NOVO NORDISK A S
Form 6-K
September 12, 2014
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

September 11, 2014

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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 [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-_____

Saxenda® for the treatment of obesity receives positive 14-1 vote in favour of approval from FDA Advisory Committee

Bagsværd, Denmark, 11 September 2014 – Novo Nordisk today announced that the Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) of the United States Food and Drug Administration (FDA) has completed its meeting regarding the New Drug Application (NDA) for Saxenda®, the intended brand name for liraglutide 3 mg, a once- daily human GLP-1 analogue for the treatment of obesity.

Based on the data contained in the NDA for Saxenda®, the FDA asked the panel members to discuss whether Novo Nordisk has provided adequate evidence to establish the efficacy and safety profile of Saxenda® for chronic weight management. Furthermore, the panel members were asked to discuss the safety database for Saxenda® for chronic weight management, given the extent of clinical trial and post-marketing experience with liraglutide for diabetes mellitus with doses up to 1.8 mg per day.

The panel members voted 14-1 that the overall benefit-risk assessment Saxenda® was favourable and supports approval for chronic weight management in individuals with a BMI 30 kg/m2 or greater, or 27 kg/m2 or greater in the presence of at least one weight- related comorbidity.

“We are pleased with the clear recommendation from the Advisory Committee,” says Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “We look forward to working with the FDA as they complete their review of Saxenda®. Obesity is a serious public health issue in the US and we are committed to making Saxenda® a new treatment option for adults with obesity.”

The recommendation was based on data from clinical trials of Saxenda®, including the phase 3 SCALE™ 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 comorbidities.

The NDA was submitted to the FDA on 20 December 2013. The Prescription Drug User Fee Act (PDUFA) date for completion of the FDA review of the Saxenda® NDA is 20 October 2014.

About FDA advisory committee meetings
FDA advisory committees are panels of independent experts who advise the FDA on specific questions raised by the FDA as they consider regulatory decisions. The FDA is not bound by the committee's recommendation, but it takes its advice into consideration when reviewing new drug applications. According to the FDA Amendment Act of 2007 (FDAAA), the FDA should refer drugs to an advisory committee meeting, or alternatively justify why an advisory committee meeting was not requested.

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, or some 100 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 food intake by decreasing hunger and increasing feelings of fullness and satiety after eating. The dual actions of Saxenda® on both appetite and blood glucose regulation (for adults with pre- diabetes or type 2 diabetes) hold therapeutic potential for adults with obesity, both those with and without type 2 diabetes.

Saxenda® is an investigational product and is not approved by the FDA or the European Medicines Agency (EMA).

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 OMX 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 56 / 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: September 11, 2014

NOVO NORDISK A/S

Lars Rebien Sørensen,
Chief Executive Officer