

NOVO NORDISK A S  
Form 20-F  
February 04, 2019

UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
FORM 20-F

(Mark One)

- REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934  
OR  
 ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2018  
OR  
 TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
OR  
 SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number: 333-82318

NOVO NORDISK A/S

(Exact name of Registrant as specified in its charter)

Not applicable

The Kingdom of Denmark

(Translation of Registrant's name into English) (Jurisdiction of incorporation or organization)

Novo Allé

DK-2880 Bagsværd

Denmark

(Address of principal executive offices)

Karsten Munk Knudsen

Executive Vice President and Chief Financial Officer

Tel: +45 4444 8888

E-mail: kmkn@novonordisk.com

Novo Allé, DK-2880 Bagsværd, Denmark

(Name, Telephone, E-mail and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class: Name of each exchange on which registered:

B shares, nominal value DKK 0.20 each New York Stock Exchange\*

American Depositary Receipts, New York Stock Exchange

each representing one B share

\* Not for trading, but only in connection with the registration of American Depositary Receipts, pursuant to the requirements of the Securities and Exchange Commission.

Securities registered or to be registered pursuant to Section 12(g) of the Act: None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the Annual Report:

A shares, nominal value DKK 0.20 each: 537,436,000

B shares, nominal value DKK 0.20 each: 1,912,564,000

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Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.  
Yes  No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes  No

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definition of “large accelerated filer”, “accelerated filer”, and “emerging growth company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  Emerging growth company

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

The term “new or revised financial accounting standard” refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

If “Other” has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow:

U.S. GAAP  International Financial Reporting Standards as issued by the International Accounting Standards Board  Other

If “Other” has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow:

Item 17  Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

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## INTRODUCTION

### INTRODUCTION

In this Form 20-F the terms ‘the Company’, ‘Novo Nordisk’ and ‘the Group’ refer to the parent company Novo Nordisk A/S together with its consolidated subsidiaries. The term ‘Novo Nordisk A/S’ is used when addressing issues specifically related to this legal entity.

Pursuant to Rule 12b-23(a) of the Securities Exchange Act of 1934, as amended, certain information for the 2018 Form 20-F of Novo Nordisk A/S set out herein is being incorporated by reference from the Company's statutory Annual Report 2018 and Annual Report 2017, i.e. including the financial statements of Novo Nordisk A/S (hereafter “Annual Report 2018” and “Annual Report 2017”, respectively). Therefore the information in this Form 20-F should be read in conjunction with our Annual Report 2018 and Annual Report 2017, which were furnished to the SEC on Form 6-K on February 4, 2019 and on February 8, 2018, respectively.

The Company publishes its financial statements in Danish kroner (DKK).

### Forward-looking statements

The information set forth in this Form 20-F contains forward-looking statements as the term is defined in the U.S. Private Securities Litigation Reform Act of 1995.

Words such as ‘believe’, ‘expect’, ‘may’, ‘will’, ‘plan’, ‘strategy’, ‘prospect’, ‘foresee’, ‘estimate’, ‘project’, ‘anticipate’, ‘can’, ‘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.

With reference to our Annual Report 2018 and Annual Report 2017, examples of forward-looking statements can be found under the headings, ‘2018 performance and 2019 outlook’ in our Annual Report 2018 and ‘2017 performance and 2018 outlook’ in our Annual Report 2017, and elsewhere.

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 our Annual Report 2018 and Annual Report 2017, 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 our 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 pages 41-43 of our 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 date of this document, whether as a result of new information, future events or otherwise.

#### Enforceability of civil liabilities

The Company is a Danish corporation and a majority of its directors and officers, as well as certain experts named herein, are non-residents of the United States. A substantial portion of the assets of Novo Nordisk A/S, its subsidiaries and such persons are located outside the United States. As a result, it may be difficult for shareholders of the Company to effect service within the United States upon directors, officers and experts who are not residents of the United States or to enforce judgments in the United States. In addition, there can be no assurance as to the enforceability in Denmark against the Company or its respective directors, officers and experts who are not residents of the United States, or in actions for enforcement of judgments of United States courts, of liabilities predicated solely upon the federal securities laws of the United States.

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ITEM 1 IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISORS  
PART I

ITEM 1 IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISORS  
Not applicable.

ITEM 2 OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3 KEY INFORMATION

A. SELECTED FINANCIAL DATA

Selected financial data

IFRS figures in DKK millions, except share and American

Depository Receipts ('ADR') data

Income statement data

	2014	2015	2016	2017	2018
Net sales	88,806	107,927	111,780	111,696	111,831
Operating profit	34,492	49,444	48,432	48,967	47,248
Net profit	26,481	34,860	37,925	38,130	38,628
Earnings per share					
Earnings per share/ADR	10.10	13.56	14.99	15.42	15.96
Diluted earnings per share/ADR	10.07	13.52	14.96	15.39	15.93

Balance sheet data

Total assets	77,062	91,799	97,539	102,355	110,769
Net assets	40,294	46,969	45,269	49,815	51,839
Capital stock	530	520	510	500	490
Treasury stock	(11 )	(10 )	(9 )	(11 )	(11 )
Dividends per share/ADR*	5.00	6.40	7.60	7.85	8.15
Dividends per share/ADR in USD*	0.82	0.94	1.08	1.26	1.25
Number of shares	2,650	2,600	2,550	2,500	2,450

\*) Total dividend for the financial year 2018 including proposed final dividend of DKK 5.15 per share and interim dividend paid in August 2018 of DKK 3.00 per share. For USD translation the exchange rate at December 28, 2018 from Danmarks Nationalbank (The Central Bank of Denmark) is used (USD 1 = DKK 6.52)

Reference is made to 'Consolidated financial statements 2018', pages 58-94 in our Annual Report 2018 for further data.

B. Capitalization and indebtedness

Not applicable.

C. Reasons for the offer and use of proceeds

Not applicable.

D. Risk factors

For information on risk factors, reference is made to our Annual Report 2018 'Risk management enables better decision-making' on pages 41-43. As identified in our Annual Report 2018, and outlined in greater details below, we are subject to cybersecurity risks and to the risks associated with the United Kingdom's planned exit from the

European Union.

The potential risk on our business as a result of cybersecurity breaches

We rely on our IT systems to protect our intellectual property, sensitive business and customer confidential information and personal data, and disruption as a result of cybersecurity breaches could negatively impact the Company's business and operations or financial results.

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### ITEM 3 KEY INFORMATION

IT systems act as a core backbone for the Company. They support processes ranging from research & development to manufacturing, sales and supply and we rely on these IT systems to protect our intellectual property, sensitive business and customer confidential information, and personal data. Disruption of these IT systems as a result of cybersecurity breaches could negatively impact the Company's business and operations or financial results. Therefore, safeguarding the confidentiality and integrity of this information is critical to our operations.

As we are a global company, the size and complexity of our IT systems are significant and our IT infrastructure and networks are spread across the geographic regions in which we operate. The Company has made, and expects to continue to make, significant hardware, software and resourcing investments in our IT security and personal data protection programmes. Despite these investments, the dedicated cybersecurity teams who operate our global IT security infrastructure may be unable to respond sufficiently to the multitude of threats facing us or may fail to prevent service interruptions or security breaches resulting from attacks by malicious third parties. The cyber threat landscape continues to change and evolve over time, and includes threats ranging from IT-based malware of varying sophistication to the unintended or inadvertent click by an employee on a malicious website. Many of these threats have the potential to cause significant downtime of critical IT systems or the unintended disclosure of confidential information. From time to time, we have in the past experienced IT security incidents, including incidents as a result of malware and third party vendor actions, and though we have not previously experienced material losses as a result of such intrusions, we cannot guarantee that we will be able to prevent similar intrusions from recurring or adversely affecting our business in the future.

We are subject to the data privacy regime in the EU, which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the EU and includes the General Data Protection Regulation ("the GDPR") and any national laws implementing or supplementing the GDPR. In the ordinary course of the Company's business, it collects and stores sensitive data, including personal data and personally identifiable information of customers, employees and other third parties. Any unauthorized access, disclosure, or other loss of personal data could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, including the GDPR, and significant regulatory penalties, disrupt the Company's operations and damage the Company's reputation.

Our focus is not limited to the operations of our own IT systems and infrastructure. Many third party vendors support our business processes and require access to sensitive information in the course of their work supporting the Company's operations. Despite clear guidance, supporting processes and requirements and audits of the Company's third party vendors, the risk that such vendors could be susceptible to cybersecurity or personal data breaches continues to be present. Any such breach could result in the unauthorized access, disclosure, or other loss of proprietary, personal or other sensitive information, or other disruption to the Company's business and operations.

The potential impact on our business as a result of the United Kingdom's decision to end its membership in the European Union is uncertain.

Following the vote of a majority of the United Kingdom (the "UK") electorate in a referendum held on June 23, 2016, in March 2017, the government of the UK (the "UK Government") triggered Article 50 of the Lisbon Treaty with a view to formally leave the European Union (the "EU") on 29 March 2019 ("Brexit").

The extent of the impact on the Company's operations in the UK will depend significantly on the outcome of the national UK political process. There is significant uncertainty regarding the future relationship between the United Kingdom and the EU. Lack of clarity about future UK laws and regulations as the UK determines which EU-derived laws and regulations to replace or replicate as part of a withdrawal, including healthcare and pharmaceutical



regulations; financial laws and regulations; tax and free trade agreements; intellectual property rights; supply chain logistics; environmental, health, and safety laws and regulations; immigration laws; and employment laws, and this could increase costs, depress economic activity, and restrict the flow of goods and services between the UK and the EU. The anticipated annual costs to the Company associated with a “No-Deal Brexit” (exit with no withdrawal agreement with the EU), primarily relate to additional personnel required to manage national licenses and to monitor a local clinical trials depot as well as costs related to batch tracing. Other measures may include, but are not limited to, changing supply routes to Ireland, changing or transferring the Company’s notified body for devices to an entity located in an EU member state, and duplicating and transferring Company licenses. In addition, if the UK leaves the EU customs union, we expect to be liable for customs duties and declarations on purchase orders fulfilled in the UK and we have already incurred (and expect to incur further) costs associated with the handling and storage of additional stock delivered, or to be delivered, to the UK prior to 29 March 2019, the anticipated date of the UK’s departure from the EU. Until the Brexit negotiations are finalized, however, it is difficult to assess the overall effect that Brexit will have on our operations and hence the expected costs to be incurred and the potential impact of Brexit on our business and financial results remains uncertain.

In addition, to the risks identified above, we may be subject to other material risks that as of the date of this report are not currently known to us or that we deem less material at this point in time.

ITEM 4 INFORMATION ON THE COMPANY  
ITEM 4 INFORMATION ON THE COMPANY

A. HISTORY AND DEVELOPMENT OF THE COMPANY

Novo Nordisk A/S was formed in 1989 by a merger of two Danish companies, Nordisk Gentofte A/S and Novo Industri A/S. Novo Industri A/S was the continuing company and its name was changed to Novo Nordisk A/S. The business activities of Nordisk Gentofte were established in 1923 by August Krogh, H. C. Hagedorn and A. Kongsted, and the business activities of Novo Industri A/S were established in 1925 by Harald and Thorvald Pedersen. From the beginning, the business of both companies was production and sale of insulin for the treatment of diabetes.

In November 2000 Novo Nordisk spun off its industrial enzyme division into a separate business, Novozymes A/S.

Novo Nordisk's B shares are listed on Nasdaq Copenhagen (NOVO-B). Its American Depositary Receipts (ADR) are listed on the New York Stock Exchange (NVO).

Legal name: Novo Nordisk A/S  
Commercial name: Novo Nordisk  
Domicile: Novo Allé 1, DK-2880 Bagsværd, Denmark  
Tel: +45 4444 8888  
Website: novonordisk.com  
(The contents of this website are not incorporated by reference into this Form 20-F.)

Date of incorporation: November 28, 1931  
Legal form of the Company: A Danish limited liability company  
Legislation under which the Company operates: Danish law  
Country of incorporation: Denmark

Important events in 2018

Reference is made to 'Management review', pages 1-3, 'Introducing Novo Nordisk', pages 4-9 and 'Performance and outlook', pages 10-21 in our Annual Report 2018 for a description of important events in 2018.

Capital expenditure in 2018, 2017 and 2016

The total net capital expenditure for property, plant and equipment was DKK 9.5 billion in 2018 compared with DKK 8.7 billion in 2017 and DKK 7.1 billion in 2016. 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 care filling capacity in Hillerød, Denmark and an expansion of the manufacturing capacity for biopharmaceutical products in Kalundborg, Denmark, all financed with cash flow from operating activities. No significant divestments took place in the period from 2016–2018.

Capital expenditure is expected to be around DKK 9.0 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. The investments are expected to be financed with cash flow from operating activities.

Public takeover offers in respect of the Company's shares  
No such offers occurred during 2018 or 2019 to date.

B. BUSINESS OVERVIEW

Novo Nordisk is a global healthcare company and a world leader in diabetes care. The Company has one of the broadest diabetes product portfolios in the industry, including new generation insulin, a full portfolio of modern insulin as well as a once-daily GLP-1 analog and a once-weekly GLP-1 analog. In addition, Novo Nordisk also has a leading position within haemophilia care and growth hormone therapy, and Novo Nordisk's first product to treat obesity, Saxenda<sup>®</sup>, was launched in the United States in April 2015 and has now been launched in an additional 40 countries. Novo Nordisk manufactures and markets pharmaceutical products and services that make a significant difference to patients, the medical profession and society. Headquartered in Denmark, Novo Nordisk employs approximately 43,200 employees in 80 countries and markets its products in more than 170 countries.

Reference is made to the section 'Our business' on pages 22-39 in our Annual Report 2018.

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## ITEM 4 INFORMATION ON THE COMPANY

### Segment information

Novo Nordisk is engaged in the discovery, development, manufacturing and marketing of pharmaceutical products and has two business segments: (i) diabetes and obesity and (ii) biopharmaceuticals. The diabetes and obesity segment covers insulin, GLP-1 and related delivery systems, oral anti-diabetic drugs and anti-obesity medication. The biopharmaceuticals segment covers the therapy areas of haemophilia care, growth hormone therapy and hormone replacement therapy.

### Seasonality

Sales of individual products in individual markets may be subject to fluctuations from quarter to quarter. However, the Company's consolidated operating results have not been subject to significant seasonality.

### Raw materials

The impact on the overall profitability of Novo Nordisk from variations in raw material prices is unlikely to be significant. There is no raw material supply shortage that is expected to significantly impact the Company's ability to supply any significant market. The Company's production is largely based on common and readily available raw materials with relatively low price volatility. Certain specific raw materials are, however, less available. For these raw materials, it is the policy of Novo Nordisk to develop close and long-term relationships with key suppliers as well as to secure at least dual sourcing whenever possible and when relevant operate with a predefined minimum safety level of raw material inventories.

