

NOVO NORDISK A S
Form 6-K
April 08, 2015
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
April 7, 2015

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- _____

US FDA accepts Tresiba® and Ryzodeg® resubmissions for review

Bagsværd, Denmark, 7 April 2015 – Novo Nordisk today announced that the US Food and Drug Administration (FDA) has accepted for review the Class II Resubmissions for Tresiba® (insulin degludec) and Ryzodeg® (insulin degludec/insulin aspart).

To preserve the integrity of the ongoing DEVOTE trial, only a small team within Novo Nordisk has access to the data. This team has prepared the interim analysis for the Class II resubmission and will interact with the FDA during the review on matters related to the interim analysis.

As previously communicated, the result of an interim analysis carries a higher level of uncertainty than the final study results as this preliminary estimate is built on a substantially lower number of observations. Accordingly, the relative risk estimate derived from the interim analysis is thus only an indication of the final trial results.

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Novo Nordisk management does not have access to the results of the interim analysis. The trial is expected to be completed in the second half of 2016.

Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. The company also has leading positions within haemophilia care, growth hormone therapy and hormone replacement therapy. Headquartered in Denmark, Novo Nordisk employs approximately 41,500 employees 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 26 / 2015

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.

Date: April 7, 2015

NOVO NORDISK A/S
Lars Rebien Sørensen,
Chief Executive Officer
