

NanoDX is transforming In Vitro Diagnostics with their Unique Nanowire Technology that can Measure almost any Biomarker in the Blood and Saliva



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CEOCFO: Mr. Joshi, what is the idea behind NanoDx?

Mr. Joshi: NanoDx has a platform technology to transform in vitro diagnostics and more importantly, point of care in vitro diagnostics. We have unique nanowire technology that allows us to measure almost any biomarker in blood, saliva etc.

Any condition in bio-science where there is a strong correlation between a biomarker in a bodily fluid, where speed of diagnosis or at point of care is important, and there is a huge economic savings, provides an opportunity for our NanoDx platform to thrive.

CEOCFO: Would you explain the nano sensor; what that means and why it makes a difference in the technology?

Mr. Joshi: It is very different from any other mechanisms inside biochemistry or your standard immunoassays, ELISA for example or even PCR, which is very commonly used throughout the industry, or even faster shortcut methods of doing the same.

Our technology is based on a nanowire circuit and the nanowire circuit can measure resistance to electrical charge throughout the circuit. We can impregnate our nanowire portion of the circuit with whatever antibody we would like to that attracts whatever we want to find in blood or in the bodily fluid. For example, for COVID or traumatic brain injury, every single molecule that hits that nanowire, we can measure in electrical charge. It creates a very sensitive circuit and a mechanism for measuring these biomarkers very rapidly with high levels of accuracy. What is unique is that we could achieve kind of accuracy from a lay person that is only enjoyed by highly trained technicians using large scale machines that are in central-core laboratories.

We can take that technology now with this nanowire circuit and bring it to the people, so it has the capability and ease of use of being able to be used for traumatic brain injury, potentially an area the size of a football field or for COVID almost anywhere such as outside of a building, for screening, TSA lines, especially with getting a rapid result inside of two minutes, really brings a powerful platform.

CEOCFO: Is the medical community overall aware of what you developed and are they skeptical?

Mr. Joshi: I would say that the vast majority of people are not aware of the NanoDx technology. We were previously known as BioDirection, Inc. The vast majority of the world are not aware of our technology because we are not on the

market as of yet. While we are inching very close to getting on the market for both traumatic brain injury and COVID as well as development in other potential clinical applications, in time, I think more and more people we become aware of our technology. However, of the physicians that are aware of NanoDx, say that if our technology can in fact do what we say it can do, and they use the word transformative, in the sense of being able to bring the identification of things like traumatic brain injury, COVID, influenza, stroke, sepsis to the market or even a full panel of testing at a point of care.

Other companies have done this, but their tests are much more complicated, the use of them are much more complicated and their results usually take 20-30 minutes, whereas ours is two minutes and we can enjoy the same levels of accuracy, if not better than those levels of accuracy. Of the physicians that we have spoken to who are aware of our technology, we get really rave reviews.

CEOCFO: *Is it a yes or no result? Is there much interpretation needed from the result? What would the person on site see so they know what to do next?*

Mr. Joshi: That is a great question. We measure biomarkers. That correlation has a lot to do with how well there is a scientific consensus for a particular biomarker for a disease or an injury state. For example, there have been a lot of studies showing really strong correlations between GFAP and traumatic brain injury, both domestically and internationally. While other biomarkers exist in traumatic brain injury, there is not as strong of a consensus for some of them.

What we do is find ailments that have a really strong consensus among the medical community and we come with a faster, better, accurate way of measuring those biomarkers in a point of care environment. That is really what we do. We rely and stand on the shoulders of the scientists who have been studying biomarkers for ten, twenty and in some cases thirty years and we come at(?) it with a better device to be able to measure it accurately and fast.

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CEOCFO: *Where are you in the development and commercialization process?*

Mr. Joshi: At this point, a large part of our development is behind us. Now we are manufacturing and developing manufacturing processes and scaling and improving our yield for those processes. As we improve those yields, we will be able to make more and more product. While the volumes for our ailments are very high, none are more urgent and important than that of COVID these days. We have a lot of interest and we are scaling tremendous amounts of manufacturing capability with our manufacturing partners to be able to bring this technology to more and more people.

CEOCFO: *Would each condition have its own piece of equipment for the diagnosis?*

Mr. Joshi: Actually, no. We have an analyzer that is about the size of a toaster and we have a handheld device that is the size of maybe a large cellphone. Then we have a single use disposable cartridge. The cartridge is largely the same for all of our ailments except for one step and that is how we functionalize our nanowire on our sensor.

