NOVO NORDISK A S

Form 6-K

December 03, 2013
UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 6-K
REPORT OF FOREIGN PRIVATE ISSUER Pursuant to Rule 13a-16 or 15d-16 of the Securities Exchange Act of 1934
December 3, 2013
NOVO NORDISK A/S (Exact name of Registrant as specified in its charter)
Novo Allé DK- 2880, Bagsvaerd Denmark (Address of principal executive offices)
Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-I
Form 20-F [X] Form 40-F [ ] Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934
Yes [ ] No [X] If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g-32(b):82

### Highlights from Novo Nordisk's Capital Markets Day 2013

**Bagsværd, Denmark, 3 December 2013 –** Today at its Capital Markets Day, Novo Nordisk will present an update on its commercial performance and key development projects, which are expected to drive long-term growth.

As a world leader in diabetes care, Novo Nordisk's ambition is to further expand its position in this market through the continuous discovery, development and marketing of new, improved insulins and GLP-1 analogues as well as combinations hereof. Moreover, the company intends to establish a presence within the treatment of obesity with liraglutide 3 mg.

The key topics covered during the day will be:

- Novo Nordisk's corporate strategy
- The company's current commercial performance and market outlook
- · The diabetes research strategy and development projects
- The opportunity for liraglutide 3 mg as an obesity treatment

#### **CORPORATE STRATEGY**

At the Capital Markets Day, Novo Nordisk reviews its corporate strategy. The focus of Novo Nordisk remains to leverage its distinctive core capabilities to expand the leadership within diabetes and growth disorders, pursue leadership in haemophilia and to establish a presence within obesity and inflammation.

As part of the strategy presentation, management will outline how in-licensing of complementary technologies and preclinical compounds have contributed to the development of current and potential future products.

Finally, Novo Nordisk will illustrate how Changing Diabetes® initiatives improve diabetes awareness, access to treatment and treatment outcomes for people with diabetes.

#### COMMERCIAL PERFORMANCE AND MARKET OUTLOOK

The update on commercial performance will focus on diabetes care and include a review of the diabetes market dynamics and the performance of Novo Nordisk's key products including Tresiba. Also included are reviews of the commercial strategies and priorities in the US and emerging markets.

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#### DIABETES RESEARCH STRATEGY AND DEVELOPMENT PROJECTS

Highlights from this review are:

- · Initiation of new trials to further explore hypoglycaemic benefits of Tresiba®
- · Initiation of five global trials as part of the phase 3a programme SUSTAIN<sup>TM</sup>, for semaglutide
- · Initiation of phase 3 trials for liraglutide as adjunct therapy to insulin in type 1 diabetes
- · Initiation of phase 2 trial for the first oral GLP-1, OG217SC

Below are further details about these events:

Initiation of new trials to further document hypoglycaemic profile of Tresiba®

Novo Nordisk plans to initiate two 64-weeks randomised, double-blind, cross-over trials, comparing the safety and efficacy of Tresiba® and insulin glargine in the first quarter of 2014. The overall purpose of the trials is to evaluate the hypoglycaemia profile of Tresiba® in the transfer from other basal insulins, and to further document the hypoglycaemic profile in type 1 diabetes and type 2 diabetes respectively compared to insulin glargine. In one trial, BEGIN<sup>TM</sup>-SWITCH 1, 450 patients with type 1 diabetes will be sequentially treated with Tresi®and insulin glargine in combination with insulin aspart in a randomised order. In the second trial, BEGIN<sup>TM</sup>-SWITCH 2, 670 patients with type 2 diabetes will be treated sequentially with Tresiba® and insulin glargine in combination with metformin in a randomised order.

*Initiation of five global trials as part of the phase 3a programme, SUSTAIN*<sup>TM</sup>, *for semaglutide (NN9535)* 

SUSTAIN<sup>TM</sup> is the name of the phase 3a programme investigating the once-weekly GLP-1 analogue, semaglutide, as a treatment for people with type 2 diabetes. In addition to SUSTAIN<sup>TM</sup> 6 initiated in February 2013 to evaluate cardiovascular outcomes and other long-term diabetes-related endpoints, the programme will include five global phase 3a trials of 30 or 56 weeks duration. These trials will investigate the efficacy and safety of treatment with 0.5 and 1.0 mg of semaglutide compared with that of placebo in monotherapy, sitagliptin, exenatide ER and insulin glargine and will examine the effect on glycaemic control of adding semaglutide to basal insulin treatment. In total, the five additional trials are expected to include 3,800 people with type 2 diabetes. The first two of the trials were initiated in December 2013 and the last is expected to be initiated towards the end of 2014.

