

Edgar Filing: NOVO NORDISK A S - Form 6-K

NOVO NORDISK A S
Form 6-K
June 12, 2008

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN ISSUER

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

June 12, 2008

NOVO NORDISK A/S
(Exact name of Registrant as specified in its charter)

NOVO ALLE
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 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-_____

RESEARCH UPDATE

NOVO NORDISK DISCONTINUES PHASE 3 CLINICAL TRIAL WITH NOVOSEVEN(R) IN TRAUMA

Novo Nordisk today announced the decision to discontinue the phase 3 clinical
trial with NovoSeven(R) for the treatment of bleeding in patients with severe
trauma. The decision was made based on the results of an analysis for futility

Edgar Filing: NOVO NORDISK A S - Form 6-K

conducted by the independent Data Monitoring Committee. The phase 3 trial was evaluating the efficacy and safety of NovoSeven(R) in severely injured trauma patients with bleeding refractory to standard treatment. The primary efficacy endpoint of the study was mortality and morbidity.

Due to an observed lower mortality than anticipated in the overall study group (around 10% in the phase 3 trial in total compared to more than 25% in the phase 2 trial), a futility analysis was conducted to assess the likelihood of reaching a successful outcome on the primary endpoint. The analysis predicted a low likelihood of obtaining a positive trial outcome with the planned study population, and as a consequence, Novo Nordisk has decided to discontinue the trial.

The decision is not due to safety concerns. In its latest review on safety data of 31 March 2008, the independent Data Monitoring Committee recommended continuation of the study.

Mads Krogsgaard Thomsen, executive vice president and chief science officer said: "It is regrettable that this trial is coming to an end. It has, however, already now provided a lot of important data on the treatment of severely injured patients. We will share these findings with the medical community as soon as the full clinical analysis has been completed."

The decision to discontinue the phase 3 clinical study with NovoSeven(R) for the treatment of bleeding in patients with severe trauma does not impact Novo Nordisk's expectations for the company's financial results for 2008, which were provided on 30 April in connection with the release of the financial results for the first quarter of 2008.

About the study

The study had enrolled more than 550 patients of the planned 1,502 in 24 countries. It was a multicentre, randomised, double-blind, parallel group, placebo-controlled trial to evaluate the efficacy and safety of NovoSeven(R) in severely injured trauma patients with bleeding refractory to standard treatment. Randomised patients received three single doses of NovoSeven(R) (200 mcg/kg + 100 mcg/kg + 100 mcg/kg) or placebo after the transfusion of the fourth unit of red blood cells)

The study has the primary endpoint of all cause 30-day mortality designed to show superiority of NovoSeven(R) compared to placebo in blunt trauma patients. If not superior, the endpoint included an analysis to demonstrate non-inferiority of NovoSeven(R) compared to placebo on all cause 30-day mortality and superiority of NovoSeven(R) compared to placebo on pulmonary and/or renal dysfunction requiring ongoing medical intervention at day 30 in blunt trauma patients. (ClinicalTrials.gov. Identifier: NCT00184548).

Novo Nordisk is a healthcare company and a world leader in diabetes care. In addition, Novo Nordisk has a leading position within areas such as haemostasis management, growth hormone therapy and hormone replacement therapy. Novo Nordisk manufactures and markets pharmaceutical products and services that make a significant difference to patients, the medical profession and society. With headquarters in Denmark, Novo Nordisk employs approximately 26,300 employees in 80 countries, and markets its products in 179 countries. Novo Nordisk's B shares are listed on the stock exchanges in Copenhagen and London. Its ADRs are listed on the New York Stock Exchange under the symbol 'NVO'. For more information, visit novonordisk.com.

Contacts for further information:

Media:

Investors:

Edgar Filing: NOVO NORDISK A S - Form 6-K

Outside North America:
Mike Rulis
Tel: (+45) 4442 3573
mike@novonordisk.com

Outside North America:
Mads Veggerby Lausten
Tel: (+45) 4443 7919
mlau@novonordisk.com

Hans Rommer
Tel: (+45) 4442 4765
hrmm@novonordisk.com

In North America:
Sean Clements
Tel: (+1) 609 514 8316
secl@novonordisk.com

In North America:
Christian Qvist Frandsen
Tel: (+1) 609 919 7937
cqfr@novonordisk.com

Stock Exchange Announcement no 34 / 2008

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: June 12, 2008

NOVO NORDISK A/S

Lars Rebien Sorensen,
President and Chief Executive Officer