

Nadav Kidron, Esq., CEO of Oramed Pharmaceuticals Inc. Discusses his Company's Revolutionary Technology for Transforming Injectable Treatments, Including Insulin, into Oral Therapies



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CEOCFO: *Mr. Kidron, you co-founded Oramed Pharmaceuticals in 2006. Would you tell us about that? What was the purpose back then and where you are today? Has the vision changed or is it the same?*

Mr. Kidron: I founded the company in 2006 along with my mother, Dr. Miriam Kidron. Her research group worked for many years to try to find alternative ways

to deliver insulin, other than injection. Based on a breakthrough they had, I took the technology out of Hadassah Medical Center and established the company. Then, Nobel Prize winner Professor Avram Hershko, M.D., Ph.D, joined the scientific team and what we had in hand was the technology that allows us to deliver medications orally that currently can only be given through injections. Our leading product is oral insulin for diabetes.

CEOCFO: *Would you tell us about your POD™ technology for transforming injectable treatments into oral therapies? How is that even possible?*

Mr. Kidron: If you look at many of the medications that are made out of peptides, delivering it orally was impossible because of two obstacles. The first obstacle was the problem of degradation; once we put the peptide into our mouth it already starts to go through the process of degradation that basically chops the molecule into pieces, so it cannot be used. The second problem is that even if we can overcome the degradation, you still have a size issue, in that the size of the peptide does not allow it to go through the walls of the intestine into the bloodstream and therefore it is considered impossible to deliver peptides orally. Oramed's technology on the one hand shields and protects the peptide from becoming degraded and, on the other hand, allows it to go intact through the stomach wall. When it is in the intestine, this coating dissolves. This coating is the protection against the proteases, which are the enzymes that cause degradation, so it allows delivery through the gut into the intestine, into the portal vein, and the peptide is delivered into the liver. In many cases it is much more advantageous to deliver peptides into the liver, such as with insulin.

CEOCFO: *What is it that makes your technology proprietary? Is it the coating?*

Mr. Kidron: There are two aspects of the technology that make it proprietary. Number one is the combination of the material used and the actual material, which is the protease inhibitor that we produce. Therefore, there are two different approaches that make our technology proprietary.

CEOCFO: *Long-term, are you looking at this as a technology that could be used with potentially any drug? Are you looking at partnerships and collaborations, or acquisitions or just drugs developed through your own R&D?*

Mr. Kidron: Our proprietary technology can be used potentially for many drugs. I would not say any drug, as there are some limitations with this technology, but there is a long list of potential targets our POD™ (Protein Oral Delivery) technology can work with. We've been working with some partners in trying to deliver their medication using our POD

technology. We are going into discussions with potential other partners so definitely the door is open to take this technology to wider use. With our own internal pipeline, we have a few products that we are working on. Oral insulin is the most advanced one, but we have a GLP-1 (Glucagon-like peptide-1) analog that is going into a Phase 2 in a few months under the FDA and an oral leptin, so we definitely are trying to explore the ability of the technology beyond insulin.

CEOFCO: *Why is oral a better route of deliver, as opposed to injection?*

Mr. Kidron: Taking insulin orally is a more physiological way to deliver insulin than with an injection, because when our body makes insulin, it is produced in the pancreas, but the liver is the organ that stores and regulates the secretion of the insulin into the bloodstream. So, when we get insulin into the liver, we actually imitate the physiological way that the body works. When we give it directly into the blood stream, such as through an injection, then there is no control of the body through the actual regulation of the insulin in the blood stream.

CEOFCO: *Is your product for Type 1 or Type 2 diabetes or both??*

Mr. Kidron: The simple answer is for both with different applications. Type 2 makes up 95% of the diabetic population, so our main focus has been on Type 2, but our goal is both Type 1 and Type 2 as we move forward with the FDA.

CEOFCO: *Would you tell us about your combination therapy of insulin and GLP-1 analogs?*

Mr. Kidron: This is simply one plus one equals three. If we put the insulin and the GLP-1 analog in one capsule, we can get a much more meaningful reduction in the glucose levels than each one by themselves. There is a synergy when combined.

“Our proprietary technology can be used potentially for many drugs... by delivering oral insulin and other products that will follow it we hope to offer people healthier lives and reduce costs in healthcare. It is our goal to try to make the world a better place for everyone.”- Nadav Kidron, Esq.

CEOFCO: *You successfully randomized more than 50% of the expected 285 patients for your 90-day dose-ranging Pivotal Phase 2b clinical study of your oral insulin capsule, ORMD-0801. Would you tell us about your efforts bringing your oral insulin through clinical trials?*

Mr. Kidron: Currently, the most important trial for Oramed is the 90 days trial. This trial will allow us to get the exact reduction in the A1c levels of those patients. Seeing the desired results will open the way to moving into Phase 3, then at the end of the Phase 3 we will be able to register the product in the United States.

