PILA PHARMA AB

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PILA PHARMA publishes year-end report January 1 - December 31, 2021

PILA PHARMA AB (publ) (FN STO: PILA) today publishes the Company´s year-end report for the period January – December 2021. The report can be found on the Company´s website: https://pilapharma.com/investors/finansiell-information/

SUMMARY OF YEAR-END REPORT

Twelve months (1 January – 31 December 2021)

- Revenue was SEK 719 kSEK (0)
- Operating loss (EBIT) was – 9 260 kSEK (- 3 380)
- Net loss was - 17 207 (- 6 982)
- Earnings per share, basic and diluted, were – 1,32 SEK (-0,70)
- Cashflow was 26 302 kSEK (- 2 159), whereof from ongoing business was – 9 364 kSEK (- 2 001)
- Cash and cash equivalents were at the end of the period 28 209 kSEK (1 907)
- Equity amounted to 30 295 kSEK (3 420)
- Solidity was 95% (64%)

Third quarter (1 July – 30 September 2021)

- Revenue was 719 kSEK (0)
- Operating loss (EBIT) was - 3 080 kSEK (-1 621)
- Net loss was - 5 422 kSEK (-5 223)
- Earnings per share, basic and diluted, were - 0,34 SEK (-0,52)
- Cashflow was – 5109 ksek (1 567), whereof from ongoing business was – 2 295 (3 209)

Significant events in the fourth quarter (1 October– 31 December 2021)

- Patent application, October 2021, for the use of XEN-D0501 as a treatment for diabetes
- CEO Dorte X. Gram bought, on November 15, 31,570 shares in the company
- Agreement with ERBC on November 26 regarding the implementation of PILA PHARMA's non-clinical toxicological studies.
- The 2021 Nobel Prize in Physiology or Medicine was in December 2021 awarded to Dr. David Julius, among other things for his discovery of TRPV1

Significant events after the quarter

- The production of a new study material (XEN-D0501 API) reached important milestones. Delivery of the API is expected before the summer of 2022.
- The scientific advisor Henning Beck Nielsen, as well as COO Lars B. Rasmussen, stepped down from their current roles
- Susanne Rugh was appointed as Project Director. She has led no less than three Novo Nordisk development candidates to registration and marketing (Levemir®, Tresiba® and Ryzodeg®).

CEO comments:
” I am very pleased to see that our operational activities, that we started shortly after the IPO, are now starting to yield results and even very good results. A bit of inertia in the start-up has now been replaced by results that exceed my expectations in terms of quality and which in addition have given us invaluable information about the chemistry around XEN-D0501 synthesis, and how to produce our development candidate smarter, faster and cheaper. This means that we will not only get the API we need to realize the next step in our development plan, but also that we have already started working on the final product's production cost.”

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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 February 18, 2022, at 08:00 CET.

About PILA PHARMA (Publ)
PILA PHARMA is a Swedish biotech company in the diabetes segment based in Malmö. The aim of the company is to develop a novel and superior tablet based treatment for type 2 diabetes. 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 is listed at Nasdaq First North GM in Stockholm in July 2021 to finance the further development of XEN-D0501. Currently, new API for further 3 months preclinical safety studies is being manufactured to permit the company to progress XEN-D0501 to a pivotal 3 month phase 2b trial in patients with diabetes, scheduled to start in first part of 2023.

About XEN-D0501 and TRPV1 antagonists
XEN-D0501 is a highly selective and very potent small molecule TRPV1 antagonist, previously in development by Bayer Healthcare and Xention/Ario Pharma. The TRPV1 target (also called the “chili-receptor”) has demonstrated applications across pain and inflammatory diseases and potentially plays a role in diabetes as well. XEN-D0501 was acquired by PILA PHARMA in March 2016, due to its very good safety and tolerability profile as compared to other clinical TRPV1-antagonist development candidates. TRPV1 antagonists as a drug-class has previously been associated with severe adverse events as fever (hyperthermia) but this has not been the case for XEN-D0501 in 8 clinical trials conducted so far. The maximal tolerable dose in non-diabetic individuals has previously been determined to be 4 milligrams twice daily, a dose level with good safety but no effect in non-diabetic patients with either overactive bladder disease or chronic cough. In November 2018, PILA PHARMA reported the completion of its first clinical trial (PP-CT01), demonstrating a good safety profile of XEN-D0501 at single doses up to 8 milligrams when administered to people with type 2 diabetes. The most recent study results were announced in September 2020. The study (PP-CT02) demonstrated that multiple doses of XEN-D0501 (4 milligrams twice daily for 28 days) were likewise well-tolerated by people with type 2 diabetes and also – with statistical significance versus placebo - that XEN-D0501 enhances the endogenous insulin response to oral glucose, thus demonstrating proof of principle.

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.