NOVO NORDISK A S Form 6-K September 27, 2011

# 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
September 27, 2011
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

Company Announcement

26 September 2011

Novo Nordisk files for regulatory approval of the ultra-long-acting insulins Degludec and DegludecPlus in Europe

Novo Nordisk today announced the submission to the European Medicines Agency of two marketing authorisation applications for the approval of ultra-long acting insulin Degludec and the insulin combination analogue DegludecPlus, respectively. This new generation of insulins has been developed for the treatment of people with type 1 and type 2 diabetes.

"We believe that the ultra-long-acting insulin Degludec has the potential to make a significant difference in insulin therapy by offering lower rates of hypoglycaemia and much greater flexibility than existing basal insulin," said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "This is a significant milestone for Novo Nordisk and for the millions of people with diabetes who require insulin. Now, we are looking forward to making these new insulins available to diabetes patients as soon as possible after completion of the regulatory processes."

Novo Nordisk expects to file the two new drug applications for Degludec and DegludecPlus to the US Food and Drug Administration within two weeks.

The filings are based on results from the BEGIN™ and BOOST™ clinical trial programmes which involved nearly 10,000 type 1 and type 2 diabetes patients. Data from the trials have shown Degludec to effectively lower blood glucose levels, while consistently demonstrating a significantly lower rate of hypo-glycaemia relative to insulin glargine, especially during the night. The trials also showed that Degludec can be administered once daily at any time of the day with the possibility to change injection time from day to day according to the needs of the individual patient, without compromising glycaemic control or safety.

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Novo Nordisk A/S Novo Allé Telephone: Internet: CVR no:

Investor Relations 2880 Bagsværd +45 4444 8888 novonordisk.com 24256790

Denmark Telefax:

+45 4444 6626

Novo Nordisk intends to make both insulins available in the FlexTouch® prefilled delivery device, the first insulin pen that can deliver up to 160 insulin units in a single injection. The FlexTouch® device was first approved in Europe earlier this year and the technology has been used in the US with other Novo Nordisk products since 2010.

#### About Degludec and DegludecPlus

**Degludec (insulin degludec)** is an ultra-long-acting basal insulin analogue discovered and developed by Novo Nordisk. It forms multi-hexamers upon subcutaneous injection, resulting in a soluble depot from which Degludec is slowly and continuously absorbed into the circulation, contributing to effective lowering of fasting glucose and minimal blood glucose variations.

**DegludecPlus (insulin degludec/insulin aspart)** contains the ultra-long-acting basal insulin Degludec in a formulation with a bolus boost of insulin aspart. DegludecPlus is the first and only soluble insulin combination of ultra-long-acting insulin degludec and the most prescribed rapid acting insulin, NovoRapid®, providing both fasting and post-prandial glucose control.

#### **BEGIN™** and **BOOST™** programmes

Novo Nordisk completed the phase 3a programmes, BEGIN $^{\text{m}}$  and BOOST $^{\text{m}}$  in 2010. The results from these studies comprise the majority of the data supporting the regulatory applications for Degludec and DegludecPlus, respectively. BEGIN $^{\text{m}}$  and BOOST $^{\text{m}}$  were the largest clinical trial programmes in the history of Novo Nordisk and in the field of insulin therapy, with nearly 10,000 type 1 and type 2 diabetes patients. The programmes were designed after consultancy with the regulatory agencies in Europe and USA.

Novo Nordisk is a global healthcare company with 88 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 32,000 employees in 74 countries, and markets its products in 179 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.

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Denmark Telefax:

+45 4444 6626

Media: Investors:

Katrine Sperling
Tel: (+45) 4442 6718
Krsp@novonordisk.com
Klaus Bülow Davidsen
Tel: (+45) 4442 3176
krsp@novonordisk.com
klda@novonordisk.com

Frank Daniel Mersebach Tel: (+45) 4442 0604 fdni@novonordisk.com

Lars Borup Jacobsen Tel: (+45) 3075 3479 <a href="mailto:lbpi@novonordisk.com">lbpi@novonordisk.com</a>

In North America:

Ken InchaustiJannick LindegaardTel: (+1) 609 514 8316Tel: (+1) 609 786 4575kiau@novonordisk.comjlis@novonordisk.com

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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: September 27, 2011 NOVO NORDISK A/S

Lars Rebien Sørensen,

President and Chief Executive Officer

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