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# Implanted Engineered Micro Pancreas offering hope in Restoring Insulin Production for Diabetes Patients

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**CEOCFO:** ***Mr. Ben-Arie, what is the focus at Betalin Therapeutics Ltd.?***
**Mr. Ben-Arie:** We are focusing on developing a complete therapy for diabetes. In order to treat diabetes, we are developing an Engineered Micro Pancreas (EMP) to be transplanted into the patient's body in order to allow the patient to restore insulin production and release from the need to inject themselves a couple of times a day.

**CEOCFO:** ***Has a similar technology been tried previously?***
**Mr. Ben-Arie:** There are technologies that are under development where insulin producing cells are being produced from different sources. However, what we are developing is not insulin producing cells, it is a complete organ. It is a totally different approach. We are giving the insulin producing cells a natural environment such as it is in our body so they can function and produce insulin, so the patient can have better control over his blood glucose level.

**CEOCFO:** ***What is the science and why do you think it can work?***
**Mr. Ben-Arie:** We think it will work because of several reasons. First, there have been pre-clinical studies and the results are very promising. The second thing is that we are using the insulin producing cells that originally are from humans. Therefore, we actually use similar protocol in the clinic as the Edmonton Protocol. In this clinical procedure, the patients are given insulin producing cells from donors, however we are jumping into this process and improving it. The process of insulin producing cells transplantation is already existing, and has already been approved in Europe and in Canada. In addition, for FDA approval, there has already been a Phase 3 clinical trial done, so I believe it will be approved in the United States very soon. So, we are jumping into this process and improving it with our technology.

**CEOCFO:** ***How does the Engineered Micro Pancreas (EMP) get into the body? Would you tell us about the procedure?***
**Mr. Ben-Arie:** The size of the Engineered Micro Pancreas is very small. We are talking about a biological implant at the size of about 300 micrometer widths and the diameter is about 7 millimeters. We are transplanting it simply under the skin. Basically, it can be injected under the skin. Therefore, it is pretty much a simple process. It requires local anesthesia and that is it.

**CEOCFO:** ***Is there a possibility the body could reject the EMP? Are there different types depending on the patient?***
**Mr. Ben-Arie:** We are going to treat the patient in a regular immunosuppressive protocol like in every other implant procedure. Therefore, we do not see any reason for rejection. A similar thing happened with the current pancreatic islet

transplantation and the Edmonton Protocol that I described before. The patient goes under the immunosuppressive protocol and they are taking some medication to reduce the immunorejection response.

**CEOCFO:** ***It sounds simple?***
**Mr. Ben-Arie:** We are going to make it even better in our future products, but this is the first one and we are doing it as simple as possible in order to be in the market with our Engineered Micro Pancreas without complications. Then we can improve it and add other technologies to completely prevent the need for immunosuppressive medications, and allowing the product to be widely used by the patient.

**CEOCFO:** ***How will you get the cells that you need?***
**Mr. Ben-Arie:** Today the cells are coming from human donors, which are people who have passed away and have donated kidneys, hearts and lungs, so they are donating also their pancreas. There are hospitals that are specializing in isolating those insulin producing cells from the pancreas. They are actually going to be our partners in the clinical development.

**CEOCFO:** ***What has been the reaction from the medical community who are aware of what you are doing?***
**Mr. Ben-Arie:** They are very enthusiastic about us. They really understand the benefits of what we are doing. In our body, the insulin producing cells are part of a tissue and today there is no cell therapy technology on the market that allows the cells having their natural environment. However, with our Engineered Micro Pancreas, the cells are first seeding on our biological scaffold and they are becoming a part of the tissue, a part of an organ, and then after we are doing some quality tests, making sure that it is functioning and everything is ok, only then are we transplant it under the patient' skin. Therefore, it is a well-controlled process and it makes a great deal of sense to use our Engineered Micro Pancreas and not just simply transplant those cells and let them try to survive by themselves.

