# 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**

**December 11, 2019**

**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 x Form 40-F o

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): o

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): o

Furnished as Exhibit 99.1 to this Report on Form 6-K is a press release (“company announcement”) of Zealand Pharma A/S or the Company, dated December 10, 2019, announcing that partner Beta Bionics, Inc. has received Breakthrough Device designation from the U.S. Food and Drug Administration (FDA) for its iLet™ Bionic Pancreas System. The Breakthrough Designation for the iLet Bionic Pancreas system contemplates configurations with most insulin analogs approved for pumping as well as dasiglucagon, Zealand Pharma’s stable glucagon analog, which has a unique stability profile in a ready-to-use aqueous solution.

Furnished as Exhibit 99.2 is the original press release from Beta Bionics, Inc., as referenced in the Zealand company announcement.

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: December 11, 2019

## EXHIBIT INDEX

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release dated December 10, 2019 |
| 99.2 | Beta Bionics, Inc. original press release dated December 10, 2019, as referenced in Exhibit 99.1 |

**Exhibit 99.1**

**Company announcement — No. 44 / 2019**

**Zealand Pharma partner Beta Bionics receives FDA Breakthrough Device Designation for the iLet™ Bionic Pancreas System**

- **The iLet is a pocket-sized, wearable investigational medical device that autonomously controls blood sugar in people with diabetes and other conditions — it is the world's first bionic pancreas system**

- **FDA's Breakthrough Device Designation Program provides Beta Bionics with priority review among other benefits related to FDA interaction**

- **The iLet Bionic Pancreas System was granted breakthrough designation in all configurations (insulin-only, glucagon-only, and bihormonal), including use with Zealand Pharma's dasiglucagon, a glucagon analog with a unique stability profile in a ready-to-use aqueous solution**

*Copenhagen, December 10, 2019* — Zealand Pharma A/S ("Zealand") (NASDAQ: ZEAL), a Copenhagen-based biotechnology company focused on the discovery and development of innovative peptide-based medicines, announces that partner Beta Bionics, Inc. has received Breakthrough Device designation from the U.S. Food and Drug Administration (FDA) for its iLet Bionic Pancreas System.

The iLet Bionic Pancreas System is a pocket-sized, wearable investigational medical device that is designed to autonomously control blood-sugar levels. The Breakthrough Designation for the iLet Bionic Pancreas system contemplates configurations with most insulin analogs approved for pumping as well as dasiglucagon, Zealand Pharma's stable glucagon analog, which has a unique stability profile in a ready-to-use aqueous solution.

"We are thrilled for Beta Bionics to receive Breakthrough Device designation from the FDA," said **Emmanuel Dulac, President and Chief Executive Officer** at Zealand Pharma. "We are further thrilled for the positive development this could be for people with insulin-dependent diabetes, and look forward to progressing dasiglucagon in the bihormonal artificial pancreas system into Phase 3 development."

Please refer to the attached original announcement from Beta Bionics, Inc.

**For further information, please contact:**

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**About Zealand Pharma A/S**

Zealand Pharma A/S (Nasdaq Copenhagen and New York: ZEAL) ("Zealand") is a biotechnology company focused on the discovery and development 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 current pipeline of internal product candidates focus on specialty gastrointestinal and metabolic diseases. Zealand's portfolio also includes two clinical license collaborations with Boehringer Ingelheim and pre-clinical license collaboration with Alexion Pharmaceuticals.

Zealand is based in Copenhagen (Søborg), Denmark. For further information about the Company's business and activities, please visit www.zealandpharma.com or follow Zealand on LinkedIn or Twitter @ZealandPharma.

**Exhibit 99.2**

**PRESS RELEASE: FOR IMMEDIATE RELEASE**

**BETA BIONICS RECEIVES FDA BREAKTHROUGH DEVICE DESIGNATION FOR THE iLet™ BIONIC PANCREAS SYSTEM**

- **The iLet is a pocket-sized, wearable investigational medical device that autonomnously controls blood sugar in people with diabetes and other conditions — it is the world's first bionic pancreas system**
- **FDA's Breakthrough Device Designation Program provides Beta Bionics with priority review among other benefits related to FDA interaction**
- **The iLet Bionic Pancreas System was granted breakthrough designation in all configurations (insulin-only, glucagon-only, and bihormonal), including use with Zealand Pharma's dasiglucagon, a glucagon analog with a unique stability profile in a ready-to-use aqueous solution**

**Boston, MA — December 10, 2019 —** Beta Bionics, Inc. — a medical technology company developing and aiming to commercialize the world's first fully automated bionic pancreas — today announced it has received Breakthrough Device designation from the U.S. Food and Drug Administration (FDA) for its investigational iLet Bionic Pancreas System.

The iLet Bionic Pancreas System is a pocket-sized, wearable investigational medical device that is designed to autonomously control blood-sugar levels. The on-body wear is similar to that of an insulin pump. Unlike insulin pump therapy, however, the investigational system is designed such that users enter only their body weight for the iLet to initialize therpay. Immediately thereafter, the iLet begins controlling blood-sugar levels automatically, without requiring the user to count carbohydrates, set insulin delivery rates, or deliver bolus insulin for meals or corrections.

The iLet is designed to function as three medical devices in one. It can be configured as an insulin-only bionic pancreas, a glucagon-only bionic pancreas, or a bihormonal bionic pancreas using insulin and glucagon. The insulin-only and bihormonal configurations

may be helpful in diabetes. The glucagon-only configuration may be helpful in rare conditions that often lead to chronic, low blood-sugar conditions, such as congenital hyperinsulinism (CHI). Beta Bionics is committed to obtaining regulatory approval and commercializing all three iLet configurations.

The Breakthrough Designation for the iLet Bionic Pancreas System contemplates configurations with most insulin analogs approved for pumping as well as dasiglucagon, Zealand Pharma's stable pumpable glucagon analog, which has a unique stability profile in a ready-to-use aqueous solution.

"We believe the iLet Bionics Pancreas System represents a true breakthrough therapy for the management of glycemia, particularly in type 1 diabetes," said Ed Damiano, President and CEO of Beta Bionics. "We are partuclarly excited by the possibility that the iLet may be able to provide safer and more effective therapy in far more people than current therapies due to its simplicity of use."

**About Beta Bionics**

Beta Bionics is a for-profit Massachusetts public benefit corporation founded in 2015 to commercialize the iLet, a revolutionary bionic pancreas that is driven by mathematical dosing algorithms, which incorporate lifelong autonomous learning to automatically control glycemia. These mathematical dosing algorithms were developed in the Damiano Lab at Boston University and refined based on results from home-use clinical trials in adults and children with T1D. Beta Bionics is a Certified B Corporation™ whose founders — in addition to Ed Damiano — include other parents of children with type 1 diabetes and people with type 1 diabetes. Beta Bionics is committed to acting in the best interests of the diabetes community and to profoundly disrupting the diabetes medical device industry by bringing the iLet to market as expeditiously and responsibly as possible. Beta Bionics is pursuing regulatory approval of its insulin-only bionic pancreas, followed by its dual-hormone system, which will also administer a glucagon analog in order to raise blood-sugar levels without the need to consume carbohydrates.

Beta Bionics operates in Massachusetts and California. For further information, please visit www.betabionics.com or follow Beta Bionics Facebook, YouTube, Instagram, LinkedIn and Twitter @BetaBionics.

**Beta Bionics**

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