PILA PHARMA AB

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PILA PHARMA publishes year-end report (1 January - 31 December 2022)

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

SUMMARY OF YEAR-END REPORT

Fourth quarter (1 October - 31 December 2022)

- Revenue was 413 kSEK (719)
- Operating loss (EBIT) was -1 951 kSEK (-3 080)
- Net loss was -4 015 kSEK (-5 422)
- Earnings per share, basic and diluted, were -0,23 SEK (-0,34)
- Cashflow was 2 121 kSEK (-5 109), whereof from ongoing business was
- -1 827 (-2 295)

Twelve months (1 January – 31 December 2022)

- Revenue was 1 881 kSEK (719)
- Operating loss (EBIT) was -8 890 kSEK (-9 260)
- Net loss was -26 777 (-17 207)
- Earnings per share, basic and diluted, were -1,55 SEK (-1,32)
- Cashflow was for twelve months -20 966 kSEK (26 302), whereof from ongoing business was -9 091 kSEK (-9 364)
- Cash and cash equivalents were at the end of the period 7 243 kSEK (28 209)
- Equity amounted to 9 529 kSEK (30 295)
- Solidity was 88% (95%)

Significant events in the fourth quarter (1 October– 31 December 2022)

- On 11 October, Pila Pharma published that a 13-week oral safety study in rats had completed the *in-life* phase with no adverse signals during the dosing phase. Outstanding investigations still to be completed included 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” had also been initiated. The *in-life* part of this 2nd part of the “13-week tox package” was due to be completed by the end of 2022 and all results of the “13-week safety package” were expected in early 2023.
- On 25 October, the Company´s Board of Directors decided, in accordance with the authorization from the Annual Shareholders meeting on June 7, 2022, to carry out a rights issue of maximum 5 366 779 new shares that upon full subscription, could add capital to the company with about 16 MSEK before subscription costs. The subscription period was 3-17 November 2022.
- On 2 November, Pila Pharma published an information memorandum related to the rights issue of new shares with the start of subscription period on 3 November 2022.
- On 10 November, Pila Pharma published that the CEO Dorte X. Gram, during the period of 3-9 November, had sold 5 063 158 subscription rights in the ongoing rights issue.
- On 22 November, Pila Pharma published the outcome of the Company´s rights issue of new shares (“Rights issue”). The Rights issue, subscribed to about 42,99%, was

performed without any guarantor commitments and totally about 6,9 MSEK was added in capital to the Company before subscription costs. The CFO Elna Lembrér Åström and the Board member Milan Zdravkovic subscribed 16 666 new shares each. The CEO Dorte X. Gram, main owner since the start of Pila Pharma", subscribed 106 670 new shares and owns now indirectly via her companies 5 142 828 shares, that corresponds to 27,94% of both votes and share capital.

Significant events after the quarter

- On 30 January 2023, Pila Pharma published that a 13-week oral safety study with the development candidate XEN-D0501 in *non-rodents* had completed the *in-life* phase with no adverse signals during the dosing phase and biological samples had been received for assay. Outstanding investigations still to be completed included 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. It followed our earlier report that a 13-week oral safety study in rodents had also completed its *in-life* phase without registration adverse signals. That rodent study had now completed its outstanding investigations and the histopathology did not either demonstrate any adverse findings, and the bioanalysis results showed that the exposure of XEN-D0501 was as expected, and in the same range as earlier studies. Final result reports from both studies were expected by early March 2023.

CEO comments:
"During the quarter and shortly after, we could conclude that no clinical side effects had been registered in the 13 week preclinical safety studies – neither in "rodents" nor in "non-rodents" - in parallel to that very high blood levels of XEN-D0501 were detected. No organ changes were noted in "rodents" either, and we expect to get similar and last results for "non-rodents" in March. After that, we hope that the combined results of the preclinical safety studies will mean that we can proceed towards regulatory approval to conduct phase 2b clinical studies of up to 3 months' duration (in diabetes, erythromelalgia or other indications), which would be a huge milestone to reach."
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 28 February 2023 at 21:30 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.
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About PILA PHARMA AB (Publ)
Pila Pharma is a Swedish biotech company 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 as well as back-up candidates. A use-patent application on the use of XEN-D0501 as treatment of diabetes was filed in October 2021. The FDA in USA in July 2022 granted Orphan Drug Designation for XEN-D0501 as treatment of Erythromelalgia. The company was listed at Nasdaq First North GM in Stockholm, Sweden in July 2021.

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. Final results from recently completed preclinical 13-week safety studies are expected in March and are needed to advance XEN-D0501 to phase 2b clinical studies of 3 months duration in diabetes (or other indications). 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.