### Market and competition

Novo Nordisk's insulin and other pharmaceutical products are marketed and distributed through subsidiaries, distributors and independent agents with responsibility for specific geographical areas. In 2018, Novo Nordisk reported based on a regional structure comprising North America Operations (the United States and Canada) and International Operations. International Operations covers all countries except those within North America and is organized in the following five regions: Region Europe; Region Latin America; Region AAMEO (Africa, Asia, Middle East & Oceania); Region Japan & Korea; and Region China. For 2018, the most important markets are the United States, China, Japan, the major European countries and Canada.

Market conditions within the pharmaceutical industry continue to change, including efforts by both private and governmental entities to reduce or control costs generally and in specific therapeutic areas.

Historically, the market for insulin has been more sensitive to the quality of products and services than to price. Most of the countries in which Novo Nordisk sells insulin subsidize or control pricing and in most markets insulin and GLP-1 are prescription drugs.

In recent years, there has been a general trend of payers managing the cost of diabetes care by exerting pressure on the price of Novo Nordisk's and our competitors' products. As the population of people with diabetes has rapidly increased, competition in the diabetes care area has also intensified, with additional competitors entering the market. In spite of this external pressure, Novo Nordisk has maintained the leading position in the overall diabetes care market through the quality and innovative value of the Company's diabetes care products. In the United States, pharmacy benefit managers and managed care organizations have continued to leverage their increasing size and control to demand higher rebates which has impacted the price level and overall value of the market. Furthermore, competition has intensified and contributed to the downward pressure on prices, especially in the basal insulin segment following the launch of a biosimilar glargine in December 2016.

The Company enters into numerous contracts with customers, suppliers, agents and industry partners. Some of the most important contracts include: commercial contracts with pharmacy benefit managers, managed care organizations and healthcare providers, in- and out-licensing of patent rights, large tender orders and long-term sub-supplier agreements.

Due to the increasing number of people with diabetes, the pharmaceutical market for treatment of diabetes continues to grow. Several of the major international pharmaceutical companies have entered the diabetes market, specifically in the area of oral products for treatment of type 2 diabetes. In the global insulin market, Novo Nordisk, Sanofi and Eli Lilly are the most significant companies measured by market share.

Tresiba<sup>®</sup>, the Company's latest generation of basal insulin, was launched broadly in the United States in January 2016 and maintains wide commercial and Medicare Part D formulary coverage. In 2018, Tresiba<sup>®</sup> obtained approval to update its labeling in the United States to include data from the DEVOTE study which showed a 40% reduction in the risk of severe hypoglycaemia vs. glargine U100. In countries outside the United States, Tresiba<sup>®</sup> has shown solid penetration in markets with reimbursement at a similar level to insulin glargine U100, whereas penetration remains modest in markets with restricted market access. In September 2017, Novo Nordisk obtained the approval of Tresiba<sup>®</sup> in China and the product was launched in China, without reimbursement and with limited market access. In addition Tresiba<sup>®</sup> has been launched in 74 other markets.

Xultophy<sup>®</sup> (IDegLira), a once-daily single-injection combination of insulin degludec (Tresiba<sup>®</sup>) and liraglutide (Victoza<sup>®</sup>), has now been launched in 26 countries, including the United States. Xultophy<sup>®</sup> has delivered strong growth in selected EU markets, however, uptake in the United States remains limited given that Xultophy<sup>®</sup> has a restricted label and is only approved as an intensification treatment after basal failure.

Ryzodeg<sup>®</sup>, a soluble formulation of insulin degludec and insulin aspart, has now been marketed in 27 countries, and feedback from patients and prescribers is encouraging.

## ITEM 4 INFORMATION ON THE COMPANY

The novel mealtime insulin Fiasp<sup>®</sup>, fast-acting insulin aspart, received marketing authorization from the European Commission in the first quarter of 2017 and approvals were also received in Norway, Iceland and Canada. In September 2017, Novo Nordisk received approval for Fiasp<sup>®</sup> in the United States and the product was launched there in February 2018. Globally, Fiasp<sup>®</sup> has now been launched in 25 countries with encouraging feedback from patients and prescribers.

Moreover, the use of glucagon-like peptide-1 (GLP-1) as a treatment option for people with Type 2 diabetes has continued to increase resulting in significant growth of the GLP-1 market. Novo Nordisk, Eli Lilly and Astra Zeneca are the most significant companies in the global GLP-1 market measured by market share. Novo Nordisk is the global market leader in the GLP-1 segment with a 46% value market share as at December 31, 2018 (Source: IQVIA, November 2018 data MAT).

In 2018, Victoza<sup>®</sup> sales increased by 5% in Danish kroner and by 9% in local currencies to DKK 24,333 million. Sales growth is predominantly driven by North America Operations comprising 66% share of growth. The GLP-1 segment's value share of the total diabetes market has increased to 14.5% as at December 31, 2018 compared with 11.8% as at December 31, 2017.

In February 2018, Novo Nordisk launched the once-weekly GLP-1 product, Ozempic<sup>®</sup>, for the treatment of adults with Type 2 diabetes in the United States and Canada. Ozempic<sup>®</sup> has also been marketed in nine European countries including Denmark, Switzerland and the Netherlands and the roll-out will continue in 2019. Ozempic<sup>®</sup> has achieved a 26% NBRx (New-to-Brand Prescriptions) market share in the United States as at December 31, 2018, and global sales in 2018 of DKK 1,796 million.

#### Patents

To maintain and expand competitiveness, Novo Nordisk strives for the strongest possible protection for those inventions that are created during the development of new products. Novo Nordisk anticipates that the expiration of certain patents could impact sales within the coming years. However, through continued investments in research and development, Novo Nordisk strives to bring novel and innovative products to the market and thereby sustain strong patent protection in the future, as new generations of products replace currently marketed products.

For patent information on all Novo Nordisk's marketed products, reference is made to the section 'Pipeline overview' on pages 20-21 in our Annual Report 2018.

In addition to the compound patents discussed in 'Pipeline overview' on pages 20-21 in our Annual Report 2018, in the following section the patent protection of our key products within each business segment is considered. For key products with recent patent expiration or with patent expiration occurring within the coming years, geographical sales splits are provided and factors that may influence the potential impact of competitive product launches are discussed.

Sales of key products with recent or upcoming patent expiration:

Product	Total sales in 2018 (in DKK million)	Hereof			Hereof				
		North America Operations	USA	International Operations	Region Europe	Region AAMEO	Region China	Region Japan & Korea	Region Latin America
NovoLog <sup>®</sup> /NovoRapid <sup>®</sup>	18,763	52	% 50	% 48	% 22	% 12	% 8	% 4	% 2

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NovoLog <sup>®</sup> Mix /NovoMix <sup>®</sup>	9,480	14	% 14	% 86	% 17	% 25	% 40	% 3	% 1
Levemir <sup>®</sup>	11,195	63	% 61	% 37	% 18	% 8	% 7	% 1	% 3
NovoSeven <sup>®</sup>	7,881	44	% 42	% 56	% 25	% 13	% 2	% 5	% 11
Norditropin <sup>®</sup>	6,834	41	% 41	% 59	% 22	% 10	% 0	% 23	% 4

Patent situation of key diabetes care products

The total sales of NovoLog<sup>®</sup>/NovoRapid<sup>®</sup> were DKK 18,763 million in 2018 (DKK 20,025 million in 2017). The compound patent for NovoLog<sup>®</sup>/NovoRapid<sup>®</sup> has expired. The patent in Japan expired in December 2010 and the European patent expired in August 2011. In the United States NovoLog<sup>®</sup>/NovoRapid<sup>®</sup> was patent protected until December 2014. In addition to the compound patent, Novo Nordisk held a formulation patent on NovoLog<sup>®</sup>/NovoRapid<sup>®</sup>, which expired in December 2017 in the United States and in June 2017 in all other markets.

The total sales of NovoLog<sup>®</sup> Mix/NovoMix<sup>®</sup> were DKK 9,480 million in 2018 (DKK 10,257 million in 2017). The compound patent for NovoLog<sup>®</sup> Mix /NovoMix<sup>®</sup> has expired. In Japan the compound patent expired in June 2014, in the United States the compound patent expired in December 2014 and in Europe the compound patent expired on a country-by-country basis throughout 2014 and into 2015. In addition, Novo Nordisk held a formulation patent on NovoLog<sup>®</sup> Mix /NovoMix<sup>®</sup> in the United States, which provided coverage until December 2017.

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#### ITEM 4 INFORMATION ON THE COMPANY

The total sales of Levemir® were DKK 11,195 million in 2018 (DKK 14,118 million in 2017). The compound patents for Levemir® will expire in June 2019 in the United States, in May 2019 in Europe, and in September 2019 in Japan. In China, the compound patents expired in September 2014.

Today, biosimilar versions of insulin can be approved in the United States via the 505(b)(2) pathway, and in the future the 351(k) pathway in the Public Health Service Act is anticipated to be applicable. In the EU, a biosimilar pathway and guidelines are available for insulins, and the guideline for biosimilar products issued in Japan is also relevant for insulins. At present, a biosimilar to NovoRapid®/NovoLog® produced by a competitor is completing phase 3 clinical trials and could be launched in 2019. Furthermore, biosimilars to Levemir®, NovoRapid® and NovoMix® have been filed for regulatory approval by a local competitor in China. In February 2017, TEVA filed an Abbreviated New Drug Application (ANDA) of liraglutide, the active pharmaceutical molecule in Victoza® for the treatment of type 2 diabetes and Saxenda® for the treatment of obesity, to the U.S. Food and Drug Administration. The compound patent on liraglutide expires in 2023.

#### Patent situation of key biopharmaceuticals products

The total sales of NovoSeven® were DKK 7,881 million in 2018 (DKK 9,206 million in 2017). While the compound patent for NovoSeven® has expired in all major markets, Novo Nordisk holds two formulation patents on the room temperature stable preparation of NovoSeven®, which provides coverage of this formulation until 2023 and 2024, respectively, in all major markets.

The expiry of the compound patent has not impacted sales of NovoSeven®. Novo Nordisk believes that this is due to the complexity of the NovoSeven® protein, rendering regulatory pathways for a 'biosimilar' recombinant human coagulation Factor VIIa (rFVIIa) inapplicable in the United States, the EU and Japan.

In the EU, guidelines for the development of biosimilar products have been available since late 2005; however, to date these guidelines do not apply to coagulation factors because of their complexity. The guideline for biosimilar products in Japan includes requirements similar to those established in Europe.

To date, we have only seen approvals of competing rFVIIa products in Russia, Kazakhstan, Azerbaijan, Uzbekistan and Iran. However, two phase 3 trials in patients with congenital haemophilia with inhibitors and FVII deficiency have been initiated with a competing product in Iran with the aim of obtaining approval in the EU. New information is regularly being compiled to assess whether the clinical programs for these compounds could contribute towards fulfilling regulatory requirements in the United States, the EU and Japan. As such, we still believe that the expiry of our compound patent for NovoSeven® will continue to have an insignificant impact on sales, results of operations and liquidity in the major geographical segments in the near term.

Total sales of Norditropin® were DKK 6,834 million in 2018 (DKK 6,655 million in 2017). Today, Norditropin® is not covered by a compound patent and the formulation used is covered by a formulation patent that expired in 2017 in the United States, Europe and Japan. However, the pen devices that patients use to inject growth hormone are covered by separate patents. Today, all Novo Nordisk growth hormone products are supplied in pen devices. While marketed growth hormone products in the United States are similar in terms of efficacy and safety profile and despite the presence of biosimilar growth hormone products on the market, Norditropin® is differentiated by its high level of temperature stability and the FlexPro® device in which it is offered. The expiry of our compound patent for Norditropin® is not expected to significantly impact sales, results of operations and liquidity in any geographical segments in the near term.

#### Impact of regulation



As a pharmaceutical company, Novo Nordisk depends on government approvals related to production, development, marketing and reimbursement of its products. Important regulatory bodies include the U.S. Food and Drug Administration, the European Medicines Agency, the Japanese Ministry of Health, Labour and Welfare and the Chinese Food and Drug Administration. Treatment guidelines from non-governmental organizations such as the European Association for the Study of Diabetes and the American Diabetes Association may also impact the Company.

Disclosure pursuant to Section 219 of the Iran Threat Reduction and Syria Human Rights Act of 2012 Pursuant to Section 13(r) of the Securities Exchange Act of 1934, ("Section 13(r)"), Novo Nordisk is obliged to provide disclosure if, during 2018, it or any of its affiliates have engaged in certain Iran-related activities or transactions with persons designated under Executive Order 13224 or Executive Order 13382. Novo Nordisk conducts limited business relating to pharmaceutical products and devices within the diabetes care and biopharmaceutical business segments in Iran. Set forth below is a description of the activities and transactions by Novo Nordisk's affiliates that are required to be disclosed pursuant to Section 13(r). Novo Nordisk's U.S. affiliates are not involved in any of Novo Nordisk's activities in Iran.

Novo Nordisk Pars ("NN Pars"), a wholly-owned affiliate of Novo Nordisk A/S located in Iran, contracts with five companies that may be controlled by the Government of Iran ("GOI") to distribute its products. NN Pars also sponsors educational programs and congresses organized by GOI-controlled medical universities, and hosts health care professionals employed by these medical universities at similar programs in Iran and other locations. Additionally, NN Pars makes donations to GOI-controlled public health organizations focusing on diabetes awareness and policy. NN Pars receives payments from, and makes payments to, Iranian banks (certain of which may be GOI-controlled) relating to the sales of pharmaceutical products and devices. NN Pars makes payments incidental to its ordinary business activities to Iranian government entities and entities that are or may be GOI-controlled, such as taxes, customs fees, insurance, product registration fees and telecommunications services expenses.

#### ITEM 4 INFORMATION ON THE COMPANY

Novo Nordisk previously maintained an inactive bank account with an Iranian bank, which became designated under Executive Order 13224 in October 2018, whereafter Novo Nordisk terminated the account.

In 2018, NN Pars contracted with a GOI-controlled company to serve as a contract manufacturer for biopharmaceutical products. However, no transactions took place under the contract and it was terminated. Currently only a Memorandum of Understanding remains in effect, and no activity is currently expected with respect thereto.

