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Isopure is Designing, Redesigning and adding Computerization to Medical Devices for End Stage Renal Failure that Reduce or Eliminate Human Intervention

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CEOCFO: ***Mr. Gillespie, what is the concept behind Isopure Corporation?***
Mr. Gillespie: Isopure is an FDA registered medical device manufacturer. Isopure was primarily started because I saw a need for developing equipment that could benefit peoples' lives with end stage renal failure.

CEOCFO: ***What have you developed?***
Mr. Gillespie: All of our equipment we have designed and/or redesigned is computerized. We started out with a redesign of the primary purification system, a Reverse Osmosis system. We are the only manufacturer in the United States manufacturing a Reverse Osmosis system that is totally computerized. What the computerization does is it will reduce or eliminate human intervention, so it reduces human errors. Patient safety is addressed because the human intervention has been reduced for the operation of the equipment. The system is manufactured with the designed operating parameters programmed in the system. The computer will operate the device base on the optimal operating parameters and will alert or stop the machine if it falls out of operating parameters that could harm a patient.

We most recently received a 510K for a new device as well as a patent on the device. The device is an acid mixer that uses cloud-based technology. The purpose of the device is to mix dry acid powder into a liquid slurry that is used to make dialysate which is used in the treatment of end stage renal disease. The device was designed to reduce or eliminate human intervention in the operation. We designed this device by addressed something that we felt the FDA and ISO could require down the road and that is validation on mixing concentrate in facilities. Currently concentrates are made at facilities, but there is minimum accountability on those concentrates that are currently being mixed.

For this new designed device, we tried to address areas that could be potential problems during the mixing of the concentrate. For example, accountability and traceability would be two key issues when mixing in-house concentrates. Also, employee PPE and cross contamination between mixed batches would be additional areas of concern. When an employee is going to mix concentrates, first, they will have to be trained on the use of the device. Once properly trained, their employee identification will be entered into the device which will allow them to mix the concentrates as well as provide accountability. The trained employee will scan their employee code the device will give them access to start the mixing process. They will begin by scanning the product code on the side of the box which will identify the prescription of the mix. Each subsequent case that is going to be used for the mix will also have to be scanned to verify that the proper

prescription is being used. After each case is scanned, they will open the case and scan each individual bag for the lot number and the expiration date of the powder. This will provide traceability for the final mixed batch. The bags will then be placed on an automatic bag opener which will provide protection to the employee from airborne powder as well as accountability of the number of bags opened. The transfer line utilizes RFID technology to reduce that chance of cross contamination by transferring to the incorrect tank as well as verification of the transfer. All of this data is logged in the system so that at the end of the whole process, the data can be downloaded or transferred to the cloud. The data that is collected is who mixed the batch, the date and time the batch was made, how much was made (volume), what the formula was mixed. Specific Gravity of the mixture, and when it was transferred to the distribution tank. No one else is doing that as of right now.

CEOCFO: ***Isopure offers a wide range of products. When does the reverse osmosis come into play?***
Mr. Gillespie: For the primary purification device, the Reverse Osmosis, basically all we are doing is we are taking city water and forcing that water under high pressure through a semi-permeable membrane where only the water molecule comes through. Therefore, calcium, magnesium, zinc, lead, iron and bacteria all get rejected by the system and goes down the drain. That water, because it comes in contact with the patient's blood, has to be very pure, because the impurities in the water could harm the patient. Reverse osmosis is the cornerstone of what is happening in dialysis.

"To develop devices that can help improve the lives of people with end stage renal failure."- Kevin Gillespie

CEOCFO: ***Are people looking for a better way? Are they appreciating the computer component you offer now and the cloud component you will be offering?***
Mr. Gillespie: The companies providing end stage dialysis treatment are looking for this technology. They appreciate what this technology can do to stream-line their business. From a compliance standpoint, the ability to download concentrate mixed data to provide to CMS is a definite benefit. Technology has advanced to the point that this is being used in everyday life. A lot of the providers use this type technology on the refrigerators in their treatment facility to monitor the temperature where they keep the drugs for patients. This is not the only device where we utilize this technology. We have a sodium bicarbonate mixing device as well as a pretreatment monitoring device that also utilizes the cloud-based technology for transmitting data. By providing the accountability and the traceability to the process, our goal is to reduce the human error in water purification and concentrate mixing which will translate into greater patient safety.

