NOVO NORDISK A S
Form 6-K
January 23, 2015
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

January 22, 2015

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-_____

Novo Nordisk receives positive opinion from the European regulatory authorities for Saxenda® (liraglutide 3 mg) for the treatment of obesity

Bagsværd, Denmark, 22 January 2015 – Novo Nordisk today announced that the Committee for Medicinal Products for Human Use (CHMP) under the European Medicines Agency (EMA) adopted a positive opinion for the use of Saxenda® (liraglutide 3 mg) for the treatment of obesity.

Saxenda®, the intended brand name of liraglutide 3 mg, is a once-daily glucagon-like peptide-1 (GLP-1) analogue, with 97% homology to naturally occurring human GLP-1, a hormone involved in appetite regulation. The CHMP positive opinion recommends that Saxenda® will be indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index (BMI) of ≥30 kg/m2 (obese), or ≥ 27 kg/m² to < 30 kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (pre-diabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea.

“Many people with obesity suffer from comorbidities. Saxenda® has the potential to help some of these people achieve and maintain a clinically significant weight loss and improve their weight-related comorbidities,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “The positive opinion from the European expert committee is an important milestone in the regulatory process for Saxenda®.”

The CHMP positive opinion is based on data from clinical trials of Saxenda®, including the phase 3 SCALE™ clinical development programme, which involved more than 5,000 people with obesity (BMI ≥30 kg/m2), or who were overweight (BMI ≥27 kg/m2) with comorbidities.

Novo Nordisk expects to receive marketing authorisation from the European Commission within two to three months. Subject to the Commission’s approval Novo Nordisk expects to launch Saxenda® in several European markets starting in 2015.

About the CHMP
The CHMP is a scientific committee composed of representatives from the 28 Member States of the European Union (EU), and Iceland and Norway. The CHMP reviews medical product applications on their scientific and clinical merit and provides advice to the European Commission that has the authority to approve medicines for the European Union.

About obesity
Obesity is a disease that requires chronic management. It is associated with serious comorbidities including type 2 diabetes, heart disease, obstructive sleep apnoea (OSA), certain types of cancer and a decreased life expectancy. The risk of morbidity and mortality increases with the severity of obesity. It is a complex and multi-factorial disease that is influenced by genetic, physiological, environmental and psychological factors.

The global increase in the prevalence of obesity is a public health issue that has significant cost implications to healthcare systems. In the EU, obesity affects approximately 10–30% of adults.

About Saxenda®
Saxenda® (liraglutide 3 mg) is a once-daily, glucagon-like peptide-1 (GLP-1) analogue with 97% similarity to naturally occurring human GLP-1, a hormone that is released in response to food intake. Saxenda® is involved in appetite regulation and lowers body weight through decreased food intake. Saxenda® does not increase 24-hour energy expenditure. Furthermore, Saxenda® plays an important role in maintaining a normal level of glucose in the blood in adults with obesity by stimulating the release of insulin and suppressing the release of glucagon in a glucose-dependent manner, when needed.

Saxenda® was evaluated in the SCALE™ (Satiety and Clinical Adiposity–Liraglutide Evidence in Non-diabetic and Diabetic people) phase 3 clinical trial programme, which involved more than 5,000 people with obesity (BMI ≥30 kg/m2) or who were overweight (BMI ≥27 kg/m2) with at least one weight-related comorbidity.

Data from the SCALE™ programme were submitted to the EMA as part of the Marketing Authorisation Application on 20 December 2013. Same day, Novo Nordisk submitted a New Drug Application for Saxenda® to the US Food and Drug Administration (FDA). On 23 December 2014, the FDA approved Saxenda®.

Novo Nordisk is a global healthcare company with more than 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 40,700 employees in 75 countries, and markets its products in more than 180 countries. Novo Nordisk's B shares are listed on Nasdaq Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com.

For further information

Media:

Mike Rulis	+45 3079 3573	mike@novonordisk.com
Ken Inchausti (US)	+1 609 514 8316	kiau@novonordisk.com

Investors:

Kasper Roseeuw Poulsen	+45 3079 4303	krop@novonordisk.com
Jannick Lindegaard Denholt	+45 3079 8519	jlis@novonordisk.com
Melanie Raouzeos	+45 3075 3479	mrz@novonordisk.com
Daniel Bohsen	+45 3079 6376	dabo@novonordisk.com
Frank Daniel Mersebach (US)	+1 609 235 8567	fdni@novonordisk.com

Novo Nordisk A/S
Investor Relations

Novo Allé
2880 Bagsværd
Denmark

Telephone:
+45 4444 8888

Internet:
www.novonordisk.com
CVR no:
24 25 67 90

Company announcement No 4 / 2015

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: January 22, 2015

NOVO NORDISK A/S

Lars Rebien Sørensen,
Chief Executive Officer