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PharmAla Biotech – the only Manufacturer of Clinical Grade MDMA in North America for use in Human Trials and Research

Nick Kadysh
President

PharmAla Biotech
(CSE:MDMA)

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: ***Mr. Kadysh, what is the overall vision at PharmAla Biotech? What is your focus right now?***
Mr. Kadysh: PharmAla is an MDMA company. MDMA is often known colloquially as the active ingredient in ecstasy on the street, but has significant clinical promise for treating a number of mental health disorders. At PharmAla Biotech, we do two things. We are the only manufacturer of clinical grade MDMA in North America. Our customer base for that is the folks who are doing the clinical trials, whether they be researchers or companies, basically anyone who wants to do scientific research into MDMA. We are the only ones who are producing this drug at a grade where you can actually use it for human trials and human research. The MDMA space is booming. There has been a ton of research initiated over the last couple of years, so that keeps us very, very busy.

The other thing that we do is that we research and develop novel analogs of MDMA, novel molecule in the MDXX class, which is the class that MDMA belongs to. Our goal there is to develop novel analogs that have better toxicology profiles. Therefore, to improve neuro toxicology and improve cardio toxicology, and of course our goal is to completely eliminate the major adverse events with MDMA, being hyperthermia, where you overheat and basically run a fever. We are in pre-clinical right now, with the intention of going to FDA before the end of the year, to present our findings. However, it looks like we, more or less, have completely eliminated the hyperthermia, and we have reduced the toxicology significantly.

CEOCFO: ***How did you get into this? What led to the creation of the company?***
Mr. Kadysh: I have spent the last decade or so working in regulatory, government relations and regulatory affairs. There are a couple of things that happened that really drove me to this. Number one is I saw government attitudes towards these types of molecules shifting pretty rapidly. There has obviously been a shift in popular culture, but I am not a popular culture expert. I am a regulatory expert. I just sort of saw that we are in this space right now, where especially after the pandemic, there are a ton of people with diagnosed and undiagnosed mental health conditions, and we do not have an awful lot of treatments for them. Because of that, for the first time I think, governments are giving what they often-called psychedelic molecules a fair shake, as therapies. That was one thing.

The other thing was that about two- and one-half years ago, I joined the board of directors of a company called Psyched Wellness, which is also a psychedelics company that are working to commercialize Amanita Muscaria. It is a naturally occurring mushroom, and the active ingredient in it is muscimol. I joined the board of that company and I really liked it a

lot, and I thought, "Wow, this is a super interesting space, people are doing great things here," and I wanted to be a part of it. Therefore, we started PharmAla.

CEOCFO: ***What was the key to getting something that people can use that will not have that hyperthermia?***
Mr. Kadysh: Unfortunately, I cannot get into the nitty-gritty of the chemistry that we use, but I will say that the hardest part was actually manufacturing it. Ultimately, the chemistry involved is not that hard. As we all know there are a bunch of black market MDMA's floating around, with some guys making it in bathtubs. The hard part is making it to a very high grade of purity, making it with the controlled processes that you need in pharmaceutical manufacturing. Any manufacturing is hard. Manufacturing something that is going to go into someone's body is incredibly challenging. Therefore, we had to build a really excellence centered manufacturing organization.

We had to build a regulatory first organization, that was going to take the letter of the law and the spirit of the law, and make it the biggest priority, in order to drive trust with our customers, and our customers are very demanding! Ultimately, they are researchers, and if we make something that they do not have faith in, then that will call into question their own research. We had to be perfect from the get-go. It was a real challenge.

SafeRX Pharmaceuticals

CEOCFO: ***What, from your past experience in the regulatory arena, do you understand that perhaps less knowledgeable people do not, that is allowing you to go on a path that is going to be successful?***
Mr. Kadysh: Honestly Lynn, I think that in this space, specifically with psychedelics, I deal with many CEOs all the time who do not think about regulatory at all, and I actually think that it is the biggest determinate of your success in this space. We are in a highly regulated space, these are controlled substances, these are pharmaceuticals, and if you do not understand what the regulators expect from you, if you do not understand what the rules are, I have to be honest, I just do not see how you could possibly thrive. Therefore, I think that regulatory is an incredibly important part of this. If you look at my team, you will find that the one commonality is that every single person on the PharmAla team has some background in regulatory, because you have to. It is just not a choice. It is mission critical.

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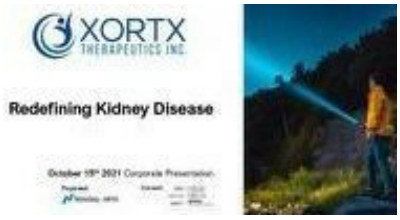
CEOCFO: ***If you are the only company that has developed this, are people flocking to PharmAla?***
Mr. Kadysh: That is a good question. There are two things. Number one, MDMA is a known molecule. We are the only ones producing it in North America, but it has been widely known for a long time now. It was first developed in, in think,

1912. It came into broader use in the late 1950s, early 1960s, before being designated as controlled substance in the 1980s.

There is also a very well-known not-for-profit called MAPS, the Multidisciplinary Association for Psychedelic Studies and they have a contract manufacturing operation set up in Europe. We just happen to be the only in North America who are doing this. I will say, I think it is largely due to the efforts of MAPS that there is so much interest in MDMA as a therapeutic molecule. Therefore, I would like to give them all the credit in the world. They are a brilliant organization, and we look to support their work whenever we can.

