

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

NOVO NORDISK A S
Form 6-K
November 21, 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

November 21, 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

NEW PHASE 2 STUDY SHOWS THAT LIRAGLUTIDE LEADS TO SIGNIFICANT WEIGHT LOSS IN
OBESE PEOPLE

Novo Nordisk today announced clinical results from a double-blind,
placebo-controlled phase 2 study comparing liraglutide, the once-daily human

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

GLP-1 analogue, with orlistat, a lipase inhibitor, for treatment of obesity in people who do not have diabetes.

The study demonstrated that liraglutide given once daily over 20 weeks at the highest dose led to a weight loss from baseline of just above 7 kg in comparison to a weight loss of just below 3 kg in the placebo group and a weight loss of just above 4 kg in the orlistat-treated group. All doses of liraglutide reduced body weight. More than 75% of the people treated with the highest dose experienced a weight loss larger than 5%, and more than 25% experienced a weight loss larger than 10% relative to their body weight at randomisation. Finally, the study revealed a beneficial effect on systolic blood pressure after treatment with liraglutide.

Approximately 30% of the 564 participants in the study showed signs of prediabetes at randomisation. Following 20 weeks of treatment with any dose of liraglutide, between 80% and 90% of these participants no longer showed any sign of prediabetes, as opposed to around 40% in the placebo- and orlistat-treated groups.

Liraglutide was generally well tolerated. The overall withdrawal rate across the study was around 20%, and no more than 10% of the people who were treated with liraglutide withdrew from the trial due to adverse events. Consistent with all previous trials, the most common adverse events were related to the gastrointestinal systems and mainly rated as mild to moderate. The most frequently reported individual adverse event was nausea. The frequency of events was dose dependent and in the range of 20% to 50%. Nausea was most frequently observed at the beginning of the study.

In order to study the long-term weight reduction of liraglutide treatment, around 85% of all participants in the study volunteered to continue into an open label extension phase of the study.

Mads Krogsgaard Thomsen, chief science officer, said: "We are very encouraged by these new results. They give us reason to believe that liraglutide has the potential to become a new and important treatment option in the fight against serious obesity."

The results of the phase 2 trial do not change Novo Nordisk's expectations for the company's financial results for 2007, which were provided on 31 October in connection with the release of the financial results for the first nine months of 2007.

CONFERENCE CALL

At 15.00 CET today, corresponding to 9.00 am New York time, a conference call for investors will be held. Investors will be able to listen in via a link on novonordisk.com, which can be found under 'Investors - Download centre'.

ABOUT THE STUDY DESIGN

After an initial run-in period of two weeks with dietary advice and daily injections of placebo, study participants 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. 564 people with an average baseline weight at randomisation of just below 100 kg entered the study.

ABOUT PREDIABETES

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

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

actual diabetes. Prediabetes is often associated with the so-called metabolic syndrome which in addition to high blood glucose levels includes 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 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 or cardiovascular disease, adjunctive treatment with medicine may be needed to reduce the risk of complications and improve quality of life.

ABOUT LIRAGLUTIDE

Liraglutide is Novo Nordisk's once-daily GLP-1 analogue, currently in phase 3 development for treatment of type 2 diabetes and phase 2 development for treatment of obesity. Results from four of five phase 3 studies in people with type 2 diabetes have been reported. The last study will be reported on around the turn of the year, and submission for regulatory approval for treatment of type 2 diabetes is expected mid 2008.

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 25,800 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.

FURTHER INFORMATION:

Media:

Outside North America:
Elin K Hansen
Tel: (+45) 4442 3450
ekh@novonordisk.com

Investors:

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

Hans Rommer
Tel (direct): (+45) 4442 4765
hrrmm@novonordisk.com

In North America:

Sean Clements
Tel: (+1) 609 902 9164
secl@novonordisk.com

In North America:

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

Stock Exchange Announcement no 32 / 2007

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the

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

Registrant has duly caused this report to be signed on its behalf of the undersigned, thereunto duly authorized.

Date: November 21, 2007

NOVO NORDISK A/S

Lars Rebien Sorensen,
President and Chief Executive Officer