

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

NOVO NORDISK A S  
Form 6-K  
June 17, 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 17, 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

SIGNIFICANT WEIGHT LOSS SUSTAINED IN OBESE PEOPLE TREATED WITH LIRAGLUTIDE  
FOR ONE YEAR

Novo Nordisk today announced clinical results from a 32-week open-label

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

extension of a 20-week phase 2 obesity study, in which treatment with liraglutide, the once-daily human GLP-1 analogue, was tested in obese people without diabetes. Novo Nordisk reported headline results from the initial 20 weeks of the phase 2 study in November 2007.

398 of the 564 participants in the original 20-week, double-blind, placebo-controlled phase 2 study comparing liraglutide with open-label orlistat, a lipase inhibitor, continued into the 32-week extension. Treatment allocation from the initial 20 weeks was maintained in the extension period.

After 52 weeks, liraglutide given once daily at the highest dose led to a mean weight loss from baseline of around 7.5-8.0 kg and a placebo-adjusted weight loss of around 5.5-6.0 kg, compared to a weight loss after 20 weeks of just above 7 kg from baseline and 4.5 kg placebo-adjusted. Around 75% of the people treated with the highest dose achieved a weight loss larger than 5% and more than 35% achieved a weight loss larger than 10% after 52 weeks of treatment compared to around 25% and around 10%, respectively, reaching the same weight loss targets with placebo. The people treated with open-label orlistat lost 3.5-4.0 kg from baseline and around 45% and around 15% achieved a weight loss larger than 5% and 10% after 52 weeks of treatment, respectively.

Of all patients participating in the extension study, around 30% showed signs of prediabetes at randomisation. After one year of being treated, around 80% of this prediabetes subgroup of patients treated with the highest dose of liraglutide no longer showed any signs of prediabetes, compared to around 30% for the placebo and orlistat-treated groups.

Liraglutide was generally well tolerated and the proportion of people that withdrew due to side effects was below 15%. Consistent with all previous trials, the most common adverse events were related to the gastrointestinal system and mainly rated as mild to moderate. The most frequently reported individual adverse event was nausea observed with a frequency decreasing over time.

Mads Krogsgaard Thomsen, executive vice president and chief science officer, said: "The results of the extension of the phase 2 obesity study clearly demonstrates that liraglutide has a sustained ability to reduce body weight while at the same time providing protection against deteriorating glycaemic control."

Novo Nordisk still expects to initiate a phase 3 programme in obese people without diabetes before the end of 2008.

The results of the study do 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 DESIGN

After an initial run-in period of two weeks with dietary advice and daily injections of placebo, 564 people with an average baseline weight of just below 100 kg were randomised to either placebo, to increasing doses of liraglutide or to an open-labelled control arm with orlistat for a treatment period of 20 weeks. After 20 weeks, 398 of the participants volunteered to continue into an open-label extension in which all participants continued on existing therapy for an additional 32 weeks.

### ABOUT PREDIABETES

Prediabetes is characterised by either increased levels of fasting glucose (Impaired Fasting Glucose) or increased levels of glucose in a glucose tolerance test (Impaired Glucose Tolerance) that are too high to be considered normal, but

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

not high enough to meet the criteria for diagnosis of diabetes. People with prediabetes are at a higher risk of developing both cardiovascular disease and actual diabetes. Prediabetes is often associated with the so-called metabolic syndrome which in addition to high blood glucose levels include abdominal obesity, abnormal blood lipid levels and elevated blood pressure.

### ABOUT TREATMENT OF OBESITY WITH LIRAGLUTIDE

Obesity is an increasing global problem which is associated with increased risk of developing type 2 diabetes and other serious conditions. It is generally agreed that the best way to tackle obesity is through exercise and healthy diets. It is, however, also recognised that for some people it is difficult to achieve and maintain the needed weight reduction even with substantial efforts. Thus, in people who are at high risk of getting obesity-related complications, for example patients with additional risk factors such as osteoarthritis, hypertension, cardiovascular disease or prediabetes, adjunctive treatment with medicine may be needed to reduce the risk of complications and improve the quality of life.

### ABOUT LIRAGLUTIDE

Liraglutide is a once-daily human GLP-1 analogue. Liraglutide works by stimulating the release of insulin only when glucose levels become too high and by inhibiting appetite. On 23 May 2008, Novo Nordisk submitted a New Drug Application to the US Food and Drug Administration as well as a marketing authorisation application to the European Medicines Agency, for the approval of liraglutide for the treatment of people with type 2 diabetes.

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](http://novonordisk.com).

### FURTHER INFORMATION:

#### Media:

Outside North America:  
Mike Rulis  
Tel: (+45) 3079 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:

An Phan  
Tel: (+1) 609 558 0420  
[anph@novonordisk.com](mailto:anph@novonordisk.com)

#### In North America:

Christian Qvist Frandsen  
Tel (direct): (+1) 609 712 8127  
[cqfr@novonordisk.com](mailto:cqfr@novonordisk.com)

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

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 17, 2008

NOVO NORDISK A/S

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