# company announcement



Financial report for the period 1 January 2018 to 31 December 2018

1 February 2019

# Novo Nordisk's operating profit decreased by 4% in Danish kroner and increased by 3% in local currencies in 2018

# Operating profit increased by 6% measured in local currencies when adjusted for the cost of severance and the priority review voucher for oral semaglutide

Sales remained broadly unchanged in Danish kroner and increased by 5% in local currencies to DKK 111.8 billion.

- Sales of Victoza<sup>®</sup> increased by 5% to DKK 24.3 billion (9% in local currencies).
- Sales of Ozempic<sup>®</sup> were DKK 1,796 million and total GLP-1 sales increased by 13% (18% in local currencies).
- Sales of Saxenda<sup>®</sup> increased by 51% to DKK 3.9 billion (60% in local currencies).
- Sales of Tresiba<sup>®</sup> increased by 10% to DKK 8.0 billion (15% in local currencies).
- Sales in International Operations increased by 2% (7% in local currencies).
- Sales in North America Operations decreased by 2% (increased 3% in local currencies).
- Sales within diabetes and obesity increased by 1% to DKK 93.9 billion (6% in local currencies) and sales within biopharmaceuticals decreased by 5% to DKK 17.9 billion (1% in local currencies).

Operating profit decreased by 4% in Danish kroner and increased by 3% in local currencies to DKK 47.2 billion, impacted by the depreciation of the US dollar and related currencies versus the Danish krone. Adjusting for severance costs related to lay-offs in second half of 2018 and the expense related to the priority review voucher for the filing of oral semaglutide, operating profit increased by 6% in local currencies.

Net profit increased by 1% to DKK 38.6 billion and diluted earnings per share increased by 4% to DKK 15.93.

In February 2018, Novo Nordisk launched Ozempic<sup>®</sup>, a new once-weekly GLP-1, in the USA. The weekly new-tobrand prescription market share for Ozempic<sup>®</sup> has now reached 26% and thereby stabilising the total Novo Nordisk GLP-1 market share. Ozempic<sup>®</sup> has now been launched in 11 countries in Europe and North America.

In November 2018, Novo Nordisk completed the phase 3a PIONEER programme for oral semaglutide, a new oncedaily GLP-1 tablet for people with type 2 diabetes, following successful completion of the remaining two trials, PIONEER 6 and 9. Novo Nordisk has decided to submit the oral semaglutide file around the end of first quarter 2019 and has notified the US Food and Drug Administration (FDA) that Novo Nordisk will request priority review of the oral semaglutide filing based on a priority review voucher.

For 2019, sales growth is expected to be 2-5% measured in local currencies. This includes the previously communicated negative impact from the changes in the funding of the Medicare Part D coverage by approximately DKK 2 billion. Sales growth reported in Danish kroner is expected to be 2 percentage points higher than in local currencies. Operating profit growth is expected to be 2-6% measured in local currencies. Operating profit growth reported to be 4 percentage points higher than in local currencies.

The Board of Directors has adjusted the long-term financial target for OPAT/NOA from 125% to 80% to reflect the new accounting principles for handling of leases (IFRS 16) as well as the investment level in tangible and intangible assets. Further, to reflect the investment level, the cash to earnings target is adjusted from 90% to 85%. The long-term financial target for operating profit growth remains unchanged.

At the Annual General Meeting on 21 March 2019, the Board of Directors will propose a final dividend of DKK 5.15 for 2018 per share of DKK 0.20. The expected total dividend for 2018 of DKK 8.15 per share, of which DKK 3.00 per share was paid as interim dividend in August 2018, corresponds to an increase of 4% compared to 2017. The Board of Directors intends to initiate a new 12-month share repurchase programme of up to DKK 15 billion.

Lars Fruergaard Jørgensen, president and CEO: "2018 was a year of change and significant progress for Novo Nordisk. We delivered on our targets for sales and operating profit and have successfully launched Ozempic<sup>®</sup>, our new once-weekly GLP-1 for people with type 2 diabetes, in several countries. The results from the broad PIONEER phase 3a programme for oral semaglutide are very encouraging for people with type 2 diabetes, and we are now close to submitting oral semaglutide for FDA approval."

#### **About Novo Nordisk**

Novo Nordisk is a global healthcare company with more than 95 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat obesity, haemophilia, growth disorders and other serious chronic diseases. Headquartered in Denmark, Novo Nordisk employs approximately 43,200 people in 80 countries, and markets its products in more than 170 countries. Novo Nordisk's B shares are listed on Nasdaq Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn and YouTube.

#### **Conference call details**

On 1 February 2019 at 13.00 CET, corresponding to 7.00 am EST, a conference call will be held. Investors will be able to listen in via a link on novonordisk.com, which can be found under 'Investors'. Presentation material for the conference call will be available approximately one hour before on the same page.

## Webcast details

On 4 February 2019 at 13.30 CET, corresponding to 7.30 am EST, management will give a presentation to institutional investors and sell-side analysts in London. A webcast of the presentation can be followed via a link on novonordisk.com, which can be found under 'Investors'. Presentation material for the webcast will be made available on the same page.

#### Financial calendar

05 March 2019	Deadline for the company's receipts of shareholder proposals for the Annual General Meeting 2019
21 March 2019	Annual General Meeting 2019
03 May 2019	Financial statement for the first three months of 2019
09 August 2019	Financial statement for the first six months of 2019
01 November 2019	Financial statement for the first nine months of 2019

# **Contacts for further information**

<b>Media:</b> Katrine Sperling Ken Inchausti (USA)	+45 3079 6718 +1 609 240 9429	krsp@novonordisk.com kiau@novonordisk.com
Investors:		
Peter Hugreffe Ankersen	+45 3075 9085	phak@novonordisk.com
Anders Mikkelsen	+45 3079 4461	armk@novonordisk.com
Valdemar Borum Svarrer	+45 3079 0301	jvls@novonordisk.com
Kristoffer Due Berg	+45 3079 2849	krdb@novonordisk.com
Ann Søndermølle Rendbæk	+45 3075 2253	arnd@novonordisk.com

Further information about Novo Nordisk is available on novonordisk.com.

# LIST OF CONTENTS

FINANCIAL PERFORMANCE	4
Consolidated financial statement for 2018	4
Sales development	6
Diabetes and obesity, sales development	6
Biopharmaceuticals, sales development	9
Development in costs and operating profit	11
Financial items (net)	11
Capital expenditure and free cash flow	11
OUTLOOK	13
RESEARCH & DEVELOPMENT UPDATE	15
SUSTAINABILITY UPDATE	18
EQUITY	20
CORPORATE GOVERNANCE	21
LEGAL MATTERS	23
MANAGEMENT STATEMENT	25
FINANCIAL INFORMATION	26
Appendix 1: Quarterly numbers in DKK	26
Appendix 2: Income statement and statement of other comprehensive income	27
Appendix 3: Cash flow statement	28
Appendix 4: Balance sheet	29
Appendix 5: Equity statement	30
Appendix 6: Regional sales split	31
Appendix 7: Key currency assumptions	33
Appendix 8: New accounting standards in 2018	33
Appendix 9: Quarterly numbers in USD (additional information)	34
Appendix 10: Non-IFRS financial measures (additional information)	35

R&D

Sustainability

#### **FINANCIAL PERFORMANCE**

#### **CONSOLIDATED FINANCIAL STATEMENT FOR 2018**

The Board of Directors and Executive Management have approved the *Annual Report 2018* of Novo Nordisk A/S including the audited consolidated financial statements. The Board of Directors and Executive Management also approved this unaudited financial statement containing condensed financial information for 2018. This financial statement is prepared in accordance with the recognition and measurement requirements of the International Financial Reporting Standards (IFRS) as issued by IASB and IFRS as endorsed by the EU. The accounting policies used in this financial statement are consistent with those used in the audited consolidated financial statements in the *Annual Report 2018*.

2018	2017	2016	2015	2014	% change 2017 to 2018
444.004		444 700	407.007		
111,831	111,696	111,780	107,927	88,806	0%
94,214	94,064	94,597	91,739	74,244	0%
84.2%	84.2%	84.6%	85.0%	83.6%	
29,397	28,340	28,377	28,312	23,223	4%
26.3%	25.4%	25.4%	26.2%	26.2%	
14,805	14,014	14,563	13,608	13,762	6%
13.2%	12.5%	13.0%	12.6%	15.5%	
3,916	3,784	3,962	3,857	3,537	3%
3.5%	3.4%	3.5%	3.6%	4.0%	
1,152	1,041	737	3,482 1	770	11%
47,248	48,967	48,432	49,444	34,492	(4%)
42.2%	43.8%	43.3%	45.8%	38.8%	
367	(287)	(634)	(5,961)	(396)	N/A
47,615	48,680	47,798	43,483	34,096	(2%)
8,987	10,550	9,873	8,623	7,615	(15%)
18.9%	21.7%	20.7%	19.8%	22.3%	
38,628	38,130	37,925	34,860	26,481	1%
34.5%	34.1%	33.9%	32.3%	29.8%	
	111,831   94,214   84.2%   29,397   26.3%   14,805   13.2%   3,916   3.5%   1,152   47,248   42.2%   367   47,615   8,987   18.9%   38,628	111,831   111,696     94,214   94,064     84.2%   84.2%     29,397   28,340     26.3%   25.4%     14,805   14,014     13.2%   12.5%     3,916   3,784     3.5%   3.4%     1,152   1,041     47,248   48,967     42.2%   43.8%     367   (287)     47,615   48,680     8,987   10,550     18.9%   21.7%     38,628   38,130	111,831   111,696   111,780     94,214   94,064   94,597     84.2%   84.2%   84.6%     29,397   28,340   28,377     26.3%   25.4%   25.4%     14,805   14,014   14,563     13.2%   12.5%   13.0%     3,916   3,784   3,962     3.5%   3.4%   3.5%     1,152   1,041   737     47,248   48,967   48,432     42.2%   43.8%   43.3%     367   (287)   (634)     47,615   48,680   47,798     8,987   10,550   9,873     18.9%   21.7%   20.7%     38,628   38,130   37,925	111,831   111,696   111,780   107,927     94,214   94,064   94,597   91,739     84.2%   84.2%   84.6%   85.0%     29,397   28,340   28,377   28,312     26.3%   25.4%   25.4%   26.2%     14,805   14,014   14,563   13,608     13.2%   12.5%   13.0%   12.6%     3,916   3,784   3,962   3,857     3.5%   3.4%   3.5%   3.6%     1,152   1,041   737   3,482     47,248   48,967   48,432   49,444     42.2%   43.8%   43.3%   45.8%     367   (287)   (634)   (5,961)     47,615   48,680   47,798   43,483     8,987   10,550   9,873   8,623     18.9%   21.7%   20.7%   19.8%     38,628   38,130   37,925   34,860	111,831   111,696   111,780   107,927   88,806     94,214   94,064   94,597   91,739   74,244     84.2%   84.2%   84.6%   85.0%   83.6%     29,397   28,340   28,377   28,312   23,223     26.3%   25.4%   25.4%   26.2%   26.2%     14,805   14,014   14,563   13,608   13,762     13.2%   12.5%   13.0%   12.6%   15.5%     3,916   3,784   3,962   3,857   3,537     3,5%   3.4%   3.5%   3.6%   4.0%     1,152   1,041   737   3,482   770     47,248   48,967   48,432   49,444   34,492     42.2%   43.8%   43.3%   45.8%   38.8%     367   (287)   (634)   (5,961)   (396)     47,615   48,680   47,798   43,483   34,096     8,987   10,550   9,873   8,623   7,615

<sup>1)</sup> Other operating income, net for 2015 includes DKK 2,376 million for the partial divestment of associated company.

Financial Performance

R&D

Sustainability

# **CONSOLIDATED FINANCIAL STATEMENT FOR 2018 - CONTINUED**

OTHER KEY NUMBERS (Amounts are in DKK million, except for earnings per share and dividend per share)	2018	2017	2016	2015	2014	% change 2017 to 2018
Depreciation, amortisation and impairment losses <sup>1)</sup>	3,925	3,182	3,193	2,959	3,435	23%
Capital expenditure, net (PP&E)	9,524	8,679	7,061	5,209	3,986	10%
Net cash generated from operating activities	44,616	41,168	48,314	38,287	31,692	8%
Free cash flow	32,536	32,588	39,991	34,222	27,396	0%
Total assets	110,769	102,355	97,539	91,799	77,062	8%
Equity	51,839	49,815	45,269	46,969	40,294	4%
Equity ratio	46.8%	48.7%	46.4%	51.2%	52.3%	
Diluted earnings per share / ADR (in DKK)	15.93	15.39	14.96	13.52	10.07	4%
Total dividend per share (in DKK) <sup>2)</sup>	8.15	7.85	7.60	6.40	5.00	4%
Payout ratio <sup>3)</sup>	50.6%	50.4%	50.2%	46.6%	48.7%	

<sup>1)</sup> Including impairments of around DKK 480 million in 2014 related to discontinuation of activities within inflammatory disorders.

<sup>2)</sup> Total dividend for the financial year 2018 including proposed final dividend of DKK 5.15 per share and interim dividend paid in August 2018 of DKK 3.00 per share.

<sup>3)</sup> Total dividend for the year as a percentage of net profit.

#### PERFORMANCE AGAINST LONG-TERM FINANCIAL TARGETS

	2018	2017	2016	2015	2014	Target <sup>2)</sup>
Operating profit growth	(3.5%)	1.1%	(2.0%)	43.3%	9.5%	5%
Operating profit growth adjusted <sup>1)</sup>	(3.5%)	1.1%	3.9 %	35.2%	9.5%	
Operating profit growth adjusted in local currencies <sup>1)</sup>	2.8 %	4.8%	6.2 %	12.7%	12.7%	
Operating profit after tax to net operating assets	116.7 %	143.2%	150.2 %	148.7%	101.0%	125%
Cash to earnings	84.2 %	85.5%	105.4 %	98.2%	103.5%	
Cash to earnings (three-year average)	91.7 %	96.4%	102.4 %	96.8%	93.1%	90%

<sup>1)</sup> Growth in operating profit for 2015 and 2016 are adjusted for DKK 2,376 million for the partial divestment of associated company and DKK 449 million for the income related to the outlicensing of assets for inflammatory disorders, both in 2015.

<sup>2)</sup> Targets effective 31 December 2018. The long-term financial targets were adjusted in February 2019. Please refer to the outlook section.

R&D

Sustainability

#### SALES DEVELOPMENT

Sales remained unchanged in Danish kroner and increased by 5% in local currencies in 2018, reflecting a significant impact from the depreciation of the US dollar and related currencies versus the Danish krone. The sales growth is in line with the latest guidance of '4-5% sales growth measured in local currencies' provided in connection with the announcement in November 2018 for the first nine months of 2018. Sales growth in local currencies was realised within diabetes and obesity with the majority of growth originating from the GLP-1 diabetes products Victoza<sup>®</sup> and Ozempic<sup>®</sup>, the obesity product Saxenda<sup>®</sup>, as well as long-acting insulin Tresiba<sup>®</sup> and Xultophy<sup>®</sup>, partly offset by declining sales of Levemir<sup>®</sup> and NovoRapid<sup>®</sup>. Declining sales within biopharmaceuticals were driven by NovoSeven<sup>®</sup> and 'Other biopharmaceuticals', partly offset by increased sales of NovoEight<sup>®</sup> and Norditropin<sup>®</sup>.

