

NOVO NORDISK A S
Form 6-K
October 05, 2004

RESEARCH UPDATE

NOVO NORDISK'S CAPITAL MARKETS DAY 2004

SOLIDIFYING THE POSITION AS A LEADER WITHIN THERAPEUTIC PROTEINS

At its 2004 Capital Markets Day today Novo Nordisk will elaborate on its biopharmaceuticals businesses, which are focused on attractive market segments, all characterised by unmet medical needs and growth opportunities.

Highlights from the day will include:

- * Insight into a broad range of protein research and development programmes - focusing on projects within haemostasis management and immunotherapy of cancer and inflammation.
- * Confirmation that Novo Nordisk still expects to file for approval of rFVIIa for the use in patients experiencing a blunt trauma in Europe in the first quarter of 2005 - and that a study for the use of rFVIIa in trauma patients in the US is on track to start early next year.
- * Mentioning that Novo Nordisk still expects to update the financial market about the regulatory process with regard to the use of rFVIIa in connection with intracerebral haemorrhage, later this year.
- * Announcement of the initiation of a clinical phase 2 study for the use of rFVIIa in patients undergoing cardiac surgery.
- * Announcement of the initiation of an exploratory clinical phase 2 study for the use of rFVIIa in patients with traumatic brain injury.
- * Announcement of the initiation of a phase 1/2 study with IL-21 for the use in cancer (malignant melanoma) in Australia.
- * Insight into a new in-licensed protein, recombinant factor XIII (rFXIII). The global rights to the intellectual property portfolio, the development and the marketing of the protein have been in-licensed from ZymoGenetics, Inc.

The known mechanism of FXIII for stabilising blood clots indicates that FXIII alone or in combination with other therapy might become an interesting new opportunity within haemostasis management.

With the extensive in-house protein experience, Novo Nordisk expects to be able to bring rFXIII to the market for the benefit of FXIII deficient patients. However, various settings of critical bleeding in other patient groups as well as combination therapy with rFXIII and rFVIIa, add to the rFXIII potential. Novo Nordisk will pay ZymoGenetics USD 15 million upon signing and up to USD 62 million in milestone payments as well as pay royalty on potential products containing rFXIII.

- * Details of the preclinical biopharmaceuticals pipeline, where seven projects within cancer and inflammation are highlighted. Of these, several are expected to enter clinical trials within the next

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

1-3 years.

* Further insight into the part of the preclinical biopharmaceuticals pipeline related to haemostasis - six projects are highlighted. All six projects are built on the properties of rFVIIa, and several are expected to enter clinical development within the next 1-3 years.

President and chief executive officer of Novo Nordisk, Lars Rebien S0rensen said: "The projects we are presenting today provide us with a robust platform for further strengthening our leadership position within therapeutic proteins, and are key for the company to continue to deliver solid growth rates."

At 8:30 CET today, corresponding to 7:30 UK time, the Capital Markets Day will be webcast. Investors will be able to listen in via a link on novonordisk.com, which can be found under 'Investors - Investor Presentations'. Presentation material for the webcast will be made available on the same page.

The above highlights from the Capital Markets Day do not change Novo Nordisk's expectations for the financial results for 2004.

About IL-21

The phase 1/2 study, which will be conducted in Melbourne, Australia, is a dose-escalation study in patients with stage IV malignant melanoma.

The primary end points in the early clinical development programme are safety and tolerability. In addition, significant resources will be allocated to identification of biomarkers that hopefully will allow the selection of dosing schedule(s) and doses of IL-21 that have significant anti-tumour effects. The effect of IL-21 on tumour size will be an important end point in trials following the phase 1/2 study.

