



# Financial report for the period 1 January 2019 to 30 June 2019

9 August 2019

# Novo Nordisk's operating profit increased by 12% in Danish kroner and by 6% at constant exchange rates (CER) in the first six months of 2019

- Sales increased by 9% in Danish kroner and by 5% at CER to DKK 59.3 billion. Sales in International Operations increased by 13% in Danish kroner (12% at CER), driven by growth in all regions. Sales in North America Operations increased by 5% in Danish kroner (decreased by 2% at CER).
- Sales within Diabetes and obesity increased by 10% to DKK 50.1 billion (6% at CER), driven by Diabetes growing 4% at CER and Obesity growing 56% at CER. Sales within Biopharmaceuticals increased by 7% to DKK 9.3 billion (3% at CER).
- Sales of Ozempic<sup>®</sup> were DKK 3,750 million and it has now been launched in 21 countries. In the USA, the new-to-brand prescription market share for Ozempic<sup>®</sup> is now 35%, bringing Novo Nordisk's combined GLP-1 new-to-brand prescription market share to 53%.
- During second quarter of 2019, Novo Nordisk initiated four late-stage clinical trials with Ozempic<sup>®</sup> (injectable semaglutide) and oral semaglutide in people with type 2 diabetes and serious complications, including cardiovascular disease, diabetic retinopathy and chronic kidney disease.
- Executive Vice President (EVP) of Business Services & Compliance Lars Green has decided to resign to take up an executive position outside of Novo Nordisk. Monique Carter has been promoted to EVP of People & Organisation and member of Novo Nordisk's Executive Management.
- For the 2019 outlook, sales growth is now expected to be 4-6% at CER (previously 2-5% at CER), and operating profit growth is now expected to be 4-6% at CER (previously 2-6% at CER).

PROFIT AND LOSS DKK million	Н1 2019	H1 2018	Growth as reported	Growth at CER*
Net sales	59,327	54,337	9%	5%
Operating profit	27,691	24,652	12%	6%
Net profit	20,040	21,094	(5%)	N/A
Diluted earnings per share (in DKK)	8.39	8.66	(3%)	N/A

<sup>\*</sup> CER: Constant exchange rates (average 2018)

**Lars Fruergaard Jørgensen, president and CEO**: "We are pleased with the sales growth in the first half of 2019, which is driven by all regions in International Operations. The launch of Ozempic<sup>®</sup> is expanding the GLP-1 market, and we are encouraged by the positive market reception in both North America and Europe. With the initiation of four major late-stage clinical trials, we continue to investigate the clinical benefits of semaglutide across multiple indications. The solid financial performance in the first half of 2019 has enabled us to raise our outlook for the full-year".

On 9 August 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'.

# **FINANCIAL PERFORMANCE**

# **CONSOLIDATED FINANCIAL STATEMENT FOR THE FIRST SIX MONTHS OF 2019**

PROFIT AND LOSS DKK million	H1 2019	H1 2018	% change H1 2019 to H1 2018
Net sales	59,327	54,337	9%
Gross profit	49,746	45,788	9%
Gross margin	83.9%	84.3%	
Sales and distribution costs  Percentage of sales	14,526 24.5%	13,541 24.9%	7%
Research and development costs  Percentage of sales	6,235 10.5%	6,617 12.2%	(6%)
Administrative costs	1,763 3.0%	1,715 3.2%	3%
Percentage of sales Other operating income, net	3.0%	737	(36%)
Operating profit	27,691	24,652	12%
Operating margin	46.7%	45.4%	/-
Financial items (net)	(2,324)	1,455	N/A
Profit before income taxes	25,367	26,107	(3%)
Income taxes	5,327	5,013	6%
Effective tax rate	21.0%	19.2%	
Net profit Net profit margin	<b>20,040</b> 33.8%	<b>21,094</b> 38.8%	(5%)
OTHER KEY NUMBERS	55.67		
Depreciation, amortisation and impairment losses	2,168	1,500	45%
Capital expenditure (tangible assets)	4,178	3,897	7%
Net cash generated from operating activities	24,929	25,585	(3%)
Free cash flow	18,675	20,468	(9%)
Total assets	117,909	103,248	14%
Equity	53,085	49,081	8%
Equity ratio	45.0%	47.5%	
Average number of diluted shares outstanding (million)	2,389.1	2,436.6	(2%)
Diluted earnings per share / ADR (in DKK)	8.39	8.66	(3%)
Full-time equivalent employees end of period	41,611	43,105	(3%)

These unaudited consolidated financial statements for the first six 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 six months of 2019 and the Management's review, have been prepared in accordance with additional Danish disclosure requirements for interim reports of listed companies. From 1 January 2019, the term 'constant exchange rates' (CER) will be used instead of 'local currencies'. There is no difference between the two terms.

# **GEOGRAPHIC SALES DEVELOPMENT**

Sales increased by 9% measured in Danish kroner and by 5% at CER to DKK 59,327 million in the first six months of 2019. Sales in International Operations increased by 13% measured in Danish kroner and by 12% at CER, positively impacted by timing of shipments primarily in Region AAMEO and Region Latin America. Sales in North America Operations increased by 5% measured in Danish kroner and decreased by 2% at CER, negatively impacted by inventory reductions in the first guarter of 2019.

Sales split per region	Sales H1 2019 DKK million	<b>Growth</b> as reported	<b>Growth</b> at CER	Share of growth at CER
International Operations	30,952	13%	12%	116%
- Region Europe	11,367	6%	6%	22%
- Region AAMEO	7,285	20%	19%	39%
- Region China	6,567	14%	12%	25%
- Region Japan & Korea	3,122	14%	8%	8%
- Region Latin America	2,611	26%	30%	22%
North America Operations	28,375	5%	(2%)	(16%)
- USA	26,978	4%	(3%)	(24%)
Total sales	59,327	9%	5%	100%

# International Operations

Sales in International Operations increased by 13% measured in Danish kroner and by 12% at CER. Sales growth was driven by all regions, with key growth regions being Region AAMEO growing 19% (CER), Region China growing 12% (CER), Region Europe growing 6% (CER) and Region Latin America growing 30% (CER). Sales growth was driven by increasing sales across all therapy areas.

# Region Europe

Sales in Region Europe increased by 6% in both Danish kroner and at CER. Sales growth was driven by Diabetes growing 8% (CER) from increased GLP-1 and new-generation insulin sales, and Obesity growing 66% (CER), partly offset by Biopharmaceuticals declining by 1% (CER).

# Region AAMEO

Sales in Region AAMEO increased by 20% measured in Danish kroner and by 19% at CER. Sales growth was driven by Diabetes growing 17% (CER) from increased insulin sales, Obesity growing 111% (CER) and Biopharmaceuticals growing by 10% (CER). Sales were positively impacted by timing of shipments, mainly in Diabetes.

# Region China

Sales in Region China increased by 14% measured in Danish kroner and by 12% at CER. Sales growth was driven by Diabetes growing 12% (CER) from increased modern insulin and GLP-1 sales.

# Region Japan & Korea

Sales in Region Japan & Korea increased by 14% measured in Danish kroner and by 8% at CER. Sales growth was driven by Obesity following the introduction of Saxenda<sup>®</sup> in Korea in 2018, Biopharmaceuticals growing by 5% (CER) and Diabetes growing 2% (CER).

# Region Latin America

Sales in Region Latin America increased by 26% measured in Danish kroner and by 30% at CER. Sales growth was driven by Diabetes growing 30% (CER) from increased insulin and GLP-1 sales, and Obesity growing 92% (CER) and Biopharmaceuticals growing by 15% (CER). Sales were positively impacted by timing of shipments.

# North America Operations

Sales in North America Operations increased by 5% measured in Danish kroner and decreased by 2% at CER. Sales decline was driven by the USA declining by 3% (CER), negatively impacted by lower realised prices following the changes in the coverage gap legislation as well as inventory reductions in the first quarter of 2019. The development in sales reflects GLP-1 sales growing by 14% (CER) and Obesity sales growing by 28% (CER), which was offset by insulin sales declining by 15% (CER), while Biopharmaceuticals sales were unchanged.

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# **SALES DEVELOPMENT ACROSS THERAPEUTIC AREAS**

Sales growth in the first six months of 2019 of 9% measured in Danish kroner and 5% at CER was driven by solid growth across all therapy areas including Diabetes sales growth of 4% (CER), Obesity sales growth of 56% (CER) and Biopharmaceuticals sales growth of 3% (CER).