Sales split per therapy The diabetes and obesity segment	Sales 2018 DKK million	Sales 2017 DKK million	Growth as reported	<b>Growth</b> in local currencies	Share of growth in local currencies
Long-acting insulin	20,844	22,174	(6%)	(2%)	(7%)
- Tresiba®	8,035	7,327	10%	15%	21%
- Xultophy®	1,614	729	121%	126%	18%
- Levemir <sup>®</sup>	11,195	14,118	(21%)	(17%)	(46%)
Premix insulin	10,194	10,749	(5%)	0%	0%
- Ryzodeg®	714	492	45%	54%	6%
- NovoMix®	9,480	10,257	(8%)	(3%)	(6%)
Fast-acting insulin	19,353	20,124	(4%)	1%	3%
- Fiasp <sup>®</sup>	590	99	-	-	10%
- NovoRapid®	18,763	20,025	(6%)	(2%)	(7%)
Human insulin	9,265	9,793	(5%)	(1%)	(3%)
Total insulin	59,656	62,840	(5%)	(1%)	(7%)
Victoza®	24,333	23,173	5%	9%	42%
Ozempic <sup>®</sup>	1,796	-	-	-	36%
Total GLP-1	26,129	23,173	13%	18%	78%
Other diabetes <sup>1)</sup>	4,250	4,302	(1%)	3%	2%
Total diabetes	90,035	90,315	0%	4%	73%
Obesity (Saxenda®)	3,869	2,562	51%	60%	30%
Diabetes and obesity total	93,904	92,877	1%	6%	103%
The biopharmaceuticals segment					
Haemophilia <sup>2)</sup>	9,576	10,469	(9%)	(5%)	(10%)
- NovoSeven®	7,881	9,206	(14%)	(11%)	(19%)
- NovoEight®	1,354	1,103	23%	26%	5%
Growth disorders (Norditropin®)	6,834	6,655	3%	7%	9%
Other biopharmaceuticals <sup>3)</sup>	1,517	1,695	(11%)	(8%)	(2%)
Biopharmaceuticals total	17,927	18,819	(5%)	(1%)	(3%)
Total sales	111,831	111,696	0%	5%	100%

<sup>1)</sup> Primarily oral antidiabetic products, needles and GlucaGen<sup>®</sup> HypoKit<sup>®</sup>.

<sup>2)</sup> Comprises NovoSeven<sup>®</sup>, NovoEight<sup>®</sup>, NovoThirteen<sup>®</sup> and Refixia<sup>®</sup>.

<sup>3)</sup> Primarily Vagifem<sup>®</sup> and Activelle<sup>®</sup>.

International Operations was the main driver of sales growth and sales increased by 2% measured in Danish kroner and by 7% in local currencies. Sales in North America Operations decreased by 2% measured in Danish kroner and increased by 3% in local currencies.

Financial Performance

Outlook

R&D

Sustainability

Equity

Corporate

Legal

Sales split per region	Sales 2018 DKK million	<b>Growth</b> as reported	<b>Growth</b> in local currencies	Share of growth in local currencies
North America Operations	56,908	(2%)	3%	29%
- USA	54,488	(2%)	2%	22%
International Operations	54,923	2%	7%	71%
- Region Europe	21,679	2%	3%	11%
- Region AAMEO	12,153	1%	11%	26%
- Region China	11,285	5%	8%	16%
- Region Japan & Korea	5,797	(5%)	(2%)	(2%)
- Region Latin America	4,009	8%	29%	20%
Total sales	111,831	0%	5%	100%

Please refer to appendix 6 for further details on sales in 2018.

In the following sections, unless otherwise noted, market data are based on moving annual total (MAT) from November 2018 and November 2017 provided by the independent data provider IQVIA.

#### DIABETES AND OBESITY, SALES DEVELOPMENT

Sales of diabetes and obesity products increased by 1% measured in Danish kroner and by 6% in local currencies to DKK 93,904 million. Novo Nordisk is the world leader in diabetes care with a global value market share of 27.9% compared with 27.4% in 2017.

#### Insulin

Sales of insulin decreased by 5% measured in Danish kroner and by 1% in local currencies to DKK 59,656 million. The decline in sales measured in local currencies was driven by North America Operations declining by 7% driven by lower prices, partly offset by International Operations increasing sales with 5%, where all regions apart from Region Japan & Korea contributed to growth. Novo Nordisk is the global leader with 46.4% of the total insulin market and 45.2% of the market for modern insulin and new-generation insulin, both measured in volume.

Sales of long-acting insulin (Tresiba<sup>®</sup>, Xultophy<sup>®</sup> and Levemir<sup>®</sup>) decreased by 6% measured in Danish kroner and by 2% in local currencies to DKK 20,844 million.

Sales of Tresiba<sup>®</sup> (insulin degludec), the once-daily new-generation insulin, reached DKK 8,035 million compared with DKK 7,327 million in 2017. Tresiba<sup>®</sup> has now been launched in 76 countries.

Sales of Xultophy<sup>®</sup>, a once-daily combination of insulin degludec (Tresiba<sup>®</sup>) and liraglutide (Victoza<sup>®</sup>), reached DKK 1,614 million compared with DKK 729 million in 2017. Sales growth was driven by both International Operations, where predominantly Region Europe contributed to growth, and North America Operations. Xultophy<sup>®</sup> has now been launched in 26 countries.

Sales of premix insulin (Ryzodeg<sup>®</sup> and NovoMix<sup>®</sup>) decreased by 5% measured in Danish kroner and remained unchanged in local currencies to DKK 10,194 million.

Sales of Ryzodeg<sup>®</sup>, a soluble formulation of insulin degludec and insulin aspart, reached DKK 714 million compared with DKK 492 million in 2017. Ryzodeg<sup>®</sup> has now been launched in 27 countries.

Sales of fast-acting insulin (Fiasp<sup>®</sup> and NovoRapid<sup>®</sup>) decreased by 4% measured in Danish kroner and increased by 1% in local currencies to DKK 19,353 million.

Sales of Fiasp<sup>®</sup>, the novel mealtime fast-acting insulin aspart, reached DKK 590 million. Fiasp<sup>®</sup> has now been launched in 25 countries.

R&D

Sustainability

Equity

Corpor governa

INSULIN MARKET SHARES (volume, MAT)		disk's share nsulin market	Novo Nordisk's share of the modern insulin and new-generation insulin market*		
	November 2018	November 2017	November 2018	November 2017	
Global	46.4%	45.9%	45.2%	44.8%	
North America Operations	40.0%	38.8%	41.1%	39.6%	
- USA	40.4%	39.0%	41.8%	40.2%	
International Operations	49.1%	48.9%	47.4%	47.6%	
- Region Europe	43.5%	44.1%	43.3%	43.8%	
- Region AAMEO**	57.0%	55.5%	50.7%	50.7%	
- Region China***	50.8%	52.9%	59.8%	61.0%	
- Region Japan & Korea	50.3%	49.6%	50.3%	49.3%	
- Region Latin America****	46.1%	42.2%	37.4%	39.2%	

Source: IQVIA, November 2018 data. \* Modern insulin and new-generation insulin comprises the following Novo Nordisk products: Levemir<sup>®</sup>, NovoRapid<sup>®</sup>, Tresiba<sup>®</sup>, Xultophy<sup>®</sup>, Ryzodeg<sup>®</sup> and Fiasp<sup>®</sup> \*\* Data available for 11 private markets representing approximately 70% of total Novo Nordisk's diabetes sales in the region. \*\*\* Data for mainland China, excluding Hong Kong and Taiwan. \*\*\*\* Data available for three private markets representing approximately 70% of total Novo Nordisk's diabetes sales in the region.

#### North America Operations

Sales of insulin in North America Operations decreased by 11% measured in Danish kroner and by 7% in local currencies. The decline in sales in the USA was driven by Levemir<sup>®</sup> and NovoLog<sup>®</sup> and lower realised prices partly offset by higher sales of the new-generation insulin Xultophy<sup>®</sup> 100/3.6 and Tresiba<sup>®</sup> following a net market share gain of approximately 5 percentage points in the basal insulin segment and underlying volume growth. The sales decline in the USA in the short-acting insulin segment was driven by lower realised prices for NovoLog<sup>®</sup>.

#### International Operations

Sales of insulin in International Operations remained unchanged in Danish kroner and increased by 5% in local currencies. Sales growth measured in local currencies was driven by long-acting, premix and fast-acting insulin, partly offset by declining human insulin sales.

#### Region Europe

Sales of insulin in Region Europe increased by 2% in both Danish kroner and local currencies. Sales were driven by the penetration of Xultophy<sup>®</sup>, Tresiba<sup>®</sup> and Fiasp<sup>®</sup> across the region, partly offset by contracting Levemir<sup>®</sup> sales reflecting the continued roll-out of Tresiba<sup>®</sup>, as well as declining NovoMix<sup>®</sup> and human insulin sales.

#### Region AAMEO

Sales of insulin in Region AAMEO increased by 1% measured in Danish kroner and by 11% in local currencies. The sales growth measured in local currencies was driven by growth of the overall diabetes market and market share gains as well as a positive contribution from all three insulin segments: long-acting, premix and fast-acting as well as human insulin.

#### **Region China**

Sales of insulin in Region China increased by 3% measured in Danish kroner and by 6% in local currencies. The sales growth measured in local currencies was driven by continued growth in the three insulin segments: long-acting, premix and fast-acting, reflecting solid underlying volume growth, partly offset by lower human insulin sales.

#### Region Japan & Korea

Sales of insulin in Region Japan & Korea decreased by 10% measured in Danish kroner and by 7% in local currencies. The decline in sales was driven by NovoMix<sup>®</sup> and NovoRapid<sup>®</sup>, as both products reached the 15-year price protection limit 1 April 2018, leading to significant mandatory price reductions as well as lower human insulin sales, partly offset by positive contribution from market share gains for Ryzodeg<sup>®</sup> and Tresiba<sup>®</sup> in Japan.

Financial Performance

Outlook

Sustainability

R&D

Equity

Corporate

Legal

# Region Latin America

Sales of insulin in Region Latin America decreased by 8% measured in Danish kroner and increased by 13% in local currencies. The sales growth measured in local currencies was driven by growth of the overall diabetes market, inflationary price effects and positive volume contribution from all three insulin segments: long-acting, premix and fast-acting.

# **GLP-1** therapy for type 2 diabetes

Sales of GLP-1 products for type 2 diabetes (Victoza<sup>®</sup> and Ozempic<sup>®</sup>) increased by 13% measured in Danish kroner and by 18% in local currencies to DKK 26,129 million. Ozempic<sup>®</sup> has now been marketed in 11 countries in North America Operations and Region Europe and initial feedback is encouraging. Sales growth is predominantly driven by North America Operations comprising 81% share of the GLP-1 growth. The GLP-1 segment's value share of the total diabetes market has increased to 14.5% compared with 11.8% 12 months ago. Novo Nordisk continues to be the market leader in the GLP-1 segment with a 46% value market share.

GLP-1 MARKET SHARES (value, MAT)		re of total s market	Novo Nordisk's share of the diabetes GLP-1 market*		
	November 2018	November 2017	November 2018	November 2017	
Global	14.5%	11.8%	46%	50%	
North America Operations	17.1%	13.9%	45%	48%	
- USA	17.3%	14.1%	45%	48%	
International Operations	7.7%	6.6%	52%	56%	
- Region Europe	11.9%	10.5%	55%	58%	
- Region AAMEO**	3.2%	2.7%	43%	48%	
- Region China***	1.3%	0.9%	87%	68%	
- Region Japan & Korea	5.9%	4.6%	33%	41%	
- Region Latin America****	6.2%	5.2%	68%	75%	

Source: IQVIA, November 2018 data MAT. \* Novo Nordisk's GLP-1 diabetes products comprise Victoza<sup>®</sup> and Ozempic<sup>®</sup> \*\* Data for 11 selected private markets representing approximately 70% of Novo Nordisk's total diabetes sales in the region. \*\*\* Data for mainland China, excluding Hong Kong and Taiwan. \*\*\*\* Data for three selected private markets representing approximately 70% of Novo Nordisk's total diabetes sales in the region.

# North America Operations

Sales of Novo Nordisk's GLP-1 diabetes products (Victoza<sup>®</sup> and Ozempic<sup>®</sup>) in North America Operations increased by 14% measured in Danish kroner and by 19% in local currencies. Sales growth is driven by an underlying prescription volume growth of the GLP-1 class of more than 25%, driven by the launch of Ozempic<sup>®</sup> and a competitive once-weekly GLP-1, and Novo Nordisk is the market leader with a 45% value market share. The value share of the GLP-1 class of the total North American diabetes market has increased to 17.1%.

In February 2018, Novo Nordisk launched Ozempic<sup>®</sup> in the USA, a new once-weekly GLP-1, and broad formulary coverage has been obtained. The weekly new-to-brand prescription market share for Ozempic<sup>®</sup> has now reached 26% and thereby stabilising the total Novo Nordisk market share. Sales of Victoza<sup>®</sup> increased by 4% measured in Danish kroner and by 8% in local currencies. Sales growth of Victoza<sup>®</sup> is driven by the positive impact from the updated label for Victoza<sup>®</sup> reflecting cardiovascular benefits and the overall growth of the GLP-1 class, partly offset by the continued competition from a once-weekly product and the impact from the launch of Ozempic<sup>®</sup>.

# International Operations

Sales of Victoza<sup>®</sup> in International Operations increased by 9% measured in Danish kroner and by 13% in local currencies. Sales growth is driven by all regions. The value share of the GLP-1 class of the total diabetes market has increased to 7.7% from 6.6% in 2017. Novo Nordisk is the market leader with a 52% value market share.

# Region Europe

Sales in Region Europe increased by 9% in both Danish kroner and local currencies. The sales development reflects positive impact from the expanded CV label for Victoza<sup>®</sup>, partly offset by competition from a once-weekly product. In Region Europe, the value share of the GLP-1 class of the total diabetes market has increased to 11.9%. Novo Nordisk remains the market leader in Region Europe with a 55% value market share.

Financial Performance

Outlook

R&D

Sustainability

Equity

orporate

Legal

# Region AAMEO

Sales in Region AAMEO decreased by 2% measured in Danish kroner and increased by 6% in local currencies. Sales growth measured in local currencies is primarily driven by a number of countries in the Middle East. The value share of the GLP-1 class of the total diabetes market increased to 3.2%. Novo Nordisk remains the GLP-1 market leader across Region AAMEO with a value market share of 43%.

