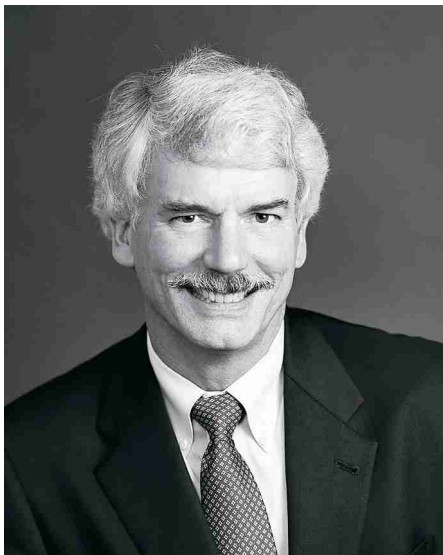


Bringing to market a revolutionary Low Cost, High Quality, Portable, Hand-Held ECG System for Sudden Cardiac Arrest, Cardea Associates Inc. is focused on Improving Cardiovascular Screening for Young Athletes

**Healthcare
Hand Held ECG Device**

**Cardea Associates Inc
855-800-0760
www.cardeascreen.com**



**David Hadley, PhD
President**

BIO:

David Hadley, PhD, is Co-Founder and President of Cardea Associates. Dr. Hadley has over 30 years of hands-on experience blending customer needs with information technology to deliver commercially successful products. He is experienced in developing business strategies and managing rapid growth, raising venture capital, acquisitions and the subsequent melding of diverse company cultures into dynamic teams. Over the past 14 years Dr. Hadley has focused on products and research in the area of diagnostic cardiology, initially recruited to rebuild the engineering team and

products for Quinton. Of his three previous ventures, two completed successful IPOs and the third was acquired. Dr. Hadley holds seven patents and completed a PhD in geophysics at Caltech.

About Cardea Associates Inc:

Sudden cardiac arrest (SCA) is the leading medical cause of death among sport participants and is often the first symptom of a cardiac condition. Current research shows that relative to the electrocardiogram (ECG), the traditional Pre-Participation Exam (PPE), consisting only of a physical exam and review of the patient and family history, has low sensitivity and high cost in detecting cardiac abnormalities.

CardeaScreen is a new portable, hand-held ECG device developed for screening young athletes' hearts. Its custom algorithms can help physicians quickly and accurately identify abnormal cardiac conditions that may lead to SCA or other quality of life limiting conditions, through high-quality ECGs and easy-to-use tools for over-reading and reporting.

CardeaScreen provides medical professionals with the diagnostic data that they need to help save lives. (Rx Only)

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

CEOCFO: Dr. Hadley, would you tell us about Cardea Associates?

Dr. Hadley: Cardea is a medical device company focused on improving

cardiovascular screening for young athletes.

CEOCFO: What have you figured out that others have not?

Dr. Hadley: The first major barrier for identifying youth at risk of SCA has been the high false positive rates of the current ECG devices. If the ECG device falsely indicates that the athlete has a cardiac issue, the follow-on additional diagnostic tests can be quite expensive. Historically, the false positive rates have been running at around ten to fifteen percent. Therefore, ten to fifteen percent of the athletes are identified incorrectly as having a problem when they do not. The needless psychological distress to the athlete and family is a further deterrent. A secondary barrier to wide use has been the cost of the ECG device, which typically starts in the \$3-5,000 range, and of the software tools for a doctor to review and over-read the ECG, which can add \$20-40,000 – well out of reach of most high school and college sports programs. Nonetheless, many European countries have adopted a standard that requires an ECG as part of the athlete PPE. Interestingly, a lot of recent research, quite a bit of it happening here at the University of Washington, is showing that the ECG is substantially more sensitive for identifying cardiovascular problems than the traditional physical exam and history of the patient and family. Therefore, the real challenges have been how to lower the false positive rates to an acceptable level and how to lower the cost of the device. These are the challenges we accepted when we incorporated Cardea. This has been our research focus for the

two years preceding incorporation and the past two years in active product development.

CEO CFO: Would you explain the difference between an EKG and an ECG?

Dr. Hadley: They are precisely the same thing. EKG simply stems from the German term “electrokardiogram”, but has exactly the same meaning.

