

NOVO NORDISK A S
Form 6-K
May 03, 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

May 3, 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 2019 to 31 March 2019

3 May 2019

Novo Nordisk's operating profit increased by 14% in Danish kroner and by 8% at constant exchange rates (CER) in the first three months of 2019

Sales increased by 9% in Danish kroner and by 4% at CER to DKK 29.3 billion. Operating profit growth of 8% at CER was positively impacted by a reversal of write-downs of oral semaglutide prelaunch inventory.

Sales in International Operations increased by 13% in Danish kroner (13% at CER), driven by growth in all regions and positively impacted by timing of shipments. Sales in North America Operations increased by 4% in Danish kroner (decreased 4% at CER), negatively impacted by inventory reductions.

Sales within Diabetes and obesity increased by 10% to DKK 24.8 billion (5% at CER), driven by Diabetes growing 4% at CER and Obesity growing 51% at CER. Sales within biopharmaceuticals increased by 3% to DKK 4.5 billion (unchanged at CER).

Sales of Ozempic® were DKK 1,425 million and it has now been launched in 19 countries. In the USA, the new-to-brand prescription market share for Ozempic® has now exceeded 30% bringing Novo Nordisk's combined GLP-1 new-to-brand prescription market share to 50%.

Oral semaglutide has been filed for regulatory approval of glycaemic control in both the USA and the EU. Furthermore, oral semaglutide and Ozempic® have been filed for regulatory approval for CV risk reduction in the USA.

- For the 2019 outlook, sales growth is still expected to be 2-5% at CER, and operating profit growth is still expected to be 2-6% at CER.

PROFIT AND LOSS	Q1 2019	Growth as reported	Growth at CER*
DKK million			
Net sales	29,291	9	% 4
Operating profit	14,239	14	% 8
Net profit	10,445	(3)	(%)N/A
Diluted earnings per share	4.36	(1)	(%)N/A

* CER: Constant exchange rates (average 2018)

Lars Fruergaard Jørgensen, president and CEO: "We delivered very solid performance in International Operations, driven by sales growth in all regions, meanwhile, sales in the USA were negatively impacted by inventory reductions. The global launch of Ozempic®, our new once-weekly GLP-1, is well on track and continues to gain market share.

Edgar Filing: NOVO NORDISK A S - Form 6-K

From a regulatory perspective, we achieved important milestones with the filing of oral semaglutide both in the USA and the EU. Based on the progress we made in the first quarter of 2019, we are on track to deliver on our outlook for the full-year.”

On 3 May 2019 at 13.00 CEST, corresponding to 7.00 am EDT, 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.

Novo Nordisk A/S Investor Relations	Novo Allé	Telephone:	CVR Number:
	2880 Bagsværd	+45 4444 8888	24 25 67 90
	Denmark	www.novonordisk.com	
		Company Announcement No 30 / 2019	

Financial report for the period 1 January 2019 to 31 March 2019 Page 3 of 28

FINANCIAL PERFORMANCE

CONSOLIDATED FINANCIAL STATEMENT FOR THE FIRST THREE MONTHS OF 2019

PROFIT AND LOSS DKK million	Q1 2019	Q1 2018	% change Q1 2019 to Q1 2018	
Net sales	29,291	26,930	9	%
Gross profit	24,559	22,733	8	%
Gross margin	83.8	% 84.4	%	
Sales and distribution costs	6,946	6,451	8	%
Percentage of sales	23.7	% 24.0	%	
Research and development costs	2,678	3,321	(19	%)
Percentage of sales	9.1	% 12.3	%	
Administrative costs	911	864	5	%
Percentage of sales	3.1	% 3.2	%	
Other operating income, net	215	351	(39	%)
Operating profit	14,239	12,448	14	%
Operating margin	48.6	% 46.2	%	
Financial items (net)	(1,017)	1,161	N/A	
Profit before income taxes	13,222	13,609	(3	%)
Income taxes	2,777	2,858	(3	%)
Effective tax rate	21.0	% 21.0	%	
Net profit	10,445	10,751	(3	%)
Net profit margin	35.7	% 39.9	%	
OTHER KEY NUMBERS				
Depreciation, amortisation and impairment losses	1,058	732	45	%
Capital expenditure (tangible assets)	2,101	2,310	(9	%)
Net cash generated from operating activities	9,890	9,815	1	%
Free cash flow	6,655	7,241	(8	%)
Total assets	110,135	93,558	18	%
Equity	47,319	44,238	7	%
Equity ratio	43.0	% 47.3	%	

Average number of diluted shares outstanding (million)	2,394.6	2,442.3	(2	%)
Diluted earnings per share / ADR (in DKK)	4.36	4.40	(1	%)
Full-time equivalent employees end of period	42,453	42,688	(1	%)

These unaudited consolidated financial statements for the first three months of 2019 have been prepared in accordance with IAS 34 'Interim Financial Reporting'. The accounting policies adopted in the preparation are consistent with those applied in the Annual Report 2018 of Novo Nordisk, except for the adoption of new, amended or revised standards and interpretations ('IFRSs'), as published by the IASB, that are endorsed by the EU and effective as of 1 January 2019. This includes IFRS 16 'Leases' applied on a modified retrospective basis, see appendix 7. Furthermore, the financial report, including the consolidated financial statements for the first three months of 2019 and the Management's review, have been prepared in accordance with additional Danish disclosure requirements for interim reports of listed companies. Going forward, the term 'constant exchange rates' (CER) will be used in stead of 'local currencies'. There is no difference between the two terms.

Financial
Performance

Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

Financial report for the period 1 January 2019 to 31 March 2019 Page 4 of 28

GEOGRAPHIC SALES DEVELOPMENT

Sales increased by 9% measured in Danish kroner and by 4% at CER to DKK 29,291 million in the first three months of 2019. Sales in International Operations increased by 13% in both Danish kroner and at CER, positively impacted by timing of shipments primarily in Region AAMEO and Region Latin America. Sales in North America Operations increased by 4% measured in Danish kroner and decreased by 4% at CER, negatively impacted by inventory reductions.

Sales split per region	Sales Q1 2019 DKK million	Growth as reported	Growth at CER	Share of growth at CER	
International Operations	15,387	13	% 13	% 143	%
- Region Europe	5,505	5	% 5	% 22	%
- Region AAMEO	3,738	29	% 29	% 70	%
- Region China	3,375	11	% 9	% 22	%
- Region Japan & Korea	1,458	16	% 9	% 10	%
- Region Latin America	1,311	14	% 20	% 19	%
North America Operations	13,904	4	%(4	%(43	%(
- USA	13,211	3	%(5	%(59	%(
Total sales	29,291	9	% 4	% 100	%

International Operations

Sales in International Operations increased by 13% in both Danish kroner and at CER. Sales growth was driven by growth in all regions, and key drivers being Region AAMEO growing 29% (CER), Region Europe growing 5% (CER) and Region China growing 9% (CER). Sales growth was driven by increasing insulin, GLP-1 and obesity sales while sales in Biopharm were broadly unchanged.

Region Europe

Sales in Region Europe increased by 5% in both Danish kroner and at CER. Sales growth was driven by Diabetes growing 7% (CER) from increased GLP-1 and new-generation insulin sales, and Obesity growing 74% (CER), partly offset by Biopharm declining by 4% (CER).

Region AAMEO

Sales in Region AAMEO increased by 29% in both Danish kroner and at CER. Sales growth was driven by Diabetes growing 27% (CER) from increased insulin sales, Obesity growing 149% (CER) and Biopharm growing by 18% (CER). Sales were positively impacted by timing of shipments, mainly in Diabetes.

Region China

Sales in Region China increased by 11% measured in Danish kroner and by 9% at CER. Sales growth was driven by Diabetes growing 8% (CER) from increased modern insulin and GLP-1 sales.

Region Japan & Korea

Sales in Region Japan & Korea increased by 16% measured in Danish kroner and by 9% at CER. Sales growth was driven by Obesity following the introduction of Saxenda® in Korea in 2018 and Biopharm growing by 9% (CER), while Diabetes sales were unchanged at CER.

Region Latin America

Sales in Region Latin America increased by 14% measured in Danish kroner and by 20% at CER. Sales growth was driven by Diabetes growing 37% (CER) from increased insulin and GLP-1 sales, and Obesity growing 90% (CER), partly offset by Biopharm declining by 17% (CER) reflecting timing of tender shipments.

North America Operations

Sales in North America Operations increased by 4% measured in Danish kroner and decreased by 4% at CER. Sales decline was driven by the USA declining by 5% (CER) negatively impacted by inventory reductions, adjusted hereof, sales are broadly unchanged, which reflects increased GLP-1 sales, partly offset by declining insulin sales as well as increased Obesity sales, partly offset by declining Biopharm sales.