# **Region China**

Sales in Region China increased by 69% measured in Danish kroner and by 73% in local currencies. The increase in sales reflects the inclusion of Victoza<sup>®</sup> in the Chinese National Reimbursement Drug List in July 2017. In China, Victoza<sup>®</sup> has increased its GLP-1 value market share to 87% and accelerated the growth of the GLP-1 class, which now represents 1.3% of the total diabetes market measured in value.

# Region Japan & Korea

Sales in Region Japan & Korea increased by 4% measured in Danish kroner and by 7% in local currencies. The sales growth reflects the continued expansion of the GLP-1 market in Japan, partly offset by intensified competition from a once-weekly product. In Region Japan & Korea, the GLP-1 class represents 5.9% of the total diabetes market value compared with 4.6% in 2017. Novo Nordisk currently holds a value market share of 33%.

# Region Latin America

Sales in Region Latin America increased by 9% measured in Danish kroner and by 27% in local currencies. The sales growth reflects the continued expansion of the GLP-1 markets across the region. In Region Latin America, the GLP-1 class represents 6.2% of the total diabetes market value compared with 5.2% in 2017. Novo Nordisk remains the leader in the class with a value market share of 68%.

# Other diabetes

Sales of other diabetes products, predominantly consisting of oral antidiabetic products, needles and GlucaGen<sup>®</sup>HypoKit<sup>®</sup>, decreased by 1% measured in Danish kroner and increased by 3% in local currencies to DKK 4,250 million. Increasing sales measured in local currencies were seen in International Operations, where Region Latin America and Region China contributed to sales growth.

# Saxenda® (obesity)

Sales of Saxenda<sup>®</sup>, liraglutide 3 mg for weight management, increased by 51% measured in Danish kroner and by 60% in local currencies to DKK 3,869 million. Sales growth was driven by both North America Operations and International Operations, where Region AAMEO, Region Latin America, Region Europe and Region Japan & Korea contributed to growth. In the USA, Saxenda<sup>®</sup> has obtained broad commercial formulary market access, but generally with prior authorisation requirements. Saxenda<sup>®</sup> has now been launched in 41 countries.

# **BIOPHARMACEUTICALS, SALES DEVELOPMENT**

Sales of biopharmaceutical products decreased by 5% measured in Danish kroner and by 1% in local currencies to DKK 17,927 million. Decreasing sales measured in local currencies were realised in North America Operations, partly offset by increasing sales in International Operations.

# Haemophilia

Sales of haemophilia products decreased by 9% measured in Danish kroner and by 5% in local currencies to DKK 9,576 million. The sales decrease was primarily driven by lower NovoSeven<sup>®</sup> sales in the USA and Region Europe reflecting increased competition from a recently introduced product as well as increased clinical trial activity from competing products, partly offset by increased NovoSeven<sup>®</sup> sales in Region Latin America due to timing of tender deliveries. Furthermore, sales of NovoEight<sup>®</sup> in Region Europe and Region AAMEO contributed positively to the sales development as well as Refixia<sup>®</sup>, the long-acting factor IX product for people with haemophilia B, which now has been launched in 12 countries.

# Growth disorders (Norditropin®)

Sales of growth disorder products increased by 3% measured in Danish kroner and by 7% in local currencies to DKK 6,834 million. The sales growth measured in local currencies was driven by positive contribution from both North America Operations and International Operations. Novo Nordisk is the leading company in the global human growth disorder market with a 26% market share measured in volume.

Financial Performance

Outlook

R&D

Sustainability

Equity

rporate renance Legal

### DEVELOPMENT IN COSTS AND OPERATING PROFIT

The cost of goods sold was broadly unchanged compared to 2017 at DKK 17,617 million, resulting in a gross margin of 84.2% measured in Danish kroner, compared with 84.2% in 2017. The unchanged gross margin reflects a negative currency impact of 0.2 percentage point. The gross margin was positively impacted by improved productivity and positive contribution from product mix due to higher Victoza<sup>®</sup>, Tresiba<sup>®</sup> and Saxenda<sup>®</sup> sales, partly countered by lower contribution from NovoSeven<sup>®</sup>. The gross margin was negatively impacted by lower prices primarily related to the basal insulin segment in the USA.

Sales and distribution costs increased by 4% in Danish kroner and by 7% in local currencies to DKK 29,397 million. The increase in sales and distribution costs reflects higher promotional activities in both North America Operations and International Operations to support Victoza<sup>®</sup> and Saxenda<sup>®</sup> as well as launch activities for Ozempic<sup>®</sup> and severance costs related to lay-offs in the commercial organisation, partly offset by lower costs for legal cases.

Research and development costs increased by 6% in Danish kroner and by 8% in local currencies to DKK 14,805 million, reflecting higher costs for both research and development. The increase in research costs was driven by increased costs for the diabetes portfolio and costs related to 'other serious chronic diseases'. The increase in development costs was predominantly driven by the expense of the priority review voucher for oral semaglutide, injectable semaglutide in obesity for the STEP and SELECT programmes, partly offset by wind-down of the PIONEER programme. Research and development costs were also impacted by severance-related costs.

Administration costs increased by 3% in Danish kroner and increased by 7% in local currencies to DKK 3,916 million impacted by severance-related costs.

Other operating income (net) was DKK 1,152 million compared with DKK 1,041 million in 2017. In 2018, Novo Nordisk received milestone payments from partners related to out-licensed clinical assets, and Novo Nordisk recorded a net gain of DKK 122 million following the disposal of 2 million shares in NNIT to Novo Holdings A/S.

Operating profit decreased by 4% in Danish kroner and increased by 3% in local currencies to DKK 47,248 million, which is in line with the latest guidance for operating profit growth measured in local currencies of '2% to 5%' in 2018. The development in operating profit growth reflects the depreciation of the US dollar and related currencies versus the Danish krone as well as costs related to lay-offs in second half of 2018. Adjusting for severance costs and the priority review voucher, operating profit increased by 6% in local currencies.

# FINANCIAL ITEMS (NET) AND TAX

Financial items (net) showed a net gain of DKK 367 million compared with a net loss of DKK 287 million in 2017. The reported net financial item in 2018 is broadly in line with the latest guidance of 'gain of around DKK 0.5 billion'.

In line with Novo Nordisk's treasury policy, the most significant foreign exchange risks for the Group have been hedged, primarily through foreign exchange forward contracts. The foreign exchange result was a gain of DKK 298 million compared with a loss of DKK 187 million in 2017. This development reflects a gain on foreign exchange hedging involving especially the US dollar versus the Danish krone, partly offset by a net loss from non-hedged currencies.

A negative market value of financial contracts as per the end of December 2018 of approximately DKK 1.7 billion has been deferred for recognition in 2019.

The effective tax rate for 2018 was 18.9%, which is broadly in line with the latest guidance of a tax rate of '19% to 20%' for the full year 2018. The effective tax rate is positively impacted by non-recurring change in tax provisions related to settlement of international tax cases covering multiple years.

# CAPITAL EXPENDITURE AND FREE CASH FLOW

i

Net capital expenditure for property, plant and equipment was DKK 9.5 billion compared with DKK 8.7 billion in 2017, which is in line with the latest guidance of 'around DKK 9.5 billion'. Net capital expenditure was primarily related to investments in a new production facility for a range of diabetes active pharmaceutical ingredients in Clayton, North Carolina, USA, a new diabetes filling capacity in Hillerød, Denmark and an expansion of the manufacturing capacity for biopharmaceutical products in Kalundborg, Denmark.

Financial Performance	Outlook	R&D	Sustainability	Equity	Corp gover
--------------------------	---------	-----	----------------	--------	---------------

Legal

Financial

Information

Free cash flow was DKK 32.5 billion compared with DKK 32.6 billion in 2017, which is in line with the latest guidance of 'DKK 29-33 billion'. The broadly unchanged free cash flow compared with 2017 primarily reflects increased capital expenditure, increased investment in intangible assets reflecting an acquisition of a priority review voucher for oral semaglutide and higher tax payments partly offset by the timing of rebate payments in the USA and higher net profit.

#### **KEY DEVELOPMENTS IN THE FOURTH QUARTER OF 2018**

Please refer to appendix 1 for an overview of the quarterly numbers in DKK and to appendix 6 for details on sales in the fourth quarter of 2018.

Sales in the fourth quarter of 2018 increased by 6% in both Danish kroner and local currencies compared with the same period in 2017. The growth was driven by Ozempic<sup>®</sup>, Saxenda<sup>®</sup>, Tresiba<sup>®</sup>, NovoRapid<sup>®</sup>, Xultophy<sup>®</sup> and Fiasp<sup>®</sup>, partly offset by Levemir<sup>®</sup>, NovoSeven<sup>®</sup> and NovoMix<sup>®</sup>. Sales growth measured in local currencies in North America Operations of 7% was positively impacted by phasing of rebates in fourth quarter of 2017. Sales growth measured in local currencies in International Operations of 4% was partly impacted by timing of shipments in Region AAMEO and Region Latin America.

The gross margin was 84.4% in the fourth quarter of 2018 compared with 83.2% in the same period last year. The increase of 1.2 percentage point of the gross margin reflects a positive currency impact of 1.2 percentage point. The gross margin was positively impacted by improved productivity and positive contribution from product mix due to higher Tresiba<sup>®</sup>, Saxenda<sup>®</sup> and Ozempic<sup>®</sup> sales, partly countered by lower contribution from NovoSeven<sup>®</sup>. The gross margin was negatively impacted by lower prices primarily within the basal insulin segment in the USA.

Sales and distribution costs increased by 5% in Danish kroner and by 2% in local currencies compared with the same period in 2017, reflecting higher promotional costs in both operating units and severance costs related to lay-offs across the commercial organisations. In North America Operations, the increase in costs reflected promotional activities for the launch of Ozempic<sup>®</sup> as well as Tresiba<sup>®</sup> promotion. In International Operations, growth in costs was mainly in Region China, Region Europe and Region Latin America related to promotional activities for the GLP-1 product portfolio.

Research and development costs increased by 14% in Danish kroner and by 16% in local currencies compared with the same period in 2017. The increase in research and development costs reflects the expense of the priority review voucher for oral semaglutide. There was an underlying decline in development costs for oral semaglutide due to the finalisation of the PIONEER trials and lower costs for the development of Ozempic<sup>®</sup> and Fiasp<sup>®</sup>, partly offset by increased costs for injectable semaglutide in obesity.

Administrative costs increased by 14% in Danish kroner and by 15% in local currencies compared with the same period in 2017, mainly related to severance costs for lay-offs and higher spend across the regions.

Other operating income (net) was DKK 245 million in the fourth quarter of 2018 compared with DKK 151 million in the same period last year.

Operating profit increased by 7% in Danish kroner and by 4% in local currencies compared with the same period in 2017. Adjusting for severance-related costs and the priority review voucher, operating profit increased by 15% in local currencies.

R&D

Sustainability

### OUTLOOK

### OUTLOOK 2019

The current expectations for 2019 are summarised in the table below:

Expectations are as reported, if not otherwise stated	Expectations 1 February 2019
Sales growth in local currencies	2% to 5%
as reported	Around 2 percentage points higher than in local currencies
Operating profit growth	
in local currencies	2% to 6%
as reported	Around 4 percentage points higher than in local currencies
Financial items (net)	Loss of around DKK 2.4 billion
Effective tax rate	20% to 22%
Capital expenditure (PP&E)	Around DKK 9 billion
Depreciation, amortisation and impairment losses	Around DKK 4.5 billion
Free cash flow	DKK 29-34 billion

For 2019, **sales growth** is expected to be 2% to 5%, measured in local currencies. This guidance reflects expectations for robust performance for the GLP-1-based diabetes products Victoza<sup>®</sup> and Ozempic<sup>®</sup> and the obesity product Saxenda<sup>®</sup> as well as the portfolio of new-generation insulin. The guidance also reflects intensifying global competition both within diabetes and biopharmaceuticals, especially within the haemophilia inhibitor segment. Furthermore, continued pricing pressure within diabetes is expected, especially in the USA. This includes the previously communicated funding of the Medicare Part D coverage gap, which has been changed based on new legislation with effect from 2019 and with an expected negative impact of approximately DKK 2 billion. Given the current exchange rates versus the Danish krone, growth reported in DKK is expected to be around 2 percentage points higher than in local currencies.

For 2019, **operating profit growth** is expected to be 2% to 6%, measured in local currencies. The expectation for operating profit growth primarily reflects the sales growth outlook and continued focus on cost control. Operating profit growth is negatively impacted due to the changes in the funding of the coverage gap. Furthermore, growth in operating profit is positively impacted by the costs for the priority review voucher, which was expensed in fourth quarter of 2018. Given the current exchange rates versus the Danish krone, growth reported in DKK is expected to be around 4 percentage points higher than in local currencies.

For 2019, Novo Nordisk expects **financial items (net)** to amount to a loss of around DKK 2.4 billion, offsetting the positive currency impact on operating profit. The current expectation for 2019 reflects losses associated with foreign exchange hedging contracts, mainly related to the US dollar versus the Danish krone and losses on non-hedged currencies.

The **effective tax rate** for 2019 is expected to be in the range of 20-22%.

**Capital expenditure** is expected to be around DKK 9 billion in 2019, primarily related to investments in additional capacity for active pharmaceutical ingredient production within diabetes and an expansion of the diabetes filling capacity. **Depreciation, amortisation and impairment losses** are expected to be around DKK 4.5 billion. The increased level of depreciation, amortisation and impairment losses in 2019 reflects the inclusion of amortisation of lease assets following the introduction of IFRS 16. **Free cash flow** is expected to be DKK 29-34 billion.

All of the above expectations are based on assumptions that the global economic and political environment will not significantly change business conditions for Novo Nordisk during 2019 including the potential implications from Brexit, major healthcare reforms, and the currency exchange rates, especially the US dollar, will remain at the current level versus the Danish krone. Neither does the guidance include the financial implications in case of a significant bolt-on acquisition during 2019. Please refer to appendix 7 for key currency assumptions.

Financial Performance Outlook

R&D

Sustainability

Equity



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

Key invoicing currencies	<b>Impact on Novo Nordisk's</b> operating profit in the next 12 months of a 5% immediate movement in currency	Hedging period (months)
USD	DKK 2,000 million	11
CNY	DKK 350 million	7*
JPY	DKK 160 million	12
GBP	DKK 85 million	10
CAD	DKK 90 million	10

\* Chinese yuan traded offshore (CNH) used as proxy when hedging Novo Nordisk's CNY currency exposure

The financial impact from foreign exchange hedging is included in Financial items (net).

# LONG-TERM FINANCIAL TARGETS

Novo Nordisk introduced four long-term financial targets in 1996 to balance short- and long-term considerations, thereby ensuring a focus on shareholder value creation. The targets were subsequently revised and updated on several occasions most recently in connection with the report for the first nine months of 2016 released in October 2016. The long-term financial targets are meant to provide the company's shareholders with a view of Novo Nordisk's general financial aspirations over an undefined period of time. Hence, the long-term financial targets are not a projection of Novo Nordisk's financial outlook or expected growth, nor do they relate to any single year.

