

A Stimulating Conversation with John Schellhorn, CEO of Vibrant Gastro



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CEOCFO: *Mr. Schellhorn, you have a long history in med-tech /health; what attracted you to Vibrant Gastro?*

Mr. Schellhorn: I have significant experience in gastroenterology, and I knew enough to recognize what an opportunity it would be to work with Vibrant, as it combines a novel and exciting technology with a very large unmet market need. There is a large population of people suffering from chronic idiopathic constipation that are either left untreated or the available treatments are sub-optimal and do not provide the kind of consistent, predictable relief that they are looking for. Vibrant's new mechanism of action promises the relief people are looking for and the predictability they seek, all without the use of drugs.

CEOCFO: *Would you explain the concept behind Vibrant?*

Mr. Schellhorn: It is a bioelectronic and ingestible capsule. The system combines a programming module and a single use capsule that is the size and shape of a fish oil pill. Just before ingestion, you insert the capsule in the pod to be programmed. This allows it to transit the stomach and small intestine and then fourteen hours later, when it gets to the colon, it goes through a series of vibrations against the colon wall, two hours on, two hours off, and two hours on until it is expelled.

The concept behind it is to reset the natural biorhythm by exciting the mechanical receptors within the colon wall. Many refer to it today as the gut-brain axis. It is highly effective in creating a peristaltic effect that contracts and helps push out the contents of the colon.

CEOCFO: *Have similar approaches been used in other arenas or in the constipation arena?*

Mr. Schellhorn: This is unique. There is no one else doing this that I am aware of and certainly not in the United States.

CEOCFO: *Where did the concept come from? Who thought this might be a viable idea?*

Mr. Schellhorn: It came from Israel. While I'm based in the US, our parent company is in Israel. We developed the technology there and have been working on it for a number of years. It took a lot of research to figure out the right vibration frequencies and on-off timing. We did a large US Phase 3 clinical trial which took several years.

CEOFCO: *Are people taken aback when they first hear about it or are patients and/or doctors so frustrated that what is available today is not working, they do not care how different it sounds from standard methods?*

Mr. Schellhorn: It does sound different. This is a prescription device, and many times it is the patients themselves asking their primary care physicians and gastroenterologists to write the script for them. I think the thing to understand about CIC patients is they are not suffering from occasional symptoms. On the contrary, so many of them have lived for years with the condition. In our clinical trial, the average time people had CIC was fifteen years.

We are talking about individuals who do not have one complete spontaneous bowel movement a week, and sometimes less than that. By the time they come along and see the Vibrant system and the vibrating capsule, whatever natural hesitation they might have in swallowing a bioelectronic capsule goes away because they are desperate at finding relief from their symptoms.

CEOFCO: *What has been the reception from the medical community?*

Mr. Schellhorn: It has been outstanding for a couple of reasons. Current prescription medications are not being well received by either the gastroenterologists or the patients, primarily because one of the side effects is spontaneous diarrhea. There is a high degree of fall-off from those drugs. That means that people do not want to go from a state where they cannot move their bowels, to one in which they cannot control them. They are looking for predictability in their lives.

Our Phase 3 clinical trial published in the peer-reviewed journal, Gastroenterology, last June, provided the scientific evidence that the Vibrant system works. It was a beautifully done trial. I think that the concept of it is novel enough that physicians have been willing to prescribe it, and it has been well-received by the patients who are using the technology.

"We are a non-pharmacological technology for a condition in which patients have had nothing but pharmacological solutions that have not worked well." John Schellhorn

CEOFCO: *I see from your literature that Vibrant is for chronic and idiopathic constipation. Is that because that is what you have tried it on first or are there differences in types of long-term constipation that make a difference in how the capsule works?*

Mr. Schellhorn: The FDA has cleared us for chronic idiopathic constipation which affects somewhere north of 35 million people in the US. This is constipation without a known cause as opposed to constipation which is a result of Parkinson's disease or opioid ingestion. Our clinical trial was done on CIC (Chronic Idiopathic Constipation) patients. We may seek additional labeling for other indications as time goes on but right now, we are in by far the largest portion of the constipation market.

CEOFCO: *Is the capsule one size fits all and the same for everyone?*

Mr. Schellhorn: It seems to work fine with the way that we have it programmed right now. The Vibrant Capsule took many years of research to figure out a well-tolerated size and the right balance between on and off sequences. It appears that it is working well on the vast majority of cases that we are presented with.

CEOFCO: *Where and how are you manufacturing and what if any are some of the special challenges?*

Mr. Schellhorn: We manufacture in Israel in a town called Tiberias. It is in the Galilee region, and it has been fortunately very quiet. While the war has been going on we have not missed a day of manufacturing. That was something that concerned all of us in the beginning, but things are actually quite stable. We use a contract manufacturer although we own all the fixtures and assembly line. We control the practices involved in manufacturing and our yields and quality are extremely high.

