

NOVO NORDISK A S  
Form 20-F  
February 10, 2016

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

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**FORM 20-F**

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(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, 2015

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

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**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)

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**Novo Allé**

**DK-2880 Bagsværd**

**Denmark**

**(Address of principal executive offices)**

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Tel: +45 4444 8888

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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, each representing one B share	New York Stock Exchange

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\* 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: 2,062,564,000

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes  No

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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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files).

Yes  No

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

Large accelerated filer  Accelerated filer  Non-accelerated  
filer

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

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

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.

Throughout this Form 20-F the Company incorporates information on the various items by reference to its *Annual Report 2015* and *Annual Report 2014*. Therefore the information in this Form 20-F should be read in conjunction with our *Annual Report 2015* and *Annual Report 2014*, which were furnished to the SEC on Form 6-K on February 10, 2016 and on February 5, 2015, 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

statements regarding the assumptions underlying or relating to such statements.

With reference to our *Annual Report 2015* and *Annual Report 2014*, examples of forward-looking statements can be found under the headings, ‘2015 performance and 2016 outlook’ in our *Annual Report 2015* and ‘2014 performance and 2015 outlook’ in our *Annual Report 2014*, 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 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 recall, 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.

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 substantially all 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 the Company, 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.

**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**

Selected financial data

IFRS figures in DKK millions, except share and American Depositary Receipts ('ADR') data	2015	2014	2013	2012	2011
Net sales	107,927	88,806	83,572	78,026	66,346
Operating profit from continuing operations	49,444	34,492	31,493	29,474	22,374
Operating profit	49,444	34,492	31,493	29,474	22,374

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Net profit from continuing operations	34,860	26,481	25,184	21,432	17,097
Net profit	34,860	26,481	25,184	21,432	17,097
Earnings per share/ADR	13.56	10.10	9.40	7.82	6.05
Total assets	91,799	77,062	70,337	65,669	64,698
Net assets	46,969	40,294	42,569	40,632	37,448
Capital stock	520	530	550	560	580
Treasury stock	(10 )	(11 )	(21 )	(17 )	(24 )
Dividends per share/ADR*	6.40	5.00	4.50	3.60	2.80
Dividends per share/ADR in USD*	0.94	0.82	0.83	0.64	0.49
Diluted earnings per share/ADR	13.52	10.07	9.35	7.77	6.00
Number of shares (million)	2,600	2,650	2,750	2,800	2,900

\*) Proposed dividend per share. For USD translation the exchange rate at December 30, 2015 from Danmarks Nationalbank (The Central Bank of Denmark) is used (USD 1 = DKK 6.83)

Reference is made to ‘Consolidated financial, social and environmental statements 2015’, pages 55-104 in our *Annual Report 2015* for further data.

#### Exchange rates

The following tables set forth, for the calendar periods indicated, certain information concerning Danmarks Nationalbank’s daily official exchange rates for U.S. dollars in terms of Danish kroner expressed in DKK per USD 1.00. These rates closely approximate the noon buying rate for Danish kroner for cable transfers in New York City as announced by the Federal Reserve Bank of New York for customs purposes on the relevant dates.

Month	<u>High</u>	<u>Low</u>
August 2015	6.86	6.49
September 2015	6.70	6.53
October 2015	6.82	6.52
November 2015	7.05	6.76
December 2015	7.04	6.79
January 2016	6.95	6.83
February 2016 (through February 2)	6.86	6.83

Year	<u>Average rate</u>	<u>Period end rate</u>	<u>High</u>	<u>Low</u>
2011	5.36	5.75	5.77	5.01
2012	5.80	5.66	6.15	5.53
2013	5.62	5.41	5.84	5.40
2014	5.62	6.12	6.12	5.35
2015	6.73	6.83	7.08	6.18

On February 2, 2016, the latest available date, the Danmarks Nationalbank's daily official exchange rate was 6.83.

#### Capitalization and indebtedness

Not applicable.

#### Reasons for the offer and use of proceeds

Not applicable.

#### Risk factors

For information on risk factors, reference is made to our *Annual Report 2015* 'Managing risks' on pages 42-43. In addition to the risks included in 'Managing risks' in our *Annual Report 2015*, 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. Such risks include the risk that our IT security set-up may not prevent all forms of unauthorized access to our computer network systems for purposes of misappropriating assets, trade secrets or sensitive information, and the risks arising

from current macro-economic conditions including the impact of fiscal austerity measures on our customers.

PCAOB inspection of our independent auditors

With Novo Nordisk being a public company listed in the United States, our independent public accounting firm, PricewaterhouseCoopers, Statsautoriseret Revisionspartnerselskab, is registered with the Public Company Accounting Oversight Board (“PCAOB”) and therefore required to undergo regular PCAOB inspections to assess the registered accounting firm’s compliance with United States law and professional standards in connection with its audits of financial statements filed with the SEC.

ITEM 4 INFORMATION ON THE COMPANY

History and development of the company

Novo Nordisk 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 were established in 1925 by Harald and Thorvald Pedersen. The business of both companies from the beginning 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. In March 2015 a successful initial public offering of NNIT A/S, an international IT service provider, was completed whereby, Novo Nordisk A/S divested 74.5% of its 100% interest held in NNIT A/S. Following the initial public offering, a non-recurring net gain of DKK 2,376 million was recognized in the income statement for 2015.

Novo Nordisk's B shares are listed on Nasdaq Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO).

Legal name: Novo Nordisk A/S  
Commercial name: Novo Nordisk  
Domicile: Novo Allé, DK-2880  
Bagsværd, Denmark  
Tel: +45 4444 8888  
Fax: +45 4449 0555  
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 2015**

Reference is made to 'Accomplishments and results 2015', pages 1-15 in our *Annual Report 2015* for a description of important events in 2015.

### **Capital expenditure in 2015, 2014 and 2013**

The total net capital expenditure for property, plant and equipment was DKK 5.2 billion in 2015 compared with DKK 4.0 billion in 2014 and DKK 3.2 billion in 2013. Net capital expenditure was primarily related to investments in additional insulin filling capacity, expansion of the manufacturing capacity for biopharmaceutical products and the construction of new research facilities. The investments were financed from cash flow from operating activities. Apart from the divestment of NNIT A/S, no significant divestments took place in the period from 2013–2015.

Novo Nordisk expects to invest approximately DKK 7.0 billion in fixed assets in 2016. The expected level of investments in 2016 is primarily related to investments in an expansion of the manufacturing capacity for biopharmaceutical products, additional capacity for active pharmaceutical ingredient production within diabetes care, an expansion of the insulin filling capacity and construction of new research facilities. Investments, which we expect will be financed from cash flow from operating activities, are also planned across the facilities to ensure continued compliance with the U.S. Food and Drug Administration (the "FDA") requirements.

Public takeover offers in respect of the Company's shares

No such offers occurred during 2015 or 2016 to date.

### 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 insulins, a full portfolio of modern insulins as well as a human once-daily GLP-1 analog. In addition, Novo Nordisk also has a leading position within haemophilia care, growth hormone therapy and hormone replacement therapy, and Novo Nordisk's first product to treat obesity, Saxenda<sup>®</sup>, was launched in the United States in April 2015 and is now also available in Denmark, Italy and Canada. 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 41,000 employees in 75 countries and markets its products in more than 180 countries.

