NOVO NORDISK A S
Form 20-F
February 05, 2014
UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

(Mark One)

REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g)

¨ OF THE SECURITIES EXCHANGE ACT OF 1934

OR
ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE

SECURITIES EXCHANGE ACT OF 1934
ý
For the fiscal year ended December 31, 2013

OR
TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE

¨ SECURITIES EXCHANGE ACT OF 1934

OR
¨ SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(D) OF
THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number: 333-82318

NOVO NORDISK A/S

(Exact name of Registrant as specified in its charter)

Not applicable	**The Kingdom of Denmark**
(Translation of Registrant's name into English)	(Jurisdiction of incorporation or organization)

Novo Allé

DK-2880 Bagsværd

Denmark

(Address of principal executive offices)

Jesper Brandgaard

Executive Vice President and Chief Financial Officer

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

* 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[1] 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: 2,212,564,000

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

Yes ý No¨

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

Yes ¨ No ý

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 ý 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 filerý 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 filling:

U.S. GAAP ¨ International Financial Reporting Standards as issued Other ¨

by the International Accounting Standards Board ý

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 ý

[1]As at January 2, 2014 a stock split of the company's B shares was conducted so that the nominal value was changed from DKK 1 to DKK 0.20.

CONTENTS

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 2013* and *Annual Report 2012*. Therefore the information in this Form 20-F should be read in conjunction with our *Annual Report 2013* and *Annual Report 2012*, which were furnished to the SEC on Form 6-K on February 5, 2014 and on February 6, 2013, respectively.

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

The trading unit of the Novo Nordisk B shares listed on NASDAQ OMX Copenhagen was changed from DKK 1 to DKK 0.20. The ratio of B shares to ADRs listed on the New York Stock Exchange will remain 1:1. These changes in trading units were effective as of January 2, 2014 for the Novo Nordisk B shares and as of January 9, 2014 for the ADRs. Comparative disclosures in this Form 20-F and our *Annual Report 2013* have been adjusted to reflect the stock split.

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 2013* and the *Annual Report 2012*, examples of forward-looking statements can be found under the headings, '2013 performance and 2014 outlook' in our *Annual Report 2013* and '2012 performance and 2013 outlook' in our *Annual Report 2012*, 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 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 expenditure, 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	**2013**	**2012**	**2011**	**2010**	**2009**
Net sales	83,572	78,026	66,346	60,776	51,078
Operating profit from continuing operations	31,493	29,474	22,374	18,891	14,933
Operating profit	31,493	29,474	22,374	18,891	14,933
Net profit from continuing operations	25,184	21,432	17,097	14,403	10,768
Net profit	25,184	21,432	17,097	14,403	10,768
Earnings per share/ADR*	9.40	7.82	6.05	4.96	3.59
Total assets	70,337	65,669	64,698	61,402	54,742
Net assets	42,569	40,632	37,448	36,965	35,734
Capital stock	550	560	580	600	620
Treasury stock	(21)	(17)	(24)	(28)	(32)
Dividends per share/ADR*	4.50**	3.60	2.80	2.00	1.50
Dividends per share/ADR in USD*	0.83**	0.64	0.49	0.36	0.29
Diluted earnings per share/ADR*	9.35	7.77	6.00	4.92	3.56
Number of shares (million)*	2,750	2,800	2,900	3,000	3,100

*) As at January 2, 2014 a stock split of the company's B shares was conducted so that the following trading unit was changed from DKK 1 to DKK 0.20. The comparative figures have been restated accordingly.

**) Proposed dividend per share. For USD translation the exchange rate at December 30, 2013 from Danmarks Nationalbank (The Central Bank of Denmark) is used (USD 1 = DKK 5.4127)

Reference is made to 'Consolidated financial, social and environmental statements 2013', pages 55-103 in our *Annual Report 2013* 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	High	Low
July 2013	5.821	05.6119
August 2013	5.646	25.5689
September 2013	5.686	45.5059
October 2013	5.527	95.4035
November 2013	5.580	85.4801
December 2013	5.511	15.4002
January 2014 (through January 29)	5.516	95.4520

Year	Average rate	Period end rate	High	Low
2009	5.3504	5.1901	5.934	4.9218
2010	5.6538	5.6133	6.228	65.1092
2011	5.3622	5.7456	5.773	45.0106
2012	5.7972	5.6591	6.153	75.5266
2013	5.6160	5.4127	5.837	15.4002

On January 29, 2014, the latest available date, the Danmarks Nationalbank's daily official exchange rate was 5.4839.