Sales split per therapy Diabetes and obesity segment	Sales H1 2019 DKK million	Sales H1 2018 DKK million	Growth as reported	Growth at CER	Share of growth at CER
Long-acting insulin	10,655	10,230	4%	0%	0%
- Tresiba®	4,642	3,707	25%	19%	25%
- Xultophy®	1,051	720	46%	42%	10%
- Levemir®	4,962	5,803	(14%)	(18%)	(35%)
Premix insulin	5,317	5,229	2%	1%	1%
- Ryzodeg®	469	320	47%	45%	5%
- NovoMix®	4,848	4,909	(1%)	(2%)	(4%)
Fast-acting insulin	9,735	9,714	0%	(3%)	(10%)
- Fiasp®	503	220	129%	122%	9%
- NovoRapid®	9,232	9,494	(3%)	(6%)	(19%)
Human insulin	4,595	4,701	(2%)	(4%)	(6%)
Total insulin	30,302	29,874	1%	(1%)	(15%)
Victoza®	11,137	11,718	(5%)	(9%)	(38%)
Ozempic <sup>®</sup>	3,750	264	-	-	112%
Total GLP-1	14,887	11,982	24%	18%	74%
Other diabetes <sup>1)</sup>	2,192	2,132	3%	1%	0%
Total diabetes	47,381	43,988	8%	4%	59%
Obesity (Saxenda®)	2,673	1,653	62%	56%	32%
Diabetes and obesity total	50,054	45,641	10%	6%	91%
Biopharmaceuticals segment					
Haemophilia <sup>2)</sup>	5,203	4,797	8%	5%	8%
- NovoSeven®	4,175	4,040	3%	(1%)	(1%)
- NovoEight®	762	635	20%	17%	4%
Growth disorders (Norditropin®)	3,313	3,184	4%	0%	0%
Other biopharmaceuticals <sup>3)</sup>	757	715	6%	5%	1%
Biopharmaceuticals total	9,273	8,696	7%	3%	9%
Total sales	59,327	54,337	9%	5%	100%

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

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

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

# **DIABETES AND OBESITY**

# Diabetes, sales development

Sales in Diabetes increased by 8% measured in Danish kroner and by 4% at CER to DKK 47,381 million driven by solid GLP-1 growth, partly offset by declining insulin sales. Novo Nordisk has improved its global diabetes value market share over the last 12 months from 27.5% to 28.3%, 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 May 2019 and May 2018 provided by the independent data provider IQVIA.

Diabetes, regional development	Novo Nordis of the total diabetes m		Diabetes, sales development	
	May 2019	May 2018	Sales H1 2019 DKK million	Growth at CER
Global	28.3%	27.5%	47,381	4%
International Operations	21.9%	22.2%	24,183	12%
- Region Europe	26.8%	26.9%	8,750	8%
- Region AAMEO *	21.6%	22.2%	5,716	17%
- Region China **	27.8%	29.6%	6,397	12%
- Region Japan & Korea	9.7%	10.2%	1,825	2%
- Region Latin America ***	16.7%	16.0%	1,495	30%
North America Operations	30.6%	29.6%	23,198	(3%)
- USA	30.9%	29.9%	22,220	(4%)

Source: IQVIA, May 2019 data. \* Data available for 9 private markets representing approximately 60% of total Novo Nordisk 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

Sales of insulin increased by 1% measured in Danish kroner and decreased by 1% at CER to DKK 30,302 million. Sales decline was driven by declining sales in the USA, partly offset by increased sales in International Operations.

Sales of long-acting insulin increased by 4% measured in Danish kroner, and remained unchanged at CER, to DKK 10,655 million. Novo Nordisk has improved its global volume market share in the long-acting insulin segment from 31.2% to 32.2% in the last 12 months. Sales were driven by Tresiba<sup>®</sup> and Xultophy<sup>®</sup>, partly offset by Levemir<sup>®</sup>. Tresiba<sup>®</sup> has now been launched in 83 countries, while Xultophy<sup>®</sup> has been launched in 32 countries.

Sales of premix insulin increased by 2% measured in Danish kroner and by 1% at CER to DKK 5,317 million. Novo Nordisk is market leader in the segment and has improved its global volume market share in the premix insulin segment from 63.7% to 64.0% in the last 12 months. The increase in sales was driven by Ryzodeg<sup>®</sup> while sales of NovoMix<sup>®</sup> declined. Ryzodeg<sup>®</sup> has now been launched in 27 countries.

Sales of fast-acting insulin remained unchanged in Danish kroner and decreased by 3% at CER to DKK 9,735 million. Novo Nordisk is market leader in the fast-acting insulin segment with a global volume market share of 51.1%, which has been broadly unchanged over the past 12 months. The decreased sales measured at CER were positively impacted by Fiasp<sup>®</sup>, offset by declining sales of NovoRapid<sup>®</sup>. Fiasp<sup>®</sup> has now been launched in 29 countries.

Sales of human insulin decreased by 2% measured in Danish kroner and by 4% at CER to DKK 4,595 million.

Insulin, regional development		Novo Nordisk's share of the total insulin market (volume, MAT)		development
	May 2019	May 2018	Sales H1 2019 DKK million	Growth at CER
Global	46.8%	46.5%	30,302	(1%)
International Operations	49.7%	49.5%	18,439	9%
- Region Europe	44.0%	44.3%	6,195	3%
- Region AAMEO *	58.9%	58.3%	4,831	18%
- Region China **	49.9%	51.8%	5,076	11%
- Region Japan & Korea	50.4%	50.0%	1,266	(2%)
- Region Latin America ***	49.8%	43.2%	1,071	21%
North America Operations	40.0%	39.5%	11,863	(15%)
- USA	40.3%	39.9%	11,379	(16%)

Source: IQVIA, May 2019 data. \* Data available for 9 private markets representing approximately 60% of total Novo Nordisk 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 10% measured in Danish kroner and by 9% at CER. Sales growth at CER was driven by long-acting, fast-acting and premix insulin as well as increasing human insulin sales.

# Region Europe

Sales of insulin in Region Europe increased by 3% in both Danish kroner and at CER. Sales growth was driven by the penetration of Tresiba<sup>®</sup>, Xultophy<sup>®</sup> and Fiasp<sup>®</sup> across the region, partly offset by contracting Levemir<sup>®</sup> sales, reflecting the continued roll-out of Tresiba<sup>®</sup> as well as declining human insulin and NovoMix<sup>®</sup> sales.

# Region AAMEO

Sales of insulin in Region AAMEO increased by 18% in both Danish kroner and at CER. The sales growth was driven by increased sales in all insulin categories.

# Region China

Sales of insulin in Region China increased by 12% measured in Danish kroner and by 11% at CER. The sales growth was driven by NovoMix<sup>®</sup>, NovoRapid<sup>®</sup> and Levemir<sup>®</sup>, partly offset by lower human insulin sales.

# Region Japan & Korea

Sales of insulin in Region Japan & Korea increased by 4% measured in Danish kroner and decreased by 2% at CER. The decline in sales at CER was driven by NovoMix<sup>®</sup> and NovoRapid<sup>®</sup>, as both products reached the 15-year price protection limit 1 April 2018 in Japan, leading to significant mandatory price reductions as well as lower human insulin sales, partly offset by positive contribution from market share gains for Ryzodeg<sup>®</sup> in both Japan and Korea.

# Region Latin America

Sales of insulin in Region Latin America increased by 15% measured in Danish kroner and by 21% at CER. The sales growth was driven by growth of the overall diabetes market, market share gains and increased sales of human insulin, Xultophy<sup>®</sup>, NovoRapid<sup>®</sup> and Tresiba<sup>®</sup>.

# North America Operations

Sales of insulin in North America Operations decreased by 9% measured in Danish kroner and by 15% at CER. The decline in sales in the USA was driven by lower realised prices due to higher rebate rates across the insulin portfolio, the changes in the coverage gap legislation, rebate adjustments related to prior periods as well as inventory reductions in the first quarter of 2019. Novo Nordisk has expanded its volume market share from 39.9% to 40.3% in the last 12 months, and the expansion was driven by continued market share gains in the basal insulin segment.

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# GLP-1 therapy for type 2 diabetes

Sales of GLP-1 products for type 2 diabetes (Victoza® and Ozempic®) increased by 24% measured in Danish kroner and by 18% at CER to DKK 14,887 million. Ozempic® has now been launched in 21 countries in North America Operations, Region Europe and Region Latin America. Sales growth was driven by both North America Operations and International Operations. The GLP-1 segment's value share of the total diabetes market has increased to 16.2% compared with 13.0% 12 months ago. Novo Nordisk continues to be the global market leader in the GLP-1 segment with a 46.4% value market share.

GLP-1, regional development		are of the diabetes (value, MAT)*	GLP-1, sales development		
	May 2019	May 2018	Sales H1 2019 DKK million	Growth at CER	
Global	46.4%	47.2%	14,887	18%	
International Operations	50.4%	53.8%	3,952	28%	
- Region Europe	53.1%	56.3%	2,268	24%	
- Region AAMEO **	38.1%	44.5%	526	13%	
- Region China ***	91.5%	77.8%	428	75%	
- Region Japan & Korea	30.6%	36.0%	334	11%	
- Region Latin America ****	66.4%	70.4%	396	66%	
North America Operations	45.7%	46.0%	10,935	14%	
- USA	45.3%	45.6%	10,510	13%	

Source: IQVIA, May 2019 data MAT. \* Novo Nordisk's GLP-1 diabetes products comprise Victoza® and Ozempic® \*\* Data for 9 selected private markets representing approximately 60% of Novo Nordisk 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 29% measured in Danish kroner and by 28% 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 8.4% from 7.1% 12 months ago. Novo Nordisk is the market leader with a 50.4% value market share.