**"There are technologies that are under development where insulin producing cells are being produced from different sources. However, what we are developing is not insulin producing cells, it is a complete organ. It is a totally different approach. We are giving the insulin producing cells a natural environment such as it is in our body so they can function and produce insulin."- Jacob Ben-Arie**

**CEOCFO:** ***You were recently recognized at the MIXiii Biomed competition?***
**Mr. Ben-Arie:** The Biomed is an international conference and is the main event in Israel and we were very happy to be announced as the Number One Innovative Pharmaceutical Company in Israel for 2017. We are very excited about it and have received a great number of calls and emails from potential partners who would like to work with us as well as research teams and also people who explore the possibility of investing in our company.

**CEOCFO:** ***What are your next steps and what is the timeline?***
**Mr. Ben-Arie:** We already approached the FDA in 2016, with a non-formal meeting. We described to them what we are doing. We shared our results with them and our plans and asked for their professional review. They simply said we are on the right track, so they asked us to move forward and submit a request to start clinical trials. We are going to meet with the FDA for a formal meeting called the Pre-IND meeting in the 1st Quarter of 2018, basically within 6 months. Then following the meeting, we will submit a request to initiate clinical studies, and hopefully they will approve us to start the studies in 2018.

**CEOCFO:** ***What do you understand from your experience in healthcare on how to bring a product to market and get it through the various hurdles?***
**Mr. Ben-Arie:** What not to do is short cuts. The most important thing is to understand the needs of the market, the need of the people who need the therapy, and what are the requirements of the regulatory authorities. You also need to make sure you have the resources to support you through the process because it is not an easy process and not a short process.

**CEOCFO:** ***How do you deal with some of the frustration in the length of time that it takes to get a new idea tested, approved, and in use?***
**Mr. Ben-Arie:** I have three children at home, as well as my wife and when I am thinking about the product and the time involved with development of a medical product, I always think of what I wanted to know and what testing the product would have to go through before someone would be able to give it to my son, daughter or wife. This is the first thing. We always want to move forward, but we need to move forward very carefully because there is a great deal of responsibility

behind it. The second thing, at least with what we are doing, is we have developed a regulatory strategy that on one hand we are not coming with the most optimal product to the market on our 1st Phase, but we are coming with an improvement to an existing clinical procedure. Therefore, it is a totally different tactic because we are not starting from scratch. There is a successful experience in the market with transplanting human insulin producing cells from donors to diabetic patients. However, we are jumping into this process and we are improving it. Therefore, from a regulatory perspective it should take less time because a major part of the process is already being approved. The second thing is we are talking about a biological implant that we have a great deal of control over the process. Even after the transplantation, when the biological implant is the patient's body under the skin, we still can control it, so if something unexpected happens, such as an infection or during the manufacturing process there was some hazard, it can be removed. You can take it out, because it is not like a medicine where you swallow and ingest it, so it is in your blood stream and that is it.

**CEOCFO:** ***Sum it up for our readers, many of which are in the business, healthcare and investment communities. Why pay attention to Betalin Therapeutics?***

**Mr. Ben-Arie:** The approach of Betalin is much more mature than the others that I am familiar with. The second thing is that the source of the insulin producing cells that we are using today are from human donors, but we can use other kind of insulin producing cells. For example, other companies that are manufacturing or developing new technologies of insulin producing cells, all eventually will function better with our biological scaffold. This is the main thing. We are developing a platform, this biological scaffold that allows us to seed on it almost any type of insulin producing cells. First we start with the most immediate choice of insulin producing cells that are coming from human donors, but in the future I hope either Betalin in our own lab, or even other players in this market will develop insulin producing cells that will be approved for use in clinical procedures. Then we can use those cells, put them on our biological scaffold and get them much better results. Therefore, from an investment point of view it is less risky than just investing in a certain type of technology. Again, the developmental stage of the company is really much advanced. We are planning to be in clinical trials within 12 to 18 months. A major part of our pre-clinical studies is really behind us. We are now focusing on the manufacturing procedure. We are not focusing as much on research.