Reference is made to the section ‘Our business’ on pages 16-43 in our *Annual Report 2015*.

### **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 care and (ii) biopharmaceuticals. The diabetes and obesity care segment covers insulins, GLP-1, other protein-related products (such as glucagon, protein-related delivery systems and needles), oral anti-diabetic drugs and obesity. 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. The most important markets are North America, China, Japan and the major European countries. In addition there is an increasing contribution to Novo Nordisk’s total sales from key markets in the sales region International Operations such as Saudi Arabia, Algeria, Turkey, Argentina, Australia, India, Brazil, Iran and Russia.

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 2015, payers globally have managed the cost of diabetes care by exerting pressure on the prices of Novo Nordisk's products and competitors have tried to capture market share from Novo Nordisk. In spite of this, Novo Nordisk has been able to maintain the leading position in the overall diabetes care market through the quality and innovative value of the company's diabetes care products. Certain price sensitive customers, predominantly in the United States have exerted price pressures that have impacted the overall value of the market.

The Company enters into numerous contracts with customers, suppliers, agents and industry partners. Some of the most important contracts include: commercial contracts with 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.



The roll-out of Tresiba® (insulin degludec), the once-daily new-generation insulin, continues and the product has now been launched in 39 countries including the United States with initial encouraging market access and Spain. In Japan, where Tresiba® was launched in March 2013 with the same level of reimbursement as insulin glargine, its share of the basal insulin market has grown steadily, and Tresiba® has captured 33% of the market (26% in 2014) measured in monthly value market share. Similarly, Tresiba® has shown solid penetration in other markets with reimbursement at a similar level to insulin glargine, whereas penetration remains modest in markets with restricted market access compared to insulin glargine. Novo Nordisk ceased distribution of Tresiba® in Germany in January 2016 as a result of the negative outcome from price negotiations with the National Association of Statutory Health Insurance Funds (GKV-SV).

Ryzodeg®, a soluble formulation of insulin degludec and insulin aspart, was recently launched in Japan as the third market, following launches in Mexico and India. Launch activities are progressing as planned and early feedback from patients and prescribers is encouraging.

## 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 'Consolidated social statement' on page 96 in our *Annual Report 2015*.

In addition to the compound patents discussed in 'Consolidated social statement' on page 100 in our *Annual Report 2015*, Novo Nordisk's key delivery devices are protected by several patents of which the first will expire in January 2019.

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. Note that in addition to the compound patents mentioned, Novo Nordisk has, like other companies engaged in production based upon recombinant DNA technology, obtained licenses under various patents which entitle Novo Nordisk to use processes and methods of manufacturing covered by such patents.

Sales of key products with recent or upcoming patent expiration:

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Product	NovoLog®/ NovoRapid®	NovoLog® mix / NovoMix®	Prandin®/ NovoNorm®	NovoSeven®	Norditropin®
Total sales in 2015 (in DKK million)	20,720	11,144	1,688	10,064	7,820
Geographical split:					
North America	61	% 25	% 2	% 50	% 46
Europe	21	% 20	% 10	% 21	% 22
International Operations	10	% 22	% 8	% 22	% 15
Region China	4	% 27	% 77	% 2	% 0
Japan & Korea	4	% 6	% 3	% 5	% 17

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*Patent situation of key diabetes care products*

The total sales of NovoLog<sup>®</sup>/NovoRapid<sup>®</sup> were DKK 20,720 million in 2015 (DKK 17,449 million in 2014). The drug 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 drug compound patent, Novo Nordisk holds a formulation patent on NovoLog<sup>®</sup>/NovoRapid<sup>®</sup>, which provides coverage until June 2017 in all major markets.

The total sales of NovoLog<sup>®</sup> Mix /NovoMix<sup>®</sup> were DKK 11,144 million in 2015 (DKK 9,871 million in 2014). The drug compound patent for NovoLog<sup>®</sup> Mix /NovoMix<sup>®</sup> has expired in most countries. In Japan the drug compound patent expired in June 2014, in the United States the drug compound patent expired in December 2014 and in Europe the drug compound patent expired on a country-by-country basis throughout 2014 and continued to do so in 2015. In addition, Novo Nordisk holds a formulation patent on NovoLog<sup>®</sup> Mix /NovoMix<sup>®</sup> in the United States, which provides coverage until June 2017.

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 also 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. However, we believe that the formulation patent for NovoLog<sup>®</sup>/NovoRapid<sup>®</sup> in all major markets and for NovoLog<sup>®</sup> Mix /NovoMix<sup>®</sup> in the United States makes it challenging to develop a biosimilar version of these compounds without infringing Novo Nordisk's intellectual property. Therefore, we do not anticipate that the expiry of our original compound NovoLog<sup>®</sup>/NovoRapid<sup>®</sup> and NovoLog<sup>®</sup> Mix /NovoMix<sup>®</sup> patents will have a significant near-term impact on sales, results of operations and liquidity.

The total sales of Prandin<sup>®</sup>/NovoNorm<sup>®</sup>, an oral antidiabetic drug, were DKK 1,688 million in 2015 (DKK 1,620 million in 2014) and together with other oral antidiabetic products of DKK 134 million in 2015 (DKK 108 million in 2014), the total sales of all oral antidiabetic products (OAD) were DKK 1,822 million in 2015 (DKK 1,728 million in 2014). Prandin<sup>®</sup>/NovoNorm<sup>®</sup> is no longer protected as the drug compound patent has expired in all key markets.

In Europe, generic copies of NovoNorm<sup>®</sup> were first introduced in Germany in 2010 and introductions of generic copies have subsequently been observed, e.g. in France, Italy, Spain and Belgium. During 2012, generic competition significantly reduced our European sales of NovoNorm<sup>®</sup> with most of the reduction, varying from country to country, occurring in the first 12 months following the introduction of generic competition. Our European sales of NovoNorm<sup>®</sup> continued to erode during 2015 due to generic competition, and we expect this trend to continue during 2016.

In the United States, generic copies of Prandin<sup>®</sup> were approved in July 2013 from respectively Caraco and Paddock, and Novo Nordisk has since then and throughout 2015 seen a significant decline in sales of Prandin<sup>®</sup> in the United States.

In China, NovoNorm<sup>®</sup> has been exposed to generic competition for several years without significantly impacting our sales. Therefore, we do not expect a significant decline in NovoNorm<sup>®</sup> sales in China in the short term due to generic competition.

*Patent situation of key biopharmaceuticals products*

The total sales of NovoSeven<sup>®</sup> were DKK 10,064 million in 2015 (DKK 9,142 million in 2014). While the drug compound patent for NovoSeven<sup>®</sup> has expired in all major markets, Novo Nordisk holds two formulation patents on the room temperature stable preparation of NovoSeven<sup>®</sup>, which provides coverage of this formulation until 2023 and 2024, respectively, in all major markets.

The expiry of the drug compound patent has had limited impact on sales of NovoSeven<sup>®</sup> due to the complexity relating to the regulatory pathways for 'biosimilar' coagulation factors in the United States, the EU and Japan.

The U.S. Health Care Reform includes the establishment of a regulatory pathway for approving biosimilar versions of originator proteins. Therefore, in the future, a biosimilar version of rFVIIa could be submitted to the FDA as a Biologics License Application ('BLA') under 351(k) of the U.S. Public Health Service Act and be approved if it fulfills the requirements, i.e. that the product is 'biosimilar' to its reference product and that no clinically meaningful differences between the products in terms of safety, purity and potency are seen.