#### Region Europe

Sales in Region Europe increased by 24% in both Danish kroner and at CER. The sales development reflects the positive impact from the introduction of Ozempic<sup>®</sup> in 18 countries and the cardiovascular indication for Victoza<sup>®</sup>, partly offset by the impact from a competing once-weekly product. The initial feedback from the launch of Ozempic<sup>®</sup> has been positive and leading to a stabilisation of the market share in launch markets. Novo Nordisk remains the market leader in Region Europe with a 53.1% value market share.

# Region AAMEO

Sales in Region AAMEO increased by 17% measured in Danish kroner and by 13% 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 38.1%.

# Region China

Sales in Region China increased by 77% measured in Danish kroner and by 75% at CER. The increase in sales reflects broad market access and continued commercial investments, which have driven the expansion of the GLP-1 class and increased the Victoza® GLP-1 value market share to 91.5%. The share of the GLP-1 class of the total diabetes market remains low.

# Region Japan & Korea

Sales in Region Japan & Korea increased by 17% measured in Danish kroner and by 11% at CER. The sales growth reflects the continued expansion of the GLP-1 market in Japan, partly offset by intensified competition from a onceweekly product. Novo Nordisk currently holds a value market share of 30.6%.

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# Region Latin America

Sales in Region Latin America increased by 55% measured in Danish kroner and by 66% at CER. The sales growth reflects the continued expansion of the GLP-1 markets across the region and the introduction of Ozempic<sup>®</sup> in Brazil. Novo Nordisk remains the market leader in the region with a value market share of 66.4%.

# North America Operations

Sales of Novo Nordisk's GLP-1 diabetes products in North America Operations increased by 23% measured in Danish kroner and by 14% at CER. Novo Nordisk is the market leader with a 45.7% value market share. The value share of the GLP-1 class of the total North American diabetes market has increased to 19.0%.

Sales growth in the USA is driven by an underlying prescription volume growth of the GLP-1 class of around 30%, primarily driven by the once-weekly GLP-1 products. In February 2018, Novo Nordisk launched Ozempic<sup>®</sup> in the USA and broad formulary coverage has been obtained. The weekly new-to-brand prescription market share for Ozempic<sup>®</sup> has now reached 35% bringing Novo Nordisk's combined GLP-1 new-to-brand prescription market share to 53%, consequently the decline in the Novo Nordisk GLP-1 market share has stabilised measured on monthly prescriptions.

Sales of GLP-1 in the USA increased by 13% 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 changes in the channel and payer mix and the changes in the coverage gap legislation, impacting average realised prices negatively, as well as inventory reductions in the first quarter of 2019. Rebate adjustments for Victoza® related to prior periods were of a similar magnitude in the second quarter of 2019 and the second quarter of 2018, respectively. Furthermore, sales of Victoza® were negatively impacted by the launch of Ozempic® and a competing once-weekly product.

# Obesity, sales development

Sales of Saxenda<sup>®</sup> increased by 62% measured in Danish kroner and by 56% at CER to DKK 2,673 million. Sales growth of Saxenda<sup>®</sup> was driven by both International Operations and North America Operations. Saxenda<sup>®</sup> has now been launched in 43 countries.

Obesity, regional development	Obesity, sales dev	Obesity, sales development		
	Sales H1 2019 DKK million	Growth at CER		
Global	2,673	56%		
International Operations	1,097	121%		
- Region Europe	150	66%		
- Region AAMEO	463	111%		
- Region China	4	_		
- Region Japan & Korea	151	_		
- Region Latin America	329	92%		
North America Operations	1,576	28%		
- USA	1,458	29%		

# International Operations

Sales of Saxenda® in International Operations increased by 119% measured in Danish kroner and by 121% at CER driven by increased sales in all regions. Novo Nordisk currently has a value market share of 38% in the Obesity market in International Operations.

# Region Europe

Sales of Saxenda<sup>®</sup> in Region Europe increased by 67% measured in Danish kroner and by 66% at CER. Saxenda<sup>®</sup> has now been launched in 18 countries in Region Europe. Novo Nordisk currently has a value market share of 50% in the obesity market in Region Europe.

# Region AAMEO

Sales of Saxenda<sup>®</sup> in Region AAMEO increased by 116% measured in Danish kroner and by 111% at CER. Saxenda<sup>®</sup> has now been launched in 16 countries in Region AAMEO. Novo Nordisk currently has a value market share of 35% in the obesity market in Region AAMEO.

# Region Japan & Korea

Sales of Saxenda<sup>®</sup> in Region Japan & Korea were driven by Korea following the launch in early 2018.

# Region Latin America

Sales of Saxenda<sup>®</sup> in Region Latin America increased by 81% measured in Danish kroner and by 92% at CER. Saxenda<sup>®</sup> has now been launched in 5 countries in Region Latin America. Novo Nordisk currently has a value market share of 34% in the obesity market in Region Latin America.

# North America Operations

Sales of Saxenda<sup>®</sup> in North America Operations increased by 37% measured in Danish kroner and by 28% 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.

# **BIOPHARMACEUTICALS**

# Biopharmaceuticals, sales development

Sales of biopharmaceutical products increased by 7% measured in Danish kroner and by 3% at CER to DKK 9,273 million. The sales development was driven by sales growth in Region AAMEO, Region Latin America, Region China and Region Japan & Korea partly offset by declining sales in the USA as well as Region Europe.

# Biopharmaceuticals, regional development

#### Biopharmaceuticals, sales development

	Sales H1 2019 DKK million	Growth at CER
Global	9,273	3%
International Operations	5,672	5%
- Region Europe	2,467	(1%)
- Region AAMEO	1,106	10%
- Region China	166	45%
- Region Japan & Korea	1,146	5%
- Region Latin America	787	15%
North America Operations	3,601	0%
- USA	3,300	(2%)

# Haemophilia

Sales of haemophilia products increased by 8% measured in Danish kroner and by 5% at CER to DKK 5,203 million. Increased sales were driven by the continued global rollout of NovoEight® and Refixia®, partly offset by lower NovoSeven® sales. Novo Nordisk continues to expand its broad global haemophilia presence.

Sales of NovoSeven<sup>®</sup> increased by 3% measured in Danish kroner and decreased by 1% at CER to DKK 4,175 million, reflecting the solid position of NovoSeven<sup>®</sup> as a haemostatic agent in critical treatment settings in an increasingly competitive environment. The development in sales is driven by declining sales in Region Europe, Region Japan & Korea as well as Region AAMEO, partly offset by increased sales in Region Latin America and North America Operations. NovoSeven<sup>®</sup> sales in the USA were positively impacted by rebate adjustments related to prior periods.

Sales of NovoEight<sup>®</sup> increased by 20% measured in Danish kroner and by 17% at CER to DKK 762 million. Sales growth was driven by Region AAMEO and Region Europe. NovoEight<sup>®</sup> has now been launched in 49 countries.

Sales of Refixia<sup>®</sup> increased to DKK 147 million. Sales growth was driven by the product launches in North America Operations, Region Europe and Region Japan & Korea. Refixia<sup>®</sup> has been launched in 14 countries.

# Growth disorders (Norditropin®)

Sales of growth disorder products increased by 4% measured in Danish kroner, and remained unchanged at CER, to DKK 3,313 million. The unchanged sales measured at CER were driven by positive contribution from International Operations increasing sales by 5% at CER, offset by declining sales in North America Operations declining by 7% at CER impacted by inventory reductions in the first quarter of 2019 in the USA. Sales in the USA were positively impacted by rebate adjustments related to prior periods. Novo Nordisk is the leading company in the global human growth disorder market with a market share measured in value of around 33% and focusing on continued expansion of the presence in the market driven by new indications and the introduction of the next-generation device.

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# **DEVELOPMENT IN COSTS AND OPERATING PROFIT**

The **cost of goods sold** increased by 12% measured in both Danish kroner and at CER to DKK 9,581 million, resulting in a gross margin of 83.9% measured in Danish kroner, compared with 84.3% in 2018. The decrease in gross margin reflects a negative impact from lower prices in the USA and growth of lower margin insulin products partly countered by a positive currency impact of 0.6 percentage point.

**Sales and distribution** costs increased by 7% measured in Danish kroner and by 4% at CER to DKK 14,526 million. The increase in sales and distribution costs was driven by International Operations reflecting resource allocation to growth markets and promotional activities for Victoza<sup>®</sup> and Saxenda<sup>®</sup> as well as launch activities for Ozempic<sup>®</sup>. In the USA, promotional activities are focusing on Ozempic<sup>®</sup> and Saxenda<sup>®</sup>.

**Research and development** costs decreased by 6% measured in Danish kroner and by 7% at CER to DKK 6,235 million, reflecting reversal of write-downs on clinical prelaunch inventory in first quarter of 2019 following the filing of oral semaglutide to the US FDA. Adjusted for the reversal of write-downs, research and development costs were broadly unchanged. The development 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, offset by increasing costs for the semaglutide in obesity clinical programmes STEP and SELECT.

**Administration costs** increased by 3% measured in Danish kroner and by 2% at CER to DKK 1,763 million, reflecting growth across the regions in International Operations.

**Other operating income (net)** was DKK 469 million compared with DKK 737 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 12% in Danish kroner and by 6% at CER to DKK 27,691 million.

