Lana: Can you give us a quick rundown of your background and what your company is about?

Ira: I am a pharmacist by undergraduate training. I went to business school and spent the last 30 years in the more traditional pharmaceutical industry in functions like sales, marketing, business development to biotech drug development, to distribution, retail, and managed care.

I got started in Bioquark because after those 30-plus years, I became a little dismayed with the fact that an industry that generates a trillion dollars a year around the world in revenue and spends $200 billion on R&D every year was *very* poor at developing cures for any of the chronic degenerative diseases responsible for human suffering and death.

So ultimately, we crafted this company from a slightly different angle – We look at nature, at all the wonderful species out there that are capable of all forms of regeneration, tissue repair, age reversal, and basically think, "*How can we reignite these capabilities in humans*?"

Most of these are things that we, as human beings, unfortunately, have lost the ability to do. If we lose any of our major organs or body parts, they don't grow back, and we are left with non-functional scar tissue.

So, ultimately, we wanted to create a company that did something a little different, looked beyond the current model of just treating a disease, and move more towards how we cure and reverse a disease.

Lana: You talked about species that are able to do age reversals. What kind of species are you referring to?

Ira: Well, most organisms that regenerate. So we're talking about lower organisms like amphibians, planarian worms, certain types of fish, have the ability to replace lost or damaged organs and tissues that are identical in both structure and function to the original, including spinal cords, limbs, hearts, eyeballs, even large parts of their brains.

And the way they do this is by basically turning back the cellular clock to a point before the damage occurred, and starting life over in those particular tissues.

In much lower organisms, like certain jellyfish and hydra, we see that they can do this on a whole organism basis. So, they basically go about their life and at some point, later on, decide, you know, "I'll become a kid again or a child, and turn back and reprogram all of my cells in the body to an earlier youthful state."

The core of what we study here, whether it's for regeneration, disease reversion, or age reversal, as in the case of those organisms, is how that cellular rewind occurs, and how we can, as a company, using biologics and other tools, stimulate that reversal in humans.

And ultimately, for the purposes of health, regenerate and repair the tissues that we, as humans, lose and degenerate as we get older and age.

Lana: How do you translate that from a fish or an amphibian to a human being?

Ira: As humans, we have a human genome, which we deciphered about 20 years ago. **And, aside from finding out all about the unique genes that humans possess, one of the things**

controlled in our architecture between the genes, and basically studying how the reversion processes that exist in nature, both in lower organisms and in humans in certain cases. Because there is one place in humans where time is reversed, and that is the point in time when we are transformed during fertilization, and basically, take those learnings which have existed now for the last 70, 80 years in our first studies back in the 1940s and '50s in cloning research, but instead of focusing on human cloning, focus on the substances and the compounds responsible for that rewind and apply them in the form of biologics and other bioproducts in humans.

So, we are not doing any genetic engineering, but we are looking at how the other natural approaches, we can take substances and compounds that can affect the genome not only in the developmental process but in the rewinding process that normally every human on this planet goes through when we are first created.

Lana: Okay. So on that note, can you tell me a little bit more about Bioquantine?

Ira: Bioquantines are what we refer to in our materials as so-called "combinatorial biologics." So, if one may think of a traditional drug, like an aspirin, or a Tylenol, or a Viagra, everything that the pharmaceutical industry produces today, for the most part, is a single drug substance.

However, when we go out and study these more complex forms of regeneration and repair in nature, for instance, when that little salamander loses his spinal cord or a part of his arm, the regrowth and regeneration isn't caused by a single substance.

Nature does not use the single magic bullet concept that the pharmaceutical industry does. It doesn't work that way. Nature is much more complex.

So, what we are trying to achieve with Bioquantines are basically to create combinations of biologic products that can recapitulate the entire process that one might see in regeneration or complex repair.

Because, as lucrative and interesting as single drug substances are, they are not good enough to yield complex biologic events of this nature. They may be very good at healing inflammation or the immune response as the traditional drugs, but when it comes to doing some of the more complex forms of regeneration that we're talking about, you need multiple bioactive substances there.

So, our thinking about combinatorial biologics and Bioquantines has…we brand them, refer to them, is, "How can we put these cocktails of substances together in the right form of standardization to yield a pharmaceutical end-product that , you know, may look like a traditional drug but can do much more than a traditional drug because it is doing it in synergy and in combination much more, like what happens in nature and happens inside or bodies than what the traditionals or drug development model is set up to do.

Lana: Speaking of single drugs and combination products, you talked a little bit about cancer on your website. How does your, I would say, technology, how is it different from, say, a single drug substance or other existing forms of treatment in terms of the way it works on the human body using what you just talked about previously, in terms of the substances that helps the genome rewind?

Ira: Excellent question. And just pointing back for a moment to nature. Everything on this planet

surgery, radiation, and chemotherapy, or the more targeted approaches that you see in the news nowadays, immunotherapy, CAR T cells, smart drugs. At the end of the day, they are both focused on a kill event. But that's not the way nature does things. And we see problems on both fronts. Whether we're taking a shotgun approach and trying to blast tumors away and killing a bunch of healthy tissue, or what we're seeing on the targeted front where you have drugs that work extremely well but for a very small amount of people. There's something that we're missing.