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 and Iran. There is to date no information available 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 in the near term on sales, results of operations and liquidity in all geographical segments.

Total sales of Norditropin® were DKK 7,820 million in 2015 (DKK 6,506 million in 2014). Today, Norditropin® is not covered by a drug compound patent. However, the formulation used is covered by a formulation patent that expires in 2017 in the United States, Europe and Japan. Furthermore, 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 as well as patient support programs offered by Novo Nordisk. Consequently, Novo Nordisk has been able to increase its sales in the United States in 2015. Therefore we believe that the expiry of our compound patent for Norditropin® will continue to have an insignificant impact in the near term on sales, results of operations and liquidity in all geographical segments.

#### 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 FDA, 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, Novo Nordisk is obliged to provide disclosure if, during 2015, 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.

As a global organization, Novo Nordisk conducts business with customers in Iran, including the Government of Iran (the "GOI"). Novo Nordisk's activities in Iran relate primarily to sales of pharmaceutical products and devices within the diabetes and obesity care and biopharmaceutical business segments.

In 2015, Novo Nordisk A/S provided a small amount of diabetes product free of charge to Exir Pharmaceutical Co. (“Exir”), a GOI-controlled company. In addition, in 2015, Novo Nordisk entered into a memorandum of understanding with the Food and Drug Administration, an agency within the Ministry of Health and Medical Education of Islamic Republic of Iran, pursuant to which Novo Nordisk will invest approximately EUR 70 million over the course of five years to build a manufacturing facility in Iran. The facility will facilitate the production of insulin pens for use in Iran. There were no revenues or net profits to Novo Nordisk in 2015 in connection with this project.

Novo Nordisk Pars (“NN Pars”), a wholly-owned subsidiary of Novo Nordisk A/S located in Iran, contracts with four GOI-controlled companies (Exir, Ferdows Distribution Co., Darou Pakhsh Distribution Co. and Hedjat Distribution Co.) 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 are owned by the GOI and/or are designated under Executive Order 13224 or Executive Order 13382) relating to the sales of pharmaceutical products and devices.

The German subsidiary of NNE Pharmaplan A/S, a wholly-owned subsidiary of Novo Nordisk A/S, has a contract with SOHA Helal Iran Medical Devices Co., a GOI-controlled company, to provide raw materials and spare parts for production of dialysis and leucocyte filters and syringes.

Novo Nordisk's gross revenue related to transactions with GOI-owned or controlled entities in 2015 were not in excess of DKK 750 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 2015.

In addition, Novo Nordisk conducts business with customers in the Crimea Region, Syria, Sudan and Cuba. These activities relate to sales of pharmaceutical products and devices within the diabetes and obesity care and biopharmaceutical business segments. Gross revenue related to transactions 2015 was not in excess of DKK 80 million in any of the four areas. Novo Nordisk estimates that their net profits attributable to the transactions with the Crimea Region, Syria, Sudan and Cuba would represent an even smaller de minimis percentage of the Group's total net profit in 2015.

The purpose of Novo Nordisk's Iran, Crimea, Syria, Sudan and Cuba-related activities is to provide access to important and life-saving pharmaceutical products such as insulins and haemophilia products to patients in these countries, and to improve the healthcare of the Iranian, Crimean, Syrian, Sudanese and Cuban people in accordance with a key component of Novo Nordisk's access to care strategy. For that purpose, Novo Nordisk intends to continue these activities.

#### Organizational structure

For information regarding the organizational structure and securities exchange listings of Novo Nordisk A/S, the parent company Novo A/S and the Novo Nordisk Foundation and the ownership structure, reference is made to the sections 'Corporate governance' on pages 46-48 and 'Shares and capital structure' on pages 44-45 in our *Annual Report 2015*.

Companies in the Novo Nordisk Group are listed in the Company's *Annual Report 2015* on page 93, 'Companies in the Novo Nordisk Group.'

#### 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>, as well as Tresiba<sup>®</sup> and Ryzodeg<sup>®</sup>, Xultophy<sup>®</sup>, Saxenda<sup>®</sup>, NovoEight<sup>®</sup>, Norditropin<sup>®</sup> and devices. Reference is made to the sections ‘Capital expenditures in 2015, 2014 and 2013’ 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, 2015 and 2014, reference is made to Note 3.2 ‘Property, plant and equipment’ in our *Annual Report 2015*.

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 31 years.



Active pharmaceutical ingredient (API) production is located in Denmark, primarily in Kalundborg and with secondary locations in Hillerød, Bagsværd and Gentofte whereas two API production sites in the United States are being established.

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

<b>Major Production Facilities</b>	<b>Size of production area (square meters)</b>	<b>Major Production Activities</b>
		Active pharmaceutical ingredients for diabetes and products for diabetes.
Kalundborg, Denmark	187,200	Active pharmaceutical ingredients for haemophilia.
		Products for biopharmaceutical.
Bagsværd, Denmark	122,600	Products for diabetes. Durable devices and components for disposable devices.
Hillerød, Denmark	94,500	Products for diabetes.
		Active pharmaceutical ingredients for haemophilia.
Tianjin, China	68,500	Products for diabetes. Production of durable devices.
		Active pharmaceutical ingredients for glucagon and growth hormone therapy.
Gentofte, Denmark	68,500	Products for growth hormone therapy, glucagon and haemophilia.
		Products for diabetes.
Montes Claros, Brazil	58,700	Gel production for active pharmaceutical ingredients.
Chartres, France	47,600	Products for diabetes.
		Products for hormone replacement therapy.
Måløv, Denmark	37,200	Products for oral antidiabetes treatment.
Clayton, North Carolina, United States	34,200	Products for diabetes.
Køge, Denmark	16,000	Gels and enzymes for active pharmaceutical ingredient production.

Kaluga, Russia	15,600	Products for diabetes.
Hjørring, Denmark	13,900	Production of needles.
Koriyama, Japan	11,000	Packaging of products for the Japanese market.
Værløse, Denmark	6,900	Products for growth hormone therapy.
Tizi Ouzou, Algeria	6,600	Products for oral antidiabetes treatment.

In addition to the active production sites listed above, Novo Nordisk acquired a production plant in New Hampshire, United States in August 2014. The new facility will increase production capacity of active pharmaceutical ingredients for the portfolio of biopharmaceuticals, and is expected to be operational in 2018. The production area of the facility is 14,800 square meters. The expected amount of investments for this new facility is approximately DKK 800 million. The facility is financed by cash flow from operating activities.

In May 2015, Novo Nordisk initiated the construction of a new facility in Kalundborg, Denmark for producing active pharmaceutical ingredients for NovoSeven® and future products for treating 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 1,500 million. 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 2,100 million. The facility is financed by cash flow from operating activities.

In August 2015, Novo Nordisk announced plans to invest an estimated DKK 12 billion in a diabetes API production facility in Clayton, North Carolina, United States. The facility is expected to be ready for use in 2020. The facility will be financed by cash flow from operating activities.

#### 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 2015*.

##### new accounting pronouncements

Reference is made to Note 1.2 'Changes in accounting policies and disclosures' in our *Annual Report 2015*.

##### 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 2015* 'Managing risks' on pages

42-43.