# **FINANCIAL ITEMS (NET) AND TAX**

Financial items (net) showed a net loss of DKK 2,324 million compared with a net gain of DKK 1,455 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 1,984 million compared with a gain of DKK 1,495 million in 2018. This development reflects a loss on foreign exchange hedging, especially related to the US dollar versus the Danish krone.

As per the end of June 2019, a negative market value of financial contracts of approximately DKK 0.6 billion has been deferred for recognition later in 2019 and 2020.

The effective tax was 21.0% in the first half of 2019 compared with an effective tax rate of 19.2% in 2018. The higher effective tax rate reflects the non-recurring change in tax provisions related to settlement of international tax cases in 2018.

# **CAPITAL EXPENDITURE AND FREE CASH FLOW**

Net capital expenditure for property, plant and equipment was DKK 4.2 billion compared with DKK 3.9 billion in 2018. Net capital expenditure was primarily related to investments in a new production facility for diabetes active pharmaceutical ingredients in Clayton, North Carolina, USA, expansion of production facilities in Chartres, France and a new diabetes filling capacity in Hillerød, Denmark.

Free cash flow was DKK 18.7 billion compared with DKK 20.5 billion in 2018. The decrease of 9% compared with 2018 primarily reflects lower net profit in the first half of 2019, a negative development in working capital, investment in intangible assets reflecting a recent acquisition of a priority review voucher, increased capital expenditure and proceeds from the partial divestment of NNIT A/S shares in the first quarter of 2018, partly offset by the timing of rebate payments in the USA.

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# **KEY DEVELOPMENTS IN THE SECOND QUARTER OF 2019**

Please refer to appendix 1 for an overview of the quarterly numbers in DKK and to appendix 6 for details on sales in the second quarter of 2019.

Sales in the second quarter of 2019 increased by 10% in Danish kroner and by 6% at CER compared with the same period in 2018. Sales growth in International Operations measured at CER was 12% and sales remained unchanged measured at CER in North America Operations. The sales growth was driven by Diabetes derived from increased GLP-1 sales offset by declining insulin sales, as well as increased Obesity and Biopharmaceuticals sales.

The gross margin was 83.9% in the second quarter of 2019 compared with 84.1% in the same period last year. The decline of 0.2 percentage point of the gross margin reflects a negative impact from lower prices in the USA partly countered by a positive currency impact of 0.5 percentage point.

Sales and distribution costs increased by 7% in Danish kroner and by 5% at CER compared with the same period in 2018. The increase in sales and distribution costs was driven by International Operations reflecting resource allocation to growth markets and promotional activities for Saxenda<sup>®</sup> as well as launch activities for Ozempic<sup>®</sup>. In the USA, promotional activities are focusing on Ozempic<sup>®</sup> and Saxenda<sup>®</sup>.

Research and development costs increased by 8% in Danish kroner and by 7% at CER compared with the same period in 2018. The development in costs is driven by increasing costs for the semaglutide in obesity clinical programmes STEP and SELECT, partly offset by the completion of the oral semaglutide phase 3a development programme.

Administrative costs remained unchanged both measured in Danish kroner and at CER compared with the same period in 2018.

Other operating income (net) was DKK 254 million in the second quarter of 2019 compared with DKK 386 million in the same period last year.

Operating profit increased by 10% in Danish kroner and by 4% at CER compared with the same period in 2018.

# **EQUITY**

Total equity was DKK 53,085 million at the end of the first six months of 2019, equivalent to 45.0% of total assets, compared with 47.5% at the end of the first six months of 2018. Please refer to appendix 5 for further elaboration of changes in equity.

# Interim dividend

The Board of Directors has decided to pay out interim dividend for 2019 of DKK 3.00 for each Novo Nordisk A and B share of DKK 0.20, which will be paid in August 2019. The ex-dividend date for the interim dividend will be 16 August 2019. The record date will be 19 August 2019 for the A and B shares as well as ADRs. The payment date for the A and B shares will be 20 August 2019, while the payment date for the ADRs will be 27 August 2019. No dividend will be paid on the company's holding of B shares.

# 2019 share repurchase programme

On 7 May 2019, Novo Nordisk announced a share repurchase programme of up to DKK 2.7 billion to be executed from 8 May to 7 August 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 8,224,508 B shares for an amount of DKK 2.7 billion in the period from 8 May to 7 August 2019. The programme was concluded on 7 August 2019. As of 7 August 2019, Novo Nordisk A/S has repurchased a total of 23,401,012 B shares equal to a transaction value of DKK 7.635 billion under the DKK 15 billion programme beginning 1 February 2019.

As of 7 August 2019, Novo Nordisk and its wholly-owned affiliates owned 30,568,156 of its own B shares, corresponding to 1.3% of the total share capital.

The execution of Novo Nordisk's 2019 share repurchase programme of DKK 15 billion to be executed during a 12-month period from February 2019 to January 2020 continues, and a new share repurchase programme will be initiated in accordance with Article 5 of Regulation No 596/2014 of the European Parliament and Council of 16 April 2014 (MAR) and the Commission Delegated Regulation (EU) 2016/1052 of 8 March 2016 (the "Safe Harbour Rules"). For that purpose, Novo Nordisk A/S has appointed Nordea Danmark, Filial af Nordea Bank Abp, as lead manager to execute the programme independently and without influence from Novo Nordisk A/S. The purpose of the programme is to reduce the company's share capital and to meet obligations arising from share-based incentive programmes. Under the agreement, Nordea Danmark, Filial af Nordea Bank Abp, will repurchase B shares on behalf of Novo Nordisk A/S during the trading period starting today, 9 August, and ending on 30 October 2019.

A maximum of 209,431,844 B shares in total can be bought during the trading period. The maximum number of B shares that can be repurchased on a single trading day may not exceed 20% of the average daily trading volume of Novo Nordisk B shares on the trading venue, on which the purchase takes place, during the preceding 20 trading days of the purchase (excluding the day of the purchase), cf Article 3(3) of the Commission Delegated Regulation (EU) 2016/1052. At least once every seven trading days, Novo Nordisk A/S will issue an announcement in respect of the transactions made under the repurchase programme.

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 Nordisk has been informed by Novo Holdings A/S that it plans to participate in the share repurchase programme. Novo Holdings A/S has an ownership of 28.3% of the Novo Nordisk share capital, and Novo Holdings A/S currently intends to maintain its ownership of the Novo Nordisk share capital around 28%.

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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 9 August 2019	Expectations 3 May 2019
Sales growth		
at CER as reported	<b>4% to 6%</b> Around 3%-points higher than at CER	2% to 5% Around 3%-points higher than at CER
Operating profit growth		
at CER as reported	<b>4% to 6%</b> Around 5%-points higher than at CER	2% to 6% Around 5%-points higher than at CER
Financial items (net)	Loss of around DKK 3.5 billion	Loss of around DKK 3.3 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 30-34 billion	DKK 29-34 billion

For 2019, **sales growth** is now expected to be 4% to 6%, 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 expected to be around 3 percentage points higher than at CER.

For 2019, **operating profit growth** is now expected to be 4% 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 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 3.5 billion, offsetting the positive currency impact on operating profit. The current expectation for 2019 primarily 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%. A potential impact on the effective tax rate from the Swiss tax reform is not included until the legislative process in Canton Zurich has been finalised.

**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 now expected to be DKK 30-34 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.

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FX	Q2 2019	Q2 2018	% change	H1 2019	H1 2018	% change	Spot rate 5 August 2019
USD	664	625	6%	661	615	7%	668
CNY	97	98	(1%)	97	97	1%	95
JPY	6.04	5.73	5%	6.00	5.66	6%	6.30
GBP	855	850	1%	855	846	1%	812
CAD	497	484	3%	495	482	3%	505

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	9
CNY	DKK 375 million	7*
JPY	DKK 170 million	12
CAD	DKK 100 million	9
GBP	DKK 80 million	11

<sup>\*</sup> 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).

#### **RESEARCH & DEVELOPMENT UPDATE**

# **Diabetes**

# Oral semaglutide filed for regulatory review in Japan

In July 2019, Novo Nordisk submitted the New Drug Application to the Japanese Authorities (PMDA) for oral semaglutide. The submission is based on the results from PIONEER phase 3a programme with oral semaglutide in adults with type 2 diabetes. In the PIONEER programme, people treated with oral semaglutide demonstrated greater HbA<sub>1c</sub> reductions and weight loss in all completed head-to-head trials versus sitagliptin, empagliflozin, liraglutide and dulaglutide, at the end of the trials. Across the PIONEER trials, oral semaglutide had a safe and well-tolerated profile consistent with the GLP-1 class; the most common adverse event being gastrointestinal-related adverse events reported at, or below, levels previously observed for injectable GLP-1 products.

# Label update with paediatric data for Victoza® approved in the USA and positive CHMP opinion in EU based on data from the Ellipse trial

In May 2019, the FDA (US Food and Drug Administration) confirmed that six months of paediatric exclusivity had been granted and added to the patents for Victoza® listed in the Orange Book, effective 1 May 2019. Furthermore, in June 2019, the FDA approved the use of Victoza®, as an adjunct to diet and exercise, to improve glycaemic control in children and adolescents (10 years and above) with type 2 diabetes.

