NOVO NORDISK A S
Form 6-K
October 19, 2017

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

October 18, 2017

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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-_____

Semaglutide receives positive 16-0 vote in favour of approval from FDA Advisory Committee

Bagsværd, Denmark, 18 October 2017 – Novo Nordisk today announced that the Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) of the US Food and Drug Administration (FDA) voted 16-0 in favour of the approval of once-weekly semaglutide to improve glycaemic control in adults with type 2 diabetes. One member of the committee abstained.

Based on the data included in the New Drug Application (NDA) for semaglutide, the FDA asked the panel members to discuss whether Novo Nordisk has provided adequate evidence to establish the efficacy and safety profile of semaglutide for the treatment of type 2 diabetes in adults.

The recommendation for approval was based on a global development programme involving more than 8,000 adults with type 2 diabetes in the eight SUSTAIN phase 3a clinical trials, including a cardiovascular outcomes trial.

“Semaglutide has demonstrated the potential to improve the treatment of type 2 diabetes and the positive recommendation from the Advisory Committee marks an important step towards making semaglutide available to adults with type 2 diabetes in the US. We look forward to working with the FDA as they complete their review of semaglutide,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer.

The NDA for once-weekly semaglutide was submitted to the FDA in December 2016 under the US FDA's Prescription Drug User Fee Act V (PDUFA V) regulation. Semaglutide is currently under review by several regulatory agencies, including the European Medicines Agency and the Japanese Pharmaceuticals and Medical Devices Agency.

Conference call

On 19 October 2017 at 8.00 am CEST (2.00 am EDT), Novo Nordisk will host a conference call for investors. Investors will be able to listen in via a link on the investor section of novonordisk.com/investors.

About advisory committees

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 data concerning the safety and efficacy of marketed drugs or new drug applications.

Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat other serious chronic conditions: haemophilia, growth disorders and obesity. Headquartered in Denmark, Novo Nordisk employs approximately 41,400 people in 77 countries and markets its products in more than 165 countries. Novo Nordisk's B shares are listed on Nasdaq Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube

Further information

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Company announcement No 80 / 2017

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: October 18, 2017

Lars Fruergaard Jørgensen

Chief Executive Officer