The target level for operating profit after tax (OPAT) to net operating assets (NOA) is adjusted from 125% to 80%. The adjusted target reflects the changes to accounting principles for leases (IFRS 16) as of 1 January 2019 and the investment level in both tangible and intangible assets.

The target level for cash to earnings (three-year average) is adjusted from 90% to 85%. The adjusted target reflects the investment level in both tangible and intangible assets. Given the inherent volatility in this ratio, the target will be pursued looking at the average over a three-year period.

The target for 'operating profit growth' remains unchanged.

The long-term financial targets have been prepared based on the assumption of a continuation of the current business environment. Significant changes to the business environment, including the structure of the US healthcare system, regulatory requirements, pricing and market access environment, competitive environment, healthcare reforms, the financial implications in case of a significant bolt-on acquisition, exchange rates and changes to accounting standards may significantly impact the time horizon for achieving the long-term financial targets or require them to be revised.

LONG-TERM FINANCIAL TARGETS	Previous target	Adjusted target
Operating profit growth	5%	5%
Operating profit after tax to net operating assets	125%	80%
Cash to earnings (three-year average)	90%	85%

R&D

Sustainability

# **RESEARCH & DEVELOPMENT UPDATE**

#### Diabetes

# Oral semaglutide (NN9924) demonstrates greater reductions in both HbA<sub>1c</sub> and body weight compared to Victoza<sup>®</sup> in Japanese people with type 2 diabetes in the PIONEER 9 trial

In November 2018, Novo Nordisk announced the headline results from PIONEER 9, a 52-week trial with oral semaglutide vs Victoza<sup>®</sup> (0.9 mg liraglutide) and vs placebo, all as monotherapy, in Japanese adults with type 2 diabetes. Oral semaglutide is an investigational GLP-1 analogue taken once daily as a tablet. PIONEER 9 was a phase 3a safety and efficacy trial investigating 3, 7 and 14 mg oral semaglutide compared with Victoza<sup>®</sup> and with placebo in 243 Japanese adults with type 2 diabetes.

The trial successfully achieved its primary objective by demonstrating that, from a mean baseline HbA<sub>1c</sub> of 8.2%, people treated with 3, 7 and 14 mg oral semaglutide experienced statistically significant reductions in HbA<sub>1c</sub> of 1.1%, 1.5% and 1.7%, respectively, compared to a reduction of 0.1% with placebo after 26 weeks. Furthermore, 14 mg oral semaglutide achieved a statistically significantly greater reduction in HbA<sub>1c</sub> compared to a reduction of 1.4% with Victoza<sup>®</sup>.

After 52 weeks, people treated with 3, 7 and 14 mg oral semaglutide experienced statistically significantly greater reductions in HbA<sub>1c</sub> of 0.9%, 1.3% and 1.5%, respectively, compared to an increase of 0.5% for people treated with placebo. Furthermore, people treated with Victoza<sup>®</sup> experienced a reduction in HbA<sub>1c</sub> of 1.1%, which was not statistically significant in favour of oral semaglutide.

The Japan Diabetes Society (JDS) treatment target of  $HbA_{1c} < 7.0\%$  was achieved by 50%, 67% and 80% of people treated with 3, 7 and 14 mg oral semaglutide, respectively, compared to 49% of people treated with Victoza<sup>®</sup> and 12% of people treated with placebo at week 52.

From a mean baseline body weight of 71.1 kg, people treated with 14 mg oral semaglutide experienced a statistically significantly greater weight reduction of 2.8 kg after 52 weeks compared to 1.0 kg with placebo and a weight increase of 0.4 kg with Victoza<sup>®</sup>. People treated with 3 and 7 mg oral semaglutide experienced a body weight reduction of 0.0 kg and 0.6 kg, respectively.

In this 52-week trial, oral semaglutide was well-tolerated and with a safety profile consistent with GLP-1-based therapy. The most common adverse events for oral semaglutide were constipation and mild to moderate nausea, which diminished over time. The proportion of people who discontinued treatment due to adverse events was 2-4% for people treated with oral semaglutide.

# Oral semaglutide demonstrates favourable cardiovascular safety profile and significant reduction in cardiovascular death and all-cause mortality in people with type 2 diabetes in the PIONEER 6 cardiovascular outcomes trial

In November 2018, Novo Nordisk announced the headline results from the last global phase 3a trial, PIONEER 6, for oral semaglutide, an investigational GLP-1 analogue taken once daily as a tablet. This double-blinded trial investigated the cardiovascular safety of oral semaglutide 14 mg compared with placebo, both in addition to standard of care, in 3,183 adults with type 2 diabetes at high risk of cardiovascular events.

The trial achieved its primary endpoint by demonstrating non-inferiority of major adverse cardiovascular events (MACE) with oral semaglutide compared with placebo, both in addition to standard of care. The results are based on the accumulated occurrence of 137 major adverse cardiovascular events, with a median follow-up time of 16 months. The primary endpoint of the PIONEER 6 trial was defined as the MACE composite outcome of the first occurrence of cardiovascular death, non-fatal myocardial infarction or non-fatal stroke, and showed a hazard ratio of 0.79 in favour of oral semaglutide compared with placebo. The 21% reduction in MACE in favour of oral semaglutide did not reach statistical significance.

The MACE results demonstrated by oral semaglutide were driven by a statistically significant reduction in cardiovascular death of 51% (HR 0.49, p=0.03), while non-fatal myocardial infarction (HR 1.18, non-significant) or non-fatal stroke (HR 0.74, non-significant) were broadly similarly distributed between the two treatment arms. In addition, a statistically significant reduction in all-cause mortality of 49% (HR 0.51, p=0.008) in favour of oral semaglutide was observed.

Financial	
Performance	

R&D

Outlook

Sustainability

```
Equity
```

orporate overnance



The improvements in secondary endpoints, including HbA<sub>1c</sub>, body weight and blood pressure, were similar to results reported throughout the PIONEER programme for oral semaglutide. Furthermore, the safety profile of oral semaglutide in PIONEER 6 was consistent with the established safety profile observed in previous PIONEER clinical trials.

#### Semaglutide regulatory update

Novo Nordisk has decided to submit the oral semaglutide file around the end of first quarter 2019 and has notified the US Food and Drug Administration (FDA) that Novo Nordisk will request priority review of the oral semaglutide filing based on a priority review voucher. Novo Nordisk still expects to file oral semaglutide for EU approval during first half of 2019.

As announced in August 2018, Novo Nordisk has since the approval of Ozempic<sup>®</sup> (once-weekly injectable semaglutide) engaged in a constructive dialogue with the FDA on minimising the need for additional individual large cardiovascular outcomes trials (CVOTs) to obtain a cardiovascular (CV) indication for semaglutide in different formulations. Following the results of the PIONEER 6 trial, Novo Nordisk is currently evaluating the potential to obtain a CV indication for Ozempic<sup>®</sup> based on the already obtained clinical data from the CVOT SUSTAIN 6 in combination with the CVOT PIONEER 6 with oral semaglutide. Novo Nordisk will continue these discussions with the FDA.

# Phase 2 trial initiated with once-weekly insulin LAI287 (NN1436) to evaluate safety and efficacy

In November 2018, Novo Nordisk initiated a phase 2 trial with once-weekly insulin LAI287 in people with type 2 diabetes. The trial is a multi-national, double-blinded, active-controlled trial with an expected enrolment of approximately 350 insulin-naïve people with type 2 diabetes. The main objective of the trial is to assess the safety and efficacy of LAI287.

# Phase 1 trial initiated with LAIsema (NN1535), the once-weekly combination of once-weekly insulin LAI287 and once-weekly injectable GLP-1 semaglutide

In January 2019, Novo Nordisk initiated a phase 1 trial with LAIsema, the combination of once-weekly insulin LAI287 and once-weekly injectable GLP-1 semaglutide. The trial will investigate single-dose pharmacokinetics of LAIsema in a fixed ratio compared with LAI287 and semaglutide given separately in people with type 2 diabetes. The trial is a single-centre, randomised, double-blinded, three-period, cross-over trial with an expected enrolment of approximately 30 people with type 2 diabetes.

# Obesity

# Embark and Novo Nordisk enter collaboration to discover novel therapeutics for obesity and metabolic diseases

In November 2018, Embark Biotech and Novo Nordisk announced that they have entered into a research collaboration focusing on the discovery of novel treatments for obesity and its associated metabolic pathologies through mechanisms that increase energy expenditure. The aim of the collaboration is to develop novel drug candidates that help people with obesity lose weight by burning off excess energy instead of storing it as fat. The potential addition of energy expenditure drugs would make a meaningful difference in the treatment of obesity. The work behind the research platform and the spin-out of Embark Biotech has been supported by Novo Seeds and the Novo Nordisk Foundation since 2016. As part of the collaboration agreement, Embark will receive research support for activities conducted in the collaboration, and Novo Nordisk has an option to licence exclusive worldwide rights to develop and commercialise products discovered in the collaboration.

# **Biopharm**

# SC N8-GP (NN7170) discontinued due to anti-drug antibodies detection

In November 2018, Novo Nordisk completed alleviate 1, a combined single- and multiple-dose trial investing safety, tolerability and pharmacokinetics with SC N8-GP. The objective of SC N8-GP was to develop N8-GP for subcutaneous administration for prophylactic treatment of patients with Haemophilia A. In the trial, anti-drug antibodies were detected after repeated treatment with SC N8-GP in five out of 26 patients. The antibody formation was considered a result of the subcutaneous route of administration as a similar antibody pattern has not been observed following intravenous administration of N8-GP. Based on the clinical findings in alleviate 1 Novo Nordisk has decided not to continue the development of SC N8-GP.

Financial Performance Outlook

R&D

Sustainability

Equity

Corporate

Legal

# Successful completion of phase 2 trial, explorer4, with concizumab (NN7415) to evaluate the efficacy and safety of prophylactic administration in people with haemophilia A and B with inhibitors

In November 2018, Novo Nordisk completed the main phase of the phase 2 trial, explorer4, with concizumab to evaluate the efficacy and safety of prophylactic administration in people with haemophilia A and B with inhibitors. In the explorer4 trial, the pre-defined criteria for clinical proof-of-concept were met, showing reduced annual bleeding rate (ABR) on daily concizumab prophylaxis compared to the control arm with NovoSeven<sup>®</sup> on-demand treatment.

The results from the two phase 2 trials: explorer4 and explorer5 (in people with severe haemophilia A without inhibitors) confirmed the correlation between increased levels of concizumab, reduced levels of TFPI and increased clotting potential as demonstrated by normalisation of the thrombin generation potential in most patients. There were no observed safety differences between the patient segments and across the two trials, and there were no issues with treatment of breakthrough bleeds and concizumab appeared to have a safe and well tolerated profile. All 57 patients completing the main phase of the two trials chose to continue in the extension phase of the trials.

Following the successful completion of the phase 2 programme with concizumab, Novo Nordisk is now preparing a broad pivotal phase 3a programme with expected initiation in second half of 2019.

# Positive results from REAL 3 phase 2 extension trial with long-acting growth hormone somapacitan (NN8640) for treatment of growth hormone deficiency (GHD).

In November 2018, Novo Nordisk completed the extension phase of REAL 3, the phase 2 trial with long-acting recombinant growth hormone, somapacitan. REAL 3 was a randomised, parallel-group active-controlled trial with the endpoint to evaluate the efficacy of multiple dose regimens of once-weekly somapacitan after a full year of treatment in 59 growth hormone treatment-naïve pre-pubertal children with growth hormone deficiency, compared to daily Norditropin<sup>®</sup> administration. The trial confirmed dose dependency for the mean annualised height velocity of the three dose levels of somapacitan as reported after 26 weeks of treatment. The observed safety profile in the study was consistent with that known for Norditropin<sup>®</sup>.

Novo Nordisk is preparing for the pivotal phase 3 somapacitan programmes in GHD children as well as a phase 2 trial in children born small for gestational age (SGA).

# **Other Serious Chronic Diseases**

# Staten Biotechnology and Novo Nordisk announce collaboration to develop novel treatment for dyslipidaemia

In December 2018, Staten Biotechnology and Novo Nordisk announced that they have entered into a collaboration and exclusive option agreement to develop novel therapeutics for the treatment of hypertriglyceridaemia. Under the collaboration agreement, Novo Nordisk will provide research and development funding and support for Staten Biotechnology to develop its lead asset STT-5058 for treatment of dyslipidaemia. Under the exclusive option agreement, Novo Nordisk has the right to acquire Staten Biotechnology and gain worldwide rights to STT-5058. Staten Biotechnology and its shareholders will potentially receive signing and exercise fees, R&D funding and milestone payments of up to 430 million euros.

Financial Performance

R&D

# SUSTAINABILITY UPDATE

SOCIAL PERFORMANCE	2018	2017	2016	2015	2014	% change 2017 to 2018
Patients						
Patients reached with Novo Nordisk diabetes products (estimate in millions)	29.2	27.7	28.0	26.8	24.4	5%
Employees						
Employees (FTE) <sup>1</sup> Employee turnover Gender in management (ratio men:women) Employee engagement	42,672 11.7% 60:40 91%	42,076 11.0% 60:40 90%	41,971 9.7% 59:41 —	40,638 9.2% 59:41 —	40,957 9.0% 60:40 —	1%
Responsible business						
Relevant employees trained in business ethics Product recalls Failed inspections Company reputation (scale 0-100)	99% 3 0 83.3	99% 6 0 79.3	99% 6 0 77.8	98% 2 0 81.1	98% 2 0 79.5	(50)%
ENVIRONMENTAL PERFORMANCE						
Resources						
Energy consumption (1,000 GJ) Share of renewable power for production Water consumption (1,000 m <sup>3</sup> )	2,890 77% 3,101	2,922 79% 3,276	2,935 78% 3,293	2,778 78% 3,131	2,556 73% 2,959	(1)% (5%)
Emissions and waste						
CO <sub>2</sub> emissions from energy consumption at production sites and product distribution (1,000 tons)	127	129	130	150	177	(2%)
Waste (1,000 tons)	142	157	153	159	141	(10%)

#### SOCIAL PERFORMANCE

#### **Patients**

Novo Nordisk's business is built on the ambition to drive change to defeat diabetes and other serious chronic diseases. This involves helping people with these diseases live better, healthier lives and enhancing access to medical treatment and quality of care.

In 2018, Novo Nordisk provided medical treatment to an estimated 29.2 million people with diabetes worldwide, compared with 27.7 in 2017. This 5% increase was primarily driven by sales of human insulin (0.6 million people) and long-acting, premix and fast-acting modern and new-generation insulin (0.6 million people).