The financial condition of the Group and its development are described in our *Annual Report 2015* and our *Annual Report 2014*. 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 Standard Board (IASB) as well as in accordance with IFRS as endorsed by the European Union.

#### **2015 compared with 2014**

The following portions of our *Annual Report 2015* constitute the Board of Directors' and Executive Management's discussion and analysis of results of operations (incorporated herein by reference):

'Accomplishments and results 2015' (pages 1-15)

#### **2014 compared with 2013**

The following portions of our *Annual Report 2014* constitute the Board of Directors' and Executive Management's discussion and analysis of results of operations (incorporated herein by reference):

'Accomplishments and results 2014' (pages 1-15)

## **Segment information**

Reference is made to Note 2.2 'Segment information' in our *Annual Report 2015* 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 2015* 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 2015*.

## **Governmental policies**

Please refer to pages 16-43 'Our business' in our *Annual Report 2015* and Item 4.

## **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.

## **Financial resources**

Reference is made to page 57 'Balance sheet' and page 58 'Statement of cash flows for the year ended 31 December' in our *Annual Report 2015*. 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 2015, 2014 and 2013**

Reference is made to page 58 'Statement of cash flows for the year ended 31 December' in our *Annual Report 2015*.

The most significant source of cash flow from operating activities is sales of diabetes and obesity care and biopharmaceutical products. Generally, other factors that affect operating earnings, such as pricing, volume, 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.

### **Trade receivable program**

Trade receivable program, as of December 31, 2015, 2014 and 2013, respectively, are shown in Note 4.2 'Financial risks' in our *Annual Report 2015*.

### **Debt financing**

No long-term loans were outstanding as of December 31, 2015 or 2014. Reference is made to page 57 'Balance sheet and 'Note 4.7 'Financial assets and liabilities' in our *Annual Report 2015* for information on Current debt.

### **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 2015* for further information on financial instruments including currency structure.

### **Commitments for capital expenditure etc.**

Contractual obligations for capital expenditure and other contingent liabilities as of December 31, 2015 and 2014, respectively, are shown in Note 5.3 'Commitments' in our *Annual Report 2015*.

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.

### **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 focus of Novo Nordisk's research and development is on therapeutic proteins within diabetes, obesity, haemophilia and growth disorders.

Reference is made to note 2.3 'Research and development costs' in our *Annual Report 2015* for Research and development costs in 2015, 2014 and 2013, respectively. Novo Nordisk's research and development organization comprised approximately 7.700 employees as of December 31, 2015.

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 expect to continue an expenditure level of around 12-14% of sales in research and development activities going forward.

The development projects that accounted for the highest research and development spend in 2015 were related to Tresiba® for the cardiovascular outcome trial for Tresiba® (DEVOTE) and the phase 3a development program for Semaglutide and the phase 3b program for Xultophy.

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 2015*.

Information related to selected research and development projects can be found under 'Pipeline overview' on pages 20-21 in our *Annual Report 2015*. Furthermore, a broader overview of our business activities can be found on pages 16-43 'Our business'.



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

<b>Compound / Brand name / Indication</b>	<b>Year entered into phase 3 or filed with the regulatory authorities</b>	<b>Patent expiration</b>
IDegLira (NN9068) / Xultophy® / Type 2 diabetes	Phase 3 completed in 2013. United States: Filed for regulatory review in September 2015.	2030 <sup>1</sup>
Semaglutide (NN9535) / Type 2 diabetes	EU: Approved September 18, 2014 Phase 3 started in 2013 Phase 3 completed in 2015.	2031 <sup>2</sup>
Faster-acting insulin aspart (NN1218) / Type 1 & 2 diabetes	United States: Filed for regulatory review December, 2015.  EU: Filed for regulatory review December, 2015. Phase 3 completed in 2013.	2030 <sup>3</sup>
N9-GP (NN7999) / Haemophilia B	United States: Filing for regulatory review expected in the first half of 2016.  EU: Filed for regulatory review January 2016. Phase 3 completed in 2014.	2027 <sup>2</sup>
N8-GP (NN7088) / Haemophilia A	Filing for regulatory review in the United States and EU expected around 2018.	2032 <sup>4</sup>
NN8640 Once-weekly human growth hormone / Growth disorder	Phase 3 in AGHD started in 2014	2034 <sup>5</sup>

<sup>1</sup> Current estimate United States. EU estimate 2028, Japan expiry 2027

<sup>2</sup> Current estimate

<sup>3</sup> Formulation patent (compound patent has expired)

<sup>4</sup> Current estimate United States. EU estimate 2034, Japan expiry 2034

<sup>5</sup> Current estimate United States. EU estimate 2035, Japan expiry 2035

During 2015 Novo Nordisk has discontinued one development project in phase 3: LATIN T1D (NN9211). This project was investigating the use of liraglutide in type 1 diabetes.

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 the ‘Managing risks’ on pages 42-43 in our *Annual Report 2015*, 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 2015 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 care group and biopharmaceuticals group.

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

### **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 642 million by 2040 from 387 million in 2015. Diabetes and obesity care is Novo Nordisk's largest segment comprising approximately 79% 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 care segment. Further, the roll-out of a number of new products within diabetes and obesity care (Tresiba<sup>®</sup>, Ryzodeg<sup>®</sup>, Xultophy<sup>®</sup> and Saxenda<sup>®</sup>) is expected to be a significant driver of performance.

The other segment of Novo Nordisk is biopharmaceuticals, which comprise haemophilia care, growth hormone therapy and hormone replacement therapy. Sales of haemophilia care products continued to increase in 2015, primarily driven by the roll-out of NovoEight<sup>®</sup> in Europe, Japan and the United States. The growth hormone therapy franchise benefited from increasing sales of the liquid formulation Norditropin<sup>®</sup>, delivered in ready-to-use prefilled devices. Sales of the hormone replacement therapy product Vagifem<sup>®</sup> increased in 2015. However, starting 2016, a decline in the sales of Vagifem<sup>®</sup> is expected due to the loss of exclusivity for the sale of Vagifem<sup>®</sup> in the United States from fourth quarter of 2016.

For further information on trends, reference is made to the section ‘Accomplishments and results 2015’ on pages 1-15 in our *Annual Report 2015*. Information about expectations for the financial year 2016 can be found on page 8 in the subsection ‘Outlook 2016.’

#### **OFF-BALANCE SHEET ARRANGEMENTS**

Reference is made to Note 4.2 ‘Financial risks’ and Note 5.3 ‘Commitments’ in our *Annual Report 2015*.

#### **TABULAR DISCLOSURE OF CONTRACTUAL OBLIGATIONS**

Reference is made to Note 5.3 ‘Commitments’ in our *Annual Report 2015*.

### ITEM 6 DIRECTORS, EXECUTIVE MANAGEMENT AND EMPLOYEES

#### **Directors and EXECUTIVE Management**

Reference is made to pages 52-53 in our *Annual Report 2015* for name, position and period of service as director for the members of the Board of Directors.

Reference is made to page 54 in our *Annual Report 2015* for name, position, age, year of appointment and year of joining Novo Nordisk for the members of Executive Management.

The Board of Directors has the overall responsibility for the affairs of the Company. Reference is made to pages 46-48 in our *Annual Report 2015*.

