PILA PHARMA AB

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PILA PHARMA publishes year-end report (1 January - 31 December 2023)

PILA PHARMA AB (publ) (FN STO: PILA) today publishes the Company´s year-end report for the period January – December 2023. 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 2023)

- Revenue was 366 kSEK (413)
- Operating loss (EBIT) was -1,274 kSEK (-1,951)
- Net loss was -1,301 kSEK (-4,015)
- Earnings per share, basic and diluted, were -0.06 SEK (-0.23)
- Cashflow was 4,807 kSEK (2,121), whereof from ongoing business was -2,255 (- 1,827)

Twelve months (1 January – 31 December 2023)

- Revenue was 1,463 kSEK (1,881)
- Operating loss (EBIT) was -6,393 kSEK (-8,890)
- Net loss was -9,930 (-26,777)
- Earnings per share, basic and diluted, were -0.47 SEK (-1.55)
- Cashflow was -1,289 kSEK (-20,966), whereof from ongoing business was -4,854 kSEK (-9,091)
- Cash and cash equivalents were at the end of the period 5,954 kSEK (7,243)
- Equity amounted to 6,661 kSEK (9,529)
- Solvency ratio was 79% (88%)

Significant events in the fourth quarter (1 October– 31 December 2023)

- On 25 October 2023, the Board of Directors of Pila Pharma resolved, with authorization from the annual general meeting held on 30 May 2023, to carry out a new issue of up to 17,487,000 shares with pre-emption rights for existing shareholders at a subscription price of SEK 1.50 per share, which, in the event the Rights Issue was fully subscribed, would provide the Company with approximately SEK 26.2 million before transaction costs (the "**Rights Issue**"). In connection thereto, it was also resolved to request that the convertible loans of SEK 1.5 million, raised in August 2023, including accrued interest of SEK 39,698.63, i.e. in total SEK 1,539,698.63, were to be converted to shares in the Rights Issue by way of set-off.
- On 16 November 2023, Pila Pharma published an information memorandum regarding the Rights Issue.
- On 26 November, Pila Pharma announced it had entered a research collaboration with the Research Group of Professor Dick Wågsäter, Uppsala University, Sweden on investigating the effect of XEN-D0501 on *Abdominal Aorta Aneurism* growth in mice.
- On 5 December 2023, Pila Pharma announced the outcome in the Rights Issue. The Rights Issue was subscribed for by approximately 30.80 percent and provided the Company with approximately SEK 8,1 million before issue costs, including the conversion of the convertible loans and accrued interest of SEK 1,539,698.63 which were converted to shares in the Rights Issue by way of set-off.

Significant events after the quarter

- On 16 January 2024, Pila Pharma announced that Pila Pharma and its CEO, Dorte X. Gram, was selected to participate cost-free in a scale-up program “10 X Health” partially sponsored by the European Regional Development Fund and organised by the SmiLe Incubator and Medicon Village in Lund, Sweden.