In June 2019, the Committee for Medicinal Products for Human Use (CHMP) recommended that Victoza<sup>®</sup>, as an adjunct to diet and exercise, is indicated for the treatment of children and adolescents (10 years and above) with insufficiently controlled type 2 diabetes. Once CHMP's recommendation has been endorsed by the European Commission, Novo Nordisk can apply for 6 months of paediatric extension to the Victoza<sup>®</sup> supplementary patent certificate.

# Xultophy® approved in Japan

In June 2019, Xultophy<sup>®</sup> was approved in Japan for the treatment of people with type 2 diabetes requiring insulin therapy. The approval was based on the results from the two DUAL trials, including more than 1,000 adults from Japan. The approval follows the approval of Victoza<sup>®</sup> 1.8 mg in Japan earlier this year.

# Ryzodeg® approved in China

In May 2019, Ryzodeg<sup>®</sup> was approved in China for the treatment of adults with type 2 diabetes. In September 2018, Ryzodeg<sup>®</sup> was included on the fast-track review list, which accelerated the approval process and Ryzodeg<sup>®</sup> was approved after only 14 months review.

Positive phase 2 results with anti-IL-21 and liraglutide in people with newly diagnosed type 1 diabetes In May 2019, Novo Nordisk completed the phase 2 trial with the combination of anti-IL-21 and liraglutide. The phase 2 trial was a multinational, randomised, parallel group, placebo-controlled proof of principle trial in people with newly diagnosed type 1 diabetes. The primary objective was to evaluate the preservation of beta cell function after treatment with anti-IL-21 and liraglutide for 54 weeks, followed by a 26 weeks observation period without treatment.

The trial demonstrated statistically significantly better beta cell function for the combination of anti-IL-21 and liraglutide after 54 weeks compared to placebo. Furthermore, there was an improvement in glycaemic parameters and a reduction in use of insulin after 54 weeks of treatment for the combination of anti-IL-21 and liraglutide. At the end of the trial, ie after the 26 weeks observation period without treatment, the beta cell function for people treated with the combination of anti-IL-21 and liraglutide appeared similar to placebo. No safety or tolerability concerns associated with the treatment of the combination of anti-IL-21 and liraglutide were observed during the trial. Novo Nordisk is now engaging with regulatory authorities to evaluate next steps.

# Three phase 3b trials initiated with subcutaneous semaglutide

In May 2019, the FOCUS trial was initiated. The objective of the trial is to assess the long-term effects of semaglutide on diabetic retinopathy in people with type 2 diabetes. The trial is expected to enrol 1,500 people from 17 countries. The five-year trial seeks to demonstrate a long-term benefit of semaglutide on eyesight - as assessed by the ETDRS score - driven by superior glucose control.

In June 2019, the SUSTAIN FORTE trial was initiated. The objective of the trial is to assess efficacy and safety of semaglutide 2 mg subcutaneous once-weekly compared to semaglutide 1 mg subcutaneous once-weekly in people with type 2 diabetes. The trial is expected to enrol approximately 1,000 people from 10 countries.

In June 2019, the FLOW trial was initiated. The objective of the trial is to assess the effect of semaglutide versus placebo on the progression of renal impairment in people with type 2 diabetes and chronic kidney disease. The trial is expected to enrol more than 3,000 people from 28 countries.

# Initiation of SOUL, a cardiovascular outcomes trial with oral semaglutide

In June 2019, the SOUL trial was initiated. SOUL is a dedicated diabetes cardiovascular outcomes trial (CVOT), aiming to confirm oral semaglutide's cardiovascular risk reduction and expand the scientific evidence base about the cardiovascular benefits of semaglutide. The trial is expected to enrol approximately 9,600 people in 34 countries.

# Phase 1 trial initiated with FSI965, investigating the safety, tolerability and pharmacokinetics of single doses in healthy male subjects

In June 2019, the first human dose trial for FSI965, a next-generation basal insulin was initiated. The trial is a single-centre, randomised, double-blinded, single-dose, dose-escalation trial. The trial is designed to investigate the safety, tolerability and pharmacokinetics of FSI965.

# Obesity

# Phase 1 initiated with LA-GDF15

In July 2019, the first human dose trial with LA-GDF15 was initiated including both single and multiple ascending doses. Human GDF15 (Growth Differentiation Factor 15, also known as MIC-1), is a stress-induced cytokine with multiple effects, one being appetite regulation leading to weight loss. LA-GDF15 is a long-acting version of human GDF15.

# **Biopharmaceuticals**

# Esperoct® (turoctocog alfa pegol, N8-GP) approved in the EU

In June 2019, Novo Nordisk announced that the European Commission has granted marketing authorisation for Esperoct® for the treatment of patients 12 years and above with haemophilia A. The authorisation covers all 28 European Union member states. Esperoct® is the brand name for turoctocog alfa pegol, N8-GP. Esperoct® is indicated for prophylaxis and on-demand treatment of bleeding as well as for surgical procedures for patients 12 years and above with haemophilia A (congenital factor VIII deficiency). The efficacy and safety evaluation was based on the results from the largest pre-registration clinical programme conducted in haemophilia A, with inclusion of 270 previously treated people with severe haemophilia A and more than 5 years of clinical exposure. The marketing authorisation follows the positive opinion from the CHMP, under the European Medicines Agency, provided 26 April 2019.

# NovoEight® submitted for regulatory approval in China

In July 2019, the Chinese Regulatory Authority accepted the marketing authorisation application for NovoEight®, which was submitted in May 2019.

Phase 3 trial (REAL 4) initiated with somapacitan in children with growth hormone deficiency In May 2019, Novo Nordisk initiated the phase 3 programme (REAL 4) for somapacitan in children with growth hormone deficiency. REAL 4 is a global trial programme and expected to enrol approximately 200 children.

# **Other Serious Chronic Diseases**

# Phase 2 initiated with semaglutide in combination with Gilead Science's cilofexor and firsocostat for treatment of NASH

In July 2019, Gilead Sciences and Novo Nordisk initiated a phase 2 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 nonalcoholic steatohepatitis (NASH).

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# **SUSTAINABILITY UPDATE**

# The number of employees in Novo Nordisk decreased by 3.5%

The number of full-time employees at the end of the first six months of 2019 decreased by 3.5% compared to 12 months ago. The total number of employees was 42,154, corresponding to 41,611 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 bans single-use plastics globally

As part of the company's Circular for Zero strategy, Novo Nordisk bans single-use plastics across the global organisation. By the end of 2019, all use of single-use plastic items will be phased out. The initiative covers products made of 100% plastic where sustainable alternatives are available, such as bottles, cups, food packaging, cutlery and straws. Exempted are products used for purposes subject to regulation and laboratory equipment.

# **CORPORATE GOVERNANCE**

# Executive Vice President of Business Service & Compliance, Lars Green has decided to resign to take up an executive position outside Novo Nordisk. Monique Carter has been promoted to executive vice president of People & Organisation

In August 2019, Executive Vice President (EVP) of Business Services & Compliance Lars Green decided to resign from his position by the end of August 2019 to take up an executive position outside of Novo Nordisk. Lars Green joined Novo Nordisk in 1992 and he has in the period between 1992 to 2017 taken up several positions across the global finance function. In July 2017, Lars Green was promoted to executive vice president and member of Executive Management in Novo Nordisk.

Following Lars Green's resignation, Monique Carter has been promoted to EVP of People & Organisation and member of Novo Nordisk's Executive Management. Monique Carter joined Novo Nordisk in November 2018 as senior vice president for Global People & Organisation. Prior to joining Novo Nordisk, Monique Carter was Group HR director and member of the Executive Committee at GKN plc, UK. Monique Carter worked in the chemicals industry from 2005 to 2014 starting with ICI plc, UK (which later became part of Akzo Nobel, the Netherlands) and held several HR positions in the UK, Singapore and the Netherlands. Monique Carter is a British and Irish national and holds a postgraduate education in Human Resource Management.

With these changes, Executive Management will have the following members:

- Lars Fruergaard Jørgensen, president and CEO
- Monique Carter, EVP, People & Organisation
- Maziar Mike Doustdar, EVP, International Operations (based in Zurich, Switzerland)
- Lars Green, EVP (until the end of August 2019)
- Ludovic Helfgott, EVP, Biopharm (based in Zurich, Switzerland)
- Karsten Munk Knudsen, EVP, chief financial officer
- Doug Langa, EVP, North America Operations (based in Princeton, New Jersey, USA)
- Camilla Sylvest, EVP, Commercial Strategy & Corporate Affairs
- Mads Krogsgaard Thomsen, EVP, chief science officer
- Henrik Wulff, EVP, Product Supply, Quality & IT

Only Danish-based members of Executive Management are registered with the Danish Business Authority.

# Restricted stock units to employees (2019 programme)

To appreciate the efforts of the employees during the latest years, all employees will be offered 75 restricted stock units. A restricted stock unit gives the right to receive one Novo Nordisk B share free of charge in February 2023 subject to continued employment. The DKK 660 million cost of the programme will be amortised over the period 2019-2023 at an annual amount of DKK 189 million.

