PILA PHARMA AB

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Malmö, 23 August, 2023

PILA PHARMA publishes interim report (1 April – 30 June 2023)

PILA PHARMA AB (publ) (FN STO: PILA) today publishes the Company´s interim report for the period April – June 2023. The report can be found on the Company´s website: https://pilapharma.com/investors/finansiell-information/

SUMMARY OF INTERIM REPORT

Second quarter (1 April- 30 June 2023)

- Operating income amounted to TSEK 301 (651)
- The operating result (EBIT) totaled to TSEK - 1 757 (- 2 250)
- The result for the period totaled to TSEK - 3 059 (- 6 501)
- Earnings per share, basic and diluted, were SEK - 0.17 (- 0.40)
- Cash flow for the period totaled to TSEK - 2 940 (- 6 949), whereof the cash flow for the operating activities totaled to TSEK - 1 639 (- 2 698)

First half year (1 January – 30 June 2023)

- Operating income amounted to TSEK 1 097 (1 186)
- The operating result (EBIT) totaled to TSEK - 3 601 (- 4 653)
- The result for the period totaled to TSEK - 7 099 (- 16 844)
- Earnings per share, basic and diluted, were SEK - 0.39 (- 1.05)
- Cash flow for the first half year totaled to TSEK - 6 801 (- 17 390), whereof the cash flow for the operating activities totaled to TSEK - 3 304 (- 5 199)
- The Company cash amounted to TSEK 442 (10 819) in the end of the half year period
- Equity amounted to TSEK 2 430 (13 451)
- The Company´s solvency ratio amounted to 70% (92%)

Significant events during the quarter (1 April– 30 June 2023)

- The subsidiary, Pila Pharma Danmark ApS Annual report for the financial year 2022 was approved, and a tax refund of DKK 2.6 M (approximately SEK 4 M) is expected in November
- Pila Pharma's capital efficiency plan is proceeding as planned
- Pila Pharma AB (publ) on 30 May 2023 held its annual general meeting with the following main outcome:
    - the company's Annual report for the financial year 2022 was approved
    - board members Dorte X. Gram and Fredrik Buch were re-elected, and Søren Weis Dahl and Richard Busellato were newly elected
    - it was decided to establish a new election committee consisting of former board member Lene Andersen Hansen and Dorte X. Gram

Significant events after the quarter

- The company engaged in XEN-D0501 partnering discussions in both diabetes and erythromelalgia
- The company firmed up strategy and plans for the phase 2a studies in diabetes and erythromelalgia
- Tablets manufactured in 2021 have been cleared by the manufacturer for use in phase 2a studies
- The company implemented further plans for maximizing capital efficiency

CEO comments

In the diabetes space, recent announcements by Eli Lilly, Novo Nordisk, and Pfizer have been met with significant media interest and a postive response from the stock market. It clearly shows that the pharma industry has a focus on diabetes and in particular the effects in obesity. Recent acquisitions in the field suggests an increasing appetite from pharma to license new projects with obesity effects. This development is positive for Pila Pharma since we expect an effect of XEN-D0501 on bodyweight and cardiovascular risk in addition to the effect in diabetes. It could potentially open for XEN-D0501 to also be a future obesity drug.

To demonstrate and fully leverage the potential of our lead candidate in both diabetes and obesity, we have decided to conduct a phase 2a study with endpoints related to both indications. This study will provide critical information in preparation for a subsequent phase 2b proof-of-concept study and increase the probability of a partnership deal. In parallel, we aim at demonstrating the effect of XEN-D0501 on reduction of pain during “flare ups” in the orphan disease erythromelalgia.

In response to the current high cost of capital, the previous Board in February approved a plan to increase capital efficiency, which is proceeding to plan. Furthermore, in November a tax-return of approximately SEK 4 M is expected in our Danish subsidiary. Pila Pharma AB is not obliged to release consolidated accounts and has historically opted not to do so for cost reasons but given the importance of this tax payment we are disclosing it here.

I’m excited to share that all project results needed for us to progress are now “in the box”. We are actively planning the studies in diabetes and erythromelalgia, and the financing of them, and plan to submit both trial applications within the next six months.

I very much look forward to us entering this new chapter of Pila Pharma.

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 23 August 2023 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 novel treatments of e.g. type 2 diabetes or of the painful rare disease erythromelalgia. 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. 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 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. Final results from recently completed preclinical 13-week safety studies show that XEN-D0501 is well tolerated in both “*rodents*” and “*non-rodents*” and the molecule can thus advance to clinical studies of up to 3 months duration.

About Diabetes
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. 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 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.