, 'Changing the Future for Children with Diabetes' aims to reach a total of 10,000 children by 2013. It will be carried out in partnership with the World Diabetes Foundation and local partners.

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# Outlook for 2009

**Expectations** are

as reported, if not otherwise stated	Current expectations 29 January 2009
Sales growth	
• in local currencies	At the level of 10%
currencies	Around 5
<ul> <li>as reported</li> </ul>	percentage points higher
Operating profit growth	
<ul> <li>in local</li> </ul>	At the level of 10%
currencies	
	Around 9
<ul> <li>as reported</li> </ul>	percentage points
Net financial	higher Around DKK 1.6
expense	billion
Effective tax rate	Around 24%
O That a second the second	Around DKK 3
Capital expenditure	billion
Depreciation, amortisation	
and impairment	Around DKK 2.6
losses	billion
Free cash flow	At least DKK 9
THE COST NOW	billion

Novo Nordisk expects sales growth in 2009 at the level of 10% measured in local currencies. This is based on expectations of continued market penetration for Novo Nordisk's key strategic products within diabetes care and biopharmaceuticals as well as expectations of continued intense competition during 2009. Given the current level of exchange rates versus Danish kroner, the reported sales growth is expected to be around 5 percentage points higher than the growth rate measured in local currencies.

For 2009, operating profit growth measured in local currencies is expected to be at the level of 10%. The forecast reflects a continued improvement of the gross margin and increased spending for sales and distribution relative to sales due to an expected high level of sales and marketing activities primarily related to the expected approval and launch of liraglutide and continued global market penetration for the portfolio of modern insulins. Given the current level of currency exchange rates versus Danish kroner, the reported operating profit growth is expected to be around 9 percentage points higher than the growth rate measured in local currencies

For 2009, Novo Nordisk expects a net financial expense of around DKK 1.6 billion, reflecting significant foreign exchange hedging losses, primarily related to the US dollar and the Japanese yen as well as expected losses related to non-hedged currencies.

The effective tax rate for 2009 is expected to be around 24%. Capital expenditure is expected to be around DKK 3 billion in 2009. Expectations for depreciations, amortisation and impairment losses are around DKK 2.6 billion, and free cash flow is expected to be at least DKK 9 billion. Business results Performance in 2008

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

Invoic Annual Nordisk of	Hedging period	
a 5% m currenc	ovement in ÿ	(months)
USD	DKK 530 million	15
JPY	DKK 150 million	14
GBP	DKK 80 million	13
CNY	DKK 80 million	15* <sup>)</sup>
CAD	DKK 40 million	5
	ed as proxy for hedging of CNY exposure.	Novo

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

Forward-looking statement

share, capital expenditures, dividends, capital structure or other financial ratios,

or failure of projects related to research and/or development, unplanned loss of patents, interruptions of supplies and

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Novo Nordisk's reports filed with or furnished to the US Securities and Exchange Commission (SEC), including this document and the company's Form 20-F (expected to be filed with the SEC in February 2009), and written information released, or oral statements made, to the public, in the future by or on behalf of Novo Nordisk, may contain forward-looking statements.

Words such as 'believe', 'expect', 'may', 'will', 'plan', 'strategy', 'prospect', 'foresee', 'estimate', 'project', 'anticipate', 'can', 'intend', 'target' and other words and terms of similar meaning in connection with any discussion of future operating or financial performance identify forwardlooking statements. Examples of such forward-looking statements include, but are not limited to:

 statements of plans, objectives or goals for future operations, including those related to Novo Nordisk's products, product research, product development, product introductions and product approvals as well as cooperations in relation thereto,

• statements containing projections of or targets for revenues, income (or loss), earnings per

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

• statements of the assumptions underlying or relating to such statements.

In this document, examples of forwardlooking statements can be found under the headings 'Our focus is our strength', 'Pursuing a focused strategy', 'Performance in 2008', including longterm financial targets, 'Outlook for 2009' and note 31, 'Financial risk', on p 76.

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 forwardlooking 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 production, product recall, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for Novo Nordisk's products, introduction of competing products, reliance on information technology, Novo Nordisk's ability to successfully market current and new products, exposure to product liability and legal proceedings and investigations, changes in governmental laws and related interpretation thereof, including on reimbursement, intellectual property protection and regulatory controls on testing, approval, manufacturing and marketing, perceived or actual failure to adhere to ethical marketing practices, investments in and divestitures of domestic and foreign companies, unexpected growth in costs and expenses, failure to recruit and retain the right employees and failure to maintain a culture of compliance. Please also refer to the overview of risk factors in 'Managing risks' on pp 24-25.

