

NOVO NORDISK A S
Form 6-K
October 11, 2016

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

October 7, 2016

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-_____

Novo Nordisk receives Complete Response Letter in the US for faster-acting insulin aspart

Bagsværd, Denmark 7 October 2016 - Novo Nordisk today announced that it has received a Complete Response Letter from the US Food and Drug Administration (FDA) regarding the New Drug Application for faster-acting insulin aspart.

In the letter, the FDA requests additional information related to the assay for the immunogenicity and clinical pharmacology data before the review of the New Drug Application can be completed. Novo Nordisk is evaluating the content of the Complete Response Letter and will work closely with the FDA to resolve the outstanding issues.

“We believe faster-acting insulin aspart can address an unmet medical need for people requiring improved blood glucose control around meals, and our ambitions for this innovative drug are unchanged”, says Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “We acknowledge the request for

information from FDA and will work closely with the agency to determine the best path forward to complete the review.”

The New Drug Application for faster-acting insulin aspart was submitted to the FDA in December 2015. Faster-acting insulin aspart is currently also under review in the EU, Switzerland, Canada, Brazil, South Africa and Argentina.

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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Company announcement No 69 / 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: October 11, 2016

Lars Rebien Sørensen.

Chief Executive Officer