

NOVO NORDISK A S
Form 6-K
May 20, 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

May 20, 2016

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-_____

FDA posts briefing materials prior to Advisory Committee meeting for IDegLira, a fixed combination product of insulin degludec and liraglutide

Bagsværd, Denmark, 20 May 2016 – Novo Nordisk announced today that the US Food and Drug Administration (FDA) has published the briefing documents ahead of the 24 May 2016 Advisory Committee meeting to discuss the New Drug Application (NDA) for IDegLira, the fixed combination product of insulin degludec (Tresiba®) and liraglutide (Victoza®).

The briefing documents from Novo Nordisk and the FDA, which will form the basis for the Advisory Committee’s discussion, provide an overview of the non-clinical and clinical data for IDegLira for the treatment of type 2 diabetes.

The briefing materials can be accessed on the FDA webpage:

<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm491062.htm>

About advisory committee meetings

FDA advisory committees are panels of independent experts who advise the FDA on specific questions raised by the FDA as they consider regulatory decisions. The FDA is not bound by the committee's recommendation, but it takes its advice into consideration when reviewing a new drug application. According to the FDA Amendment Act of 2007 (FDAAA), the FDA should refer new drugs to an advisory committee meeting, or alternatively justify why an advisory committee meeting was not requested.

About IDegLira

IDegLira is a once-daily, single injection combination product consisting of insulin degludec (Tresiba®), a once-daily new-generation basal insulin analogue, and liraglutide (Victoza®), a once-daily GLP-1 analogue.

IDegLira was submitted to the FDA in September 2015 under the US FDA's Prescription Drug User Fee Act V (PDUFA V) regulation. In Europe, IDegLira was approved in September 2014 and is marketed under the brand name Xultophy®.

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 41,600 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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			24 25 67 90

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: May 20, 2016

Lars Rebien Sørensen,

Chief Executive Officer