NOVO NORDISK A S
Form 6-K
March 26, 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

March 26, 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 [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 has decided to resubmit the New Drug Applications of Tresiba® and Ryzodeg® in the US

Bagsværd, Denmark, 26 March 2015 – Novo Nordisk today announced that the company has decided to submit the prespecified interim analysis of DEVOTE as part of a Class II Resubmission of the New Drug Applications (NDAs)

of Tresiba® and Ryzodeg® to the US Food and Drug Administration (FDA). The resubmission is expected to take place within the next month.

The cardiovascular outcomes trial for Tresiba® (insulin degludec), DEVOTE, was initiated in October 2013 and the required number of major adverse cardiovascular events (MACE) for the prespecified interim analysis were accumulated by the end of January 2015.

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 that has been derived from the interim analysis is thus only an indication of the final trial results.

In addition to the data from the interim analysis of DEVOTE, the Class II Resubmission will comprise a safety update including data from all clinical trials with insulin degludec as well as an overview of postmarketing data.

Following the submission of the Class II Resubmission, the FDA is expected to communicate either its acceptance of the filing or issue an ‘Incomplete Response Letter’. This usually occurs within a month of resubmission.

To preserve the integrity of the ongoing DEVOTE trial, only a small team within Novo Nordisk has access to the data. 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

For further information

Media:		
Mette Kruse Danielsen	+45 3079 3883	mkd@novonordisk.com
Ken Inchausti (US)	+1 609 514 8316	kiau@novonordisk.com
Investors:		
Kasper Roseeuw Poulsen	+45 3079 4303	krop@novonordisk.com
Melanie Raouzeos	+45 3075 3479	mrz@novonordisk.com
Daniel Bohsen	+45 3079 6376	dabo@novonordisk.com
Frank Daniel Mersebach (US)	+1 609 235 8567	fdni@novonordisk.com

Novo Nordisk A/S Investor Relations	Novo Allé 2880 Bagsværd Denmark	Telephone: +45 4444 8888	Internet: www.novonordisk.com CVR no: 24 25 67 90

Company announcement No 23 / 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: March 26, 2015

NOVO NORDISK A/S

Lars Rebien Sørensen,
Chief Executive Officer