CEO CFO: You have set about to change what is going on. Where are you in that process?

Dr. Hadley: To lower the false positive rates and remove the first barrier, we focused our initial research on the ECG criteria that would characterize an abnormal athletic heart. My business partner and colleague, Dr. Froelicher, led a team of cardiac specialists and published a consensus paper in one of the leading cardiology journals in May 2011 that proposed more appropriate diagnostic criteria. This work has continued with additional collaborative efforts lead by Dr. Drezner here at the University of Washington that further advanced the ECG criteria, now known as the “Seattle Criteria”. The new criteria have reduced false positive rates from about ten or fifteen percent to less than about three percent. We have managed to cut the false positive rates dramatically. I think with continued research we will be able to lower them even further. We attacked the second barrier, product hardware and software costs, through careful engineering and leveraging of high quality, low-price consumer technologies such as Bluetooth, thus dramatically lowering the cost of the specialized ECG electronics. The software engineering work has gone well and our system includes not only the ECG data acquisition and analysis technologies, but also the over-reading tools the doctor needs to finalize an interpretation. We are able to sell our complete system for \$1,495. So, with good solutions for lowering false positive rates, improved accuracy and low cost of goods in place, we filed with the FDA last summer and received our FDA clearance in February 2013. It is an exciting time for us.

We are just beginning our sales process and we are quite excited about how this is coming together.

CEO CFO: Why for young athletes rather than just doctors’ offices or regular people?

Dr. Hadley: Broadly speaking, cardiac conditions can be divided into plumbing and electrical problems – both can lead to serious complications and SCA. The ECG is primarily a tool for sensing electrical problem in the heart. The higher you drive your heart rate, in the presence of some conditions, the greater the risk that the electrical activity in the heart becomes disorganized and life threatening. Because of the impact of strenuous exercise on heart rate, young athletes have about three times higher risk than sedate individuals. Although everyone has high heart rate on occasions, the highest risk is to those with frequent high rates. From a cost-benefit basis, the

“We are bringing a revolutionary low cost and high quality ECG system to a previously ignored market segment with the objective of saving young lives.”

- David Hadley, PhD

most value is derived by starting with those at greatest risk. Hence our initial focus on young athletes.

CEO CFO: How have you judged the receptivity of the industry if they have shied away? How easy will it be to convince them that this is not going to give you that many false positives and that it is the way to go?

Dr. Hadley: In the U.S. this is very much an open question and I think research will ultimately lead us to broadly accepted answers. We are just finishing a study at the University of Washington and sponsored by the NCAA. We had CardeaScreen in fourteen NCAA Division I schools and collected ECGs on almost 2,500 athletes. Those are all being over-read by cardiologists. All athletes who had abnormal ECGs or abnormalities in their family history or physical exam are undergoing additional follow-up diagnostic testing (see: <http://www.amssm.org/News-Release-Article.php?NewsID=67>). This is the first of what will be a growing number

of research projects that will critically assess the benefit of adding the ECG to the pre-participation exam. I think it is this research that will lead us to the right answers. Some very interesting work has been done recently, looking at death rates by sport activity. For youth with fairly sedate lifestyles, the SCA rates are really quite low: one in 30-40,000. Other complications, such as obesity and high blood pressure, are a greater concern in these youth. However, we have also seen that the SCA rates among participants in some activities that drive the heart to high rates, such as basketball, are substantially higher. SCA rates are also influenced by ethnicity, which I do not think we fundamentally understand. On the extreme side, research is showing that African-American basketball athletes have about a one in 5,000 chance of sudden death per year of play. For a youth who plays four years of college ball, preceded by several years in high school, the risk of sudden death is less than one in a thousand. I think it is pretty hard to argue that those kids should not be more carefully screened.

CEO CFO: Are there organizations of student athletes’ parents? Is there a way to get to the parents to be in the driving portion of getting this done?

