

NOVO NORDISK A S
Form 6-K
March 20, 2014
UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

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

March 19, 2014

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-_____

Novo Nordisk reports positive results from first phase 3 trial with N8-GP, a long-acting factor VIII for treatment of haemophilia A

Bagsværd, Denmark, 19 March 2014 – Novo Nordisk today announced the completion of pathfinder™2, the first phase 3 trial with long-acting recombinant factor VIII, N8-GP (turoctocog alfa pegol) for haemophilia A patients. Pathfinder™2 is a multi-national trial evaluating safety and efficacy of N8-GP, when administered for prophylaxis and on-demand treatment in patients with haemophilia A, who are 12 years or older.

In the trial, 175 patients were treated with a prophylactic regimen of 50 U/kg every fourth day and 11 patients received on-demand treatment, when bleedings occurred. Patients were treated for up to 21 months, resulting in median annualised bleeding rates of 1.3 and 30.9 episodes for patients treated prophylactically and on-demand, respectively.

The pharmacokinetic data documented a single dose half-life of 18.4 hours and a mean trough level of 8% measured immediately before next dose for patients on prophylaxis treatment.

N8-GP appeared to have a safe profile and to be well tolerated. Among the 186 patients in the trial, one patient who responded well to prophylactic treatment throughout the trial developed an FVIII inhibitor. This is in line with expectations in a population of previously treated haemophilia A patients.

“We are very pleased with the results of pathfinder™2. These results show that N8-GP has the potential to reduce the burden of treatment by decreasing the number of intravenous infusions while achieving strong results in terms of efficacy and safety for people with haemophilia A”, said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk.

Novo Nordisk is expecting the three remaining trials in the pathfinder™ programme to be finalised within the next 12 months. These trials investigate N8-GP as a treatment for paediatric patients, surgical procedures and as once-weekly prophylactic treatment.

Novo Nordisk A/S
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About N8-GP and pathfinder™

N8-GP (turoctocog alfa pegol) is a glycopegylated form of turoctocog alfa designed for prolonged half-life. The modification that renders N8-GP long-acting is located in the B- domain whereby the active factor VIII generated by thrombin activation is identical to endogenous FVIII and to activated turoctocog alfa.

Pathfinder™ is a Novo Nordisk registered trademark for trials conducted with N8-GP. The programme includes more than 200 patients with haemophilia A investigating pharmacokinetics, safety and efficacy of N8-GP in adults and children as well as patients undergoing surgery.

About Novo Nordisk

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

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therapy. Headquartered in Denmark, Novo Nordisk employs approximately 38,000 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) and its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com.

For further information

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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: March 19, 2014

NOVO NORDISK A/S

Lars Rebien Sørensen,
President and Chief Executive Officer