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 2013* 'Risks to be aware of' on pages 42-43. In addition to the risks included in the 'Risks to be aware of' in our *Annual Report 2013*, 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 time. Such risks include the risk that our IT security system 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 U.S. law and professional standards in connection with its audits of financial statements filed with the SEC. The

PCAOB is currently unable to conduct inspections of Danish auditors' audit work and procedures without the approval of the Danish authorities, which prevents it from regularly evaluating our auditor's audits and its quality control procedures. As a result, investors who rely on our auditor's audit report are deprived of the benefits of PCAOB inspections of our auditor.

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. Following the spin-off Novo Nordisk became a focused healthcare company with more than 90 years of experience in diabetes care.

Novo Nordisk's B shares are listed on NASDAQ OMX 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 2013

Reference is made to ‘Accomplishments and results 2013’, pages 1-15 in our *Annual Report 2013* for a description of important events in 2013.

Capital expenditure in 2013, 2012 and 2011

The total net capital expenditure for property, plant and equipment was DKK 3.2 billion in 2013 compared with DKK 3.3 billion in 2012 and DKK 3.0 billion in 2011. The capital expenditure in 2013 was primarily related to the ongoing establishment of a new facility for filling and formulation of insulin products in Russia, expansion of production facilities for GLP-1, expansion of the device capacity in Denmark and the United States, filling capacity in biopharmaceuticals, the construction of new laboratory facilities in Denmark and new office facilities in Denmark. The investments were financed from cash flow from operating activities. No significant divestitures took place in the period from 2011–2013.

Novo Nordisk expects to invest approximately DKK 3.5 billion in fixed assets in 2014. The expected level of investment in 2014 is primarily related to continued expansion of production facilities for GLP-1 and devices in Denmark and in the United States, expansion of insulin filling capacity in the

United States and France, finalization of a new biopharmaceutical filling facility in Denmark, continued investments in new facility for filling and formulation of insulin products in Russia, the continued construction of new laboratory facilities in Denmark and expansion of CMC and protein pilot capacity in Denmark.

Public takeover offers in respect of the Company's shares

No such offers occurred during 2013 or 2014 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. 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 more than 38,000 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 the *Annual Report 2013.*

Segment information

Novo Nordisk is engaged in the discovery, development, manufacturing and marketing of pharmaceutical products and has two business segments: diabetes care and biopharmaceuticals. The diabetes care segment covers insulins, GLP-1, other protein-related products (such as glucagon, protein-related delivery systems and needles), obesity (Novo Nordisk currently has no marketed obesity products) and oral antidiabetic drugs. The biopharmaceuticals segment covers the therapy areas of haemophilia care, growth hormone therapy, hormone replacement therapy and inflammation (Novo Nordisk currently has no products marketed within inflammation).

For information on sales by business and geographic segment, reference is made to Note 2.2 'Segment information' in our *Annual Report 2013*.

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 Algeria, Argentina, Australia, Brazil, India, Russia and Turkey.

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. During 2013 key markets including China and various European countries have experienced an increased pricing pressure due to austerity measures. Additionally, Japan, certain European countries and certain countries in the International Operations sales region as well as China have also experienced competitive pressure and challenging market conditions. In most markets insulin is a prescription drug.

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, France and Eli Lilly, United States are the most significant companies.

The once-daily GLP-1 analogue, Victoza® has now been launched globally, including countries in Europe from 2009, the United States and Japan in 2010 and China in 2011. In the GLP-1 market, Novo Nordisk and Astra Zeneca, United Kingdom are the most significant global companies.

The new generation insulin, Tresiba®, has now been commercially launched in eight countries, including Japan, Mexico and selected European markets such as the UK, Denmark and Switzerland. Novo Nordisk has to date not experienced any significant cannibalization of sales of the existing insulin portfolio as a consequence of the roll-out of Tresiba®.

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 99 in the *Annual Report 2013*.