CEOCFO: ***How do you connect with companies that are doing research in the area? Is it easy to do?***
Mr. Kadysh: As it happens, next Friday, the 27th of May, I am happy to say that we are going to be launching the first Trade Association for Psychedelics Companies in Canada. I believe this is the first national level trade association for psychedelic companies anywhere in the world, as far as I have seen. It is called Psychedelics Canada and we are launching it on this coming Friday. Therefore, in terms of connecting with other companies and working together, to improve the regulatory landscape, the change the way that these products are used by the general public, that is how we do it.

We do it by working together through our trade association. I happen to be the Chair of the Board of that association. I am super, super pleased that we have gotten to the point where the companies in this industry have come together and formed it, and it argues well for the future of this sector.



XORTX Therapeutics

CEOCFO: ***What is involved in the manufacturing process?***
Mr. Kadysh: Basically, a whole bunch of chemistry that I am not qualified to describe to you.

CEOCFO: ***Are you doing that in house, or are you contracting out?***
Mr. Kadysh: We have a value chain that we have developed. We have a series of contract manufacturing labs that work on the product at different stages of its development.

CEOCFO: ***Are you able to ramp up as needed?***
Mr. Kadysh: Absolutely! Absolutely! I will be honest, right now it is very much a low volume, high profit sort of environment, because we obviously make a product that is not going to end users, it is going to researchers. Therefore, a very, very high regulatory bar, but at the same time, functionally in B2B sales. I hope that in the future, there will be an opportunity to sell to the general public, as an approved therapeutic molecule, but we are not there yet.

CEOCFO: ***What have you learned up to the point you are today?***
Mr. Kadysh: I could easily fill a book! I think the biggest thing I have learned is that success in this space will come, not from one company succeeding, or even two companies succeeding. It will come from a bunch of companies all working together. This is this economic theory of clusters, if you have ever heard of that idea, which is the reason that environments like Silicon Valley are so successful. It is because you have a bunch of companies that all work together, they are all packed into one small geographic area and they all do business with each other, and that allows them to grow in an incubated way together, until they can blossom out and do great work globally. The launch of the association and everything that we have accomplished thus far, that is it.

We are seeing the building of a nascent cluster here in Canada, which is where I think most of the work on psychedelic molecules, globally, is happening right now. I am very happy and proud to see that, but I think that is the biggest think I have learned. You see a lot of stuff out there about, "One lone CEO, one company going it alone," and that is garbage. It does not work that way. You really need a multitude of people, all developing complimentary skills, and working together in order to be successful.

CEOCFO: ***What has been the interest from the investment community? How do you get more people to pay attention?***
Mr. Kadysh: To be honest, I went public in January, right before Russia invaded Ukraine. However, we have had great volume and there has been a lot of interest in the stock. All of our core investors are sticking with us, which is very gratifying to see. Other than that, we will see how it goes. Obviously, there is the hope that the markets improve in time, and everything bounces back, but we are well capitalized. We are a post revenue company, so I am not just burning cash for the sake of burning cash. Our belief is that we could continue to survive for a very long time and we can continue to do our work.

CEOCFO: ***What gives you confidence that the MDMA aspect of the psychedelics market will prevail, or will be something that people will look into?***
Mr. Kadysh: There are two things really. Number one is that out of all of the molecules that make up the broad category of psychedelics, MDMA, which ironically is not a psychedelic molecule, is furthest along. It has been through Phase 3 clinical trial already, and there is a second Phase 3 that is currently being populated by MAPS, so very far along. That is one. From a regulatory perspective, I think that further along in the development process means more likely to succeed.

The other thing is that I truly do believe in the molecule. MAPS has done their clinical trials in to PTSD, post-traumatic stress disorder. Statistics Canada, for instance, recently put out stats to the affect that they believe that about 8% of the Canadian population has PTSD in some form, or the symptoms of PTSD in some form. Therefore, it is a very, very big population base, and there are no good treatments. There is psychotherapy, sure, but it is not very effective at treating that condition. That is a big part of it obviously, the fact that it is treating a series of conditions, sort of fear-based disorders, for which there are not good treatments. Ultimately, we would love to see this broadened out.

We have some pretty aggressive plans and timelines for clinical trials, ourselves, and hopefully the FDA allows is to move forward with them.

CEOCFO: ***Why pay attention to PharmAla Biotech; why is the company important?***
Mr. Kadysh: There are three reasons. Number one, we have best in class regulatory, which, as I said, I think the regulatory expertise with the ability to understand what the government is thinking, is really going to determine success in this space. That is one. Two is our ability to connect with other companies in this space, to build networks of success and excellence. I think we have proved it by now, but we will continue to work towards proving it.

Number three is the fact that we are the only ones in this space who are focusing on this specific molecule, which in my estimation, is the furthest along. It is the quickest turn around, the quickest patent revenue, the quickest way to get to success.

For those three reasons, the regulatory, our networking ability, and the fact that we are focused on MDMA, which has been through Phase 3 clinical trials. It is still biotech, so there is still risk involved, of course, but we have worked very, very hard to de-risk our business plan as much as possible. In this environment, I think that is why you should look at us.