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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Business results Financial highlights

## Sales

	2004	2005	2006	2007	2008	2007– 2008	2007	2008
	DKK million	DKK million	DKK million	DKK million	DKK million	Change	EUR million	EUR million
Diabetes care:								
Modern insulins (insulin analogues)	4,507	7,298	10,825	14,008	17,317	3,309	1,880	2,323
Human insulins	13,033	13,543	13,451	12,572	11,804	(768)	1,687	1,583
Insulin-related sales	1,350	1,463	1,606	1,749	1,844	95	235	247
Oral antidiabetic products (OAD)	1,643	1,708	1,984	2,149	2,391	242	288	321
Diabetes care total	20,533	24,012	27,866	30,478	33,356	2,878	4,090	4,474
Biopharmaceuticals:								
Haemostasis management	4,359	5,064	5,635	5,865	6,396	531	788	858
Growth hormone therapy	2,317	2,781	3,309	3,511	3,865	354	471	518
Hormone replacement therapy	1,488	1,565	1,607	1,668	1,612	(56)	224	216
Other products	334	338	326	309	324	15	41	43
Biopharmaceuticals total	8,498	9,748	10,877	11,353	12,197	844	1,524	1,635
Total sales by segment	29,031	33,760	38,743	41,831	45,553	3,722	5,614	6,109
Europe *)	12,887	14,020	15,300	16,350	17,219	869	2,194	2,309
North America	7,478	9,532	12,280	13,746	15,154	1,408	1,845	2,032
International Operations *)	4,368	5,497	6,494	7,295	8,425	1,130	979	1,130
Japan & Oceania	4,298	4,711	4,669	4,440	4,755	315	596	638
Total sales by	20.024	22 760	20 742	44 004	45 550	2 700	E 644	C 400
geographical area	29,031	33,760	38,743	41,831	45,553	3,722	5,614	6,109
Price and volume/mix	15%	15%	16%	13%	12%			
Currency	(4%)	1%	(1%)	(5%)	(3%)			
Total growth	11%	16%	15%	8%	9%			

## Key figures

	DKK million	DKK million	DKK million	DKK million	DKK million	Change	EUR million	EUR million
Operating profit	6,980	8,088	9,119	8,942	12,373	3,431	1,200	1,660
Operating profit excl AERx <sup>®**)</sup>	-	-	-	10,267	12,698	2,431	1,378	1,704
Net financials Profit before income taxes	477 7,457	146 8,234	45 9,164	2,029 10,971	322 12,695	(1,707) 1,724	272 1,472	43 1,703

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Free cash flow	4,278	4,833	4,707	9,012	11,015	2,003	1,210	1,478
Capital expenditure (net)	2,999	3,665	2,787	2,268	1,754	(514)	304	235
Total assets	37,433	41,960	44,692	47,731	50,603	2,872	6,401	6,792
Equity	26,504	27,634	30,122	32,182	32,979	797	4,316	4,426
Net profit	5,013	5,864	6,452	8,522	9,645	1,123	1,144	1,294

## Per share/ADR of DKK1

	DKK	DKK	DKK	DKK	DKK	Change	EUR	EUR
Earnings per share	7.45	8.95	10.05	13.49	15.66	2.17	1.81	2.10
Earnings per share, diluted	7.42	8.92	10.00	13.39	15.54	2.15	1.80	2.08
Proposed dividend	2.40	3.00	3.50	4.50	6.00	1.50	0.60	0.81
Quoted price at year-end for B shares	150	178	236	335	271	(64)	44.96	36.35

## Ratios

	%	%	%	%	%	Long-term financial target in % ***)
Growth in operating profit	8.7	15.9	12.7	(1.9)	38.4	15%
Growth in operating profit excl AERx <sup>®</sup> ** <sup>)</sup>	-	-	-	12.6	23.7	
Growth in operating profit, three-year average	8.9	11.0	12.4	8.9	16.4	
Operating profit margin	24.0	24.0	23.5	21.4	27.2	25%
Operating profit margin excl AERx <sup>®</sup> ** <sup>)</sup>	-	-	-	24.5	27.9	
Return on invested capital (ROIC)	21.5	24.7	25.8	27.2	37.4	30%
Cash to earnings	85.3	82.4	73.0	105.7	114.2	
Cash to earnings, three-year average	59.0	82.4	80.2	87.0	97.6	70%
Net profit margin	17.3	17.4	16.7	20.4	21.2	
Equity ratio	70.8	65.9	67.4	67.4	65.2	

\*) Comparative sales figures from 2004 to 2006 have been adjusted in order to reflect a changed organisational structure from 1 January 2007 which transferred eight countries, incl Bulgaria and Romania, from International Operations to Europe.

