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Q&A with Gary Seamans, Chairman and CEO of IDx, LLC bringing to market the first FDA approved Artificial Intelligence-based Algorithm Medical Diagnostic System that Searches for Definitive Disease Biomarkers and has clinically proven to detect Diabetic Retinopathy

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CEOCFO: Mr. Seamans, according to your site, IDx, LLC is transforming healthcare through automation. How so?
Mr. Seamans: We are using artificial intelligence as the basis for a diagnostic system to be deployed in the front lines of medicine. It is the first such approved by the FDA system in any area of medicine.

CEOCFO: *How does it work?*
Mr. Seamans: The patient walks into their front line of medicine care facility, whether that is their primary care doctor or a community clinic. Along with their wellness check and the services they get at that level, they are then taken to a room where there is a very small robotic camera. It is associated with our system, which is referred to as an intelligent node. The patient sits down in front of the camera and a member of the clinical staff, who is not a professional operator, takes pictures of the retina of two eyes. Those pictures are immediately assessed for accessible quality for interpretation of the image and the state of the condition if they have diabetic retinopathy. Then, once the photographs are verified by our artificial intelligence system to be acceptable for quality, the artificial intelligence diabetic retinopathy algorithm, in twenty seconds, interprets the state of retinopathy or lack of and provides that information back to the operator with specific instructions on what to do or not to do.

CEOCFO: *How is diabetic retinopathy measured today?*
Mr. Seamans: The standard of care is that the thirty point four million people diagnosed with diabetes have an annual eye exam to look for a complication of diabetes in the eye. It is called diabetic retinopathy. That standard of care means that they need to be seen by an eye care specialist once a year to look for this condition. Unfortunately, only about fifty percent of the people with diabetes actually do that. Whether that is because it is the second visit, whether it's because there are costs involved, whether it's because transportation is involved - half are not getting the exam. Unfortunately, that is leading to about twenty four thousand people going blind each year in this country, needlessly.

CEOCFO: *You mentioned FDA approval. What is it about your system that enabled the go ahead?*
Mr. Seamans: Two things, actually. We did a very large pivotal clinical trial last year; nine hundred patients in ten sites, seven states across this country, all in primary care settings and we achieved outstanding clinical trial results! In all cases, we significantly exceeded the primary outcomes that we were to achieve. That was terrific evidence to FDA that in fact an

autonomous diagnostic system deployed outside of a specialist's office, everywhere that a specialist is not, could provide a diagnosis of referable or treatable diabetic retinopathy. That it is a big step, because today, in the artificial intelligence world, so much of it is assistive in nature, where it assists the physician in making a diagnosis. This is quite different. This actually makes the diagnosis without a physician needing to interpret the results. That is a very big step for the FDA to make, but a very necessary step, for two reasons. One: by increasing access to care, it can help close the gap for the 50% of patients who aren't getting tested for diabetic retinopathy, which may prevent blindness. Two: it dramatically affects the productivity of the healthcare system. There are a small number of eye care specialists in this country. There are about two thousand retina specialists. There are about twenty thousand ophthalmologists. When you have thirty point four million people diagnosed with diabetes and another eighty four million that are pre-diabetic, it is a tidal wave! It does require those limited number of specialists to be able to treat and provide the treatments for people who do develop diabetic retinopathy. They have sight saving treatments and those treatments are what the eye care specialists are trained and skilled at doing.

CEOCFO: ***What is the plan to get the system in use? How do you reach out? How do you garner attention when there is so much going on in the medical field; doctors are bombarded all the time?***
Mr. Seamans: Lynn, what is that expression; "Build it and they shall come?" When the FDA announced the approval of our diagnostic system, literally, the world of media, medical and investor communities descended upon IDx. Until we had FDA approval, we were absolutely prohibited from marketing. We cannot do anything in that regard. In the two weeks since it was approved to do marketing, very significant entities have really aggressively come after this. That is because they see the promise for it. They see the potential for it. Our biggest problem is not convincing people that this is a system that they need; it is responding to all of the demand, literally globally, for the ability to learn, use, adopt and employ this system.

"You cannot pick up a newspaper and not find the words "artificial intelligence" or even "algorithm." What is different is you now have a medically driven AI-based algorithm that searches for definitive disease biomarkers and has been proven to get outstanding results in a real world clinical trial."- Gary Seamans

CEOCFO: ***Is there a reimbursement code in place?***
Mr. Seamans: We are working with CMS and medical society stakeholders to ensure that there is clear coding guidance for IDx-DR. Providers, physicians and suppliers should contact their third-party payers for specific and current information on their coding, coverage, and payment policies.