Financial
Performance

Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

Financial report for the period 1 January 2019 to 31 March 2019 Page 5 of 28

SALES DEVELOPMENT ACROSS THERAPEUTIC CATEGORIES

Total sales growth in the first three months of 2019 of 9% in Danish kroner and 4% measured at CER was driven by solid growth in Diabetes of 4% (CER) and Obesity growth of 51% (CER), partly offset by unchanged Biopharm sales when measured at CER.

Sales split per therapy	Sales Q1 2019 DKK million	Sales Q1 2018 DKK million	Growth as reported	Growth at CER	Share of growth at CER	
Diabetes and obesity segment						
Long-acting insulin	5,244	4,873	8	% 3	% 11	%
- Tresiba®	2,147	1,755	22	% 16	% 23	%
- Xultophy®	477	338	41	% 38	% 11	%
- Levemir®	2,620	2,780	(6)	%(10)	%(23)	%(%)
Premix insulin	2,757	2,642	4	% 3	% 6	%
- Ryzodeg®	212	141	50	% 49	% 6	%
- NovoMix®	2,545	2,501	2	% 0	% 0	%
Fast-acting insulin	4,977	4,778	4	% 0	% 2	%
- Fiasp®	231	83	178	% 167	% 12	%
- NovoRapid®	4,746	4,695	1	% (3)	%(10)	%(%)
Human insulin	2,415	2,366	2	% 0	% 0	%
Total insulin	15,393	14,659	5	% 2	% 19	%
Victoza®	5,722	5,989	(4)	%(10)	%(48)	%(%)
Ozempic®	1,425	69	-	-	104	%
Total GLP-1	7,147	6,058	18	% 11	% 56	%
Other diabetes ¹⁾	1,067	1,121	(5)	%(7)	%(7)	%(%)
Total diabetes	23,607	21,838	8	% 4	% 68	%
Obesity (Saxenda®)	1,211	770	57	% 51	% 33	%
Diabetes and obesity total	24,818	22,608	10	% 5	% 101	%

Biopharmaceuticals segment						
Haemophilia ²⁾	2,533	2,503	1	% (3	%(6	%)
- NovoSeven [®]	2,012	2,154	(7	%(11	%(19	%)
- NovoEight [®]	393	296	33	% 29	% 7	%
Growth disorders (Norditropin [®])						
Other biopharmaceuticals ³⁾	385	338	14	% 13	% 4	%
Biopharmaceuticals total	4,473	4,322	3	% 0	% (1	%)
Total sales	29,291	26,930	9	% 4	% 100	%

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

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

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

Financial Performance Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

Financial report for the period 1 January 2019 to 31 March 2019 Page 6 of 28

DIABETES AND OBESITY

Diabetes, sales development

Sales in Diabetes increased by 8% measured in Danish kroner and by 4% at CER to DKK 23,607 million driven by solid GLP-1 and insulin growth. Novo Nordisk has improved the global diabetes value market share over the last 12 months from 27.5% to 28.1%, driven by improved global insulin market share and growth of the GLP-1 segment, partly offset by declining GLP-1 market share.

In the following sections, unless otherwise noted, market data are based on moving annual total (MAT) from February 2019 and February 2018 provided by the independent data provider IQVIA.

Diabetes, regional development	Novo Nordisk's share of the total diabetes market (value, MAT)		Diabetes, sales development	Growth at CER	
	February 2019	February 2018			
Global	28.1%	27.5%	23,607	4	%
International Operations	22.1%	22.3%	12,039	13	%
- Region Europe	26.7%	26.9%	4,226	7	%
- Region AAMEO *	21.8%	21.9%	2,925	27	%
- Region China **	28.1%	30.1%	3,291	8	%
- Region Japan & Korea	9.8%	10.4%	833	0	%
- Region Latin America ***	16.4%	15.7%	764	37	%
North America Operations	30.4%	29.6%	11,568	(5)	%
- USA	30.7%	29.9%	11,105	(6)	%

Source: IQVIA, February 2019 data. * 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.

Insulin

Total sales of insulin increased by 5% measured in Danish kroner and by 2% at CER to DKK 15,393 million. Sales growth was driven by International Operations, partly offset by declining sales in the USA.

Sales of long-acting insulin increased by 8% measured in Danish kroner and by 3% at CER to DKK 5,244 million. Novo Nordisk has improved its global volume market share in the long-acting insulin segment from 30.9% to 32.1% the last 12 months. Sales were driven by Tresiba® and Xultophy®, partly offset by Levemir®. Tresiba® has now been launched in 79 countries, while Xultophy® now has been launched in 32 countries.

Sales of premix insulin increased by 4% measured in Danish kroner and by 3% at CER to DKK 2,757 million. Novo Nordisk is market leader in the segment and has improved its global volume market share in the premix insulin segment from 63.6% to 64.3% the last 12 months. The increase in sales was driven by Ryzodeg[®] while sales of NovoMix[®] were broadly unchanged. Ryzodeg[®] has been launched in 27 countries.

Sales of fast-acting insulin increased by 4% measured in Danish kroner, and remained unchanged at CER, to DKK 4,977 million. Novo Nordisk is market leader in the segment and the global volume market share in the fast-acting insulin segment of 51.0% has been unchanged over the past 12 months. The unchanged sales measured at CER were positively impacted by Fiasp[®], offset by declining sales of NovoRapid[®]. Fiasp[®] has now been launched in 27 countries.

Sales of human insulin increased by 2% measured in Danish kroner, and remained unchanged at CER, to DKK 2,415 million.

Financial
Performance

Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

Financial report for the period 1 January 2019 to 31 March 2019 Page 7 of 28

Novo Nordisk's share of the total insulin market (volume, MAT)

Insulin, regional development of the total insulin market (volume, MAT)

	February 2019	February 2018	Sales Q1 2019 DKK million	Growth at CER	
Global	46.7%	46.1%	15,393	2	%
International Operations	49.4%	49.1%	9,333	13	%
- Region Europe	43.9%	44.4%	3,041	3	%
- Region AAMEO *	57.0%	55.6%	2,479	30	%
- Region China **	50.7%	52.7%	2,640	9	%
- Region Japan & Korea	50.4%	49.8%	582	(5)	%
- Region Latin America ***	47.8%	42.5%	591	40	%
North America Operations	40.2%	39.2%	6,060	(13)	%
- USA	40.6%	39.5%	5,828	(14)	%

Source: IQVIA, February 2019 data. * 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.

International Operations

Sales of insulin in International Operations increased by 13% in both Danish kroner and at CER. Sales growth measured at CER was driven by long-acting, premix and fast-acting insulin as well as increasing human insulin sales.

Region Europe

Sales of insulin in Region Europe increased by 4% measured in Danish kroner and by 3% at CER. Sales growth was 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 human insulin and NovoMix® sales.

Region AAMEO

Sales of insulin in Region AAMEO increased by 29% measured in Danish kroner and by 30% at CER. The sales growth was driven by increased sales of NovoRapid®, human insulin and NovoMix®.

Region China

Sales of insulin in Region China increased by 12% measured in Danish kroner and by 9% at CER. The sales growth was driven by NovoMix®, NovoRapid® and Levemir®, partly offset by lower human insulin sales.

Region Japan & Korea

Sales of insulin in Region Japan & Korea increased by 1% measured in Danish kroner and decreased by 5% at CER. The decline in sales at CER was driven by NovoRapid® and NovoMix®, 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® in Japan.

Region Latin America

Sales of insulin in Region Latin America increased by 30% measured in Danish kroner and by 40% at CER. The sales growth was driven by growth of the overall diabetes market, market share gains, inflationary price effects and increased sales of human insulin, NovoRapid® and Tresiba®.

North America Operations

Sales of insulin in North America Operations decreased by 6% measured in Danish kroner and by 13% at CER. The sales were negatively impacted by inventory reductions, impacting all insulin segments. Novo Nordisk expanded its volume market share from 39.2% to 40.2% measured over the last 12 months, and the expansion was driven by continued market share gains in the basal insulin segment. In addition to the inventory reductions, the decline in sales in the USA was driven by lower realised prices, including negative impact from changes in the payer mix in short-acting insulin and the changes in the coverage gap legislation.

Financial Performance Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

Financial report for the period 1 January 2019 to 31 March 2019 Page 8 of 28

GLP-1 therapy for type 2 diabetes

Sales of GLP-1 products for type 2 diabetes (Victoza® and Ozempic®) increased by 18% measured in Danish kroner and by 11% at CER to DKK 7,147 million. Ozempic® has now been launched in 19 countries in North America Operations and Region Europe. Sales growth was driven by both International Operations and North America Operations. The GLP-1 segment's value share of the total diabetes market has increased to 15.3% compared with 12.3% 12 months ago. Novo Nordisk continues to be the global market leader in the GLP-1 segment with a 46.1% value market share.

