PILA PHARMA AB

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Pila Pharma publishes interim report July 1 - September 30, 2022

PILA PHARMA AB (publ) (FN STO: PILA) today publishes the Company´s interim report for the period July – September 2022. The report can be found on the Company´s website: **https://pilapharma.com/investors/finansiell-information/**

SUMMARY OF YEAR-END REPORT

Third quarter (July 1 – September 30, 2022)

- Revenue was SEK 281 kSEK (0)
- Operating loss (EBIT) was – 2 286 kSEK (- 3 174)
- Net loss was – 5 917 (- 5 577)
- Earnings per share, basic and diluted, were - 0,37 SEK (-0,39)
- Cashflow was – 5 697 kSEK (26 926), whereof from ongoing business was - 2 066 kSEK (- 3 535)

Nine months (January 1 – September 30, 2022)

- Revenue was SEK 1 468 kSEK (0)
- Operating loss (EBIT) was kSEK – 6 937 (- 6 180)
- Net loss was kSEK – 22 760 (- 11 785)
- Earnings per share, basic and diluted, were SEK - 1,41 (- 0,91)
- Cashflow was kSEK – 23 087 (31 411), whereof from ongoing business was kSEK – 7 264 (- 7 069)
- Cash and cash equivalents were at the end of the period kSEK 5 122 (33 318)
- Equity amounted to kSEK 7 535 (35 717)
- Solidity was 87% (95%)

Significant events in the third quarter (July 1 – September 30, 2022)

- On June 30, 2022 Pila Pharma announced that the preclinical toxicological three-month studies of the active substance XEN-D0501 has begun. Pila Pharma is, as previously announced, preparing a clinical phase 2b study of the drug candidate XEN-D0501 for type 2 diabetes.
- On June 30, the CEO Dorte X. Gram, bought 12,700 shares in the Company. The shares were purchased at an average price of SEK 3.93. The transaction took place through the company Gram Equity Invest, which she owns together with her son Gustav Hanghøj Gram. Dorte X. Gram is the main owner of Pila Pharma and after the most recent acquisition, she owns via companies a total of 5,063,158 shares, which corresponds to just over 31 percent of the votes and capital.
- 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 joined Pila Pharma to lead the development of XEN-D0501 in pain in general, as well as the development of a drug for erythromelalgia.

Significant events after the quarter

- On October 11, Pila Pharma published that a 13-week oral safety study in rats has completed the *in-life* phase with no adverse signals during the dosing phase. Outstanding investigations still to be completed include the pathology, and the bioanalysis and toxicokinetic analyses which are necessary to determine the safety margin for the coming 3-month clinical phase 2b study in diabetes. A pivotal 13-week study in “non-rodents” has now also been initiated. The *in-life* part of this 2nd part of the “13-week tox package” is due to be completed by the end of 2022 and all results of the “13-week safety package” are expected in early 2023.

- The Board of Directors has, pursuant to the authority granted by the general meeting on June 7, 2022, on October 25, 2022 decided to carry out a rights issue in respect of not more than 5,366 779 shares that, if full rights issue subscription, will provide about 16 MSEK before issue costs. The planned subscription period for subscription of shares will run from and including November 3, 2022 to and including November 17, 2022.

CEO comments:
” *"During the third quarter of the year, we continued our operational activities as planned and have started the 13-week preclinical toxicology studies. The dosing period of the first 'rodent' part is complete - very promising without registration of any clinical side effects. We are expecting an overall result in early 2023 and hope that it will show that XEN-D0501 is safe in animals during 3 months of oral dosing so we can move on to the clinical phase 2b study. In addition to this, during the summer, we received the good news that XEN-D0501 has achieved 'Orphan drug status' in the USA as a treatment for the rare disease erythromelalgia. This means that we as a company see more development opportunities for the same development candidate and can hopefully create more value for our shareholders than was initially expected. Last, but not least, we announced yesterday, that the board has decided on a new share issue. We primarily address our existing shareholders, but of course not everyone can subscribe fully pro-rata. I personally subscribe as much as I can - this time SEK 250,000. This means that others who are not, yet, shareholders can also have the opportunity to subscribe for new shares, to the extent that there are subscription rights left.” says Dorte X. Gram.*” says Dorte X. Gram.

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This information is such information that PILA PHARMA AB is obliged to publish in accordance with the EU Market Abuse Regulation. The information was submitted for publication on October 26, 2022, at 10:30 CET.

Pila Pharma’s share ticker PILA is subject to trade on Nasdaq First North Growth Market, Sweden with Aqurat Fondkommission AB as Certified Adviser. Contact: M: info@aqurat.se, T: +46 (0)8 684 05 800

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 FDA in USA recently granted Orphan Drug Designation for XEN-D0501 as treatment of Erythromelalgia. The company was listed at Nasdaq First North GM in Stockholm, Sweden in 2021.

About XEN-D0501 and TRPV1 antagonists

XEN-D0501 is a selective, synthetic potent small molecule TRPV1 antagonist that was inlicensed 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 PPCT02), 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. Preclinical 13-week safety studies are ongoing and are needed to be able to take XEN-D0501 further into a 13-week phase 2b clinical study in patients with type 2 diabetes. Considerations for the best clinical development of XEN-D0501 as a treatment for erythromelalgia are also ongoing.

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.