

NOVO NORDISK A S
Form 6-K
August 26, 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

August 26, 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 to initiate phase 3a development of oral semaglutide, a once-daily oral GLP-1 analogue

Bagsværd, Denmark, 26 August 2015 - Novo Nordisk today announced the decision to initiate a phase 3a programme with oral semaglutide; a once-daily oral formulation of the long-acting GLP-1 analogue semaglutide. The decision follows the encouraging results of the proof-of-concept phase 2 trial announced on 20 February 2015 and the subsequent consultations with regulatory authorities.

Novo Nordisk intends to initiate a global phase 3a programme, named PIONEER, comprising seven trials with approximately 8,000 people with type 2 diabetes. The PIONEER programme will include six safety and efficacy trials and one trial for evaluating the cardio-vascular safety of oral semaglutide. The first trial in the programme is planned for initiation in first quarter of 2016 and will investigate the efficacy and safety of once- daily oral semaglutide doses of 3 mg, 7 mg and 14 mg, compared to once-daily oral anti- diabetic sitagliptin dose of 100 mg. The remaining six trials of the PIONEER programme are all expected to be initiated during 2016.

In order to meet capacity requirements for current and future diabetes care products, including oral semaglutide, Novo Nordisk expects to invest an estimated 2 billion US dollars over the coming five years in two new production facilities; a new production facility for a range of active pharmaceutical ingredients in Clayton, North Carolina, US and a new drug-product facility in Måløv, Denmark. The final design and cost of the new production facilities will be presented for approval by the company's board of directors in 2016.

“Delivering protein-based medicine like semaglutide in the form of a tablet and producing it on a large scale is a major challenge, and with the announcement today we have reached a significant milestone towards achieving that goal”, said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “We are excited about the opportunities oral semaglutide represents as a new oral anti-diabetic agent to further improve type 2 diabetes treatment”.

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About semaglutide

Semaglutide (NN9924) is a new glucagon-like peptide-1 (GLP-1) analogue that can help people with type 2 diabetes achieve substantial lowering of blood glucose with a low risk of hypoglycaemia. In addition, semaglutide induces weight loss by decreasing appetite and food intake. The oral formulation of semaglutide is provided in a tablet formulation with SNAC, 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. 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 39,700 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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Company announcement No 52 / 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: August 26, 2015

Lars Rebien Sørensen.

Chief Executive Officer