GLP-1, regional development	Novo Nordisk's share of the diabetes GLP-1 market (value, MAT)*		GLP-1, sales development		
	February 2019	February 2018	Sales Q1 2019 DKK million	Growth at CER	
Global	46.1%	48.5%	7,147	11	%
International Operations	50.6%	54.9%	1,842	25	%
- Region Europe	53.9%	57.2%	1,050	21	%
- Region AAMEO **	41.8%	47.6%	272	11	%
- Region China ***	89.3%	72.2%	214	90	%
- Region Japan & Korea	31.7%	38.1%	147	10	%
- Region Latin America ****	66.7%	72.5%	159	35	%
North America Operations	46.1%	47.3%	5,305	7	%
- USA	44.8%	46.8%	5,109	6	%

Source: IQVIA, February 2019 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.

International Operations

Sales of GLP-1 in International Operations increased by 25% in both Danish kroner and at CER. Sales growth is driven by all regions. The value share of the GLP-1 class of the total diabetes market has increased to 7.9% from 6.8% in 2018. Novo Nordisk is the market leader with a 50.6% value market share.

Region Europe

Sales in Region Europe increased by 21% in both Danish kroner and at CER. The sales development reflects the positive impact from the expanded CV label for Victoza® and the introduction of Ozempic® in 17 countries, partly offset by competition from a once-weekly product. The initial feedback from the launch of Ozempic® has been positive. Novo Nordisk remains the market leader in Region Europe with a 53.9% value market share.

Region AAMEO

Sales in Region AAMEO increased by 15% measured in Danish kroner and by 11% at CER. The value share of the GLP-1 class of the total diabetes market remains low and Novo Nordisk is the GLP-1 market leader across Region AAMEO with a value market share of 41.8%.

Region China

Sales in Region China increased by 95% measured in Danish kroner and by 90% at CER. The increase in sales reflects the inclusion of Victoza® in the Chinese National Reimbursement Drug List in July 2017 as well as continued investments, which have driven the expansion of the GLP-1 category and increased the Victoza® GLP-1 value market share to 89.3%. The share of the GLP-1 class of the total diabetes market still remains low.

Region Japan & Korea

Sales in Region Japan & Korea increased by 17% measured in Danish kroner and by 10% at CER. The sales growth reflects the continued expansion of the GLP-1 market in Japan, partly offset by intensified competition from a once-weekly product. Novo Nordisk currently holds a value market share of 31.7%.

Financial Performance Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

Region Latin America

Sales in Region Latin America increased by 25% measured in Danish kroner and by 35% at CER. The sales growth reflects the continued expansion of the GLP-1 markets across the region. Novo Nordisk remains the market leader in the region with a value market share of 66.7%.

North America Operations

Sales of Novo Nordisk's GLP-1 diabetes products in North America Operations increased by 16% measured in Danish kroner and by 7% at CER. Novo Nordisk is the market leader with a 46.1% value market share. The value share of the GLP-1 class of the total North American diabetes market has increased to 18.1%.

Sales growth in the USA is driven by an underlying prescription volume growth of the GLP-1 segment of more than 25%. In February 2018, Novo Nordisk launched Ozempic® in the USA and broad formulary coverage has been obtained. The weekly new-to-brand prescription market share for Ozempic® has now reached 30% bringing Novo Nordisk's combined GLP-1 new-to-brand prescription market share to 50%, consequently the decline in the total Novo Nordisk GLP-1 market share has stabilised when measured on monthly prescriptions.

Sales of total GLP-1 in the USA increased by 6% at CER. The increase in sales was driven by continued uptake of Ozempic®, partly offset by declining sales of Victoza®. The declining sales of Victoza® reflects a negative impact from inventory reductions, changes in the payer and channel mix and the changes in the coverage gap legislation, impacting average realised prices negatively. Furthermore, Victoza® was impacted by the continued competition from a once-weekly product, as well as the impact from the launch of Ozempic®.

Financial Performance Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

Financial report for the period 1 January 2019 to 31 March 2019 Page 10 of 28

Obesity, sales development

Sales of Saxenda® increased by 57% measured in Danish kroner and by 51% at CER to DKK 1,211 million. Sales growth of Saxenda® was driven by both International Operations and North America Operations. Saxenda® has been launched in 41 countries.

Obesity, regional
development

Obesity, sales
development

Sales Q1 2019 Growth
DKK million at CER

Global	1,211	51	%
International Operations	540	146	%
- Region Europe	66	74	%
- Region AAMEO	236	149	%
- Region China	2	—	
- Region Japan & Korea	77	—	
- Region Latin America	159	90	%
North America Operations	671	13	%
- USA	616	13	%

International Operations

Sales of Saxenda® in International Operations increased by 145% measured in Danish kroner and by 146% at CER driven by increased sales in all regions where Saxenda® has been introduced. Novo Nordisk currently has a value market share of 38% in the obesity market in International Operations.

Region Europe

Sales of Saxenda® in Region Europe increased by 74% in both Danish kroner and at CER. Saxenda® has now been launched in 18 countries in Region Europe. Novo Nordisk currently has a value market share of 45% in the obesity market in Region Europe.

Region AAMEO

Sales of Saxenda® in Region AAMEO increased by 157% measured in Danish kroner and by 149% at CER. Saxenda® has now been launched in 14 countries in Region AAMEO. Novo Nordisk currently has a value market share of 52% in the obesity market in Region AAMEO.

Region Japan & Korea

Sales of Saxenda® in Region Japan & Korea were driven by sales in South Korea following the launch in early 2018.

Region Latin America

Sales of Saxenda® in Region Latin America increased by 77% measured in Danish kroner and by 90% at CER. Saxenda® has now been launched in five countries in Region Latin America. Novo Nordisk currently has a value market share of 33% in the obesity market in Region Latin America.

North America Operations

Sales of Saxenda® in North America Operations increased by 22% measured in Danish kroner and by 13% at CER and were driven by increased sales in both the USA and Canada. Sales in the USA were negatively impacted by inventory reductions. Novo Nordisk currently has a value market share of 68% in the obesity market in North America Operations.

Financial Performance Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

Financial report for the period 1 January 2019 to 31 March 2019 Page 11 of 28

BIOPHARMACEUTICALS

Biopharmaceuticals, sales development

Sales of biopharmaceutical products increased by 3% measured in Danish kroner, and remained unchanged at CER, to DKK 4,473 million. The sales development measured at CER was driven by declining sales in North America Operations as well as Region Latin America and Region Europe offset by sales growth in Region AAMEO, Region Japan & Korea and Region China.

Biopharmaceuticals, regional development	Biopharmaceuticals, sales development
---	--

	Sales Q1 2019	Growth	
	DKK million	at CER	

Global	4,473	0	%
International Operations	2,808	1	%
- Region Europe	1,213	(4	%)
- Region AAMEO	577	18	%
- Region China	82	41	%
- Region Japan & Korea	548	9	%
- Region Latin America	388	(17	%)
North America Operations	1,665	(3	%)
- USA	1,490	(9	%)

Haemophilia

Sales of haemophilia products increased by 1% measured in Danish kroner and decreased by 3% at CER to DKK 2,533 million. Declining sales were driven by lower NovoSeven® sales, partly offset by increased NovoEight® and Refixia® sales.

Sales of NovoSeven® decreased by 7% measured in Danish kroner and by 11% at CER to DKK 2,012 million, reflecting the continued competitive pressure from a recently introduced product. The development in sales is driven by declining sales in Region Europe and Region Latin America as well as in North America Operations.

Sales of NovoEight® increased by 33% measured in Danish kroner and by 29% at CER to DKK 393 million. Sales growth was driven by Region AAMEO and Region Europe. NovoEight® has now been launched in 46 countries.

Sales of Refixia® increased to DKK 77 million. Sales growth was driven by the product launches in North America Operations and Region Europe. Refixia® has now been launched in 14 countries.

Growth disorders (Norditropin®)

Sales of growth disorder products increased by 5% measured in Danish kroner and by 1% at CER to DKK 1,555 million. The sales growth measured at CER was driven by positive contribution from International Operations, partly offset by declining sales in North America Operations impacted by inventory reductions in the USA. Novo Nordisk is the leading company in the global human growth disorder market with a 33% market share measured in value.

Financial
Performance Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

DEVELOPMENT IN COSTS AND OPERATING PROFIT

The cost of goods sold increased by 13% in Danish kroner and by 12% at CER to DKK 4,732 million, resulting in a gross margin of 83.8% measured in Danish kroner, compared with 84.4% in 2018. The decrease in gross margin reflects a negative impact from growth of lower margin insulin products and lower prices, primarily related to the insulin segment in the USA, partly countered by improved productivity and a positive currency impact of 0.6 percentage point.