\*\*\*) Excluding costs related to the discontinuation of pulmonary projects.
 \*\*\*) The long-term financial targets were updated in January 2009. See p 9.

Key figures are translated into EUR as supplementary information - the translation of income statement items is based on the average exchange rate in 2008 (EUR 1 = DKK 7.45593) and the translation of balance sheet items is based on the exchange rate at the end of 2008 (EUR 1 = DKK 7.45060).

### Economics

			2004	2005	2006	2007	2008
R&D	R&D expenditure to tangible investments *)	Ratio	1.5:1	1.4:1	2.3:1	3.2:1	4.3:1
	R&D as share of sales *)	%	15.0	15.1	16.3	3.2:1 17.2 32 81,600 5.9	16.5
Remuneration	Remuneration as share of cash received	%	34	34	33	32	31
Employment	Employment impact worldwide (direct and indirect)	Number of jobs	73,100	78,000	82,700	81,600	88,500
Corporate tax	Total corporate tax as share of sales	%	8.4	7.0	7.0	5.9	6.7
Exports	Novo Nordisk exports as share of Danish exports (estimated)	%	3.9	4.7	4.0	3.4	2.7

## Environment

Resources	Water consumption	1,000 m <sup>3</sup>	2,756	3,014	2,995	3,231	2,684
	Energy consumption	1,000 GJ	2,397	2,679	2,712	2,784	2,533
	Raw materials and packaging materials	1,000 tons	111	135	142	152	132
Wastewater	COD	Tons	1,448	1,303	1,000	813	891
	Nitrogen	Tons	121	126	107	107	95
	Phosphorus	Tons	21	22	19	107 14 17,576 38 236 72 81	15
Waste	Total waste	Tons	21,855	23,776	24,165	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	20,346
	Recycling percentage	%	40	33	35		51
Emissions to air	CO <sub>2</sub>	1,000 tons	210	228	229	236	215
	CO <sub>2</sub> emissions/sales in DKK (Index 2003 = 100)	Tons/Sales in DKK	92	86	75	72	60
	Organic solvents	Tons	115	124	102	81	93
EIR Water	Diabetes care	m <sup>3</sup> /MU	-	-	7.8	107 14 17,576 38 236 72 81 7.3 4.1 5.1 7.9	5.5
	Biopharmaceuticals	m <sup>3</sup> /g API	-	-	4.8	4.1	3.7
EIR Energy	Diabetes care	GJ/MU		-	5.5	5.1	4.0
	Biopharmaceuticals	GJ/g API	-	-	9.2	7.9	7.3
Compliance	Breaches of regulatory limit values	Number	74	174	123	22	28
	Accidental releases	Number	29	104	135	105	91

## Social

Living our values	Importance of social and environmental issues for the future						
	of the company **)	Scale 1-5	4.2	4.2	4.3	4.4	4.5

	Managers' behaviour consistent with Novo Nordisk's values ** <sup>)</sup>	Scale 1–5	4.0	4.0	4.1	4.2	4.3
	FulfIlment of action points from facilitations of the NNWoM	%	96	100	99	99	99
People	Employees (total)	Number	20,725	22,460	23,613	26,008	27,068
	Rate of absence	%	3.2	3.2	3.0	2.7	2.2
	Rate of employee turnover	%	7.3	8.0	10.0	11.6	12.1
	Engaging culture (employee engagement) **)	Scale 1-5	-	-	4.0	4.1	4.2
	Opportunity to use and develop competences/skills **)	Scale 1–5	3.8	3.8	3.9	4.0	4.1
	People from diverse backgrounds have equal opportunities $^{\star\star)}$	Scale 1–5	3.8	3.9	3.9	4.0	4.1
Health & safety	Frequency of occupational injuries	No/million work	5.6	7.3	6.2	5.9	5.4
	Fatalities	Number	1	0	0	0	0
Training costs	Annual training costs per employee	DKK	8,992	9,899	11,293	13,130	13,192
Access to health	LDCs where Novo Nordisk operates	Number	35	35	35	38	36
	LDCs where Novo Nordisk sells insulin at or below the policy price	Number	33	32	34	36	32
	Healthcare professionals trained or educated	1,000	-	-	297	336	380
	People with diabetes trained or treated	1,000	-	-	1,060	1,260	1,854
Patent families	Active patent families to date	Number	778	812	913	1,003	890
	New patent families (flrst flling)	Number	145	130	149	116	71
Animals	Animals purchased	Number	47,311	57,905	56,533	54,675	57,253