In addition, in 2016, NN Pars purchased land from a GOI-controlled land holding company in order to construct a manufacturing facility in Iran, and during 2018 made payments to the GOI-controlled land holding company for services and utilities required for construction and operation of its local manufacturing site. This relationship was terminated. For a brief period during 2018, NN Pars contracted with another entity which may have been GOI-controlled for utility and related services, but terminated the relationship with this entity. NN engaged a non-GOI-controlled entity for the delivery of utility and related services going forward. Novo Nordisk expects to invest approximately DKK 520 million over the course of five years to build the manufacturing facility, which will be used for assembly and packaging of insulin pens for use in Iran.

The German affiliate of NNE A/S, a wholly-owned subsidiary of Novo Nordisk A/S, sold raw materials and spare parts for production of dialysis filters and leucocyte filters and syringes to a GOI-controlled company. This business relationship, however, was wound down during 2018. NNE A/S also contracts with a privately owned pharmaceutical manufacturer to provide engineering consulting services for an end-user that is a basic and applied medical research centre which may be GOI-controlled. During 2018, however, no activities were conducted under this contract.

Novo Nordisk's gross revenue related to transactions with GOI-owned or controlled entities in 2018 were not in excess of DKK 700 million. Novo Nordisk does not allocate its net profit on a country-by-country or activity-by-activity basis, other than as set forth in Novo Nordisk's consolidated financial statements prepared in accordance with IFRS as issued by the IASB; however, Novo Nordisk estimates that its net profit attributable to the transactions with the GOI discussed above would not exceed a de minimis percentage of the Group's total net profit in 2018.

The purpose of Novo Nordisk's Iran-related activities is to provide access to important and life-saving pharmaceutical products such as insulin and haemophilia products to patients in Iran, and to improve the healthcare of the Iranian people in accordance with Novo Nordisk's access to care strategy. For that purpose, Novo Nordisk intends to continue these activities.

#### C. ORGANIZATIONAL STRUCTURE

For information regarding the organizational structure and securities exchange listings of Novo Nordisk A/S, the parent company Novo Holdings A/S (formerly Novo A/S) and the Novo Nordisk Foundation and the ownership structure of Novo Nordisk A/S, reference is made to the sections 'Corporate governance' on pages 46-49 and 'Shares and capital structure' on pages 44-45 in our Annual Report 2018.

Companies in the Novo Nordisk Group are listed in the Company's Annual Report 2018 on page 94, 'Companies in the Novo Nordisk Group.'

#### D. PROPERTY, PLANT AND EQUIPMENT

The Company has its headquarters in Bagsværd, Denmark, where it occupies a number of buildings.

The Company believes that its current production facilities, including facilities under construction and planned for construction, are sufficient to meet its capacity requirements, including the capacity for meeting growing demand in the future for the products NovoLog<sup>®</sup>/ NovoRapid<sup>®</sup>, NovoLog Mix<sup>®</sup>/ NovoMix<sup>®</sup>, Levemir<sup>®</sup>, Victoza<sup>®</sup>, Tresiba<sup>®</sup>, Ryzodeg<sup>®</sup>, Xultophy<sup>®</sup>, Fiasp<sup>®</sup>, Ozempic<sup>®</sup>, Saxenda<sup>®</sup>, NovoSeven<sup>®</sup>, NovoEight<sup>®</sup>, Rebinyn<sup>®</sup>/ Refixia<sup>®</sup>, Norditropin<sup>®</sup> and devices. Reference is made to the sections ‘Capital expenditures in 2018, 2017 and 2016’ under Item 4 for more information about the current expansion programs. For the nature of the Company’s property, plant and equipment, as of December 31, 2018 and 2017, reference is made to Note 3.2 ‘Property, plant and equipment’ in our Annual Report 2018.

The major production facilities owned by the Company are located at a number of sites in Denmark, and internationally in the United States, France, China and Brazil. There are no material encumbrances on the properties; however, the facilities in Tianjin, China are constructed on land where the remaining term of the lease is 28 years.

Active pharmaceutical ingredient (API) production is located in Denmark, primarily in Kalundborg and with secondary locations in Hillerød and Gentofte, both in Denmark, and New Hampshire, United States, although a new API production site in the United States is being established.

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## ITEM 4 INFORMATION ON THE COMPANY

The following table sets forth certain information regarding our major production sites.

MAJOR PRODUCTION FACILITIES	Size of production area (square meters)	Major Production Activities
Kalundborg, Denmark	167,100	<ul style="list-style-type: none"> <li>• Active pharmaceutical ingredients for diabetes and obesity as well as products for diabetes care</li> <li>• Active pharmaceutical ingredients for haemophilia.</li> <li>• Products for biopharmaceuticals</li> </ul>
Hillerød, Denmark	156,700	<ul style="list-style-type: none"> <li>• Durable devices and components for disposable devices</li> <li>• Products for diabetes and obesity</li> <li>• Active pharmaceutical ingredients for haemophilia</li> </ul>
Bagsværd, Denmark	118,400	<ul style="list-style-type: none"> <li>• Products for diabetes and obesity</li> </ul>
Gentofte, Denmark	70,800	<ul style="list-style-type: none"> <li>• Active pharmaceutical ingredients for glucagon and growth hormone therapy</li> <li>• Products for growth hormone therapy, glucagon and haemophilia</li> </ul>
Tianjin, China	68,500	<ul style="list-style-type: none"> <li>• Products for diabetes</li> <li>• Production of durable devices</li> </ul>
Montes Claros, Brazil	56,500	<ul style="list-style-type: none"> <li>• Products for diabetes</li> <li>• Gel production for active pharmaceutical ingredients</li> </ul>
Måløv, Denmark	54,800	<ul style="list-style-type: none"> <li>• Products for hormone replacement therapy</li> <li>• Products for oral antidiabetes treatment</li> </ul>
Clayton, North Carolina, United States	42,800	<ul style="list-style-type: none"> <li>• Products for diabetes and obesity</li> </ul>
Chartres, France	28,600	<ul style="list-style-type: none"> <li>• Products for diabetes</li> </ul>
New Hampshire, United States	14,800	<ul style="list-style-type: none"> <li>• Active pharmaceutical ingredients for haemophilia</li> </ul>

In May 2015, Novo Nordisk initiated the construction of a new facility in Kalundborg, Denmark for producing API for NovoSeven® and future products for the treatment of haemophilia. The facility is expected to be operational by the end of 2020. The production area of the facility is 7,500 square meters. The expected amount of expenditures for this facility is approximately DKK 1.8 billion. The facility is financed by cash flow from operating activities.

In November 2015, Novo Nordisk initiated the construction of a new facility in Hillerød, Denmark for producing medicines for the treatment of diabetes and obesity. The facility is expected to be ready for use in 2019. The production area of the facility is 10,300 square meters. The expected amount of expenditures for this facility is approximately DKK 2.4 billion. The facility is financed by cash flow from operating activities.

In March 2016, Novo Nordisk initiated the construction of a new diabetes API production facility in Clayton, North Carolina, United States. The majority of the facility is expected to be ready for use in 2020 while the remaining part is expected to be operational in 2022. The expected amount of expenditures for this facility is more than USD 2 billion. The facility will be financed by cash flow from operating activities.

In May 2016, Novo Nordisk initiated construction of a new production facility for oral GLP-1 tablets in Måløv, Denmark. The facility is expected to be operational in 2019. The expected amount of expenditures for this facility is approximately DKK 1 billion. The facility is financed by cash flow from operating activities.

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ITEM 4A Unresolved staff comments

ITEM 4A UNRESOLVED STAFF COMMENTS

None.

ITEM 5 OPERATING AND FINANCIAL REVIEW AND PROSPECTS

Critical accounting estimates

Reference is made to Note 1.1 'Principal accounting policies and key accounting estimates' in our Annual Report 2018.

New accounting pronouncements

Reference is made to Note 1.2 'Changes in accounting policies and disclosures' in our Annual Report 2018.

A. OPERATING RESULTS

Reference is made to the section 'Forward-looking statements' contained on page 2 and the discussion under the caption 'Risk factors' contained under Item 3. Reference is further made to our Annual Report 2018 'Risk management enables better decision-making' on pages 41-43.

The financial condition of the Group and its development are described in our Annual Report 2018 and our Annual Report 2017. The information in this section is based on these reports and should be read in conjunction with the annual reports. The analysis and discussions included in the annual reports are primarily based on the consolidated financial statements which are prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB).

2018 compared with 2017

The following portions of our Annual Report 2018 constitute the Board of Directors' and Executive Management's discussion and analysis of results of operations (incorporated herein by reference):

'Management review' (pages 1-3)

'Introducing Novo Nordisk' (pages 4-9)

'Performance and Outlook' (pages 10-21)

2017 compared with 2016

The following portions of our Annual Report 2017 constitute the Board of Directors' and Executive Management's discussion and analysis of results of operations (incorporated herein by reference):

'Accomplishments and results 2017' (pages 1-15)

Segment information

Reference is made to Note 2.2 'Segment information' in our Annual Report 2018 for details on segmented results.

Inflation

Inflation for the three most recent fiscal years has not had a material impact on the Group's Net sales or Net profit.

Foreign currencies

The majority of Novo Nordisk's sales are in foreign currencies, mainly USD, EUR, CNY, JPY, GBP and CAD, while a significant proportion of production, research and development costs are carried in DKK. Consequently, Novo Nordisk has significant exposure to foreign exchange risks and engages in significant hedging activities where the most significant exposure and hedging are related to USD, CNY, JPY, GBP and CAD, while the EUR exchange rate risk is regarded as low due to the Danish fixed-rate policy towards EUR. Thus, Novo Nordisk does not hedge the EUR exchange rate risk. For further description of foreign currency exposure, reference is made to the disclosure in Note 4.2 'Financial risks' in our Annual Report 2018 and for further description of foreign currency exposure and hedging activities, reference is made to the description of financial instruments in Note 4.3 'Derivative financial instruments' in our Annual Report 2018.

#### Governmental policies

Please refer to pages 22-39 'Our business' in our Annual Report 2018 and Item 4.

### B. LIQUIDITY AND CAPITAL RESOURCES

Novo Nordisk maintains a centralized approach to the management of the Group's financial risks. The overall objectives and policies for Novo Nordisk's financial risk management are outlined in the Novo Nordisk Treasury Policy, which is approved by the Board of Directors. The Treasury Policy governs the Group's use of financial instruments. For further information, reference is made to Item 11.

## ITEM 5 OPERATING AND FINANCIAL REVIEW AND PROSPECTS

### Financial resources

Reference is made to page 59 'Cash flow statement for the year ended 31 December' and page 60 'Balance sheet' in our Annual Report 2018. In addition Novo Nordisk has obtained a credit rating from two independent external rating agencies.

Novo Nordisk believes its financial resources are sufficient to meet its requirements for at least the next 12 months.

### Cash flow in 2018, 2017 and 2016

Reference is made to page 59 'Cash flow statement' for the year ended 31 December' in our Annual Report 2018.

The most significant source of cash flow from operating activities is sales of diabetes and obesity and biopharmaceutical products. Generally, other factors that affect operating earnings, such as pricing, volume, product mix, costs and exchange rates, also have an impact on realized cash flow from operating activities.

There are no material restrictions on the ability of subsidiaries with material cash amounts to transfer funds to the parent company, Novo Nordisk A/S. Reference is made to note 4.4 'Cash and cash equivalents, financial resources and free cash flow' in our Annual Report 2018 for information on restricted cash.

### Trade receivable program

Trade receivable program, as of December 31, 2018, 2017 and 2016, respectively, are shown in Note 4.2 'Financial risks' in our Annual Report 2018.

### Debt financing

No long-term loans were outstanding as of December 31, 2018 or 2017. Reference is made to page 60 'Balance sheet' and Note 4.7 'Financial assets and liabilities' in our Annual Report 2018 for information on Current debt.

### Derivative financial instruments

Novo Nordisk only hedges commercial exposures and consequently does not enter into derivative transactions for trading or speculative purposes. Currency hedging is done with foreign exchange forwards and foreign exchange options. Reference is made to Note 4.2 'Financial risks' and Note 4.3 'Derivative financial instruments' in our Annual Report 2018 for further information on financial instruments including currency exposure.

### Commitments for capital expenditure etc.

Contractual obligations for capital expenditure and other contingent liabilities as of December 31, 2018 and 2017, respectively, are shown in Note 5.2 'Commitments' in our Annual Report 2018.

The Executive Management of the Group believes that the obligations are covered by the Group's financial resources as well as expected future cash flows from operating activities.

## C. RESEARCH AND DEVELOPMENT, PATENTS AND LICENSES, ETC.

Novo Nordisk's research activities utilize biotechnological methods based on genetic engineering, advanced protein chemistry and protein engineering. These methods have played a key role in the development of the production technology which is used in the manufacturing of insulin, GLP-1, recombinant blood clotting factors, human growth hormone and glucagon.



The primary focus of Novo Nordisk's research and development is on therapeutic proteins within diabetes, obesity, haemophilia, growth disorders and other serious chronic diseases such as NASH (non-alcoholic steatohepatitis) and atherosclerosis cardiovascular diseases.

Reference is made to Note 2.3 'Research and development costs' in our Annual Report 2018 for research and development costs in 2018, 2017 and 2016, respectively. Novo Nordisk's research and development organization comprised approximately 8,000 employees as of December 31, 2018.

In general, we expect that growth in research and development spending will follow a trend in line with sales growth indicating that the research and development cost to sales ratio is expected to be relatively constant in the foreseeable future. Thus, we currently expect to continue an expenditure level of around 13% of sales in research and development activities going forward. Development costs in 2018 were driven by significant investments in oral semaglutide and semaglutide obesity with phase 3a/3b trials and CV outcome trials running for both projects in 2018.

Information related to the spend ratio on clinical development activities and research activities can be found in Note 2.3 'Research and development costs' in our Annual Report 2018.

Information related to selected research and development projects can be found under 'Pipeline overview' on pages 20-21 in our Annual Report 2018. Furthermore, a broader overview of our business activities can be found on pages 22-39 'Our business'.

## ITEM 5 OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The following Novo Nordisk compounds are currently in phase 3 development or have recently been filed for regulatory approval:

COMPOUND / BRAND NAME / INDICATION	Year entered into phase 3 or filed with the regulatory authorities	Patent expiration
Oral semaglutide (NN9924) / Type 2 diabetes	Phase 3 initiated in 2016.	2031 <sup>1</sup>
N8-GP (NN7088) / Haemophilia A	Phase 3 completed in 2014, production facility operational in 2018. Filings for regulatory review in the United States, the EU and Japan made in 2018.	2032 <sup>2</sup>
NN8640 Once-weekly human growth hormone / Growth disorder	Phase 3 in ADGH completed in 2018. Phase 3 in GHD initiated in 2018.	2034 <sup>3</sup>
Semaglutide obesity (NN9536) / Obesity	Phase 3 initiated in 2018	2031 <sup>1</sup>

<sup>1</sup> Current estimate

<sup>2</sup> Current estimate United States. EU estimate 2034, Japan expiry 2034

<sup>3</sup> Current estimate United States. EU estimate 2035, Japan expiry 2035

During 2018 Novo Nordisk has not discontinued any development projects in phase 3.

