

Betalin Therapeutics Ltd.
Quarterly Shareholders Update
Q1 – 2022

By

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Chief Executive Officer



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Introduction

My name is David Nitsan, and I have recently replaced Dr. Nikolai Kunicher as Betalin's new CEO. I hold an MSc. degree In Biomedical and an Executive MBA degree, emphasizing tech management, both from Tel-Aviv University. I have about 15 years of experience as a MEDTECH CEO in the global medical device industry and a track record of successful company establishment from idea to commercial realization with a successful EXIT (Sold JetPrep Medical to a US-based global company). Based on my executive leadership experience, skillset, and education, I believe it's in my ability to fulfill your expectations in realizing the full potential of the Betalin technology to be a leader in Diabetes treatment.

I am happy to report that the Betalin team has reached a Design Freeze (DF), which is an important milestone for both the Micro-Organ Matrix (MOM) (the "scaffold") and EMP.

The DF is a significant milestone for the company and outstanding achievement that enables us to undertake the lengthy and demanding process of testing and validations in preparation for the planned FDA IND filing.

Working as a unified team to achieve scientific progress enabled us to reach the Design Freeze phase while accomplishing the following significant milestones:

- Approval of the tissue supplier** - From which the engineered micro pancreas is constructed as a validated quality source for the MOM's biological tissue.
- MOM manufacturing process** - The company's ability to get the decellularization process up to FDA-acceptable DNA levels and more.
- Increased islet cells seeding** - The ability to attach islet cells to the MOM with X3-fold larger quantity than before.
- Method of transplantation** - validation of the EMP transplantation method and procedure with surgeons.
- The regulatory plans for IND** submission and approval move toward clinical studies.

Pre-Clinical Activities

Betalin has performed extensive preclinical experiments on small (Rats) and big (pigs) animals in Israel and the US. This further confirms the safety profile, initial efficacy with Human Insulin tracing found in animals, and many other essential oils performances required for regulatory submission and our ongoing development plans.

To conclude the pre-clinical testing:

- In Israel and the US, the feasibility of EMP1 activity has been shown in mice and pigs, both with rats and human islets.
- The subcutaneous implantation procedure has been successfully performed on pigs, which can simulate the operation in humans.

Production and Operation

As part of the V&V on the MOM activities required for the regulatory submission, the Betalin team produced over 10,000 MOMs of high quality. This rigorous production was possible thanks to the high motivation of the entire Betalin team to accomplish our ambitious goals.

Product Pipeline

Betalin intends to continue its efforts to develop the next generation of the EMP producing insulin with human stem cell-derived β cells to stay at the forefront of technology innovation. Derived β (SC- β) cells have the potential to revolutionize diabetes treatment over Islet Cells, mainly thanks to their significantly higher availability and higher quality of reproducibility.

Regulatory update

Betalin has recently completed a broad regulatory road-mapping overview for the US/EU/UK to evaluate the ultimate scenario and work plan. The decision on where to initiate the Phase I study (First-In-Man) is critical. It will consider different factors, such as: when, primary investigator, availability of quality human islet donors, best in class partners to collaborate on the on-site Islet Cell Seeding on the MOM to create the EMP. During Q1/22, Betalin submitted a Pre-IND meeting request and received positive answers and feedback on our plans and approach, giving better clarity of the deliverables required to apply for the IND successfully. We are continuing the dialogue with the FDA and other possible clinical sites outside the US, UK, and EU.

Betalin plans to initiate further testing as part of the regulatory plan in the coming months which are planned to be completed during first half of FY 2023 and to submit the IND right after and seek IND approval by end of FY 2023 to initiate the phase I of the clinical study.

Intellectual Property

We entered the national phase in the US European Patent Office, China, and Canada during November-December 2021 with patent family name COMPOSITIONS AND METHODS FOR GENERATING INSULIN-PRODUCING BETA CELLS. The compositions and methods of the invention involve stepwise differentiation while the differentiating cells are cultured on a lung tissue-derived acellular scaffold.

New inventions - Betalin scientist and the team continue developing new IP actively and accumulating experience and unique know-how processing and working with a different types of cells and insulin processing.

HR Update

The Betalin team currently consists of 10 full-time employees, among which all critical functions required for development, pre-clinical testing, manufacturing, and regulatory activities are well supported. Additional employees with relevant experience needed to expedite our plans may be recruited, such as Tissue Engineering experts, scientific researchers, and executive leaders.

Finance and budget control

I am leading the implementation of a cloud-based ERP system (Priority), which will serve Betalin in all operational and financial management aspects.

Following a successful implementation, Priority will enable us to maintain a controlled procurement process, real-time budget monitoring, budget vs. actual multi-currency reports, etc.

Financing

Betalin's current cash position is to support our ongoing activities described above until end of first half of FY 2023 (*assuming Betalin will receive all additional grant payments)

Betalin has recently received a significant capital investment from the European Innovation Council (EIC) of 500,000 euros. The EIC investment is a testament to the EU's confidence in the company management and the unique technology Betalin is developing for the many patients with diabetes in need.

***** Please note that concerning the IPO** - Betalin is not actively pursuing an IPO due to unfavorable market conditions and our intention to potentially keep a low profile vis-à-vis our competitors and potential strategic partners.

If you have any questions, feel free to contact me directly via mail: david@betalintherapeutics.com and via phone at +972-52-3959796)

I value your ongoing support of our endeavors,

Yours truly,

David Nitsan, CEO