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Fzata's Biologic in a Pill is a Game-changing Therapeutic for Gastrointestinal Disorders

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CEOCFO: ***Dr. Yang, what is the idea behind Fzata, Inc?***
Dr. Yang: We are developing a therapeutic biologics platform with the vision of reducing health inequities by expanding patient access to biologics. Conventional biologics are very large and complex protein drugs. These are expensive and are administered mainly through IV injection or infusion. To address these problems, we developed a first-in-class platform enabling 'Live Biologics in a Pill', which we call BioPYM, **Bio**-engineered **P**robiotic **Y**east **P**latform. Using live biologics in a pill is a completely novel modality. We genetically modify probiotic yeast, so that the yeast can function as a micro-factory in the gut to express therapeutic biologics at the disease site. This way the medicine can be delivered orally at home, instead of through systemic injections or infusions given at a clinic.

BioPYM is patient friendly, safe, easy to manufacture, and unlike conventional biologics, there is no need for cold-chain delivery and storage. With BioPYM even people in remote locations will be able to access the benefits of biologics.

CEOCFO: ***What are the challenges? How did you go about creating this?***
Dr. Yang: For BioPYM we had to break the barrier of engrained thinking to create this completely novel, first-in-class approach. We had many technical issues to overcome to make the BioPYM platform yeast secretion effective and stable. We also had to do extensive experimentation to show that our approach works. Sometimes it can be pretty challenging to find a proper animal model for human diseases to test our BioPYM drug.

CEOCFO: ***Where are you in the development process?***
Dr. Yang: We have spent years developing and optimizing the BioPYM this platform. We have now developed about a dozen therapeutic drug candidates that have been proven out in their respective animal models. The front runner of our products is FZ002 for C diff infection, which is an urgent threat to US health. FZ002 is in GMP manufacturing right now. It is projected to enter first-in-human clinical study next year (2023). Our following drug candidate, FZ006, will be for Inflammatory bowel disease (IBD) including both ulcerative colitis and Crohn's Disease. We are raising money to support further progression of FZ006.

CEOCFO: ***Would you tell us a little bit about the importance of the gut?***
Dr. Yang: Yes. Previously people just thought of the gut as an organ for food digestion and passage. However, more and more data are telling us that the gut is connected to many different systems, like the brain, the heart, the liver, the skin, and even oral health. Therefore, we call it gut-health-axis. And a huge proportion of our immune system, about 70%, is actually in our gut. Inside the gut there are a lot of bacterial species, which we refer to as the microbiota. They really have formed a balanced harmony environment in healthy people. However, when this system gets disturbed, like when people are taking antibiotics to treat diseases, some bacteria get killed and the balance gets disturbed. Then it is easy to get both gut and gut-axis problems. We believe our BioPYM drugs have great potential in treating diseases of other systems through the modulation of gut function.

CEOCFO: ***Fzata is working on something for diabetes as well. Tell us about that if you would?***
Dr. Yang: Yes, one of the products in our pipeline, FZ010, is targeting diabetes. We used our BioPYM platform to genetically modify yeast to secrete a cytokine that has been proven to alleviate diabetes. Then we tested the yeast drug in a couple of animal diabetes models. In one model, we fed the mice with a high fat diet, and then the blood glucose level in the mice quickly rose up. However, if we fed the mice a high fat diet plus our candidate FZ010, we could significantly bring the blood glucose level down. We also tested FZ010 in some transgenic mouse diabetes models, and we saw similar blood glucose level reducing effects. We are super excited about bringing an oral solution to diabetes to the market and the potential impact FZ010 may have for patients.

"We are bringing a novel modality of biologics to the medical field. With removal of needles, our oral innovation is expected to be really patient friendly, efficacious and safe and also cost-effective. It is a breakthrough to the field that can impact patient access to biologic therapeutics around the world." Zhiyong Yang PhD

CEOCFO: ***Would you tell us about the Nova Innovation Award?***
Dr. Yang: Yes, we are very honored to have received that award! That is the Mid-Atlantic Innovation Award, and we won in the Biotechnology vertical for our BioPYM platform. The Nova Innovation covers many areas from consumer products to healthcare. The judging panel was more than a dozen venture capitalists and investment bankers, so we are proud of gaining their endorsement through this win!

CEOCFO: ***What is the interest from the medical industry? Do they recognize what you are doing?***
Dr. Yang: Yes. Currently the medical industry is keenly interested in oral delivery of biologics. We received consistently positive feedback at the BIO 2022 convention in June. We are now engaged in conversations with multiple pharmaceutical companies and we are pursuing collaboration opportunities for Fzata.

As I mentioned, our BioPYM is very patient friendly, and it also has a lot of other competitive advantages compared to the currently available therapeutics. For example, with Inflammatory Bowel Disease (IBD), Humira® or other biologic treatments are administered with a needle. They can be very effective at the beginning of treatment, but they gradually lose their effect when the body mounts an immune response, attacking the drug after repeated use. This causes safety issues and patients have to switch drugs. Oral BioPYM is superior. It directly targets the gut, avoiding side effects. Patients are expected to be able to use an oral BioPYM drug long-term with very high safety for chronic diseases like IBD.

With all of these clear advantages, the medical industry is highly interested; however, they are awaiting our clinical results. After all, it is a first-in-class novel modality for biologic administration. Everyone is really excited to see the first-in-human data which will derisk the platform and open the path for our pipeline.

CEOCFO: ***Are you seeking investment, funding, or partnerships?***
Dr. Yang: Yes. We are proud to have already raised $17M non-dilutive funding from the NIH. This is highly competitive and peer-reviewed funding. The money supports several of our BioPYM products, including the FZ002 for *C diff* infection. We are now seeking a series B seed round of $10 million. This will support the continued development of the FZ006 for IBD and will move the FZ006 program through completion of clinical phase 1.

CEOCFO: ***What is the interest from the investment community?***

Dr. Yang: Their response is similar to that of the pharmaceutical companies. They are very excited and show great interest. Although we have very beautiful animal data, they want to see how it will work in humans, which we will see in 2023 clinical trials.

CEOCFO: ***What are your next steps? What does the next year or so look like for Fzata?***
Dr. Yang: Right now, our leading compound is under good manufacturing practices (GMP) manufacturing to be used for human phase 1 clinical trial. We really want to wrap up the GMP run, talk to the FDA in a pre-investigational new drug (pre-IND) meeting, get IND clearance and start the clinical trial. The most important step for us is that we successfully complete the phase 1 clinical trial. That is mainly what big pharma and VCs are concerned about. The next couple of years and clinical milestones are critical to Fzata.

CEOCFO: ***There are so many ideas and so many companies to look at in health. Why pay attention to Fzata, Inc? Why is the company important?***
Dr. Yang: We are bringing a novel modality of biologics to the medical field. With removal of needles, our oral innovation is expected to be really patient friendly, efficacious and safe and also cost-effective. It is a breakthrough to the field that can impact patient access to biologic therapeutics around the world.