

NOVO NORDISK A S
Form 6-K
January 10, 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

January 10, 2017

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-_____

Fiasp® (fast-acting insulin aspart) approved in Europe

Bagsværd, Denmark, 10 January 2017 - Novo Nordisk today announced that the European Commission has granted marketing authorisation for Fiasp® for the treatment of diabetes in adults. The authorisation covers all 28 European Union member states.

Fiasp® is the brand name for fast-acting insulin aspart. Fiasp® provides improved mealtime and overall glucose control with a similar safety profile versus NovoRapid®.

"Fiasp® is a new-generation mealtime insulin; it is an innovative faster formulation of insulin aspart that more closely mimics the physiological insulin response around meals. The incremental benefits with Fiasp® are comparable to

those observed for the last generation of mealtime insulins when introduced more than a decade ago", said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk.

Fiasp® will be available in vial, Penfill® and FlexTouch® pen.

Novo Nordisk expects to launch Fiasp® in the first European countries in the first half of 2017.

About Fiasp®

Fiasp® (fast-acting insulin aspart) is an ultra-fast rapid-acting insulin now approved in Europe that improves 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 earlier, greater and faster 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.

Fiasp® also received marketing authorisation from Health Canada on 6 January 2017, and has been filed for regulatory review in the US, Switzerland, Australia, Canada, Brazil, South Africa and Argentina.

Further information

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Company announcement No 3 / 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: January 10, 2017

Lars Rebien Sørensen,

Chief Executive Officer