

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

NOVO NORDISK A S
Form 6-K
January 26, 2010

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

January 26, 2010

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-_____

REGULATORY APPROVAL

Novo Nordisk receives US approval for Victoza(R) (liraglutide) for the treatment
of type 2 diabetes

Novo Nordisk announced today that the US Food and Drug Administration (FDA) has
granted marketing authorisation for Victoza(R) for the treatment of type 2
diabetes in adults.

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

Victoza(R) is the brand name approved in the US and Europe for liraglutide, the first once-daily human Glucagon-Like Peptide-1 (GLP-1) analogue developed for the treatment of type 2 diabetes. In the US, Victoza(R) is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes. This provides for Victoza(R) to be used in monotherapy, as second-line treatment and in combination with commonly prescribed oral medications for diabetes.

"The US approval of Victoza(R) represents a major advancement in the treatment of type 2 diabetes and is an important milestone for Novo Nordisk that follows the recent approval in Japan and the ongoing successful launch in Europe." says Lars Rebien S0rensen, president and CEO. "We are convinced that Victoza(R) will prove to be a valuable treatment option for people with type 2 diabetes in the US. The ability of Victoza(R) to substantially improve glucose control with a low risk of hypoglycaemia creates an opportunity for more patients with type 2 diabetes to achieve their individual treatment goals."

Novo Nordisk expects to introduce Victoza(R) in the US market within weeks.

CLINICAL RESULTS: LEAD(TM) (LIRAGLUTIDE EFFECT AND ACTION IN DIABETES)

The Victoza(R) phase 3 clinical trial programme, entitled LEAD(TM), which formed the basis of the regulatory submission, is comprised of randomised, controlled, double-blinded studies comparing Victoza(R) to commonly prescribed treatments. These multinational trials evaluated Victoza(R) in monotherapy as well as in combination with one or two oral antidiabetic medications and showed better or equivalent lowering of blood glucose than active comparators such as sulphonylureas and thiazolidinediones.

Unlike many other diabetes medications, Victoza(R) is not associated with weight gain. For patients with type 2 diabetes, clinical trial data demonstrate a reduction in body weight in the LEAD(TM) programme. Body weight was a secondary endpoint in the clinical development trials.

The most common adverse events reported during the clinical development programme in patients treated with Victoza(R) were associated with the gastrointestinal system. Gastrointestinal adverse events, including nausea, vomiting and diarrhoea were reported most frequently in the early part of the treatment period with Victoza(R) and few patients withdrew due to these adverse events.

IMPORTANT SAFETY INFORMATION

The US prescribing information includes a boxed warning for the risk of thyroid c-cell tumours. In preclinical testing, Victoza(R) caused thyroid c-cell tumours in rodents. In clinical trials there were no reported cases of medullary thyroid carcinoma (MTC) in patients treated with Victoza(R), but human relevance of the rodent findings could not be ruled out by clinical or non-clinical studies. Victoza(R) is contraindicated in patients with a personal or family history of MTC or Multiple Endocrine Neoplasia syndrome type 2.

The marketing authorisation further includes a risk evaluation and mitigation strategy (REMS) programme comprised of a Medication Guide to patients and a Communication Plan directed at healthcare providers - both informing about the risk of pancreatitis and the potential risk of MTC.

CONFERENCE CALL

On 26 January 2010 at 08:00 am CET, corresponding to 02:00 am EST, a conference

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

call for investors will be held. Investors will be able to listen in via a link on the investor section of novonordisk.com. Presentation material for the conference call will be made available approximately one hour before on the same page, and a replay of the conference call will be available approximately two hours after its conclusion.

ABOUT VICTOZA(R)

Once-daily Victoza(R) is the first human Glucagon-Like Peptide-1 (GLP-1) analogue developed for the treatment of type 2 diabetes. Victoza(R) works by stimulating the release of insulin from the pancreatic beta cells only when blood sugar levels are high. Clinical trial data demonstrate a reduction in body weight. Victoza(R) is broken down naturally in the body and does not depend upon renal excretion.

In Europe, Novo Nordisk received marketing authorisation for Victoza(R) on 30 June and Victoza(R) has subsequently been launched in the UK, Germany, Denmark, Norway and Ireland. In Japan, Novo Nordisk received marketing authorisation for Victoza(R) on 20 January 2010. A regulatory decision is pending in China where a New Drug Application was submitted in August 2009.

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 more than 29,000 employees in 81 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:

Katrine Sperling
Tel: (+45) 3079 6718
krsp@novonordisk.com

Investors:

Klaus Bulow Davidsen
Tel: (+45) 4442 3176
klda@novonordisk.com

Kasper Roseeuw Poulsen
Tel: (+45) 4442 4471
krop@novonordisk.com

In North America:

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

In North America:

Hans Rommer
Tel: (+1) 609 919 7937
hrrmm@novonordisk.com

Company Announcement no 3 / 2010

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: January 26, 2010

NOVO NORDISK A/S

Lars Rebien Sorensen,

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

President and Chief Executive Officer