NOVO NORDISK A S
Form 6-K
December 29, 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

December 23, 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 [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 FDA approval for Saxenda® for the treatment of obesity

Bagsværd, Denmark, 23 December 2014 — Novo Nordisk today announced that the US Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for Saxenda® (liraglutide 3 mg), the first once-daily human glucagon-like peptide-1 (GLP-1) analogue for the treatment of obesity. Saxenda® is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with obesity (BMI ≥30 kg/m2) or who are overweight (BMI ≥27 kg/m2) with at least one weight-related comorbidity such as type 2 diabetes and cardiovascular disease.

“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 approval follows the FDA’s Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) meeting on 11 September 2014, which voted 14–1 that the overall risk-benefit of Saxenda® was favourable and supported approval for chronic weight management.

Novo Nordisk expects to launch Saxenda® in the US in the first half of 2015.

About obesity
Obesity is a disease1 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 severe cost implications to healthcare systems. In the US, approximately 35% of adults, equivalent to approximately 80 million people, live with obesity.

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. Like human GLP-1, Saxenda® regulates appetite and lowers body weight through decreased food intake. As with other GLP-1 receptor agonists, liraglutide stimulates insulin secretion and reduces glucagon secretion in a glucose- dependent manner. These effects can lead to a reduction of blood glucose. 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 FDA as part of the NDA on 20 December 2013. Same day, Novo Nordisk submitted a Marketing Authorisation Application for Saxenda® to the European Medicines Agency (EMA). The application is currently under review by the agency.

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 41,000 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

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References

1 American Medical Association (AMA). Declaration to classify obesity as a disease. Annual Meeting Report. 19 June 2013.

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Company announcement No 77 / 2014

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: December 23, 2014

NOVO NORDISK A/S

Lars Rebien Sørensen,
Chief Executive Officer