

NOVO NORDISK A S
Form 6-K
February 09, 2018

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 9, 2018

NOVO NORDISK A/S

(Exact name of Registrant as specified in its charter)

Novo Allé

DK- 2880, Bagsvaerd

Denmark

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(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-_____

Ozempic® (semaglutide) approved in the EU for the treatment of type 2 diabetes

Bagsværd, Denmark, 9 February 2018 - Novo Nordisk today announced that the European Commission (EC) has granted marketing authorisation for Ozempic® (semaglutide) for the treatment of adults with type 2 diabetes. Ozempic® is a new once-weekly analogue of human glucagon-like peptide-1 (GLP-1) indicated as monotherapy when metformin is considered inappropriate due to intolerance or is contraindicated, and as an addition to other medicinal products for the treatment of diabetes. The marketing authorisation applies to all 28 European Union member states.

The label reflects the superior and sustained reductions in HbA_{1c} and body weight achieved with Ozempic® relative to comparator treatments, cardiovascular benefits and the statistically significant reduction in diabetic nephropathy with Ozempic® relative to standard of care.

Ozempic® has been approved in the EU for use in a multi-dose Ozempic® pen, the latest generation of Novo Nordisk prefilled devices. However, Novo Nordisk intends to submit a variation application to the European Medicines Agency (EMA) seeking approval of an updated Ozempic® pen offering. The new pen offering will help facilitate reimbursement for patients with type 2 diabetes using Ozempic®. The launch of Ozempic® is expected to take place in the first EU countries in the second half of 2018 following the approval of the variation application for the updated pen offering.

“We are very excited about the approval of Ozempic® in the EU, as we believe it has the potential to set a new standard for the treatment of type 2 diabetes,” said Mads Krosgaard Thomsen, executive vice president and chief science officer. “Type 2 diabetes is a complex disease and the strong clinical profile of Ozempic® provides a much needed treatment option for people looking for efficacious solutions to manage their disease.”

About Ozempic®

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Ozempic® (semaglutide) is a new once-weekly analogue of human glucagon-like peptide- 1 (GLP-1) that has been developed for the treatment of type 2 diabetes. The approval of Ozempic® is based on the SUSTAIN programme, a global clinical development

programme that comprised eight phase 3a trials, encompassing more than 8,000 adults with type 2 diabetes. The phase 3a programme involved a broad range of people with type 2 diabetes, including some with high cardiovascular risk profiles and people with and without renal disease. Ozempic® was approved by the US FDA on 5 December 2017 and by Health Canada on 9 January 2018.

Novo Nordisk is a global healthcare company with 95 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat obesity, haemophilia, growth disorders and other serious chronic diseases. Headquartered in Denmark, Novo Nordisk employs approximately 42,100 people in 79 countries and markets its products in more than 170 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 12 / 2018

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: February 9, 2018

Lars Fruergaard Jørgensen

Chief Executive Officer