



Merging Traditional Medical Devices with the mHealth, eHealth and Digital Health Industries, AliveCor, Inc. is Launching a Product that Turns an iPhone into a Medical Quality Heart Monitor, Electrocardiogram Monitor and ECG Monitor for Anywhere, Anytime Diagnosis of Potentially Serious Cardiac Problems

**Healthcare
Mobile Heart Monitor**

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**Dr. Dave Albert.
Chief Medical Officer**

BIO: David E. Albert, MD is an Oklahoma native. He is a physician, inventor and serial entrepreneur who has developed medical and other life-saving technologies and products over the last 30 years, turning a number of those innovations into tech startups. Today, he is the Chief Medical Officer and co-founder of AliveCor, Inc., and founder of InnovAlarm, and Lifetone Technology. His previous startups include Corazonix Corp (sold to Arrhythmia Research Technology and Data Critical (sold to GE). Dr. Albert

left GE in 2004 as Chief Scientist of GE Cardiology to disrupt several new markets. His latest invention, the iPhone ECG, became a global sensation via a 4-minute YouTube Video in January around the Consumer Electronics Show and was featured on local media, ABC, CBS, CNN and Fox News among many other media outlets. Dr. Albert has 32 issued US patents, a large number pending and several new "secret inventions" in development. He has authored or co-authored over 50 scientific abstracts and publications principally in the Cardiology literature. Also, Dr. Albert has lectured at the Entrepreneurship programs at the MIT Sloan School and the University of Oklahoma. Dr. Albert graduated with Honors from Harvard College and from Duke University Medical School. Dr. Albert lives in Oklahoma City with his wife and his two "young kids". The Albert's two other children are a recent graduate from Duke and a Clinical Research Associate with AliveCor.

About AliveCor, Inc.:

AliveCor, Inc., a privately held company headquartered in San Francisco, CA, wants everyone to have their health at their fingertips. That's why they make the vital health signs of people (and animals) around the globe easily visible and actionable, at exceptionally low cost. This improves everything from public health to the lives and possibilities of people all over the world.

**Interview conducted by:
Lynn Fosse, Senior Editor**

CEOCFO: Dr. Albert, what is the vision and focus at AliveCor?

Dr. Albert: AliveCor operates in a completely new area. Today we have traditional medical device companies and an industry that has a long-standing history. The US is a leader in that industry with companies like Medtronic and GE and so on, and then the new mobile health, mHealth, eHealth, digital health industry, which has been pioneered by companies such as FitBit and Withings with tools and apps and smartphone related devices to help people live healthier lives. AliveCor really merged these two areas; traditional medical devices and the new mHealth industry, the nascent mHealth industry and has developed and is launching a product that turns an iPhone into a medical quality heart monitor; electrocardiogram monitor, ECG monitor. It enables anywhere, anytime diagnosis of potentially serious cardiac problems. We are at this junction where we are acting as a pioneer, bringing traditional medical technology into the new smart phone generated economy. Therefore, we do have an app and we do have an iPhone device that acts like a case. However, those have also been put through both the FDA clearance process as well as the international CE-mark conformity process. That is where we are. The vision is to save lives in a very cost effective manner.

CEOCFO: How does the device work?

Dr. Albert: The device combines an iPhone 4 or 4S, and very soon an iPhone 5 and later in the year Android

phones; we snap on a case, like a traditional iPhone case, except ours has embedded electronics and two metallic sensors on the back. Once you download the free corresponding AliveECG app, available from the app store, it enables a person or patient to hold the device in two hands with one hand touching each of the two electrodes, and displays and records their EKG on the screen on the smartphone for analysis. Once they are finished after thirty seconds or a minute (you can set the recording length from as short as 30 seconds to as long as continuous) it uploads to the Cloud and enables it to be further processed and analyzed and reviewed by a cardiologist, literally within seconds, anywhere in the world. Therefore, it brings remote diagnosis of any kind of heart rhythm abnormality now as a real possibility. The limits of distance and time are removed and it does so at an extremely low cost, depending on the features, anywhere from ninety nine to one hundred and ninety nine dollars, at a price that, quite frankly, unprecedented in medical device type products.