Dr. Hadley: Most definitely! There is a national umbrella organization called “Parent Heart Watch” (www.parentheartwatch.org) that is supported by many smaller organizations throughout the country that have been founded by parents who have lost a child to SCA, who are very proactive in trying to ensure that this does not happen to anyone else. Many of these groups have dedicated themselves to youth screening programs. There is one such group here in Seattle; I think it is probably one of the “gold standards” in the country for doing it well. A young athlete by the name of Nick died suddenly of hypertrophic cardiomyopathy, one of the more common causes of sudden death in youth. His mother started the “Nick-of-Time Foundation”. They do a screening program here in Seattle and once a month go to one of the many area high schools. They have a large

number of volunteers; EMTs, doctors and nurses from local hospitals - they all come together in the gym. The team does a brief physical, takes blood pressure and records an ECG. A doctor reviews these data and the student's medical history. If there is anything that is abnormal, the student immediately gets a mini-ultrasound (ECHO) exam. Those that cannot be cleared at this point are referred to their physician or Children's Hospital for follow-on assessment. We just did an event this week screening 382 kids and found an unusually high number of abnormalities. We found nine serious issues, which was shocking for all of us. More usually we find a couple that need some additional follow-up. One thing I should mention, that I think is very important, is that although the national focus is on sudden death in youth, cardiovascular disease is still the leading cause of death in adults in the US. We find that a couple percent of youth, although probably not at risk of sudden death, have real cardiovascular problems. They are going to be impacted by cardiovascular problems over the course of their lives. Therefore, early detection is an important and useful part of their health management.

CEO CFO: Development and certainly commercialization are always expensive. Are you funded for the next steps? Will you be looking for partnerships or funding to move forward?

Dr. Hadley: We are currently funded through angel investors. At the moment we are in good financial shape. I am hopeful that by summer we will

move to cash flow positive as our sales progress. As we expand into Europe and other areas it is quite likely that we will look for additional cash to fuel growth. There are also logical product extensions for this market. For example, some youth have a normal resting ECG as measured by our CardeaScreen, but have a history of unexplained loss of consciousness. There is a cardiac condition in which the build-up of adrenaline, and the associated increasing heart rate, lead to a flurry of ventricular beats and eventual ventricular fibrillation and SCA. Extending the current software for analysis of the ECG during exercise could be very helpful for follow-on assessments.

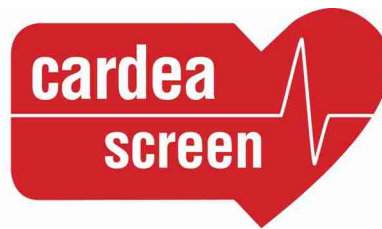
CEO CFO: Are you encouraged with the general atmosphere in the government influence in lowering costs? Cost seems to be much more important than it ever was.

Dr. Hadley: I also sit on the Board of Trustees for a major hospital here in Seattle and see healthcare from the executive management side as well as from the device manufacturer perspective. I think there are a lot of dollars that can be taken out of healthcare and it is appropriate that we focus on doing that. Lowering the cost of delivering care will take major changes across a broad range of areas. Lowering reimbursement certainly is a driver for change, but real change will require many complex realignments of values and political stances. We have just gone through the FDA review process for a device that has a long history of use in the industry and very low risk of patient

harm. Our submission, and responses for additional information, totaled 3,000 pages and took seven months. Regulatory oversight is very important, but it is also extremely expensive and is a nearly prohibitive barrier for small entrepreneurial start-up companies with bright ideas on how to lower the cost of care.

CEO CFO: Why should investors and people in the business community pay attention to Cardea Associates? What makes you an exceptional company?

Dr. Hadley: We are a start-up company trying to break a paradigm and save young lives. There are some doctors strongly opposed to adding the ECG to the pre-participation exam. But the research that we're supporting, and the discoveries that are being made would not have happened if we had followed the conventional wisdom of many in the industry, that it is not worth doing. The research is clearly showing that the ECG has substantial value, and I believe the US will eventually follow the Europeans in this area. We are bringing a revolutionary low cost and high quality ECG system to a previously ignored market segment with the objective of saving young lives. As we grow this segment, and reach critical mass, there is the opportunity for us to expand into the more traditional segments and capture market share from some of the larger vendors – particularly in the primary care setting. With the national focus on medical costs, and our exceptionally low COGS, there is an opportunity for us. It is an exciting time!



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