



**PILA PHARMA AB**

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## **Pila Pharma publishes interim report April 1 - June 30, 2022**

PILA PHARMA AB (publ) (FN STO: PILA) today publishes the Company's interim report for the period April – June 2022. The report can be found on the Company's website: <https://pilapharma.com/investors/finansiell-information/>

### **SUMMARY OF YEAR-END REPORT**

#### **Second quarter (April 1 – June 30, 2022)**

- Revenue was SEK 651 kSEK (0)
- Operating loss (EBIT) was - 2 250 kSEK (- 1 595)
- Net loss was - 6 501 (- 4 797)
- Earnings per share, basic and diluted, were - 0,40 SEK (-0,43)
- Cashflow was - 6 949 kSEK (- 5 347), whereof from ongoing business was - 2 698 kSEK (- 2 078)

#### **Six months (January 1 – June 30, 2022)**

- Revenue was SEK 1 186 kSEK (0)
- Operating loss (EBIT) was kSEK - 4 653 (- 3 921)
- Net loss was kSEK - 16 844 (- 7 123)
- Earnings per share, basic and diluted, were SEK - 1,05 (- 0,64)
- Cashflow was kSEK - 17 390 (4 485), whereof from ongoing business was kSEK - 5 199 (- 4 449)
- Cash and cash equivalents were at the end of the period kSEK 10 819 (6 392)
- Equity amounted to kSEK 13 451 (8 431)
- Solidity was 92% (82%)

#### **Significant events in the second quarter (April 1 – June 30, 2022)**

- Pila Pharma applied for Orphan Drug Designation at the US FDA for XEN-D0501 as a treatment for the pain disease erythromelalgia.
- Production of study material in diabetes (XEN-D0501 API) was completed with very good results and certificate of analysis was obtained.
- Agreement was signed with British Quay Pharma on the development of a suitable formulation of XEN-D0501 API for use in future preclinical studies in diabetes type-2.
- Agreement was signed with British LGC Drug Development Solutions regarding the establishment of an analytical method to measure XEN-D0501 in samples from the preclinical studies.
- On June 7, 2022, Pila Pharma held an annual general meeting, whereby the board was authorized to, in the time until the next annual general meeting, make decisions on new issue of shares, warrants and/or convertibles.
- At the meeting on June 7, Milan Zdravkovic was elected as a board member. Milan contributes with 25 years of experience from life science, including drug development in diabetes.
- The three-month preclinical toxicological studies of the active substance XEN-D0501 were initiated.

**Significant events after the quarter**

- In July 2022, Pila Pharma was granted Orphan Drug Designation (designated drug status) in the USA for XEN-D0501 for the treatment of the rare disease erythromelalgia.
- Dr Hans Qviding has been hired as Project Director for the work on new projects, including the ODD project in pain (analgesia).

**CEO comments:**

"We have completed the second quarter of 2022 successfully. Our work towards a phase 2b clinical trial of XEN-D0501 for type-2 diabetes is progressing according to plan and we have a very exciting journey ahead of us since we have received orphan drug status in the US for erythromelalgia. We have also recruited extremely experienced and competent people to the company who will make important contributions to our continued development."

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*Pila Pharma's share ticker PILA is subject to trade on Nasdaq First North Growth Market, Sweden with Aqurat Fondkommission AB as Certified Adviser.  
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### **About Pila Pharma AB (Publ)**

Pila Pharma is a Swedish biotech company in the diabetes segment based in Malmö, Sweden. The aim of the company is to develop TRPV1 antagonists as novel treatments. The company currently develop XEN-D0501, as a new oral antidiabetic agent. The company owns both use patents for treating diabetes and obesity with TRPV1 antagonists, and the intellectual property rights for the mid stage clinical development candidate XEN-D0501. The company was listed at Nasdaq First North GM in Stockholm, Sweden on 15 July 2021 to finance the further development of XEN-D0501.

### **About XEN-D0501 and TRPV1 antagonists**

XEN-D0501 is a selective, synthetic potent small molecule TRPV1 antagonist that was in-licensed in 2016 and, previously, developed by Bayer Healthcare, Germany and Xention/Ario Pharma, UK. The TRPV1 target (also called the “chili-receptor”) and TRPV1 antagonists that down-regulate neurogenic inflammation, has demonstrated applications across pain and inflammatory diseases and potentially plays a role in diabetes as well. Prior to in-licensing, XEN-D0501 had been found to have a good safety profile in other (non-diabetic) patient groups. Pila Pharma has to date completed two phase 2a clinical trials (PP-CT01 and PP-CT02), that both demonstrated that XEN-D0501 is well tolerated by type 2 diabetic patients. Further, PP-CT02, demonstrated that XEN-D0501 (administered as 4 mg BID for 28 days) – with statistical significance versus placebo – enhance the endogenous insulin response to oral glucose.

The company has recently completed the manufacture of new API needed for the conduct of 13-week preclinical safety studies, that are needed to further progress XEN-D0501 into a clinical 13-week phase 2b trial in patients with type 2 diabetes. The preclinical studies have recently been initiated and are ongoing. Considerations for best clinical development of XEN-D0501 in erythromelalgia in addition to diabetes are on-going.

### **About Diabetes**

Diabetes is a world-wide pandemic with a staggering prevalence of 537 million diabetics corresponding to approximately 8-10% of the population. Approximately 90 % of all diabetics suffer from type 2 diabetes, whilst approximately 10% suffers from type 1 diabetes. The disease can lead to cardiovascular disease resulting in reduction of quality of life for the patient, increased risk of death and high health care expenses. Despite recent therapeutic advances, large and growing unmet needs exist both from an efficacy, safety, accessibility, and affordability perspective.

### **About Erythromelalgia**

Erythromelalgia is a rare disease where neurogenic inflammation plays a role in the development of symptoms. The disease can cause near-constant or episodic erythema, pain (ranging from mild tingling to severe burning sensations), and redness to extremities. It most commonly affects the feet but may also occur in the hands, face, or other parts of the body with both nerves and blood vessels involved. Symptoms are frequently managed through avoidance of pain triggers. The disorder can be extremely debilitating, with a significant negative impact on quality of life and with potential to impact mortality rates among young people and the suicide rates among adults.