

NOVO NORDISK A S  
Form 6-K  
March 19, 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

**March 18, 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-\_\_\_\_\_



## **People with type 2 diabetes achieve 6% weight loss with liraglutide 3 mg in phase 3a obesity trial**

**Bagsværd, Denmark, 18 March 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 overweight or obese people with type 2 diabetes. This is the second 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, 846 overweight or obese people with type 2 diabetes were randomised 2:1:1 to treatment with liraglutide 3 mg, liraglutide 1.8 mg or placebo. After 56 weeks, treatment was discontinued and the subjects were followed during a 12-week observational period.

### **Results regarding weight loss**

From a mean baseline weight of approximately 106 kg and a BMI of 37, the weight loss for people treated with liraglutide 3 mg and liraglutide 1.8 mg after 56 weeks were 6% and 5%, respectively compared to a 2% weight loss for people treated with placebo. The proportion of people achieving a weight loss of at least 5% or 10% was 50% and 22% for liraglutide 3 mg, 35% and 13% for liraglutide 1.8 mg, and 13% and 4% for placebo treatment. All differences for both doses of liraglutide were statistically significantly different from placebo and the trial met all three co-primary endpoints. During the 12-week follow-up period after treatment discontinuation, people in both liraglutide treatment groups experienced a moderate weight regain.

### **Results regarding glycaemic control**

Starting from a baseline HbA<sub>1c</sub> of 8.0%, approximately 69%, 67% and 27% of people treated with liraglutide 3 mg, liraglutide 1.8 mg and placebo achieved the HbA<sub>1c</sub> treatment target of

7% recommended by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). In the trial, the rate of hypoglycaemia was comparable to that observed in previous trials with liraglutide.

In the trial, liraglutide was generally well tolerated and the 56-week completion rate was 77%, 78% and 66% for liraglutide 3 mg, liraglutide 1.8 mg and placebo, respectively. Withdrawals due to adverse events were below 10% in all treatment groups. In line with previous liraglutide trials, the most common adverse events were related to the gastrointestinal system and diminished over time. No other apparent differences between the treatment groups were observed with respect to adverse events and standard safety parameters.

**Novo Nordisk A/S**  
Investor Relations  
Novo Allé  
2880 Bagsværd  
Denmark

Telephone: +45 4444 8888  
CVR no: 24 25 67 90  
Internet:  
[www.novonordisk.com](http://www.novonordisk.com)

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"We are pleased about the outcome of this trial and look forward to getting the results from the two remaining trials in the SCALE™ programme", said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "This SCALE™ trial shows that it is possible to achieve both clinically significant weight loss and excellent glucose control with a single treatment in patients with type 2 diabetes. Weight management is often a greater challenge for this patient population and there is a need for new and effective treatment options."

Novo Nordisk expects to complete the two remaining phase 3a trials in the SCALE™ programme by mid-2013.

### **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 of approximately 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.

*SCALE™ Obesity and Pre-diabetes* (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.

**Novo Nordisk A/S**  
Investor Relations  
Novo Allé  
2880 Bagsværd  
Denmark

Telephone:  
+45 4444 8888  
Telefax:  
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*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**

#### *Media:*

Katrine Sperling	+45 3079 6718	<a href="mailto:krsp@novonordisk.com">krsp@novonordisk.com</a>
Ken Inchausti	+1 609 786 8316	<a href="mailto:kiau@novonordisk.com">kiau@novonordisk.com</a>
Ambre Morley	+1 609 987 5898	<a href="mailto:abmo@novonordisk.com">abmo@novonordisk.com</a>

#### *Investors:*

Kasper Roseeuw Poulsen	+45 4442 4303	<a href="mailto:krop@novonordisk.com">krop@novonordisk.com</a>
Frank Daniel Mersebach	+45 4442 0604	<a href="mailto:fdni@novonordisk.com">fdni@novonordisk.com</a>
Lars Borup Jacobsen	+45 3075 3479	<a href="mailto:lbpj@novonordisk.com">lbpj@novonordisk.com</a>
Jannick Lindegaard (US)	+1 609 786 4575	<a href="mailto:jlis@novonordisk.com">jlis@novonordisk.com</a>

<b>Novo Nordisk A/S</b>	Novo Allé	Telephone:	Internet:
Investor Relations	2880 Bagsværd	+45 4444 8888	<a href="http://www.novonordisk.com">www.novonordisk.com</a>
	Denmark	Telefax:	CVR no:
		+45 4444 2314	24 25 67 90

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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: March 18, 2013

NOVO NORDISK A/S

Lars Rebien Sørensen,

President and Chief Executive Officer