\*) R&D costs adjusted for costs related to discontinuation of all pulmonary diabetes projects. \*\*) On a scale of 1–5, with 5 being the highest. See the consolidated non-financial statements on pp 89–99.

Business results Pipeline progress

## Pipeline progress

Diabetes care

Biopharmaceuticals

In 2008, significant progress was made across Novo Nordisk's clinical development pipeline.

This overview illustrates key development activities: entries into the pipeline, progression of development compounds, exits from the pipeline and major regulatory approvals.

See more at novonordisk.com/investors/rd pipeline/rd pipeline.asp.

#### Phase 1

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

rFVIIa subcutaneous formulation (NN7720) (Haemophilia patients with inhibitors)

Novo Nordisk is conducting a phase 1 study investigating bioavailability of subcutaneous injections of innovative formulation technologies to increase convenience of administration for patients. The trial is expected to be completed in 2009.

Long-acting factor VIIa derivative (NN7128) (Haemophilia patients with inhibitors)

In 2008, Novo Nordisk completed a phase 1 study of its long-acting recombinant factor VIIa analogue involving 40 healthy males. The analogue is a potential next-generation derivative of NovoSeven<sup>®</sup> in the treatment of haemophilia patients with inhibitors. With its long duration of action, it is intended to enable prevention of bleeding for the patient. Novo Nordisk expects to initiate a phase 2 clinical trial in 2009.

rFXIII (NN1810) (Cardiac surgery)

In 2008, Novo Nordisk completed a phase 1 study of recombinant blood-clotting factor FXIII in patients undergoing cardiac surgery involving 43 patients and

#### Phase 2

Testing a drug at various dose levels in a larger group of patients to learn about its effect on the condition and its side effects.

## NN1250

(Type 1 and type 2 diabetes)

In 2008, Novo Nordisk completed a phase 2 programme for NN1250, a neutral, soluble, long-acting new generation of insulin with a flat and predictable profile, potentially providing more than 24-hour coverage by once-daily injection. Novo Nordisk expects to initiate phase 3 trials in the second half of 2009.

#### NN5401

(Type 1 and type 2 diabetes)

In 2008, Novo Nordisk completed a phase 2 programme for NN5401, a neutral, soluble, dual-acting new generation of insulin with improved properties and potential duration of action above 24 hours. Novo Nordisk expects to initiate phase 3 trials in the second half of 2009.

Once-weekly GLP-1 analogue (NN9535) (Type 2 diabetes)

Novo Nordisk is conducting a phase 2 clinical trial of a once-weekly GLP-1 human analogue, designed for people with type 2 diabetes. The phase 2 clinical trial

Sanofi Exhibit 2136.043 Mylan v. Sanofi IPR2018-01676 expects to initiate a phase 2 trial in 2009.

Anti-IL20

(Psoriatic arthritis and rheumatoid arthritis)

In 2008, Novo Nordisk initiated a phase 1 clinical study of anti-IL20, a monoclonal antibody neutralising the interleukin 20 protein. The clinical trial programme involves a study of about 80 patients with moderate-tosevere plaque psoriasis as well as a smaller combined phase 1 trial in healthy volunteers and patients with rheumatoid arthritis.

Anti-C5aR (Rheumatoid arthritis and systemic lupus erythematosus)

A phase 1 clinical study was initiated in 2008 for anti-C5aR, a monoclonal antibody blocking the C5a receptor. The study involved around 50 healthy volunteers. If successful, this will be followed by trials in patients with rheumatoid arthritis and systemic lupus erythematosus. completed in the first half of 2009.

involves more than 400 patients and is expected to be

**rFVIIa analogue (NN1731)** (Haemophilia patients with inhibitors)

Novo Nordisk is conducting a phase 2 trial of its fastacting recombinant analogue of rFVIIa involving about 75 haemophilia patients with inhibitors. The targeted and topicalised mode of action is expected to deliver predictable, fast and sustainable haemostasis. The trial is expected to be completed in 2009.