Sales and distribution costs increased by 8% in Danish kroner and by 3% at CER to DKK 6,946 million. The increase in sales and distribution costs is driven by International Operations reflecting resource allocation to growth markets and promotional activities for Victoza® and Saxenda® as well as launch activities for Ozempic®. In the USA, promotional activities are focusing on Ozempic®, Saxenda® and Tresiba®.

Research and development costs decreased by 19% in Danish kroner and by 21% at CER to DKK 2,678 million, reflecting reversal of write-downs on clinical prelaunch inventory of approximately DKK 500 million, following the filing of oral semaglutide to the US FDA. Adjusted for the reversal of write-downs, research and development costs declined by 6%. The decline in costs is driven by the completion of the oral semaglutide phase 3a development programme and the completion of the head-to-head study between Tresiba® and insulin glargine U300, partly offset by increasing costs for the semaglutide in obesity clinical programmes STEP and SELECT.

Administration costs increased by 5% in Danish kroner and by 3% at CER to DKK 911 million, reflecting growth across the regions in International Operations.

Other operating income (net) was DKK 215 million compared with DKK 351 million in 2018. 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 A/S to Novo Holdings A/S.

Operating profit increased by 14% in Danish kroner and by 8% at CER to DKK 14,239 million. Adjusting for the positive impact from the reversal of write-downs of oral semaglutide prelaunch inventory operating profit growth was 4% at CER.

FINANCIAL ITEMS (NET)

Financial items (net) showed a net loss of DKK 1,017 million compared with a net gain of DKK 1,161 million in 2018.

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 loss of DKK 876 million compared with a gain of DKK 1,107 million in 2018. This development reflects a loss on foreign exchange hedging, involving especially the US dollar versus the Danish krone.

As per the end of March 2019, a negative market value of financial contracts of approximately DKK 1.8 billion has been deferred for recognition later in 2019 and 2020.

CAPITAL EXPENDITURE AND FREE CASH FLOW

Net capital expenditure for property, plant and equipment was DKK 2.1 billion compared with DKK 2.3 billion in 2018. 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.

Free cash flow was DKK 6.7 billion compared with DKK 7.2 billion in 2018. The broadly unchanged free cash flow compared with 2018 primarily reflects proceeds from the the partial divestment of NNIT A/S shares in first quarter of 2018, a negative development in working capital and increased capital expenditure, partly offset by lower investment in intangible assets, reflecting the acquisition of a priority review voucher in 2018.

Financial
Performance

Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

EQUITY

Total equity was DKK 47,319 million at the end of the first three months of 2019, equivalent to 43.0% of total assets, compared with 47.3% at the end of the first three months of 2018. Please refer to appendix 5 for further elaboration of changes in equity.

Reduction in share capital

At the Annual General Meeting of Novo Nordisk A/S, held on 21 March 2019, a 2.04% reduction in the total share capital was approved. The reduction was effectuated by a cancellation of 50,000,000 treasury B shares of DKK 0.20 at a nominal value of DKK 10,000,000. After the legal implementation of the share capital reduction on 24 April 2019, Novo Nordisk's share capital now amounts to DKK 480,000,000 divided into an A share capital of DKK 107,487,200 and a B share capital of DKK 372,512,800.

2019 share repurchase programme

On 1 February 2019, Novo Nordisk announced a share repurchase programme of up to DKK 2.7 billion to be executed from 1 February to 1 May 2019, as part of an overall programme of up to DKK 15 billion to be executed during a 12-month period from February 2019 to January 2020. 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 8,164,004 B shares for an amount of DKK 2.7 billion in the period from 1 February to 1 May 2019. The programme was concluded on 1 May 2019.

As of 1 May 2019, Novo Nordisk and its wholly-owned affiliates owned 15,356,501 of its own B shares, corresponding to 0.6% of the total share capital.

Share repurchase under the overall programme of up to DKK 15 billion in the period February 2019 to January 2020 is expected to be resumed shortly. As announced in February 2019, 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 Holdings A/S has informed Novo Nordisk that it plans to participate in the share repurchase programme. Novo Holdings A/S has an ownership of 28.6% of the Novo Nordisk share capital after the implementation of the share capital decrease and Novo Holdings A/S currently intends to maintain its ownership of the Novo Nordisk share capital around 28%.

Financial Performance Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

Financial report for the period 1 January 2019 to 31 March 2019 Page 14 of 28

OUTLOOK

OUTLOOK 2019

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

Expectations are as reported, if not otherwise stated	Expectations 3 May 2019	Expectations 1 February 2019
Sales growth at CER as reported	2% to 5% Around 3%-points higher than at CER	2% to 5% Around 2%-points higher than at CER
Operating profit growth at CER as reported	2% to 6% Around 5%-points higher than at CER	2% to 6% Around 4%-points higher than at CER
Financial items (net)	Loss of around DKK 3.3 billion	Loss of around DKK 2.4 billion
Effective tax rate	20% to 22%	20% to 22%
Capital expenditure (PP&E)	Around DKK 9 billion	Around DKK 9 billion
Depreciation, amortisation and impairment losses	Around DKK 4.5 billion	Around DKK 4.5 billion
Free cash flow	DKK 29-34 billion	DKK 29-34 billion

For 2019, sales growth is expected to be 2% to 5%, measured at CER. 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 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 now expected to be around 3 percentage points higher than at CER.

For 2019, operating profit growth is expected to be 2% to 6%, measured at CER. 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 now expected to be around 5

percentage points higher than at CER.

For 2019, Novo Nordisk now expects financial items (net) to amount to a loss of around DKK 3.3 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.

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 depreciation of lease assets following the adoption 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 that 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 the table below for the key currency assumptions.

Financial
Performance

Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

Financial report for the period 1 January 2019 to 31 March 2019 Page 15 of 28

FX	Q1 2019	Q1 2018	% change	Spot rate 30 April 2019
USD	657	606	8	% 665
CNY	97	95	2	% 99
JPY	5.97	5.59	7	% 5.98
GBP	856	843	2	% 865
CAD	494	480	3	% 495

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 2,100 million	10
CNY	DKK 375 million	6*
JPY	DKK 160 million	12
GBP	DKK 85 million	10
CAD	DKK 100 million	9

* 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).

Financial Performance Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

Financial report for the period 1 January 2019 to 31 March 2019 Page 16 of 28

RESEARCH & DEVELOPMENT UPDATE

Diabetes

Oral semaglutide filed in the USA and EU for glycaemic control and oral semaglutide and Ozempic® filed in the USA for CV risk reduction indication

In March 2019, Novo Nordisk announced the submission of New Drug Applications (NDAs) to the US Food and Drug Administration (FDA) for oral semaglutide, a once-daily GLP-1 analogue in a tablet, seeking approval for an indication for the treatment of adults with type 2 diabetes. A priority review voucher (PRV) has been applied to the NDA, leading to an anticipated review time of six months from the submission. Furthermore, an NDA for oral semaglutide and a supplementary NDA (sNDA) for Ozempic® (once-weekly injectable semaglutide) were submitted, seeking approval for a cardiovascular (CV) risk reduction indication in adults with type 2 diabetes. The NDA for oral semaglutide and the sNDA for Ozempic® for the CV risk reduction indications have an anticipated 10-month review time from the submission date, according to standard FDA review timelines. For more information, please read the company announcement on www.novonordisk.com/media/news-details.2239031.html (the contents of the company's website do not form a part of this Form 6-K).

In April 2019, Novo Nordisk announced the submission of a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for oral semaglutide, for the treatment of adults with type 2 diabetes. For more information, please read the company announcement on www.novonordisk.com/media/news-details.2242550.html (the contents of the company's website do not form a part of this Form 6-K).

Tresiba® shows an overall lower risk of hypoglycaemia compared with insulin glargine U300 accompanied by significantly lower HbA_{1c}

In March 2019, Novo Nordisk completed a head-to-head trial comparing the hypoglycaemia profile of Tresiba® with insulin glargine U300 in more than 1,600 adults with type 2 diabetes. All endpoints related to hypoglycaemia were assessed during a 36-week maintenance period and a total treatment period of 88 weeks. In the maintenance period, both severe and nocturnal hypoglycaemic risks were significantly reduced following Tresiba® treatment and overall confirmed hypoglycaemia risk was lower, albeit not statistically significant. For the entire trial period, overall hypoglycaemia risk, as well as severe and nocturnal hypoglycaemia risks were statistically significantly lower in the Tresiba® arm. All the observed reductions in the risk of hypoglycaemic events are considered clinically meaningful. In addition to showing an overall lower risk of hypoglycaemia compared to insulin glargine U300, Tresiba® also showed statistically significantly higher reductions in HbA_{1c}. The significant HbA_{1c} difference in favour of Tresiba® occurred despite a significantly lower end-of-trial insulin dose for Tresiba® compared to insulin glargine U300. Novo Nordisk plans to present the results at a medical conference in second half of 2019.