In determining whether or not any project or group of related projects is significant, we consider the following qualitative and quantitative criteria:

- Assessment of the unmet medical need targeted with the specific project;
- The inherent project risk including the risk of safety issues, unsatisfactory tolerability profile, limitations on the efficacy of the compound;
- Timeline for completing the clinical testing and submitting an application for approval to regulatory authorities;
- Regulatory authorities' position towards approval and drug label;
- Changes in competitive landscape during the development and approval cycle including competing drugs being developed by others;
- Changes in medical practice during the development period;
- Position of payers, the medical society and patients towards treatment with drug and price of drug;
- Expected uptake in market following launch; and
- Expected net present value of the project.

In assessing the criteria listed above, and as described in 'Risk management enables better decision-making' on pages 41-43 in our Annual Report 2018, it is important to note that at any one stage of development, due to the uncertainties inherent to clinical development and the regulatory approval process, there is a significant degree of uncertainty and risk that the project will not be successful. The nature of our development activities is such that a compound must first be proven to work by means of multiple clinical trials, which may require treatment of thousands of patients and could take years to complete. Even if initial results of preclinical studies or clinical trial results are promising, we may obtain different results that fail to show the desired levels of safety and efficacy, or we may not obtain applicable regulatory approval for a variety of other reasons. The compound must be accepted by either the FDA, the European Medicines Agency or similar agencies around the world, each of which may have differing requirements. During each stage, there is a substantial risk that we will encounter serious obstacles which will further delay us, or that we will not

achieve our goals and, accordingly, may abandon a product in which we have invested substantial resources. Furthermore, the commercial potential of a project is dependent on the label granted by the regulatory authority upon approval. The label specifies for which indications a product can be used, major and minor safety concerns associated with drug treatment as well as if the drug can be combined with other types of medication. Thus a label can restrict usage substantially.

Due to the risks and uncertainties involved in progressing through pre-clinical development and clinical trials, and the time and cost involved in obtaining regulatory approvals, we cannot reasonably estimate the nature, timing, completion dates and costs of the efforts necessary to complete the development.

Given the uncertainties related to the process of product development, during the periods presented in our 2018 Form 20-F no single project in product development was significant based on the qualitative and quantitative criteria. However, during the periods presented two groups of projects were considered significant; the diabetes and obesity group and the biopharmaceuticals group.

Reference is made to the caption 'Risk factors' contained under Item 3.

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## ITEM 5 OPERATING AND FINANCIAL REVIEW AND PROSPECTS

### D. TREND INFORMATION

The key drivers behind Novo Nordisk's performance continue to be the changes in demographics globally reflecting a continuous growth in the proportion of people who live in cities (urbanization), an increasing proportion of elderly people and a growing problem of obesity. These trends have contributed to the significant increase in the number of people with diabetes worldwide. According to the International Diabetes Federation, the number of people with diabetes is expected to increase to around 629 million by 2045 from 425 million in 2017. Diabetes and obesity is Novo Nordisk's largest segment comprising more than 80% of sales. The epidemic growth in the number of people with diabetes, continuing transition from older to newer insulin generations, and new delivery devices and market share gains in some segments of the market are all driving Novo Nordisk's growth within the diabetes and obesity segment. Further, the roll-out of a number of new products within diabetes and obesity (Ozempic®, Tresiba®, Ryzodeg®, Xultophy®, Fiasp® and Saxenda®) are expected drivers of sales in the segment.

The other segment of Novo Nordisk is biopharmaceuticals, which comprises haemophilia care, growth hormone therapy and hormone replacement therapy. In 2018, haemophilia sales decreased due to lower NovoSeven® sales in North America given intensified competition and a new product launch, offset by continued uptake of NovoEight® both in North America and across markets where launched in International Operations. Sales of growth disorder products increased moderately driven by growth in North America.

In the United States, significant sales rebates are paid in connection with public healthcare insurance programs, such as Medicare and Medicaid, as well as rebates to pharmacy benefit managers (PBMs) and managed care organizations. Key customers in the United States include private payers, PBMs and government payers. Increasingly, PBMs and managed care organizations play a key role in negotiating price concessions with drug manufacturers on behalf of payers for both the commercial and government channels, and determining the list of drugs covered in the health plan's formulary. Specifically, there are three primary drivers:

#### Competitive pressure from other manufacturers' diabetes products

Payer pressure to reduce the overall drug costs has resulted in continued focus on negotiating higher rebates from drug manufacturers. Private payers remain keen to adopt narrow formularies that exclude certain drugs, while securing increased rebates from the preferred brands.

Recent industry consolidation among payers has over time led to increasing pricing pressure for pharmaceutical companies.

In 2018, payers continued to leverage their size and control to demand higher rebates, while the level of competition intensified, particularly in the basal insulin segment. As a result, average prices after rebates for the Novo Nordisk portfolio in 2018 in the United States declined.

For 2019, average prices after rebates are expected to decline further compared with 2018 prices, predominantly driven by the basal insulin segment and the 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 but, importantly, market access for Novo Nordisk's products is expected to remain at a level similar to that experienced in 2018.

For further information on trends, reference is made to the section 'Performance and outlook' on pages 10-21 in our Annual Report 2018. Information about expectations for the financial year 2019 can be found on page 12 in the subsection 'Outlook 2019'.

E. OFF-BALANCE SHEET ARRANGEMENTS

Reference is made to Note 4.2 'Financial risks' and Note 5.2 'Commitments' in our Annual Report 2018.

F. TABULAR DISCLOSURE OF CONTRACTUAL OBLIGATIONS

Reference is made to Note 5.2 'Commitments' in our Annual Report 2018.

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ITEM 6 DIRECTORS, EXECUTIVE MANAGEMENT AND EMPLOYEES  
 ITEM 6 DIRECTORS, EXECUTIVE MANAGEMENT AND EMPLOYEES

A. DIRECTORS AND EXECUTIVE MANAGEMENT

Reference is made to pages 50-51 in our Annual Report 2018 for name, position and period of service as director for the members of the Board of Directors.

Reference is made to page 52 in our Annual Report 2018 for name, position, age, year of appointment and year of joining Novo Nordisk for the members of Executive Management. On February 15, 2018, Karsten Munk Knudsen was appointed CFO, succeeding Jesper Brandgaard, who has retained responsibility for Biopharm and Legal Affairs as a continuing member of Executive Management.

The Board of Directors has the overall responsibility for the affairs of the Company. Reference is made to pages 46-49 in our Annual Report 2018.

The activities of the members of Board of Directors and members of Executive Management outside the Company are included in our Annual Report 2018 on pages 50-52.

There are no family relationships between the Board of Directors, Executive Management or between any of the members of the Board of Directors and any member of Executive Management. No director or member of Executive Management has been elected according to an arrangement or understanding with shareholders, customers, suppliers or others. As required by the Danish Companies Act, directors are elected at General Meetings by simple majority vote. In addition, four employee representatives are elected for four-year terms by the employees of Novo Nordisk A/S.

B. COMPENSATION

Reference is made to the section 'Remuneration' on pages 53-57 and note 5.1 'Share-based payment schemes' in our Annual Report 2018 regarding compensation.

C. BOARD PRACTICES

Reference is made to 'Corporate governance' on pages 46-49 in our Annual Report 2018 regarding board practices. The year of election for each member of the Board of Directors and the year of appointment for each member of Executive Management is included in our Annual Report 2018 on pages 50-52.

D. EMPLOYEES

Reference is made to the section entitled 'Employees' on page 15 and 'Performance highlights' on pages 18-19 in our Annual Report 2018 regarding the total number of full-time employees in Novo Nordisk at year-end for the years 2014–2018.

EMPLOYEES	2018	2017	2016
Employees outside Denmark as a percentage of total number of employees	60	%59	% 57 %

Executive Management believes that the Company has a good relationship with its employees in general and with the labor unions of the Novo Nordisk employees.

Novo Nordisk believes that the current personnel policy results in low staff turnover, high engagement, and ease in recruiting new employees. The Company has not experienced any significant labor disputes.

#### E. SHARE OWNERSHIP

For information on the Board of Directors' and Executive Management's individual holdings of shares and restricted stock units and granting of shares, reference is made to the section 'Remuneration' on pages 53-57 and note 5.1 'Share-based payment schemes' in our Annual Report 2018. The members of the Board of Directors and Executive Management and key management executives in the aggregate hold less than 1% of the beneficial ownership of the Company.

For information on the Board of Directors' and Executive Management's individual holdings of and trading in Novo Nordisk shares during 2018, reference is made to the section 'Remuneration' on pages 53-57 and note 5.1 'Share-based payment schemes' in our Annual Report 2018. As of January 31, 2019 the Board of Directors and Executive Management owned 805,761 B shares.

## ITEM 7 MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

In the period from January 1, 2019 until February 1, 2019, no B shares were sold or purchased by the members of the Board of Directors or Executive Management. The internal rules on trading in Novo Nordisk securities by members of the Board of Directors and Executive Management only permit trading in the 15 calendar-day period following each quarterly earnings announcement. Following the quarterly earnings announcement release on February 1, 2019, the Executive Management received 103,744 B shares in accordance with the long-term incentive program and a total of 61,398 B shares were sold, hence as of February 1, 2019, the Board of Directors and Executive Management owned 848,107 B shares.

Reference is made to Note 5.1 ‘Share based payment schemes’ in our Annual Report 2018.

## ITEM 7 MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

### A. MAJOR SHAREHOLDERS

The total share capital of Novo Nordisk A/S is split into two classes, A shares and B shares, each with different voting rights. The A shares have 200 votes per DKK 0.20 of the A share capital and the B shares have 20 votes per DKK 0.20 of the B share capital. The voting rights of treasury shares cannot be exercised at the general meetings.

All of the A shares of Novo Nordisk A/S are held by Novo Holdings A/S, a wholly-owned subsidiary of the Novo Nordisk Foundation (the ‘Foundation’). As of December 31, 2018, the A shares represented approximately 74% of the votes exercisable at the Annual General Meeting.

The Foundation is a self-governing and self-owned organization whose main purposes are to be a stable base for the business and research activities of the subsidiaries of Novo Holdings A/S, and to support medical research and other scientific, humanitarian and social objectives.

The purpose of Novo Holdings A/S in relation to Novo Nordisk A/S is to administer its portfolio of securities and minority capital interests and to administer and vote on the A shares and B shares in Novo Nordisk A/S, thereby creating a satisfactory financial return for the Foundation.

Under its statutes, the Foundation is governed by a Board of Directors, which must be comprised of at least six and not more than 12 members and at least two members must have a medical or scientific background. Members of the Foundation’s Board of Directors are typically nominated by the nomination committee and elected by a two-thirds vote of the members who have themselves been elected pursuant to the statutes. Any member can be removed as provided for in the Danish Act on Foundations (‘lov om erhvervsdrivende fonde’). In addition, employee representatives are elected for four-year terms by the employees of the foundation and of the subsidiaries of the Foundation, in accordance with Danish law. No person or entity exercises any kind of formal influence over the Foundation’s Board. The Foundation’s Board currently consists of nine persons, one of whom is also an employee elected member of the Board of Directors of Novo Nordisk A/S (Anne Marie Kverneland).

Under its statutes, Novo Holdings A/S is governed by a Board of Directors, which must be comprised of at least three and not more than nine members who are elected annually by shareholder vote. According to the Foundation’s statutes, its Board of Directors can and shall provide for members of its own Board of Directors to be elected to Novo Holdings A/S’s Board of Directors. Novo Holdings A/S’s Board of Directors currently has six members, with two directors who are also members of the Board of the Foundation (Steen Risgaard and Lars Rebien Sørensen) and one director who is also a member of the Board of Directors of Novo Nordisk A/S (Jeppe Christiansen). Moreover, the chief executive officer of Novo Holdings A/S (Kasim Kutay) is also a member of the Board of Directors of Novo Nordisk A/S. The



Chairman of the Foundation's Board of Directors (Lars Rebien Sørensen) serves as the Chairman of Novo Holdings A/S's Board of Directors.

A shares held by Novo Holdings A/S cannot be sold or be subject to any disposition so long as the Foundation exists. The dissolution of the Foundation or any change in its objectives requires the unanimous vote of the Foundation's Board of Directors. Other changes in the Foundation's statutes require the approval of two-thirds of the members of the Foundation's Board of Directors. In addition, changes in the Foundation's statutes require approval of the Danish foundation authorities. According to its statutes, the Foundation is required to maintain material influence over Novo Nordisk A/S and its majority vote in Novo Holdings A/S.

For further information reference is made to 'Shares and capital structure' on pages 44-45 in our Annual Report 2018 and to 'Shares and capital structure' on pages 44-45 in our Annual Report 2017.

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## ITEM 7 MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

The B shares of the Novo Nordisk A/S are registered with VP Securities A/S ('VP Securities') and are not represented by certificates. Generally, VP Securities does not provide the Company with information with respect to registration. However, set forth below is information as of January 31, 2019 with respect to (a) any shareholder who is known to the Company to be the owner of more than 5% of any class of Novo Nordisk A/S' securities and (b) the total amount of any class owned by Novo Nordisk A/S and its affiliates (treasury shares) and by the Board of Directors and Executive Management as a group:

Title of class	Identity of person or group	Shares owned	Percent of class	Percent of total votes
A shares	Novo Holdings A/S	537,600,400 *	100.00	73.75
B shares	Novo Holdings A/S	149,789,000	7.83	2.06
B shares	Novo Nordisk A/S and subsidiaries (treasury shares)	55,756,648 **	2.92	0.77
B shares	Board of Directors and Executive Management	805,761 ***	0.04	0.01

\*) The number of A shares is calculated as an equivalent of the trading size (DKK 0.20) of the listed B shares but is not formally divided into number of shares. The A shares are not listed on any stock exchange.

\*\*) Treasury shares are included, however, voting rights of treasury shares cannot be exercised.

\*\*\*) As of February 1, 2019 the shares owned by Board of Directors and Executive Management was 848,107 (corresponding to 0.04 percent of class and 0.01 percent of total votes).

In 2016 and 2017, shares with an aggregate purchase price of DKK 15.1 billion and DKK 16.8 billion, respectively, were repurchased under the Company's share repurchase program.