Once-weekly growth hormone (Growth hormone deficiency)

In 2008, Novo Nordisk moved its long-acting growth hormone compound into a phase 2 trial involving more than 30 adults. The product is intended to improve patient convenience by reducing the number of injections needed. The trial is expected to be completed in 2009.

Business results Pipeline progress

"Novo Nordisk will sustain its leadership in diabetes care by providing new treatments to achieve safe glycaemic control and weight benefits."

#### Mads Krogsgaard Thomsen Chief science officer

#### 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 establish its benefit-risk relationship.

#### Liraglutide (Obesity)

In 2008, Novo Nordisk moved its study for the use of liraglutide as an antiobesity treatment into phase 3. The phase 3 programme will include around 5,000 people and will focus on weight loss and delayed onset of type 2 diabetes, weight loss in subjects with type 2 diabetes and prevention of weight regain. Novo Nordisk expects to complete the programme in 2011.

## rFXIII (NN1841)

(Congenital rFXIII deficiency)

Novo Nordisk is developing a recombinant FXIII intended to treat congenital FXIII deficiency. FXIII is part of the coagulation cascade and functions by cross-linking fibrin to increase the stability of the clot, making it mechanically stronger and more rigid and elastic. The phase 3 trial involves 40 patients and is expected to be completed in 2009. **Filed/regulatory approval** A New Drug Application is submitted for review by various government regulatory agencies.

#### Liraglutide (Type 2 diabetes)

In 2008, Novo Nordisk applied for regulatory approval for liraglutide in the US, Europe and Japan among many other countries. Liraglutide is a long-acting human GLP-1 analogue. The clinical development programme involved around 6,200 patients. It is targeted as a treatment for type 2 diabetes as an adjunct to diet and exercise, both as monotherapy and in combination with commonly used antidiabetic medications.

**NovoMix<sup>®</sup> 50 and 70** (Type 1 and type 2 diabetes)

NovoMix<sup>®</sup> 50 and 70 are premixed formulations of the rapid-acting modern insulin aspart. The phase 3 programme involved around 1,500 patients with type 1 or type 2 diabetes. NovoMix<sup>®</sup> 50 and 70 have been launched in Europe and NovoMix<sup>®</sup> 50 is approved in the US. Phase 3 trials are under way in Japan.

PrandiMet<sup>®</sup> (Type 2 diabetes)

> Sanofi Exhibit 2136.045 Mylan v. Sanofi IPR2018-01676

A tablet formulation combining the short-acting insulin secretagogue repaglinide with the insulin-sensitising agent metformin in a single tablet. The clinical development programme for this combination regimen has involved more than 550 patients. PrandiMet<sup>®</sup> has been approved and launched in the US.

#### Activelle<sup>®</sup>/Eviana<sup>®</sup> low dose (Hormone replacement therapy)

The low-dose version of Activelle<sup>®</sup> (Activella<sup>®</sup> 0.5 mg/0.1 mg in the US) is a continuous-combined hormone replacement therapy intended for treatment of menopausal symptoms and as one of the treatment alternatives for osteoporosis prevention. In 2008, it was launched in the US and approved by EU regulatory authorities.

Vagifem<sup>®</sup> low dose (Hormone replacement therapy)

Vagifem<sup>®</sup> low dose is a topical product for vaginal appli cation. It was filed for approval in the EU in November 2008.

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Business environment Doing business the Novo Nordisk Way

# Doing business the Novo Nordisk Way

The Novo Nordisk Way of Management forms the values-based governance framework for the company. From vision to policies, it guides how people at Novo Nordisk put values into action and defines the principles for how the company does business.

The Novo Nordisk Way of Management describes the principles for how to work and behave as an employee of Novo Nordisk. It consists of three elements: the vision, the charter and a set of global policies.

This comprehensive framework was developed more than a decade ago to help grow a culture of empowerment and innovation, and it has proven to be a robust system.

#### Pursuing the vision

Novo Nordisk's aspiration is to be the world's leading diabetes care company and, ultimately, to defeat diabetes. This is the core business proposition, the essence of Novo Nordisk's contribution to sustainable development and the heart of the vision.

The vision sets Novo Nordisk's objectives in context and inspires people in their work. It serves to keep everyone's focus on creating long-term shareholder value and leveraging the company's unique qualities to gain competitive advantage.