The activities of the members of Board of Directors and members of Executive Management outside the Company are included in our *Annual Report 2015* on pages 52-54.

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.

### Compensation

Reference is made to the section 'Remuneration' on page 49-51 and Notes 5.1 and 5.2 in our *Annual Report 2015* regarding compensation.

### Board practices

Reference is made to 'Corporate governance' on pages 46-48 in our *Annual Report 2015* regarding board practices. The year of election for each member of the Board of Directors and each member of Executive Management is included in our *Annual Report 2015* on pages 52-54.

### Employees

Reference is made to the section entitled 'Employees' on page 11 and 'Performance highlights' on page 15 in our *Annual Report 2015* regarding the total number of full-time employees in Novo Nordisk at year-end for the years 2011–2015.

Employees	2015	2014	2013
Employees outside Denmark as a percentage of total number of employees	58%	57%	58%

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.

#### Share ownership

For information on the Board of Directors' and Executive Management's individual holdings of share options and granting of shares, reference is made to the section 'Remuneration' on page 49-51 and Note 5.2 'Management's holdings of Novo Nordisk shares' in our *Annual Report 2015*. 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 2015, reference is made to the section 'Remuneration' on page 49-51 and Note 5.2 'Management's holding of Novo Nordisk shares' in our *Annual Report 2015*. As of February 2, 2016 the Board of Directors and Executive Management owned 1,319,148 B shares.

In the period from January 1, 2016 until February 3, 2016, 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 3, 2016, the Executive Management received 168,105 B shares in accordance with the long-term incentive program and a total of 79,335 B shares were sold, hence as of February 3, 2016, the Board of Directors and Executive Management owned 1,407,918 B shares.

To commemorate that the turnover of the group passed DKK 100 billion for the first time in 2015 all employees in the Company (excluding NNE Pharmaplan and Steno Diabetes Center A/S) as per January 1, 2016 were offered 50 restricted stock units. A restricted stock unit gives the holder the right to receive one Novo Nordisk B-share free of charge in February 2019 subject to continued employment.

It is estimated that 1,500,000 shares will be needed for the program. No dividends will be paid on the restricted stock units and the holders will have no voting rights until the restricted stock units are converted to shares in February 2019.

Reference is made to Note 5.1 'Share based payment schemes' in our *Annual Report 2015*.

## ITEM 7 MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

### Major Shareholders

The total share capital of the Company is split in 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. Treasury shares have no votes at the Annual General Meeting.

All of the A shares of the Company are held by Novo A/S, a wholly-owned subsidiary of the Novo Nordisk Foundation (the 'Foundation'). As of December 31, 2015, the A shares represented approximately 73% 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 A/S, and to support medical research and other scientific, humanitarian and social objectives.

The purpose of Novo 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 Governors, 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 Governors are typically nominated by the chairman 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 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 A/S is governed by a Board of Directors, which must be comprised of at least three and not more than six 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 A/S's Board of Directors. Novo A/S's Board of Directors currently has five members, with two directors who are also members of the Board of the Foundation (Sten Scheibye and Steen Risgaard) and two directors who are also members of the Board of Directors of Novo Nordisk A/S (Göran Ando and Jeppe Christiansen). The Chairman of the Foundation's Board of Governors (Sten Scheibye) serves as the Chairman of Novo A/S's Board of Directors. In addition, the Chief Executive Officer of Novo A/S is also a member of the Board of Directors of Novo Nordisk A/S (Eivind Kolding).

According to the statutes, the Foundation, in exercising its voting rights through Novo A/S at Novo Nordisk A/S's General Meetings, must vote with regard for what is in Novo Nordisk's best interest. A shares held by Novo 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 Governors. Other changes in the Foundation's statutes require the approval of two-thirds of the members of the Foundation's Board of Governors. 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 A/S.

For further information reference is made to 'Shares and capital structure' on pages 44-45 in our *Annual Report 2015* and to 'Shares and capital structure' on pages 44-45 in our *Annual Report 2014*.

The B shares of the Company are registered with Værdipapircentralen ('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 February 2, 2016 with respect to (a) any shareholder who is known to the Company to be the owner of more than 5% of any class of the Company's securities and (b) the total amount of any class owned by Novo Nordisk A/S and its affiliates (treasury shares) and by the directors and Executive Management as a group:

<u>Title of class</u>	<u>Identity of person or group</u>	<u>Shares owned</u>	<u>Percent of class</u>	<u>Percent of total votes</u>
A shares	Novo A/S	537,436,000*	100.00	72.8
B shares	Novo A/S	163,814,000	7.94	2.2
B shares	Novo Nordisk A/S and subsidiaries (treasury shares)	56,325,667	2.73	0.00
B shares	Board of Directors and Executive Management	1,319,148**	0.06	0.02

\*) 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.

\*\*\*) As of February 3, 2016 the shares owned by Board of Directors and Executive Management was 1,407,918 (corresponding to 0.07 percent of class and 0.2 percent of total votes).

In 2013 and 2014, shares with an aggregate purchase price of DKK 14.0 billion and DKK 15.0 billion, respectively, were repurchased under the Company's share repurchase program.

In January 2015, Novo Nordisk announced a new DKK 15.0 billion share repurchase program, which was increased by DKK 2.5 billion to DKK 17.5 billion in April 2015. Under this program and the previous share repurchase program completed in January 2015, 48,217,251 shares corresponding to DKK 16.0 billion were repurchased during 2015. The share repurchase program was completed in January 2016.

In February 2016, Novo Nordisk announced a new DKK 14.0 billion share repurchase program to be executed during the following 12 months.

After the shareholders' approval of the proposed reduction of the Company's share capital at the Annual General Meeting on March 19, 2015, 50,000,000 shares were canceled in April 2015, reducing the number of treasury shares accordingly.

As the B shares are in bearer form, it is not possible to give an accurate breakdown of the holdings and number of shareholders per country. It is, however, estimated that approximately 20% of the B share capital was held in Denmark as of December 31, 2015. Approximately 43% of the B share capital is estimated to be held in North America. The estimated total number of shareholders is more than 230,000 of whom more than 170,000 are estimated to be Danish residents and more than 50,000 to be resident in the United States.

#### Related Party Transactions

Related parties include the Novo Nordisk Foundation, Novo A/S, Novozymes A/S, Xellia Pharmaceuticals ApS (due to shared controlling shareholder, Novo A/S) and NNIT A/S being an associated company with shared controlled shareholding between Novo A/S and Novo Nordisk A/S. Novo Nordisk has access to certain assets of and can purchase certain services from Novo 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 2015, 2014 and 2013 were primarily payments for services provided between the Novo Nordisk Group and the Novozymes Group and transactions with associated companies. There have not been any material transactions with Xellia Pharmaceuticals ApS during this period. The overall financial impact of these related party transactions is limited.

As a result of the initial public offering of NNIT A/S on 6 March 2015, Novo Nordisk A/S disposed 74.5% out of the 100% interest held in NNIT A/S. Consequently, NNIT A/S has changed status from a subsidiary to 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' and Note 4.8 'Investment in associated company' in our *Annual Report 2015*.

Since December 31, 2015, there have been no significant transactions with related parties out of the ordinary course of business. For further information reference is made to Note 5.4 'Related party transactions' in our *Annual Report 2015* and Note 5.5 'Related party transactions' in our *Annual Report 2014*.