Obesity

AM833 initiated in phase 2 in people with overweight or obesity

In March 2019, Novo Nordisk initiated a phase 2 trial for the long-acting amylin analogue AM833, intended for chronic weight management with a once-weekly subcutaneous administration. The primary objective of the trial is to assess and compare the dose-response of increasing doses of AM833, versus placebo and versus liraglutide 3.0 mg, on body weight in people with overweight or obesity, when added as an adjunct to a reduced-calorie diet and increased physical activity.

Biopharm

Novo Nordisk receives US FDA approval and CHMP positive opinion of Esperoct® (turoctocog alfa pegol, N8-GP)

Edgar Filing: NOVO NORDISK A S - Form 6-K

In February 2019, Novo Nordisk announced the US FDA approval of the Biologics License Application for Esperoct® for the treatment of adults and children with haemophilia A. Esperoct® is the brand name for turoctocog alfa pegol, N8-GP. In the USA, Esperoct® is indicated for use in adults and children with haemophilia A (congenital factor VIII deficiency) using routine prophylaxis to reduce the frequency of bleeding episodes as well as on-demand treatment for control of bleeding episodes and perioperative management of bleeding. For additional information, please read the company announcement on www.novonordisk.com/media/news-details.2235689.html (the contents of the company's website do not form a part of this Form 6-K).

Financial
Performance

Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

In April 2019, Novo Nordisk announced that the Committee for Medicinal Products for Human Use (CHMP), under the European Medicines Agency (EMA), adopted a positive opinion for the use of Esperoct® recommending marketing authorisation for the treatment of adolescents and adults with haemophilia A. The CHMP recommends Esperoct® to be indicated for both prophylaxis and for on-demand treatment of bleeding and coverage during surgical procedures in adolescents ≥ 12 years of age) and adults with haemophilia A (congenital factor VIII deficiency). For additional information, please read the company announcement on www.novonordisk.com/media/news-details.2242741.html (the contents of the company's website do not form a part of this Form 6-K).

Concizumab granted Breakthrough Therapy Designation in the USA for people with haemophilia B and inhibitors
In March 2019, concizumab was granted Breakthrough Therapy Designation (BTD) for prophylaxis to prevent or reduce the frequency of bleeding episodes in people with haemophilia B and inhibitors by the FDA. The designation means amongst others that the FDA will work closely with Novo Nordisk to develop concizumab expeditiously for this indication.

Macrilen® phase 1/2 paediatric trial initiated

In February, a phase 1/2 paediatric trial with Macrilen® (macimorelin) was initiated. Macrilen® is a ghrelin receptor agonist stimulating the secretion of growth hormone and currently indicated for diagnosis of adult growth hormone deficiency. The paediatric trial is an open-label, group comparison and dose escalation trial to investigate safety, tolerability, pharmacokinetics and pharmacodynamics of Macrilen® after single oral dosing of 0.25 mg/kg, 0.5 mg/kg and 1 mg/kg. The trial aims to enrol 24 children and adolescents under the age of 18 years. In 2018, Novo Nordisk acquired the rights for Macrilen® in the USA and Canada, and the product is currently marketed for diagnosis of adult growth hormone deficiency. The trial is conducted by Aeterna Zentaris GmbH with Novo Nordisk as a partner.

Other Serious Chronic Diseases

Gilead Sciences and Novo Nordisk announced the intention to initiate a clinical collaboration in NASH

In April 2019, Gilead Sciences, Inc. and Novo Nordisk announced that the companies intend to collaborate on a clinical trial combining compounds from their respective pipelines in nonalcoholic steatohepatitis (NASH). The intended clinical trial will be a proof-of-concept study combining Novo Nordisk's semaglutide (GLP-1 analogue) and Gilead's cilofexor (FXR agonist) and firsocostat (ACC inhibitor) for the treatment of patients with NASH.

Financial
Performance Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

SUSTAINABILITY UPDATE

The number of employees in Novo Nordisk decreased by 0.5%

The number of full-time employees at the end of the first three months of 2019 decreased by 0.5% compared to 12 months ago. The total number of employees was 43,007, corresponding to 42,453 full-time positions. This reflects a decline in Research & Development and North America Operations, countered by an increase in the global service centre in Bangalore, India, Product Supply and International Operations.

Novo Nordisk responds to affordability in the USA

In April 2019, Novo Nordisk was invited to participate in a hearing convened by the House Committee on Energy and Commerce on the topic of the rising cost of insulin. During the hearing, Doug Langa, executive vice president and president of Novo Nordisk Inc., provided the company's perspective on the complexity of the US healthcare system and also presented Novo Nordisk's approach to affordability in the USA. As a market leader in the diabetes market, Novo Nordisk has always been dedicated to bringing innovation to the market. Novo Nordisk has also committed to limit list price increases on its medicines to single-digit percentages annually. However, escalating rebates, discounts and fees (to PBMs, health insurers and other participants in the supply chain) have resulted in realised (net) prices declining on Novo Nordisk's insulin portfolio year-over-year since 2015. Despite the decline in net price, some patients face significant out-of-pocket costs for their medicines, including the uninsured and those in high deductible health plans or with co-insurance. To address affordability challenges, Novo Nordisk has since 2003 offered a Patient Assistance Programme, which provides free medicines to eligible patients who do not have insurance and certain eligible Medicare beneficiaries. With a maximum income requirement of 400 percent of the federal poverty limit, an individual with an annual income up to USD 49,960 and a family of four with an annual income up to USD 103,000 may qualify for free Novo Nordisk medicines under the programme which includes all Novo Nordisk insulin medications. Furthermore, through partnerships with Walmart since 2000, CVS Health and ESI, Novo Nordisk human insulin is available for approximately USD 25 per vial at pharmacies across the US to any cash-paying patient, regardless of income and insurance coverage status. Through these partnerships, Novo Nordisk estimates that it is currently providing high-quality, affordable Novo Nordisk-manufactured human insulin to over 500,000 people in the USA.

Novo Nordisk invests in solar panel installation to achieve target of 100% renewable electricity in production by 2020. In April 2019, Novo Nordisk announced the investment in a 672-acre solar panel installation in North Carolina, USA. With this investment, Novo Nordisk expects to achieve its target to use only renewable electricity in its global production facilities by 2020. The target was made to achieve Novo Nordisk's commitment to RE100, a global business initiative, and Novo Nordisk will be the first pharmaceutical company among this group to achieve 100% renewable electricity in production. A new target has been set for achieving zero CO₂ emissions from all operations and transport by 2030. The goal is part of Novo Nordisk's new environmental strategy, 'Circular for Zero' with the ambition to have zero environmental impact by embracing a circular approach.

LEGAL MATTERS

Novo Nordisk settles US patent litigation case on Victoza[®] (liraglutide) with Teva

In March 2019, Novo Nordisk announced that a settlement between Novo Nordisk and Teva Pharmaceuticals USA, Inc. (Teva) has been reached on the US patent litigation case for Victoza[®] (liraglutide). Consequently, Teva is licenced to launch a generic version of Victoza[®] as of 22 December 2023. Under certain circumstances Teva could launch a generic version of Victoza[®] earlier, but not before 22 March 2023, unless the Victoza[®] patents are no longer in force or there is another generic version of Victoza[®] on the market. If Novo Nordisk is granted six months paediatric extension for Victoza[®], all above-mentioned timelines will be extended by six months. All other terms of the agreement are confidential. The agreement is subject to review by the US Federal Trade Commission and the US Department of Justice.

Edgar Filing: NOVO NORDISK A S - Form 6-K

Congressional committees request information involving pricing practices from several pharmaceutical companies including Novo Nordisk

As announced on 1 February 2019, Novo Nordisk was one of several pharmaceutical companies that received requests for information involving pricing practices from the chairpersons of two committees of the United States House of Representatives. Since those two letters were received in January 2019, Novo Nordisk has received three additional letters from committees of the United States House of Representatives and/or United States Senate. Four

Financial
Performance Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

of the five requests are specific to insulin products. Novo Nordisk is working with the staff of the various committees to respond to their questions.

Novo Nordisk receives Civil Investigative Demand (CID) from the Office of the Attorney General of Texas. In March 2019, Novo Nordisk received a CID from the Office of the Attorney General of Texas, Medicaid Fraud Control Unit, calling for information regarding the company's marketing and promotional practices for Ozempic®. Novo Nordisk is cooperating with the Texas Attorney General's office in this investigation. Novo Nordisk does not expect the investigation to have a material impact on Novo Nordisk's financial position, operating profit or cash flow.

