

Executive Summary

Company Overview: Levicure is an Israeli pharmaceutical startup focused on developing a proprietary oral fixed-dose combination therapy for Type 1 Diabetes Mellitus (T1D). The company is currently in the clinical research stage, working on a patent-protected therapy that combines GABA, DPP-4i, and PPI (Triple Therapy) to address multiple pathogenic targets simultaneously, aiming to achieve complete insulin independence and long-term remission in recent T1D patients.

Opportunity: Type 1 diabetes is a life-threatening chronic disease affecting over 8.4 million people worldwide, significantly impacting patients' quality of life and healthcare costs. Current treatments, including insulin replacement therapy and emerging immune therapies, have limitations regarding effectiveness, safety, and scalability. Levicure aims to provide a safe, convenient, and scalable solution for T1D patients, addressing an urgent need in the market.

Unique Selling Proposition (USP): Levicure's product offers a single oral pill that can potentially lead to complete insulin independence and long-term remission in recent T1D patients. This innovative therapy uniquely combines well-established drugs and a supplement supported by clinical studies and patents. The treatment promises the convenience of once-a-day oral dosing, reduced insulin dependency with the opportunity for long-lasting insulin discontinuation, stabilised glucose levels, and improved quality of life for T1D patients.

Status and Achievements:

- Levicure has published a proof-of-concept study in collaboration with Uppsala University and Assuta Medical Centers, demonstrating promising results in recent T1D patients, with 70% achieving complete insulin discontinuation. (<https://doi.org/10.3389/fendo.2023.1171886>)
- NOD mice studies have further validated the efficacy of the Triple Therapy. (<https://doi.org/10.3389/fendo.2022.1028114>)
- The company has obtained patents in the EU and USA and is pursuing additional patents for a quadruple therapy.
- Levicure has received positive feedback from the FDA during a pre-IND meeting, paving the way for Phase 2a clinical trial.
- The combination therapy is eligible for multiple market exclusivities, providing significant protection.

Market and Competition: The target market for Levicure includes 8.4 million T1D patients globally, focusing on the USA and EU markets. The estimated potential target market size is approximately \$9 billion. Levicure's competition primarily consists of preventative immune suppression and beta-cell replacement interventions, with no existing solutions promoting sustainable T1D remission in diagnosed patients.

Funding Request: Levicure is fundraising for a Series A round, estimated at \$25 million. These funds will be used to conduct the Phase 2a clinical trial and develop the final once-a-day fixed-dose combination.

Team: Levicure has a solid and experienced team consisting of CEO Daniil Koshelev, CMO Dr. Shmuel Levit, and former Executive Team Members of Teva, including Chief Pharmaceutical Officer Mike Teiler, Head of Clinical Development Yafit Stark and Strategic Advisor Amos Anatot. The team is further supported by diverse advisors and experts with extensive backgrounds in biotech, clinical development, legal, and regulatory affairs, such as Alexander Fleming and Alex Rabinovitch, among others.

Conclusion: Levicure presents an innovative solution to address the urgent unmet needs of T1D patients worldwide. With promising clinical results, patents, and a solid team, the company is well-positioned to significantly impact the field of diabetes treatment and improve the lives of millions of patients.