

NOVO NORDISK A S  
Form 6-K  
December 04, 2012

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 6-K**

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**REPORT OF FOREIGN PRIVATE ISSUER**

Pursuant to Rule 13a-16 or 15d-16  
of the Securities Exchange Act of 1934

**December 3, 2012**

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**NOVO NORDISK A/S**

(Exact name of Registrant as specified in its charter)

**Novo Allé**

**DK- 2880, Bagsvaerd**

**Denmark**

(Address of principal executive offices)

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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-\_\_\_\_\_



## **Ryzodeg® (insulin degludec/insulin aspart) passed the review by the First Committee on Drugs of Pharmaceutical Affairs in Japan**

**Bagsværd, Denmark, 3 December 2012** – Novo Nordisk today announced that Ryzodeg® (insulin degludec/insulin aspart) has passed the review by the First Committee on Drugs of Japan's Pharmaceutical Affairs. The remaining step in the regulatory process is an approval from the Ministry of Health, Labour and Welfare.

The First Committee on Drugs of Pharmaceutical Affairs serves as an advisory body to the Ministry in matters related to pharmaceuticals including new drug applications. The passing of the review by the drug committee is an essential milestone in the Japanese review process prior to a marketing authorisation from the Ministry.

Novo Nordisk expects to receive marketing authorisation from the Ministry within a few months.

In Japan, price negotiations for Tresiba® (insulin degludec) continue and are expected to be completed in the first quarter of 2013. The exact launch timing for Ryzodeg® is to be decided after the Tresiba® price listing.

### **About Tresiba® and Ryzodeg®**

**Tresiba®** is the intended brand name for insulin degludec, the first once-daily new-generation basal insulin analogue, with an ultra-long duration of action, discovered and developed by Novo Nordisk. Tresiba® has a distinct slow absorption which provides a flat and stable action profile. Tresiba® has been studied in a large-scale clinical trial programme, BEGIN™, examining its impact on glucose control, hypoglycaemia and the possibility to flexibly adjust Tresiba® dosing time to suit patient needs.

**Ryzodeg®** is the intended brand name for insulin degludec/insulin aspart, which contains the new-generation basal insulin degludec in a formulation with a bolus boost of insulin aspart. Ryzodeg® is the first and only soluble insulin combination of ultra-long-acting insulin degludec and the most prescribed rapid-acting insulin, NovoRapid® (NovoLog® in the US), providing both fasting and post-prandial glucose control.

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

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Tresiba® and Ryzodeg® were submitted for regulatory approval to the Japanese Ministry of Health, Labour and Welfare (MHLW) in December 2011 and March 2012, respectively. Tresiba® was approved in Japan in September 2012 and in October 2012 Tresiba® and Ryzodeg® received positive CHMP opinions in Europe. In November, the products received a positive vote for approval from an FDA Advisory Committee. In addition, applications have been submitted for regulatory approval in Canada, Switzerland and a range of other countries.

*Novo Nordisk is a global healthcare company with 89 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 33,900 employees in 75 countries, and markets its products in more than 190 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](http://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: December 3, 2012

NOVO NORDISK A/S

Lars Rebien Sørensen,

President and Chief Executive Officer