Financial
Performance Outlook R&D Sustainability Equity Corporate governance Legal Financial Information

Company announcement No 30 / 2019

Financial report for the period 1 January 2019 to 31 March 2019 Page 20 of 28

MANAGEMENT STATEMENT

The Board of Directors and Executive Management have reviewed and approved the financial report of Novo Nordisk A/S for the first three months of 2019. The financial report has not been audited or reviewed by the company's independent auditors.

The financial report for the first three months of 2019 has been prepared in accordance with IAS 34 'Interim Financial Reporting'. The accounting policies adopted in the preparation are consistent with those applied in the Annual Report 2018 of Novo Nordisk, except for the adoption of new, amended or revised standards and interpretations (IFRSs) as published by the IASB that are endorsed by the EU effective as of 1 January 2019. This includes IFRS 16 'Leases' applied modified retrospectively. Furthermore, the financial report for the first three months of 2019 and Management's Review are prepared in accordance with additional Danish disclosure requirements for interim reports of listed companies.

In our opinion, the accounting policies used are appropriate and the overall presentation of the financial report for the first three months of 2019 is adequate. Furthermore, in our opinion, Management's Review includes a true and fair account of the development in the operations and financial circumstances of the results for the period and of the financial position of the Group as well as a description of the most significant risks and elements of uncertainty facing the Group in accordance with Danish disclosure requirements for listed companies.

Besides what has been disclosed in the quarterly financial report, no changes in the Group's most significant risks and uncertainties have occurred relative to what was disclosed in the consolidated annual report for 2018.

Bagsværd, 3 May 2019
Executive Management:

Lars Fruergaard Jørgensen President and CEO	Karsten Munk Knudsen CFO	Lars Green
--	-----------------------------	------------

Camilla Sylvest	Mads Krogsgaard Thomsen	Henrik Wulff
-----------------	-------------------------	--------------

Board of Directors:

Helge Lund Chair	Jeppe Christiansen Vice chair	Brian Daniels
---------------------	----------------------------------	---------------

Laurence Debroux	Andreas Fibig	Sylvie Grégoire
------------------	---------------	-----------------

Liz Hewitt	Mette Bøjer Jensen	Kasim Kutay
------------	--------------------	-------------

Anne Marie Kverneland	Martin Mackay	Thomas Rantzau
-----------------------	---------------	----------------

Stig Strøbæk

Financial Performance Equity Outlook R&D Sustainability Legal Financial Information

About Novo Nordisk

Novo Nordisk is a global healthcare company with more than 95 years of innovation and leadership in diabetes. 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.

Financial calendar

09 August 2019 Financial statement for the first six months of 2019

01 November 2019 Financial statement for the first nine months of 2019

05 February 2020 Financial statement for 2019

Contacts for further information

Media:

Mette Kruse Danielsen +45 4442 3883 mkd@novonordisk.com

Ken Inchausti (USA) +1 609 240 9429 kiau@novonordisk.com

Investors:

Peter Hugrefte Ankersen +45 3075 9085 phak@novonordisk.com

Valdemar Borum Svarrer +45 3079 0301 jvls@novonordisk.com

Ann Søndermølle Rendbæk +45 3075 2253 arnd@novonordisk.com

Kristoffer Due Berg (USA) +1 609 235 2989 krdb@novonordisk.com

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

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 both 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.

Financial
Performance Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

Financial report for the period 1 January 2019 to 31 March 2019 Page 22 of 28

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).

	2019 Q1	2018 Q4	Q3	Q2	Q1	% change Q1 2019 vs. Q1 2018	
Net sales	29,291	29,732	27,762	27,407	26,930	9	%
Gross profit	24,559	25,079	23,347	23,055	22,733	8	%
Gross margin	83.8	% 84.4	% 84.1	% 84.1	% 84.4	%	
Sales and distribution costs	6,946	8,728	7,128	7,090	6,451	8	%
Percentage of sales	23.7	% 29.4	% 25.7	% 25.9	% 24.0	%	
Research and development costs	2,678	4,544	3,644	3,296	3,321	(19)	%
Percentage of sales	9.1	% 15.3	% 13.1	% 12.0	% 12.3	%	
Administrative costs	911	1,269	932	851	864	5	%
Percentage of sales	3.1	% 4.3	% 3.4	% 3.1	% 3.2	%	
Other operating income, net	215	245	170	386	351	(39)	%
Operating profit	14,239	10,783	11,813	12,204	12,448	14	%
Operating margin	48.6	% 36.3	% 42.6	% 44.5	% 46.2	%	
Financial income	13	(37)	(78)	1,039	1,198	N/A	
Financial expenses	1,030	376	597	745	37	N/A	
Financial items (net)	(1,017)	(413)	(675)	294	1,161	N/A	
Profit before income taxes	13,222	10,370	11,138	12,498	13,609	(3)	%
Income taxes	2,777	1,873	2,101	2,155	2,858	(3)	%
Net profit	10,445	8,497	9,037	10,343	10,751	(3)	%
Depreciation, amortisation and impairment losses	1,058	1,642	783	768	732	45	%
Capital expenditure (net)	2,101	3,311	2,316	1,587	2,310	(9)	%
Net cash generated from operating activities	9,890	7,412	11,619	15,770	9,815	1	%
Free cash flow	6,655	3,313	8,755	13,227	7,241	(8)	%
Total assets	110,135	110,769	101,895	103,248	93,558	18	%
Total equity	47,319	51,839	47,512	49,081	44,238	7	%
Equity ratio	43.0	% 46.8	% 46.6	% 47.5	% 47.3	%	
Full-time equivalent employees end of period	42,453	42,672	43,161	43,105	42,688	(1)	%

Edgar Filing: NOVO NORDISK A S - Form 6-K

Basic earnings per share/ADR (in DKK)	4.37	3.54	3.74	4.27	4.41	(1	%)
Diluted earnings per share/ADR (in DKK)	4.36	3.53	3.74	4.26	4.40	(1	%)
Average number of shares outstanding (million)	2,390.3	2,401.2	2,414.1	2,425.8	2,437.3	(2	%)
Average number of diluted shares outstanding (million)	2,394.6	2,406.1	2,419.2	2,430.9	2,442.3	(2	%)
Sales by business segment:							
Long-acting insulin	5,244	5,456	5,158	5,357	4,873	8	%
Premix insulin	2,757	2,438	2,527	2,587	2,642	4	%
Fast-acting insulin	4,977	5,030	4,609	4,936	4,778	4	%
Human insulin ¹⁾	2,415	2,178	2,386	2,335	2,366	2	%
Total insulin	15,393	15,102	14,680	15,215	14,659	5	%
Total GLP-1	7,147	7,492	6,655	5,924	6,058	18	%
Other diabetes	1,067	1,074	1,044	1,011	1,121	(5	%)
Total diabetes	23,607	23,668	22,379	22,150	21,838	8	%
Obesity (Saxenda [®])	1,211	1,229	987	883	770	57	%
Diabetes and obesity total	24,818	24,897	23,366	23,033	22,608	10	%
Haemophilia	2,533	2,478	2,301	2,294	2,503	1	%
Growth disorders (Norditropin [®])	1,555	1,962	1,688	1,703	1,481	5	%
Other biopharmaceuticals	385	395	407	377	338	14	%
Biopharmaceuticals total	4,473	4,835	4,396	4,374	4,322	3	%
Sales by geographic segment:							
International Operations	15,387	13,882	13,659	13,818	13,564	13	%
- Region Europe	5,505	5,594	5,392	5,460	5,233	5	%
- Region AAMEO	3,738	2,993	3,067	3,194	2,899	29	%
- Region China	3,375	2,712	2,793	2,751	3,029	11	%
- Region Japan & Korea	1,458	1,610	1,446	1,484	1,257	16	%
- Region Latin America	1,311	973	961	929	1,146	14	%
North America Operations	13,904	15,850	14,103	13,589	13,366	4	%
- USA	13,211	15,182	13,476	12,952	12,878	3	%
Segment operating profit:							
Diabetes and obesity	11,828	8,153	9,995	9,760	9,934	19	%
Biopharmaceuticals	2,411	2,630	1,818	2,444	2,514	(4	%)

