



PILA PHARMA AB

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Malmö, April 26, 2022

PILA PHARMA publishes interim report January 1 - March 31, 2022

PILA PHARMA AB (publ) (FN STO: PILA) today publishes the Company's interim report for the period January – March 2021. The report can be found on the Company's website: <https://pilapharma.com/investors/finansiell-information/>

SUMMARY OF YEAR-END REPORT

First quarter (1 January – 31 March 2022)

- Revenue was SEK 535 kSEK (0)
- Operating loss (EBIT) was – 2 403 kSEK (- 2 462)
- Net loss was - 10 343 (- 2 462)
- Earnings per share, basic and diluted, were – 0,64 SEK (-0,24)
- Cashflow was 10 441 kSEK (- 9 832), whereof from ongoing business was – 2 501 kSEK (- 3 706)
- Cash and cash equivalents were at the end of the period 17 768 kSEK (14 496)
- Equity amounted to 19 952 kSEK (14 496)
- Solidity was 93% (87%)

Significant events in the first quarter (1 January – 31 March 2022)

- The production of study material (XEN-D0501-API) reached several important sub-milestones and delivery of the completed API for the preclinical studies is expected to take place before the summer of 2022
- The scientific advisor Henning Beck Nielsen and COO Lars B. Rasmussen left their current assignments
- Susanne Rugh joined Pila Pharma as clinical project director. She has previously, on behalf of Novo Nordisk, led no less than three development candidates to registration and marketing (Levemir®, Tresiba® and Ryzodeg®).
- In February, CEO Dorte X. Gram increased its shareholding to a total of 5,050,458 shares, corresponding to just over 31 percent of votes and capital

Significant events after the quarter

- Pila Pharma applied for Orphan Drug Designation (ODD) from the FDA in the USA for an application of XEN-D0501 in pain caused by a rare disease
- The production of more study material (XEN-D0501 API) was completed with very good results (both quality and quantity) and analysis certificates were obtained
- Agreement signed with British Quay Pharma on development of appropriate formulation of XEN-D0501 API for use in future preclinical studies
- Agreement signed with British LGC on establishment of analysis method to measure XEN-D0501 in samples from the preclinical studies



CEO comments:

“We have successfully completed the first quarter of 2022. Our work towards a clinical phase 2b study of XEN-D0501 is going according to plan and we have achieved an important milestone by obtaining large amounts of new study material of the highest quality. Our financial resources are sufficient as planned for ongoing work for the rest of the year. In addition, we have been able to get a new formulation of XEN-D0501 for preclinical studies and submit an application for Orphan Drug Designation for XEN-D0501. I look forward to leading Pila Pharma safely through the next preclinical phase and to the forthcoming crucial clinical study.”

For more information:

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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 April 26, 2022, at 08:00 CET.

*PilaPharma's share, ticker PILA, is subject to trade on Nasdaq First North Growth Market with Aqurat Fondkommission AB as Certified Adviser. info@aqurat.se.
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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.