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Issue: March 9, 2020



Medical is the new Mobile™



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CEOCFO: Mr. Jadcherla, what is the focus behind iMedrix Inc?

Mr. Jadcherla: iMedrix was formed in 2015, but even before that, I had a vision that all things medical were going to go mobile. I have been working on mobile systems like laptops and phones for more than twenty years and I sensed that medical was going to be the new mobile. In fact, that's the mantra of the company. Our goal is to bring mobile medical electronics systems to life. Right now, we are focused on cardiology because heart disease is the number one killer in the world. We thought we would go after the biggest problem that our technology could solve. The whole mobile medical era is going to evolve in three parts; first, devices, followed by integrated systems and then the data and analytics era. iMedrix stands for Intelligent Medical Metrics and that is what we think is going to happen.

CEOCFO: One of the first things I see on your site is "Transforming Cardiac Care." What is the plan to do that?

Mr. Jadcherla: Let me give you a snapshot of where the company is and then it makes more sense. As you know, we have been around for four plus years. We introduced our first product, KardioScreen, outside the US in India and other Asian and African markets in 2017. Since then, we have been in sixteen countries. Even before we applied for FDA 510(K), we were CE Marked for European standards and we have been serving patients day in and day out. We actually have about 150,000 patients now which makes for one of the largest mobile cardiac databases in the world.

What we focus on and, in fact, the way we are transforming cardiac care, is by changing the way heart disease is detected, managed and treated. This is partly because of the way mobile technology works. Previously, people would not think of checking on their heart unless there was an acute event. Even in the US, for example, four out of five people who end up in the emergency room with a heart attack were not aware that they had heart disease or were at high risk for it. Outside of the US it is even worse! Therefore, we focus on using this mobile device. We can perform electrocardiograms for people at their location, add analytics to their report that help classify them into risk categories and then we make sure that those who needed follow up care got it. This has been transformative for patients because it has been able to cut costs and time of access dramatically. There is a lot of hype in the market about mobile cardiology, however, when it comes to a clinical solution in the market that can be fully integrated with leading hospitals, I believe we are the only viable ones in the market today.

CEOCFO: How do you integrate with a hospital? How would someone typically use your device in the field?

Mr. Jadcherla: That is a great question. Let's say I come into your office with a small device. I do a quick check on everyone and we find someone who needs attention; not that they are having a heart attack or a stroke right then, but they need attention because there are signs of cardiac disease present that they were unaware of. We would provide them with a copy of their ECG. In parallel and in real time, an analytics report is sent directly to a hospital system that we are connected to and the cardiologists there follow up with that patient. Typically, the outcome is the patient that was

flagged gets a secondary checkup such as an echocardiogram, stress test or further blood work, and once their condition is confirmed, they are prescribed medications and often lifestyle changes to manage their disease.

In about 3% percent of cases, we see the cardiologists marking it as acute which flags the patient. They are brought in urgently for testing and often that results in an intervention. Interventions would include things like stents, bypass surgery or ablations which are procedures that occur often. For these people, our technology can be life-saving. That is how our mobile technology works. Otherwise, without a problem, people do not end up going to a clinic or a hospital. Even people who receive annual physicals; they just get a static ECG check and they do not get an analytics report to say how bad the disease is. There is some blood work and it is all risk scoring right now.

What we have transformed it into is basically a deep-down analytics intelligence on a specific person's level of risk or injury to their cardiovascular system. The cardiovascular system has three parts; the nervous system controls it, the heart muscles pump blood and the arteries carry the blood around. All three have to be working properly. We have transformed it to a point where you get a deep insight into how all of these three things are working together. All of this can be done without the patient ever leaving their location or having to go see a doctor. It is all done remotely and mobile and it happens with an app installed on their phone or tablet device.

“The way we are transforming cardiac care, is by changing the way heart disease is detected, managed and treated.”- Srikanth (Sree) Jadcherla

CEOCFO: *What were some of the challenges in putting this together?*

Mr. Jadcherla: Funding has been the first big challenge. We formed in 2015, when the Theranos scandal was breaking out, and none of the venture capitalists that we spoke to, despite me being a successful entrepreneur, wanted to touch digital health. Overall, in the digital health market, apart from the scandals, there have been a lot of false promises, a lot of hype about AI replacing doctors and fancy gadgets that were not really scalable. Added to that, there has still been a lot of heartburn about electronic health records and the promises not being delivered. That is why we saw many VCs shying away from healthcare investment when we started. Also, we were perceived as a device level play as opposed to an algorithmics play. Many people did not understand that you need to get the mobile device out first before you can get the analytics out. We basically just stuck to our vision, despite the funding challenge. Because of tight funding, we decided to go with an “outside the US” strategy. Luckily that strategy worked well. In the US, as we begin to deploy here, finding skilled talent especially with experience in the area of mobile health, would also be a key challenge.

CEOCFO: *Would you tell us about the recent FDA clearance?*

Mr. Jadcherla: We were doing very well in the international market and kept a keen eye on the US market. We saw a boom in telehealth initiatives and reimbursement clarifications from CMS that indicated it was time. There was a lot of demand building up and many people in the US were asking us for access to our technology. They had tried other mobile devices but none of them were clinically satisfactory or robust enough. We were the only functional device and surprisingly, we are still the only one in the market. Therefore, we applied for our 510K clearance in July 2019 and received it in January of this year.