Initiation of phase 3 for LATIN T1D (NN9211), liraglutide as adjunct therapy to insulin in type 1 diabetes

Novo Nordisk has initiated the first of two phase 3a trials, ADJUNCT ONE<sup>TM</sup> and ADJUNCT TWO<sup>TM</sup>, investigating the efficacy and safety of liraglutide as an adjunct therapy to insulin in people with type 1 diabetes. ADJUNCT ONE<sup>TM</sup>, which was initiated in November 2013, is expected to include 1,400 people with type 1 diabetes who will be randomised to treatment for 52 weeks with liraglutide or placebo, both in addition to intensification (treat-to-target concept) of the insulin treatment. ADJUNCT TWO<sup>TM</sup>, which is expected to be initiated in the first half of 2014, is planned to include 800 people with type 1 diabetes. In this trial, treatment will be for 26 weeks with liraglutide or placebo, both in addition to insulin treatment with an upper cap of the average daily total insulin dose when entering the trial.

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*Initiation of phase 2 for the first oral GLP-1, OG217SC (NN9924)* 

In December, Novo Nordisk initiated the first phase 2a trial with an oral GLP-1, OG217SC. The trial will examine the dose range, escalation and efficacy of oral semaglutide compared with subcutaneously administered semaglutide and placebo in 600 people with type 2 diabetes for 26 weeks.

#### THE OPPORTUNITY FOR LIRAGLUTIDE 3 MG AS AN OBESITY TREAMENT

Novo Nordisk still expects to file liraglutide 3 mg for regulatory review in the US and EU as a treatment for obesity around the turn of the year. Today, Novo Nordisk will present data showing the increasing obesity prevalence and the associated cost to society as well as the key data generated in the SCALE<sup>TM</sup> phase 3a development programme for liraglutide 3 mg in obesity. Furthermore, the high-level commercialisation strategy will be outlined.

### WEB CAST DETAILS

All sessions of the capital markets day will be webcast live and a replay will be available on novonordisk.com/investors. Presentation material for the Capital Markets Day 2013 will be made available today, 3 December, at approximately 8.00 CET, corresponding to 2.00 am EST, on novonordisk.com/investors.

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### FORWARD-LOOKING STATEMENTS

Novo Nordisk's reports filed with or furnished to the US Securities and Exchange Commission (SEC), including this document as well as the company's Annual Report 2012 and Form 20-F, both filed with the SEC in February 2013, and written information released, or oral statements made, to the public in the future by or on behalf of Novo Nordisk, may contain forward-looking statements. Words such as 'believe', 'expect', 'may', 'will', 'plan', 'strategy', 'prospect', 'forese 'estimate', 'project', 'anticipate', 'can', 'intend', 'target' and other words and terms of similar meaning in connection with any discussion of future operating or financial performance identify forward-looking statements. Examples of such forward-looking statements include, but are not limited to:

- · statements of targets, plans, objectives or goals for future operations, including those related to Novo Nordisk's products, product research, product development, product introductions and product approvals as well as cooperation in relation thereto
- statements containing projections of or targets for revenues, costs, income (or loss), earnings per share, capital expenditures, dividends, capital structure, net financials and other financial measures
- $\cdot$  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.

These statements are based on current plans, estimates and projections. By their very nature, forward-looking statements involve inherent risks and uncertainties, both general and specific. Novo Nordisk cautions that a number of important factors, including those described in this document, could cause actual results to differ materially from those contemplated in any forward-looking statements.

Factors that may affect future results include, but are not limited to, global as well as local political and economic conditions, including interest rate and currency exchange rate fluctuations, delay or failure of projects related to research and/or development, unplanned loss of patents, interruptions of supplies and production, product recalls, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for Novo Nordisk's products, introduction of competing products, reliance on information technology, Novo Nordisk's ability to successfully market current and new products, exposure to product liability and legal proceedings and investigations, changes in governmental laws and related interpretation thereof, including on reimbursement, intellectual property protection and regulatory controls on testing, approval, manufacturing and marketing, perceived or actual failure to adhere to ethical marketing practices, investments in and divestitures of domestic and foreign companies, unexpected growth in costs and expenses, failure to recruit and retain the right employees, and failure to maintain a culture of compliance.

Please also refer to the overview of risk factors in the 'Risk overview' on p 43 of the Annual Report 2012 available on the company's website novonordisk.com.

Unless required by law, Novo Nordisk is under no duty and undertakes no obligation to update or revise any forward-looking statement after the distribution of this document, whether as a result of new information, future events or otherwise.

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Novo Nordisk is a global healthcare company with 90 years of innovation and leadership in diabetes care. The company also has leading positions within haemophilia care, growth hormone therapy and hormone replacement therapy. Headquartered in Denmark, Novo Nordisk employs approximately 37,000 employees in 75 countries, and markets its products in more than 180 countries. Novo Nordisk's B shares are listed on NASDAQ OMX Copenhagen (Novo-B) and its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com.

#### **Further information**

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## **SIGNATURES**

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

## NOVO NORDISK A/S

Date: December 3, 2013 Lars Rebien Sørensen,

President and Chief Executive Officer