Financial Performance Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

Financial report for the period 1 January 2019 to 31 March 2019 Page 23 of 28

APPENDIX 2: INCOME STATEMENT AND STATEMENT OF COMPREHENSIVE INCOME

DKK million	Q1 2019	Q1 2018
Income statement		
Net sales	29,291	26,930
Cost of goods sold	4,732	4,197
Gross profit	24,559	22,733
Sales and distribution costs	6,946	6,451
Research and development costs	2,678	3,321
Administrative costs	911	864
Other operating income, net	215	351
Operating profit	14,239	12,448
Financial income	13	1,198
Financial expenses	1,030	37
Profit before income taxes	13,222	13,609
Income taxes	2,777	2,858
NET PROFIT	10,445	10,751
Basic earnings per share (DKK)	4.37	4.41
Diluted earnings per share (DKK)	4.36	4.40
Segment Information		
Segment sales:		
Diabetes and obesity	24,818	22,608
Biopharmaceuticals	4,473	4,322
Segment operating profit:		
Diabetes and obesity	11,828	9,934
Operating margin	47.7	% 43.9

Biopharmaceuticals	2,411	2,514	
Operating margin	53.9	% 58.2	%
Total segment operating profit	14,239	12,448	
Statement of comprehensive income			
Net profit for the period	10,445	10,751	
Other comprehensive income			
Items that will not subsequently be reclassified to the Income statement			
Remeasurements on defined benefit plans	(90) 76	
Items that will be reclassified subsequently to the Income statement			
Exchange rate adjustments of investments in subsidiaries	211	33	
Cash flow hedges, realisation of previously deferred (gains)/losses	852	(1,084)
Cash flow hedges, deferred gains/(losses) incurred during the period	(929) 637	
Other items	16	13	
Tax on other comprehensive income, income/(expense)	154	62	
Other comprehensive income for the period, net of tax	214	(263)
TOTAL COMPREHENSIVE INCOME FOR THE PERIOD	10,659	10,488	

Financial Performance Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

Financial report for the period 1 January 2019 to 31 March 2019 Page 24 of 28

APPENDIX 3: CASH FLOW STATEMENT

DKK million	Q1 2019	Q1 2018
Net profit	10,445	10,751
Adjustment for non-cash items:		
Income taxes in the Income Statement	2,777	2,858
Depreciation, amortisation and impairment losses	1,058	732
Other non-cash items	2,249	(821)
Change in working capital	(2,128)	644
Interest received	13	12
Interest paid	(43)	(33)
Income taxes paid	(4,481)	(4,328)
 Net cash generated from operating activities	 9,890	 9,815
 Purchase of intangible assets	 (393)	 (885)
Purchase of property, plant and equipment	(2,644)	(2,073)
Proceeds from other financial assets	—	6
Proceeds from the partial divestment of associated company	—	368
Dividend received from associated company	11	10
 Net cash used in investing activities	 (3,026)	 (2,574)
 Purchase of treasury shares	 (2,949)	 (4,334)
Dividends paid	(12,309)	(11,810)
Repayment of borrowings, net	(357)	—
Withheld dividend tax	2,090	2,007
 Net cash used in financing activities	 (13,525)	 (14,137)
 NET CASH GENERATED FROM ACTIVITIES	 (6,661)	 (6,896)
 Cash and cash equivalents at the beginning of the year	 15,629	 17,158
Exchange gain/(loss) on cash and cash equivalents	78	23
 Cash and cash equivalents at the end of the year	 9,046	 10,285

Financial
Performance

Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

Financial report for the period 1 January 2019 to 31 March 2019 Page 25 of 28

APPENDIX 4: BALANCE SHEET

DKK million	31 Mar 2019	31 Dec 2018	
ASSETS			
Intangible assets	5,302	5,145	
Property, plant and equipment	47,350	41,891	
Investment in associated company	516	531	
Deferred income tax assets	3,043	2,893	
Other financial assets	1,190	1,242	
TOTAL NON-CURRENT ASSETS	57,401	51,702	
Inventories	16,838	16,336	
Trade receivables	21,486	22,786	
Tax receivables	1,910	1,013	
Other receivables and prepayments	3,164	3,090	
Derivative financial instruments	281	204	
Cash at bank	9,055	15,638	
TOTAL CURRENT ASSETS	52,734	59,067	
TOTAL ASSETS	110,135	110,769	
EQUITY AND LIABILITIES			
Share capital	490	490	
Treasury shares	(13) (11)
Retained earnings	48,584	53,406	
Other reserves	(1,742) (2,046)
TOTAL EQUITY	47,319	51,839	
Borrowings	3,204	—	
Deferred income tax liabilities	12	118	
Retirement benefit obligations	1,353	1,256	
Provisions	3,487	3,392	
Total non-current liabilities	8,056	4,766	
Borrowings	1,114	515	
Trade payables	4,222	6,756	
Tax payables	3,927	4,610	

Other liabilities	14,674	14,098
Derivative financial instruments	2,319	2,024
Provisions	28,504	26,161
Total current liabilities	54,760	54,164
TOTAL LIABILITIES	62,816	58,930
TOTAL EQUITY AND LIABILITIES	110,135	110,769

Financial
Performance

Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

Financial report for the period 1 January 2019 to 31 March 2019 Page 26 of 28

APPENDIX 5: EQUITY STATEMENT

DKK million	Share capital shares	Treasury shares	Retained earnings	Other reserves			Total other reserves	Total
				Exchange rate adjust-ments	Cash flow hedges	Tax and other adjust-ments		
Q1 2019								
Balance at the beginning of the period	490	(11)53,406	(1,065)(1,677)696	(2,046)51,839
Net profit for the period			10,445					10,445
Other comprehensive income for the period			(90)211	(77)170	304	214
Total comprehensive income for the period			10,355	211	(77)170	304	10,659
Transactions with owners:								
Dividends			(12,309)				(12,309)
Share-based payments			71					71
Tax related to restricted stock units			8					8
Purchase of treasury shares	(2)	(2,947)				(2,949
Balance at the end of the period	490	(13)48,584	(854)(1,754)866	(1,742)47,319

DKK million	Share capital shares	Treasury shares	Retained earnings	Other reserves			Total other reserves	Total
				Exchange rate adjust-ments	Cash flow hedges	Tax and other adjust-ments		
Q1 2018								
Balance at the beginning of the period	500	(11)48,977	(1,556)(2,027	(122)349	49,815
Change in accounting policy, IFRS 9 (net of tax)			(90)		90	90	—
Net profit for the period			10,751					10,751
Other comprehensive income for the period			76	33	(447)75	(339)(263
Total comprehensive income for the period			10,737	33	(447)165	(249)10,488

Transactions with owners:

Dividends			(11,810)					(11,810)
Share-based payments			97					97
Tax related to restricted stock units			(18)					(18)
Purchase of treasury shares	(3)		(4,331)					(4,334)
Balance at the end of the period	500	(14)	43,652	(1,523)	1,580	43	100	44,238

Financial Performance [Equity Outlook](#) [R&D Sustainability](#) [Legal Financial Information](#)

Company announcement
No 30 / 2019

Financial report for the period 1 January 2019 to 31 March 2019 Page 27 of 28

APPENDIX 6: REGIONAL SALES SPLIT

Q1 2019 sales
split per region

DKK million	Total	Inter-national Operations	Region Europe	Region AAMEO	Region China	Region Japan & Korea	Region Latin America	North America Operations	USA	
The diabetes and obesity segment										
Long-acting insulin	5,244	2,217	1,150	400	270	207	190	3,027	2,929	
% change at CER	3	% 17	% 14	% 32	% 29	% (1	%)14	% (6	%) (7	%)
Tresiba®	2,147	808	393	101	14	184	116	1,339	1,290	
% change at CER	16	% 26	% 43	% 8	% —	1	% 26	% 11	% 7	%
Xultophy®	477	347	295	38	—	—	14	130	129	
% change at CER	38	% 41	% 33	% 100	% —	—	200	% 28	% 27	%
Levemir®	2,620	1,062	462	261	256	23	60	1,558	1,510	
% change at CER	(10	%)6	% (10	%)37	% 24	% (12	%) (15	%) (19	%) (19	%)
Premix insulin	2,757	2,468	401	767	1,112	158	30	289	281	
% change at CER	3	% 10	% (7	%)22	% 10	% 2	% (3	%) (35	%) (36	%)
Ryzodeg®	212	212	17	91	—	96	8	—	—	
% change at CER	49	% 49	% 78	% 64	% —	36	% 14	% —	—	
NovoMix®	2,545	2,256	384	676	1,112	62	22	289	281	
% change at CER	0	% 7	% (8	%)18	% 10	% (26	%) (8	%) (35	%) (36	%)
Fast-acting insulin	4,977	2,611	1,142	700	461	177	131	2,366	2,270	
% change at CER	0	% 17	% 4	% 43	% 22	% (12	%)77	% (14	%) (15	%)
Fiasp®	231	133	126	7	—	—	—	98	91	
% change at CER	167	% 110	% 98	% —	—	—	—	—	—	
NovoRapid®	4,746	2,478	1,016	693	461	177	131	2,268	2,179	
% change at CER	(3	%)14	% (2	%)41	% 22	% (12	%)77	% (17	%) (18	%)