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#### **LEGAL MATTERS**

# Product liability lawsuits related to Victoza®

Novo Nordisk, along with the majority of incretin-based product manufacturers in the USA, is a defendant in product liability lawsuits related to use of incretin-based medications. As of 5 August 2019, 312 plaintiffs have named Novo Nordisk in product liability lawsuits, predominantly claiming damages for pancreatic cancer that allegedly developed as a result of using Victoza® and other GLP-1/DPP-IV incretin-based products. 200 of the Novo Nordisk plaintiffs have also named other defendants in their lawsuits. Most Novo Nordisk plaintiffs have filed suit in California federal and state courts. In November 2015, all pancreatic cancer cases pending in the California federal and state courts were dismissed on federal pre-emption grounds. Plaintiffs subsequently appealed these rulings to the federal and California state appeals courts. In November 2017, the U.S. Court of Appeals for the Ninth Circuit reversed and vacated the Federal District Court Judge's ruling, thereby reinstating the dismissed federal lawsuits and sending them back to the Federal District Court in California for further proceedings. In November 2018, the California Court of Appeal issued a similar ruling, thus sending the California state court cases back to state trial court for further proceedings. Currently, Novo Nordisk does not have any individual trials scheduled in 2019. Novo Nordisk does not expect the pending claims to have a material impact on its financial position, operating profit or cash flow.

# Mylan has filed an Abbreviated New Drug Application for liraglutide with the US FDA

In July 2019, Mylan notified Novo Nordisk that it had filed an Abbreviated New Drug Application (ANDA) for liraglutide with the US FDA. According to Mylan, the ANDA contains Paragraph IV certifications to obtain approval to engage in the commercial manufacture, use or sale of liraglutide before the expiration of seven patents currently listed for liraglutide in the Orange Book with expiration dates ranging from July 2021 until March 2033, including the drug substance patent expiring February 2023 (all dates including a six month paediatric extension). Novo Nordisk is currently assessing its legal options, which could lead to litigation against Mylan. Novo Nordisk does not expect the matter to have a material impact on Novo Nordisk's financial position, operating profit or cash flow.

# Subpoena from New York State Attorney General's office calling for information related to practices for Novo Nordisk's insulin products

In July 2019, the New York State Attorney General's office served Novo Nordisk Inc. with a subpoena calling for the production of documents and information relating to pricing and trade practices for Novo Nordisk's insulin products from 1 July 2013 through the present. Novo Nordisk is cooperating with the New York State Attorney General 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.

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# **MANAGEMENT STATEMENT**

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

The financial report for the first six 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 six 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 six 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.

Lars Green

Corporate

Bagsværd, 9 August 2019

# **Executive Management:**

Lars Fruergaard Jørgensen

Financial

Performance

President and CEO	CFO	
Camilla Sylvest	Mads Krogsgaard Thomsen	Henrik Wulff
Board of Directors:		
Helge Lund <i>Chair</i>	Jeppe Christiansen <i>Vice chair</i>	Brian Daniels
Laurence Debroux	Andreas Fibig	Sylvie Grégoire
Liz Hewitt	Mette Bøjer Jensen	Kasim Kutay
Anne Marie Kverneland	Martin Mackay	Thomas Rantzau
Stig Strøbæk		

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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. 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 41,600 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

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

20 November 2019 Capital Markets Day

05 February 2020 Financial statement for 2019

# Contacts for further information

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# 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.

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

(Amounts in DKK million,	except number of	of full-time equivaler	it employees,	earnings per	share and num	ber of shares ou	utstanding).

,	2019		04	2018		01	% change Q2 2019 vs.
	Q2	Q1	Q4	Q3	Q2	Q1	Q2 2018
Net sales	30,036	29,291	29,732	27,762	27,407	26,930	10%
Gross profit  Gross margin	25,187 <b>83.9</b> %	24,559 <b>83.8%</b>	25,079 <b>84.4%</b>	23,347 <b>84.1</b> %	23,055 <b>84.1%</b>	22,733 <b>84.4</b> %	9%
Sales and distribution costs	7,580	6,946	8,728	7,128	7,090	6,451	7%
Percentage of sales	25.2%	23.7%	29.4%	25.7%	25.9%	24.0%	00/
Research and development costs  Percentage of sales	3,557 <b>11.8%</b>	2,678 <b>9.1%</b>	4,544 <b>15.3%</b>	3,644 <b>13.1%</b>	3,296 <b>12.0%</b>	3,321 <b>12.3</b> %	8%
Administrative costs	852	911	1,269	932	851	864	0%
Percentage of sales	2.8%	3.1%	4.3%	3.4%	3.1%	3.2%	
Other operating income, net	254	215	245	170	386	351	(34%)
Operating profit Operating margin	<b>13,452</b> <i>44.8</i> %	<b>14,239</b> <i>48.6%</i>	<b>10,783</b> <i>36.3%</i>	11,813 <i>42</i> .6%	<b>12,204</b> <i>44</i> .5%	<b>12,448</b> <i>46.2%</i>	10%
Financial income	15	13	(37)	(78)	1,039	1,198	N/A
Financial expenses	1,322	1,030	376	597	745	37	N/A
Financial items (net)	(1,307)	(1,017)	(413)	(675)	294	1,161	N/A
Profit before income taxes Income taxes	12,145 2,550	13,222 2,777	10,370 1,873	11,138 2,101	12,498 2,155	13,609 2,858	(3%) 18%
Net profit	9,595	10,445	8,497	9,037	10,343	10,751	(7%)
Depreciation, amortisation and impairment	1,110	1,058	1,642	783	768	732	45%
losses							
Capital expenditure (net)  Net cash generated from operating activities	2,077 15,039	2,101 9,890	3,311 7,412	2,316 11,619	1,587 15,770	2,310 9,815	31% (5%)
Free cash flow	12,020	6,655	3,313	8,755	13,227	7,241	(9%)
Total assets	117,909	110,135	110,769	101,895	103,248	93,558	14%
Total equity	53,085	47,319	51,839	47,512	49,081	44,238	8%
Equity ratio	45.0%	43.0%	46.8%	46.6%	47.5%	47.3%	
Full-time equivalent employees end of period	41,611	42,453	42,672	43,161	43,105	42,688	(3%)
Basic earnings per share/ADR (in DKK)	4.03	4.37	3.54	3.74	4.27	4.41	(6%)
Diluted earnings per share/ADR (in DKK)	4.03	4.36	3.53	3.74	4.26	4.40	(5%)
Average number of shares outstanding (million)  Average number of diluted shares	2,380.2	2,390.3	2,401.2	2,414.1	2,425.8	2,437.3	(2%)
outstanding (million)	2,383.5	2,394.6	2,406.1	2,419.2	2,430.9	2,442.3	(2%)
Sales by business segment:							
Long-acting insulin	5,411	5,244	5,456	5,158	5,357	4,873	1%
Premix insulin	2,560	2,757	2,438	2,527	2,587	2,642	(1%)
Fast-acting insulin	4,758	4,977	5,030	4,609	4,936	4,778	(4%)
Human insulin <sup>1)</sup> Total insulin	2,180	2,415	2,178	2,386	2,335	2,366	(7%)
Total GLP-1	14,909 7,740	15,393 7,147	15,102 7,492	14,680 6,655	15,215 5,924	14,659 6,058	(2%) 31%
Other diabetes	1,125	1,067	1,074	1,044	1,011	1,121	11%
Total diabetes	23,774	23,607	23,668	22,379	22,150	21,838	7%
Obesity (Saxenda®)	1,462	1,211	1,229	987	883	770	66%
Diabetes and obesity total	25,236	24,818	24,897	23,366	23,033	22,608	10%
Haemophilia	2,670	2,533	2,478	2,301	2,294	2,503	16%
Growth disorders (Norditropin®)	1,758	1,555	1,962	1,688	1,703	1,481	3%
Other biopharmaceuticals	372	385	395	407	377	338	(1%)
Biopharmaceuticals total	4,800	4,473	4,835	4,396	4,374	4,322	10%
Sales by geographic segment: International Operations	15,565	15,387	13,882	13,659	13,818	13,564	13%
- Region Europe	5,862	5,505	5,594	5,392	5,460	5,233	7%
- Region AAMEO	3,547	3,738	2,993	3,067	3,194	2,899	11%
- Region China	3,192	3,375	2,712	2,793	2,751	3,029	16%
- Region Japan & Korea	1,664	1,458	1,610	1,446	1,484	1,257	12%
- Region Latin America	1,300	1,311	973	961	929	1,146	40%
North America Operations	14,471	13,904	15,850	14,103	13,589	13,366	6%
- USA	13,767	13,211	15,182	13,476	12,952	12,878	6%
Segment operating profit:							
Diabetes and obesity	11,393	11,828	8,153	9,995	9,760	9,934	17%
Biopharmaceuticals	2,059	2,411	2,630	1,818	2,444	2,514	(16%)

