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
UNDER THE SECURITIES EXCHANGE ACT OF 1934

June 4, 2021

Commission File Number: 001 - 38178

Zealand Pharma A/S

(Exact Name of Registrant as Specified in Its Charter)

Sydmarken 11
2860 Søborg (Copenhagen)
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 if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

Furnished as Exhibit 99.1 to this Report on Form 6-K is a company announcement of Boehringer Ingelheim and Zealand Pharma Receive FDA Fast Track Designation for Investigational Treatment for NASH

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Zealand Pharma A/S

By: /s/ Matthew Dallas

Name: Matthew Dallas
Title: Chief Financial Officer

Date: June 4, 2021

EXHIBIT INDEX

Exhibit No.	Description
99.1	Company announcement – No. 35 / 2021

Exhibit 99.1

Company announcement – No. 35 / 2021

Boehringer Ingelheim and Zealand Pharma Receive FDA Fast Track Designation for Investigational Treatment for NASH

Boehringer Ingelheim and Zealand Pharma Receive FDA Fast Track Designation for Investigational Treatment for NASH

- **FDA's Fast Track Designation for the GLP-1/glucagon dual agonist underscores the urgent need for new treatment options to fulfill the unmet medical needs of people affected by NASH**

- **Boehringer Ingelheim's focus on the development of next generation NASH treatments builds on its strong track record of bringing new therapies to people with cardiometabolic diseases**

Ingelheim, Germany and Copenhagen, Denmark, 2 June, 2021 – Boehringer Ingelheim and Zealand Pharma A/S (Nasdaq: ZEAL) (CVR-no. 20045078) today announced that the US Food and Drug Administration (FDA) has granted Fast Track Designation to the GLP-1/glucagon dual agonist BI 456906 for adults with non-alcoholic steatohepatitis (NASH). The Fast Track Designation facilitates the development and expedites the review of new therapies to treat serious conditions and fill an unmet medical need. BI 456906 is currently being evaluated in a Phase II study in adults with NASH and liver fibrosis (F2/F3) with and without diabetes.

"The FDA Fast Track Designation for our dual agonist is an important step forward in addressing the high unmet medical need among the up to 444 million adults estimated to be living with NASH," said Waheed Jamal, MD, Corporate Vice President and Head of CardioMetabolic Medicine, Boehringer Ingelheim. "Together with our partner Zealand Pharma, we look forward to working closely with the FDA as we explore the potential of the GLP-1/glucagon agonist to improve outcomes for adults with NASH."

"Boehringer Ingelheim and Zealand Pharma are committed to delivering innovative solutions that address public health challenges of cardiometabolic diseases, including NASH," said Adam Steensberg, Executive Vice President and Chief Medical Officer at Zealand Pharma. "By combining Boehringer Ingelheim's expertise in drug development in the cardio-metabolic area with our strength in the discovery of innovative peptide-based medicines, we have the potential to bring forward a novel therapy option in an area with limited available treatments."

The GLP-1/glucagon compound derived from the natural gut hormone oxyntomodulin activates both the GLP-1 and glucagon receptors that are critical to controlling metabolic functions. The dual agonist BI 456906 has the potential to be a new, once-weekly treatment that may offer therapeutically relevant benefits compared to currently available treatments. It is also being investigated as a potential treatment option for adults living with diabetes and for adults living with obesity. It is part of Boehringer Ingelheim's research and development portfolio in the cardiometabolic disease areas.

About the Phase 2 Study

The Phase 2 randomized double-blind placebo-controlled dose-finding trial (NCT04771273) will evaluate BI 456906 in people with NASH and liver fibrosis (F2/F3) with and without diabetes. The primary endpoint of this trial is the histological improvement of steatohepatitis without worsening of fibrosis after 48 weeks of treatment. Participants will receive a weekly subcutaneous injection of either different doses of BI 456906 or placebo for the duration of the trial.

About NASH

Non-alcoholic steatohepatitis (NASH) is caused by a metabolic-induced inflammation of the liver and is one of the major causes of liver fibrosis and cirrhosis. Its symptoms are often silent or non-specific to NASH, making it difficult to diagnose. It is an area of high unmet medical need with no approved treatments currently available. NASH is the more serious form of non-alcoholic fatty liver disease (NAFLD), which is the most common liver disease in Western industrialized nations, affecting one out of four adults. NASH and NAFLD are especially prevalent in, but not limited to, people with metabolic disorders such as type 2 diabetes and obesity. The prevalence of NASH has been estimated to range up to 444 million people worldwide.

About Boehringer Ingelheim

Boehringer Ingelheim is working on breakthrough therapies that improve the lives of humans and animals. As a leading research-driven biopharmaceutical company, the company creates value through innovation in areas of high unmet medical need. Founded in 1885 and family-owned ever since, Boehringer Ingelheim takes a long-term perspective. Around 52,000 employees serve more than 130 markets in the three business areas, Human Pharma, Animal Health, and Biopharmaceutical Contract Manufacturing. Learn more at https://link.edgepilot.com/s/f96c8152/ehuB5rCPD0KKx1uqmwIugA?u=http://www.boehringer-ingelheim.com/.

About Zealand Pharma A/S

Zealand Pharma A/S (Nasdaq: ZEAL) ("Zealand") is a biotechnology company focused on the discovery, development and commercialization of innovative peptide-based medicines. More than 10 drug candidates invented by Zealand have advanced into clinical development, of which two have reached the market. Zealand's robust pipeline of investigational medicines includes three candidates in late stage development, and one candidate being reviewed for regulatory approval in the United States. Zealand markets V-Go®, an all-in-one basal-bolus insulin delivery option for people with diabetes. License collaborations with Boehringer Ingelheim and Alexion Pharmaceuticals create opportunity for more patients to potentially benefit from Zealand-invented peptide therapeutics.
Zealand was founded in 1998 in Copenhagen, Denmark, and has presence throughout the U.S. that includes key locations in New York, Boston, and Marlborough (MA). For more information about Zealand's business and activities, please visit https://link.edgepilot.com/s/1c6540eb/iPzeuxkIdUywpc6MA9fEIg?u=http://www.zealandpharma.com/.

Forward-Looking Statement

The above information contains forward-looking statements that provide Zealand Pharma's expectations or forecasts of future events. Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions, which may cause actual results to differ materially from expectations set forth herein and may cause any or all of such forward-looking statements to be incorrect. If any or all of such forward-looking statements prove to be incorrect, our actual results could differ materially and adversely from those anticipated or implied by such statements. All such forward-looking statements speak only as of the date of this release and are based on information available to Zealand Pharma as of the date of this release.

Media Contacts

Boehringer Ingelheim
Dr. Birgit Leimer
Product Communications Manager
Boehringer Ingelheim Corporate Center GmbH
Media + PR
E-Mail: press@boehringer-ingelheim.com

Zealand Pharma Investor Relations
Claudia Styslinger
Argot Partners
E-Mail: investors@zealandpharma.com

Zealand Pharma Media Relations
David Rosen
Argot Partners
E-Mail: media@zealandpharma.com