Edgar Filing: NOVO NORDISK A S - Form 6-K

Human insulin	2,415	2,037	348	612	797	40	240	378	348	
% change at CER	0	% 7	% (14	%)26	% (3	%) (10	%)57	% (28	%) (29	%)
Total insulin	15,393	9,333	3,041	2,479	2,640	582	591	6,060	5,828	
% change at CER	2	% 13	% 3	% 30	% 9	% (5	%)40	% (13	%) (14	%)
Victoza®	5,722	1,761	969	272	214	147	159	3,961	3,847	
% change at CER	(10	%)19	% 11	% 11	% 90	% 10	% 35	% (19	%) (19	%)
Ozempic®	1,425	81	81	—	—	—	—	1,344	1,262	
% change at CER	—	—	—	—	—	—	—	—	—	
Total GLP-1	7,147	1,842	1,050	272	214	147	159	5,305	5,109	
% change at CER	11	% 25	% 21	% 11	% 90	% 10	% 35	% 7	% 6	%
Other diabetes ¹⁾	1,067	864	135	174	437	104	14	203	168	
% change at CER	(7	%) (6	%) (2	%) 8	% (14	%) 17	% (17	%) (14	%) (15	%)
Total diabetes	23,607	12,039	4,226	2,925	3,291	833	764	11,568	11,105	
% change at CER	4	% 13	% 7	% 27	% 8	% 0	% 37	% (5	%) (6	%)
Obesity (Saxenda®)	1,211	540	66	236	2	77	159	671	616	
% change at CER	51	% 146	% 74	% 149	% —	—	90	% 13	% 13	%
Diabetes and obesity total	24,818	12,579	4,292	3,161	3,293	910	923	12,239	11,721	
% change at CER	5	% 16	% 8	% 31	% 8	% 9	% 44	% (4	%) (5	%)
The biopharmaceuticals segment										
Haemophilia	2,533	1,506	660	323	73	130	320	1,027	911	
% change at CER	(3	%) (6	%) (7	%) 13	% 37	% (8	%) (23	%) 3	% (7	%)
NovoSeven®	2,012	1,151	423	258	67	91	312	861	785	
% change at CER	(11	%) (16	%) (21	%) (2	%) 25	% (9	%) (25	%) (3	%) (9	%)
NovoEight®	393	301	201	56	6	30	8	92	86	
% change at CER	29	% 35	% 20	% 250	% —	(15	%) 100	% 12	% 5	%
Growth disorders (Norditropin®)	1,555	1,020	369	177	7	399	68	535	531	
% change at CER	1	% 8	% (3	%) 15	% 75	% 13	% 23	% (10	%) (11	%)
Other biopharmaceuticals	385	282	184	77	2	19	—	103	48	

Edgar Filing: NOVO NORDISK A S - Form 6-K

% change at CER	13	% 26	% 11	% 59	% 100	% 143	% —	(13	%)	(28	%)		
Biopharmaceuticals total	4,473	2,808	1,213	577	82	548	388	1,665		1,490			
% change at CER	0	% 1	% (4	%)	18	% 41	% 9	% (17	%)	(3	%)	(9	%)
Total sales	29,291	15,387	5,505	3,738	3,375	1,458	1,311	13,904		13,211			
% change at CER	4	% 13	% 5	% 29	% 9	% 9	% 20	% (4	%)	(5	%)		
% change as reported	9	% 13	% 5	% 29	% 11	% 16	% 14	% 4		% 3	%		
Share of growth	100	% 143	% 22	% 70	% 22	% 10	% 19	% (43	%)	(59	%)		

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

Financial Performance Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

APPENDIX 7: SIGNIFICANT ACCOUNTING MATTERS

New accounting standards in 2019

As of 1 January 2019, Novo Nordisk applies, for the first time, IFRS 16 'Leases' using the modified retrospective approach. Under this method, the cumulative effect of initially applying the standard is recognised at 1 January 2019. Rights-of-use assets and lease liabilities have been recognised for those leases previously classified as operating leases, except for short-term leases and leases of low value assets. The rights-of-use assets have been recognised based on the amount equal to the lease liabilities, adjusted for any related prepaid and accrued lease payments previously recognised. Lease liabilities are recognised based on the present value of the remaining lease payments, discounted using the incremental borrowing rate as of 1 January 2019. The comparative information has not been restated.

Impact from IFRS 16 as of 1 January 2019

DKK million	1 January 2019
Property, plant and equipment	3,778
Prepayments	(5)
Borrowings (non-current)	3,330
Borrowings (current)	658
Other liabilities	(215)
Net assets	—

The change in policy has had a insignificant impact on the income statement. In the cash flow statement the principal repayment of lease liabilities is presented in 'net cash used in financing activities', whereas the full lease payment under previous policies was presented in 'net cash generated from operating activities'. The change in policy has had no impact on free cash flow due to a change in definition, as described in Appendix 8.

Recognition exemptions and practical expedients applied

- ✕ Excluded initial direct costs from measuring the right-of-use asset at the date of initial application
- ✕ Used hindsight when determining the lease term if the contract contains option to extend or terminate
- ✕ Exempted short-term lease contracts with a remaining duration of 12 months or less as at 1 January 2019

Accounting policy applicable from 1 January 2019

For contracts which are, or contain, a lease, Novo Nordisk recognises a right-of-use asset and a lease liability. The right-of-use asset is initially measured at cost, being the initial amount of the lease liability adjusted for any lease payments made at or before the commencement date. The right-of-use asset is subsequently depreciated using the straight-line method over the lease term. The right-of-use asset is periodically reduced by impairment losses, if any, and adjusted for certain remeasurements of the lease liability. The lease liability is initially measured at the present value of the lease payments outstanding at the commencement date, discounted using Novo Nordisk's incremental borrowing rate. The lease liability is measured using the effective interest method. It is remeasured when there is a change in future lease payments, typically due to a change in index or rate (e.g. inflation) on property leases, or if there is a reassessment of whether an extension or termination option will be exercised. A corresponding adjustment is made to the right-of-use asset, or in the income statement when the right-of-use asset has been fully depreciated.

The right-of-use asset is presented in Property, Plant and Equipment and the lease liabilities in Borrowings. Lease contracts that have a lease term of 12 months or less and low value assets are not recognised on the balance sheet. These lease payments are expensed on a straight-line basis over the lease term.

Oral semaglutide prelaunch inventory

In March 2019, Novo Nordisk filed oral semaglutide for US regulatory approval of glycaemic control. A priority review voucher (PRV) was used with the filing, leading to an anticipated review time of six months from the submission date, according to standard FDA review timelines. The successful finalisation and filing of the New Drug Application (NDA) during Q1 2019 supports Management's view that there is a high probability of regulatory approval being obtained, considering the company's historical experience with developing and commercially producing a product with similar active pharmaceutical ingredients.

Subsequent to filing, write-downs on prelaunch inventory have been reversed with a net positive income statement effect of DKK 510 million on Research and development costs.

Financial
Performance

Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

Financial report for the period 1 January 2019 to 31 March 2019 Page 29 of 28

APPENDIX 8: 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 at CER and Free cash flow.

Sales and operating profit growth at CER

'Growth at CER' 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 at CER is artificially inflated.

Growth at CER 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 at CER

DKK million	Q1 2019	Q1 2018	% change	Q1 2019 to Q1 2018	
Net sales	29,291	26,930	9		%
Effect of exchange rates	(1,162)	—			
Sales at CER	28,129	26,930	4		%

Operating profit at CER

DKK million	Q1 2019	Q1 2018	% change	Q1 2019 to Q1 2018	
Operating profit	14,239	12,448	14		%
Effect of exchange rates	(789)	—			
Operating profit at CER	13,450	12,448	8		%

Free cash flow

From 1 January 2019, Novo Nordisk defines free cash flow as 'net cash generated from operating activities', less 'net cash used in investing activities', less repayment on lease liabilities and excluding net change of marketable securities. The updated definition reflects the implementation of IFRS 16, which accordingly have a neutral effect on free cash flow. 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 eg dividends, share repurchases and repayment of debt (excl lease liability repayments) or for retaining in the business to fund future growth.

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	Q1 2019	Q1 2018
Net cash generated from operating activities	9,890	9,815

Edgar Filing: NOVO NORDISK A S - Form 6-K

Net cash used in investing activities	(3,026)	(2,574)
Repayment on lease liabilities	(209)	—
Free cash flow	6,655	7,241

Financial
Performance

Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf of the undersigned, thereunto duly authorized.

Date: May 3, 2019
Novo Nordisk A/S

Lars Fruergaard Jørgensen
Chief Executive Officer

Financial Performance Equity Outlook R&D Sustainability Legal Financial Information

Company announcement
No 30 / 2019