And so, we are taking the approach that history and the world of systems biology now is showing us that tumors, as we've looked at them for the last several decades, are not exactly what we've thought them to be. We've always come into this as an oncology system looking at tumors as this homogenous mixture of cells. So basically, a one-cell type that's just going crazy and producing millions of itself. That's not what we're finding out in the year 2017. We're finding out that tumors are baskets of cells. They are combinations of cells that are heterogenic. And so, whether you blast it away with chemo or whether you are looking for that smart drug, if you're only hitting part of the tumor that has X mutation and the rest of the tumor does not, you're doing a big disservice.

So ultimately, our model, once again, is about reprogramming. It is not about a kill event up front. It is about how we look at that tumor, and with the same reprogramming concepts that we see in nature, take those cells that are now, because of mutation X, Y, and Z, are now in a metastatic, malignant state, and erasing what has happened, and putting them back in time towards the origin of the tissue where they now metastasize to, turning them into normal tissue within that environment.

And we think that this is a much more holistic approach to the problem that still kills eight million of us every year. And you begin to see this wave, although much of the oncology system is still based on a kill centric approach. I have been, since the last eight or nine years, beginning to see this challenge emerging in the cancer system that says, "Hey, let's not just look at this as a cell-based disease anymore, but more of a tissue-based one." And when we do that and we look at, you know sort of the concept of what cancer is and what it is not, we can have much more integrated approaches that avoid the problems of both historical and, unfortunately, a lot of the sort of the hot stuff that's in the news nowadays.

Lana: If I were to kind of put what you just said to visualize it, how do you reverse someone who already has cancer? How do you reverse that to the day before the person has cancer? How does that work?

Ira: Well, if you think of a cancer cell as a normal cell that just has a variety of genetic and epigenetic damage that has been accumulated over time, our goal is to target that tissue and erase those changes. And that is the same basket of tools, with the Bioquantine materials that we use for regeneration for tissue reversion.

So basically, using these materials to erase the damage that is done already, and then also, feeding the cells that now have been cleaned up and clothed with other bioactive substances that allow them to integrate and form into the tissue they are currently in as new, healthy tissue. So basically, we are erasing the history and then stimulating the cells forward in time to be part of the new, healthy microenvironment that they find themselves in.

While it may seem somewhat of a unique concept, you actually go back in the literature, back

And it was always one of those things that you might be scratching your heads and say, “Well, this one’s messing with my experiment.” No. what we’re finding out now, 80 years later, is that it’s the regenerative dynamic that we saw responsible. We didn’t understand it then, but now that we understand the underlying reprogramming and rewinding of cells in the regenerative dynamic, we are now understanding, hey, it is the same dynamic that we’re seeing in both cases. And now, we’re reconnecting it here, unfortunately, you know, 90 years later, but with a sort of a 21st-century mindset on what’s going on.

Lana: So, if someone actually has cancer, do they just pop up a pill with Bioquantine? Or how does it work?

Ira: No. Most of the Bioquantine materials will be parenteral delivery because we are dealing with proteins, peptides, micro RNAs, a variety of naturally occurring bioactive materials that, unfortunately, do not work well in the gut because of the pH. So, at the end of the day, we will not have pills, but we will have other parenteral formulations very similar to most of the biologics, whether they are proteins or interferons, or vaccines, to be administered in a more traditional pharmaceutical sense from a biopharmaceutical context.

Lana: And, any recent tests or trials that support your approach?

Ira: Yeah, we have been making a lot of headway aside from the work that we’ve been doing in terms of CNS models and cancer models in our own labs, we have begun partnering XUS because, while we are a U.S. company, we realized that there’s 200 other countries out there with different regulatory systems and we have to plug in and do relationships and collaborations all over the place based on the nature of how research is done nowadays, with the globalization in the medical training.

But we have had some very interesting preliminary clinical data, phase one type work, in both spinal cord injury and related lesions, whereby we are studying the reversion and regeneration of scar lesions in paralyzed patients.

And some of this is going on right now, and we will be reporting one shortly. But we have seen rather fascinating transitions from the ASIA A status of sort of complete paralysis with no movement, no sensation, on up to ASIA C so far with every establishment of sensation and urination function and some minor movement that is getting us very excited in terms of our strategy and our process.

Because one of the major problems has been, specifically on this front, which has been sort of thought of as something that sort of stem cells would be able to address by themselves.

It’s not just how you stimulate new nerve growth in a spinal cord that’s been injured, but how you get rid of the scar tissue that is present and how you ultimately make the nerves reconnect in the proper way.

And this has been extremely eye-opening for us. In fact, we’re a biologics company, not a stem cell company per se, but some of these results have been quite eye-opening. The CNS as an area for us, as a company, is extremely important just because of the nature of the market and how it is predicted to develop in the next 10, 20 years. But this has been an important part of our plan.

Ultimately, upstream, something else is happening and that tissue is damaged to ultimately create the autoimmune state.

