

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

NOVO NORDISK A S
Form 6-K
April 03, 2009

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

April 3, 2009

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

UPDATE ON FDA ADVISORY COMMITTEE MEETING ON LIRAGLUTIDE FOR THE TREATMENT OF
TYPE 2 DIABETES

Novo Nordisk today announced that the Endocrinologic and Metabolic Drugs
Advisory Committee of the United States Food and Drug Administration (FDA) has
finalised its discussions of questions related to liraglutide, a once-daily

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

human GLP-1 analogue.

The Advisory Committee voted on questions related to the risk profile of liraglutide.

- o A majority of Advisory Committee members supported that appropriate evidence of cardiovascular safety had been provided to rule out excess cardiovascular risk of liraglutide relative to comparators.
- o While a majority of Advisory Committee members did not find that Novo Nordisk based on the available data had ruled out that the finding of C-cell tumours in rodents was not relevant to humans, the Advisory Committee was split on the FDA question related to whether the available data on C-cell tumours permitted approvability.
- o Finally, the Advisory Committee unanimously supported approvability of liraglutide with regard to risk of papillary thyroid cancer.

"We remain convinced that liraglutide has a positive benefit:risk profile and represents an important advance for people with type 2 diabetes. We will work closely with the FDA as it completes its review of our application to address the concerns expressed by members of the Advisory Committee," said Mads Krosgaard Thomsen, executive vice president and chief science officer of Novo Nordisk.

The Advisory Committee reviewed data from 40 clinical studies involving more than 6,800 people with type 2 diabetes of which more than 4,600 were treated with liraglutide.

The timing of US launch of liraglutide will be determined after completion of the FDA's review of the application.

The outcome of the FDA Advisory Committee is not expected to significantly impact Novo Nordisk's expectations for the company's financial results for 2009, which were provided on 29 January in connection with the release of the financial results for 2008. Novo Nordisk will update the expectations for the company's financial results for 2009 on 30 April 2009 in connection with the release of the financial results for the first quarter of 2009.

FDA advisory committees are panels of independent experts who advise the FDA as they consider regulatory decisions. The FDA is not bound by the committee's recommendation, but it takes its advice into consideration when reviewing new drug applications.

CONFERENCE CALL

On 3 April at 8am CET, corresponding to 2am EDT, a conference call for investors will be held. Investors will be able to listen in via a link on the investor section of novonordisk.com.

ABOUT LIRAGLUTIDE

Liraglutide is the first once-daily human Glucagon-Like Peptide-1 (GLP-1) analogue developed for the treatment of type 2 diabetes. 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 Food and Drug Administration in the US as well as a marketing authorisation application to the European Medicines Agency in Europe, for the approval of liraglutide for the treatment of people with type 2 diabetes. A New Drug Application was also submitted for approval in Japan on 15 July 2008.

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

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

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 27,000 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.

CONTACTS FOR FURTHER INFORMATION

Media:

Mike Rulis
Tel: (+45) 4442 3573
mike@novonordisk.com

Investors:

Mads Veggerby Lausten
Tel: (+45) 4443 7919
mlau@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 20 / 2009

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: April 3, 2009

NOVO NORDISK A/S

Lars Rebien Sorensen,
President and Chief Executive Officer