NOVO NORDISK A S
Form 6-K
July 10, 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

July 10, 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 first phase 3a trial with semaglutide in people with type 2 diabetes

Bagsværd, Denmark, 10 July 2015 - Novo Nordisk today announced the headline results from SUSTAIN 1, the first phase 3a trial for semaglutide, a new GLP-1 analogue administered once-weekly. The trial investigated the efficacy and safety of 0.5 mg and 1.0 mg semaglutide as monotherapy during 30 weeks of treatment compared with placebo in 388 people with type 2 diabetes previously on diet and exercise.

The trial achieved its primary objective by demonstrating that from a mean baseline HbA1c of 8.1%, people treated with doses of 0.5 mg and 1.0 mg semaglutide, achieved superior improvements in HbA1c of 1.5% and 1.6%, respectively, compared to no change in HbA1c in the placebo group.

74% and 73% of the people treated with 0.5 mg and 1.0 mg semaglutide, respectively, achieved the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) treatment target of HbA1c below 7% compared with 25% of the people treated with placebo.

Furthermore, from a mean baseline of 92 kg, people treated with semaglutide in both doses of 0.5 mg and 1.0 mg experienced a superior weight loss of 3.8 kg and 4.6 kg, respectively, compared with a weight loss of 1.0 kg for people treated with placebo.

In the trial, semaglutide appeared to have a safe and well-tolerated profile. The most common adverse events were related to the gastrointestinal system, primarily nausea, were comparable to Victoza® in similar trials and diminished over time. The discontinuation rates due to all adverse events for 0.5 mg and 1.0 mg semaglutide were 6% and 5% compared to a discontinuation rate of 2% for placebo.

“We are excited about these results, which confirm that semaglutide has the potential to help people with type 2 diabetes achieve both good glycaemic control and a significant weight loss with one weekly injection,” says Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “We look forward to further results from the SUSTAIN clinical development programme.”

Novo Nordisk expects to announce headline results of the five remaining SUSTAIN trials within the next nine months.

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 exenatide ER 2.0 mg once-weekly as add-on to 1-2 oral antidiabetic drugs in 811 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 sulphonylurea 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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Company announcement No 41 / 2015

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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.

Date: July 10, 2015

NOVO NORDISK A/S

Lars Rebien Sørensen,
Chief Executive Officer