

NOVO NORDISK A S
Form 6-K
January 04, 2005

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
1 January 2005**

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 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):8a-

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.

NOVO NORDISK A/S

Lars Rebien Sørensen, President and Chief
Executive Officer

Date: 3 January 2005

Stock Exchange Announcement

3 January 2005

Novo Nordisk continues to make progress towards label expansion for NovoSeven® in Europe

Novo Nordisk has now completed the compilation of the regulatory dossier related to the use of NovoSeven® in blunt trauma, and Novo Nordisk is in the process of filing for marketing approval with the European Medicines Agency, which will receive the filing by 7 January 2005. Furthermore, following consultations with the US regulatory authorities (FDA), Novo Nordisk now expects to initiate a US trauma trial in the second quarter of 2005.

Novo Nordisk still expects to file an application by mid-2005 for marketing approval in Europe for the use of NovoSeven® in connection with intracerebral haemorrhage (ICH).

Following recent consultations with the FDA, Novo Nordisk is now in the process of preparing for a confirmatory clinical trial for the use of NovoSeven® in connection with ICH. The trial is expected to be initiated around mid-2005, involving around 450 patients. Novo Nordisk expects this trial to generate further clinical documentation for filing with the FDA for regulatory approval in the US of NovoSeven® in connection with ICH.

The confirmatory trial will be conducted in the US, Europe as well as in other countries, and will be designed as a randomised, double-blind and placebo-controlled clinical trial in patients with spontaneous ICH confirmed by Computed Tomography (CT) scan within three hours of symptom onset.

Lars Rebién Sørensen, president and CEO of Novo Nordisk, says: We are excited about the filing of the trauma-related NovoSeven® data in Europe, and we look forward to the opportunity to generate the clinical documentation that is expected to allow Novo Nordisk to file in the US for label expansion of NovoSeven®.

The above information does not impact Novo Nordisk's expectations for the financial results for 2004. The financial results will be released on 28 January 2005 when the company will also announce its financial expectations for the year 2005.

Stock Exchange Announcement No 1 / 2005

Page 1 of 2

Novo Nordisk A/S
Corporate Communications

Novo Allé
2880 Bagsværd
Denmark

Telephone:
+45 4444 8888
Telefax:
+45 4444 2314

Internet:
www.novonordisk.com

CVR Number:
24256790

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

Novo Nordisk is a healthcare company and a world leader in diabetes care. The company has the broadest diabetes product portfolio in the industry, including the most advanced products within the area of insulin delivery systems. 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 20,000 full-time employees in 69 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.

For further information please contact:

Media:

Outside North America:

Mike Rulis

Tel (direct): (+45) 4442 3573

In North America:

Susan T Jackson

Tel (direct): (+1) 609 919 7776

Investors:

Outside North America:

Mogens Thorsager Jensen

Tel (direct): (+45) 4442 7945

Palle Holm Olesen

Tel (direct): (+45) 4442 6175

In North America:

Christian Kanstrup

Tel (direct): (+1) 609 919 7937

Stock Exchange Announcement No 1 / 2005

Page 2 of 2

Novo Nordisk A/S

Corporate Communications

Novo Allé

2880 Bagsværd

Denmark

Telephone:

+45 4444 8888

Telefax:

+45 4444 2314

Internet:

www.novonordisk.com

CVR Number:

24256790