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# Transforming Injections into Ingestibles for Oral Delivery of Biologics

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**CEOCFO: *Mr. Niichel, what is the concept behind SmartTab?***

**Mr. Niichel:** SmartTab is a wireless ingestible capsule that is working on targeted drug delivery for patients. The biggest thing is moving a delivery of biologics, which is typically a syringe and a needle, into a capsule that will deliver the active ingredients into the stomach or the upper GI tract.

**CEOCFO: *Why do we want to do it this way?***

**Mr. Niichel:** There are a number of reasons, but some of the main ones, number one, syringe and needle is very antiquated, it gives people a lot of anxiety. A lot of anxiety leads to poor compliance. If you can move that technology to a capsule, people do not feel pain, you get better patient outcomes; compliance goes way up and overall health costs go way down.

**CEOCFO: *How are you able to get what was injectable into a capsule?***

**Mr. Niichel:** It is a proprietary mechanism, so we basically have two methods. You have a capsule that has an injection system, where we can either inject a solid state, which is basically a time released sphere into the side of the stomach or a liquid injection to where there is a poly needle that is injected first and then we follow on with the liquid. Therefore, either we can injection the dry state through the proprietary pharmaceutical grade implant needles or we can do a liquid state.

**CEOCFO: *How long would the medication last?***

**Mr. Niichel:** The good news there is that with the implants you can design them to be immediate release, so very fast release or using our pharmaceutical technology, you could to a time release or you could have it last for hours or days.

**CEOCFO: *There are time release capsules now that supposedly will release medication over a day. Would you explain what wireless means? What is the technology that is allowing this to happen once it is injected?***

**Mr. Niichel:** There are two things. I will just follow up. You mentioned that there are already time release capsules out there. You are correct. There are no time release capsules for biologics; things like insulin, Humira, Enbrel. Those are large molecule proteins. If you put them into a conventional capsule, time release or not, the proteins get broken down in

the stomach or the upper GI tract, so there is no good way to deliver these biologics through a conventional time release capsule. That is why you have to do an injection, either on the outside in the skin or on the inside of the stomach. That is that point.

The wireless business is really neat. Now you can control the way the active ingredients are released in the capsule. You can monitor the location of the capsule. You have a two-way communication with the capsule that will either track where it is, or you can control where it is. The wireless piece also has sensors in it, so there is a temperature sensor, there is a pH sensor. Those are twofold, number one, not only to trigger when the reactive ingredients are triggered to release, per the pH sensor, the temperature sensor, but also to monitor the internal vitals of a person. We can add more sensors as the technology grows, but this idea of having wireless communication with your cell phone and iWatch, or a PC in a clinical setting. We see some of these applications having a large impact in nursing homes and assisted living, where they have to do a much better job of tracking how a medicine is delivered to their residents. All of those things fit into the wireless platform.

**CEO CFO: *Do you see people not being comfortable with something inside that is tracking or is that idea more commonplace today?***

**Mr. Niichel:** I think that with each generation that comes up it becomes more and more common. People like us, we did not have computers when we were growing up and we had to kind of figure out how they fit into our lifestyle, but at a much older age, whereas kids today are growing up with iWatches. They have cell phones. If you know any teenagers, the cell phone is like an extension of their arm! They are growing up with technology. They are growing up with tracking devices. They are growing up with watches, so I believe that with each generation it becomes more conventional, more commonplace to have these systems. Therefore, really now you are just talking about instead of wearing a wearable, if you will, on the wrist or your watch and so on, it is just basically internally.

**"Our vision five years from now, is that if you go to a pharmacy you will not need to use needles or syringes for biologics. You will take a capsule and most capsules will have some type of an electronic delivery system to help people with their prescription medicine." Robert Niichel**

The focus though, for us, is to alleviate some of the major problems that affect millions of people. With doing our consumer focus groups, many people who have to self-inject once a week, whether it is something in the direction of Humira, Enbrel or even daily insulin; if they could take a pill and not have to self-inject or even go to a clinic to have the injection completed; that would be just a huge advancement in the deployment and compliance for prescription drugs.

**CEO CFO: *Has anything similar been tried or in the works?***

**Mr. Niichel:** You have two fronts. One is the wireless. There is a company called Proteus that has made some very good progress for a chip that they embed into a single tablet that tracks when you consume the active ingredient. They do not do a drug delivery, it is just basically a simple tablet, they can add a chip to it. However, they do have it commercialized and their partnership with Otsuka Pharmaceutical Co., Ltd. and they do have FDA approval on the device. They do have FDA approval on the drug itself, so it is making good progress for everyone in the industry around in ingestible electronics.

There is another company called Rani Therapeutics. They do not use any type of electronics, but they do have a system which is a capsule that touches on a time release, which you mentioned before. It is wrapped with an enteric coating, so once it passes through the stomach and into the GI and into the intestine where the pH changes. The pH change then initiates an erosion of the capsule shell and this balloon expands. That is based upon your angioplasty where you have this balloon that expands. Then on the outside of that balloon that have these polysaccharide tips that then will imbed these molecules and medicine into the side of the GI tract. It is a very basic system that is loosely kind of what we are doing, although ours is much more advanced, with the electronics that support the pharmaceutical types of grade injections that we are doing.

There are people out there that are making some progress and our vision five years from now, is that if you go to a pharmacy you will not need to use needles or syringes for biologics. You will take a capsule and most capsules will have some type of an electronic delivery system to help people with their prescription medicine.

**CEOFCO: *Where was the greatest challenge in creating SmartTab?***

**Mr. Niichel:** The initial infrastructure on how do we design a capsule that will be patient friendly. We have done several consumer focus groups. What does a patient really want? They want a capsule that is autonomous, and what I mean by that is the one where we are injecting things like biologics; you swallow it, it has on board power, it has the two-way communication control. However, people are used to taking a pill with a glass of water and then forgetting about it. Therefore, our challenge is to design a system that fulfills patient needs and values.