Through Novo Nordisk's Access to Insulin Commitment, the company guarantees to provide low-priced human insulin to governments in the poorest parts of the world and selected humanitarian organisations at a ceiling price of USD 4 per vial. As a result, an estimated 0.3 million people were treated with insulin for on average USD 0.12 per day as in 2017. Beyond this commitment, Novo Nordisk sold human insulin at or below the ceiling price in other countries, reaching an estimated 5 million people in 2018, which is the same level as in 2017.

Financial Performance

Outlook

R&D

**Sustainability** 



Legal

As of 2019, the guarantee is expanded to include 29 middle-income countries as defined by the World Bank. This means that a total of 78 countries, home of 124 million people with diabetes as well as selected humanitarian organisations, can benefit from this guarantee.

### **Employees**

Novo Nordisk aims to be an attractive employer that offers a safe and healthy, inclusive and engaging working environment in which all employees have equal opportunities to realise their potential. At the end of 2018, the total number of employees was 43,202, corresponding to 42,672 full-time positions, which is a 1% increase compared with 2017. The development in employees was mainly driven by Region China, Region Europe, the global service centre in Bangalore, India and expansions of production facilities in Algeria, China and the US. Employee turnover increased from 11.0% in 2017 to 11.7% in 2018 as a result of organisational adjustments in line with the company's strategy for growth.

In 2018, Novo Nordisk restructured the R&D organisation to accelerate the expansion and diversification of its pipeline and enable increased investment in transformational biological and technological innovation. Additional restructuring initiatives across functions and geographies were made to support the commercial activities for the portfolio of innovative products. Consequently, the total workforce was reduced by approximately 1,300 employees. These reductions are not yet fully reflected in the reported number of full-time positions for the year 2018 due to notice periods in the various jurisdictions.

By the end of 2018, the gender distribution among managers was 60% men and 40% women, unchanged from 2017. Of the newly promoted managers, 38% were women, compared with 43% in 2017. The decreasing share of women among newly appointed managers was driven by fewer women appointed to entry level positions (manager and team leader). At the same time a higher share of women were appointed to senior management positions (SVP, CVP, VP and GM), especially among external hires.

The level of employee engagement and commitment to the company's values remains high. In the annual employee survey, conducted in the second quarter of 2018, 91% of employees responded positively to a set of questions to measure the level of engagement compared with 90% in 2017.

The average frequency rate of occupational accidents with absence was 2.4 per million working hours in 2018 compared with 2.7 in 2017. As in 2017, there were no work-related fatalities in 2018. Novo Nordisk works with a zero-injury mindset and remains committed to continuously improving safety performance. Employees are encouraged to always make the safe choice, and it is emphasised that safety behaviour is part of the company values.

#### **Responsible business**

Novo Nordisk had three product recalls from the market in 2018, compared with six in 2017. None of these recalls were critical. Local health authorities were informed in all instances to ensure that distributors, pharmacies, doctors and patients received appropriate information.

Novo Nordisk's reputation among key stakeholders - people with diabetes, general practitioners and diabetes specialists - is an indicator of the extent to which the company lives up to stakeholders' expectations and the likelihood that they will trust, support and engage with the company. The company reputation score, measured on a scale of 0-100, increased to 83.3, from 79.3 in 2017. Data were collected between June and September 2018; a score between 70 and 80 is considered strong.

#### **ENVIRONMENTAL PERFORMANCE**

#### Resources

In 2018, the energy consumption at production sites remained stable compared with 2017. 77% of the power (electricity) used at the production sites came from renewable sources such as wind and hydropower.

Water consumption at production sites decreased by 5% in 2018. Three facilities in Algeria, Brazil and China, accounting for 14% of Novo Nordisk's total water use in 2018, are located in areas that could be impacted by water stress or large seasonal variations.

Financial Performance

Outlook

R&D

Sustainability

y Equity

Corpora

Legal

# **Emissions and waste**

In 2018, CO<sub>2</sub> emissions from production sites and product distribution decreased by 2% to 127,000 tons. As of 2018, Novo Nordisk has expanded the scope to also cover the company's global CO<sub>2</sub> emissions from global offices, laboratories, company cars and business flights, which amounted to 269,000 tons.

Several Novo Nordisk suppliers have committed to targets and actions to reduce their carbon emissions. As part of Novo Nordisk's supply chain programme, more than 30 key suppliers were engaged in 2018 to increase energy efficiency and use of renewable energy in their operations.

Compared to 2017, waste from production sites decreased by 10% in 2018. This was primarily due to decreased amounts of organic residues from fermentation processes generated at the API facility in Kalundborg, Denmark.

A new biogas plant was put in operation in 2018 in Denmark for local handling of the organic residues. The biogas plant converts residues into bio-natural gas and fertiliser, which is used on local farmland. The project is a partnership between Novo Nordisk, Novozymes and the energy company, Ørsted.

# **Circular for Zero**

In 2018, Novo Nordisk set an ambition to have zero negative environmental impact. To get there, a new environmental strategy was adopted that addresses risks across the entire value chain, including climate change, water and resource scarcity, pollution and plastic waste.

The strategy embraces a circular mindset - designing and producing products so that they can be recovered and reused, and reshaping business practices to minimise consumption and eliminate waste by turning it into new resources.

In 2018, a new target was set, as part of the environmental strategy, committing to zero  $CO_2$  emissions from operations and transportation by 2030. The target covers global operations, including offices and laboratories, along with company cars, business flights and product distribution. The target will be met by shifting to renewable energy sources whenever possible, using hybrid and electric cars and increasing use of virtual meetings. For emissions that cannot be eliminated, Novo Nordisk will compensate by investing in  $CO_2$ -reducing projects.

# EQUITY

Total equity was DKK 51,839 million at the end of 2018, equivalent to 46.8% of total assets, compared with 48.7% at the end of 2017. Please refer to appendix 5 for further elaboration of changes in equity.

# 2018 share repurchase programme

On 5 November 2018, Novo Nordisk announced a share repurchase programme of up to DKK 3.2 billion to be executed from 6 November 2018 to 30 January 2019, as part of an overall programme of up to DKK 15 billion to be executed during a 12-month period beginning 1 February 2018. The purpose of the programme was to reduce the company's share capital and to meet obligations arising from share-based incentive programmes. Under the programme, Novo Nordisk has repurchased 10,569,282 B shares for an amount of DKK 3.2 billion in the period from 6 November 2018 to 30 January 2019. The programme was concluded on 30 January 2019.

As of 30 January 2019, Novo Nordisk A/S has repurchased a total of 49,755,912 B shares equal to a transaction value of DKK 15.0 billion under the DKK 15 billion programme beginning 1 February 2018.

As of 30 January 2019, Novo Nordisk A/S and its wholly-owned affiliates owned 59,669,930 of its own B shares, corresponding to 2.4% of the total share capital.

# Proposed final dividend of DKK 5.15 for each Novo Nordisk A and B share of DKK 0.20

At the Annual General Meeting on 21 March 2019, the Board of Directors will propose a final dividend of DKK 5.15 for each Novo Nordisk A and B share of DKK 0.20. The total dividend for 2018 of DKK 8.15 for each Novo Nordisk A and B share of DKK 0.20 includes both the interim dividend of DKK 3.00 for each Novo Nordisk A and B share of DKK 0.20, which was paid in August 2018, and the proposed final dividend of DKK 5.15 for each Novo Nordisk A and B share of DKK 0.20 to be paid in March 2019. The total dividend is hence expected to increase by 4% compared with the 2017 dividend of DKK 7.85 for each Novo Nordisk A and B share of DKK 0.20. The total dividend for 2018 corresponds to a payout ratio of 50.6%, in line with a payout ratio of around 50.2% for Novo Nordisk's

Financial	
Performance	

R&D

Sustainability



orporate



peer group of comparable pharmaceutical companies in 2017. No dividend will be paid on the company's holding of own B shares.

### 2019 share repurchase programme

The Board of Directors has approved a new share repurchase programme of up to DKK 15 billion to be executed during the coming 12 months. The total programme may be reduced in size, in case of a significant bolt-on acquisition during 2019.

As part of the up to DKK 15 billion 2019 share repurchase programme, Novo Nordisk A/S will initiate a new share repurchase programme for an amount of up to DKK 2.7 billion in accordance with Article 5 of Regulation No 596/2014 of the European Parliament and Council of 16 April 2014 (MAR) and the Commission Delegated Regulation (EU) 2016/1052 of 8 March 2016 (the "Safe Harbour Rules"). For that purpose, Novo Nordisk A/S has appointed Nordea Danmark, Filial af Nordea Bank Abp, as lead manager to execute the programme independently and without influence from Novo Nordisk A/S. The purpose of the programme is to reduce the company's share capital and to meet obligations arising from share-based incentive programmes. Under the agreement, Nordea Danmark, Filial af Nordea Bank Abp, will repurchase B shares on behalf of Novo Nordisk A/S during the trading period starting today, 1 February, and ending on 1 May 2019.

A maximum of 185,330,070 B shares in total can be bought during the trading period. The maximum number of B shares that can be repurchased on a single trading day may not exceed 20% of the average daily trading volume of Novo Nordisk B shares on the trading venue, on which the purchase takes place, during the preceding 20 trading days of the purchase (excluding the day of the purchase). Compared to previous share repurchase programmes initiated by Novo Nordisk A/S the method of determining the average daily trading volume has been updated, cf Article 3(3) of the Commission Delegated Regulation (EU) 2016/1052. At least once every seven trading days, Novo Nordisk A/S will issue an announcement in respect of the transactions made under the repurchase programme.

Novo Nordisk's majority shareholder Novo Holdings A/S, a holding company fully owned by the Novo Nordisk Foundation, has informed Novo Nordisk that it intends to consider its participation in the Novo Nordisk share repurchase programme on a year-by-year basis. For 2019, Novo Nordisk has been informed by Novo Holdings A/S that it plans to participate in the share repurchase programme. Novo Holdings A/S has an ownership of 28.1% of the Novo Nordisk share capital, and Novo Holdings A/S currently intends to maintain its ownership of the Novo Nordisk share capital around 28%.

# **CORPORATE GOVERNANCE**

#### **Remuneration principles for executives**

Novo Nordisk's remuneration principles aim to attract, retain and motivate members of Executive Management. Remuneration levels are designed to be competitive and to align the interests of the executives with shareholder interests. The current remuneration principles were approved at the Annual General Meeting in March 2018.

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

Members of Novo Nordisk's Executive Management (9 at the end of 2018) and other members of the Management Board (32 in 2018) have participated in a performance-based incentive programme. In 2018, the performancebased incentive programme operated with a yearly maximum allocation equal to 18 months' fixed base salary plus pension contribution for the chief executive officer, 13.5 months' fixed base salary plus pension contribution for the other members of Executive Management and nine months' fixed base salary plus pension contribution for other members of the Management Board. Once the share allocation per member of the Management Board has been approved by the Board of Directors, the total cash amount is converted into Novo Nordisk B shares at market price. The market price is calculated as the average trading price for Novo Nordisk B shares on Nasdaq Copenhagen in the open trading window following the release of the full-year financial results for the year prior to the relevant performance year. The shares allocated per member of the Management Board are locked up for a three-year period before they are transferred to the individual member.

For 2015, 378,421 shares were allocated to the members of the Management Board and the value at launch of the programme (DKK 108 million) was expensed in 2015. The number of shares in the 2015 performance-based incentive programme has not subsequently been reduced by the Board of Directors as the financial performance in the following years (2016-2018) reached specified threshold levels. Hence, the original number of shares allocated to the members of the Management Board will, according to the principles of the scheme, be transferred to 33

Financial Performance

Outlook

Sustainability

R&D

Equity

Corporate governance Financial Information

Legal

current and former members of the Management Board immediately after the announcement of the 2018 full-year financial results on 1 February 2019.

In 2018, Novo Nordisk exceeded the target for economic value creation by 4.4%, primarily driven by higher operating profit, a lower effective tax rate partly offset by an unfavourable net impact from currencies. Sales were 1.0% above the target level in local currencies. One of the non financial targets within R&D were ceased for strategic reasons and the weight was re-allocated to other R&D related targets. All of the remaining non-financial targets were reached in 2018. On this basis, 70% of the maximum share allocation will be allocated to the participants in the long-term share-based incentive programme.

On 31 January 2019, the Board of Directors consequently approved the allocation of a total of 411,090 Novo Nordisk B shares in relation to the long-term incentive programme for 2018. This allocation equals 12.6 months' fixed base salary plus pension contribution for the chief executive officer, whereas shares equalling 9.4 months' fixed base salary plus pension contribution will be allocated to the executive vice presidents and shares equalling 7 months' fixed base salary plus pension contribution will be allocated to the senior vice presidents. The shares allocated have a three-year vesting period. The amount of shares allocated may be reduced or increased by up to 30%, depending on whether the average sales growth per year in the three-year vesting period deviates from a target set by the Board of Directors.

The value at launch of the programme is DKK 115 million. The value of the programme will be amortised over four years (2018-2021). According to the principles of the programme, the share price used for the conversion of the performance programme to Novo Nordisk B shares was the average share price (DKK 304 per share of DKK 0.20) for Novo Nordisk B shares on Nasdaq Copenhagen in the 15 days trading window (1 February-15 February 2018) following the release of the annual report for 2017 when the programme was approved by the Board of Directors.

# Long-term, share-based incentive programme for corporate vice presidents and vice presidents

A number of key employees below senior management also participate in a share-based programme with similar performance criteria as the programme for senior management. The share-based incentive programme for key employees will, as is the case for the programme for senior management, be based on an annual calculation of economic profit generation compared to the planned performance for the year. At the beginning of each year, the Board of Directors defines a maximum number of shares per participant equal to a specific number of months of fixed base salary. The shares in the pool are also locked up for a three-year period before they may be transferred to the participants.

For 2015, 879,988 shares were allocated to a share pool for key employees, and the value at launch of the programme (DKK 251 million) has been amortised over the period 2015-2018. The number of shares in the 2015 share pool has not subsequently been reduced by the Board of Directors as the financial performance in the following years (2016-2018) reached specified threshold levels. 667,573 shares will be transferred to 670 employees after the announcement of the 2018 full-year financial results on 1 February 2019. The number of shares to be transferred is lower than the original number of shares allocated to the share pool as some participants have left the company before the release conditions of the programme have been met.

For 2018, based on an assessment similar to the senior management programme, the Board of Directors on 31 January 2019 approved the allocation 1,114,455 Novo Nordisk B shares for approximately 1,050 key employees. This allocation corresponds to a value at launch of the programme of DKK 312 million using the same share price mechanism as described for the senior management programme. The value of the programme will be amortised over four years (2018-2021). The amount of shares allocated may be reduced or increased by up to 30%, depending on whether the average sales growth per year in the three-year vesting period deviates from a target set by the Board of Directors.

