NOVO NORDISK A S
Form 6-K
November 14, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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FORM 6-K

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REPORT OF FOREIGN PRIVATE ISSUER

Pursuant to Rule 13a-16 or 15d-16

of the Securities Exchange Act of 1934

November 11, 2016

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NOVO NORDISK A/S

(Exact name of Registrant as specified in its charter)

Novo Allé

DK- 2880, Bagsvaerd

Denmark

(Address of principal executive offices)

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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 [X] 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 [X]

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

Novo Nordisk receives positive opinion from the European regulatory authorities for Fiasp® (fast-acting insulin aspart) for the treatment of diabetes

Bagsværd, Denmark, 11 November 2016 - Novo Nordisk today announced that the Committee for Medicinal Products for Human Use (CHMP), under the European Medicines Agency (EMA), adopted a positive opinion for the use of Fiasp® (fast-acting insulin aspart), recommending marketing authorisation for the treatment of adults with type 1 and type 2 diabetes.

The CHMP recommends Fiasp®, the intended brand name for fast-acting insulin aspart, to be indicated for use as the bolus component of basal-bolus therapy in combination with basal insulin and for continuous subcutaneous insulin infusion via an insulin pump. Novo Nordisk has developed Fiasp® as mealtime insulin with an earlier and greater glucose- lowering effect than NovoRapid® (insulin aspart).

“We believe Fiasp® provides an important evolution in mealtime insulin, which can address the unmet medical need for people requiring further improved blood glucose control around meals or flexibility of dosing,” says Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk.

Novo Nordisk expects to receive final marketing authorisation from the European Commission in the first quarter of 2017.

About Fiasp®

Fiasp® (fast-acting insulin aspart) is a mealtime insulin for improved control of postprandial glucose (PPG) excursions and has been developed for the treatment of people with type 1 and type 2 diabetes, as well as for pump treatment. Fiasp® is insulin aspart (NovoRapid®) in a new formulation, in which two new excipients have been added to ensure early and fast absorption thereby providing earlier insulin action. The review of Fiasp® was based on the onset programme, a phase 3 clinical programme comprising of 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 42,300 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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Novo Nordisk A/S

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CVR no:
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Company announcement No 78 / 2016

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: November 11, 2016

Lars Rebien Sørensen,

Chief Executive Officer