

Working with the concept of Induced Endogenous Regeneration, Bioquark Inc. has shown in Preclinical Studies with Mice Models the possibility of Tissue Reprogramming using Biological Drugs that will Result in Curing a Number of Diseases

**Biotechnology  
Regenerative Medicine  
(Private)**

**Bioquark Inc.  
5811 Memorial Highway  
Unit#107  
Tampa, FL 33615  
267-971-7725  
www.bioquark.com**



**Ira Pastor  
CEO**

**BIO:**

Ira Pastor has 25 years of experience across multiple sectors of the pharmaceutical industry including pharmaceutical commercialization, biotech drug development, managed care, distribution, OTC, and retail; Served as VP, Business Development for drug development company Phytomedics Inc., raising \$40 million of private equity, consummating over \$50 million of licensing deals, and bringing lead drug candidate from

discovery stage to Phase III development; Prior to that, employed by SmithKline Beecham Pharmaceuticals working in sales, marketing, and business strategy positions. Mr. Pastor has also served as Vice President of Corporate Development for the pharmacy benefit management company Prescription Delivery Systems (acquired by Cigna Health Insurance); MBA, Temple University; BS, Pharmacy, Rutgers University.

**Company Profile:**

Bioquark Inc. is a biopharmaceutical company, developing proprietary biological drugs for the regeneration and repair of human organs and tissues.

**Interview conducted by:  
Lynn Fosse, Senior Editor  
CEOCFO Magazine**

**CEOCFO:** Mr. Pastor, what is the focus of Bioquark today?

**Mr. Pastor:** Bioquark is a biopharmaceutical company that is developing biologic drugs that can be used for both the regeneration as well as the repair of complex human organs and tissues.

**CEOCFO:** What is your approach?

**Mr. Pastor:** The concept that we are working with is called Induced Endogenous Regeneration. The closest analogy that one can think of what we are doing is that most people are aware that many members of the animal kingdom, both invertebrates and vertebrates alike, are very good at regeneration and repair, with salamanders coming to the top of the mind for most people. Salamanders can lose a substantial portion of their spinal cord, their eyeball, their heart,

even parts of their brain, and they grow back in both perfect structure and function in a matter of weeks. We are trying, with biological drugs, to mimic that; with no stem cells, no transplantation, but using an understanding of what those organisms do so very well and trying to export the capability to humans.

**CEOCFO:** What have you learned so far that you think you will be able to replicate?

**Mr. Pastor:** The very process that these animals use, in the sense that they "turn back time" on the cells that remain in the damaged heart, the spinal cord, the brain, etc, and then they take them forward along a developmental like program; there is only place that those same dynamics exist in human beings. That is the moment that we are conceived right after fertilization. It is the biochemical events that take place at that moment that ensure that all of our children are born "aged 0". It is the reason they come out as complete organisms with trillions of cells, even though they start with only two. It is also the reason that most children are not born with chronic diseases of older age. Children do not come out of the womb with Alzheimer's, or Parkinson's disease or heart failure. What we have done and have demonstrated to date in our preclinical work is that it is possible to export that biochemistry that exists in the egg to other living tissue, and show that it is possible to replicate those tissue reprogramming capabilities. We have studied a variety of models to date across the board to look at the universality of this possibility. We have studied a traumatic brain injury model, we have studied a can-

cer model of malignant melanoma, and we have also studied two dermatological models; one for hair loss and one for skin wrinkling. In all of these models we have seen now, the ability to remodel and regenerate tissue in the living organism. We are only working with mice now, but that is fine because these regenerative and repair capabilities are not seen in mice either. They pretty much end at the amphibian kingdom. The fact that we have been able to see this capability across the board in a variety of different models of disease, degeneration and damage is pretty exciting. The other exciting thing is that we have also been studying our drug materials in healthy animals for long periods of time, for over a year and a half now. The interesting thing that has come from these studies, although they were done, more or less, as a safety study on long term tolerability, was pretty fascinating; that the animals that were treated for a long period time lived seventy percent longer than your normal animal in the lab. That was an interesting data point in its own right due to the fact that the only organisms on this planet that are technically biologically immortal do so and accomplish this by spinning back their cells in time and starting over. This process which now we are able to capture in the form of a biologic drug may have some very far reaching implications beyond just disease and health care. Therefore, there are many possibilities that come out of this basic mechanism that we are approaching.

