

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

NOVO NORDISK A S  
Form 6-K  
August 20, 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

August 20, 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

LIRAGLUTIDE IMPROVES GLUCOSE CONTROL AND LOWERS BODY WEIGHT IN TWO PHASE 3  
STUDIES COMPRISING MORE THAN 2,000 PATIENTS

Novo Nordisk today announced clinical results from the second and third of five  
phase 3 studies with liraglutide - the once-daily human GLP-1 analogue. The two

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

26-week studies are part of the LEAD(R) (Liraglutide Effect and Action in Diabetes) programme and comprised 2,132 patients in total. The two studies investigated the effect of different doses of liraglutide in combination with a single oral antidiabetic drug. Patients inadequately controlled by one or two oral antidiabetic drugs could enter the studies.

After a run-in period to reach the maximal dose of glimepiride, patients in the LEAD(R) 1 study were randomised to treatment with placebo, rosiglitazone or liraglutide. Likewise, after a run-in period to reach the maximal dose of metformin, patients in the LEAD(R) 2 trial were randomised to treatment with placebo, glimepiride or liraglutide. Consequently, liraglutide treatment in the two studies represented either add-on to previous monotherapy or substitution of one oral antidiabetic drug. In both trials, the average HbA1c level at the beginning of the study was just below 8.5% and the average body weight was 80 to 90 kg.

In the LEAD(R) 1 study, liraglutide provided statistically significantly better glucose control than rosiglitazone. Liraglutide treatment led to around 40% of patients reaching the American Diabetes Association goal of HbA1c <7% at study completion. However, among the patients that had previously been treated with only a single oral antidiabetic drug, liraglutide treatment led to more than 50% of patients reaching this goal. These success rates were the result of an HbA1c reduction of approximately 1 to 1.5 percentage points. As would be expected from a study in which all patients received glimepiride treatment, hypoglycaemia related to the degree of blood glucose control was observed in all study arms.

In the LEAD(R) 2 study, liraglutide treatment led to an HbA1c improvement that was similar to that observed in the glimepiride-treated group and at the highest dose of liraglutide, more than 40% of patients achieved the HbA1c target of 7%. Among patients previously treated with a single oral antidiabetic drug, close to 65% of the patients on this dose reached the target. These success rates were the result of an HbA1c reduction of between 1 and 1.5 percentage points. In the LEAD(R) 2 study, liraglutide-treated patients achieved blood glucose control in the presence of hypoglycaemia rates similar to placebo, contrasting with the glimepiride-treated group where hypoglycaemia occurred in a larger number of patients.

At the end of the LEAD(R) studies, a weight difference of between 2 and 4 kg in favour of liraglutide was found when compared to rosiglitazone and glimepiride treatment, respectively.

Liraglutide in combination with glimepiride or metformin was well tolerated. The most frequently reported adverse event during liraglutide treatment was nausea at an absolute level of between 5% and 20% when used in combination with glimepiride and metformin.

Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk, said: "The encouraging clinical results from the two new trials confirm the positive effect of liraglutide on blood glucose control, body weight and hypoglycaemia risk seen in previous studies and leave us confident that we are on track to submit for regulatory approval mid-2008."

Novo Nordisk expects to announce headline results from the remaining two LEAD(R) studies during the second half of 2007 and 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.

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

## 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.

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  
[hrrm@novonordisk.com](mailto:hrrm@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 24 / 2007

SIGNATURES

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

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: August 20, 2007

NOVO NORDISK A/S

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