# APPENDIX 2: INCOME STATEMENT AND STATEMENT OF COMPREHENSIVE INCOME

DKK million	H1 2019	H1 2018	Q2 2019	Q2 2018
Income statement				
Net sales Cost of goods sold	59,327 9,581	54,337 8,549	30,036 4,849	27,407 4,352
Gross profit	49,746	45,788	25,187	23,055
Sales and distribution costs Research and development costs Administrative costs Other operating income, net	14,526 6,235 1,763 469	13,541 6,617 1,715 737	7,580 3,557 852 254	7,090 3,296 851 386
Operating profit	27,691	24,652	13,452	12,204
Financial income Financial expenses	28 2,352	2,237 782	15 1,322	1,039 745
Profit before income taxes	25,367	26,107	12,145	12,498
Income taxes	5,327	5,013	2,550	2,155
NET PROFIT	20,040	21,094	9,595	10,343
Basic earnings per share (DKK) Diluted earnings per share (DKK)	8.40 8.39	8.68 8.66	4.03 4.03	4.27 4.26
Segment Information				
Segment sales: Diabetes and obesity Biopharmaceuticals	50,054 9,273	45,641 8,696	25,236 4,800	23,033 4,374
Segment operating profit: Diabetes and obesity Operating margin Biopharmaceuticals	23,221 <b>46.4%</b> 4,470	19,694 <b>43.1%</b> 4,958	11,393 <b>45.1%</b> 2,059	9,760 <b>42.4</b> % 2,444
Operating margin	48.2%	57.0%	42.9%	55.9%
Total segment operating profit	27,691	24,652	13,452	12,204
Statement of comprehensive income				
Net profit for the period	20,040	21,094	9,595	10,343
Other comprehensive income Items that will not subsequently be reclassified to the Income statement				
Remeasurements on defined benefit plans	(202)	68	(112)	(8)
Items that will be reclassified subsequently to the Income statement				
Exchange rate adjustments of investments in subsidiaries Cash flow hedges, realisation of previously deferred (gains)/losses Cash flow hedges, deferred gains/(losses) incurred during the period Other items Tax on other comprehensive income, income/(expense)	184 1,484 (399) 16 (187)	125 (1,758) (1,574) (10) 704	(27) 632 530 — (341)	92 (674) (2,211) (23) 642
Other comprehensive income for the period, net of tax	896	(2,445)	682	(2,182)
TOTAL COMPREHENSIVE INCOME FOR THE PERIOD	20,936	18,649	10,277	8,161

# **APPENDIX 3: CASH FLOW STATEMENT**

DKK million	H1 2019	H1 2018
Net profit	20,040	21,094
Adjustment for non-cash items:		
Income taxes in the Income Statement	5,327	5,013
Depreciation, amortisation and impairment losses	2,168	1,500
Other non-cash items	5,548	3,435
Change in working capital	(3,026)	27
Interest received	27	22
Interest paid	(84)	(45)
Income taxes paid	(5,071)	(5,461)
Net cash generated from operating activities	24,929	25,585
	(1.025)	(4.050)
Purchase of intangible assets	(1,025)	(1,059)
Proceeds from sale of property, plant and equipment	(4.701)	(4.450)
Purchase of property, plant and equipment Proceeds from other financial assets	(4,791)	(4,458) 21
	(48)	21
Investment in associated company	, ,	768
Proceeds from the divestment of Group and associated companies  Dividend received from associated company	(6) 11	368 10
Net cash used in investing activities	(5,859)	(5,117)
	(1)	
Purchase of treasury shares	(7,529)	(7,750)
Dividends paid	(12,309)	(11,810)
Repayment of borrowings, net	(433)	_
Net cash used in financing activities	(20,271)	(19,560)
NET CASH GENERATED FROM ACTIVITIES	(1,201)	908
Cash and cash equivalents at the beginning of the year	15,629	17,158
Exchange gain/(loss) on cash and cash equivalents	18	81
Cash and cash equivalents at the end of the year	14,446	18,147

# **APPENDIX 4: BALANCE SHEET**

DKK million	30 Jun 2019	31 Dec 2018
ASSETS		
Intangible assets	5,900	5,145
Property, plant and equipment	48,204	41,891
Investments in associated companies	997	531
Deferred income tax assets	2,987	2,893
Other financial assets	1,101	1,242
TOTAL NON-CURRENT ASSETS	59,189	51,702
Inventories	17,129	16,336
Trade receivables	23,246	22,786
Tax receivables Other receivables and prepayments	475 3,279	1,013 3,090
Derivative financial instruments	134	204
Cash at bank	14,457	15,638
TOTAL CURRENT ASSETS	58,720	59,067
TOTAL ASSETS	117,909	110,769
EQUITY AND LIABILITIES		
Share capital	480	490
Treasury shares	(5)	(11)
Retained earnings Other reserves	53,558 (948)	53,406 (2,046)
TOTAL EQUITY	53,085	51,839
Borrowings Deferred income tax liabilities	2,977 542	118
Retirement benefit obligations	1,317	1,256
Provisions	3,393	3,392
Total non-current liabilities	8,229	4,766
Borrowings	1,255	515
Trade payables	5,269	6,756
Tax payables	4,228	4,610
Other liabilities	13,595	14,098
Derivative financial instruments Provisions	1,151 31,097	2,024 26,161
Total current liabilities	56,595	54,164
TOTAL LIABILITIES	64,824	58,930
TOTAL EQUITY AND LIABILITIES	117,909	110,769

# **APPENDIX 5: EQUITY STATEMENT**

					Other re	serves		
DKK million	Share capital	Treasury shares	Retained earnings	Exchange rate adjust- ments	Cash flow hedges	Tax and other adjust-ments	Total other reserves	Total
H1 2019								
Balance at the beginning of the period Net profit for the period	490	(11)	53,406 20,040	(1,065)	(1,677)	696	(2,046)	51,839 20,040
Other comprehensive income for the period			(202)	184	1,085	(171)	1,098	896
Total comprehensive income for the period			19,838	184	1,085	(171)	1,098	20,936
Transactions with owners:								
Dividends			(12,309)					(12,309)
Share-based payments			142					142
Tax related to restricted stock units			6					6
Purchase of treasury shares		(4)	(7,525)					(7,529)
Reduction of the B share capital	(10)	10						_
Balance at the end of the period	480	(5)	53,558	(881)	(592)	525	(948)	53,085

					Other re	serves		
DKK million	Share capital	Treasury shares	Retained earnings	Exchange rate adjust- ments	Cash flow hedges	Tax and other adjust-ments	Total other reserves	Total
H1 2018			,					
Balance at the beginning of the period Change in accounting policy, IFRS 9 (net of tax) Net profit for the period	500	(11)	48,977 (90) 21,094	(1,556)	2,027	(122) 90	349 90	49,815 — 21,094
Other comprehensive income for the period			68	125	(3,332)	694	(2,513)	(2,445)
Total comprehensive income for the period			21,072	125	(3,332)	784	(2,423)	18,649
Transactions with owners: Dividends Share-based payments Tax related to restricted stock units			(11,810) 194 (17)					(11,810) 194 (17)
Purchase of treasury shares Reduction of the B share capital	(10)	(5) 10	(7,745)					(7,750)
Balance at the end of the period	490	(6)	50,671	(1,431)	(1,305)	662	(2,074)	49,081

