

NOVO NORDISK A S  
Form 6-K  
May 24, 2013

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**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

**May 23, 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  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 8% weight loss in phase 3a obesity trial with liraglutide 3 mg**

**Bagsværd, Denmark, 23 May 2013** -Novo Nordisk today announced the headline results from a 56-week double-blind phase 3a clinical trial investigating the potential of liraglutide to induce and maintain weight loss in people without diabetes who are obese or overweight with comorbidities such as prediabetes, hypertension and dyslipidaemia. This is the third phase 3a trial to be completed as part of SCALE™, the clinical development programme for liraglutide 3 mg as an obesity treatment.

In the trial, 3,731 overweight or obese people were randomised 2:1 to treatment with liraglutide 3 mg or placebo, both in combination with diet and exercise. In the trial, people without signs of prediabetes were treated for 56 weeks, followed by a 12-week follow-up period. People with signs of prediabetes at the time of randomisation are currently continuing treatment for two additional years. The announced results are for all people at 56 weeks.

From a mean baseline weight of 106 kg and a BMI of 38 kg/m<sup>2</sup>, the average weight loss for people treated with liraglutide 3 mg at 56 weeks was 8.0% compared to 2.6% for people treated with placebo. The proportion of people achieving a weight loss of at least 5% was 64% for liraglutide 3 mg and 27% for placebo. The proportion of people achieving a weight loss of at least 10% was 33% for liraglutide 3 mg and 10% for placebo treatment. All differences between liraglutide and placebo were statistically significantly different and the trial met all three co-primary endpoints.

Of all people participating in the trial, 61% had prediabetes at randomisation. At 56 weeks, 69% of the prediabetes subgroup treated with liraglutide 3 mg no longer showed signs of prediabetes, compared to 33% for the placebo-treated group. Of the 39% of the people without prediabetes at randomisation, 7% of the liraglutide 3 mg treated people developed prediabetes, compared to 21% of the people in the placebo group. Both differences between liraglutide 3 mg and placebo were statistically significant.

Finally, people treated with liraglutide 3 mg experienced statistically significant improvements in obesity-related risk factors, including blood pressure, cardiovascular risk biomarkers, lipids and patient-reported quality of life, compared to people treated with placebo.

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Company announcement No 39 / 2013

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In the trial, liraglutide was generally well tolerated. The 56-week completion rate was 72% and 64% for liraglutide 3 mg and placebo, respectively. Withdrawals due to adverse events were below 10% in both treatment groups. The most common adverse events were related to the gastrointestinal system and they diminished over time.

“We are very pleased with the results of this trial,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “These data, together with previously reported phase 3 trials, consistently demonstrate clinically significant weight loss and improvements in obesity-related risk factors in people with obesity.”

Novo Nordisk expects to complete the remaining phase 3a trial in the SCALE™ programme in the third quarter of 2013 and to file liraglutide 3 mg for regulatory review as a treatment for obesity in the US and EU around the turn of the year.

### **About liraglutide 3 mg**

Liraglutide 3 mg is a once-daily GLP-1 analogue with 97% homology to human GLP-1. Like human GLP-1, liraglutide 3 mg acts as a natural satiety hormone to reduce appetite and food intake. 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 only, under the brand name Victoza®. Victoza® is not approved for weight management and should not be prescribed for its 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  $\geq$  27 kg/m<sup>2</sup>) and with comorbidities such as hypertension, dyslipidaemia, or type 2 diabetes or who are obese (BMI  $\geq$  30 kg/m<sup>2</sup>) with or without comorbidities. In addition to demonstrating safety and efficacy for weight management with liraglutide 3 mg, each of the four trials has its own distinct focus:

SCALE™ Maintenance (422 people randomised) – a 56-week randomised, placebo-controlled trial designed to show weight loss maintenance in obese or overweight people with comorbidities who have successfully achieved a 5% or greater weight loss during a three-month run-in period of a lifestyle modification 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 obese or overweight people with type 2 diabetes. The results of SCALE™ Diabetes were reported in March 2013.

SCALE™ Obesity and Prediabetes (3,731 people randomised) – a 56-week and 160-week randomised, placebo-controlled trial in obese or overweight people with comorbidities designed to demonstrate clinically meaningful and safe weight loss after 56 weeks of treatment with liraglutide 3 mg.

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Company announcement No 39 / 2013

SCALE™ Sleep apnoea (approximately 340 people randomised) – a 32-week randomised, double-blind, placebo-controlled trial in obese people with moderate or severe obstructive sleep apnoea (OSA) to investigate the effect of liraglutide 3 mg in reducing the severity of OSA, in combination with diet and exercise.

*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 35,000 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). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit [novonordisk.com](http://novonordisk.com).*

## 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: May 23, 2013

NOVO NORDISK A/S

Lars Rebien Sørensen,

President and Chief Executive Officer