

NOVO NORDISK A S
Form 6-K
March 01, 2004

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

27 February 2004

NOVO NORDISK A/S

(Exact name of Registrant as specified in its charter)

Novo Allé
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 ☒ [X]

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 ☒ [X]

If ☒ Yes is marked, indicate below the file number assigned to the registrant in connection with Rule 12g-32(b):82-_____

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: 27 February 2004

NOVO NORDISK A/S

Stock Exchange Announcement

27 February 2004

Novo Nordisk receives positive opinion on LevemirTM (insulin detemir) from EU committee

Novo Nordisk today announced that the European Union's Committee for Proprietary Medicinal Products (CPMP) has adopted a positive opinion, recommending granting marketing authorisation for LevemirTM (insulin detemir), a long-acting insulin analogue for the treatment of diabetes.

Following the positive opinion from CPMP, Novo Nordisk anticipates that the European Commission will issue marketing authorisation for LevemirTM in the European Union within the coming months. Subsequent to the marketing authorisation Novo Nordisk expects to launch LevemirTM in key European markets in the second half of 2004.

LevemirTM is a long-acting insulin analogue that provides more consistent day-to-day control of blood glucose levels compared to conventional insulin preparations¹⁻⁶. Among the benefits for people with diabetes, it has been demonstrated that LevemirTM reduces fasting blood glucose and the risk of hypoglycaemia, especially at night-time¹⁻⁵. In addition, studies have shown that people using LevemirTM do not experience the undesirable weight gain often associated with conventional insulin preparations^{1-5,7}.

The positive opinion by CPMP for LevemirTM does not change Novo Nordisk expectations for the financial results for 2004.

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 18,800 full-time employees in 69 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.

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Novo Nordisk A/S
Corporate Communications

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References:

- 1 Home P, Bartley P, Landin-Olsson M et. al. Insulin detemir offers superior glycaemic control compared to NPH insulin in people with type 1 diabetes. Diabetes Care 2004;(In press)
- 2 Pieber T, Grill V, Kristensen A et. al. Treatment with Insulin Detemir Allows Flexible Timing of Administration in Subjects with Type 1 Diabetes. Diabetologia 2003;46(Suppl.2):A7
- 3 Hermansen K, Fontaine P, Kukolja KK et al. Benefits of Insulin Analogues over Human Insulins: Lower HbA1c and less hypoglycaemia using insulin detemir and insulin aspart. Diabetologia (In press)
- 4 Russell-Jones D, Bolinder J, Simpson R et al. Lower and more predictable fasting blood glucose and reduced risk of nocturnal hypoglycaemia with once daily insulin detemir vs. NPH in subjects with type 1 diabetes. Diabetologia 2002; 45 (suppl. 2): A51.
- 5 De Leeuw I, Vague P, Selam JL, Skeie S, Elte JWF, Lang H, Draeger E. Lower risk of nocturnal hypoglycaemia and favourable weight development in type 1 diabetic subjects after 12 months treatment with insulin detemir vs. NPH insulin. Diabetologia 2002; 45 (suppl. 2); A257.
- 6 Heise T, Nosek L, Draeger E, et. al. Lower within-subject variability of insulin detemir in comparison to NPH insulin and insulin glargine in subjects with type 1 diabetes. Diabetes 2003; 52(Suppl 1): A121.
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