There have not been and are no loans to members of the Board of Directors or Executive Management in 2015, 2014 or 2013.

Interests of experts and counsel

Not applicable.

ITEM 8 FINANCIAL INFORMATION

Consolidated Statements and Other Financial Information

The financial statements required by this item accompany this annual report in the form of our *Annual Report 2015* (see Exhibit no. 15.1).

**Legal proceedings**

Reference is made to Note 3.6 'Provisions and contingent liabilities' in the Annual Report 2015 regarding legal proceedings.

**Dividends**

At the Annual General Meeting on March 18, 2016, the Board of Directors will propose a dividend of DKK 6.40 per share corresponding to a pay-out ratio of 46.6%. Adjusting for the impact from the divestment of shares in NNIT A/S, where the related cash flow was returned to shareholders via an expansion of the 2015 share repurchase program, the payout ratio will be 50.0%. For 2014, the pay-out ratio was 48.7%, whereas Novo Nordisk's peer group of comparable pharmaceutical companies operated with a pay-out ratio of around 54%. 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 2015*.

At the Annual General Meeting in March 2015, the Board was granted an authorization to distribute extraordinary dividends. Hence the Board of Directors has been given authority to pay biannual dividends without obtaining specific approval from the Annual General Meeting. Subject to final approval, Novo Nordisk intends to introduce the first

interim dividend in August 2016.

Significant changes

No significant events have occurred since the date of the annual financial statements. For description of important events and achievements in 2015, reference is made to 'Accomplishments and results 2015', on pages 1-15 in our *Annual Report 2015*.

ITEM 9 THE OFFER AND LISTING

**Offer and listing details**

The table below sets forth for the calendar periods indicated, in the first two columns, high and low prices for the B shares as reported by the Nasdaq Copenhagen and, in the third and fourth columns, high and low ADR prices as reported by the New York Stock Exchange.

	<u>DKK per B</u>		<u>USD per</u>	
	<u>share*</u>		<u>ADR*</u>	
	<b>High</b>	<b>Low</b>	<b>High</b>	<b>Low</b>
2011	140.60	101.40	26.58	18.92
2012	196.20	129.60	34.05	22.83
2013	220.00	169.60	38.89	29.90
2014	286.20	198.00	49.11	36.61
2015	415.00	260.70	60.34	41.72

#### **2014**

1st Quarter	265.30	198.00	48.42	36.61
2nd Quarter	256.50	226.20	46.55	42.08
3rd Quarter	285.00	239.30	49.11	43.83
4th Quarter	286.20	244.50	48.17	42.11

#### **2015**

1st Quarter	382.00	260.70	54.95	41.72
2nd Quarter	400.20	353.90	58.21	53.39
3rd Quarter	415.00	339.30	60.34	52.35
4th Quarter	403.30	346.00	59.00	52.61

August 2015	415.00	339.30	60.34	52.35
September 2015	392.00	357.30	57.30	52.76
October 2015	384.40	346.00	57.27	52.87
November 2015	390.50	360.00	56.09	52.61
December 2015	403.30	373.20	59.00	55.02
January 2016	406.70	352.50	58.16	51.56
February 1-2 2016	388.40	375.10	56.04	54.94

\*) Following the change in trading units as of January 2, 2014, all quotes for 2011 to 2013 are restated to reflect the new trading unit of DKK 0.2 per B share and a ratio of B shares to ADRs of 1:1.

Reference is made to our *Annual Report 2015* 'Shares and capital structure' on pages 44-45.

#### Plan of distribution

Not applicable.

#### 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 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 JP Morgan Chase Bank of New York, as the Depositary, have been listed on the New York Stock Exchange since 1981. As of December 31, 2015, 241,037,873 B share equivalents (representing 12% of the outstanding B shares, adjusted for the treasury shares) were held in the form of ADRs.



Selling shareholders

Not applicable.

Dilution

Not applicable.

Expenses of the issue

Not applicable.

ITEM 10 ADDITIONAL INFORMATION

Share capital

Not applicable.

Memorandum and articles of association

This section summarizes certain material provisions of Novo Nordisk A/S'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, socially, and environmentally 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 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 himself, or any business involving agreements between any member of the Group and any third party or legal actions brought against any third party, if he has a major interest therein that might conflict with Novo Nordisk A/S's interests. The Danish Companies Act also prohibits Novo Nordisk A/S from granting loans or providing securities to any member of the Board of Directors and anyone particularly close to such a member of the Board of Directors.

The remuneration of the Board of Directors must be approved by Novo Nordisk A/S'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 1/2% of the nominal share capital 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 the Company'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 the Company through a central securities depository and an account-holding bank to shareholders registered by VP Securities at the time of payment.



At the Annual General Meeting in March 2015, the Board of Directors was given authority to distribute extraordinary dividends. This authority has been included in the Articles of Association of Novo Nordisk A/S. Hence the Board of Directors has been given authority to pay biannual 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 authorised 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 the company. 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 the General Meeting. 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 A/S and according to the Articles of Association of Novo 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 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'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 in writing to all shareholders entered in the Register of Owners who have so requested and be advertised in the applicable system of the Danish Business Authority.

A shareholder's right to attend and vote at a General Meeting shall be determined by the shares which such shareholder owns at the record date. The record date shall be one week prior to the General Meeting. The shares held by each shareholder at the 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. Any shareholder who is entitled to attend the General Meeting as previously described and who wants 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.

### **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'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 A/S, veto power against any change of control.

### **Ownership disclosure**

According to the Danish Securities Trading Act, a shareholder of Novo Nordisk A/S must disclose their ownership if they own more than 5% of the voting rights or share capital. Also, shareholders must disclose changes in holdings if thresholds of 5%, 10%, 15%, 20%, 25%, 50% or 90% 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.

### **Material contracts**

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

### 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.

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.

### Taxation

#### **Danish Taxation**

The following summary outlines certain Danish tax consequences to U.S. Holders (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').

Until December 2015, a simplified withholding tax refund procedure was available for U.S. Holders of ADRs. Under the simplified refund procedure, U.S. Holders of ADRs that provided a properly completed Internal Revenue Service ('IRS') Form 6166 to the Depository would receive a refund from the Depository of the Excess Withholding Tax. The simplified procedure was cancelled by the Danish Tax Authorities in December 2015.

Any U.S. Holders of ADRs wishing to apply for a refund of Excess Withholding Tax after December 17, 2015 will have to apply for a refund under the generally applicable Danish withholding tax refund procedure. In addition to providing a Danish Claim for Refund of Danish Dividend Tax and an IRS Form 6166, the Danish Tax Authorities will require 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 (800) 929 5484 or +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. 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 political subdivision thereof, 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 10% or more of Novo Nordisk voting stock. 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.

#### *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, under proposed Treasury regulations, certain 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 foreign tax consequences of owning and disposing of ADRs or B shares in their particular circumstances.

Dividends and paying agents

Not applicable.

Statement by experts

Not applicable.

Documents on display

## Edgar Filing: NOVO NORDISK A S - Form 20-F

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.

Copies of the Form 20-F as well as our *Annual Report 2015* and *Annual Report 2014* 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. The Form 20-F is also filed and can be viewed via EDGAR on [www.sec.gov](http://www.sec.gov).

### 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 the 'Managing risks' on pages 42-43 in our *Annual Report 2015*.