In addition to the compound patents discussed in 'Consolidated Social Statement' on page 99 in the *Annual Report 2013*, 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:

Product	NovoLog®/ NovoRapid®	NovoLog® mix / NovoMix®	Prandin®/ NovoNorm®	NovoSeven	Norditropin®
Total sales in 2013 (in DKK million)	16,848	9,759	2,151	9,256	6,114
Geographical split:					
North America	59%	28%	39%	48%	37%
Europe	23%	25%	9%	25%	28%
International Operations	10%	19%	9%	18%	14%
Japan & Korea	5%	8%	2%	7%	21%
Region China	3%	20%	41%	2%	0%

Patent situation of key diabetes care products

The total sales of NovoLog®/NovoRapid® were DKK 16,848 million in 2013 (DKK 15,693 million in 2012).

The drug compound patent for NovoLog®/NovoRapid® has expired in Japan and in Europe. The patent in Japan expired in December 2010 and the European patent expired in August 2011. In the U.S. NovoLog®/NovoRapid® is patent protected until December 2014. In addition to the drug compound patent, Novo Nordisk holds a formulation patent on NovoLog®/NovoRapid®, which provides coverage until 2017 in all major markets.

The total sales of NovoLog® Mix /NovoMix® were DKK 9,759 million in 2013 (DKK 9,342 million in 2012).

NovoLog® Mix /NovoMix® is protected by patents in Japan, in Europe and in the United States. In Japan the drug compound patent expires in June 2014, in the United States the drug compound patent expires in December 2014 and in Europe the drug compound patent expires on a country-by-country basis throughout 2014 and 2015. In addition, Novo Nordisk holds a formulation patent on NovoLog® Mix /NovoMix® 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®/NovoRapid® in all major markets and for NovoLog® Mix /NovoMix® 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®/NovoRapid® and NovoLog® Mix /NovoMix® patents will have a significant near-term impact on sales, results of operations and liquidity.

The total sales of Prandin®/NovoNorm® , an oral antidiabetic drug, were DKK 2,151 million in 2013 (DKK 2,679 million in 2012) and together with other oral antidiabetic products of DKK 95 million in 2013 (DKK 79 million in 2012), the total sales of all Oral antidiabetic products (OAD) were DKK 2,246 million in 2013 (DKK 2,758 million in 2012). Prandin®/NovoNorm® is no longer protected as the drug compound patent has expired in all key markets.

In Europe, generic copies of NovoNorm® 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® 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® continued to erode during 2013 due to generic competition, and we expect this trend to continue during 2014.

In the United States, Novo Nordisk sales of Prandin® have been protected by a patent with claims directed toward the treatment of type 2 diabetes using a combination of repaglinide (Prandin®) and metformin, which expires in 2018.

In a patent infringement lawsuit in the United States against Caraco Pharmaceutical Laboratories, Ltd. (Caraco) regarding Caraco's abbreviated new drug application (ANDA) for a generic version of Prandin® (repaglinide), the U.S. Court of Appeals for the Federal Circuit in June 2013 affirmed a 2011 District Court decision that a claim in a Novo Nordisk patent related to the use of repaglinide in combination with metformin for the treatment of type 2 diabetes was invalid, and reversed the District Court decision that Novo Nordisk had committed inequitable conduct during the time the company attempted to acquire the patent. This decision increased the probability of approval and launch of a generic repaglinide product in the United States.

Subsequently, in July 2013 generic repaglinide products from respectively Caraco and Paddock have been approved, and Novo Nordisk has since then seen a significant decline in sales of Prandin® in the United States, commensurate with our experience from the introduction of generic repaglinide in Europe. We expect that our U.S. sales of Prandin® will continue to erode during 2014 due to generic competition.

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

Patent situation of key biopharmaceuticals products

The total sales of NovoSeven® were DKK 9,256 million in 2013 (DKK 8,933 million in 2012).

While the drug compound patent for NovoSeven® has expired in all major markets, Novo Nordisk holds two formulation patents on the room temperature stable preparation of NovoSeven®, which provides coverage of this formulation until 2023 and 2024, respectively, in all major markets.

The expiry of the drug compound patent has had limited impact on sales of NovoSeven® due to the complexity relating to the regulatory pathways for 'biosimilar' coagulation factors in 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 U.S. Food and Drug Administration (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 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 6,114 million in 2013 (DKK 5,698 million in 2012).

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.