And we are focusing not just on the downstream, but ultimately, how we can erase that tissue so that, you know, we can turn back time and you don't have to worry about the condition raising its hand. So that's another important area for us as a company.

Lana: So, you know, summarizing or listening to what you just said, you've talked a lot about erasing "the bad cell memories" as well as, you know, reprogramming it. So, that would be the areas you probably mentioned earlier as regenerative medicine. And also, you guys have entered into organ regeneration. Tell me a little bit more about that in terms of…I mean, how does your technology help people, say, regenerate organs? And if you were to go a little bit deeper, how does that reprogram the DNA?

Ira: Sure. So, organ regeneration is clearly a major target for us. We lose millions of people every year around the world that are on organ waiting lists. And there is, you know, as an example, we, as a company, are focusing and have a lot of interest on the human kidney. Why the human kidney? You come with two of them, at the end of the day, when they start to degenerate, there are two major options, and that is either dialysis or kidney transplant, and both do not yield an extremely positive quality life at the end of the day. Plus, that represents about $60 billion annually of costs, direct costs, not to mention the indirect.

We are looking for an option between drug, which really there is nothing for you nowadays, and transplant. Because most of the very smart people in this space will tell you that you do not need an entirely new organ until a lot of it has been damaged. And so, we are trying to fill the space of sort of endogenous regeneration that says, "Look, if we can prevent you from going downhill using our technology and regenerate your kidney, pancreas, heart, what have you, as it's deteriorating, we wanna prevent you from ever having to get a transplant in the first place, because there's not much for you." And although, you know, there is a lot of excitement, of course, in ex vivo organ development, that technology is truly decades out. So, you know, we are looking at our technology as a major stop-gap that says, "Look, if you have kidney degeneration because of one of many situations and you're losing function, let's endogenously repair and regenerate that part of your kidney tissue to make you whole again."

And that, again, feeds into our process of reprogramming and tissue remodeling using the same basket of tools. So, once again, the kidney is a complex tissue, just like many other tissues are. They're not just made of one cell type.

And so, our approach is not a stem cell approach that says, "Hey, let's just throw some cells in," because that doesn't give you the end-point that you want. We basically wanna say, "With our biologics and Bioquantine combination tissue erase this damage in this particular area and reform the tissue that should be here, which is kidney, or heart, or liver, pancreas, what have you." And that is the nature of the model, ultimately, creating the right tissue and recapitulating the development process as it originally occurs.

We look at it sort of bottom-up development as opposed to top-down in terms of, say, human wound healing. The erasure is once again the epigenetic and genetic damage that happens throughout your life that yields that disease state that allows your kidney, as an example, to begin to go downhill. And that once again ties into the various swarms of epigenetic and genetic modifying agents that are present in the reprogramming milieu of substances that we

Ira: So, we talk about top-down versus bottom-up regeneration. So, you know, you and I and everyone listening, and around the world, we're not formed by our parents mixing together millions of blood cells and bone and connective tissue in a bowl and having a baby come out. We were formed by one cell, the egg. Ultimately, that developed. It was one, it became two, and it ultimately became several billons that formed us at the end of the day. So, we're making an analogy between top-down and bottom-up. A toy example, when I'm talking to my children about this is, you know, think of Legos, creating a little bird versus an origami where every step in the process dictates the next step. That is how development normally occurs. So, how we differentiate ourselves is we are doing what the tissue naturally, originally did in terms of a stepwise development process where each step was dictating what happened next in a development process that evolution said and has drafted for us over millions of years.

To try to recapitulate that with stem cells is more of a top-down approach. Now, stem cells and top-down regeneration does occur. It occurs, for instance, in our wound healing process, whereby, we don't care much if we're bleeding to appropriately form that tissue, and we just want the scab and the scar tissue to form and we care less about functionality.

So we see top-down regeneration happening in humans but not for critical stuff. When you have top-down regeneration, you try it in more complex tissues, it doesn't work. And that's why when we have a heart attack, we form scar tissue. We don't form new functional heart tissues.

So, this is the difference and this is where we're trying to bridge the gap between simple regenerative processes and the more complex ones that require combinatorial out of the box thinking to how you address them.

Lana: So, to sum up, what you're saying is, if someone needs to regenerate the heart, your technology will help them regenerate new tissues versus stem cell technology wouldn't be able to help them do so.

Ira: Stem cell technology has not done a great job in complex three-dimensional organs that have multiple tissue types that need to work in synergy. Let's say, a reductionist's view on repair and development that, unfortunately, isn't how the system works.

And, you know, it's the same analogy to why taking a single drug substance for any disease nowadays doesn't cure you. It's just not the way the complex body works. And so, we need…our strategy and our philosophy is we need to take that complexity into account. In the last hundred years, we've looked at it one way and it's built a wonderful industry for the big players, but now, using the tools that are available to us today, we need to think more holistically on how this is done.

Lana: Okay. Well, Ira, thank you very much for your time. I really appreciate it.

Ira: It was a pleasure. I hope I didn't ramble too much. But yeah, if you have any questions on any of these topics or you need follow-up, please don't hesitate to reach out.