#### 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 30, 2015.

#### **Interest rate sensitivity analysis**

For information on Interest rate sensitivity analysis in the financial year of 2015, reference is made to Note 4.2 'Financial risks' in our *Annual Report 2015*.

#### **Foreign exchange sensitivity analysis**

For information on Foreign exchange sensitivity analysis in the financial year of 2015, reference is made to Note 4.2 'Financial risks' and the 'Managing risks' on pages 42-43 in our *Annual Report 2015*.

## 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 DEPOSITORY SHARES

Novo Nordisk's ADR program is administered by J.P. Morgan Depositary Receipts Group as Depositary, JPMorgan Chase Bank, N.A., 4 One Chase Manhattan Plaza, New York, United States.

The ADRs are traded under the code NVO on the New York Stock Exchange and the underlying security is the Novo Nordisk B share, NOVOB on the 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. No fees are charged to the holders of the ADRs in relation to these procedures.

The holder of an ADR has to pay the following fees and charges related to services in connection with the ownership of the ADR:

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
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, 2015, the Depositary reimbursed USD 833,052 for costs related to investor relations programs and special investor relations promotional activities. The amounts the Depositary reimbursed are not related to the amount of fees collected by the Depositary from ADR holders.



## 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, 2015. Based on this evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that as of December 31, 2015, 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 and as endorsed by the European Union.

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, 2015, 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, 2015, 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, 2015 has been audited by PricewaterhouseCoopers, Statsautoriseret Revisionspartnerselskab, Denmark, an independent registered public accounting firm, as stated in their report which appears on page 44 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, 2015 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

The Audit Committee is comprised of four members and one non-voting observer elected by the Board of Directors. Two members qualify as independent as defined by the SEC. One member is designated as chairman and two members are designated as Audit Committee Financial Experts as defined by the SEC.

In March 2015, the Board of Directors elected the following individuals to the Audit Committee: Liz Hewitt (Audit Committee Chairman and Financial Expert), Jeppe Christiansen (Audit Committee Member and Financial Expert), Sylvie Grégoire (Audit Committee Member), Stig Strøbæk (Audit Committee Member) and Eivind Kolding (non-voting observer on the Audit Committee). See Item 16D below. Financial expert Liz Hewitt is independent as defined by the SEC. Jeppe Christiansen, an additional financial expert, relies on an exemption from the independence standards.

#### 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 policy and related business ethics procedures where the requirements for how to conduct business in Novo Nordisk are outlined. The Novo Nordisk Way applies 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 'Novo Nordisk Way' on pages 18-19 in our *Annual Report 2015*, and Novo Nordisk Way may be found on Novo Nordisk's 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 5.5 'Fee to statutory auditors' in our *Annual Report 2015* 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 fully-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 2015* 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, transfer pricing and tax planning services.

#### 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, advisory service in connection with the IPO of NNIT, review of IT security plans, Benchmark reports and training of employees.

#### 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 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 (Selskabsloven) which 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. In addition, one member, Jeppe Christiansen, serves as a board member of Novo A/S (the controlling shareholder of Novo Nordisk A/S), and relies on an exemption in paragraph (b)(1)(iv)(B) of Rule 10A-3. Finally, one non-voting observer, Eivind Kolding, who is not an executive officer of Novo Nordisk A/S and is not the chairman of the Audit Committee, is an executive officer of Novo A/S (the controlling shareholder of Novo Nordisk A/S) and relies on an exemption in paragraph (b)(1)(iv)(D) of Rule 10A-3. Novo Nordisk does not believe the reliance on such exemptions 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

	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)
2014 repurchase program				
At year end 2014**	54,346,995	252.16	53,854,000	1,295,903,221
January 1–28	4,635,000	280.51	58,489,000	0
Total***	58,981,995	254.39	58,489,000	0
2015 repurchase program				
January 30–31	215,000	297.08	215,000	17,500,000,000
February 1–28	4,134,481	292.59	4,349,481	17,436,127,544
March 1–31	4,120,000	335.27	8,469,481	16,226,416,593
April 1–30	2,908,423	385.36	11,377,904	14,845,088,753
May 1–31	3,380,000	378.85	14,757,904	13,724,289,291
June 1–30	4,240,000	374.33	18,997,904	12,443,763,377
July 1–31	4,457,200	388.58	23,455,104	10,856,584,144
August 1–31	4,165,000	383.16	27,620,104	9,124,612,435
September 1–30	4,520,000	369.03	32,140,104	7,528,762,857
October 1–31	4,193,147	361.97	36,333,251	5,860,735,575
November 1–30	4,145,000	377.13	40,478,251	4,342,957,179
December 1–31	3,104,000	389.22	43,582,251	2,779,744,509
Total	43,582,251	365.48	43,582,251	1,571,609,801

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

\*\*\*) On January 31, 2014 Novo Nordisk purchased 492,995 B-shares from employees. The transaction amounted to DKK 0.1 billion. The shares in this transaction were not part of the Safe Harbour repurchase program, but were part of the overall DKK 15.0 billion repurchase program.

\*\*\*\*) As of January 28, 2015, Novo Nordisk had repurchased a total of 58,981,995 B shares equal to a transaction value of DKK 15,004,281,371. The DKK 15.0 billion share repurchase program announced 30 January 2014 was thereby concluded.

#### Note to column (a) and (d)

The Board of Directors has authorization from the annual shareholders' 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 of DKK 15 billion was completed in January 2015. A new share repurchase program of DKK 15 billion initiated in February 2015, and increased by DKK 2.5 billion to DKK 17.5 billion in April 2015, was completed in January 2016. The shares have been purchased through a bank directly in the market.

Column (a) shows shares we purchased as part of our share repurchase program initiated in February 2014 (completed in January 2015) and our share repurchase program initiated in February 2015.

**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 18, 2016, 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 402,512,800. This would correspond to a 1.92% reduction of the total share capital.



#### ITEM 16F CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

#### 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 Danish Corporate Governance Recommendations as amended on May 6, 2013 in respect of its corporate governance practices. Novo Nordisk has ADRs listed on the New York Stock Exchange (the "NYSE") and is therefore required to comply with U.S. Securities laws, 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 is permitted to follow the corporate governance practice of its home country in lieu of certain provisions of the NYSE Standards.

Novo Nordisk 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 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 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 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, 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 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 member serves as executive of the majority shareholder, Novo 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.

In addition, 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.

#### **Remuneration Committee**

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 is. In 2015, the Board of Directors decided to establish a Remuneration Committee. The Board of Directors considers all factors relevant to determine whether the members of the Remuneration Committee have a relationship to Novo Nordisk A/S which is material to the director's ability to be independent from management when performing its duties. Under the Danish Corporate Governance Recommendations two members of the Remuneration Committee qualify as independent and three members qualify as non-independent. At least half of the members of the Remuneration Committee shall qualify as independent as defined by the Danish Corporate Governance Standards. 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 the composition of the Remuneration Committee allows for both the Chairmanship, which recently was responsible for oversight of the remuneration, as well as an employee representative being on the Remuneration Committee while maintaining the Remuneration Committee small.

#### **Nomination Committee**

Furthermore, 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 Nomination Committee consists of three members who are independent, and two members who are non-independent. At least half of the members of the Nomination Committee shall qualify as independent as defined by the Danish Corporate Governance Recommendations. Hence, the composition of the Nomination Committee conform to the Danish Corporate Governance Recommendations.