We also have our TargetTab™ that we are working on with inductive power. Inductive power in as much as it is being used at very close distances for cell phone charging today, to develop the inductive power to go over longer distances, so we can control or power the capsule from a wireless external device. Those are really the two biggest challenges. Once all of those things have been figured out we have a lot of internal workings that make the systems work that are still proprietary, but those are the two biggest challenges. Then, right now we believe we have a good clean sight through the regulatory process to get these commercialized to really help people and improve their overall quality of life.

**CEOFCO: *What do you and your team understand, from past experience, on how to go through that FDA process and be successful?***

**Mr. Niichel:** That is a good question. The FDA process is to really have items presented in a way to what the FDA is looking for. The purpose of the FDA, a governmental agency, very structured, is to make sure that you are presenting things that are very orderly and that you follow their format that they like to have things submitted in. A few years ago, they went to an all-electronic system, so you have to upload the documents electronically and make sure that you are following it. Therefore, in as much as the data are important, which they are, and the clinical tests are important, which they are, it is how you run the process of uploading, of filing, to get to a very efficient streamlined FDA review and then ultimately approval.

**CEOFCO: *What has been the response from the medical community or people that are aware of what you have developed?***

**Mr. Niichel:** It is an absolute game changer. If you can take biologics for all the millions of people that once a day or once a week, if you can get rid of a syringe and a needle and you just take a capsule that you do not feel and it gives you the same dose of a better dose; it is a game changer. It changes the way that medicines are delivered for ultimately billions of people.

**CEOFCO: *Are you seeking funding, partnerships or investment? Where are you today?***

**Mr. Niichel:** We will be starting on our Series A round later this year. We are looking at strategic partnerships for ongoing development, so it is two sources of funding; number one, the Series A, and number two, strategic partnerships. Those are the two main focuses right now.

**CEOFCO: *We actually came upon SmartTab from your recognition as a TechCrunch biotech and health tech Top Pic. Would you tell us about recognition of that type? How does it help you? Are you actively looking at other areas like that to get attention?***

**Mr. Niichel:** The recognition is helpful to build out our networking and portfolio strategic partners. What we are working on is new territory, so many companies may not be aware of what we are working on, that this is even a possibility. Therefore, the ability to be recognized in a very large formal format like TechCrunch is a big deal. It gets our name out there.

You may have noticed, last week in the Wall Street Journal, that Samsung is building the world's largest biologics facility manufacturing plant in the world. They build all of these great medicines' biologics. How do they deliver them to people? They do it through a syringe and a needle. We are working on that missing link, to where you do not need a needle and a syringe anymore. You take a capsule. It does the injection internally.

To your point, these recognition types of activities and events gets us in front of people like that; like the Samsungs of the world, who have resources and are looking for new innovation, and in our case, really would be able to fill a gap with what they are building on for their biologics systems.

**CEOCFO: *Are you able to work with or should you be working with something like the American Diabetes Association or large organizations whose people should welcome this with open arms?***

**Mr. Niichel:** Yes, and we have been. We are an active member today with the Crohn's and Colitis Foundation. One of the early applications was around treating Crohn's Disease; our TargetTab™ to go deep in the colon to release active ingredients. Crohn's and Colitis also benefits from, as you get a little bit further down the path in Crohn's Disease, you will be switched over to biologics, so now people have to take an injection once a week to have a biologic. We have held some focus groups with them to advance our patient-centered activities.

Moving on to the American Diabetes Association, we have had conversations with them, so we are working down that path as well. We will be conducting our first pre-clinical animal study next month for the InjectTab™. We have already done pre-clinical animal studies and were very successful with TargetTab™. Each one of these milestones adds additional credibility for these associations. However, you are exactly right. Those are the types of associations that we will continue to pursue and be active members. One of the benefits with organizations like that is that we can get very solid consumer feedback. Therefore, then we are able to design our products that are patient-centered to really deliver on what people are looking for, for their therapy.

**CEOCFO: *What surprised you through this whole process? What have you learned?***

**Mr. Niichel:** One of the big things is innovation. Innovation resides in smaller companies. They are innovative, they are nimble and they are quick. Larger corporations are not and it has been beneficial that we are innovative to pair with larger corporations to commercialize things. Therefore, we are a little bit surprised in as much larger companies will talk about, maybe having an innovation group. At least in the United States, many of your good ideas come from smaller companies that are looking to work on new things that they have the ability to work on and to find the correct people to work on these projects. That has been a very interesting process, seeing how the talent pools are spread across and certainly different as you move around different sizes of companies.

**CEOCFO: *Why pay attention to SmartTab?***

**Mr. Niichel:** Again, this is a game changer. You think of all the people that have to complete injections with a syringe and a needle; now think of someday to where you can make it painless and take a capsule. You do not feel it, you take it with a glass of water; it is finished. You get your same dose or a better dose. Just in the United States you have better outcomes. Now, you start going on a global level. You expand to a global level. It is tough to go into second or third world countries and you give them syringes and then the applications and, okay, we do the injection and then you have infection. Maybe people would try to use the same syringe and the same needle and so on. If you take a capsule, all of that goes away. Disposing of these things – how do you dispose of a needle and syringe? You are supposed to follow a very specific path to dispose of a needle and the syringe. The capsule automatically goes into the waste system, so there are several things that, beyond a much-improved patient outcome, beyond a much more user-friendly patient experience; there are all these supply chain issues and then waste issues that we help alleviate. However why? The biggest reason is that this is a game changer. This will change the face of the way medicine is delivered to people.