NOVO NORDISK A S
Form 6-K
February 11, 2013

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

February 11, 2013

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 [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 Complete Response Letter in the US for Tresiba® and Ryzodeg®

Bagsværd, Denmark, 10 February 2013 – Novo Nordisk today announced that on 8 February 2013 it received a Complete Response Letter from the US Food and Drug Administration (FDA) regarding the New Drug Applications for Tresiba® (insulin degludec) and Ryzodeg® (insulin degludec/insulin aspart). A Complete Response Letter is issued by the FDA, when the agency determines that an application cannot be approved in its current form.

In the letter, the FDA requests additional cardiovascular data from a dedicated cardiovascular outcomes trial before the review of the New Drug Applications can be completed. Novo Nordisk is evaluating the content of the Complete Response Letter and will work closely with the FDA to provide the requested data. Novo Nordisk does not expect to be able to provide the requested data during 2013.

In the letter, the FDA also states that approvals for Tresiba® and Ryzodeg® cannot be granted until the violations cited in the previously announced Warning Letter, dated 12 December 2012, have been resolved.

“We are convinced that Tresiba® and Ryzodeg® offer significant benefits for people who require insulin”, said Lars Rebien Sørensen, chief executive officer of Novo Nordisk. “We are surprised and disappointed to receive this letter, but we acknowledge this decision by the FDA and will work with the agency to determine the best path forward to completing the review.”

The New Drug Applications for Tresiba® and Ryzodeg® were submitted by Novo Nordisk to the FDA in September 2011. In November 2012, at an FDA Endocrinologic and Metabolic Drugs Advisory Committee meeting, a panel of independent scientific experts unanimously recommended that a cardiovascular outcomes trial should be conducted and voted eight to four in favour of approving the products with a post-approval cardiovascular outcomes trial commitment.

Tresiba® and Ryzodeg® are approved in Japan, the EU and Mexico and under regulatory review in a number of countries throughout the world.

Novo Nordisk A/S
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CVR no:
24 25 67 90

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The Complete Response Letter is not expected to significantly impact Novo Nordisk's expectations for the company's financial results for 2013, which were provided on 31 January 2013 in connection with the release of the financial results for 2012.

Conference call

On 11 February at 8.00 am CET, corresponding to 2.00 am EST, a conference call for investors will be held. Investors will be able to listen in via a link on the investor section of novonordisk.com.

Novo Nordisk is a global healthcare company with 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 35,000 employees in 75 countries, and markets its products in more than 180 countries. Novo Nordisk's B shares are listed on NASDAQ OMX Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com.

Further information

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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: February 11, 2013

NOVO NORDISK A/S

Lars Rebien Sørensen,

President and Chief Executive Officer