#### **Audit Committee**

Under Section 303A.06 of the NYSE Standards, listed company audit committees 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). Novo Nordisk's Audit Committee has four members and a non-voting observer. Two 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.

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), one Audit Committee member serves as board member of Novo A/S relying on the exemption provided for in paragraph (b)(1)(iv)(B) of Rule 10A-3 and the non-voting observer relies on the exemption in paragraph (b)(1)(iv)(D) 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 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 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 framework of rules and guidelines, including but not limited to the Novo Nordisk Way, which describe corporate values and required mindsets on business conduct and ethics. 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 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.

## 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 2015* (see Exhibit no. 15.1).

#### 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 2015* are:

- Free cash flow;
- Cash to earnings;
- Operating profit after tax to net operating assets;
- Financial resources at the end of the year;
- Underlying sales 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 in marketable securities'.

Management believes free cash flow is an important liquidity metric because it measures, during a given period, the amount of cash generated that is available to make investments, fund acquisitions and for certain other activities. A positive free cash flow shows that the Group is able to finance its activities and that external financing is thus not necessary for the Group's operating activities. 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'.

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

### Reconciliation of free cash flow

DKK Million	2015	2014	2013
Free cash flow	34,222	27,396	22,358
+Net purchase of marketable securities	(2,033)	2,232	811
+Net cash used in investing activities	6,098	2,064	2,773
<b>=Net cash generated from operating activities</b>	<b>38,287</b>	<b>31,692</b>	<b>25,942</b>

## 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 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/earnings in %':

**Reconciliation of cash to earnings**

DKK Million	2015	2014	2013
Free cash flow	34,222	27,396	22,358
/ Net profit (as reported in Annual Report)	34,860	26,481	25,184
<b>=Cash to earnings (as reported in the Annual Report) in %</b>	<b>98.2%</b>	<b>103.5%</b>	<b>88.8%</b>
Net cash generated from operating activities	38,287	31,692	25,942
/ Net profit (as reported in the Annual Report)	34,860	26,481	25,184
<b>=Cash flow generated from operating activities / Net profit in %</b>	<b>109.8%</b>	<b>119.7%</b>	<b>103.0%</b>

## 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	2015	2014	2013
Operating profit after tax	39,654	26,800	24,376
/ Average non-interest bearing balance sheet items	26,668	26,537	25,080
<b>Operating profit after tax to net operating assets (as reported in the Annual Report) in</b> <b>= %</b>	<b>148.7%</b>	<b>101.0%</b>	<b>97.2%</b>

**Numerator**

Reconciliation of Operating profit after tax to Operating profit

Operating profit after tax	39,654	26,800	24,376
/ (1 minus effective tax rate) in %	80.2%*	77.7%	77.4%
<b>=Operating profit (as reported in the Annual Report)</b>	<b>49,444</b>	<b>34,492</b>	<b>31,493</b>

**Denominator**

Reconciliation of Average non-interest bearing balance sheet items to Equity

Non-interest bearing balance sheet items at the beginning of the year	26,830	26,243	23,916
+Non-interest bearing balance sheet items at the end of the year	26,505	26,830	26,243
/ 2			
<b>= Average non-interest bearing balance sheet items as used in Operating profit after tax to net operating assets</b>	<b>26,668</b>	<b>26,537</b>	<b>25,080</b>
Non-interest bearing balance sheet items at the end of the year	26,505	26,830	26,243
+Investment in associated company	811	-	-
+Other financial assets	1,339	856	551
+Marketable securities	3,542	1,509	3,741
+Derivative financial instruments	304	30	1,521
+Cash at bank and in hand	16,923	14,396	10,728
- Loans	-	-	-
- Current debt	(1,073)	(720)	(215)
- Derivative financial instruments	(1,382)	(2,607)	-
<b>=Equity (as reported in the Annual Report)</b>	<b>46,969</b>	<b>40,294</b>	<b>42,569</b>
Operating profit (as reported in Annual Report)	49,444	34,492	31,493
/ Equity	46,969	40,294	42,569
<b>=Operating profit/Equity in %</b>	<b>105.3%</b>	<b>85.6%</b>	<b>74.0%</b>

\*) The effective tax rate in 2015 is impacted by 1.3% from the non-taxable income from partial divestment of NNIT A/S.

## Financial resources at the end of the year

Financial resources at the end of the year 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.

Management believes that the Financial resources at the end of the year 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 at the end of the year**

DKK Million	2015	2014	2013
Financial resources at the end of the year	27,601	23,373	19,103
- Marketable securities at the end of the year	(3,542)	(1,509)	(3,741)
- Undrawn committed credit facilities	(8,209)	(8,188)	(4,849)
<b>= Cash and cash equivalents at the end of the year (as reported in the Annual report)</b>	<b>15,850</b>	<b>13,676</b>	<b>10,513</b>

**Underlying sales growth in local currencies**

Underlying sales growth in local currencies is defined as sales for the year measured at prior year average exchange rates compared with sales for prior year measured at prior year average exchange rates.

Management believes that the underlying 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 local currency fluctuations.

## ITEM 19 EXHIBITS

**a. Annual Report**

The following pages from our *Annual Report 2015*, furnished to the SEC on Form 6-K, dated February 10, 2016, 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.

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Companies in the Novo Nordisk Group	93
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Statement by the Board of Directors and Executive Management on the Annual Report	109

**b. Exhibits**

List of exhibits:

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>	<b><u>Method of filing</u></b>
1.1	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 23, 2015.
8.1	Companies in the Novo Nordisk Group	Incorporated by reference to page 93 of our <i>Annual Report 2015</i> filed on Form 6-K dated February 10, 2016.
12.1	Certification of Lars Rebien Sørensen, 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 for 2015.
12.2	Certification of Jesper Brandgaard, 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 for 2015.
13.1	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 for 2015.
15.1	Extracts from Registrant's Annual Report for the fiscal year ended December 31, 2015.	Incorporated by reference to the portions of Registrant's Report furnished to the SEC on Form 6-K on February 10, 2016 identified in Item 19.a of this Form 20-F.
15.2	Extracts from Registrant's Annual Report for the fiscal year ended December 31, 2014.	Incorporated by reference to the portions of the Registrant's Report furnished to the SEC on Form 6-K on February 5, 2015 identified in Item 19.a of the Form 20-F filed on February 5, 2015.
15.3	Consent of independent registered public accounting firm.	Filed together with this Form 20-F for 2015.



***Report of Independent Registered Public Accounting Firm***

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

In our opinion, the consolidated financial statements listed in the index appearing under Item 19(a) present fairly, in all material respects, the financial position of Novo Nordisk A/S and its subsidiaries at 31 December 2015 and 31 December 2014, and the results of their operations and their cash flows for each of the three years in the period ended 31 December 2015 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board and in conformity with International Financial Reporting Standards as adopted by the European Union. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of 31 December 2015, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these 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. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. 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.

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

Bagsværd, Denmark

February 2, 2016

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 Rebien Sørensen

Name: Lars Rebien Sørensen

Title: President and Chief Executive Officer

/s/ Jesper Brandgaard

Name: Jesper Brandgaard

Title: Executive Vice President and Chief Financial Officer

Bagsværd, Denmark

Dated: February 10, 2016

