

NOVO NORDISK A S
Form 6-K
February 23, 2015
UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

Pursuant to Rule 13a-16 or 15d-16
of the Securities Exchange Act of 1934

February 20, 2015

NOVO NORDISK A/S
(Exact name of Registrant as specified in its charter)

Novo Allé
DK- 2880, Bagsvaerd
Denmark
(Address of principal executive offices)

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 ☒ 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 ☒

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g-32(b):82-_____

Novo Nordisk announces positive results for phase 2 trial with oral semaglutide in people with type 2 diabetes

Bagsværd, Denmark, 20 February 2015 – Novo Nordisk today announced that it has successfully completed the phase 2 trial for OG217SC; an oral formulation of the long- acting GLP-1 analogue semaglutide, investigating dose range, escalation, efficacy and safety of once-daily oral semaglutide compared with oral placebo or once-weekly subcutaneously administered semaglutide in around 600 people with type 2 diabetes treated for 26 weeks.

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From a mean baseline HbA1c of 7.9%, people treated with oral semaglutide in five different doses ranging from 2.5 mg to 40 mg achieved dose-dependent improvements in HbA1c of 0.7% to 1.9% after 26 weeks. By comparison, people treated with a dose of 1 mg subcutaneous semaglutide or placebo achieved improvements of 1.9% and 0.3% respectively. Confirming the primary end-point of the trial, all doses of oral semaglutide were statistically significantly superior to placebo.

Furthermore, from a mean baseline weight of 92 kg, people treated with subcutaneous semaglutide experienced a weight loss of around 6.5 kg, which was comparable to the weight loss experienced by the people treated with the highest doses of oral semaglutide. People treated with placebo experienced a weight loss of just over 1 kg.

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 and vomiting, and diminished over time. The gastrointestinal adverse events appeared to be dose-dependent and were more prevalent for the highest doses of oral semaglutide compared to subcutaneous semaglutide. No other apparent differences between the treatment groups were observed with respect to overall adverse events and standard safety parameters.

“We are very pleased with the results of this trial confirming the potential of semaglutide to treat type 2 diabetes, both as a once-weekly subcutaneous injection and as a once- daily tablet”, said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “This clinical proof of concept marks an important milestone for oral peptide therapy within the field of diabetes”.

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Based on these results, Novo Nordisk will initiate consultations with regulatory authorities subsequent to which a decision of whether to progress OG217SC into phase 3 development will be made.

About semaglutide and OG217SC

Semaglutide is a long-acting human GLP-1 analogue that stimulates insulin and suppresses glucagon secretion in a glucose-dependent manner. The molecule is in development for once-weekly subcutaneous use and for once-daily oral administration for the treatment of type 2 diabetes. The oral formulation, OG217SC, is provided in a tablet formulation with an absorption-enhancing excipient, SNAC. SNAC is an absorption-enhancing excipient included in the Eligen® Carrier Concept. The Eligen® technology is licenced from Emisphere Technologies, Inc.

Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. The company also has leading positions within haemophilia care, growth hormone therapy and hormone replacement therapy. Headquartered in Denmark, Novo Nordisk employs approximately 41,500 employees 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 14 / 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.

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Date: February 20, 2015

NOVO NORDISK A/S

Lars Rebien Sørensen,
Chief Executive Officer