About cardiac surgery

Intra-operative and postoperative bleeding, which might result from inadequate surgical haemostasis, coagulopathic bleeding, or combination hereof, is a complication in many patients undergoing cardiac surgery and/or coronary artery bypass graft surgery (CABG). It may result in increased post-operative morbidity and mortality as transfusion can alter long-term survival after cardiac operation. Type of surgical procedure performed and duration of cardiopulmonary bypass (CPB) influence, for example, the dilution of coagulation factors and fibrinolytic activity altering the risk of post-operative bleeding and need for transfusion. Given the limited effectiveness of existing management options, new therapies are urgently needed.

Novo Nordisk has now initiated a multicentre, multinational, randomised, double-blind, placebo-controlled, dose escalation trial on safety and efficacy. The study will have three dosing tiers, 70 patients in each, with the active arms being 40, 80, and 160 ug/kg bw, respectively, to be administered as a single bolus injection.

About traumatic brain injury

Traumatic brain injury (TBI) occurs as a result of a sudden injury to the head. TBI is defined as the presence of focal lesions of low, mixed or high density on CT examination. TBI is most commonly caused by road traffic accidents and is primarily affecting younger men.

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

Novo Nordisk has initiated an explorative multi-centre, multi-national, randomised, double-blind, placebo-controlled, dose escalation trial on safety and efficacy with patients experiencing a TBI. Injuries from penetrating objects such as gun shots and knives are not included in the definition of TBI.

Each subject will receive a single intravenous injection with either active drug or placebo within 5 hours of injury. The doses are divided into five dose tiers of 40, 80, 120, 160 and 200 ug/kg.

About recombinant factor FXIII

ZymoGenetics has been developing rFXIII for the prevention and treatment of bleeding complications and abnormalities in blood clotting associated with FXIII deficiency. FXIII is the terminal enzyme in the clotting cascade and is responsible for stabilising blood clots. Its primary function is to crosslink individual fibrin molecules into a strong fibrin mesh.

ZymoGenetics has completed phase 1 studies to evaluate the safety and pharmacokinetics of rFXIII in patients with congenital FXIII deficiency, a rare disease affecting approximately 100 individuals in the United States, as well as in healthy volunteers. Individuals who are born with congenital FXIII deficiency are usually diagnosed within hours of birth and have a high risk of bleeding into the brain and in soft tissues. Acquired FXIII deficiencies may occur in people born with normal levels of FXIII following trauma, various surgical procedures (such as cardiopulmonary bypass) or as a result of a disease process (such as graft versus host disease of the gut and ulcerative colitis).

FORWARD-LOOKING STATEMENTS

The above sections contain forward-looking statements as the term is defined in the US Private Securities Litigation Reform Act of 1995. Forward-looking statements provide current expectations or forecasts of events such as new product introductions, product approvals and financial performance. Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions. This may cause actual results to differ materially from expectations. Factors that may affect future results include interest rate and currency exchange rate fluctuations, delay or failure of development projects, production problems, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for Novo Nordisk's products, introduction of competing products, Novo Nordisk's ability to successfully market both new and existing products, exposure to product liability and other lawsuits, changes in reimbursement rules and governmental laws and related interpretation thereof, and unexpected growth in costs and expenses.

Risks and uncertainties are further described in reports filed by Novo Nordisk with the US Securities and Exchange Commission (SEC) including the company's Form 20-F, which was filed on 27 February 2004. Please also refer to the section 'Management of risk in Novo Nordisk' in the Annual Financial Report 2003. Novo Nordisk is under no duty to update any of the forward-looking statements or to conform such statements to actual results, unless required by law.

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

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

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 19,600 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:

Investors:

Outside North America:

Outside North America:

Mike Rulis
Tel (direct):
(+45) 4442 3573

Mogens Thorsager Jensen
Tel (direct):
(+45) 4442 7945

Palle Holm Olesen
Tel (direct):
(+45) 4442 6175

Peter Haahr
Tel: (+45) 3079 1207

In North America:

In North America:

Susan T Jackson
Tel (direct):
(+1) 609 919 7776

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

Stock Exchange Announcement No 57 / 2004