NOVO NORDISK A S
Form 6-K
December 30, 2013
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

December 20, 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 [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 files for regulatory approval of liraglutide 3 mg for the treatment of obesity

Bagsværd, Denmark, 20 December 2013 – Novo Nordisk today announced two separate regulatory submissions for a 3 mg dose of liraglutide, a once-daily human GLP-1 analogue, as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with obesity, or who are overweight with comorbidities. The company filed a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) and a Marketing Authorisation Application (MAA) with the European Medicines Agency (EMA).

The submissions for liraglutide 3 mg include data from the Phase 3 SCALE™ clinical trial programme, which involved more than 5,000 people with obesity (BMI ≥30 kg/m^2), or who are overweight (BMI ≥27 kg/m^2) with comorbidities. In addition to the data from the SCALE™ programme, data from earlier development phases and data related to the use of liraglutide in type 2 diabetes were also included in the submissions.

Data from the SCALE™ clinical trial programme have consistently demonstrated that liraglutide 3 mg, in combination with diet and exercise, induces and maintains weight loss, while also significantly improving obesity-related comorbidities such as hypertension, dyslipidaemia and sleep apnoea. Furthermore, in people with obesity and type 2 diabetes or prediabetes, trials have demonstrated that liraglutide 3 mg significantly improves glycaemic control, in addition to lowering weight.

“We believe that liraglutide 3 mg has the potential to make a significant difference in the management of obesity by providing both a sustainable weight loss and an improvement in several obesity-related comorbidities”, said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk.

About obesity

Obesity is a disease[1] that requires chronic management. It is often linked to serious comorbidities – including type 2 diabetes, heart disease, obstructive sleep apnoea and certain types of cancer – accompanied by a decreased life expectancy of 5–10 years. The risk of morbidity and mortality increases with the severity of obesity. It is a complex and multifactorial disease, influenced by genetic, physiological, environmental and psychological factors.

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The global increase in the prevalence of obesity is a public health issue with huge cost implications to healthcare systems. In the US, approximately 35% of adults, or some 100 million people are obese. A sustained weight loss of 5–10% has been shown to be associated with significant health benefits.

About liraglutide 3 mg

Liraglutide 3 mg is a once-daily GLP-1 analogue with 97% homology to naturally occurring human GLP-1. Like human GLP-1, liraglutide 3 mg regulates appetite by increasing feelings of fullness and reducing feelings of hunger, allowing people to feel satisfied with eating less. GLP-1 also plays an important role in maintaining normal blood glucose levels. This dual action of GLP-1 holds therapeutic potential for the treatment of people with obesity. Liraglutide 3 mg is not an approved treatment.

Liraglutide is currently approved and marketed at lower doses (1.2 and 1.8 mg once-daily, as well as 0.9 mg in Japan) for type 2 diabetes, under the brand name Victoza®. Victoza® is not approved for weight management and should not be prescribed for this treatment.

About the SCALE™ clinical programme

SCALE™ (Satiety and Clinical Adiposity – Liraglutide Evidence in Non-diabetic and Diabetic people) consists of four trials encompassing more than 5,000 people who are overweight (BMI ≥27 kg/m^2) and with comorbidities such as hypertension, dyslipidaemia, or type 2 diabetes, or who have obesity (BMI ≥30 kg/m^2) with or without comorbidities. In addition to demonstrating safety and efficacy for weight management with liraglutide 3 mg, each of the four trials had a specific focus:

SCALE™ Obesity and Prediabetes (3,731 people randomised) – a 56-week and 160-week randomised, placebo-controlled trial in people with obesity, or overweight people with comorbidities, designed to demonstrate clinically meaningful and safe weight loss after 56 weeks of treatment with liraglutide 3 mg. The 56-week results were reported in May 2013. The 160-week extension study is ongoing and investigates the long-term effect of liraglutide 3 mg, in combination with diet and exercise, on the progression to type 2 diabetes.

SCALE™ Maintenance (422 people randomised) – a 56-week randomised, placebo-controlled trial designed to show maintenance of weight loss in people with obesity or overweight people with comorbidities, who have successfully achieved a 5% or greater weight loss during a three-month run-in period that included a lifestyle intervention programme of low-calorie diet and exercise alone. The results of SCALE™ Maintenance were reported in 2010.

SCALE™ Diabetes (846 people randomised) – a 56-week randomised, placebo-controlled trial designed to demonstrate clinically meaningful and safe weight loss with liraglutide 3 mg in people with obesity, or overweight people with type 2 diabetes. The results of SCALE™ Diabetes were reported in March 2013.

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SCALE™ Sleep Apnoea[5] (359 people randomised) – a 32-week randomised, double-blind, placebo-controlled trial in people with obesity with moderate or severe obstructive sleep apnoea (OSA) to investigate the effect of liraglutide 3 mg, in combination with diet and exercise, in reducing the severity of OSA. The results of SCALE™ Sleep Apnoea were reported in August 2013.

Headquartered in Denmark, 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 37,000 employees in 75 countries, and markets its products in more than 180 countries. For more information, visit novonordisk.com.

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.

[2] ClinicalTrials.gov study registration: NCT01272219

[3] ClinicalTrials.gov study registration: NCT00781937

[4] ClinicalTrials.gov study registration: NCT01272232

[5] ClinicalTrials.gov study registration: NCT01557166

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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.

NOVO NORDISK A/S

Date: December 20, 2013 Lars Rebien Sørensen,

President and Chief Executive Officer