In February 2018, Novo Nordisk announced a new DKK 14 billion share repurchase program. In November 2018 this share repurchase program was expanded by DKK 1 billion to DKK 15 billion. Under this program and the previous share repurchase program completed in January 2018, 50,811,303 shares corresponding to DKK 15.5 billion were repurchased during 2018. The February 2018 share repurchase program was completed in January 2019.

In February 2019, Novo Nordisk announced a new DKK 15 billion share repurchase program to be executed during the following 12 months.

After the shareholders' approval of the proposed reduction of Novo Nordisk A/S' share capital at the Annual General Meeting on March 23, 2018, 50,000,000 shares were cancelled in April 2018, reducing the number of treasury shares accordingly.

As no complete records of all holders of B shares exist, it is not possible to give an accurate breakdown of the holdings and number of holders of B-shares per country. It is, however, estimated that approximately 29% of the B share capital was held in Denmark as of December 31, 2018. Approximately 33% of the B share capital is estimated to be held in North America. The estimated total number of shareholders is more than 250,000 of whom more than 200,000 are estimated to be Danish residents and more than 30,000 to be resident in the United States.

## B. RELATED PARTY TRANSACTIONS

Related parties include the Novo Nordisk Foundation, Novo Holdings A/S, Novozymes A/S, Innate Pharma SA, Xellia Pharmaceuticals ApS (due to shared controlling shareholder, Novo Holdings A/S) and NNIT A/S being an associated company with shared controlled shareholding between Novo Holdings A/S and Novo Nordisk A/S. Novo Nordisk has access to certain assets of and can purchase certain services from Novo Holdings A/S and Novozymes A/S and vice versa. All agreements relating to such assets and services are based on the list prices used for sales to

third parties where such list prices exist, or the price has been set at what is regarded as market price. The material terms of these agreements are renegotiated on a regular basis.

Related party transactions in 2018, 2017 and 2016 were primarily payments for services provided between the Novo Nordisk Group and the Novozymes Group, Xellia Pharmaceuticals ApS and transactions with associated companies. The overall financial impact of these related party transactions is limited.

As a result of the initial public offering of NNIT A/S in March 2015, Novo Nordisk A/S disposed 74.5% out of the 100% interest held in NNIT A/S. On February 2, 2018, Novo Nordisk disposed further 8.0% of the shareholding in NNIT A/S to Novo Holdings A/S. Consequently, Novo Nordisk holds 17.5% of the shareholding in NNIT A/S. NNIT A/S is considered to be an associated company. Being an associated company to Novo Nordisk A/S, NNIT A/S is considered to be a related party. For further information reference is made to Note 2.5 'Other operating income, net' in our Annual Report 2018.

On June 2, 2017, Novo Nordisk A/S entered into an agreement with Innate Pharma SA under which Innate Pharma SA acquired an exclusive license to Novo Nordisk A/S's anti-C5aR antibody program. The terms of the agreement provided for an upfront payment of EUR 40 million, of which EUR 37.2 million was paid in Innate Pharma SA shares and EUR 2.8 million was paid in cash. Novo Nordisk A/S is eligible for up to an additional EUR 370 million by way of development, regulatory and sales milestone payments and to double digit royalties on future net sales. With the allocation of shares in Innate Pharma SA, Novo Nordisk A/S stake in the share capital of Innate Pharma SA is 15.5%.

## ITEM 8 FINANCIAL INFORMATION

As part of the share repurchase program for 2018 of DKK 15 billion, a number of transactions have been entered into with Novo Holdings A/S. On February 5, 2018, 3,087,410 shares were purchased from Novo Holdings A/S at a price of DKK 308.90 per share. On May 4, 2018, 3,415,895 shares were purchased from Novo Holdings A/S at a price of DKK 303.83 per share. On August 10, 2018, 3,120,644 shares were purchased from Novo Holdings A/S at a price of DKK 305.61 per share. On November 5, 2018, 4,401,051 shares were purchased from Novo Holdings A/S at a price of DKK 286.71 per share.

Since December 31, 2018, there have been no further significant transactions with related parties out of the ordinary course of business. For further information reference is made to Note 5.3 'Related party transactions' in our Annual Report 2018 and Note 5.3 'Related party transactions' in our Annual Report 2017.

There have not been and there are no loans to members of the Board of Directors or Executive Management in 2018, 2017 or 2016.

### C. INTERESTS OF EXPERTS AND COUNSEL

Not applicable.

## ITEM 8 FINANCIAL INFORMATION

### A. CONSOLIDATED STATEMENTS AND OTHER FINANCIAL INFORMATION

The financial statements required by this item accompany this annual report in the form of our Annual Report 2018 (see Exhibit no. 15.1).

#### Legal proceedings

Reference is made to Note 3.6 'Provisions and contingent liabilities' in the Annual Report 2018 regarding legal proceedings.

#### Dividends

At the Annual General Meeting in March 2015, the Board of Directors was granted an authorization to distribute extraordinary dividends. Hence the Board of Directors has been given authority to pay interim dividends without obtaining specific approval from the Annual General Meeting. In August 2018 Novo Nordisk paid out an interim dividend of DKK 3.00 per share.

At the Annual General Meeting scheduled for March 21, 2019, the Board of Directors will propose a final dividend of DKK 5.15 for each Novo Nordisk A and B share. The total dividend for 2018 of DKK 8.15 includes both the interim dividend of DKK 3.00 for each Novo Nordisk A and B share which was paid in August 2018, and the final dividend of DKK 5.15 for each Novo Nordisk A and B share to be paid in March 2019. The total dividend increased by 4% in 2018 compared with the 2017 dividend of DKK 7.85 for each Novo Nordisk A and B share. The total dividend for 2018 corresponds to a payout ratio of 50.6%, whereas Novo Nordisk's peer group of comparable pharmaceutical companies operated with a payout ratio of around 50.2% in 2017. No dividends will be paid on the Company's holding of its treasury shares. For further information reference is made to 'Shares and capital structure', on pages 44-45 in our Annual Report 2018.

### B. SIGNIFICANT CHANGES

No significant events have occurred since the date of the annual financial statements. For description of important events and achievements in 2018, reference is made to 'Management review', pages 1-3, 'Introducing Novo Nordisk', pages 4-9 and 'Performance and outlook', pages 10-21 in our Annual Report 2018.

## ITEM 9 THE OFFER AND LISTING

### A. OFFER AND LISTING DETAILS

Our B shares are listed in Denmark on Nasdaq Copenhagen, and traded under the symbol "NOVO-B". Our ADRs are traded on the New York Stock Exchange under the symbol "NVO".

Reference is made to our Annual Report 2018 'Shares and capital structure' on pages 44-45.

### B. PLAN OF DISTRIBUTION

Not applicable.

ITEM 9 THE OFFER AND LISTING

C. MARKETS

The Company's share capital consists of A shares and B shares. As described above, the A shares are owned by the Novo Nordisk Foundation through its wholly-owned subsidiary Novo Holding A/S and are not listed or traded on any stock exchange. The B shares have been publicly traded since 1974 and have been listed on Nasdaq Copenhagen since that time. The Nasdaq Copenhagen is the main trading market for the B shares.

American Depositary Receipts representing the B shares ('ADRs'), as evidenced by American Depositary Receipts issued by JPMorgan Chase Bank of New York, as the Depositary, have been listed on the New York Stock Exchange since 1981. As of December 31, 2018, 207,847,937 B share equivalents (representing 10.87% of the outstanding B shares, adjusted for the treasury shares) were held in the form of ADRs.

D. SELLING SHAREHOLDERS

Not applicable.

E. DILUTION

Not applicable.

F. EXPENSES OF THE ISSUE

Not applicable.

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ITEM 10 ADDITIONAL INFORMATION  
ITEM 10 ADDITIONAL INFORMATION

A. SHARE CAPITAL

Not applicable.

B. MEMORANDUM AND ARTICLES OF ASSOCIATION

This section summarizes certain material provisions of Novo Nordisk A/S' Articles of Association, certain other constitutive documents and relevant Danish corporate law. See Exhibit 1.1 to this Form 20-F for a translation into English language of the Articles of Association.

General

Novo Nordisk A/S is a limited liability company organized under the laws of Denmark and registered with the Danish Business Authority under CVR number 24256790. Novo Nordisk A/S's objectives are to carry out research and development and to manufacture and commercialize pharmaceutical, medical and technical products and services as well as any other activity related thereto as determined by its Board of Directors. It strives to conduct its activities in a financially, environmentally and socially responsible way. Novo Nordisk A/S's objectives are set out in Article 2 of its Articles of Association.

Powers of the Board of Directors

All members of the Board of Directors have equal voting rights, and all resolutions are passed by a simple majority of votes. However, in the event of a tie, the Chairman shall have the casting vote. The Board of Directors forms a quorum when at least a majority of its members is present.

According to the Danish Companies Act, no member of the Board of Directors or the Executive Management may take part in the consideration of any business involving agreements between any member of the Group and himself, legal actions brought against the individual, or any business involving agreements between any member of the Group and any third party or legal actions brought against any third party, if the individual has a major interest therein that might conflict with Novo Nordisk A/S's interests. The Danish Companies Act also includes restrictions on Novo Nordisk A/S' ability to grant loans or provide security to any member of the Board of Directors or anyone particularly close to such a member of the Board of Directors. Novo Nordisk A/S' ability to grant loans or provide security is subject to a number of conditions including shareholder approval or delegation of authorization to the Board of Directors by the General Meeting.

The remuneration of the Board of Directors must be approved by Novo Nordisk A/S' shareholders at the Annual General Meeting.

According to Novo Nordisk A/S' Articles of Association a person cannot be nominated for election or re-election if such person has reached the age of 70 at the time of the General Meeting.

Rights, restrictions and preferences attaching to the shares

If the shareholders at an Annual General Meeting approve a recommendation by the Board of Directors to pay dividends, dividends shall be distributed as follows: a priority dividend of 0.5% to the holders of A shares and then up to a dividend of 5% to the holders of B shares. Any distribution of additional dividends shall be subject to the provision that the holders of A shares shall never receive a total dividend exceeding the percentage rate of the dividend paid to the holders of B shares. A shares take priority for dividends below 0.5%. B shares take priority for dividends between 0.5% and 5%. However, in practice, A shares and B shares receive the same amount of dividends per share of DKK 0.01. Dividends on A shares shall be remitted to the shareholders at the addresses entered in Novo

Nordisk A/S' Register of Shareholders as at the date of the Annual General Meeting. Dividends on B shares shall be paid with fully discharging effect for Novo Nordisk A/S through a central securities depository and an account-holding bank to shareholders registered by VP Securities at the time of payment.

The Board of Directors has been granted authority to distribute extraordinary dividends. This authority is included in the Articles of Association of Novo Nordisk A/S. Hence the Board of Directors has been granted authority to pay interim dividends without obtaining specific approval from the Annual General Meeting. Any Board resolution to pay extraordinary dividends must be accompanied by a balance sheet showing that sufficient funds are available for distribution. An authorized auditor must review the balance sheet.

Subject to the preference mechanism described above, the A shares and the B shares rank as equal in the event of a return on capital by Novo Nordisk A/S. Upon a winding-up, liquidation or otherwise, the B shares rank ahead of the A shares with regard to payment of each share's nominal amount. All shares rank as equal in respect of further distributions from a winding-up.

Each A share of DKK 0.20 carries 200 votes and each B share of DKK 0.20 carries 20 votes at General Meetings. A shares are non-negotiable instruments whereas B shares are negotiable instruments.

The holders of A shares have a pro-rata right of first refusal with regard to any A shares sold by another shareholder. However, currently all A-shares are owned by Novo Holdings A/S and according to the Articles of Association of Novo Holdings A/S, the A shares cannot be divested.

The share capital has been fully paid up and shareholders are not liable to further capital calls by Novo Nordisk A/S. No shareholder shall be obliged to have his shares redeemed in whole or in part. There is no sinking fund provision in the Articles of Association. There is no provision in the Articles of Association discriminating against any existing or prospective holder of such securities as a result of such shareholder

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## ITEM 10 ADDITIONAL INFORMATION

owning a substantial number of shares. The members of the Board of Directors do not stand for reelection at staggered intervals and there is no cumulative voting arrangement.

### Changes in shareholders' rights

Changes in the rights of holders of A shares or B shares require an amendment of the Articles of Association. Unless stricter requirements are made under the Danish Companies Act for any such resolution to be passed, (i) at least 2/3 of the total number of votes in Novo Nordisk A/S shall be represented at the General Meeting, and (ii) at least 2/3 of the votes cast and of the voting share capital shall vote in favor of such a resolution. If the quorum requirement in (i) is not fulfilled, the Board of Directors shall within two weeks convene another General Meeting at which the resolution may be passed irrespective of the number of votes represented.

### General Meetings

Novo Nordisk A/S' General Meetings shall be held at a venue in the Capital Region of Denmark. The Annual General Meeting shall be held before the end of April in every year. Extraordinary General Meetings shall be held as resolved by the General Meeting or the Board of Directors, or upon the request of the auditors or shareholders representing in total at least 5% of the share capital. The Extraordinary General Meeting shall then be called not later than two weeks after receipt of such request.

General Meetings shall be called by the Board of Directors not earlier than five weeks and not later than three weeks prior to the General Meeting. The notice calling such General Meeting, stating the agenda for the meeting, shall be published on the Company's website: [novonordisk.com](http://novonordisk.com) (the contents of this website are not incorporated by reference into this Form 20-F). The notice convening the meeting shall also be forwarded by mail or by email in writing to all shareholders entered in the Register of Owners who have so requested.

A shareholder's right to attend and vote at a General Meeting shall be determined by the shares or ADRs which such shareholder owns at the applicable record date. The Danish record date is one week prior to the General Meeting. Any shareholder who is entitled to attend the General Meeting is required to apply for an admission card to such General Meeting no later than three days prior to the date of such General Meeting. ADR holders who wish to attend the General Meeting in Denmark should contact Investor Relations, via e-mail to [IRofficer@novonordisk.com](mailto:IRofficer@novonordisk.com).

The shares held by each shareholder at the Danish record date shall be calculated based on the registration of the shareholder's shares in the Register of Owners as well as any notification received by the Company with respect to registration of shares in the Register of Owners, which have not yet been entered in the Register of Owners.

### Ownership restrictions

There are no limitations on the rights of non-resident or foreign owners to hold or vote the shares imposed by the laws of Denmark, Novo Nordisk A/S' Articles of Association, or any other of its constituent documents.