Financial Performance R&D

Sustainability

Equity

Corporate governance

#### **LEGAL MATTERS**

#### Product liability lawsuits related to Victoza®

Novo Nordisk, along with the majority of incretin-based product manufacturers in the USA, is a defendant in product liability lawsuits related to use of incretin-based medications. As of 31 January 2019, 290 plaintiffs have named Novo Nordisk in product liability lawsuits, predominantly claiming damages for pancreatic cancer that allegedly developed as a result of using Victoza<sup>®</sup> and other GLP-1/DPP-IV incretin-based products.187 of the Novo Nordisk plaintiffs have also named other defendants in their lawsuits. Most Novo Nordisk plaintiffs have filed suit in California federal and state courts.

In November 2015, all cases pending in the California federal and state courts were dismissed on federal preemption grounds. Plaintiffs subsequently appealed these rulings to the federal and California state appeals courts. In November 2017, the U.S. Court of Appeals for the Ninth Circuit reversed and vacated the Federal District Court Judge's ruling, thereby reinstating the dismissed federal lawsuits and sending them back to the Federal District Court in California for further proceedings. The ruling by the U.S. Court of Appeals does not bind the California State Appeals Court, which is currently reviewing the state court judge's pre-emption ruling. Currently, Novo Nordisk does not have any individual trials scheduled in 2019. Novo Nordisk does not expect the pending claims to have a material impact on its financial position, operating profit or cash flow.

# US House of Representatives Committee on Oversight and Reform requests information involving pricing practices from several pharmaceutical companies including Novo Nordisk

In January 2019, Novo Nordisk was one of several pharmaceutical companies that received a request for information involving pricing practices from United States Representative Elijah Cummings, chair of the United States House of Representatives Committee on Oversight and Reform. The Company will be cooperating with the Committee and will respond to the requests set forth in the Committee's letter. Novo Nordisk does not expect this inquiry to have a material impact on Novo Nordisk's financial position, operating profit or cash flow.

### US House of Representatives Committee on Energy and Commerce and Subcommittee on Oversight and Investigations requests information involving insulin pricing practices from three pharmaceutical companies including Novo Nordisk

In January 2019, Novo Nordisk was one of three pharmaceutical companies that received a request for information involving insulin pricing practices from United States Representatives Frank Pallone, Jr. and Diana DeGette, chairs of the United States House of Representatives Committee on Energy and Commerce and Subcommittee on Oversight and Investigations, respectively. The Company will be cooperating with the Committee and will respond to the requests set forth in the Committee's letter. Novo Nordisk does not expect this inquiry to have a material impact on Novo Nordisk's financial position, operating profit or cash flow.

R&D



# Forward-looking statements

Novo Nordisk's reports filed with or furnished to the US Securities and Exchange Commission (SEC), including this document as well as the company's statutory *Annual Report 2018* and Form 20-F, which are both expected to be filed with the SEC in February 2019 in continuation of the publication of the *Annual Report 2018*, and written information released, or oral statements made, to the public in the future by or on behalf of Novo Nordisk, may contain forward-looking statements. Words such as 'believe', 'expect', 'may', 'will', 'plan', 'strategy', 'prospect', 'foresee', 'estimate', 'project', 'anticipate', 'can', 'intend', 'target' and other words and terms of similar meaning in connection with any discussion of future operating or financial performance identify forward-looking statements. Examples of such forward-looking statements include, but are not limited to:

- statements of targets, plans, objectives or goals for future operations, including those related to Novo Nordisk's products, product research, product development, product introductions and product approvals as well as cooperation in relation thereto,
- statements containing projections of or targets for revenues, costs, income (or loss), earnings per share, capital expenditures, dividends, capital structure, net financials and other financial measures,
- statements regarding future economic performance, future actions and outcome of contingencies such as legal proceedings, and
- statements regarding the assumptions underlying or relating to such statements.

In this document, examples of forward-looking statements can be found under the headings 'Outlook', 'Research and Development update' and 'Equity'.

These statements are based on current plans, estimates and projections. By their very nature, forward-looking statements involve inherent risks and uncertainties, both general and specific. Novo Nordisk cautions that a number of important factors, including those described in this document, could cause actual results to differ materially from those contemplated in any forward-looking statements.

Factors that may affect future results include, but are not limited to, global as well as local political and economic conditions, including interest rate and currency exchange rate fluctuations, delay or failure of projects related to research and/or development, unplanned loss of patents, interruptions of supplies and production, product recalls, 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.

For an overview of some, but not all, of the risks that could adversely affect Novo Nordisk's results or the accuracy of forward-looking statements in this document, reference is made to the overview of risk factors in 'Risk management enables better decision-making' on pp 41-43 of the *Annual Report 2018*.

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.

R&D

Sustainability

### **MANAGEMENT STATEMENT**

The Board of Directors and Executive Management have approved the Annual Report 2018 of Novo Nordisk A/S, including the audited consolidated financial statements. The Board of Directors and Executive Management have also approved this financial statement containing condensed financial information for 2018.

The consolidated financial statements in the Annual Report 2018 have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and with the IFRS as endorsed by the EU. Furthermore, the Annual Report 2018, including the consolidated financial statements and management review, is prepared in accordance with additional Danish disclosure requirements for listed companies and in accordance with the International Integrated Reporting Framework.

This financial statement has been prepared in accordance with the recognition and measurement requirements in the IFRS, the accounting policies as applied in the audited consolidated financial statements of 2018 and additional Danish disclosure requirements for listed companies.

In our opinion, the accounting policies used are appropriate, and the overall presentation of this financial statement is adequate. Furthermore, in our opinion, this company announcement of the financial statement for 2018 includes a true and fair account of the development in the operations and financial circumstances of the results for the year and of the financial position of the Group as well as a reference to the most significant risks and elements of uncertainty facing the Group in accordance with Danish disclosure requirements for listed companies.

Bagsværd, 1 February 2019

#### **Executive Management:**

Lars Fruergaard Jørgensen President and CEO	Karsten Munk Knudsen <i>CFO</i>	Jesper Brandgaard
Lars Green	Camilla Sylvest	Mads Krogsgaard Thomsen
Henrik Wulff		
Board of Directors:		
Helge Lund <b>Chairman</b>	Jeppe Christiansen <b>Vice chairman</b>	Brian Daniels
Andreas Fibig	Sylvie Grégoire	Liz Hewitt
Mette Bøjer Jensen	Kasim Kutay	Anne Marie Kverneland
Martin Mackay	Thomas Rantzau	Stig Strøbæk
Financial Outlook R&		Corporate Legal Financial overnance Legal Information

# **APPENDIX 1: QUARTERLY NUMBERS IN DKK**

(Amounts in DKK million, except number of full-time equivalent employees, earnings per share and number of shares outstanding).

	2018 2017					20	17		% change Q4 2018
	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1	Q4 2017
Net sales	29,732	27,762	27,407	26,930	27,992	26,614	28,638	28,452	6%
Gross profit	25,079	23,347	23,055	22,733	23,292	22,342	24,229	24,201	8%
Gross margin	84.4%	84.1%	84.1%	84.4%	83.2%	83.9%	84.6%	85.1%	
Sales and distribution costs	8,728	7,128	7,090	6,451	8,295	6,497	6,761	6,787	5%
Percentage of sales	29.4%	25.7%	25.9%	24.0%	29.6%	24.4%	23.6%	23.9%	
Research and development costs Percentage of sales	4,544 <b>15.3%</b>	3,644 <b>13.1%</b>	3,296 <b>12.0%</b>	3,321 <b>12.3%</b>	3,983 <b>14.2%</b>	3,328 <b>12.5%</b>	3,414 <b>11.9%</b>	3,289 <b>11.6%</b>	14%
Administrative costs	1,269	932	851	864	1,118	896	857	913	14%
Percentage of sales	4.3%	3.4%	3.1%	3.2%	4.0%	3.4%	3.0%	3.2%	
Other operating income, net	245	170	386	351	151	423	189	278	62%
<b>Operating profit</b> Operating margin	<b>10,783</b> <i>36.3%</i>	<b>11,813</b> <i>42.6%</i>	<b>12,204</b> 44.5%	<b>12,448</b> 46.2%	<b>10,047</b> <i>35.9%</i>	<b>12,044</b> <i>45.3%</i>	<b>13,386</b> <i>46.7%</i>	<b>13,490</b> <i>47.4%</i>	7%
Financial income	(37)	(78)	1,039	1,198	175	392	421	258	N/A
Financial expenses	376	597	, 745	37	(349)	(26)	1,164	744	N/A
Financial items (net)	(413)	(675)	294	1,161	524	418	(743)	(486)	N/A
Profit before income taxes	10,370	11,138	12,498	13,609	10,571	12,462	12,643	13,004	(2%)
Income taxes	1,873	2,101	2,155	2,858	2,318	2,692	2,692	2,848	(19%)
Net profit	8,497	9,037	10,343	10,751	8,253	9,770	9,951	10,156	3%
Depreciation, amortisation and impairment losses	1,642	783	768	732	905	706	863	708	81%
Capital expenditure (net)	, 3,311	2,316	1,587	2,310	3,043	2,098	1,934	1,604	9%
Net cash generated from operating activities	7,412	11,619	15,770	9,815	6,032	12,921	10,117	12,098	23%
Free cash flow	3,313	8,755	13,227	7,241	2,866	10,930	8,392	10,400	16%
Total assets	110,769	101,895	103,248	93,558	102,355	97,891	97,825	94,213	8%
Total equity	51,839	47,512	49,081	44,238	49,815	46,946	48,436	40,301	4%
Equity ratio	46.8%	46.6%	47.5%	47.3%	48.7%	48.0%	49.5%	42.8%	
Full-time equivalent employees end of period	42,672	43,161	43,105	42,688	42,076	41,656	41,385	41,636	1%
Basic earnings per share/ADR (in DKK)	3.54	3.74	4.27	4.41	3.38	3.96	4.01	4.07	5%
Diluted earnings per share/ADR (in DKK)	3.53	3.74	4.26	4.40	3.36	3.96	4.01	4.06	5%
Average number of shares outstanding (million) Average number of diluted shares	2,401.2	2,414.1	2,425.8	2,437.3	2,451.2	2,465.6	2,480.2	2,495.8	(2%)
outstanding (million)	2,406.1	2,419.2	2,430.9	2,442.3	2,456.1	2,469.4	2,484.1	2,500.0	(2%)
Sales by business segment:									
Long-acting insulin	5,456	5,158	5,357	4,873	5,494	5,098	5,976	5,606	(1%)
Premix insulin	2,438	2,527	2,587	2,642	2,622	2,562	2,704	2,861	(7%)
Fast-acting insulin	5,030	4,609	4,936	4,778	4,618	5,087	5,102	5,317	9%
Human insulin <sup>1)</sup>	2,178	2,386	2,335	2,366	2,393	2,429	2,455	2,516	(9%)
Total insulin Total GLP-1	15,102 7,492	14,680 6,655	15,215 5,924	14,659 6,058	15,127 6,305	15,176 5,343	16,237 5,775	16,300 5,750	0% 19%
Other diabetes <sup>1)</sup>	1,074	1,044	1,011	1,121	1,014	1,044	1,072	1,172	6%
Total diabetes	23,668	22,379	22,150	21,838	22,446	21,563	23,084	23,222	5%
Obesity (Saxenda <sup>®</sup> )	1,229	987	883	770	697	640	686	539	76%
Diabetes and obesity total	24,897	23,366	23,033	22,608	23,143	22,203	23,770	23,761	8%
Haemophilia	2,478	2,301	2,294	2,503	2,750	2,404	2,739	2,576	(10%)
Growth disorders (Norditropin <sup>®</sup> ) Other biopharmaceuticals	1,962 395	1,688 407	1,703 377	1,481 338	1,709 390	1,621 386	1,679 450	1,646 469	15%
Biopharmaceuticals total	4,835	407 4,396	<b>4,374</b>	4,322	4,849	4,411	430 4,868	409 4,691	1% <b>0%</b>
Sales by geographic segment:			•			·			
North America Operations	15,850	14,103	13,589	13,366	14,434	13,532	15,103	14,940	10%
- USA	15,182	13,476	12,952	12,878	13,879	12,967	14,583	14,402	9%
International Operations	13,882	13,659	13,818	13,564	13,558	13,082	13,535	13,512	2%
- Region Europe	5,594	5,392	5,460	5,233	5,418	5,190	5,355	5,226	3%
- Region AAMEO - Region China	2,993 2,712	3,067 2,793	3,194 2,751	2,899 3,029	3,068 2,510	2,929 2,531	3,057 2,608	2,964 3,060	(2%) 8%
- Region China - Region Japan & Korea	2,712 1,610	2,793 1,446	1,484	3,029	2,510 1,570	1,462	2,608	3,060 1,467	8% 3%
- Region Latin America	973	961	929	1,146	992	970	942	795	(2%)
Segment operating profit:									
Diabetes and obesity	8,153	9,995	9,760	9,934	7,689	9,298	10,735	10,631	6%
Biopharmaceuticals	2,630	1,818	2,444	2,514	2,358	2,746	2,651	2,859	12%

R&D

Financial Performance

Outlook

Sustainability

Equity

Corporate governance

Legal

# **APPENDIX 2: INCOME STATEMENT AND STATEMENT OF COMPREHENSIVE INCOME**

DKK million	2018	2017
	2010	
Income statement		
Net sales	111,831	111,696
Cost of goods sold	17,617	17,632
Gross profit	94,214	94,064
Sales and distribution costs	29,397	28,340
Research and development costs	14,805	14,014
Administrative costs	3,916	3,784
Other operating income, net	1,152	1,041
Operating profit	47,248	48,967
Financial income	2,122	1,246
Financial expenses	1,755	1,533
Profit before income taxes	47,615	48,680
Income taxes	8,987	10,550
NET PROFIT	38,628	38,130
Basic earnings per share (DKK)	15.96	15.42
Diluted earnings per share (DKK)	15.93	15.39
Segment Information		

Segment sales:		
Diabetes and obesity	93,904	92,877
Biopharmaceuticals	17,927	18,819
Segment operating profit:		
Diabetes and obesity	37,842	38,353
Operating margin	40.3%	41.3%
Biopharmaceuticals	9,406	10,614
Operating margin	52.5%	56.4%
Total segment operating profit	47,248	48,967

# Statement of comprehensive income

TOTAL COMPREHENSIVE INCOME FOR THE YEAR	36,230	39,925
Other comprehensive income for the year, net of tax	(2,398)	1,795
Tax on other comprehensive income, income/(expense)	755	(1,041)
Other items	(27)	(577)
Cash flow hedges, deferred gains/(losses) incurred during the period	(1,677)	1,987
Cash flow hedges, realisation of previously deferred (gains)/losses	(2,027)	1,955
Exchange rate adjustments of investments in subsidiaries	491	(632)
Items that will be reclassified subsequently to the Income statement		
Remeasurements on defined benefit plans	87	103
Items that will not subsequently be reclassified to the Income statement		
Other comprehensive income		
Net profit for the year	38,628	38,130