CEOCFO: ***What will physically be placed in the doctor's office and how have you decided how to price your service?***
Mr. Seamans: First of all, the actual equipment probably occupies two square feet of space. It is not large. One of the things the FDA required for our clinical trial was that non-professional staff, with less than four hours of training, would be able to execute all the operations of the system. In fact, one of the hurdles, one of the primary outcomes, was that the FDA wanted to show that in the non-specialist environment, in the frontline care setting - which could be a physician's office, retail healthcare centers, community clinics, urgent care clinics, any number of places - that the people there on staff could in fact operate this system effectively. The FDA wanted to show that over eighty percent of the patients could be diagnosed using our system. Well, I am happy to tell you that in our study we found that ninety six percent of the patients, using non-professional people, were able to get a diagnostic result for the patient. That is just terrific!

CEOCFO: ***How are you keeping up with the interest? Do you have staff in place, facilities in place and manufacturing in place to address everyone that is ready?***
Mr. Seamans: The answer is yes. We are essentially doubling the size of IDx in key positions. That is technical and that is marketing and sales positions. This system is not going to be a shiny shoe salesman with a briefcase walking around somewhere, looking for a little shingle that says, "Doc In". About forty six percent of the primary care physicians today are associated with a larger hospital system. There are one hundred and fifty thousand primary care doctors with almost half of them associated with a system; the primary care systems roll up into large integrated health centers. It is not a matter of us selling or marketing or communicating with one hundred and fifty thousand people. It is more like ten or fifteen thousand. Therefore, we do have the staff in place to do that. It is a very talented group of people. We are responding and working that usual twenty-four hours a day, seven days a week.

CEOCFO: ***Why is diabetic retinopathy the first condition for IDx? What is next?***
Mr. Seamans: That is the right question! Thank you for that! The reason diabetic retinopathy was first is that it is such a massive issue. It is, if you will, the low hanging fruit for what an AI based diagnostic system can do so very, very well. In

any given year about ninety or ninety five percent of the people that have diabetes will not have either a referable or treatable level of diabetic retinopathy. Therefore, with a standard of care, it says 30.4 million people need to go have an exam, yet only five or maybe ten percent in a given year actually need a treatment, which that specialist can do beautifully. There is an awful lot of opportunity to enhance the healthcare system, advance patient care, advance the care that the patients get, but also to provide a needed productivity boost. We actually believe that there is going to be a nice benefit for all of the payor community. When this is fully deployed, instead of saying thirty point four million people need to have this specialist exam, only five or ten percent may need to. What that does is it gets the patients that really need treatment in to the specialist's office to get treatment. Therefore, the answer to your question is that it is just the massive size of that issue. Right behind it are solutions for other eye conditions as well as systemic issues in the human body that can be identified through the eye or retina. The eye truly is the window to the soul and to the body. In fact, it is the only place in the human body where you can see arteries, veins and nerves in vivo. That is live and in color, just like they are, without some form of imaging. Therefore, from an eye disease standpoint, the next prevalent condition would be glaucoma. That is certainly our plan, to have that be next, as with age related macular degeneration. For example, if you take diabetic retinopathy, glaucoma and age related macular degeneration, there is a fifty percent chance that those people towards their upward and golden years will have one of those conditions. It makes sense for us to go after diabetic retinopathy first, because the entirety of the biomarkers are able to be beautifully imaged and determined by our system. Behind that would be AMD and glaucoma. I mentioned the systemic conditions that the eye can show. The first area we are looking to identify through arteries and veins and nerves, that you can actually see what is going on in the system and the body right there in the back of the eye, is cardiovascular risk or stroke risk. As we all know in today's world, these events usually reveal themselves, not in the doctor's office, but in the emergency room. The earliest warning of the state of cardiovascular and stroke risk can be shown within the eye. Therefore, it is a gold mine of information and it is in our entirety of plans to provide, and this is key, an autonomous - meaning not requiring that physicians are involved in reading the images to make a diagnosis. Those algorithms are on our system, which is a platform system. I mentioned the intelligent node at the presence where the patient is. At the other end of this system, which can be in the same room or it can be next door or it can be somewhere else, is a HIPAA compliant server. That server does the pre-processing of the diagnosis; in this case an image quality check. It then communicates back to the intelligent node right there where the patient is, where it is in fact diagnosed. It is the same as what happens in a specialist's office, except it is right there in the primary care office, so the patient immediately knows the diagnosis; as I said, all of that in less than twenty seconds. There is one other component of our system. It is the IDx Network Management Command and Control Center. This is at our headquarters in Coralville, Iowa. It is a system that interacts with both ends of our system. This is kind of in the middle. It continually monitors the performance, it upgrades the software, any maintenance issues, but it also downloads the algorithms for disease conditions - autonomous, AI based diagnostic algorithms to be deployed at the front line in medicine.

CEOCFO: ***Therefore, everyone should be paying attention today!***
Mr. Seamans: Indeed for sure! This is the notion of a fully autonomous AI. You cannot pick up a newspaper and not find the words "artificial intelligence" or even "algorithm." What is different is you now have a medically driven AI-based algorithm that searches for definitive disease biomarkers and has been proven to get outstanding results in a real world clinical trial. Yes, people should be paying attention, and people are all over the world. It is a first ever, and with the first ever is quite a journey to get there. People themselves are absolutely excited; this is an improvement in their personal healthcare.