### Change of control

There is no provision in the Articles of Association, nor any other constituent document, that would have an effect of delaying, deferring or preventing a change in control of Novo Nordisk A/S and that would operate only with respect to a merger, acquisition or corporate restructuring involving the Company (or any of its subsidiaries). However, based on the current shareholder structure, the voting rights held by holders of A shares outlined above afford the Novo Nordisk Foundation, acting through its wholly-owned subsidiary Novo Holdings A/S, to have veto power against any change of control.

### Ownership disclosure

According to the Danish Capital Markets Act and the Danish Companies Act, shareholders of Novo Nordisk A/S must notify the Danish Financial Supervisory Authority and Novo Nordisk A/S of their ownership if they own 5% or more of the voting rights or share capital. Also, shareholders must notify changes in holdings if thresholds of 5%, 10%, 15%, 20%, 25%, 50%, 90% or 100% and 1/3 and 2/3 of the voting rights or share capital are crossed.

Changes in capital

Novo Nordisk A/S's Articles of Association do not contain conditions governing changes in the capital more stringent than those contained in the Danish Companies Act.

C. MATERIAL CONTRACTS

There have been no material contracts outside the ordinary course of business.

D. EXCHANGE CONTROLS

There are no governmental laws, decrees, or regulations in Denmark (including, but not limited to, foreign exchange controls) that restrict the export or import of capital, or that affect the remittance of dividends, interest or other payments to non-resident holders of the B shares or the ADRs.

## ITEM 10 ADDITIONAL INFORMATION

There are no limitations on the right of non-resident or foreign owners to hold or vote the B shares or the ADRs imposed by the laws of Denmark or the Articles of Association of the Company.

### E. TAXATION

#### Danish Taxation

The following summary outlines certain Danish tax consequences to U.S. Holders (as defined below):

#### Withholding Tax

Generally, Danish withholding tax is deducted from dividend payments to U.S. Holders at a 27% rate, the rate generally applicable to non-residents in Denmark without regard to eligibility for a reduced treaty rate. Under the current Convention between the Government of the United States of America and the Government of the Kingdom of Denmark for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (the 'Current Convention'), however, the maximum rate of Danish tax that may be imposed on a dividend paid to a U.S. Holder that does not have a 'permanent establishment' (as defined therein) in Denmark is generally 15% and, for certain pension funds, 0% (each, the 'Treaty Rate'). U.S. Holders eligible for the Treaty Rate may apply to the Danish tax authorities to obtain a refund to the extent that the amount withheld reflects a rate in excess of the Treaty Rate (any such amount, the 'Excess Withholding Tax').

Any U.S. Holders of ADRs wishing to apply for a refund of Excess Withholding Tax will have to provide a Danish Claim for Refund of Danish Dividend Tax, a properly completed U.S. Internal Revenue Service Form 6166 and additional documentation including: proof of dividend received; proof of ownership of the ADR and eligibility for the dividend received and proof that the dividend received was reduced by an amount corresponding to the Danish withholding tax. These documentation requirements may be expanded and may be subject to change. Refund claims must be filed within the three-year period following the date in which the dividend was paid in Denmark.

Information on tax reclaims, how they should be filed and the requisite tax forms may be obtained from:

JPMorgan Chase Bank, N.A.  
c/o Globe Tax Services, Inc.  
1 New York Plaza, 34th Floor  
New York, New York 10004 USA  
Phone: +1 (212) 747 9100

U.S. Holders should consult their tax advisers regarding dividend withholding tax refunds.

#### Sale or Exchange of ADRs or B Shares

Any gain or loss realized on the sale or other disposition of ADRs or B shares by a U.S. Holder that is not either a resident of Denmark or a corporation that is doing business in Denmark is not subject to Danish taxation. In addition, any non-resident of Denmark may remove from Denmark any convertible currency representing the proceeds of the sales of ADRs or B shares in Denmark.

#### U.S. Taxation

The following summary outlines certain U.S. federal income tax consequences for U.S. Holders (defined below) of owning and disposing of ADRs or B shares. A 'U.S. Holder' is a holder who, for U.S. federal income tax purposes, is a beneficial owner of ADRs or B shares that is eligible for the benefits of the Current Convention and is (i) a citizen or individual resident of the United States, (ii) a corporation, or other entity taxable as a corporation, created or organized

in or under the laws of the United States or any state therein or the District of Columbia, or (iii) an estate or trust the income of which is subject to U.S. federal income taxation regardless of its source. This discussion applies only to a U.S. Holder that holds ADRs or B shares as capital assets for U.S. tax purposes and does not apply to persons that own or are deemed to own ADRs or common shares representing 10% or more of the voting power or value of Novo Nordisk. In addition, this discussion does not describe all of the tax consequences or potentially different tax consequences that may be relevant in light of the U.S. Holder's particular circumstances, including tax consequences applicable to U.S. Holders subject to special rules, such as certain financial institutions, entities classified as partnerships for U.S. federal income tax purposes, persons subject to the provisions of the U.S. Internal Revenue Code and Treasury regulations thereunder commonly known as the Medicare contribution tax, persons subject to the alternative minimum tax, or persons holding ADRs or B shares in connection with a trade or business conducted outside of the United States. This discussion is based, in part, on certain representations by the Depositary and assumes that each obligation under the deposit agreement will be performed in accordance with its terms. This discussion assumes that the Company is not, and will not become, a passive foreign investment company for U.S. federal income tax purposes.

For U.S. federal income tax purposes, the holders of ADRs will be treated as the beneficial owners of the underlying B shares. Accordingly, no gain or loss for U.S. federal income tax purposes will be recognized if a U.S. Holder exchanges ADRs for the underlying B shares represented by those ADRs or B shares for ADRs.

The U.S. Treasury has expressed concern that parties to whom American depositary receipts are released before shares are delivered to the depositary (referred to as a 'pre-release'), or intermediaries in the chain of ownership between holders and the issuer of the security underlying the American depositary receipts, may be taking actions that are inconsistent with the claiming of foreign tax credits by holders of American depositary receipts. These actions would also be inconsistent with the claiming of the reduced rates of tax, described below, applicable to dividends received by certain non-corporate U.S. Holders. Accordingly, the creditability of Danish taxes, and the availability of the reduced tax rates for dividends received by certain non-corporate U.S. Holders, each described below, could be affected by actions taken by such parties or intermediaries.

## ITEM 10 ADDITIONAL INFORMATION

### Taxation of Distributions

For U.S. federal income tax purposes, distributions on ADRs or B shares received by U.S. Holders, before reduction for any Danish tax withheld, generally will be included in the U.S. Holder's income as foreign source dividend income and will not be eligible for the dividends-received deduction generally available to U.S. corporations. The amount of any dividend income paid in Danish kroner will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of the U.S. Holder's, or, in the case of ADRs, the Depositary's receipt of the dividend regardless of whether the payment is in fact converted into U.S. dollars at that time. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt. U.S. Holders that receive a refund of Danish withholding tax after the dividend is received, as discussed above under the section 'Danish Taxation – Withholding Tax,' may be required to recognize foreign currency gain or loss with respect to the amount of the refund. U.S. Holders should consult their tax advisers regarding whether any foreign currency gain or loss should be recognized in connection with distributions on ADRs or B shares.

Subject to applicable limitations and conditions under U.S. federal income tax law and the discussion above regarding concerns expressed by the U.S. Treasury, dividends paid to certain non-corporate U.S. Holders may be taxable at favorable rates. In order to be eligible for the favorable rates, a non-corporate U.S. Holder must fulfill certain holding period and other requirements.

Subject to applicable limitations under U.S. federal income tax law and the discussion above regarding concerns expressed by the U.S. Treasury, a U.S. Holder may be eligible to credit against its U.S. federal income tax liability Danish taxes withheld from dividends on ADRs or B shares at a rate not exceeding the applicable rate under the Current Convention. Danish taxes withheld in excess of the applicable rate under the Current Convention will not be eligible for credit against a U.S. Holder's federal income tax liability. The rules governing foreign tax credits are complex and, therefore, U.S. Holders should consult their tax advisers regarding the availability of foreign tax credits in their particular circumstances.

Alternatively, subject to applicable limitations, U.S. Holders may elect to deduct Danish taxes withheld from dividend payments. An election to deduct foreign taxes instead of claiming a foreign tax credit must apply to all taxes paid or accrued in the taxable year to foreign countries and possessions of the United States.

### Sale or Exchange of ADRs or B Shares

A U.S. Holder will recognize capital gain or loss for U.S. federal income tax purposes on a sale or other disposition of ADRs or B shares, which will be long-term capital gain or loss if the U.S. Holder held the ADRs or B shares for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder's tax basis in the ADRs or B shares disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars. Such gain or loss will generally be U.S. source gain or loss for foreign tax credit purposes.

### Information Reporting and Backup Withholding

Payments of dividends and sales proceeds that are made within the United States or through certain U.S. related financial intermediaries may be subject to information reporting and backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding.

The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the holder's U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the Internal Revenue Service.

Certain U.S. Holders who are individuals (and certain specified entities) may be required to report information relating to securities issued by a non-U.S. person or foreign accounts through which such securities are held, subject to certain exceptions (including an exception for securities held in accounts maintained by U.S. financial institutions). U.S. Holders should consult their tax advisers regarding their possible reporting obligations with respect to the ADRs or B shares.

The foregoing sections offer a general description and U.S. Holders should consult their tax advisers to determine the U.S. federal, state, local and non-U.S. tax consequences of owning and disposing of ADRs or B shares in their particular circumstances.

#### F. DIVIDENDS AND PAYING AGENTS

Not applicable.

#### G. STATEMENTS BY EXPERTS

Not applicable.

#### H. DOCUMENTS ON DISPLAY

Documents referred to and filed with the SEC together with this Form 20-F can be read and copied at the SEC's public reference room located at 100 F Street, NE, Washington, DC 20549. Please call the United States Securities and Exchange Commission at 1-800-SEC-0330 for further information on the public reference rooms.

## ITEM 11 QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISKS

Copies of this Form 20-F as well as our Annual Report 2018 and Annual Report 2017 can be downloaded from the Investors pages at [novonordisk.com](http://novonordisk.com). The contents of this website are not incorporated by reference into this Form 20-F. This Form 20-F is also filed and can be viewed via EDGAR on [www.sec.gov](http://www.sec.gov).

### I. SUBSIDIARY INFORMATION

Not applicable.

## ITEM 11 QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISKS

### Financial exposure and financial risk management

For a description and discussion of the Company's foreign exchange risk management, interest rate risk management, counterparty risk management and equity price risk management, reference is made to Note 4.2 'Financial risks' and 'Risk management enables better decision-making' on pages 41-43 in our Annual Report 2018.

### Sensitivity analysis

When conducting a sensitivity analysis, the Group assesses the change in fair value on the market-sensitive instruments following hypothetical changes in market rates and prices. The rates used to mark-to-market the instruments are market data as of December 28, 2018.

### Interest rate sensitivity analysis

For information on Interest rate sensitivity analysis in the financial year of 2018, reference is made to Note 4.2 'Financial risks' in our Annual Report 2018.

### Foreign exchange sensitivity analysis

For information on Foreign exchange sensitivity analysis in the financial year of 2018, reference is made to Note 4.2 'Financial risks' and 'Risk management enables better decision-making' on pages 41-43 in our Annual Report 2018.

## ITEM 12 DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

### ITEM 12A DEBT SECURITIES

Not applicable.

### ITEM 12B WARRANTS AND RIGHTS

Not applicable.

### ITEM 12C OTHER SECURITIES

Not applicable.

### ITEM 12D AMERICAN DEPOSITARY SHARES

Novo Nordisk's ADR program is administered by J.P. Morgan Depositary Receipts Group as Depositary, JPMorgan Chase Bank, N.A., 383 Madison Avenue, Floor 11, New York, United States.

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The ADRs are traded under the code NVO on the New York Stock Exchange and the underlying security is the Novo Nordisk B share, NOVO-B on Nasdaq Copenhagen. Each ADR represents one deposited Novo Nordisk B share. One ADR carries the same voting rights as one Novo Nordisk B share. The Depositary distributes relevant notices, reports and proxy materials to the holders of the ADRs. When dividends are paid to shareholders, the Depositary converts the amounts into U.S. dollars and distributes the dividends to the holders of the ADRs.

The holder of an ADR may have to pay the following fees and charges related to services in connection with the ownership of the ADR up to the amounts set forth in the table below.

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ITEM 12 DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

Service	Fee
Issuance or delivery of an ADR, surrendering of an ADR for delivery of a Novo Nordisk B share, cancellation of an ADR, including issuance, delivery, surrendering or cancellation in connection with share distributions, stock splits, rights and mergers	A maximum of USD 5.00 for each 100 ADRs (or portion thereof), to be paid to the Depositary
Distribution of dividend to the holder of the ADR	A maximum of USD 0.05 per ADR (or portion thereof), to be paid to the Depositary
Transfer of the Novo Nordisk B shares from the Danish custodian bank to the holder of the ADR's account in Denmark	USD 20.00 cabling fee per transfer, to be paid to the Depositary
Taxes and other governmental charges the holder of the ADR has to pay on any ADR or share underlying the ADR	As necessary

J.P. Morgan, as Depositary, has agreed to reimburse certain reasonable expenses related to Novo Nordisk's ADR program and incurred by Novo Nordisk in connection with the program. In the year ended December 31, 2018, the Depositary reimbursed USD 4,210,099 for costs related to investor relations activities.

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ITEM 13 DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES  
PART II

ITEM 13 DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

ITEM 14 MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF  
PROCEEDS

None.

ITEM 15 CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures

Novo Nordisk maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in reports that Novo Nordisk files or submits under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the United States Securities and Exchange Commission, and that such information is accumulated and communicated to management of the Company, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Novo Nordisk Management, including the Chief Executive Officer and Chief Financial Officer, evaluated the Company's disclosure controls and procedures as of December 31, 2018. Based on this evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that as of December 31, 2018, the Company's disclosure controls and procedures were effective at the reasonable assurance level.

In designing and evaluating the disclosure controls and procedures, Management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Report of Novo Nordisk Management on Internal Control over Financial Reporting

Novo Nordisk's Management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, the Chief Executive Officer and Chief Financial Officer, and effected by the Company's Board of Directors, Management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS as issued by the IASB.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Novo Nordisk Management, including the Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2018, using the criteria established in the Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ('COSO'). Based on this assessment, Novo Nordisk Management, including the Chief Executive Officer and Chief Financial Officer, concluded that, as of December 31, 2018, the Novo Nordisk Group's internal control over financial reporting was effective based on criteria stated in Internal Control –

Integrated Framework (2013) issued by the COSO.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2018 has been audited by PricewaterhouseCoopers, Statsautoriseret Revisionspartnerselskab, Denmark, an independent registered public accounting firm, as stated in their report which appears on page 37 of this Form 20-F.