CEOCFO: How does the accuracy compare with the traditional model?
Dr. Albert: I am glad that

you asked! On my last job I was the chief scientist at GE Cardiology, the leading cardiology company in the world. In 2012, we had clinical studies and presented papers on which I was the co-author at the American College of Cardiology. The first author was Dr. Leslie Saxon, the Chief of Cardiology at USC Medical Center and one of the most prominent cardiologists in the country, and that was talking about the usability, accuracy and the clinical validity. Then two months later in May we presented a paper I was co-author on at the Heart Rhythm Society, which was here in San Francisco, and that comparing the recordings of our device with the identical ECG lead recordings from GE's top of the line ECG machine. We showed, essentially identical recordings, with ex-

tremely high correlation showing that basically, they were clinically identical. That was published in May. Then in November I was co-author on a paper published at the American Heart Association Annual Scientific Sessions in LA with an investigator from Australia Professor of Cardiology, showing that we could automatically diagnose the most prevalent cardiac rhythm problem, which is called atrial fibrillation, in extremely high accuracy in just thirty seconds with our device. That is really addressing a major global public health problem. It represents a real breakthrough. Therefore, we got significant clinical validation. We had these studies done before we submitted our 510(k) application. We got through

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the 510(k) process and got our clearance in seventy-five days; fifteen days sooner than the ninety days that the law prescribes. We have done a lot of homework; months and months and months of validation and testing and that enabled us to, not necessarily “sail” through the FDA, but go through the FDA with a minimum of questions. It is a clinical quality device despite its cost.

CEOCFO: Do you envision a time when that would be the only way that it is done, even in a doctor's office?

Dr. Albert: I do not think that it will be the only way. I do not think it will supplant, in many situations, what we call a twelve lead ECG. However, it enables us to have that information available in many places where, to-

day, it is simply not available. Such as the scene of an accident, out in a rural area, someplace in rural China or India or in a primary care office where a physician does not have a traditional machine or in a home health environment. It brings ECG rhythm diagnosis, and if your ECG rhythm is a problem then you have real problems. It brings that capability and the remote expertise diagnostic capability to places where it has never existed before. And again, it does so at an extremely low cost.

CEOCFO: How are you going to be commercializing the product?

Dr. Albert: Last week we announced that we received 510(k) clearance from the FDA. We announced that we received CE-mark conformity clearance, so that we can sell in the twenty-four EU countries covered by the CE-mark. We had our first patent issued. We announced all of those at once at a wonderful review. We have a number of pre-orders already. We will begin shipping at the beginning of January. Today we have a number of different sales efforts. I am very confident that we will have channel partners around the world who understand their medical markets and their situations better than we

ever could, because our product is just as appropriate in India, China or Africa as it here in the United States or Western Europe. Therefore, I would tell you to go to AliveCor.com to buy it, but you may well have someone show up at your medical office. I would tell you that almost any channel that you can imagine, ultimately, in 2013 we should be direct, we should be through distribution and we will probably be in retail also, literally around the world.

CEOCFO: When you first show this to medical people do they believe? How do you get them to understand, in spite of the clearance and the research, that it really does it?

Dr. Albert: You are absolutely right. Physicians are, by nature, skeptics.

The good news is I have a lot of credibility. As I said, I have been in the cardiology area for twenty-five years and was chief scientist at GE Cardiology. I have academic medical friends who are premier cardiologists all over the world and I have been in this business for a long time. An old entrepreneur like me, and I will be fifty-eight at the end of this week, I have some credibility. However, the bottom line is that it is really the independent validation that proves the value of any technology and medical device. Do not listen to what I say – listen to what the science says. Therefore, that is why we had to focus on independent clinical validation from the beginning, to prove to people that this is not a toy; this is a real medical tool. We have people as prominent as Dr. Eric Topol, who for ten years was chief of cardiology at the Cleveland Clinic, the top cardiology program in the world, who is a huge advocate. He has never been paid; never received a dime. Just like Dr. Leslie Saxon. Those are two of the most prominent male and female cardiologists in the United States, neither of which have received a dime from us and both of which are serious advocates who have, by themselves, saved lives with our device. That is wonderful validation. Those are people at the pinnacle of the thought leader ladder. We are very appreciative of their support.

CEOCFO: Have there been attempts in the past to create such a device?

Dr. Albert: There has been and I was party to them. This idea started in 1997. I had an idea, I filed a patent, I received a patent, and I actually built a prototype using a 1997 personal digital assistant. However, at the time the technology could not make it good enough in quality, easy enough to use, the wireless connectivity was not available, there was no Wi-Fi, there was no 3G, and we did not have smartphones at the time, that it was not a practical product. The idea was just as valid in 1997 as it was in 2011. However, in 2011 we have these incredibly powerful smartphones in all of our pockets and purses that have the power of what people would have considered twenty years ago to be a super computer or that are more pow-

erful than the computers that we had on our desk top ten years ago. We carry it in our pockets and they are connected to a global network of wireless networks. We have instant communication and that technology enables this idea to become a reality. An idea often times precedes the technology that enables it and this is an example of that.

CEOCFO: You mentioned retail; what kinds of people would be looking at this?

