

NOVO NORDISK A S
Form 6-K
December 09, 2002

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
December 8, 2002

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 ☒ 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-

**Stock Exchange
Announcement**

8 December 2002

Novo Nordisk submits New Drug Application in the US for NN304 (insulin detemir), a new long-acting insulin analogue

Novo Nordisk A/S today announced it has submitted a New Drug Application (NDA) to the US Food and Drug Administration (FDA) for the approval of NN304 (insulin detemir), a long-acting insulin analogue for the treatment of diabetes mellitus.

NN304 (insulin detemir) is designed to provide an improved basal insulin profile which is smoother, longer-acting and with less day-to-day variation than conventional NPH insulin preparations. Novo Nordisk anticipates an indication for use in individuals with both type 1 and type 2 diabetes.

On 5 November, Novo Nordisk submitted a Marketing Authorisation Application (MAA) to the European Medicines Evaluation Agency (EMA) for the approval of NN304 in Europe.

Upon approval of NN304 (insulin detemir) by the regulatory authorities, Novo Nordisk will be the only diabetes company with a complete insulin analogue portfolio comprising rapid-acting, premixed and long-acting insulin analogue products.

The filing of NN304 (insulin detemir) will not impact Novo Nordisk's expectations for the financial results for 2002.

Forward-looking statement

The above sections contain forward-looking statements as the term is defined in the US Private Securities Litigation Reform Act of 1995. Forward-looking statements provide current expectations or forecasts of events such as new product introductions, product approvals and financial performance.

Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions. This may cause actual results to differ materially from expectations. Factors that may affect future results include interest rate and currency exchange rate fluctuations, delay or failure of

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Novo Nordisk A/S
Corporate Communications

Novo Allé
2880 Bagsvaerd
Denmark

Telephone:
+45 4444 8888
Telefax:
+45 4444 2314

Internet:
www.novonordisk.com

CVR Number:
24256790

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development projects, production problems, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for Novo Nordisk's products, introduction of competing products, Novo Nordisk's ability to successfully market both new and existing products, exposure to product liability and other lawsuits, changes in reimbursement rules and governmental laws and related interpretation thereof, unexpected growth in costs and expenses.

Risks and uncertainties are further described in reports filed by Novo Nordisk with the U.S. Securities and Exchange Commission (SEC) including the company's Form 20-F, which was filed on 26 April 2002. Please also refer to the section "Financial Risk Factors" in the Annual Financial Report 2001. Novo Nordisk is under no duty to update any of the forward-looking statements or to conform such statements to actual results, unless required by law.

Novo Nordisk is a focused healthcare company and the 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 17,900 people in 68 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 further company information visit www.novonordisk.com

For further information please contact:

Media:

Outside North America:

Mike Rulis

Phone (direct): (+45) 4442 3573

In North America:

Susan T Jackson

Phone: (+1) 609 919 7776

Investors:

Outside North America:

Peter Haahr

Phone (direct): (+45) 4442 1207

Palle Holm Olesen

Phone (direct): (+45) 4442 6175

In North America:

Rasmus Jorgensen

Phone (direct): (+1) 212 582 3676

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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.

NOVO NORDISK A/S

Date: December 8, 2002

Lars Rebien Sørensen, President and
Chief Executive Officer