

NOVO NORDISK A S
Form 6-K
September 19, 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

September 18, 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 ☒ 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-_____

Xultophy® (IDegLira) approved in Europe

Bagsværd, Denmark, 18 September 2014 – Novo Nordisk today announced that the European Commission has granted marketing authorisation for Xultophy® for the treatment of type 2 diabetes mellitus in adults. The authorisation covers all 27 European Union member states.

Xultophy® is the brand name for IDegLira, the first once-daily single injection combination of insulin degludec (Tresiba®) and liraglutide (Victoza®). Xultophy® is indicated for the treatment of adults with type 2 diabetes mellitus to improve glycaemic control in combination with oral glucose-lowering medicinal products when these alone or combined with basal insulin do not provide adequate glycaemic control.

“We believe that Xultophy® represents a new paradigm with the potential to transform how type 2 diabetes is treated. We look forward to making the product available to people with type 2 diabetes in Europe,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk.

Xultophy® was approved in Switzerland on 12 September 2014. Novo Nordisk expects to launch Xultophy® in the first European countries in the first half of 2015.

About Xultophy®

Xultophy® is a once-daily, single injection combination product consisting of insulin degludec (Tresiba®), a once-daily basal insulin analogue with an ultra-long duration of action, and liraglutide (Victoza®), the once-daily human GLP-1 analogue.

Xultophy® has shown consistent results in improving glycaemic control in insulin-naïve people with type 2 diabetes as well as those uncontrolled on basal insulin. For people uncontrolled on basal insulin therapy, Xultophy® has demonstrated a significant reduction in HbA1C of 1.9% with a mean weight loss of 2.7 kg and a low rate of hypoglycaemia comparable to that of insulin degludec.

Novo Nordisk submitted the application for marketing authorisation for Xultophy® in the EU on 31 May 2013.

About Novo Nordisk

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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Company announcement
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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: September 18, 2014

NOVO NORDISK A/S

Lars Rebien Sørensen,
Chief Executive Officer