**CEOCFO:** Has the medical community paid attention or is it too early?

**Mr. Pastor:** I come from the pharmaceutical industry. I have spent the last twenty five years there in different capacities. I get the word out as best I can. This is, of course, what we consider preclinical development. It is early stage drug development but most folks 'get it' right way; the moment that we prove an endogenous regeneration event in a human, which in our schedule in our clinical development program is three years from today, the moment that that happens a lot of things are going to change in the health care industry. We are not

going to make a lot of people too happy in pharma, nor in certain health care services. Our initial program is in the area of kidney regeneration. If we can do that and demonstrate it, it can help many people that will not have to go onto dialysis. There will be many people that will not need kidney transplants nor kidney transplant drugs any more. Therefore, it is going to impact many things. I think most people understand it and are keeping an eye on it.

**CEOCFO:** Are there concerns that you will be able to do this, but the "powers that be" will not let it happen? How do you address that concern?

**Mr. Pastor:** At the end of the day, this all has a life of its own. The pharmaceutical industry, the health care industry, and many of the greatest things that every happened in medicine, from penicillin to insulin, to X-rays, to small pox vaccine, even Viagra, as an example; these were all accidents. These were things that

**"The pharmaceutical industry today however is all about treatment – not about cure. We are on the verge of changing that." - Ira Pastor**

people were not really thinking about; they came as a result of an "A-ha" moment. Some of these things in healthcare take on a life their own, I do not think there is any holding this back. Sure, there will be many people that will be angry; there are many that are going to be "nay sayers", but like any cycle in healthcare or technology, eventually when you start proving your point, people are going to sit up and take notice and have to accept the inevitable. The way we set it up our program, we tried to find a short term opportunity to get there and prove the point much quicker than some other opportunities. If we can get to human proof of concept in our lead indication in a three year time frame we are going to be pretty happy. Other diseases are equally valuable, such as Alzheimer's but your clinical proof may take a lot longer and you may have to wait a few additional years to test, ultimately if someone has better long term memory recall for instance. However, we have pretty aggressive yet disciplined approach to moving this thing

along and getting to the point where we have done it in humans and you would have to sit up and take notice.

**CEOCFO:** You mentioned, potentially, three years down the road. What are the steps and what are the milestones to get to that point?

**Mr. Pastor:** Over the next three years, the development program is carved up by year. The first year we are continuing our experiments, but in larger animals. We have worked with mice to date. We are going to be moving up to the rabbit, to the cats and to the dogs and at the same time building our initial raw material supply for the biologic production. There is some very interesting data, even in year one when we get into larger animals, that could possibly be peeled off, because the diseases that kill all of our cats and dogs are the same things that kill us; kidney failure, diabetes, cancer and there thus could be some very large and lucrative opportunities in the companion animal health industry. However, moving past that into year two, we do more of your conventional, FDA required toxicology, pharmacokinetics,

pharmacodynamics work and by the end of year two, are applying for our initial new drug applications to test the drug in humans in the year three. We have chosen a kidney indication for three reasons. While the kidney might not have the cache' of the spinal cord or the heart or the brain, we spend thirty five billions dollars a year, annually in the United States alone on kidney transplants and dialysis. If we can keep one person from going down that path, in our eyes that is worth thirty five billion dollars, because kidney regeneration ultimately trickles up to all disease of the kidney. We have chosen an indication called Focal segmental glomerulosclerosis (FSGS) which not many people have heard of, but yet it represents a very rapidly degenerative kidney disorder. After a couple years these patients are in essence urinating out their kidneys and a large percentage of them have to go on dialysis or transplants. Therefore it is an easy population for us to latch on to and test our principal and prove the point very quickly. By that time, at the

end of year three we will be standing on an important piece of data, at which point we can then make the decision to finish completing the development of the drug on our own, or license the kidney application to someone in specialty pharma that is good with developing kidney drugs and then we can move on to the pancreas or the liver or the eye, or what have you.