CEO comments:
“In 2023, our main operational achievement was to demonstrate a very good tolerability of XEN-D0501 following 13 weeks administration of very high doses in 2 animal species. The good results were fundamental for us to further progress XEN-D0501 into longer clinical trials. However, the most significant results we shared in 2023, were the late-incoming results from our last 4-week trial in overweight and obese persons with diabetes (PP-CT02).
This showed that XEN-D0501 with highly statistical significance reduced the heart failure biomarker ANP, suggesting that XEN-D0501 may reduce the risk of premature cardiovascular death. The cardiovascular disease Heart Failure is a major cause of death in diabetes.
In early December the Board announced the outcome of a rights issue of approximately SEK 8.1 million that was below what we planned to raise, but enough to finance the initialisation of the next diabetes trial. I really look forward to the coming period where we will step further down the clinical development path. After New Year we have adjusted the trial design to a more cost-effective version whilst still answering certain key questions: 1) is there a good 3-month safety and tolerability of XEN-D0501 and 2) is there then a trend for reductions of blood glucose and body weight?” 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 2024 at 08:00 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 a novel treatment of type 2 diabetes and potentially of other diseases with an inflammatory background, such as the painful rare disease erythromelalgia. The Company owns a TRPV1 asset with data and chemical entities including the development candidate XEN-D0501. Further, the Company owns use-patents covering the use of TRPV1-antagonists as treatment of obesity and diabetes and intends to submit further patents regarding the synthesis, formulation or use of XEN-D0501 or back-up compounds. In July 2022, the Company was awarded orphan drug designation ("Orphan drug designation") for XEN-D0501 as a treatment for erythromelalgia.
Pila Pharma currently has focus on 3 projects within Diabetes/Obesity (ongoing, next step 3 mo phase 2a trial to assess maximal tolerable dose), Erythromelalgia (on hold pending funding, next step phase 2a PoC on pain during flare ups) and Abdominal Aorta Aneurism (ongoing, preclinical research collaboration).

About XEN-D0501 and TRPV1 antagonists
XEN-D0501 is a selective, synthetic potent small molecule TRPV1 antagonist that was inlicensed in 2016. TRPV1 antagonists that down-regulate neurogenic inflammation, has demonstrated applications across pain and inflammatory diseases and potentially plays a role in diabetes and obesity 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. Further, ANP, a heart failure biomarker, was highly statistically significantly reduced. During 2023 we could report a very good tolerability of XEN-D0501 following 13 weeks administration of very high doses in 2 animal species, and XEN-D0501 can thus progress into longer clinical trials. Recently, finances to sponsor a phase 2a dose-escalation study was secured and the study is being prepared with the objective of identifying the maximal tolerable dose of XEN-D0501 in overweight or obese people with type 2 diabetes as well as to identify (trends for) a reduction of HbA_{1c}, body weight and ANP, a relevant marker of CVD.

About Diabetes and Obesity
Diabetes is a world-wide pandemic with a staggering prevalence of 537 million people with diabetes 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. Despite recent therapeutic advances, large and growing unmet needs exist both from an efficacy, safety, affordability, and accessibility exists for treatment of people with type 2 diabetes. Obesity is most often preceding the development of type 2 diabetes and a serious risk-factor for not only developing type 2 diabetes but also all the co-morbidities resulting in "whole body dysfunction" and subsequent development of several diseased. The accumulated effect is a year-long reduction in of quality of life for obese persons with or without diabetes. Obesity leads to an increased risk of developing cardiovascular disease that eventually results in premature death and shortening of life duration. Recent advances by "Big Pharma" in the development of effective anti-obesity drugs, has proven that pharmacological weight management is possible and leads to obvious quality-of-life and longevity benefits for people with obesity. Even long-term public health costs are expected to be reduced if the clinical negative effects of the obesity pandemic can be limited. This has sparked a general interest in future potential oral treatments that can meet the accessibility/ affordability criteria and several deals have recently been done in the obesity segment.

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 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. Currently the project is on hold awaiting finances to sponsor a small proof of concept study in persons with erythromelalgia to demonstrate an effect of XEN-D0501 on reducing perceived pain during “flare ups”.

About Abdominal Aorta Aneurism
Abdominal Aorta Aneurism is a cardiovascular disease with ‘balooning’ of the lower part of the main artery of the body, aorta. The cause is unknown, but risk factors are atherosclerosis, high blood pressure, cardiovascular inflammation and infection as well as trauma. It affects millions of people globally and accounts for the death of 1% of men over the age of 65. It develops gradually over several years up to a dilatation of more than 3mm in diameter when surgery to insert a stent to prevent rupture is then the only treatment option, both expensive and with complications. Currently no preventive treatment is available.
In November 2023 a research collaboration was entered on investigating the effect of XEN-D0501 on Abdominal Aorta Aneurism growth in mice.