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EndObetes, Inc. is bring patients Endoscopic Devices that Mimics the Anatomy and Physiology of Gastric Bypass for the Treatment of Obesity and Diabetes

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CEOCFO: ***Dr. Bessler, what is the vision behind EndObetes?***
Dr. Bessler: At EndObetes, we are focused on bring patients endoscopic devices for treatments of obesity and diabetes. Our first device is EndoBypass.

CEOCFO: ***Would you please explain the device and what it does?***
Dr. Bessler: EndoBypass is placed endoscopically, without surgery. It mimics the anatomy and the physiology of gastric bypass, which is a primary operation used for treatment of obesity and diabetes. By endoscopically mimicking that anatomy and physiology EndoBypass will have the effectiveness of the operation without the risks, pain, recovery and cost of surgery.

CEOCFO: ***When you say mimic it, what happens with the device?***
Dr. Bessler: In a gastric bypass you have to staple off and divide the stomach. You divide the small intestine and you attach the small intestine to the top portion of the stomach. You are bypassing the stomach and the first portion of the intestine. That results in a physiologic change in reaction to the food that releases hormones that creates a satiety or fullness sensation and as well, increases the release of insulin that improves diabetes and can put it into remission!

EndoBypass, is anchored in the esophagus where food enters the device which passes through the stomach and the first portion of the intestines. The food stays within the device, so that it does not interact with the stomach or intestine until it is deposited at the second portion of the intestine undiluted and undigested, just where and as it would enter with a gastric bypass. This stimulates the hormonal response causing satiety and improved insulin production.

CEOCFO: ***Where are you in the development process?***
Dr. Bessler: We have a functioning prototype in an animal model. We have had success in this model with significant weight loss for ten months so far. It is not a diabetic model, but we know from humans with other types of devices that this is going to have a significant effect on the diabetes. We are raising funds to get this into humans, probably first outside the United States and then come to the United States.

CEOCFO: ***Is that just because it is easier to get approval outside of the US?***
Dr. Bessler: Yes, and less expensive. We will do a pivotal trial of EndoBypass in the United States and get get FDA approval, but do research outside the US first.

CEOCFO: ***When did you think about the device? What went into your thought process in getting this off the ground?***
Dr. Bessler: I am a surgeon and during surgery one day a student asked me, "Why do we have to do such complicated surgery to have this impact on obesity and diabetes? Is there not a simpler way we can do this?" This got me thinking about possible alternatives. I have the second patent in the world on an implantable percutaneous cardiac valve replacement, which was based on a stent technology. Therefore, I was familiar with how this stent technology works. I am a surgeon, so I use it in my clinical practice. I said, "Okay, we can use a stent based device in the esophagus and bypass internally", so we worked that out a little bit and applied for a patent.

CEOCFO: ***What has been the reaction from people in the medical community who are aware of what you are developing at EndObetes?***
Dr. Bessler: Many physicians who we have spoken with are excited to have a less invasive and less risky treatment that can make such a dramatic impact on the care of obese and diabetic patients. Because the risk is so much lower it could be offered to lower weight patients and to patients who refuse to have surgery because of the associated risks of mortality and serious complications with gastric bypass surgery.

Some others have tried to do this. They have shown that the physiology works, but they have not been able to keep their device in place. I like to say that the GI tract is designed by God to move things along and it does it really well. But we have come up with a technology that allows our device to stay in place, as it has done for ten months in our animal model, which is more than many other devices have been able to achieve.

"There is no device on the market that has this significant an impact on obesity and diabetes… A solution to this problem is more than a home run! It is a grand slam!"- Dr. Marc Bessler

CEOCFO: ***How do you assess the long-term effect?***
Dr. Bessler: The early device is going to be focused on a one year implant for treatment of diabetes. That is the first thing we are going to go for. The return on investment for a diabetic patient who can be off injectable therapy will be at 1 year. We also know that there is a legacy effect even when the device is taken out so the return is even greater. With regard to the stent based portion of the device, stents have been used for a long, long time, so we already know what the reaction of the human esophagus is to having these stents in place.

