NOVO NORDISK A S
Form 6-K
April 28, 2016

**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

April 28, 2016

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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-_____

**Semaglutide significantly reduces the risk of major adverse cardiovascular events in the SUSTAIN 6 trial**

**Bagsværd, Denmark, 28 April 2016 -** Novo Nordisk today announced the top-line results from the sixth and last global phase 3a trial, SUSTAIN 6, for semaglutide; a new GLP-1 analogue, which is administered subcutaneously once weekly in the SUSTAIN trials. This double-blinded trial investigated the long-term cardiovascular and other safety outcomes of 0.5 mg and 1.0 mg semaglutide compared with placebo, both in addition to standard-of-care. In the trial, approximately 3,300 people with type 2 diabetes were treated for 104 weeks.

The trial achieved its primary endpoint of showing non-inferiority of major cardiovascular events (MACE) with semaglutide compared with placebo, as well as a statistically significant reduction in cardiovascular risk. In the trial, around 250 MACE were accrued. The primary endpoint of the study was defined as the composite outcome of the first occurrence of cardiovascular death, non-fatal myocardial infarction or non-fatal stroke.

The safety profile of semaglutide in SUSTAIN 6 was as expected and consistent with previous semaglutide clinical studies.

“We are very encouraged by the potential for reduction of CV risk in people with type 2 diabetes with semaglutide based on the results of SUSTAIN 6. In addition to the strong efficacy profile, we have also established the safety profile for semaglutide by concluding the six SUSTAIN trials” says Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “With the strong results from SUSTAIN 6, we look forward to the regulatory filing of semaglutide.”

Novo Nordisk expects to file semaglutide for regulatory review in the US and EU in the fourth quarter of 2016.

**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 subcutaneously once weekly is in phase 3

development for the treatment of type 2 diabetes. Furthermore, semaglutide is currently being developed in an oral tablet version for treatment of type 2 diabetes as well as in once-daily subcutaneous versions for treatment of type 2 diabetes and weight management.

**About the SUSTAIN clinical programme**

The SUSTAIN programme is a phase 3 clinical programme comprising six global trials of semaglutide administered subcutaneously 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. The results were reported in July 2015.

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. The results were reported in December 2015.

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. The results were reported in September 2015.

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. The results were reported in November 2015.

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. The results were reported in February 2016.

SUSTAIN 6 – a 2-year trial to evaluate cardiovascular and other long-term outcomes with semaglutide in approximately 3,300 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 41,000 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*

**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: April 28, 2016

Lars Rebien Sørensen,

Chief Executive Officer