

NOVO NORDISK A S  
Form 6-K  
November 13, 2012

**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

**November 13, 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-\_\_\_\_\_



Company Announcement

**Insulin degludec and insulin degludec/insulin aspart receive positive vote for approval from FDA Advisory Committee**

**Bagsværd, Denmark, 9 November 2012** Novo Nordisk today announced that the Endocrinologic and Metabolic Drugs Advisory Committee of the United States Food and Drug Administration (FDA) has completed its meeting regarding the New Drug Applications (NDA) for insulin degludec and insulin degludec/insulin aspart.

At the meeting, the Advisory Committee was asked to discuss the data contained in the NDAs and subsequent submissions regarding the benefits associated with a lower risk of hypoglycaemia and the cardiovascular risk profiles of the two products.

The FDA asked the panel members to vote on whether a cardiovascular outcomes trial should be conducted and whether sufficient safety and efficacy data had been provided to support marketing of insulin degludec and insulin degludec/insulin aspart.

The committee 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 outcomes trial commitment.

“The positive vote from the Advisory Committee marks an important step towards making insulin degludec and insulin degludec/insulin aspart available to patients with diabetes in the US. We look forward to completing the regulatory process with the agency, including the design of the post-approval cardiovascular outcomes trial,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk.

The FDA has not informed Novo Nordisk of when it expects to complete its review of the NDAs.

**Conference call**

On 9 November at 8.30 am CET, corresponding to 2.30 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](http://novonordisk.com).

**Novo Nordisk A/S**  
Investor Relations

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Company announcement No 72 / 2012

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### **About advisory committee meetings**

FDA advisory committees are panels of independent experts who advise the FDA on specific questions raised by the FDA as they consider regulatory decisions. The FDA is not bound by the committee's recommendation, but it takes its advice into consideration when reviewing new drug applications. According to the FDA Amendment Act of 2007 (FDAAA), the FDA should refer new drugs to an advisory committee meeting, or alternatively justify why an advisory committee meeting was not requested.

### **About insulin degludec and insulin degludec/insulin aspart**

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

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

Insulin degludec and insulin degludec/insulin aspart 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. Insulin degludec was approved in Japan in September 2012, and in October 2012 insulin degludec and insulin degludec/insulin aspart received positive CHMP opinions in Europe.

*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).*

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Company announcement No 72 / 2012

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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: November 13, 2012

NOVO NORDISK A/S

Lars Rebien Sørensen,

President and Chief Executive Officer

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