#### Values in action

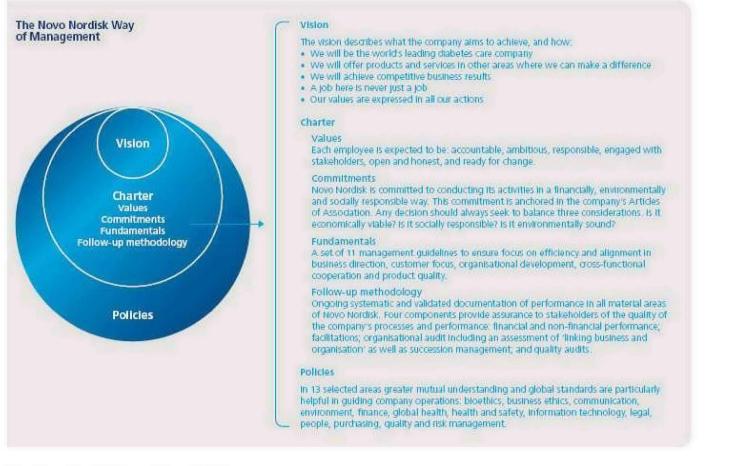
The charter includes the values, the commitment to corporate responsibil-

ity, expressed by the Triple Bottom Line, fundamental principles of management, as well as a follow-up methodology to ensure adherence to the principles across the organisation.

As part of the follow-up methodology Novo Nordisk has a global facilitator team consisting of senior people with deep insight into the business and the business environment. On a three-year basis, or more frequently, they measure the extent to which business units operate in compliance with the Novo Nordisk Way of Management.

The head of the facilitation group has a formal reporting line to the chairman of the Board.

Sanofi Exhibit 2136.047 Mylan v. Sanofi IPR2018-01676



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## Values drive performance

In today's interconnected economy the ability to manage the complexity of business and societal challenges helps ensure sustained growth. The Triple Bottom Line principle enables Novo Nordisk to balance corporate profitability with corporate responsibility, stay attuned to stakeholder concerns and exploit opportunities for innovative collaboration.

From one perspective, the financial downturn is likely to slow economic wealth creation and hamper equitable social development. From another, the current challenges may offer opportunities for alternative solutions that generate longterm value. Energy efficiency supports operational excellence and helps mitigate climate change, healthier lifestyles reduce costs for public healthcare systems and enhance people's quality of life, and costconsciousness sharpens focus on valueadding activities. The implications of the current global economic situation are yet to be seen, but history presents ample evidence that businesses that operate with a long-term view and a broad approach are more likely to be risk resilient and adaptable to change.

#### Earning trust

Novo Nordisk's values-based approach to doing business drives performance and enhances shareholder value. The Triple Bottom Line principle expresses Novo Nordisk's commitment to sustainable deve lopment and balanced growth and is



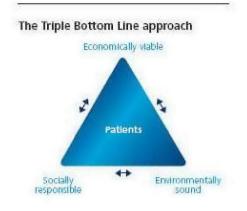
Novo Nordisk employee Jeppe Kjems took personal leave to travel across South America to help raise awareness and screen people for diabetes.

consistent with the principles of the United Nations Global Compact. Through this approach, the company seeks to build its business in a way that is financially, environmentally and socially responsible. Decision-making seeks to balance short-term gains with long-term profitability and shareholder return with other stakeholder interests.

In the current business environment

licence to operate and innovate. It helps build reputation and earn trust among stakeholders, attract talent and engage people, build customer loyalty and drive innovation. Ultimately, the commitment to pursue ambitious long-term targets for socially, environmentally and ethically responsible conduct strengthens the company's competitive position in its markets.

> Sanofi Exhibit 2136.049 Mylan v. Sanofi IPR2018-01676



there is more focus than ever on accountability and transparency. Renewed attention is given to risk management, and for the pharmaceutical industry reputational risk is of particular importance. Regulatory authorities, policy-makers, payers, patients and other stakeholder groups seek assurance that companies act with integrity and can demonstrate consistency of words and deeds.

The Triple Bottom Line plays a key role in earning and maintaining Novo Nordisk's This is why Novo Nordisk has chosen to account for the company's financial and non-financial performance in one, inclusive report. The intent is to enhance shareholders' valuation of the company and demonstrate accountability to other stakeholders.

See how Novo Nordisk defines materiality of sustainability-driven issues on p 89 and performance data for prioritised actions on pp 90–99.