

NOVO NORDISK A S
Form 6-K
September 29, 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

September 29, 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-_____

Novo Nordisk's new fast-acting mealtime insulin Fiasp® approved in the US

Bagsværd, Denmark, 29 September 2017 – Novo Nordisk today announced that the US Food and Drug Administration (FDA) has approved Fiasp® (fast-acting insulin aspart), a new fast-acting mealtime insulin, for the treatment of adults with diabetes. The FDA's decision comes after Fiasp® in clinical trials demonstrated benefits for people in need of improved overall glucose control.

Fiasp® is an innovative formulation of insulin aspart (NovoLog®) developed with the aim of obtaining pharmacokinetic and pharmacodynamic properties that more closely match the natural physiological insulin mealtime response of a person without diabetes.

In clinical trials Fiasp® has demonstrated clinically relevant improvement in long-term glucose level (HbA1c). These results were achieved with a comparable overall rate of severe or blood-sugar confirmed hypoglycaemia, between Fiasp® and insulin aspart.

“We are very pleased that Fiasp® will now also be available to people with diabetes in the US,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “The fast action profile of Fiasp® allows people with diabetes convenient timing in terms of when to take their insulin in connection with meals to achieve the optimal blood sugar control.”

About Fiasp®

Fiasp® is insulin aspart in an innovative formulation, in which two excipients have been added: Vitamin B3 (niacinamide) to increase the speed of absorption and a naturally occurring amino acid (L-Arginine) for stability. The review of Fiasp® was based on the 'onset' programme, a phase 3 clinical programme comprising four trials encompassing more than 2,100 people with type 1 and 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

Further information

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CVR no:

24 25 67 90

Company announcement No 74 / 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: September 29, 2017

Lars Fruergaard Jørgensen

Chief Executive Officer