R&D

Sustainability



# **APPENDIX 3: CASH FLOW STATEMENT**

DKK million	2018	2017
Net profit	38,628	38,130
Adjustment for non-cash items:		
Income taxes in the Income Statement	8,987	10,550
Depreciation, amortisation and impairment losses	3,925	3,182
Other non-cash items	6,098	2,027
Change in working capital	(3,370)	(3,634)
Interest received	51	101
Interest paid	(89)	(87)
Income taxes paid	(9,614)	(9,101)
Net cash generated from operating activities	44,616	41,168
Durchass of interraible assets	(2 774)	(1 0 2 2)
Purchase of intangible assets	(2,774)	(1,022) 9
Proceeds from sale of property, plant and equipment	13	5
Purchase of property, plant and equipment Proceeds from other financial assets	(9,636) 178	(7,626) 73
Purchase of other financial assets		
Sale of marketable securities	(248)	(40) 2,009
Proceeds from the partial divestment of associated company	368	2,009
Dividend received from associated company	19	26
Net cash used in investing activities	(12,080)	(6,571)
		(15.0.15)
Purchase of treasury shares	(15,567)	(16,845)
Dividends paid	(19,048)	(18,844)
Proceeds from borrowings, net	94	
Net cash used in financing activities	(34,521)	(35,689)
NET CASH GENERATED FROM ACTIVITIES	(1,985)	(1,092)
Cash and cash equivalents at the beginning of the year	17,158	18,461
Reclassification of bank overdraft to liability from financing activity	412	_
Exchange gain/(loss) on cash and cash equivalents	44	(211)
Cash and cash equivalents at the end of the year	15,629	17,158

R&D

Sustainability

Equity



# **APPENDIX 4: BALANCE SHEET**

DKK million	31 Dec 2018	31 Dec 2017
ASSETS		
Intangible assets	5,145	3,325
Property, plant and equipment	41,891	35,247
Investment in associated company	531	784
Deferred income tax assets	2,893	1,941
Other financial assets	1,242	978
TOTAL NON-CURRENT ASSETS	51,702	42,275
Inventories	16,336	15,373
Trade receivables	22,786	20,165
Tax receivables	1,013	958
Other receivables and prepayments	3,090	2,428
Derivative financial instruments	204	2,304
Cash at bank	15,638	18,852
TOTAL CURRENT ASSETS	59,067	60,080
TOTAL ASSETS	110,769	102,355

#### **EQUITY AND LIABILITIES**

TOTAL EQUITY AND LIABILITIES	110,769	102,355
TOTAL LIABILITIES	58,930	52,540
Total current liabilities	54,164	47,056
Provisions	26,161	20,755
Derivative financial instruments	2,024	309
Other liabilities	14,098	14,446
Tax payables	4,610	4,242
Trade payables	6,756	5,610
Current debt	515	1,694
Total non-current liabilities	4,766	5,484
Provisions	3,392	3,302
Retirement benefit obligations	1,256	1,336
Deferred income tax liabilities	118	846
TOTAL EQUITY	51,839	49,815
Other reserves	(2,046)	349
Retained earnings	53,406	48,977
Treasury shares	(11)	(11)
Share capital	490	500

R&D

# **APPENDIX 5: EQUITY STATEMENT**

			_	Other reserves				
DKK million	Share capital	Treasury shares	Retained earnings	Exchange rate adjust- ments	Cash flow hedges	Tax and other adjust- ments	Total other reserves	Total
2018								
Balance at the beginning of the year Change in accounting policy, IFRS 9 (net of tax) Net profit for the period	500	(11)	48,977 (90) 38,628	(1,556)	2,027	(122) 90	349 90	49,815 — 38,628
Other comprehensive income for the year			87	491	(3,704)	728	(2,485)	(2,398)
Total comprehensive income for the year			38,625	491	(3,704)	818	(2,395)	36,230
Transactions with owners: Dividends Share-based payments Tax related to restricted stock units Purchase of treasury shares Reduction of the B share capital	(10)	(10) 10	(19,048) 414 (5) (15,557)					(19,048) 414 (5) (15,567) —
Balance at the end of the year	490	(11)	53,406	(1,065)	(1,677)	696	(2,046)	51,839

At the end of the year proposed final dividends (not yet declared) of DKK 12,309 million (5.15 DKK per share of DKK 0.20) are included in Retained earnings. No dividend is declared on treasury shares.

			-	Other reserves				
DKK million	Share capital	Treasury shares	Retained earnings	Exchange rate adjust- ments	Cash flow hedges	Tax and other adjust- ments	Total other reserves	Total
2017								
Balance at the beginning of the year Net profit for the period	510	(9)	46,111 38,130	(924)	(1,915)	1,496	(1,343)	45,269 38,130
Other comprehensive income for the year			103	(632)	3,942	(1,618)	1,692	1,795
Total comprehensive income for the year			38,233	(632)	3,942	(1,618)	1,692	39,925
Transactions with owners:								
Dividends			(18,844)					(18,844)
Share-based payments			292					292
Tax related to restricted stock units			18					18
Purchase of treasury shares		(12)	(16,833)					(16,845)
Reduction of the B share capital	(10)	10						_
Balance at the end of the year	500	(11)	48,977	(1,556)	2,027	(122)	349	49,815

At the end of the year proposed final dividends of DKK 11,810 million (4.85 DKK per share of DKK 0.20) are included in Retained earnings. No dividend is declared on treasury shares.

R&D

Sustainability



# **APPENDIX 6: REGIONAL SALES SPLIT**

#### Q4 2018 sales split per region

DKK million	Total	North America Operations	USA	Inter- national Operations	Region Europe	Region AAMEO	Region China	Region Japan & Korea	Region Latin America
The diabetes and obesity segment		-		-					
Long-acting insulin	5,456	3,447	3,362	2,009	1,120	294	195	220	180
% change in local currencies	(2%)	(6%)	(7%)	2,009	1,120	(11%)	17%	(8%)	9%
Tresiba®	2,172	1,445	1,416	770	339	(1170) <b>79</b>	7	(070) 195	107
% change in local currencies	14%	13%	1,410	17%	36%	4%	0%	(5%)	15%
Xultophy <sup>®</sup>	452	162	162	290	275	478 7	0 /8	(578)	8
% change in local currencies	68%	45%	45%	84%	73%	_	_	_	0
Levemir®	2,832	1,840	1,784	992	506	208	188	25	65
% change in local currencies	(16%)	(20%)	(20%)	(9%)	(10%)	(18%)	13%	(25%)	(9%)
Premix insulin	2,438	271	261	2,167	431	626	913	167	30
				2,107	(7%)	3%			(8%)
% change in local currencies Ryzodeg®	(6%) 199	(42%)	(43%)	2 % 199	16	5 % 72	9%	(13%) <i>102</i>	(8%) <b>9</b>
, .		_	_						9
% change in local currencies	24%		-	24%	88%	21%		23%	
NovoMix®	2,239	271	261	1,968	415	554	913	65	21
% change in local currencies	(8%)	(42%)	(43%)	0%	(9%)	1%	9%	(41%)	(11%)
Fast-acting insulin	5,030	2,632	2,525	2,398	1,193	554	345	201	105
% change in local currencies	9%	13%	13%	4%	5%	1%	16%	(19%)	49%
Fiasp®	206	85	78	121	121	_	_		-
% change in local currencies	312%	—	_	165%	165%	_	_	_	_
NovoRapid®	4,824	2,547	2,447	2,277	1,072	554	345	201	105
% change in local currencies	5%	9%	10%	1%	(2%)	1%	16%	(19%)	49%
Human insulin	2,178	432	396	1,746	396	508	677	47	118
% change in local currencies	(9%)	(22%)	(22%)	(5%)	(13%)	17%	(6%)	(18%)	(33%)
Total insulin	15,102	6,782	6,544	8,320	3,140	1,982	2,130	635	433
% change in local currencies	0%	(3%)	(4%)	2%	4%	3%	5%	(14%)	(1%)
Victoza®	6,500	4,919	4,785	1,581	943	179	133	174	152
% change in local currencies	1%	0%	0%	7%	3%	(4%)	37%	7%	22%
Ozempic <sup>®</sup>	992	960	896	32	32	_	—	_	_
% change in local currencies	_	—	—	—	-	_	—	_	_
Total GLP-1	7,492	5,879	5,681	1,613	975	179	133	174	152
% change in local currencies	17%	20%	19%	9%	7%	(4%)	37%	7%	22%
Other diabetes <sup>1)</sup>	1,074	252	210	822	147	175	388	94	18
% change in local currencies	7%	(6%)	(8%)	11%	(3%)	0%	25%	3%	34%
Total diabetes	23,668	12,913	12,435	10,755	4,262	2,336	2,651	903	603
% change in local currencies	5%	6%	6%	4%	4%	2%	9%	(9%)	5%
Obesity (Saxenda <sup>®</sup> )	1,229	833	772	396	62	97	1	103	133
% change in local currencies	78%	63%	67%	117%	72%	35%	_	_	82%
Diabetes and obesity total	24,897	13,746	13,207	11,151	4,324	2,433	2,652	1,006	736
% change in local currencies	7%	8%	8%	6%	5%	3%	9%	2%	13%
The biopharmaceuticals segment									
Haemophilia	2,478	1,051	992	1,427	700	359	52	146	170
% change in local currencies	(10%)	(19%)	(22%)	(3%)	(3%)	3%	2%	(25%)	4%
NovoSeven®	1,956	881	855	1,075	462	297	51	102	163
% change in local currencies	(20%)	(26%)	(27%)	(14%)	(19%)	(10%)	0%	(29%)	3%
NovoEight <sup>®</sup>	396	90	85	306	208	57	1	33	7
% change in local currencies	45%	28%	22%	51%	51%	253%		(27%)	23%
Growth disorders (Norditropin <sup>®</sup> )	1,962	918	916	1,044	374	160	7	437	66
% change in local currencies	15%	27%	27%	6%	(4%)	27%	, 50%	6%	22%
Other biopharmaceuticals	395	135	67	260	196	41	1	21	22 /0
% change in local currencies	1%	34%	88%	(10%)	8%	(50%)	(100%)	17%	(50%)
Biopharmaceuticals total	4,835	2,104	1,975	(10%) 2,731	1,270	(30 %) 560	(100 %) 60	<b>604</b>	(30%) <b>237</b>
% change in local currencies	0%	0%	(2%)	(1%)	(2%)	0%	4%	(3%)	8%
Total sales	29,732	15,850	15,182	13,882	5,594	2,993	2,712	1,610	973
% change in local currencies	6%	7%	7%	4%	3%	3%	9%	0%	12%
% change as reported	6%	10%	9%	2%	3%	(2%)	8%	3%	(2%)
Share of growth	100%	63%	56%	37%	11%	5%	14%	0%	7%

Financial Performance

Outlook

R&D

Sustainability

Equity

Corporate governance

Legal

# **APPENDIX 6: REGIONAL SALES SPLIT (CONTINUED)**

#### 2018 sales split per region

DKK million	Total	North America Operations	USA	Inter- national Operations	Region Europe	Region AAMEO	Region China	Region Japan & Korea	Region Latin America
The diabetes and obesity segment									
Long-acting insulin	20,844	12,902	12,600	7,942	4,282	1,281	814	857	708
% change in local currencies	(2%)	(9%)	(9%)	12%	10%	16%	20%	1%	22%
Tresiba®	8,035	5,271	5,192	2,764	1,246	337	16	751	414
% change in local currencies	15%	11%	9%	24%	30%	38%	0%	4%	32%
Xultophy®	1,614	529	528	1,085	1,007	58	_	_	20
% change in local currencies	126%	241%	240%	93%	81%	_			_
Levemir®	11,195	7,102	6,880	4,093	2,029	886	798	106	274
% change in local currencies	(17%)	(23%)	(23%)	(4%)	(14%)	5%	18%	(19%)	5%
Premix insulin	10,194	1,332	1,294	8,862	1,701	2,606	3,783	650	122
% change in local currencies	0%	(22%)	(22%)	4%	(9%)	9%	9%	(4%)	8%
Ryzodeg®	714	—	—	714	56	275	_	351	32
% change in local currencies	54%	—	—	54%	119%	68%	—	43%	13%
NovoMix®	9,480	1,332	1,294	8,148	1,645	2,331	3,783	299	90
% change in local currencies	(3%)	(22%)	(22%)	1%	(11%)	5%	9%	(31%)	6%
Fast-acting insulin	19,353	10,021	9,634	9,332	4,558	2,194	1,450	779	351
% change in local currencies	1%	(4%)	(5%)	7%	5%	10%	18%	(15%)	38%
Fiasp <sup>®</sup>	590	233	211	357	357	—	—	—	—
% change in local currencies	507%	—	—	293%	293%	—	—	—	—
NovoRapid®	18,763	9,788	9,423	8,975	4,201	2,194	1,450	779	351
% change in local currencies	(2%)	(7%)	(7%)	4%	(1%)	10%	18%	(15%)	38%
Human insulin	9,265	1,917	1,778	7,348	1,580	2,065	2,821	187	695
% change in local currencies	(1%)	3%	5%	(3%)	(11%)	14%	(7%)	(17%)	(4%)
Total insulin	59,656	26,172	25,306	33,484	12,121	8,146	8,868	2,473	1,876
% change in local currencies	(1%)	(7%)	(7%)	5%	2%	11%	6%	(7%)	13%
Victoza®	24,333	18,093	17,561	6,240	3,720	841	521	614	544
% change in local currencies	9%	8%	8%	13%	8%	6%	73%	7%	27%
Ozempic <sup>®</sup>	1,796	1,757	1,634	39	39	—	—	—	—
% change in local currencies	—					_			_
Total GLP-1	26,129	19,850	19,195	6,279	3,759	841	521	614	544
% change in local currencies	18%	19%	19%	14%	9%	6%	73%	7%	27%
Other diabetes <sup>1)</sup>	4,250	890	733	3,360	579	675	1,672	368	66
% change in local currencies	3%	(1%)	(2%)	4%	(4%)	(3%)	10%	1%	37%
Total diabetes	90,035	46,912	45,234	43,123	16,459	9,662	11,061	3,455	2,486
% change in local currencies	4%	2%	2%	6%	3%	10%	8%	(4%)	16%
Obesity (Saxenda <sup>®</sup> )	3,869	2,658	2,446	1,211	207	418	1	175	410
% change in local currencies Diabetes and obesity total	60%	39%	40%	131%	104%	136%	11,062	2 620	73%
•	93,904 6%	49,570 4%	47,680 4%	44,334 8%	16,666 4%	10,080 12%	8%	3,630 1%	2,896 22%
% change in local currencies	0 %	4 70	4 %	<b>0</b> %	4 %	12 %	0 70	1 70	22 70
The biopharmaceuticals segment									
Haemophilia	9,576	4,004	3,723	5,572	2,781	1,177	199	557	858
% change in local currencies	(5%)	(17%)	(20%)	6%	(1%)	9%	(4%)	(16%)	70%
NovoSeven®	7,881	3,457	3,278	4,424	1,944	1,049	194	400	837
% change in local currencies	(11%)	(22%)	(23%)	0%	(13%)	3%	(6%)	(18%)	71%
NovoEight <sup>®</sup>	1,354	308	291	1,046	776	109	5	135	21
% change in local currencies	26%	2%	(3%)	35%	41%	125%	400%	(18%)	62%
Growth disorders (Norditropin <sup>®</sup> )	6,834	2,834	2,823	4,000	1,511	680	20	1,538	251
% change in local currencies	7%	16%	16%	2%	(4%)	11%	33%	0%	19%
Other biopharmaceuticals	1,517	500	262	1,017	721	216	4	72	4
% change in local currencies	(8%)	(10%)	(22%)	(6%)	1%	(16%)	(20%)	(29%)	33%
Biopharmaceuticals total	17,927	7,338	6,808	10,589	5,013	2,073	223	2,167	1,113
% change in local currencies	(1%)	(6%)	(8%)	3%	(2%)	6%	(2%)	(6%)	54%
Total sales	111,831	56,908	54,488	54,923	21,679	12,153	11,285	5,797	4,009
% change in local currencies	5%	3%	2%	7%	3%	11%	8%	(2%)	29%
% change as reported	0%	(2%)	(2%)	2%	2%	1%	5%	(5%)	8%
Share of growth	100%	29%	22%	71%	11%	26%	16%	(2%)	20%

<sup>1)</sup> Primarily oral antidiabetic products, needles and GlucaGen<sup>®</sup> HypoKit<sup>®</sup>.

