

Gene Therapy Focused on Ageing and Age Related Diseases



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CEOCFO: *Ms. Parrish, your site indicates that BioViva USA is changing the paradigm of aging and disease. How are you doing that?*

Ms. Parrish: We absolutely are doing that. Instead of going after the symptoms of the ageing cell, which are things like Alzheimer's and heart disease, nephropathy, which is kidney failure, and frailty, which is sarcopenia or muscle wasting, we are actually looking at the ageing cell. We are looking at the biological ageing of the cell and trying to reverse that ageing. Therein lies the cures for all of those diseases and more and more, science is pointing to this evidence. We are seeing this in research models, we are starting to see this in therapeutics, and we are actually seeing pharmaceutical companies starting to go after ageing as a disease. We are seeing drugs like Metformin being tested against ageing. It has become evident now that this is why we get these diseases. It is the underlying biological ageing of the cell. That is what we are going after specifically, and we are going after it with gene therapy.

CEOCFO: *Why Metformin?*

Ms. Parrish: This is a drug that they have been using in patients with diabetes type 2. Cellularly it seems to almost mimic calorie restriction. When tests are done on animals, it appears that when they are on calorie restrictions they actually live longer. If exercise is also optimized they live even longer. To put things in perspective we will use gene therapy rather than with pharmaceuticals like Metformin. When you take a wild mouse, a wild mouse out in the bushes, it lives about 8 months on average, and usually it dies from predation. It gets a little bit slower and less aware of its surroundings and gets eaten. If you take that same mouse and put it into the lab, that mouse will actually live 12 to 18 months, which is fantastic. You have doubled its lifespan, which is great. However, if you put that mouse on calorie restrictions with optimal exercise, that mouse will live for 24 to 30 months. You would only give the mouse their nutritional needs and then exercise them. However, if you change one gene, you can double that lifespan without calorie restriction and exercise. You can get a mouse to live 60 healthy months with the change of one gene. That is one of the great explanations as to why we would chase the genes rather than a drug like Metformin.

CEOCFO: *You mentioned that science is starting to pay attention. How is your approach different than others in the same field?*

Ms. Parrish: Our approach is different because we are going for the therapeutics of the gene therapy. Instead of looking for a pill that you would have to take daily, or an injection that you might have to receive bi-monthly, we are actually looking for a cellular fix. We are looking at genes that are up regulated in animals that do not age, and there are several species of animals that do not age like humans, and their cells have negligible senescence. When we look at those animals, they do not get the ageing diseases. They do eventually die of something, but they do not get the specific age diseases, the ageing look, and the detriment. We think of grey hair and wrinkly skin, and all of those things are happening internally, inside of our body. If you look at the brain of an 80 year old, even if they do not have dementia, there is atrophy. Therefore, we are looking at therapies that keep this from happening. That is what is really different about what we do.

CEOCFO: *How did you decide on this path?*

Ms. Parrish: I actually got involved with this to try to find cures for childhood diseases. I started looking at the stem cell modalities and seeing the benefits that those therapies were creating in the human bodies, but I have always had this love of genetics. Looking at the chromosomes. I say if you do not believe in gene therapy, you do not believe in evolution. It just does not make sense to think of it any other way. We evolve from our genes. What we look like, how we think, and how we express ourselves has everything to do with our gene set. There is a little bit of nurture in there too, but there is mostly nature and it really defines us. When we put genes in, we know that we can change the body. We already know

that we can increase muscle mass, it has been done in humans, and reverse ageing in animals, because it has already been done in mice. Therefore, what we want to do is see how these therapeutics work in humans and how it will change the paradigm of the diseases at the level of the cell.

CEOCFO: Are you funded for the steps that you would like to take?

Ms. Parrish: We are seeking funding. We have been funded for our first tests, and on Friday we announced that we have treated our first patient for ageing with gene therapy. We did that specifically on our first bit of funding, We had one investor come forward with money and we then stopped all talks and we decided to go for proof. We are now opening our doors back up and looking for investors. We also have ways to move forward and to become profitable, unlike other biotech companies. Many people are adverse to biotech companies because it take so long to get products through to market and it is very likely to not pass for the target disease, it costs about \$1 billion to get through the US FDA. However, we have a different game plan. We are going to do our clinical trials off shore, so that it cost investors a fraction of the amount of money that it would take if it were done here in the US. This will then allow us to come out with cures and treatments that cost a fraction of the amount that you will see from US companies who are doing the regular route of bringing a product to market in the US.

CEOCFO: Does the idea of finding the fountain of youth ring true to investors?

Ms. Parrish: It does get a great deal of people excited and we are happy about that. There are many people around the industry who what to live a long time and we are excited about that. What we do is disease mitigation, so what we are trying to do is keep you from getting end stage diseases. We do not talk about things like living an extraordinary amount of time, although I am often asked to speak on panels that talk about those kinds of things. However, there is a basic fact, and anyone who is intelligent can see it, and that is if you are healthy, what do you die of?

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CEOCFO: What is the quality of testing outside of the US? Are people confident enough or will you face some skepticism?

Ms. Parrish: What is important is that you have to do it right. There is doing off shore testing and then there is doing it right. What we have been committed to, which bumps up the cost a little bit, is that we do need an FDA specialist to come in. Our goal is to meet and beat all of the bars of safety and efficacy for the US standard. Therefore, in order to do that you have to bring in an FDA specialist and an International Review Board (IRB). We want to do our testing at a standard that we can actually bring this evidence back to the US and demand that these therapeutics get passed. In fact, it has a multi-benefit. We could also do therapies at a fraction of the cost of onshore gene therapy treatments. We have to not only think about getting a therapy out there that cures people, but getting it out in a cost effective way. That is where the elegance lies in what we want to do. If we can come back with treatments that insurance companies will cover, then average people could get the treatments they need. You would not need to have an extra million dollars sitting around, because insurance companies often will not cover those types of therapeutics. We have seen that in Europe with a passed gene therapy there that costs \$1.3 million, so insurance companies will not touch it.

CEOCFO: Where do you see the biggest challenges?

Ms. Parrish: The first challenge is funding. Finding an investor who has the same vision that you do and does not want to leave a legacy behind, they want to live it. Help us crack this nut, then you can watch what happens when you give back through your money. The second one is bringing therapeutics back to the US and demanding that people pay attention to what you have to offer and getting people excited. We are a very enthusiastic group.

CEOCFO: Put it all together for our readers. Why pay attention to BioViva USA?

Ms. Parrish: The best thing about us is that we are really a company for the world. We are going to be built by the people for the people, and we are revolutionary. We have already moved forward in areas where others have not moved forward. I have tried to get universities and governments involved with what we are doing, but they work in decades. They do not work in a matter of years. Every day over 100,000 people die of ageing diseases, and children die of congenital diseases that we could possibly cure. Therefore, we really need to move this forward and we need to move this fast. For that 100,000 people, there is no tomorrow, and these are diseases that we all face. They inflict suffering and financial loss, as well as financial loss for the people who are left behind. The faster we can move the better and there is no company on this planet that is moving as fast as BioViva.

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