# **APPENDIX 6: REGIONAL SALES SPLIT**

Q2 2019 sales split per region		Inter- national	Region	Region	Region	Region Japan &	Region Latin	North America	
DKK million	Total	Operations	Europe	AAMEO	China	Korea	America	Operations	USA
The diabetes and obesity segment									
Long-acting insulin	5,411	2,300	1,208	412	261	239	180	3,111	2,997
% change at CER	(3%)	13%	12%	22%	28%	0%	2%	(12%)	(13%)
Tresiba®	2,495	897	445	112	17	213	110	1,598	1,531
% change at CER	22%	26%	40%	30%	_	3%	8%	21%	17%
Xultophy <sup>®</sup>	574	363	310	39	_	_	14	211	209
% change at CER	46%	42%	29%	236%	_	_	367%	55%	53%
Levemir®	2,342	1,040	453	261	244	26	56	1,302	1,257
% change at CER	(25%)	(2%)	(13%)	10%	21%	(14%)	(23%)	(37%)	(37%)
Premix insulin	2,560	2,429	410	719	1,079	190	31	131	123
% change at CER	(2%)	6%	(4%)	0%	14%	7%	(9%)	(58%)	(59%)
$Ryzodeg^{\circledast}$	257	257	16	111	1	119	10	_	_
% change at CER	41%	41%	0%	69%	_	30%	13%	_	_
NovoMix <sup>®</sup>	2,303	2,172	394	608	1,078	71	21	131	123
% change at CER	(5%)	3%	(4%)	(7%)	14%	(17%)	(17%)	(58%)	(59%)
Fast-acting insulin	4,758	2,585	1,185	679	429	210	82	2,173	2,075
% change at CER	(6%)	6%	3%	7%	20%	1%	7%	(18%)	(19%)
Fiasp®	272	147	140	6	_	1	_	125	119
% change at CER	94%	81%	73%	_	_	_	_	113 %	118 %
<i>NovoRapid®</i>	4,486	2,438	1,045	673	429	209	82	2,048	1,956
% change at CER	(9%)	4%	(2%)	6%	20%	0%	7%	(21%)	(22%)
Human insulin	2,180	1,792	351	542	667	45	187	388	356
% change at CER	(8%)	(1%)	(12%)	4%	1%	(18%)	5%	(31%)	(32%)
Total insulin	14,909	9,106	3,154	2,352	2,436	684	480	5,803	5,551
% change at CER	(4%)	6%	3%	6%	12%	1%	3%	(18%)	(19%)
Victoza®	5,415	1,876	1,048	254	214	187	173	3,539	3,422
% change at CER	(9%)	17%	9%	14%	63%	11%	45%	(19%)	(19%)
Ozempic <sup>®</sup>	2,325	234	170	_	_	_	64	2,091	1,979
% change at CER	_	_	_	_	_	_	_	_	_
Total GLP-1	7,740	2,110	1,218	254	214	187	237	5,630	5,401
% change at CER	25%	32%	26%	14%	63%	11%	97%	22%	22%
Other diabetes <sup>1)</sup>	1,125	928	152	185	456	121	14	197	163
% change at CER	9%	14%	(1%)	17%	18%	17%	7%	(8%)	(7%)
Total diabetes	23,774	12,144	4,524	2,791	3,106	992	731	11,630	11,115
% change at CER	4%	10%	8%	8%	16%	4%	23%	(2%)	(3%)
Obesity (Saxenda <sup>®</sup> )	1,462	557	84	227	2	74	170	905	842
% change at CER	60%	101%	60%	82%	_	450%	93%	41%	43%
Diabetes and obesity total	25,236	12,701	4,608	3,018	3,108	1,066	901	12,535	11,957
% change at CER	6%	13%	9%	11%	16%	11%	32%	0%	(1%)
The bienhaumescuticals comment									
The biopharmaceuticals segment Haemophilia	2.670	1,528	687	293	74	143	331	1 142	1,081
	2,670							1,142	
% change at CER NovoSeven®	13% <b>2,163</b>	15% 1 170	3%	0% <b>249</b>	44% <b>71</b>	(12%) <b>103</b>	109% <b>315</b>	10% <i>984</i>	15% <b>945</b>
	2,163	1,179 12%	441		71 44%	103 (15%)	315 105%	984 9%	945 14%
% change at CER			(4%)	(7%)					
NovoEight®	369	294 110/	204	41 1110/	3 50%	30 (10%)	16 275%	75 (89/ )	71 (19/ )
% change at CER	7%	11%	1%	111%	50%	(19%)	275%	(8%)	(1%)
Growth disorders (Norditropin®)	1,758	1,069	373	185	100%	435	68	689 (E0/.)	685
% change at CER	(1%)	2%	(4%)	(2%)	100%	7%	23%	(5%)	(5%)
Other biopharmaceuticals	372	267	194	51 26%	100%	(179/.)	(100)9/	(20%)	(26%)
% change at CER	(2%)	7%	6%	26%	100%	(17%)	(100)%		(36%)
Biopharmaceuticals total % change at CER	4,800 6%	2,864 9%	1,254 1%	529 2%	84 49%	598 1%	399 83%	1,936 2%	1,810 5%
Total sales	30,036	15,565	5,862	3,547	3,192	1,664	1,300	14,471	13,767
% change at CER	6%	12%	7%	10%	16%	7%	44%	0%	0%
% change as reported	10%	13%	7%	11%	16%	12%	40%	6%	6%
Share of growth	100%	97%	23%	18%	26%	6%	24%	3%	0%

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

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H1 2	019	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	10,655	4,517	2,358	812	531	446	370	6,138	5,926
% change at CER	0%	15%	13%	27%	29%	0%	8%	(9%)	(11%)
Tresiba®	4,642	1,705	838	213	31	397	226	2,937	2,821
% change at CER	19%	26%	42%	19%	_	2%	17%	16%	12%
Xultophy®	1,051	710	605	77	_	_	28	341	338
% change at CER	42%	42%	31%	152%	_	_	263%	43%	42%
Levemir®	4,962	2,102	915	522	500	49	116	2,860	2,767
% change at CER	(18%)	2%	(11%)	22%	22%	(13%)	(19%)	(28%)	(29%)
Premix insulin	5,317	4,897	811	1,486	2,191	348	61	420	404
% change at CER	1%	8%	(5%)	11%	12%	5%	(6%)	(44%)	(45%)
Ryzodeg®	469	469	33	202	1	215	18	(4-170)	(4570)
% change at CER	45%	45%	28%	66%		32%	13%	_	_
NovoMix®	4,848	4,428	778	1,284	2,190	133	43	420	404
% change at CER	(2%)	5%	(6%)	5%	12%	(22%)	(12%)	(44%)	(45%)
Fast-acting insulin	9,735	5,196	2,327	1,379	890	387	213	4,539	4,345
% change at CER	(3%)	11%	3%	23%	21%	(6%)	42%	(16%)	(17%)
Fiasp®	503	280	266	13	2170	1	42 70	223	210
% change at CER	122%	94%	84%	- 13 	_	_	_	223 175%	191%
_					 890				
NovoRapid®	9,232	4,916	2,061	1,366		386	213	4,316	4,135
% change at CER	(6%)	9%	(2%)	22%	21%	(6%)	42%	(19%)	(20%)
Human insulin	4,595	3,829	699	1,154	1,464	85	427	766	704
% change at CER	(4%)	3%	(13%)	15%	(1%)	(14%)	30%	(30%)	(31%)
Total insulin	30,302	18,439	6,195	4,831	5,076	1,266	1,071	11,863	11,379
% change at CER	(1%)	9%	3%	18%	11%	(2%)	21%	(15%)	(16%)
Victoza <sup>®</sup>	11,137	3,637	2,017	526	428	334	332	7,500	7,269
% change at CER	(9%)	18%	10%	13%	75%	11%	40%	(19%)	(19%)
Ozempic <sup>®</sup>	3,750	315	251	_	_	_	64	3,435	3,241
% change at CER					_			_	
Total GLP-1	14,887	3,952	2,268	526	428	334	396	10,935	10,510
% change at CER	18%	28%	24%	13%	75%	11%	66%	14%	13%
Other diabetes1)	2,192	1,792	287	359	893	225	28	400	331
% change at CER	1%	3%	(2%)	12%	0%	17%	(6%)	(11%)	(11%)
Total diabetes	47,381	24,183	8,750	5,716	6,397	1,825	1,495	23,198	22,220
% change at CER	4%	12%	8%	17%	12%	2%	30%	(3%)	(4%)
Obesity (Saxenda®)	2,673	1,097	150	463	4	151	329	1,576	1,458
% change at CER	56%	121%	66%	111%	_	_	92%	28%	29%
Diabetes and obesity total	50,054	25,280	8,900	6,179	6,401	1,976	1,824	24,774	23,678
% change at CER	6%	14%	8%	21%	12%	10%	38%	(2%)	(3%)
The biopharmaceuticals segment									
Haemophilia	5,203	3,034	1,347	616	147	273	651	2,169	1,992
% change at CER	5%	3%	(2%)	6%	41%	(10%)	13%	6%	4%
NovoSeven®	4,175	2,330	864	507	138	194	627	1,845	1,730
% change at CER	(1%)	(4%)	(13%)	(4%)	35%	(12%)	11%	4%	2%
NovoEight®	762	595	405	97	9	60	24	167	157
% change at CER	17%	22%	10%	174%	350%	(17%)	188%	2%	1%
Growth disorders (Norditropin®)	3,313	2,089	742	362	15	834	136	1,224	1,216
% change at CER	0%	5%	(4%)	6%	88%	10%	23%	(7%)	(7%)
Other biopharmaceuticals	757	549	378	128	4	39		208	92
% change at CER	5%	16%	8%	44%	100%	20%	(100%)	(17%)	(33%)
Biopharmaceuticals total	9,273	5,672	2,467	1,106	166	1,146	787	3,601	3,300
% change at CER	3%	5%	(1%)	10%	45%	5%	15%	0%	(2%)
Total sales	59,327	30,952	11,367	7,285	6,567	3,122	2,611	28,375	26,978
% change at CER	5%	12%	6%	19%	12%	8%	30%	(2%)	(3%)
% change as reported	9%	13%	6%	20%	14%	14%	26%	5%	4%
Share of growth	100%	116%	22%	39%	25%	8%	22%	(16%)	(24%)

# **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.

# **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 Net 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	H1 2019	H1 2018	% change H1 2019 to H1 2018	Q2 2019	Q2 2018	% change Q2 2019 to Q2 2018
						,
Net sales	59,327	54,337	9%	30,036	27,407	10%
Effect of exchange rates	(2,086)	_		(924)	_	
Sales at CER	57,241	54,337	5%	29,112	27,407	6%
Operating profit at CER						
DKK million	H1 2019	H1 2018	% change H1 2019 to H1 2018	Q2 2019	Q2 2018	% change Q2 2019 to Q2 2018
Operating profit	27,691	24,652	12%	13,452	12,204	10%
Effect of exchange rates	(1,509)	_		(720)	_	
Operating profit at CER	26,182	24,652	6%	12,732	12,204	4%

# 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	H1 2019	H1 2018	Q2 2019	Q2 2018
				_
Net cash generated from operating activities	24,929	25,585	15,039	15,770
Net cash used in investing activities	(5,859)	(5,117)	(2,833)	(2,543)
Repayment on lease liabilities	(395)	_	(186)	_
Free cash flow	18,675	20,468	12,020	13,227