Financial Performance

Outlook

R&D

Sustainability

Equity

Corporate governance

Legal

# **APPENDIX 7: KEY CURRENCY ASSUMPTIONS**

FX	Q4 2018	Q4 2017	% change	FY 2018	FY 2017	% change	Spot rate 28 Jan 2019
USD	654	632	3%	631	660	(4%)	654
CNY	94	96	(1%)	95	98	(3%)	97
JPY	5.79	5.60	3%	5.72	5.88	(3%)	5.97
GBP	842	839	0%	842	849	(1%)	860
CAD	496	498	0%	487	508	(4%)	494

# **APPENDIX 8: NEW ACCOUNTING STANDARDS IN 2018**

As of 1 January 2018 Novo Nordisk applies, for the first time, IFRS 9 'Financial Instruments' and IFRS 15 'Revenue from Contracts with Customers'. The effect of the implementation is disclosed below.

The impact of the implementation of IFRS 9 and IFRS 15 has been immaterial in relation to recognition and measurement.

#### Effect from IFRS 9

The implementation of IFRS 9 'Financial instruments' that replaces IAS 39 'Financial Instruments: Recognition and Measurement', has had the effect that the changes to the fair value of minor shareholdings are now, on an investment-by-investment basis, either recognised in the income statement or other comprehensive income. For the current minor shareholdings all changes in the fair value are recognised in the income statement. Previously fair value changes were recognised in other comprehensive income.

As a result of changed accounting practice relating to minor shareholdings, DKK 90 million is moved from other reserves to retained earnings within equity as an adjustment to opening equity 1 January 2018.

Furthermore, hedge accounting is applied for the time value of currency options. Novo Nordisk has implemented these changes using the prospective approach.

# Effect from IFRS 15

The group has implemented IFRS 15 'Revenue from Contracts with Customers' using the modified retrospective approach. IFRS 15 replaces the current standards on revenue (IAS 11 'Construction Contracts' and IAS 18 'Revenue').

There is no significant effect on the financial statements.

R&D



# **APPENDIX 9: QUARTERLY NUMBERS IN USD (ADDITIONAL INFORMATION)**

Key figures are translated into USD as additional information - the translation is based on the average exchange rate for income statement and the exchange rate at the balance sheet date for balance sheet items. The specified percent changes in DKK are based on the changes in the 'Quarterly numbers in DKK', see appendix 1. The specified percentage change in USD is calculated as a development in USD numbers in this appendix.

(Amounts in USD million, except number of full-time equivalent employees, earnings per share and number of shares outstanding).

		20	18			20	17		% Q4 2018	Q4 20
	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1	Q4 2017 in USD	Q4 20 in D
Net sales	4,552	4,328	4,384	4,446	4,418	4,198	4,230	4,073	3%	
Gross profit G <b>ross margin</b>	3,840 84.4%	3,639 <b>84.1%</b>	3,688 <b>84.1%</b>	3,753 <b>84.4%</b>	3,678 83.2%	3,526 <b>83.9%</b>	3,579 <b>84.6%</b>	3,465 <b>85.1%</b>	4%	à
ales and distribution costs	1,343	1,111	1,136	1,065	1,299	1,023	999	972	3%	5
ercentage of sales esearch and development costs	29.4% 700	<b>25.7%</b> 570	<b>25.9%</b> 527	<b>24.0%</b> 548	29.6% 625	<b>24.4%</b> 523	<b>23.6%</b> 504	<b>23.9%</b> 471	12%	1.
Percentage of sales	15.3%	13.1%	12.0%	12.3%	14.2%	12.5%	11.9%	11.6%	420/	
Idministrative costs Percentage of sales	196 4.3%	145 <b>3.4%</b>	136 <b>3.1%</b>	143 <b>3.2%</b>	175 4.0%	141 <b>3.4%</b>	126 <b>3.0%</b>	131 <b>3.2%</b>	12%	1
Other operating income, net	37	25	62	58	25	65	28	40	48%	6
p <b>erating profit</b> Dperating margin	<b>1,638</b> <i>36.3%</i>	<b>1,838</b> 42.6%	<b>1,951</b> 44.5%	<b>2,055</b> 46.2%	<b>1,604</b> 35.9%	<b>1,904</b> 45.3%	<b>1,978</b> 46.7%	<b>1,931</b> 47.4%	2%	
nancial income	(10)	(18)	166	198	29	61	62	37	N/A	
nancial expenses	57	94	121	6	(49)	3	172	106	N/A	
nancial items (net)	(67)	(112)	45	192	78	58	(110)	(69)	N/A	
rofit before income taxes	1,571	1,726	1,996	2,247	1,682	1,962	1,868	1,862	(7%)	
ncome taxes	283	325	343	472	368	424	398	408	(23%)	(
let profit	1,288	1,401	1,653	1,775	1,314	1,538	1,470	1,454	(2%)	
Pepreciation, amortisation and impairment losses Capital expenditure (net)	256 512	122 363	123 252	121 381	142 473	112 327	127 285	101 230	80% 8%	ė
let cash generated from operating activities	1,102	1,805	2,538	1,620	988	2,017	1,499	1,732	12%	
ree cash flow	468	1,358	2,131	1,195	497	1,706	1,244	1,489	(6%)	
otal assets	16,986	15,828	16,143	15,577	16,491	15,540	15,004	13,532	3%	
otal equity <b>quity ratio</b>	7,949 46.8%	7,380 <b>46.6%</b>	7,674 <b>47.5%</b>	7,365 <b>47.3%</b>	8,026 48.7%	7,452 <b>48.0%</b>	7,429 <b>49.5%</b>	5,789 <b>42.8%</b>	(1%)	
ull-time equivalent employees end of period	42,672	43,161	43,105	42,688	42,076	41,656	41,385	41,636	1%	
asic earnings per share/ADR (in USD)	0.54	0.58	0.68	0.73	0.54	0.62	0.60	0.58	0%	
viluted earnings per share/ADR (in USD)	0.53	0.58	0.68	0.73	0.53	0.63	0.59	0.58	0%	
werage number of shares outstanding (million) werage number of diluted shares	2,401.2	2,414.1	2,425.8	2,437.3	2,451.2	2,465.6	2,480.2	2,495.8	(2%)	
utstanding (million)	2,406.1	2,419.2	2,430.9	2,442.3	2,456.1	2,469.4	2,484.1	2,500.0	(2%)	
ales by business segment:										
Long-acting insulin	836	804	857	805	868	806	883	802	(4%)	
Premix insulin Fast-acting insulin	371 769	393 717	414 790	436 789	414 732	405 800	399 755	410 761	(10%) 5%	
Human insulin <sup>1)</sup>	331	372	373	391	378	382	363	360	(12%)	
Total insulin	2,307	2,286	2,434	2,421	2,392	2,393	2,400	2,333	(4%)	
Total GLP-1 Other diabetes <sup>1)</sup>	1,152 164	1,039 163	947 161	1,000 185	991 161	843 165	853 158	823 168	16% 2%	
Total diabetes	3,623	3,488	3,542	3,606	3,544	3,401	3,411	3,324	2%	
Obesity (Saxenda <sup>®</sup> ) Diabetes and obesity total	190 <b>3,813</b>	154 <b>3,642</b>	142 <b>3,684</b>	127 <b>3,733</b>	109 <b>3,653</b>	101 <b>3,502</b>	101 <b>3,512</b>	77 <b>3,401</b>	74% <b>4%</b>	:
Haemophilia	378	358	367	413	434	380	403	369	(13%)	(
Growth disorders (Norditropin <sup>®</sup> )	301	264	273	244	269	255	248	236	12%	
Other biopharmaceuticals	60	64	60	56	62	61	67	67	(3%)	
Biopharmaceuticals total	739	686	700	713	765	696	718	672	(3%)	
ales by geographic segment: North America Operations	2,432	2,200	2,174	2,206	2,279	2,139	2,230	2,139	7%	;
- USA	2,329	2,102	2,072	2,126	2,191	2,050	2,154	2,062	6%	
International Operations - Region Europe	<b>2,120</b> 855	<b>2,128</b> 839	<b>2,210</b> 875	<b>2,240</b> 864	<b>2,139</b> 855	<b>2,059</b> 816	<b>2,000</b> 791	<b>1,934</b> 748	(1%) 0%	
- Region AAMEO	457	478	511	479	483	461	452	424	(5%)	
- Region China	413	435	439	500	397	401	386	438	4%	
- Region Japan & Korea - Region Latin America	247 148	226 150	237 148	208 189	248 156	230 151	232 139	210 114	0% (5%)	
egment operating profit:									(2.3)	
Diabetes and obesity	1,234	1,558	1,560	1,640	1,229	1,472	1,586	1,522	0%	
Biopharmaceuticals Comparative figures have been restated as sales of bu	404	280	391	415	375	432	392	409	8%	

R&D

Financial Performance

Outlook

Sustainability

Equity

Corporate governance

Legal

# APPENDIX 10: NON-IFRS FINANCIAL MEASURES (ADDITIONAL INFORMATION)

In this Company Announcement, Novo Nordisk discloses certain financial measures of the Group's financial performance, financial position and cash flows that reflect adjustments to the directly comparable measures calculated and presented in accordance with IFRS. These non-IFRS financial measures may not be defined and calculated by other companies in the same manner and may thus not be comparable with such measures.

The non-IFRS financial measures presented in the Company Announcement are:

- Sales and operating profit in local currencies
- Free cash flow
- Cash to earnings
- Operating profit after tax on net operating assets

#### Sales and operating profit growth in local currencies

'Growth in local currencies' means that the effect of changes in exchange rates is excluded. It is defined as sales/operating profit for the period measured at the average exchange rates for the same period prior year compared with Net sales/Operating profit for the same period prior year. Price adjustments within hyperinflation countries as defined in IAS 29 'Financial reporting in hyperinflation economies' are excluded from the calculation to avoid that growth in local currencies is artificially inflated.

Growth in local currencies is considered to be relevant information for investors in order to understand the underlying development in sales and operating profit by adjusting for the impact of currency fluctuations.

#### Sales in local currencies

DKK million	2018	2017
Net sales	111,831	111,696
Effect of exchange rates	5,043	2,609
Sales in local currencies	116,874	114,305
Net sales in same period previous year	111,696	111,780
% increase/(decrease) in local currencies	5%	2%
% increase/(decrease) in reported currencies	0%	0%

#### Operating profit in local currencies

DKK million	2018	2017
Operating profit	47,248	48,967
Effect of exchange rates	3,098	1,770
Operating profit in local currencies	50,346	50,737
Operating profit in same period previous year	48,967	48,432
% increase/(decrease) in local currencies	3%	5%
% increase/(decrease) in reported currencies	(4%)	1%

#### Free cash flow

Novo Nordisk defines free cash flow as 'net cash generated from operating activities' less 'net cash used in investing activities' excluding net change of marketable securities. Free cash flow is a measure of the amount of cash generated in the period which is available for the Board to allocate between Novo Nordisk's capital providers, through e.g. dividends, share repurchases and repayment of debt (excl. lease liability repayments) or for retaining in the business to fund future growth.

With IFRS 16 'Leases' becoming effective 1 January 2019, lease payments will transfer from 'net cash flow from operating activities' to 'cash flow from financing activities' (excluding interest expense). Effective from 1 January 2019, the definition of free cash flow will be amended to also deduct the principal repayment on lease liabilities. Accordingly the implementation of IFRS 16 will have a neutral impact on free cash flow. The free cash flow outlook guidance for 2019 (p. 13) is calculated on the amended definition of free cash flow.

Financial Performance

Outlook

R&D

Sustainability

ity Equity

Legal



# **APPENDIX 10: NON-IFRS FINANCIAL MEASURES (ADDITIONAL INFORMATION) (CONTINUED)**

The following table shows a reconciliation of Free cash flow with Net cash generated from operating activities, the most directly comparable IFRS financial measure:

#### Free cash flow

DKK million	2018	2017
Net cash generated from operating activities	44,616	41,168
Net cash used in investing activities	(12,080)	(6,571)
Net purchase of marketable securities	—	(2,009)
Free cash flow	32,536	32,588

#### Cash to earnings

Cash to earnings is defined as 'free cash flow as a percentage of net profit'. Management believes that Cash to earnings is an important performance metric because it measures the Group's ability to turn earnings into cash. Hence it is considered a meaningful measure for investors to understand the development of the Group's net cash generated from operating and investing activities. Since Management wants this measure to capture the ability of the Group's operations to generate cash, free cash flow is used as the numerator instead of net cash flow.

#### Cash to earnings

DKK million	2018	2017
Free cash flow	32,536	32,588
/ Net profit	38,628	38,130
Cash to earnings	84.2%	85.5%

#### Operating profit after tax to net operating assets

Operating profit after tax to net operating assets is defined as 'operating profit after tax (using the effective tax rate) as a percentage of average inventories, receivables, property, plant and equipment, intangible assets and deferred tax assets less non-interest-bearing liabilities including provisions and deferred tax liabilities (where average is the sum of the above assets and liabilities at the beginning of the year and at year-end divided by two)'.

Management believes Operating profit after tax to net operating assets is a useful measure in providing investors and Management with information regarding the Group's performance. The calculation of the financial target 'Operating profit after tax to net operating assets' is a widely accepted measure of earnings efficiency in relation to total capital employed.

#### Operating profit after tax to net operating assets

DKK million	2018	2017
Operating profit after tax	38,318	38,341
/ Average net operating assets	32,832	26,776
Operating profit after tax to net operating profit	116.7%	143.2%

R&D

Sustainability

