

NOVO NORDISK A S
Form 6-K
February 01, 2019
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

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

February 1, 2019

NOVO NORDISK A/S
(Exact name of Registrant as specified in its charter)

Novo Allé
DK-2880 Bagsværd
Denmark
(Address of principal executive offices)

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

Form 20-F Form 40-F

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

Yes No

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

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® increased by 5% to DKK 24.3 billion (9% in local currencies).

• Sales of Ozempic® were DKK 1,796 million and total GLP-1 sales increased by 13% (18% in local currencies).

• Sales of Saxenda® increased by 51% to DKK 3.9 billion (60% in local currencies).

• Sales of Tresiba® 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®, a new once-weekly GLP-1, in the USA. The weekly new-to-brand prescription market share for Ozempic® has now reached 26% and thereby stabilising the total Novo Nordisk GLP-1 market share. Ozempic® 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 once-daily 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 in Danish kroner is expected 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.

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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®, 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.”

Novo Nordisk A/S Investor Relations	Novo Allé 2880 Bagsværd Denmark	Telephone: +45 4444 8888 www.novonordisk.com	CVR Number: 24 25 67 90 Company announcement No 6 / 2019
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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

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

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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.

INCOME STATEMENT	2018	2017	2016	2015	2014	% change 2017 to 2018	
DKK million							
Net sales	111,831	111,696	111,780	107,927	88,806	0	%
Gross profit	94,214	94,064	94,597	91,739	74,244	0	%
Gross margin	84.2	% 84.2	% 84.6	% 85.0	% 83.6	%	
Sales and distribution costs	29,397	28,340	28,377	28,312	23,223	4	%
Percentage of sales	26.3	% 25.4	% 25.4	% 26.2	% 26.2	%	
Research and development costs	14,805	14,014	14,563	13,608	13,762	6	%
Percentage of sales	13.2	% 12.5	% 13.0	% 12.6	% 15.5	%	
Administrative costs	3,916	3,784	3,962	3,857	3,537	3	%
Percentage of sales	3.5	% 3.4	% 3.5	% 3.6	% 4.0	%	
Other operating income, net	1,152	1,041	737	3,482	¹ 770	11	%
Operating profit	47,248	48,967	48,432	49,444	34,492	(4	%)
Operating margin	42.2	% 43.8	% 43.3	% 45.8	% 38.8	%	
Financial items (net)	367	(287) (634) (5,961) (396) N/A	
Profit before income taxes	47,615	48,680	47,798	43,483	34,096	(2	%)
Income taxes	8,987	10,550	9,873	8,623	7,615	(15	%)
Effective tax rate	18.9	% 21.7	% 20.7	% 19.8	% 22.3	%	
Net profit	38,628	38,130	37,925	34,860	26,481	1	%
Net profit margin	34.5	% 34.1	% 33.9	% 32.3	% 29.8	%	

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

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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 ¹⁾	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) ²⁾	8.15	7.85	7.60	6.40	5.00	4	%
Payout ratio ³⁾	50.6	%50.4	%50.2	%46.6	%48.7	%	

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

²⁾ 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.

³⁾ Total dividend for the year as a percentage of net profit.

PERFORMANCE AGAINST LONG-TERM FINANCIAL TARGETS

	2018	2017	2016	2015	2014	Target ²⁾	
Operating profit growth	(3.5 %)	1.1 %	(2.0 %)	43.3 %	9.5 %	5 %	%
Operating profit growth adjusted ¹⁾	(3.5 %)	1.1 %	3.9 %	35.2 %	9.5 %	%	
Operating profit growth adjusted in local currencies ¹⁾	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 %	%

¹⁾ 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 out-licensing of assets for inflammatory disorders, both in 2015.

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

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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® and Ozempic®, the obesity product Saxenda®, as well as long-acting insulin Tresiba® and Xultophy®, partly offset by declining sales of Levemir® and NovoRapid®. Declining sales within biopharmaceuticals were driven by NovoSeven® and 'Other biopharmaceuticals', partly offset by increased sales of NovoEight® and Norditropin®.

Sales split per therapy	Sales 2018 DKK million	Sales 2017 DKK million	Growth as reported	Growth in local currencies	Share of growth in local currencies	
The diabetes and obesity segment						
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®	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®	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®	1,796	-	-	-	36	%
Total GLP-1	26,129	23,173	13	% 18	% 78	%
Other diabetes ¹⁾	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 ²⁾	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 ³⁾	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	%

1) Primarily oral antidiabetic products, needles and GlucaGen[®] HypoKit[®].

2) Comprises NovoSeven[®], NovoEight[®], NovoThirteen[®] and Refixia[®].

3) Primarily Vagifem[®] and Activelle[®].

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.

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Sales split per region	Sales 2018 DKK million	Growth as reported	Growth 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)	%(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[®], Xultophy[®] and Levemir[®]) decreased by 6% measured in Danish kroner and by 2% in local currencies to DKK 20,844 million.

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

Sales of Xultophy[®], a once-daily combination of insulin degludec (Tresiba[®]) and liraglutide (Victoza[®]), 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[®] has now been launched in 26 countries.

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

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

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

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

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INSULIN MARKET SHARES (volume, MAT)	Novo Nordisk's share of the total 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®, NovoMix®, NovoRapid®, Tresiba®, Xultophy®, Ryzodeg® and Fiasp® ** 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® and NovoLog® and lower realised prices partly offset by higher sales of the new-generation insulin Xultophy® 100/3.6 and Tresiba® 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®.

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®, Tresiba® and Fiasp® across the region, partly offset by contracting Levemir® sales reflecting the continued roll-out of Tresiba®, as well as declining NovoMix® 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® and NovoRapid®, 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® and Tresiba® in Japan.

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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® and Ozempic®) increased by 13% measured in Danish kroner and by 18% in local currencies to DKK 26,129 million. Ozempic® 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)	Novo Nordisk's share of the diabetes GLP-1 market*			
	GLP-1 share of total diabetes market	November 2018	November 2017	November 2018
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® and Ozempic® ** 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® and Ozempic®) 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® 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® 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® has now reached 26% and thereby stabilising the total Novo Nordisk market share. Sales of Victoza® increased by 4% measured in Danish kroner and by 8% in local currencies. Sales growth of Victoza® is driven by the positive impact from the updated label for Victoza® 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®.

International Operations

Sales of Victoza® 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®, 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.

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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® in the Chinese National Reimbursement Drug List in July 2017. In China, Victoza® 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®HypoKit®, 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®, 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® has obtained broad commercial formulary market access, but generally with prior authorisation requirements. Saxenda® 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® 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® sales in Region Latin America due to timing of tender

deliveries. Furthermore, sales of NovoEight® in Region Europe and Region AAMEO contributed positively to the sales development as well as Refixia®, 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.

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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[®], Tresiba[®] and Saxenda[®] sales, partly countered by lower contribution from NovoSeven[®]. 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[®] and Saxenda[®] as well as launch activities for Ozempic[®] 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

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.

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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[®], Saxenda[®], Tresiba[®], NovoRapid[®], Xultophy[®] and Fiasp[®], partly offset by Levemir[®], NovoSeven[®] and NovoMix[®]. 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[®], Saxenda[®] and Ozempic[®] sales, partly countered by lower contribution from NovoSeven[®]. 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[®] as well as Tresiba[®] 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[®] and Fiasp[®], 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.

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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 as reported	2% to 5% Around 2 percentage points higher than in local currencies
Operating profit growth in local currencies as reported	2% to 6% 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® and Ozempic® and the obesity product Saxenda® 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.

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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	Impact on Novo Nordisk's 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