In a large part, as we build our manufacturing capacity, we are also building the capability for a wide variety of clinical conditions. Almost all of it is in common with only one small step for our cartridge that is unique to each healthcare vertical whether it be sepsis, COVID or traumatic brain injury. That is the only part that is unique and fortunately for us, everything else stays the same.

CEOCFO: *You have personally been involved with medical devices for a long time in a number of ventures. What have you learned about bringing a new concept to market that has and will continue to help with NanoDx?*

Mr. Joshi: I have been in medical devices for well over thirty years now and I have brought a lot of products to market with some great talent in the industry during that time, but I have never been involved in a company as unique as NanoDx in that it is on the forefront of not one but three significant technologies. It is one the forefront of nano technology, on the forefront of in vitro diagnostics and more importantly, point of care in vitro diagnostics, which is one of the fastest areas of growth within the \$60 billion marketplace of in vitro diagnostics. The \$23.5 billion segment that is

point of care is growing at a significantly higher rate than others, not only here in the United States but around the world and especially in emerging markets.

Now with COVID, the emphasis of doing testing outside of the emergency room at a point of care, urgent care facility, doctor's office or even in the home is gaining a greater acceptance and I suspect the growth rate will increase even further. This is a really unique opportunity and I have never seen anything like it before. When it comes to COVID, we have a unique opportunity to with not only massive demand and to be able to help the world in a very significant way, we can also move things more rapidly through emergency use authorization in various countries as well as the United States. In my experience, I have never seen anything like this where medicine, technology and business conditions are aligning like starts.

CEOCFO: *Are you seeking funding, partnership and investment now?*

Mr. Joshi: Yes, we are. We have been very lucky to partner with some great people out there in terms of license fields to bring in non-dilutive funding to our company. We have also closed the Series C during 2020 and we also are seeking some additionally investment to really scale to a larger volume right now and we are very close to closing that so we can execute on the larger plans. The volumes of product that we are planning on building today are about well over a hundred times greater than the volumes we were seeking to develop and manufacture just a year ago.

CEOCFO: *Where does cost come into play?*

Mr. Joshi: I think anything in healthcare needs to be cost conscious because in today's world, not only do you have to have cutting edge technology and good science that builds that technology and is transparent but you also have to do it in such a way where you can really make a difference economically in order for large scale adoption. Fortunately, in all of our verticals, we seek three different areas. We seek not only strong levels of biomarker consensus among the medical professionals but also the fact that we win in areas where speed and point of care counts, but the biggest area is where there is a huge economic savings. For example. In traumatic brain injury, the cost of a CT scan, which we would seek to potentially reduce the use of, about 92% of all CT scans that are used for traumatic brain injury are negative and only 8% are actually hemorrhagic, which is a dangerous condition.

There is a huge opportunity for a device like ours to make an impact on reducing the number of CT scans, which the national average ranges anywhere from \$800 to \$1200. In all cases, we seek to reduce the cost of healthcare, complexity and time and then prove the efficacy of diagnosis in all of our areas. Of course, that produces enormous economic savings and that is what part of our mission is to do.

CEOCFO: *Why does NanoDx stand out in a crowded field?*

Mr. Joshi: I think a lot of it comes from our name which is relatively new branding from our BioDirection days. Nano is the technology that propels us and brings us forward. That is the differentiating factor that gives us the speed, gives us the point of care opportunities, and the huge economic savings and really high levels of accuracy in the assay. Of course, Dx is what we are all about. We are a diagnostic company. We can take a wide range of ailments and be able to diagnose them quickly and accurately. That is embedded in our name, NanoDx System.

CEOCFO: *Is there anything people might miss when they look at NanoDx?*

Mr. Joshi: I think there is a crowded marketplace of point of care diagnostics, not only for COVID but also now increasingly for other technologies. There is an enormous amount of growth in the biotech world where we not only diagnose but perform predictive analytics. What is really unique is that we can do that much more efficiently given that nanotechnology, but we are also an IoT connected device.

Just as important as being able to diagnose is the aggregation of data, which can be tremendously powerful as we as a society start to take individual patient data and aggregate it in a way where we understand the medical condition in ways that have never been studied before, using potentially artificial intelligence or big data learning and to be able create even better assays that diagnose more accurately than they have in the past.