

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

NOVO NORDISK A S  
Form 6-K  
September 17, 2007

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

September 17 2007

-----  
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

PHASE 3 STUDY CONFIRMS THAT LIRAGLUTIDE TREATMENT LEADS TO BOTH GLUCOSE AND  
WEIGHT REDUCTION WITH A LOW RISK OF HYPOGLYCAEMIC EVENTS

Novo Nordisk today announced clinical results from the fourth of five phase 3  
studies with liraglutide - the once-daily human GLP-1 analogue. The 26-week  
LEAD(R) 4 study is part of the LEAD(R) (Liraglutide Effect and Action in

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

Diabetes) programme. The study investigated the effect of different doses of liraglutide in combination with metformin and rosiglitazone, and included 533 patients with type 2 diabetes.

After a run-in period of metformin and rosiglitazone, patients in the study were randomised to add-on treatment with either liraglutide or placebo. The average HbA1c level at the beginning of the study was around 8.5% and the average body weight was just above 95 kg.

At the end of the study, more than 50% of the patients in the liraglutide-treated group had reached the American Diabetes Association goal of HbA1c <7%. Furthermore, more than 35% achieved the American Association of Clinical Endocrinologists HbA1c target of  $\leq 6.5\%$ . The HbA1c reduction achieved in the liraglutide-treated group was close to 1.5 percentage points compared to baseline. In addition, a weight difference of around 2.5 kg compared to placebo in favour of liraglutide was observed.

Liraglutide in combination with metformin and rosiglitazone was well tolerated. The most frequently reported adverse event during liraglutide treatment was nausea, reported by around 30-40% of the subjects with a frequency decreasing over time. As expected, a low rate of hypoglycaemic events was reported, and these were related to the degree of blood glucose control.

Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk, said: "The new clinical results confirm the strong efficacy data in terms of glucose control with a low risk of hypoglycaemia together with weight loss that we have seen in the previously announced phase 3 trials. With data from now approximately 85% of all patients in the phase 3 programme, we are confident that liraglutide will become a valuable new treatment option for people with type 2 diabetes."

Novo Nordisk expects to announce headline results from the last outstanding study (LEAD(R) 3) before the end of the first quarter of 2008. Detailed results from the full LEAD(R) programme are expected to be published in peer-reviewed journals and communicated at future scientific meetings.

The results of the phase 3 trial do not change Novo Nordisk's expectations for the company's financial results for 2007, which were provided on 3 August in connection with the release of the financial results for the first six months of 2007.

### ABOUT LIRAGLUTIDE, LEAD(R) AND HBA1C

Liraglutide is a once-daily human analogue of the naturally occurring hormone Glucagon-Like Peptide-1 (GLP-1). The compound is being developed by Novo Nordisk for the treatment of type 2 diabetes, and is currently in phase 3 development. Liraglutide works by stimulating the release of insulin only when glucose levels become too high. In contrast to most other antidiabetic treatments, liraglutide also leads to weight loss instead of weight increase.

The LEAD(R) programme (Liraglutide Effect and Action in Diabetes) is comprised of five randomised, controlled, double-blind studies conducted in more than 40 countries. The programme includes around 3,800 patients with type 2 diabetes whose blood glucose is inadequately controlled.

Results from the LEAD(R) 5 study were reported on 21 June 2007. This study compared the effect of liraglutide with insulin glargine when used as add-on therapy in patients inadequately controlled by two of the most widely used oral antidiabetic drugs: metformin and a sulfonylurea (glimepiride).

Results from the LEAD(R) 1 and LEAD(R) 2 studies were announced on 20 August 2007. The two studies investigated the effect of different doses of liraglutide in combination with a single oral antidiabetic drug, glimepiride and metformin

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

respectively.

HbA1c is an abbreviation for glycated haemoglobin HbA1c. The level of HbA1c reflects the average blood glucose level over the past two to three months and a decrease is therefore a measure of treatment effect. The higher the blood glucose, the more glucose binds to haemoglobin (glycation).

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 25,350 employees in 79 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](http://novonordisk.com).

### FURTHER INFORMATION:

#### Media:

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

#### Investors:

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

Hans Rommer

Tel (direct): (+45) 4442 4765  
[hrrmm@novonordisk.com](mailto:hrrmm@novonordisk.com)

#### In North America:

Sean Clements  
Tel (direct): (+1) 609 514 8316  
[secl@novonordisk.com](mailto:secl@novonordisk.com)

#### In North America:

Christian Qvist Frandsen  
Tel (direct): (+1) 609 919 7937  
[cqfr@novonordisk.com](mailto:cqfr@novonordisk.com)

Stock Exchange Announcement No. 25 / 2007

### 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 17 2007

NOVO NORDISK A/S

-----  
Lars Rebien Sorensen,  
President and Chief Executive Officer