**Changes in internal controls over financial reporting**

There were no changes in the Company's internal control over financial reporting that occurred during the year ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**ITEM 16A AUDIT COMMITTEE FINANCIAL EXPERTS**

In March 2018, the Board of Directors elected the following individuals to the Audit Committee: Liz Hewitt (Audit Committee Chairman and financial expert), Andreas Fibig (Audit Committee member), Sylvie Grégoire (Audit Committee member) and Stig Strøbæk (Audit Committee member and employee representative).

As such, the Audit Committee is comprised of four members elected by the Board of Directors. One member is designated as Chairman and one member, the Chairman, is designated as an Audit Committee financial expert as defined by the SEC.

## ITEM 16A AUDIT COMMITTEE FINANCIAL EXPERTS

Three members qualify as independent as defined by the SEC and one member relies on an exemption. See item 16D below. The Chairman and financial expert, Liz Hewitt, is independent as defined by the SEC.

## ITEM 16B CODE OF ETHICS

Novo Nordisk has a vision and a set of essentials named the Novo Nordisk Way. The Novo Nordisk Way describes who Novo Nordisk as a company is, where Novo Nordisk wants to go and how its employees work. The Novo Nordisk Way is principle-based and describes corporate essentials and the required values and mindset of employees on business conduct and ethics including a number of the topics required by the Sarbanes–Oxley Act and the NYSE Listed Company Manual. In addition to the Novo Nordisk Way, a number of policies and related procedures have been established including a Business Ethics Code of Conduct and related business ethics requirements on how to conduct business in Novo Nordisk are outlined. The Novo Nordisk Way and our Business Ethics Code of Conduct apply to all employees in Novo Nordisk including the Chief Executive Officer and Chief Financial Officer.

For further information on the Novo Nordisk Way, reference is made to ‘Leading the Novo Nordisk Way’ on pages 6-7 in our Annual Report 2018. The Novo Nordisk Way and our Business Ethics Code of Conduct may be found on our website at [novonordisk.com](http://novonordisk.com) (the contents of the website are not incorporated by reference into this Form 20-F).

## ITEM 16C PRINCIPAL ACCOUNTANT FEES AND SERVICES

Reference is made to Note 5.4 ‘Fee to statutory auditors’ in our Annual Report 2018 regarding fees paid to our statutory auditors.

### Statutory Audit Fees

Statutory audit fees consist of fees billed for the annual audit of the Company’s Annual Report, the financial statements of the Parent Company, Novo Nordisk A/S, and financial statements of wholly-owned affiliates including audit of internal controls over financial reporting (Sarbanes–Oxley Act, Section 404). The fees also include fees billed for other audit services, which are those services that only the statutory auditor can provide, and include the review of documents filed with the SEC.

### Audit-Related Fees

Fees for audit-related services consist of fees billed for assurance and related services that are related to the performance of the audit or review of the Company’s social and environmental reporting included in our Annual Report 2018 and also include consultations concerning financial accounting reporting standards.

### Tax Fees

Fees for tax advisory services include fees billed for tax compliance services, tax consultations, such as assistance and representation in connection with tax audits and appeals and transfer pricing.

### Other Fees

Fees for other services comprise fees billed for other permitted services such as compliance reviews in connection with healthcare laws and regulations and assessment of their impact on the distribution chain, review of IT security plans and preparation of Benchmark reports etc.

### Pre-approval policies

The Audit Committee assesses and pre-approves all audit and non-audit services provided by the statutory auditors. The pre-approval includes the type of service and a fee budget. Furthermore, the Audit Committee receives a quarterly update on actual services provided and fees realized.

ITEM 16D EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Novo Nordisk's ADRs are listed on the New York Stock Exchange, the corporate governance rules of which require a foreign private issuer such as Novo Nordisk to have an Audit Committee that satisfies the requirements of Rule 10A-3 under the U.S. Securities Exchange Act of 1934, as amended. These requirements include a requirement that the Audit Committee be composed of members that are "independent" of the issuer, as defined in the Rule, subject to certain exemptions. Of the current four members of Novo Nordisk's Audit Committee, Stig Strøbæk is a current employee of Novo Nordisk who has been elected to the Board of Directors by the employees pursuant to the Danish Companies Act (in Danish: "Selskabsloven"). The Danish Companies Act requires any limited liability company with more than 35 employees on average over a three-year period to organize a vote in which the employees are entitled to decide whether they would like employee representation on the Board of Directors. Stig Strøbæk is not an executive officer of Novo Nordisk. Accordingly, his service on the Audit Committee is permissible pursuant to the exemption from the independence requirements provided for by paragraph (b)(1)(iv)(C) of Rule 10A-3. Novo Nordisk does not believe the reliance on such exemption would materially adversely affect the ability of the Audit Committee to act independently and to satisfy the other requirements of the Rule 10A-3.

ITEM 16E PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS  
 ITEM 16E PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

	Total Number of Shares Purchased (a)*	Average Price Paid per Share in DKK (b)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (c)	Maximum Approximate Value of Shares that may yet be purchased under the Plans or Programs in DKK (d)
2017 repurchase program				
Status year end 2017**	54,442,831	281.07	54,442,831	1,697,935,084
January 1-31, 2018	4,968,673	341.73	59,411,504	0
Total***	59,411,504	286.14	59,411,504	0
2018 repurchase program				
February 1-28, 2018	5,628,661	309.45	5,628,661	14,000,000,000
March 1-31, 2018	2,972,366	303.42	8,601,027	12,258,194,883
April 1-30, 2018	2,754,500	294.08	11,355,527	11,356,330,876
May 1-31, 2018	5,715,195	304.05	17,070,722	10,546,300,039
June 1-30, 2018	2,958,548	291.95	20,029,270	8,808,575,273
July 1-31, 2018	3,145,000	315.56	23,174,270	7,944,832,992
August 1-31, 2018	5,605,809	310.16	28,780,079	6,952,410,426
September 1-30, 2018	2,740,000	306.75	31,520,079	5,213,691,560
October 1-31, 2018	3,265,500	281.26	34,785,579	4,373,204,791
November 1-30, 2018****	8,272,051	290.27	43,057,630	3,454,758,457
December 1-31, 2018	2,785,000	301.95	45,842,630	2,053,561,012
Total	45,842,630	300.75	45,842,630	1,212,618,952

\*) All shares purchased through a publicly announced program.

\*\*) Shares purchased under 2017 repurchase program during 2017.

\*\*\*) As of January 31, 2018, Novo Nordisk had repurchased a total of 59,411,504 B shares equal to a transaction value of DKK 17 billion. The DKK 17 billion share repurchase program announced February 3, 2017 and increased by DKK 1 billion on November 1, 2017 was thereby concluded.

\*\*\*\*) In November the repurchase program was increased from DKK 14 billion to DKK 15 billion.

Note to column (a) and (d)

The Board of Directors has been authorized by the Annual General Meeting to acquire up to 10% of the share capital at the price quoted at the time of the purchase with a deviation of up to 10%. This authorization is renewed annually at the Annual General Meeting. If the limit of 10% is reached, a number of shares would have to be cancelled before further purchases can be made. The cancellation of shares must be approved by the shareholders.

Under this authorization, a share repurchase program for 2017 of DKK 16 billion initiated in February 2017, and increased by DKK 1 billion on November 1, 2017, was completed in January 2018. A new share repurchase program for 2018 of DKK 14 billion initiated in February 2018 was completed in January 2019. The shares have been purchased through a bank directly in the market.

Column (a) shows shares Novo Nordisk purchased as part of our share repurchase program initiated in February 2017 (completed in January 2018) and our share repurchase program initiated in February 2018.

Notes to columns (c) and (d)

In order to maintain capital structure flexibility, the Board of Directors intends to propose at the Annual General Meeting on March 21, 2019, a reduction in the B share capital, by cancellation of 50 million shares (nominal value DKK 0.20) of current treasury B shares, to DKK 382,512,800. This would correspond to a 2% reduction of the total share capital.

ITEM 16F CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

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ITEM 16G CORPORATE GOVERNANCE  
ITEM 16G CORPORATE GOVERNANCE

Novo Nordisk A/S is a public limited company incorporated in Denmark and admitted to trading on Nasdaq Copenhagen. As a result, it follows the applicable Danish Corporate Governance Recommendations issued in November 2017 (applicable to the financial years commencing on January 1, 2018 or later) in respect of its corporate governance practices.

Novo Nordisk A/S has ADRs listed on the New York Stock Exchange (the “NYSE”) and is therefore required to comply with U.S. securities laws and regulations, including the Sarbanes-Oxley Act and the NYSE Corporate Governance Standards (the “NYSE Standards”) applicable to listed companies as described in the NYSE Listed Company Manual’s section 303A. As a foreign private issuer, Novo Nordisk A/S is permitted to follow the corporate governance practice of its home country in lieu of certain provisions of the NYSE Standards.

Novo Nordisk A/S complies with the requirements of the SEC and NYSE except that Novo Nordisk as a “controlled company” (a listed company of which more than 50% of the voting power for the election of directors is held by an individual, a group or another company) pursuant to section 303A.00 of the NYSE Listed Company Manual is not obliged to comply with sections 303A.01 (majority independent directors), 303A.04 (nominating/corporate governance committee) and 303A.05 (compensation committee) of the NYSE Listed Company Manual.

Moreover, Novo Nordisk A/S as a foreign private issuer is permitted to follow home country practice in lieu of sections 303A.02 (independence tests), 303A.03 (executive sessions), 303A.07 (audit committee), 303A.08 (shareholder approval of equity compensation plans), 303A.09 (corporate governance guidelines), 303A.10 (code of business conduct and ethics) and 303A.12 (a) (certification requirements).

Below is a list of practices followed by Novo Nordisk A/S as a foreign private issuer that differ from certain corporate governance requirements under the NYSE Standards:

**Independence requirements**

Under the NYSE Standards, listed companies must have at least a majority of independent directors and no director qualifies as “independent” unless the Board of Directors affirmatively determines that the director has no material relationship with the listed company (either directly or as a partner, shareholder or officer of an organization that has a relationship with the Company).

Under the Danish Corporate Governance Recommendations, at least half of the elected members of the Board of Directors, excluding any members that have been elected by employees of the company, must be independent. Employees are entitled to be represented by half of the total number of Board members elected at the Annual General Meeting.

Under the NYSE Standards a director is not deemed independent if the director is, or has been within the last three years, an employee of the listed company, or an immediate family member is, or has been within the last three years, an executive officer, of the listed company. Rule 303A.02 defines ‘listed company’, for purposes of the independence standards, to include ‘any parent or subsidiary in a consolidated group with the listed company or such other company as is relevant to any determination under the independence standards set forth in this Section 303A.02(b)’.

Four employees have in accordance with the requirements in the Danish Companies Act been elected as board members by the Danish employees of the Company. One board member is an executive of Novo Holding A/S. No other board member or the board member’s immediate family members have within the last three years been an



employee or executive of Novo Nordisk A/S or any parent or subsidiary in a consolidated group with Novo Nordisk A/S or received any fees from Novo Nordisk A/S.

The Board has determined whether board members qualify as independent under the Danish Corporate Governance Recommendations. The Board has also determined whether the board members, who are members of the Audit Committee, qualify as independent under Rule 10A-3 in the Securities Exchange Act. Such determination is disclosed in the Annual Report. Further, the Annual Report provides detailed and individual information regarding the board members, but it does not explicitly identify which board members the Board considers independent under the NYSE Standards.

#### Remuneration Committee

Pursuant to the NYSE Standards listed companies must have a compensation committee composed entirely of independent directors. Compensation committee members must satisfy the additional independence requirements specific to compensation committee membership set forth in section 303A.02(a)(ii). The NYSE Standards states that in affirmatively determining the independence of any director who will serve on the compensation committee of the listed company's Board of Directors, the Board of Directors must consider all factors specifically relevant to determining whether a director has a relationship to the listed company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member.

As a controlled company, Novo Nordisk A/S is exempt from the requirement to establish a separate compensation committee in the same manner as U.S. companies are. Novo Nordisk A/S has established a Remuneration Committee and at a Board of Directors meeting immediately following the Annual General Meeting the members of the Remuneration Committee are elected. When electing the members the Board of Directors considers all factors relevant to determine whether the members of the Remuneration Committee have a relationship to the Company which is material to the director's ability to be independent from management when performing its duties. At least a majority of the members of a board committee shall qualify as independent as defined by the Danish Corporate Governance Recommendations. Under the Danish Corporate Governance Recommendations, two members qualify as non-independent members,

including the Chairman, and two members qualify as independent members.

#### ITEM 16G CORPORATE GOVERNANCE

Hence, the composition of the Remuneration Committee does not conform to the Danish Corporate Governance Recommendations. This is due to the fact that the Board of Directors finds that it is beneficial for Novo Nordisk A/S that the composition of the Remuneration Committee allows a member from the Chairmanship, who is a representative of the majority shareholder, as well as an employee representative, both of whom qualify as non-independent Board members, to remain on the Remuneration Committee while maintaining an operational structure of the Remuneration Committee with relatively few members.

#### Nomination Committee

Under the NYSE Standards listed companies must have a nominating/corporate governance committee composed entirely of independent directors, which requirement does not apply to Novo Nordisk A/S as a controlled company. Novo Nordisk A/S has established a Nomination Committee and at a Board of Directors meeting immediately following the Annual General Meeting the members of the Nomination Committee are elected. Novo Nordisk A/S' Nomination Committee consists of two members who are independent, including the Chairman, and two members who are non-independent. A majority of the members of a board committee shall qualify as independent as defined by the Danish Corporate Governance Recommendations. Hence, the composition of the Nomination Committee does not conform to the Danish Corporate Governance Recommendations. This is due to the fact that the Board of Directors finds that it is beneficial for Novo Nordisk A/S that the composition of the Nomination Committee allows a representative of the majority shareholder, who qualifies as a non-independent board member, as well as an employee representative, who also qualifies as a non-independent board member, to remain on the Nomination Committee while maintaining an operational structure of the Nomination Committee with relatively few members.

#### Audit Committee

Under Section 303A.06 of the NYSE Standards, the Audit Committee in a listed company must be composed entirely of independent directors as set out in section 303A.02 and, in the absence of an applicable exemption, Rule 10A-3(b)(1). At a Board of Directors meeting immediately following the Annual General Meeting the members of the Audit Committee are elected. Novo Nordisk A/S' Audit Committee has four members. Three of the members satisfy the independence requirements of Rule 10A-3(b)(1) of the Securities Exchange Act and section 303A.02 of the NYSE Listed Company Manual and one member relies on an exemption.