What we do not know is how long the device can stay in place with the traction of the intestine on the sleeve attached to it. As I said, in our animal model, that is working well and suggests we will have more than a year of stability. We are going to be studying this in hundreds and hundreds of patients before we get FDA approval. This is not a 510K device that is similar to something else. There is no device on the market that has this significant an impact on obesity and diabetes.

CEOCFO: ***Why is there a legacy effect?***
Dr. Bessler: The stimulation of the insulin released comes from hormones released from the GI tract that cause growth within the insulin secreting cells in the pancreas. It stimulates them by increasing the cells ability to produce insulin and even when you take out the device those are still more able to more robustly produce insulin, number one. Number two, the weight loss that is associated with the device improves insulin sensitivity until and if the patient puts weight back on, they will have that benefit, regardless.

CEOCFO: ***Would it be the same as with a gastric bypass with your device, where you have to eat a certain way, and are on a special diet or you will have a big problem?***
Dr. Bessler: Certainly, if you drink lots of juices you are going to get the potential for cramping abdominal pain and diarrhea. If you are eating lots of sweets or fats, there could be some ill effect on your digestion that might give you similar symptoms. Therefore, you have to modify your eating a bit. However, ultimately the way these operations work are by making you feel more satiated from a small amount of food. As long as you are not eating particularly wrong foods for the bypass, it does not seem to have negative effects. There are certain vitamins and minerals that with gastric bypass has to be supplemented. Those vitamins are usually taken by mouth.

Our device is also completely reversible. It is not just placed endoscopically but it can be completely removed that way as well which is obviously different than a surgical gastric bypass. If a patient is having any problems we can just remove the device. It does not have to be a permanent implant. I hope that we can have a permanent implant, but right now it is not intended to be.

CEOCFO: ***Where are you in the process with your animal trials?***
Dr. Bessler: We have an ongoing chronic animal model and we are gearing up to do implantation in humans outside the United States. We are trying to raise funding to get that done. After a first in man and proof of concept trial we will move on to getting approval in the United States with a much bigger trial.

CEOCFO: ***What do you find when you are speaking with potential investors? How do you get the attention and what has been the response?***
Dr. Bessler: The attention comes from the fact that this disease is so common. Obesity occurs in one third of people in the United States and nearly 10% worldwide. Diabetes is present in about ten percent of the people in the United States and the numbers are staggering around the world. The cost of diabetes and obesity to the world economy is some two trillion dollars and the potential sales for a device like this reaches into the tens of billions of dollars. That grabs your attention right away! Everyone understands that obesity and diabetes are chronic diseases that are not well managed right now.

The fact that these have already been de-risked in some ways, as this is a stent based device and stents have been used in the human esophagus for a decade and the sleeve has been used by others who have proven that physiology actually works, even though they could not keep their device in place long enough or safely enough. Therefore, the risk is reduced a little bit, by the fact that we understand what we these devices do and how they interact with the body, even though they have not been implanted in patients long-term or exactly the way we are doing it. And so between the size of the market and the known effective physiology there is significant interest. However, we have no human data yet. There have been other failures in this space which gives pause to some investors. That is why we are focusing on a first in man trial.

CEOCFO: ***Would this procedure be done by a gastroenterologist?***
Dr. Bessler: It can be done by an interventional gastroenterologist or a surgeon with endoscopic skills. There are some surgeons that are interested in the most minimally invasive approach to things and those surgeons would potentially be interested in something like this. This would be true, especially with bariatric surgeons who are already doing weight loss surgery and have endoscopic skills.

CEOCFO: ***What type of training would be involved or is it intuitive?***
Dr. Bessler: Most interventional gastroenterologists and some surgeons already have the skills required to do this already. Specific training with our device focused on exactly where to put it could be done in a short course.

CEOCFO: ***Why does EndObetes standout?***
Dr. Bessler: This is one of the largest diseases in the world; obesity and obese Type II diabetes. There is no significant disease that is more prevalent than this. It has become the one disease that is going to reduce life span in the future and that we have no truly non-surgical effective treatment for, especially the obesity part. Therefore, the market is tremendous.

A solution to this problem is more than a home run! It is a grand slam! Our solution to this problem has already been proven to work as far as the physiology of what we are doing. This is a tremendous opportunity because of the size of the market and the importance of the disease.