

NOVO NORDISK A S  
Form 6-K  
January 22, 2013

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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

**January 21, 2013**

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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-\_\_\_\_\_



## **Tresiba® and Ryzodeg® receive marketing authorisations in Europe**

**Bagsværd, Denmark, 21 January 2013** – Novo Nordisk today announced that the European Commission has granted marketing authorisations for Tresiba® (insulin degludec) and Ryzodeg® (insulin degludec/insulin aspart) for the treatment of diabetes in adults. The authorisations cover all 27 European Union member states.

Tresiba®, the brand name for insulin degludec, is a once-daily new-generation basal insulin analogue with an ultra-long duration of action. In „treat-to-target“ studies supporting the new drug application where Tresiba® was compared to insulin glargine, Tresiba® demonstrated a significantly lower risk of overall and nocturnal hypoglycaemia, while successfully achieving equivalent reductions in HbA<sub>1c</sub>. Further, with a duration of action beyond 42 hours, Tresiba® is the first basal insulin to offer patients the possibility of adjusting the time of injection, when needed.

Ryzodeg®, the brand name for insulin degludec/insulin aspart, contains the new-generation once-daily basal insulin degludec in a soluble formulation with insulin aspart. Ryzodeg® can be administered once or twice daily with the main meal(s). In a „treat-to-target“ study supporting the new drug application where Ryzodeg® was compared to NovoMix®, Ryzodeg® demonstrated a significantly lower risk of overall and nocturnal hypoglycaemia while successfully achieving equivalent reductions in HbA<sub>1c</sub>.

In Europe, Tresiba® and Ryzodeg® will be available in FlexTouch®, Novo Nordisk's latest prefilled insulin pen, which has an easy auto-injector mechanism. Tresiba® will be offered in two concentrations enabling maximum doses of 80 and 160 units per injection, respectively.

“These marketing authorisations constitute significant milestones for Novo Nordisk and the treatment of diabetes,” says Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “We look forward to making Tresiba® and Ryzodeg® available to many people with diabetes in Europe.”

Novo Nordisk expects to launch Tresiba® in the UK and Denmark during the first half of 2013 and in other European markets throughout the rest of 2013 and 2014. Ryzodeg® is currently expected to be launched approximately one year after Tresiba®.

**Novo Nordisk A/S** Novo Allé  
Investor Relations 2880 Bagsværd  
Denmark

Telephone:  
+45 4444 8888  
Telefax:  
+45 4444 6626

Internet:  
[www.novonordisk.com](http://www.novonordisk.com)  
CVR no:  
24 25 67 90

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## About Tresiba® and Ryzodeg®

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

Tresiba® and Ryzodeg® were submitted to the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) in September 2011 for regulatory review. In addition, applications have been submitted for regulatory approval in Japan, Canada, Switzerland and a range of other countries. Tresiba® and Ryzodeg® were approved in Japan in September and December 2012, respectively. In November 2012, the products received a positive vote for approval from an FDA Advisory Committee in the US.

*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

#### Media:

|                   |                 |  |
|-------------------|-----------------|--|
| Mike Rulis        | +45 4442 3573   | <a href="mailto:mike@novonordisk.com">mike@novonordisk.com</a> |
| Ambre Morley (US) | +1 609 216 5240 | <a href="mailto:abmo@novonordisk.com">abmo@novonordisk.com</a> |

#### Investors:

|                        |               |  |
|------------------------|---------------|--|
| Kasper Roseeuw Poulsen | +45 4442 4303 | <a href="mailto:krop@novonordisk.com">krop@novonordisk.com</a> |
| Frank Daniel Mersebach | +45 4442 0604 | <a href="mailto:fdni@novonordisk.com">fdni@novonordisk.com</a> |
| Lars Borup Jacobsen    | +45 3075 3479 | <a href="mailto:lbj@novonordisk.com">lbj@novonordisk.com</a>   |

Jannick Lindegaard (US)

+1 609 786 4575

[jlis@novonordisk.com](mailto:jlis@novonordisk.com)

**Novo Nordisk A/S** Novo Allé  
Investor Relations 2880 Bagsværd  
Denmark

Telephone:  
+45 4444 8888  
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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: January 21, 2013

NOVO NORDISK A/S

Lars Rebien Sørensen,

President and Chief Executive Officer