NOVO NORDISK A S
Form 6-K
August 18, 2017

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

August 16, 2017

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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 superior to dulaglutide on glucose control and weight loss in people with type 2 diabetes in SUSTAIN 7

Bagsværd, Denmark, 16 August 2017 - Novo Nordisk today announced the SUSTAIN 7 trial results, demonstrating that people with type 2 diabetes treated with once-weekly semaglutide experienced superior reduction in HbA_{1c} and body weight compared to treatment with dulaglutide. The 40-week trial investigated the efficacy and safety of 0.5 mg semaglutide compared with 0.75 dulaglutide and 1.0 mg semaglutide compared with 1.5 mg dulaglutide, when added to metformin.

From a mean baseline HbA_{1c} of 8.2%, 0.5 mg semaglutide achieved a statistically significant and superior reduction of 1.5% compared with a reduction of 1.1% with 0.75 mg dulaglutide. People treated with 1.0 mg semaglutide experienced a statistically significant and superior reduction of 1.8% compared with a reduction of 1.4% with 1.5 mg dulaglutide.

Using the American Diabetes Association (ADA) treatment target of HbA_{1c} below or equal to 7.0%, 69% of people treated with 0.5 mg semaglutide compared with 52% of people treated with 0.75 mg dulaglutide reached the treatment goal, and 79% of people treated with 1.0 mg semaglutide compared to 68% with 1.5 mg dulaglutide reached the treatment goal.

Using the American Association of Clinical Endocrinologists (AACE) treatment target of HbA_{1c} below or equal to 6.5%, 51% of people treated with 0.5 mg semaglutide compared with 36% of people treated with 0.75 mg dulaglutide reached the treatment goal, and 68% of people treated with 1.0 mg semaglutide compared to 49% with 1.5 mg dulaglutide reached the treatment goal.

Furthermore, from a mean baseline body weight of 95 kg and a BMI of 33.5 kg/m^2, people treated with 0.5 mg semaglutide experienced a statistically significant and superior weight loss of 4.6 kg compared to 2.3 kg with 0.75 mg dulaglutide. People treated with 1.0 mg semaglutide experienced a statistically significant and superior weight loss of 6.5 kg compared to 3.0 kg with 1.5 mg dulaglutide.

44% of people treated with 0.5 mg semaglutide compared with 23% of people treated with 0.75 mg dulaglutide achieved more or equal to 5% body weight loss and 63% of people with 1.0 mg semaglutide compared with 30% of people treated with 1.5 mg dulaglutide.

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In the trial, semaglutide demonstrated a safe and well-tolerated profile consistent with results from the SUSTAIN programme. The most common adverse event for both semaglutide dosages was mild to moderate nausea, which was overall comparable to dulaglutide and diminished over time. Premature treatment discontinuation due to adverse events was less than 10% across all treatment groups. The number of people reporting an adverse event of diabetic retinopathy was low and comparable in both the semaglutide and dulaglutide groups (4 and 5 events, respectively).

"The superior glucose control and weight loss achieved with semaglutide compared to dulaglutide in this trial reinforces the unprecedented results observed in the entire SUSTAIN programme" said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "We are excited about the potential of semaglutide to set a new standard for treatment of type 2 diabetes".

About semaglutide
Semaglutide is a once-weekly analogue of human glucagon-like peptide-1 (GLP-1) that stimulates insulin and suppresses glucagon secretion in a glucose-dependent manner, while decreasing appetite and food intake. Once-weekly semaglutide is currently under review by seven regulatory agencies, including the US Food and Drug Administration, the European Medicines Agency and the Japanese Pharmaceuticals and Medical Devices Agency.

SUSTAIN 7
SUSTAIN 7 is a phase 3b, 40-week, efficacy and safety trial of 0.5 mg semaglutide vs 0.75 mg dulaglutide and 1.0 mg semaglutide vs 1.5 mg dulaglutide, both once-weekly, as add-on to metformin in 1,201 people with type 2 diabetes. The primary outcome measure was change in HbA_{1c} from baseline after 40 weeks of treatment with semaglutide compared to dulaglutide.

About the SUSTAIN clinical programme
SUSTAIN (Semaglutide Unabated Sustainability in Treatment of Type 2 Diabetes) is a clinical trial programme for semaglutide, administered once weekly, that comprises seven phase 3 global clinical trials, including a cardiovascular outcomes trial, involving more than 8,000 adults 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 41,400 people in 77 countries and markets its products in more than 165 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

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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: August 16, 2017

Lars Fruergaard Jørgensen

Chief Executive Officer