NOVO NORDISK A S
Form 6-K
September 25, 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

September 25, 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-_____

Novo Nordisk successfully completes second phase 3a trial with semaglutide in people with type 2 diabetes

Bagsværd, Denmark, 25 September 2015 - Novo Nordisk today announced the headline results from the second phase 3a trial for semaglutide, SUSTAIN 3. Semaglutide is a new GLP-1 analogue administered subcutaneously once weekly. The trial investigated the efficacy and safety of 1.0 mg semaglutide compared with 2.0 mg exenatide once-weekly after 56 weeks of treatment added on to 1–2 oral antidiabetic drugs in 813 people with type 2 diabetes.

The trial achieved its objective by demonstrating that from a mean baseline HbA1c of 8.4%, people treated with 1.0 mg semaglutide achieved a statistically significant and superior improvement in HbA1c of 1.5% compared to the improvement in HbA1c of 0.9% with 2.0 mg exenatide once-weekly.

66% of the people treated with 1.0 mg semaglutide achieved the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) treatment target of HbA1c below 7% compared with 40% of the people treated with 2.0 mg exenatide once-weekly.

Furthermore, from a mean baseline body weight of 96 kg, people treated with 1.0 mg semaglutide experienced a statistically significant and superior weight loss of 5.6 kg compared with a weight loss of 1.8 kg for people treated with 2.0 mg exenatide once-weekly.

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 22% of people treated with 1.0 mg semaglutide once-weekly compared with 11% of people treated with 2.0 mg exenatide once-weekly. The discontinuation rate due to all adverse events for 1.0 mg semaglutide was 9.4% compared to 7.2% for 2.0 mg exenatide.

“We are excited about these trial results, which show that 1.0 mg semaglutide injected once weekly provided better glycaemic control and greater weight loss than 2.0 mg exenatide once-weekly,” says Mads Krogsgaard Thomsen, executive vice president and

chief science officer of Novo Nordisk. “These results support that semaglutide has the potential to become the most efficacious GLP-1 product for people with type 2 diabetes. We look forward to further results from the SUSTAIN clinical development programme.”

Novo Nordisk expects to announce headline results of the four remaining SUSTAIN trials within the next coming quarters.

About semaglutide

Semaglutide is a new glucagon-like peptide-1 (GLP-1) analogue that can help people with type 2 diabetes achieve substantial improvement of blood glucose with a low risk of hypoglycaemia. In addition, semaglutide induces weight loss by decreasing appetite and food intake. Semaglutide administered once weekly is in development for the treatment of type 2 diabetes.

About the SUSTAIN clinical programme

The SUSTAIN programme is a phase 3 clinical programme comprising six global trials of semaglutide administered once weekly encompassing more than 7,000 people with type 2 diabetes.

SUSTAIN 1 – a 30-week efficacy and safety trial of semaglutide versus placebo in 388 drug-naïve people with type 2 diabetes.

SUSTAIN 2 – a 56-week efficacy and safety trial of semaglutide versus sitagliptin once-daily as add-on to metformin and/or TZD in 1,231 people with type 2 diabetes.

SUSTAIN 3 – a 56-week efficacy and safety trial of semaglutide versus 2.0 mg exenatide once-weekly as add-on to 1–2 oral antidiabetic drugs in 813 people with type 2 diabetes.

SUSTAIN 4 – a 30-week efficacy and safety trial of semaglutide versus insulin glargine once-daily as add-on to metformin with or without sulfonylurea in 1,089 insulin-naïve people with type 2 diabetes.

SUSTAIN 5 – a 30-week efficacy and safety trial of semaglutide versus placebo as add-on to basal insulin alone or basal insulin in combination with metformin in 397 people with type 2 diabetes.

SUSTAIN 6 – a 2-year trial to evaluate cardiovascular and other long-term outcomes with semaglutide in 3,297 people with type 2 diabetes.

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 39,000 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

For further information

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Novo Nordisk A/S

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Company announcement No 57 / 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: September 25, 2015

Lars Rebien Sørensen,

Chief Executive Officer