

NOVO NORDISK A S
Form 6-K
December 15, 2017

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

December 15, 2017

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) recommended for approval by the European regulatory authorities

Bagsværd, Denmark, 15 December 2017 - Novo Nordisk today announced that the Committee for Medicinal Products for Human Use (CHMP) under the European Medicines Agency (EMA) has adopted a positive opinion, recommending marketing authorisation for Ozempic® (semaglutide) for the treatment of adults with type 2 diabetes mellitus.

The CHMP recommends Ozempic®, the intended brand name for once-weekly semaglutide, to be indicated as monotherapy when metformin no longer provides sufficient treatment or is contraindicated and as an addition to other medicinal products for the treatment of diabetes. The indication also refers to specific sections of the label for study results with respect to combination with other diabetes medications, effects on glycaemic control, cardiovascular events and the populations studied. The label furthermore reflects the superior reduction in body weight achieved with Ozempic® relative to comparator treatments and the statistically significant reduction in diabetic nephropathy with Ozempic® relative to standard of care.

As an integral part of the approval, Novo Nordisk has committed to conduct post- approval safety studies including a long-term diabetic retinopathy outcome study. Furthermore, as required for all long-acting GLP-1 products approved in the EU, Ozempic® will be enrolled in the data collection for the registry of medullary thyroid carcinoma.

“We are very excited about the positive opinion for Ozempic® for treatment of people with type 2 diabetes in Europe, many of whom are still looking for new and more efficacious solutions to better manage their disease,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer. “We believe Ozempic®, with its unique clinical profile, has the potential to set a new standard for treatment of type 2 diabetes.”

Novo Nordisk expects to receive final marketing authorisation from the European Commission in the first quarter of 2018.

About Ozempic®

Ozempic® (semaglutide) is a once-weekly analogue of human glucagon-like peptide-1 (GLP-1) that has been developed for the treatment of type 2 diabetes. The review of

Ozempic® is based on the SUSTAIN programme, a global clinical development programme that comprises eight phase 3a trials, encompassing more than 8,000 adults with type 2 diabetes. The phase 3a programme involves a broad range of people with type 2 diabetes, including some individuals with high cardiovascular risk profiles and people with and without renal disease.

Ozempic® was recently approved by the US Food and Drug Administration and is currently under review by several regulatory agencies, including the Japanese Pharmaceuticals and Medical Devices Agency.

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 obesity, haemophilia, growth disorders and other serious chronic diseases. Headquartered in Denmark, Novo Nordisk employs approximately 41,700 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

Further information

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Company announcement No 92 / 2017

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: December 15, 2017

Lars Fruergaard Jørgensen

Chief Executive Officer