CEOFCO: *Would you tell us about the customer service aspect and how you interact with the patients?*

Mr. Schellhorn: One of the other big advantages to the Vibrant system is the digital component. We have a relationship with the patients who are prescribed our system. When we fulfill a prescription, a few days after it arrives at the patient's house, they get a call from our customer service team welcoming them and asking if they have any questions and also encouraging them to download and use our companion app. We find that the patients who use the app have much better

outcomes than those who do not. Right now, we have about 60% of the patients using our app which in med-tech is an exceptionally high rate. I have never heard of a company in the digital space where the app usage was this high. The reason is that patients can track their outcomes and track the progress they are making on the technology.

This also provides us tremendous amounts of post-market data and that data is exceptionally valuable and gives us unique insights into both patient behavior and the disease that help us better tailor our product and services to them. It is a win/win and provides clinicians with post-market data which gives them the confidence that their patients are being well looked after.

CEO CFO: *What might be a concern from the patient; what are they looking for from your app?*

Mr. Schellhorn: They can track their progress and that is both encouraging but also a positive reinforcement. They can track their progress and what they will see over the weeks that they begin using the technology is that they are having one then maybe two, and up to three complete spontaneous bowel movements a week. This continues to encourage them.

We find that the people who use the app stay on the technology longer and are getting better results. I think some of it is compliance. It has been a revelation in terms of the information that we get back and how we can use that to better provide care for people who use our system.

CEO CFO: *When someone starts using Vibrant, would they still use some of the other things like laxatives or stool softener, or does Vibrant supersede everything else?*

Mr. Schellhorn: The answer from our post-market data is some people drop off all other medications whether they are over-the-counter or prescription and some wean themselves off over time but may use an occasional over-the-counter medication. If they have been on some of the other drugs, they may take it on occasion. It depends. Some only use the Vibrant system. A lot of patients will settle in on which regimen works best for them and stay with it.

CEO CFO: *Do many patients feel something as it is working when it gets to the colon or is it just not noticeable?*

Mr. Schellhorn: A lot of it is variable. We find people with low body mass index or BMI sometimes feel the vibrations. In our clinical trial where we had 250 people in treatment, 11% of them reported that they felt vibration. Interestingly, 6% said they felt the vibration in the placebo arm and the placebo did not vibrate. Also, of the 11% that felt the vibration in the control arm, no one dropped out because of it. It is not like it is shaking your body. In the patients that I have spoken with who felt it, some felt reassured by it because they knew it was working.

CEO CFO: *Where are you today in the commercialization process?*

Mr. Schellhorn: We are just starting in the US, and it is an exciting time for us because we are working with the health insurance companies to get the technology covered by them. We are working on guidelines with medical societies as well as introducing ourselves to patients and clinicians. It has been a good first year. We still have a long way to go, but it has been an exciting time.

CEO CFO: *What have you learned from your experience that has been most helpful in getting to this point with Vibrant?*

Mr. Schellhorn: I have learned to listen to the patient's journey for insights into how we can better meet their needs. This condition affects people's lives in such a powerful way. We listen carefully to what their needs and requirements are. We listen to what they are looking for and what they aspire to. It provides humility for the organization, and we continue to search for answers to relieve them from the challenges they currently have.

CEO CFO: *What is your funding situation today?*

Mr. Schellhorn: We are looking to raise our next round of financing later this year.

CEO CFO: *Do potential investors easily understand your unique concept?*

Mr. Schellhorn: I think it is new to a lot of investors. If we were a drug-eluting stent or a new catheter or an x-ray technology, I think most investors have seen many companies present to them over the years and would be familiar with those spaces. I think that a lot of them are learning about the CIC market. We do a lot of education, and we do it as a

way to introduce them to what is a multibillion-dollar market opportunity. (Right now, about 4.6 billion dollars a year is spent on constipation treatments, not including the significant number of emergency room visits that some people with constipation face.)

We educate investors and try to help them understand that with a bioelectronic medical device, they can participate in the same arena as a multibillion-dollar-a-year drug. It is an exciting opportunity to present.

CEOCFO: *What, if anything, might the medical or investment community misunderstand about Vibrant that they need to know?*

Mr. Schellhorn: We are a non-pharmacological technology for a condition in which patients have had nothing but pharmacological solutions that have not worked well. We do not interact with other drugs, so if you are on heart medication for example, there is no interaction. The technology works very well. We are very proud of that, and we are happy to continue introducing it to the market and to continue to build on the momentum that we are seeing so far.