CEOCFO: ***Do customers buy directly from you? Do they buy from distributors? Are people looking for the Isopure name?***
Mr. Gillespie: We have contracts with a lot of the major end stage dialysis treatment providers. We also work with a lot of dealers throughout the United States. The dealers are an advantage to us because they can provide local support. As a medical device manufacturer, we need to provide 24/7 support. The operation of the equipment is imperative to patients receiving end stage dialysis treatment.

We are located in Louisville Kentucky which is centrally located distance wise between the largest population areas. For example, it is about the same amount of time from Louisville to NY, as it is from Louisville to Miami, as it is from Louisville to Houston, as it is from Louisville to Chicago. The other advantage about our location in Louisville, Kentucky is it is UPS's next day hub. Therefore, we have gotten replacement parts out of our manufacturing facility as late as eleven o'clock at night and they have made it to their location the next morning. That is an advantage to us. We have also utilized airlines like Southwest Airlines to get parts on weekends to areas if a part breaks or something happens that the provider needs a part to operate the equipment for treatment the next day.

CEOCFO: ***Are there disposables or maintenance with the equipment? Is it typically one piece of equipment?***
Mr. Gillespie: There are disposables. You have the basic filters, that once the filters get dirty you throw them away and put a new filter in. Cleaning and disinfectant chemicals would also be disposables. The average system which a dialysis provider will use will consist of 15 different components to process the water and mix concentrates. The longevity, the equipment on average is seven years. Depending on the usage of the equipment, a facility may decide to replace some or all of the equipment to continue to provide the highest level of care for the treatment of the patients. Technology is

changing so fast which makes the safety of the equipment for patients less expensive and more comprehensive addressing safety issues.

CEOCFO: ***When will you be rolling out the new cloud version that just received FDA approval?***
Mr. Gillespie: We just received approval about three weeks ago. We are now in the process of final validations. We are planning on building about twenty units for additional testing this year. What I mean by additional testing is that we will test them in different parts of the country, for example, like Denver because of the altitude, New Orleans, again for the altitude, California, New York, etc. The whole purpose of that is to see if there are any environmental concerns once we start mass producing these units. It is also for training purposes. We will outline obstacles, problems, anything on training operators on how to use the device, so we can put together a training program.

One of the things that we are doing differently for training on this device, is using virtual reality. That is something different, but it is something we are going to try on this, to see if we can have success as far as when you have a very technologically advanced piece of equipment, you need the operators to be fully aware of all the features on it and how to operate the device safely. Therefore, we are hoping that with virtual reality will help with training because virtual reality utilizes all of the human senses such as sight, touch, and hearing it will be easier and more advantageous to train people. We have found that keeping an operator's attention during training can be a challenge. We are experimenting using virtual reality to see if the operator training will be enhanced.

CEOCFO: ***What is the competitive landscape?***
Mr. Gillespie: There are currently four other companies such as Isopure in the United States.

CEOCFO: ***That is not very much!***
Mr. Gillespie: That is not very much; no. We have been in business for 24 years. When we started out, there were 14 companies similar to Isopure. Today there are 4. Most of the other 10 were adsorbed through acquisitions or went out of business. Different technologies and different advancements are changing that demographic of the marketplace, so we are trying to use technologies to give us an advantage compared to our competitors.

CEOCFO: ***Have you always looked to be a step ahead?***
Mr. Gillespie: I have to have a competitive advantage over my competitors. I always tried to design equipment to address a need in the marketplace not to copy something my competitors are doing. Isopure is definitely not a "me too" organization. This was also a benefit in the premise of the company originally, "to develop devices that can help improve the lives of people with end stage renal failure".

CEOCFO: ***Why pay attention to Isopure Corp? Why is the company important?***
Mr. Gillespie: One reason is that we feel like we are producing and advancing new, technologically advanced products, so we want to be the forefront of that. Why people would want to look at Isopure is for that reason. We currently have probably fifteen R&D projects going on now. We are addressing some new areas that are not in dialysis, but yet still in healthcare, that we feel that are areas that are not being addressed and could be potential problems. Therefore, we strive to continue to do that, to look at new areas and new potential problems that we could address with our technology.

CEOCFO: ***Is there anything that people might miss when they first look at Isopure that should be recognized?***
Mr. Gillespie: The work environment that we have here. One thing I do have to say is that I think we have the best most dedicated employees than any of the four competitors. My employees are very dedicated, very intelligent and very hard working and really have a lot of customer service. The customers are the first and foremost in our business because of the patient safety. We have people that answer calls all night long. We have people that have gone out on Thanksgiving to make repairs on equipment, because they need to dialyze the next day. Therefore, they gave up their own personal Thanksgiving in order to repair equipment. They are very dedicated and Isopure would not be anywhere without those people.