Dr. Albert: Here is an example. You go to your doctor and maybe you are on antihypertensive blood pressure medication and the doctor tells you to go to the drug store, buy a blood pressure monitor and write down your values so that the next time you come in he can see those. Or the doctor will say, “you are a diabetic, go to the drug store, get your glucometer, write down your values, I want you to prick your finger three times a day; morning, noon, night and I want you to keep track if those and bring them in.” And in the future the doctor will say, “You have got atrial fibrillation. You have got this heart problem. I want you to go to the drug store, buy the AliveCor Heart Monitor device and record your ECG every day and the next time you come in we can review them together.” However, they will already be in the medical records. They would have already been uploaded. Just as today you can buy a blood pressure monitor or a scale or a glucometer that automatically uploads through a smartphone into the medical record. With that part of it you will not have to write anything down in the future. With an ECG it would be hard to write it down anyway. This is just like a blood pressure device, accept your doctor will say “go buy one of these and record your ECG every night before you go to bed or every morning when you get up.” It is the evolution of being able to do testing that only used to be available in hospitals, then it was available in doctors’ offices, and now it will be available in your own home. Understand that the information is most valuable when you and your physician use it to guide your therapy. That is the appropriate use of it. Just like the blood pressure

devices are, just like the glucometers are.

CEOCFO: Where are you manufacturing? Are you able to ramp up for the anticipated business?

Dr. Albert: We are manufacturing tens of thousands of units where all of the smartphones are manufactured; in China right now. We said in the beginning that we are at this fusion junction between mobile health and traditional medical devices. We had to find a manufacturer who is both high quality and high volume. That is because we need to be able to make low cost devices and still meet all of the medical regulations. Therefore, the manufacturer that we are using meets all of the international medical regulations, has all of the approvals, and all of these numbered and lettered suites that you have to meet. We found such a manufacturer, we qualified a number of them and they are able to produce in volumes sufficient to meet our demand.

CEOCFO: What, if any, challenges are you anticipating, and how are you ready?

Dr. Albert: This is a brand new area. Therefore, predictions are difficult when there is not a predicate. You cannot say, “This is another EKG machine.” It is not. It is and it is not. One of the challenges is just getting the education and benefits out there, one of the things that you mentioned before; the right channels to get to the customers. Obviously, for different customers, getting to nurses might be a different channel than getting to emergency medical personnel, than getting to cardiologists, patients, and consumers. Those all might be different channels. Therefore, figuring out the appropriate channel for the appropriate market segment is one of our challenges at the moment.

CEOCFO: Will you be ramping up your personnel? Will you be hiring sales people directly or strictly through the channel system that you talked about?

Dr. Albert: The product sells for one hundred and ninety nine dollars. It is hard to rationalize a direct sales force. However, there are a number of or-

ganizations that already have sales forces that deliver a whole basket of products for which this could be a very smart addition to their product portfolio. I believe there are potential distribution partners that can help their customers, that help educate; but I suspect we will not be doing a direct sales force. Yes, we will be ramping up our hiring. We anticipate adding a significant number of people, if not doubling our people from our current thirty-five during 2013.

CEOCFO: Does AliveCor have the funds to do the roll out that you are anticipating?

Dr. Albert: We have been very fortunate over the last twelve to fourteen months. We have raised a little over thirteen to fourteen million dollars in series A and series B funding. Our investors, including Burrill and Company, Khosla Ventures, and Qualcomm Life, have given us tremendous support and are enthusiastic.

We have also been approached by a number of other entities; firms and individuals looking to see if we are looking for more money. At the moment we are not. However, I anticipate that if we hit our growth target that we will be raising additional funds. We will cross that river when we come to it. However, I am cautiously optimistic that if we hit our targets that we will be able to raise money at the appropriate valuation.

CEOCFO: Why should investors and people in the business community pay attention to AliveCor?

Dr. Albert: We are pioneers. We are at this junction of traditional medical devices and mobile health, fitness and wellness. The United States healthcare system is currently unsustainable. There is not anyone I have heard who has said it is economically sustainable in its current form, therefore we are going to have to change the Accountable Care Act. This is

simply the beginning, not the end of that change. Therefore, the ability to deliver what Americans have come to expect, which is the best, highest quality medical care at a new, disruptively low cost and keep people out of hospitals and do so appropriately. We will become an absolute necessity. I believe that there will be no "dumb phones" in five years. Therefore, whether you are a senior citizen or teenager, everyone will have a smartphone, and we will be a leader at AliveCor in delivering appropriate healthcare on a global basis through those phones that everyone will have in their pocket. That global opportunity, as well as the opportunity to be a part of the reengineering of the US healthcare system, represents an excellent investment opportunity.



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