CEOFCO: *Has anything like this ever been tried before or are you the first?*

Mr. Kidron: Today is actually the 127TH birthday of Sir Frederick Grant Banting KBE MC FRS FRSC (November 14, 1891 – February 21, 1941), the Nobel Prize winner who essentially discovered insulin. When insulin was discovered at first, they tried to give it was orally, but it failed, so since then insulin has been delivered through injection. There have been different trials throughout the history of insulin to deliver it orally, but I think that Oramed today is at the most advanced stage in getting oral insulin into the market than any of the previously tried products.

CEOFCO: *How will your oral product impact the market? Will it have an impact on healthcare costs, which is a big issue?*

Mr. Kidron: Unfortunately, diabetes is an epidemic disease. The numbers are growing because of, for example, unhealthy lifestyles, so over the coming years a significant number of patients will be diagnosed. One in every nine dollars that is spent on healthcare, goes into treating diabetes and that is a huge weight on society and the healthcare system. Last year we saw \$600 billion spent in treating diabetics, and we believe that successful oral insulin can potentially push away the point that patients need to inject and become insulin dependent. This should allow for less complications and lower costs. Potentially that will benefit the healthcare systems by requiring less funding in order to treat diabetes. Therefore, we believe that oral insulin, beyond patient compliance and beyond the advantage of the physiological delivery, can potentially result in lower costs for the overall treatment of diabetes.

CEOFCO: *Is your oral insulin a product that will be able to be self-administered or will it need to be taken in a clinic, hospital or doctor's office setting?*

Mr. Kidron: Self-administered. For the first line and second line patient it would be the oral insulin. They would just take the pills.

CEO CFO: Do you have the funding in place to continue development and clinical trials, or will you have to reach out to investors or partners?

Mr. Kidron: Currently we have close to \$50 million cash and we have also done a very successful licensing deal with a Chinese partner. The licensing deal resulted in a \$50 million payment, of which to date we have received \$30 million and we expect to receive another \$20 million down the line. That puts us in a strong financial position that allows us to move forward with our trials towards registration.

CEO CFO: Oramed has done one of the most successful partnerships between a Western company and a Chinese company. Can you tell us more about it and how it came about?

Mr. Kidron: We signed a deal at the end of 2015 with leading insulin manufacturer out of China where we granted them the rights for oral insulin in the territory of China and in return, they paid the \$50 million, which I mentioned earlier. They are going to invest \$650 million in China in order to build the facilities that will allow them to produce oral insulin at their own insulin facility and will allow them to take it to the Chinese FDA. Once they start sales, they will pay us 10% royalties. It has been a very successful partnership because they are working hard at building the facilities and going through the scale up process and we believe that we are probably going to enter the Chinese market even before we will enter the market in the United States.

CEO CFO: Will they be manufacturing this for you globally, or does the partnership include the manufacturing just for the Chinese market?

Mr. Kidron: They are manufacturing it for China, but we will have the option because they are going to build their facilities to the US and global standards. Therefore, we will have the option to buy it from them.

CEO CFO: What are you doing to get the word out about such an exciting product? You recently presented at the Tides Europe 2018 Conference. How did that go and will you be attending industry and investor conferences as a regular part of your future efforts?

Mr. Kidron: What we have discovered is that we have a simple story and that it is easy to digest. It is important for us to tell the story because patients with diabetes are very encouraged that our oral insulin technology is in such an advanced phase. We definitely aim to increase the exposure of Oramed, and to present and lecture at different opportunities as we move forward.

CEO CFO: Have you encountered skeptics along the way?

Mr. Kidron: We used to get more skepticism. However, once we showed our Phase 2 results, which clearly demonstrated a significant difference between the placebo arm and the insulin arm, and one could see in a way that is much harder to argue with that the Oramed technology can deliver insulin to the liver and bloodstream, the level of skepticism from professional people has gone down.

CEO CFO: Bringing new products through development and trials is a lengthy and difficult process. What is it about your board and management team that will position you to succeed, where so many others have faltered?

Mr. Kidron: Typically, in the world of pharma it is a difficult process to advance something from development to clinical trials to commercialization. We have been very fortunate to have a very supportive board with a tremendous amount of experience. We also have a very good scientific advisory board. Having a committed management team in place who understand the challenges of taking a drug through the pathway to approval is essential. Thanks to everyone involved we have been able, since 2006, to make the progress that allows us to look ahead towards future Phase 3 studies.

CEO CFO: In closing, why will Oramed Pharmaceuticals have an impact on healthcare as we know it?

Mr. Kidron: Our dream is to have a huge impact on one of the biggest issues that the world is facing today. By delivering oral insulin and other products that will follow it we hope to offer people healthier lives and reduce costs in healthcare. It is our goal to try to make the world a better place for everyone.

