NOVO NORDISK A S
Form 6-K
November 19, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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FORM 6-K

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REPORT OF FOREIGN PRIVATE ISSUER

Pursuant to Rule 13a-16 or 15d-16

of the Securities Exchange Act of 1934

November 18, 2015

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NOVO NORDISK A/S

(Exact name of Registrant as specified in its charter)

Novo Allé

DK- 2880, Bagsvaerd

Denmark

(Address of principal executive offices)

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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F

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 to be presented at Novo Nordisk’s Capital Markets Day 2015

Bagsværd, Denmark, 18 November 2015 – At Novo Nordisk’s Capital Markets Day tomorrow, 19 November 2015, the company will provide updates on key development projects, market dynamics and commercial strategy.

Novo Nordisk’s ambition is to further expand its leadership in the global diabetes care market by discovering, developing and marketing improved insulin and GLP-1 analogues, and combinations hereof, as well as completely new classes of anti-diabetic biologics.

The key topics of the day will be:

·Novo Nordisk's research strategy and key development projects within diabetes care

·Novo Nordisk's commercial strategy in the global diabetes care market

·The market dynamics in the United States pharmaceutical market with focus on upcoming product launches

In addition, the Capital Markets Day will include presentations of the company's production strategy, plans for building a leading position within medical treatment of obesity, as well as break-out sessions covering International Operations, China and the company's biopharmaceuticals business.

NOVO NORDISK'S RESEARCH STRATEGY AND KEY DEVELOPMENT PROJECTS WITHIN DIABETES CARE

Highlights from this session include:

Introduction to Novo Nordisk's research strategy and key early development projects Novo Nordisk's dedicated research and development strategy will be presented with special focus on what Novo Nordisk considers its key competitive advantages throughout the research and development value chain. The presentation will outline the company's research strategy for delivering future innovative protein-based therapies addressing unmet medical needs within the four core disease areas in Novo Nordisk's corporate strategy; Diabetes Care, Obesity, Haemophilia and Growth Disorders. Moreover, it will review Novo Nordisk's development organisation with focus on clinical trial design and execution.

Results from the SUSTAIN 4 trial comparing once-weekly subcutaneous administration of the GLP-1 analogue semaglutide with once-daily insulin glargine

SUSTAIN 4, the third phase 3a trial for semaglutide to report results, included a total of 1,089 people with type 2 diabetes previously treated with metformin with or without sulfonylurea. From a mean baseline, HbA1c of 8.2%, people treated once-weekly with doses of 0.5 mg and 1.0 mg semaglutide achieved statistically significant and superior improvements in HbA1c of 1.2% and 1.6%, respectively, compared to 0.8% with insulin glargine after 30 weeks of treatment. The mean daily insulin glargine dose was 29 units. Furthermore, from a mean baseline body weight of 93 kg, people treated with 0.5 mg and 1.0 mg semaglutide experienced statistically significant and superior weight loss of 3.5 kg and 5.2 kg, respectively, compared with a weight gain of 1.2 kg with insulin glargine. In the trial, semaglutide appeared to have a safe and well-tolerated profile. The most common adverse event was nausea which diminished over time. Nausea was reported by up to 22% of people treated with semaglutide compared with 4% of people treated with insulin glargine. Severe or blood glucose-confirmed symptomatic hypoglycaemia was experienced by 4% and 6% of people treated with 0.5 mg or 1.0 mg once-weekly semaglutide, respectively, compared with 11% in the insulin glargine group.

Results from the phase 2 programme with oral semaglutide and the design of the phase 3a programme PIONEER

Further details from the phase 2 programme with the once-daily oral GLP-1 analogue, oral semaglutide, will be presented. The design of the pivotal phase 3a programme for oral semaglutide, PIONEER, will be highlighted. A total of 10 studies with more than 9,000 patients will be initiated under the planned phase 3a programme. The first trial will be initiated in the first quarter of 2016 and the majority of the remaining trials will be initiated in 2016. Results from the 10 clinical trials are expected to be available in 2018.

Novo Nordisk’s plans for post-approval phase 3b and phase 4 development trials

In addition to the extensive investments in pivotal phase 3a development programmes, Novo Nordisk plans to expand investments in phase 3b and phase 4 clinical trials, in order to support the recently approved products. More than 20 late-stage diabetes care development trials are currently ongoing or planned for initiation in the coming years.

Biopharmaceuticals break-out session to highlight results from the N8-GP (NN7088) pathfinder 2 extension trial

In a separate session, Novo Nordisk will present the company’s biopharmaceuticals business including results from the completion of the first part of the pathfinder 2 extension trial. The reported data provide additional support that the long-acting recombinant factor VIII, N8-GP (turoctocog alfa pegol), appears to have a safe and well- tolerated profile, and that 95% of mild to moderate bleeds can be managed with 1-2 infusions. Additionally, a subset of 55 patients,

who experienced ≤2 bleeds during 6 months on every four days prophylaxis, were in the extension phase randomised to either every four days (50 IU/kg) or once-weekly (75 IU/kg) treatment. During the 180- day observation period of this sub-study, the median annualised bleeding rate (ABR) was 0 (zero) for patients in both treatment arms.

NOVO NORDISK’S COMMERCIAL STRATEGY IN THE GLOBAL DIABETES CARE MARKET

Based on a review of the dynamics of the global diabetes care market, this session will highlight Novo Nordisk’s current and expected future growth drivers. These include focusing on the underlying diabetes care market volume growth and Novo Nordisk’s introduction of novel drug candidates in the diabetes care market leading to potential market share gains and value upgrade. In the coming years, Novo Nordisk will promote a complete diabetes care product offering by continuing the global launches of Tresiba®, Ryzodeg® and Xultophy® as well as the planned introduction of faster-acting insulin aspart and semaglutide upon successful completion of the clinical trials and subsequent regulatory processes.

NOVO NORDISK’S COMMERCIAL STRATEGY IN THE UNITED STATES PHARMACEUTICAL MARKET WITH FOCUS ON UPCOMING PRODUCT LAUNCHES

This session includes an update on recent changes in the US healthcare system and payer landscape. The business update will highlight Novo Nordisk’s position in the US diabetes care market where the basal insulin segment represents the company’s largest opportunity. Tresiba® is expected to be launched in early 2016, and the launch plans will be outlined during the session.

WEB CAST DETAILS

All sessions of the Capital Markets Day will be webcast live, and replay will be made available on the investor section of novonordisk.com. Presentation material for the Capital Markets Day 2015 will be available 19 November at approximately 8.00 CET, corresponding to 2.00 am EST on the investor section of novonordisk.com.

Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat other serious chronic conditions: haemophilia, growth disorders and obesity. Headquartered in Denmark, Novo Nordisk employs approximately 40,300 people in 75 countries and markets its products in more than 180 countries. Novo Nordisk's B shares are listed on Nasdaq Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube

Further information

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Company announcement No 72 / 2015

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: November 18, 2015

Lars Rebien Sørensen,

Chief Executive Officer