CEOCFO: *What are your plans for the next year or so regarding KardioScreen and a possible US rollout?*

Mr. Jadcherla: Healthcare is a very complex marketplace. In general, our style across the world has been to work with major industry players to take it to market. There are providers, physicians, payers, pharmaceutical companies along with major medical vendors; it is a complex system. We tend to work with some of the bigger players like Abbott and many of the pharma and insurance companies. In Asia, we deploy with another major company I cannot name. We found that many of those models are generating great interest in the US. In fact, some of the experts from the US have actually traveled to India to study these models and have come back to apply them here. Having said that, the US has probably some of the most active, vibrant teaching hospitals and research communities. We have received a lot of interest from many leading institutions about the algorithmics and analysis of our database or the newer versions of the device and telehealth services. Remote patient monitoring is also becoming extremely popular for cardiac patients. Therefore, with all the different areas, we are seeing a mushrooming of interest around us. We will be selecting a few channel partners or distribution partners to work with to enter the market.

CEOCFO: *What do you see as the most common case scenarios here for use of the device? Would people be using it themselves? Rural communities? Hospitals?*

Mr. Jadcherla: KardioScreen, outside the US, is used in multiple use models. The first of them is basically going into a community and screening people for heart disease at their location such as an office, church or school. In public health,

we call that mass screening or community health. In the US, that has traditionally been frowned upon, but is becoming popular as an idea. I've had a lot of community health experts across the US reach out to us.

Use model two is point of care usage. Today, every doctor's office has an ECG machine where they roll the cart in. There are some distinct advantages for a digital system over some of the machines that they use today. One is that it can take away the total cost of operation by almost forty percent, sometimes more, and the ease of use is much better.

Further, emergency transport such as ambulances are not always equipped with ECG machines. In addition, ambulances in the US today do not necessarily coordinate with the ER ahead of the arrival. We have set it up in such a way that the receiving physicians are connected from the get go and prepping for any intervention needed – this saves critical time in the golden hour. The added benefit is that we can do this at one tenth of the cost of the current systems.

Aging at home is another emerging use model. This is a huge phenomenon of the longevity economy. The average age of the US population is rising with statistics showing that there could soon be more people over sixty than under sixteen. We are not approved for at home use now but in the future, we anticipate that these machines will be self-administered at home and connected to the healthcare systems for either monitoring or alerts. Right now, there is a hybrid use model called remote patient monitoring administered by medical professionals. This is one of the biggest trends we are seeing in the US.

Also, you touched on rural telehealth. Multiple states are running telehealth initiatives to reach their rural populace. Texas, for example, runs these mobile clinics through the University of Texas system. Because we are a small, lightweight mobile unit that is cloud connected, we are seeing a lot of traction from rural initiatives as well. I want to emphasize that while there are many use models clinically possible and deployed across the world, our US use models will stick to what is approved.

CEOCFO: *Is there any maintenance involved in the machine, any calibration? How do we know it is working every time it is being used?*

Mr. Jadcherla: That is a very insightful question! Let's start with what do ECG machines do? As the brain controls the heart, the heart is pumping and the blood is circulating, there are electrical surface potentials that are propagating across your body and coming to the skin. That is what the electrodes from the ECG are measuring. The reason you need to calibrate them is because the device is very sensitive to noise and has metal interference issues. If you wear metal, it can be very disruptive to the reading. For example, in the "old days" when we used to take photographs, the process was very sensitive to the film number, focal length, aperture, depth of field, you had to hold the camera steady and so on. You had to calibrate every photo, so to speak. And that was traditionally the issues with ECG in the past.

Mobile and digital work very differently. They work more like the cameras in your phone. There is no difference between a camera and a camcorder. It stabilizes the image automatically, and there is no need for red eye reduction. All that is gone with a digital camera. Our analogy for what we are doing for ECGs is also the same. We have removed a lot of those things. As part of the FDA process, we are also required to go through extensive UL testing and every unit goes through factory testing to calibrate before it ships out. Once it is in the field, we rarely ever run into an issue. We have been around for more than two and a half years now with about 150,000 patients and we've operated within extreme conditions.

Moreover, we are designed to be in the field. We have been in 50 degree Celsius heat in Saudi Arabia and -20 degrees Celsius in the Himalayas. We've been used in motorcycle ambulances and have been through extensive, harsh conditions, so that is how we have calibrated the device. One of the core technologies of the company is active noise cancellation. We kind of sense what is going on in the body, what is going on in the environment and ambulance and cancel the noise out. That is how we can generate a great signal each time. Finally, how do we know it is a great, reliable signal? How can you bet someone's life on it? I would say we have been through at least thirty clinical trials in different parts of the world for various things, for various modes of operation. Even in ICUs, we have been tried out in ICUs very successfully.

CEOCFO: *What have you learned as the iMedrix device has been in use?*

Mr. Jadcherla: In the technology world, we expect everything to march at the pace of Moore's Law with rapid scaling. The healthcare world moves at a much slower, methodical pace.

Our team has learned that in people's lives, healthcare is an essential thing, but many people do not pay attention and when you intercept them early and you can give them quantitative evidence about what is happening to their own body, they actually tend to pay a lot more attention!

One of the things that we have delivered to people is a process that is much more efficient in time, cost and effort for the patient and the physician. This has actually prompted a lot more people to be compliant to their healthcare protocols. That is one of those behavioral revolutions or transformations I think we have accomplished. That again, is a little bit of a pleasant surprise for me.

Something we knew and has been confirmed along the way is that in general, the Asian markets are moving much faster on mobile and digital health, partly because they do not have an incumbent system to intercept.