One Audit Committee member is an employee representative relying on the exemption from the independence requirements in Rule 10A-3(b)(1) provided for by paragraph (b)(1)(iv)(C) of Rule 10A-3. See Item 16D above for further details.

Further, Novo Nordisk's Audit Committee, is among other things, responsible for oversight of and reporting to the Board of Directors on the elements described in section 303A.07(b)(i)(A) of the NYSE Listed Company Manual. However, with respect to legal and regulatory requirements, the Audit Committee's oversight responsibility only includes oversight of compliance with legal and regulatory requirements relating to business ethics compliance.

#### Equity-compensation plans

Under Section 303A.08 of the NYSE Standards, shareholders must be given the opportunity to vote on all equity compensation plans and material revisions thereto, with certain limited exceptions. Novo Nordisk's Remuneration Principles are approved by the Annual General Meeting and describe the framework for incentive programs for the Board of Directors and Executive Management. All incentive programs offered to the Board and/or Executive Management shall comply with this framework. However, under Danish law, the practice of voting on equity-compensation plans is not contemplated and accordingly, equity compensation plans are only subject to shareholder approval if they result in the issuance of new shares (and not if treasury shares are used).

Code of business conduct and ethics

Under Section 303A.10 of the NYSE Standards, listed companies must adopt and disclose a code of business conduct and ethics for directors, officers and employees, and promptly disclose any waivers of the code for directors or executive officers. Novo Nordisk has a global framework of rules and guidelines, including but not limited to the Novo Nordisk Way and a Business Ethics Code of Conduct, which describe the corporate principles on ethical business conduct. See Item 16B. While certain topics mentioned in the NYSE Listed Company Manual are addressed in this framework of rules and guidelines, there may be topics which are not covered.

CEO certification

Under Section 303A.12(a) of the NYSE Standards, each listed company's Chief Executive Officer must certify to the NYSE each year that he or she is not aware of any violation by the listed company of NYSE Standards, qualifying the certification to the extent necessary. Novo Nordisk has opted to follow Danish law and regulations which do not contemplate such certifications. However, in accordance with NYSE Standards, Novo Nordisk will notify the NYSE promptly in writing if it becomes aware of any non-compliance with NYSE Standards applicable to the Company.

ITEM 16H MINE SAFETY DISCLOSURE

Not applicable.

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ITEM 17 FINANCIAL STATEMENTS  
PART III

ITEM 17 FINANCIAL STATEMENTS

See response to Item 18.

ITEM 18 FINANCIAL STATEMENTS

The financial statements required by this item accompany this annual report in the form of our Annual Report 2018 (see Item 19).

Reconciliation of non-IFRS financial measures

In the Financial statements, Novo Nordisk discloses certain financial measures of the Group's financial performance, financial position and cash flows that reflect adjustments to the most directly comparable measures calculated and presented in accordance with IFRS. The inclusion of non-IFRS measures has been expressly permitted by the Danish Business Authorities and thereby exempted from the prohibition in Item 10(e)(1)(ii)(C) of Regulation S-K. However, 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 our Annual Report 2018 are:

- Free cash flow;
- Cash to earnings;
- Operating profit after tax to net operating assets;
- Financial resources;
- Sales growth in local currencies; and
- Operating profit growth in local currencies.

Free cash flow

Novo Nordisk defines free cash flow as 'net cash generated from operating activities' less 'net cash used in investing activities' excluding net change of marketable securities. Free cash flow is a measure of the amount of cash generated in the period which is available for the Board to allocate between Novo Nordisk's capital providers, through e.g. dividends, share repurchases and repayment of debt (excl. lease liability repayments) or for retaining in the business to fund future growth. Therefore, management believes that this non-IFRS liquidity measure provides useful information to investors in addition to the most directly comparable IFRS financial measure 'Net cash generated from operating activities'.

With IFRS 16 'Leases' becoming effective 1 January 2019, lease payments will transfer from 'net cash flow from operating activities' to 'cash flow from financing activities' (excluding interest expense). Effective from 1 January 2019, the definition of free cash flow will be amended to also deduct the principal repayment on lease liabilities. Accordingly the implementation of IFRS 16 will have a neutral impact on free cash flow. The free cash flow outlook guidance for 2019 on page 12 in our Annual Report 2018 is calculated on the amended definition of free cash flow.

The following table shows a reconciliation of free cash flow to 'Net cash generated from operating activities'.

Reconciliation of free cash flow	2018	2017	2016
DKK million			
Free cash flow	32,536	32,588	39,991

+ Net purchase of marketable securities	—	2,009	1,533
+ Net cash used in investing activities	12,080	6,571	6,790
= Net cash generated from operating activities	44,616	41,168	48,314

Cash to earnings

Cash to earnings is defined as ‘free cash flow as a percentage of net profit’.

Management believes that Cash to earnings is an important performance metric because it measures the Group’s ability to turn earnings into cash and is, therefore, in the eyes of management a meaningful measure for investors to understand the development of the Group’s net cash generated from operating and investing activities. Because management wants this measure to capture the ability of the Group’s operations to generate cash, free cash flow is used as the numerator instead of net cash flow.

The following table shows the reconciliation of Cash to earnings to the most comparable IFRS financial measure ‘Cash flow from operating activities/net profit in %’:

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Reconciliation of cash to earnings DKK million	2018	2017	2016
Free cash flow	32,536	32,588	39,991
/ Net profit (as reported in the Annual Report)	38,628	38,130	37,925
= Cash to earnings	84.2 %	85.5 %	105.4 %
Net cash generated from operating activities	44,616	41,168	48,314
/ Net profit (as reported in the Annual Report)	38,628	38,130	37,925
= Cash flow generated from operating activities / net profit in %	115.5 %	108.0 %	127.4 %

## Operating profit after tax to net operating assets

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

Management believes Operating profit after tax to net operating assets is a useful measure in providing investors and management with information regarding the Group's performance. The calculation of the financial target Operating profit after tax to net operating assets is a widely accepted measure of earnings efficiency in relation to total capital employed. Management believes that the income level relative to total capital employed, as measured by Operating profit after tax to net operating assets, is an effective measure of increases or decreases, as the case may be, in shareholder value generation.

The following table reconciles Operating profit after tax to net operating assets with 'Operating profit/equity in %', the most directly comparable IFRS financial measure:

Reconciliation of Operating profit after tax to net operating assets DKK million	2018	2017	2016
Operating profit after tax	38,318	38,341	38,407
/ Average non-interest bearing balance sheet items	32,832	26,776	25,578
= Operating profit after tax to net operating assets (as reported in the Annual Report) in %	116.7 %	143.2 %	150.2 %

## ITEM 18 FINANCIAL STATEMENTS

	2018	2017	2016
DKK million			
Numerator			
Reconciliation of Operating profit after tax to Operating profit			
Operating profit after tax	38,318	38,341	38,407
/ (1 minus effective tax rate) in %	81.1 %	78.3 %	79.3 %
= Operating profit (as reported in the Annual Report)	47,248	48,967	48,432
Denominator			
Reconciliation of Average non-interest bearing balance sheet items to Equity			
Non-interest bearing balance sheet items at the beginning of the year	28,900	24,651	26,505
+ Non-interest bearing balance sheet items at the end of the year	36,763	28,900	24,651
/ 2			
= Average non-interest bearing balance sheet items as used in Operating profit after tax to net operating assets	32,832	26,776	25,578
Non-interest bearing balance sheet items at the end of the year	36,763	28,900	24,651
+ Investment in associated company	531	784	809
+ Other financial assets	1,242	978	1,388
+ Marketable securities	—	—	2,009
+ Derivative financial instruments	204	2,304	529
+ Cash at bank and in hand	15,638	18,852	18,690
—Loans	—	—	—
—Current debt	(515 )	(1,694 )	(229 )
—Derivative financial instruments	(2,024 )	(309 )	(2,578 )
= Equity (as reported in the Annual Report)	51,839	49,815	45,269
Operating profit (as reported in the Annual Report)	47,248	48,967	48,432
/ Equity (as reported in the Annual Report)	51,839	49,815	45,269
= Operating profit/Equity in %	91.1 %	98.3 %	107.0 %

## Financial resources

Financial resources is defined as the sum of cash and cash equivalents at the end of the year, bonds with original term to maturity exceeding three months and undrawn committed credit facilities less current debt (including bank overdrafts).

Management believes that the Financial resources is an important measure of the Group's financial strength from an investor's perspective, capturing the robustness of the Group's financial position and its financial preparedness for unforeseen developments.

Reconciliation of financial resources	2018	2017	2016
DKK million			
Financial resources	26,697	25,348	28,648
—Marketable securities	—	—	(2,009 )
—Undrawn committed credit facilities	(11,574)	(8,190 )	(8,178 )
—Current debt (bank overdrafts)	506	—	—
= Cash and cash equivalents at the end of the year (as reported in the Annual report)	15,629	17,158	18,461





## ITEM 18 FINANCIAL STATEMENTS

## Sales growth in local currencies

Sales growth in local currencies is defined as sales for the period measured at the average exchange rates for the same period prior year compared with Net sales for the same period prior year. The effect of changes in exchange rate is excluded. Price adjustments within hyperinflation countries as defined in IAS 29 'Financial reporting in hyperinflation economies' are excluded from the calculation to avoid artificially growth in local currencies.

Management believes that the sales growth in local currencies is relevant information for investors in order to understand the underlying development in sales by adjusting for the impact of currency fluctuations.

Sales in local currencies DKK million	2018	2017	2016	
Net sales	111,831	111,696	111,780	
+ Effect of exchange rate	5,043	2,609	2,110	
= Sales in local currencies	116,874	114,305	113,890	
Net sales previous year	111,696	111,780	107,927	
% increase/(decrease) in local currencies	5	% 2	% 6	%
% increase/(decrease) in reported currencies	0	% 0	% 4	%

## Operating profit growth in local currencies

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

Management believes that the operating profit growth in local currencies is relevant information for investors in order to understand the underlying development in operating profit by adjusting for the impact of currency fluctuations.

Operating profit in local currencies DKK million	2018	2017	2016	
Operating profit	47,248	48,967	48,432	
+ Effect of exchange rate	3,098	1,770	1,099	
= Operating profit in local currencies	50,346	50,737	49,531	
Operating profit previous year	48,967	48,432	49,444	
% increase/(decrease) in local currencies	3	% 5	% 0	%
% increase/(decrease) in reported currencies	(4	)% 1	% (2	)%

ITEM 19 EXHIBITS  
ITEM 19 EXHIBITS

a. Annual Report

The following pages from our Annual Report 2018, furnished to the SEC on Form 6-K, dated February 4, 2019, are incorporated by reference into this Form 20-F. The content of websites, scientific articles and other sources referenced on these pages are not incorporated by reference into this Form 20-F.

	Page(s) in the Annual Report
Management Discussion and Analysis	1-3
Management review	1-3
Introducing Novo Nordisk Performance and outlook	4-6
Pipeline overview	10-21
Our business	20-21
Risk management enabling better decision-making	22-39
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## ITEM 19 EXHIBITS

## b. Exhibits

## List of exhibits:

Exhibit No.	Description	Method of filing
<u>1.1</u>	Articles of Association of Novo Nordisk A/S	Incorporated by reference to the Registrant's Report furnished to the SEC on Form 6-K on April 24, 2018.
<u>8.1</u>	Companies in the Novo Nordisk Group	Incorporated by reference to page 94 of our Annual Report 2018 filed on Form 6-K dated February 4, 2019.
<u>12.1</u>	Certification of Lars Fruergaard Jørgensen, President and Chief Executive Officer of Novo Nordisk, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed together with this Form 20-F 2018
<u>12.2</u>	Certification of Karsten Munk Knudsen, Executive Vice President and Chief Financial Officer of Novo Nordisk, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed together with this Form 20-F 2018
<u>13.1</u>	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed together with this Form 20-F 2018
<u>15.1</u>	Extracts from Registrant's Annual Report for the fiscal year ended December 31, 2018	Incorporated by reference to the portions of Registrant's Report furnished to the SEC on Form 6-K on February 4, 2019 identified in Item 19.a of this Form 20-F.
<u>15.2</u>	Extracts from Registrant's Annual Report for the fiscal year ended December 31, 2017	Incorporated by reference to the portions of the Registrant's Report furnished to the SEC on Form 6-K on February 8, 2018 identified in Item 19.a of the Form 20-F filed on February 8, 2018.
<u>15.3</u>	Consent of independent registered public accounting firm.	Filed together with this Form 20-F 2018
<u>EX-101.INS</u>	XBRL Instance Document	Incorporated by reference to the Registrant's Report furnished to the SEC on Form 6-K on February 4, 2019.
<u>EX-101.SCH</u>	XBRL Taxonomy Extension Schema Document	Incorporated by reference to the Registrant's Report furnished to the SEC on Form 6-K on February 4, 2019.

EX-101.CAL XBRL Taxonomy Extension Calculation Linkbase Document Incorporated by reference to the Registrant's Report furnished to the SEC on Form 6-K on February 4, 2019.

EX-101.DEF XBRL Taxonomy Extension Definition Linkbase Document Incorporated by reference to the Registrant's Report furnished to the SEC on Form 6-K on February 4, 2019.

EX-101.LAB XBRL Taxonomy Extension Labels Linkbase Document Incorporated by reference to the Registrant's Report furnished to the SEC on Form 6-K on February 4, 2019.

EX-101.PRE XBRL Taxonomy Extension Presentation Linkbase Document Incorporated by reference to the Registrant's Report furnished to the SEC on Form 6-K on February 4, 2019.

Report of Independent Registered Public Accounting Firm  
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Novo Nordisk A/S

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Novo Nordisk A/S and its subsidiaries (the "Company") as of December 31, 2018 and December 31, 2017, and the related consolidated income statements, statements of comprehensive income, equity statements and cash flow statements for each of the three years in the period ended December 31, 2018, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and December 31, 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the Report of Novo Nordisk Management on Internal Control Over Financial Reporting appearing under Item 15 of this Form 20-F. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers  
Statsautoriseret Revisionspartnerselskab  
Hellerup, Denmark  
February 1, 2019

We have served as the Company's auditor since 1982.



SIGNATURES  
SIGNATURES

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this Annual Report on its behalf.

NOVO NORDISK A/S

/s/ Lars Fruergaard Jørgensen

Name: Lars Fruergaard Jørgensen

Title: President and Chief Executive Officer

/s/ Karsten Munk Knudsen

Name: Karsten Munk Knudsen

Title: Executive Vice President and Chief Financial Officer

Bagsværd, Denmark

Dated: February 4, 2019

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