

NOVO NORDISK A S  
Form 6-K  
May 20, 2013

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 6-K**

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**REPORT OF FOREIGN PRIVATE ISSUER**

Pursuant to Rule 13a-16 or 15d-16  
of the Securities Exchange Act of 1934

**May 17, 2013**

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**NOVO NORDISK A/S**

(Exact name of Registrant as specified in its charter)

**Novo Allé**

**DK- 2880, Bagsvaerd**

**Denmark**

(Address of principal executive offices)

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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-\_\_\_\_\_



## **Novo Nordisk reports positive results from first phase 3 trial with long-acting factor IX for treatment of haemophilia B**

**Bagsværd, Denmark, 17 May 2013** -Novo Nordisk today announced the completion of paradigm™ 2, the first phase 3 trial with a long-acting FIX derivative, N9-GP (glycopegylated recombinant factor IX), for haemophilia B patients. Paradigm™ 2 is a multi-centre, blinded trial evaluating the safety and efficacy of N9-GP when used for on-demand or prophylactic treatment in patients with haemophilia B.

In the trial, 74 patients were treated for six months on-demand, or 12 months by a prophylactic regimen of 40 U/kg or 10 U/kg N9-GP once weekly. The median bleeding rate for patients treated on-demand was 15.6 episodes per year. Patients on prophylaxis had a median annualised bleeding rate of 1.0 and 2.9 episodes per year, when treated with weekly doses of 40 U/kg and 10 U/kg, respectively.

Among patients randomised to receive 40 U/kg N9-GP, 99% of bleeding episodes were treated with only one infusion, and two-thirds of the patients experienced complete resolution of bleeding in their target joints. Patients in this dose group also reported an improvement in quality of life during the trial.

Pharmacokinetic data documented a steady state half-life of 110 hours.

In the trial, N9-GP appeared to have a safe and well-tolerated profile. No patients in the trial developed inhibitors, and no apparent differences between the treatment groups were observed with respect to adverse events and standard safety parameters.

“We are very excited about the strong results from this trial, which could represent a paradigm shift in the treatment of haemophilia B,” said Mads Krosgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “The trial demonstrated that once-weekly prophylactic administration of N9-GP can reduce the risk of bleeds by more than 90% compared to on-demand treatment and enable 99% of the few occurring bleeds to be stopped with a single dose.”

Novo Nordisk is expecting the two remaining phase 3 trials in the paradigm™ programme involving paediatric patients and patients undergoing surgery respectively to be completed

within the next 12 months. Regulatory submission of N9-GP in all major markets is expected in 2015 to enable validation of the commercial scale production.

**Novo Nordisk A/S**  
Investor Relations

Novo Allé  
2880 Bagsværd  
Denmark

Telephone:  
+45 4444 8888

Internet:  
[www.novonordisk.com](http://www.novonordisk.com)

CVR no:  
24 25 67 90

Company announcement No 37 / 2013

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**About N9-GP and paradigm™**

N9-GP is a proprietary glycopegylated recombinant factor IX for patients with haemophilia B. Glycopegylation is a well-established protraction technology applied by Novo Nordisk on recombinant factor IX. The technology increases the circulating half-life of recombinant factor IX allowing for lower bleeding frequency with less frequent intravenous dosing.

The paradigm™ programme is a Novo Nordisk registered trademark for trial conducted with N9-GP. The programme currently comprises seven clinical trials investigating pharmacokinetics, immunogenicity, efficacy and safety of N9-GP in adult and paediatric haemophilia B patients as well as in patients undergoing surgery.

*Novo Nordisk is a global healthcare company with 90 years of innovation and leadership in diabetes care. The company also has leading positions within haemophilia care, growth hormone therapy and hormone replacement therapy. Headquartered in Denmark, Novo Nordisk employs approximately 35,000 employees in 75 countries, and markets its products in more than 180 countries. Novo Nordisk's B shares are listed on NASDAQ OMX Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit [novonordisk.com](http://novonordisk.com).*

**Further information***Media:*

Mike Rulis	+45 3079 3573	<a href="mailto:mike@novonordisk.com">mike@novonordisk.com</a>
Ken Inchausti (US)	+1 609 514 8316	<a href="mailto:kiau@novonordisk.com">kiau@novonordisk.com</a>

*Investors:*

Kasper Roseeuw Poulsen	+45 4442 4303	<a href="mailto:krop@novonordisk.com">krop@novonordisk.com</a>
Frank Daniel Mersebach	+45 4442 0604	<a href="mailto:fdni@novonordisk.com">fdni@novonordisk.com</a>
Lars Borup Jacobsen	+45 3075 3479	<a href="mailto:lbpj@novonordisk.com">lbpj@novonordisk.com</a>
Jannick Lindegaard (US)	+1 609 786 4575	<a href="mailto:jlis@novonordisk.com">jlis@novonordisk.com</a>

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Investor Relations  
Novo Allé  
2880 Bagsværd  
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Telephone:  
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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.

Date: May 17, 2013

NOVO NORDISK A/S

Lars Rebien Sørensen,

President and Chief Executive Officer