

PILA PHARMA reviews an eventful first half, with focus on upcoming obesity trials

PILA PHARMA published its interim report yesterday, reviewing an eventful first half of the year with a focus on upcoming obesity trials.

PILA PHARMA is a clinical-stage biotech company seeking to develop its lead candidate, the TRPV1 inhibitor 'XEN-D0501', as a new first-in-class oral drug for the treatment of obesity, diabetes, related comorbidities, and a rare painful condition.

The company reported its results for the first half of the year yesterday, 27 August. As PILA PHARMA does not yet have products on the market, the financial figures are of secondary importance, since the company's potential lies in the development of new drug candidates. Nevertheless, it is still relevant to mention the overall financial performance. In the first half of the year, PILA PHARMA recorded an EBIT of SEK -3.85 million, compared with SEK -4.01 million in the same period last year, reflecting a relatively consistent cash burn. In February, PILA PHARMA saw the exercise of its TO2 warrants, which contributed to the company having equity of SEK 16.1 million and a cash position of SEK 13.4 million at the end of the period.

Key events in the first half of the year

In the first half of 2026, PILA PHARMA entered into an agreement with a new clinical CRO to prepare an application for a new trial in humans with obesity. This followed a couple of preclinical obesity studies that had been mishandled, in which the active substance was not properly dissolved during dosing, resulting in what the company described as inconclusive results. The company concluded that, with no dissolution having taken place, it was naturally also impossible to draw conclusions about the actual effect.

PILA PHARMA therefore placed extra emphasis on completing the application, finalizing the protocol, and updating the key documents in order to strengthen the chances of the application being approved by the authorities.

Activity has continued after the first half of the year

PILA PHARMA has also announced significant news after the end of the first half of the year. Earlier this month, the company received regulatory approval to carry out the trial in humans with obesity. The clinical trial is named PP-CT04 and will investigate the safety, tolerability, and efficacy of the drug candidate XEN-D0501. Participants will be dose-escalated up to 16 mg, twice daily, and the trial will involve three months of treatment. This represents markedly higher possible doses and a considerably longer treatment period than PILA PHARMA has previously tested, as the most recent trial, PP-CT02, involved one month of treatment at a fixed dose of 4 mg twice daily. The company assesses that it is necessary to identify the best tolerable level in order to achieve maximum efficacy.

The biological approach is entirely different from existing treatments such as GLP-1, and the company therefore expects that the product may have a markedly different side-effect profile, without the vomiting, nausea, diarrhea, and constipation that patients often experience with current products on the market. In addition, it is formulated as a simple and stable tablet, which is expected to suit a future consumer market well, where oral products are estimated to account for 40-50% of consumption of weight-loss products.

Gustav Hanghøj Gram, CEO of PILA PHARMA, commented in connection with the interim report:

A giant leap forward for PILA PHARMA! It's exciting to be back from summer with the positive news that we got regulatory approval from European Medicines Agency to conduct a new 3-month clinical trial in people living with obesity! The trial seeks to explore a within-subject dose titration approach to reach anticipated therapeutic plasma concentrations of XEN-D0501 not previously investigated.

Huge kudos to our CSO and mastermind Dorte X. Gram who together with our scientific collaborators got study design and the application on-point for what is a crucial step in our clinical development path!

It is therefore a substantial step forward to assess potentially much higher doses and longer durations, but we have long thought and said publicly that we believe that is needed to achieve the best results. The results from the study can carve out a platform from which new clinical efficacy studies in diseases beyond obesity, can be effectively launched. That will be potentially very important for our ambitions in diabetes and erythromelalgia among others! It serves as key gateway our the future clinical development path. And now we are excited to execute!

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