**CEOCFO:** You have an extensive background in the industry in many different segments. What have you learned that is most important to bring to Bioquark as you do your development and ultimately commercialization?

**Mr. Pastor:** I have spent twenty five years as a business development generalist from big pharma, biotech, distribution, managed care, and retail. I have seen it all and I have been in the industry my entire life. I have been able to separate myself from the fear of taking risks, although, if you look at pharmaceuticals, it is all about risk. It is about clinical risk, regulatory risk, manufacturing risk; there are so many things that can technically go wrong and as a result it has become a very risk adverse industry. I have been fortunate, just from the different angles that I have come in at, I have been able to sit back and observe. I have been able to bring with me the lack of that fear of taking risk. It is all about taking chances. This is an industry that has a tremendous amount of money and resources' and many things can be done for human kind. However, unfortunately too often decisions are made internally, "Hey, let's develop the next anti-inflammatory – Hey, let's develop the next cholesterol lowering drug." No. Let's focus on the bigger issues and do things a little

more creative than what are being done today. Therefore, the combination of the exposure, understanding what the possibilities are, and then my own ability to be able to deal with risk and thinking totally outside of the box, are probably the most important things I have brought to the table at this point.

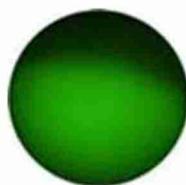
**CEOCFO:** What is the financial picture like for Bioquark today? How far can you go on current funding?

**Mr. Pastor:** We have raised about three quarters of a million dollars to date from high net worth accredited individuals. We have a fairly low burn rate of about 15thousand dollars a month. We have the ability to keep moving forward at a nice pace. What we are in the process of doing now is we are raising an additional million via a Reg D 504 offering to be followed by a direct registration of twenty million total. There is a point where things ramp up once we pull the trigger on the FDA regulatory program and start spending substantial amount of money to get where we need to get. However, we feel that we have the right combination of the right management, the right science, and an exceptional story. Obviously, everything goes in cycles. Some years are good for raising money for biotech, some years are not, but in my own experience, having raised funds from different sources in the past for these opportunities, folks get this one right away. It is just a matter of getting in front of enough of the right people. This story, in many ways, sells itself. Not to say that I do not have to do the leg work. Everybody needs to get out and sell, but we think the combination of having put together the right team, the right group of advisors and this

story, we have a very good chance or getting where we want to go.

**CEOCFO:** What should investors and people in the business community remember the most about Bioquark? Why should they pick Bioquark out of the crowd?

**Mr. Pastor:** I am going to put one number on the table. I know it is a silly number, but I am going to put it there anyway. This year we surpassed, globally, six trillion dollars in healthcare expenditures. No matter what industry you are talking about, healthcare services or pharma or medical devices, they could carve that number up millions of different ways, by diseases, by product categories and so forth. At the end of the day, for us that number, six trillion dollars, trickles down to only two things; diseases that either have a cellular degeneration or a cellular damage component to them. Then what you are left over with are infectious diseases which really are taken care of by the antibiotic and the vaccine. At the end of the day, of that six trillion dollars, which is currently addressed by organ transplantation or pharmaceuticals or stem cells, a tremendous amount of that is left on the table. We have the ability, in a single biologic agent, to address a range of the diseases that make up the majority of that money. Although it is a large number it ultimately all trickles down into our basket and what we are about. I love the pharmaceutical industry. I have spent twenty five years there. The pharmaceutical industry today however is all about treatment – not about cure. We are on the verge of changing that. The ability to regenerate and repair is about cure, not about treatment. That is the number one thing you should think about.



# Bioquark Inc.

**Bioquark Inc.**  
**5811 Memorial Highway**  
**Unit#107**  
**Tampa, FL 33615**  
**267-971-7725**  
**[www.bioquark.com](http://www.bioquark.com)**