



ceocfointerviews.com
All rights reserved!
Issue: September 1, 2014



AUM Cardiovascular

The Most Powerful Name in Corporate News

Non-Invasive Handheld Device for Obstructive Coronary Artery Disease Detection

About AUM Cardiovascular, Inc.

In 2002, Marie Johnson was a PhD student working with 3M scientists to develop a computerized stethoscope when her husband died suddenly at age 41. Guion's cause of death was a shock to Johnson: The 6-foot, 2-inch 180-pound man she considered in "perfect condition" was felled by a heart attack. An autopsy showed that several of Guion's coronary arteries were significantly blocked, including the ultimate cause of his death: a ruptured plaque in the LAD (left anterior descending) vessel, which supplies blood to the heavy real estate of the heart.

Coincidentally (or not), Johnson had gathered data about her husband's heart months before his death by using a prototype she was developing as part of her Ph.D. degree thesis work. She decided to apply the principles of frequency analysis coupled with statistics to create an acoustic device to identify blockage in the coronary arteries.

Interview with: Marie Johnson, CEO

Conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

CEOCFO: Dr. Johnson, what is the concept at AUM Cardiovascular?

Dr. Johnson: The team at AUM is on the cusp of commercializing a fast, inexpensive, non-invasive, handheld device for detection of obstructive coronary artery disease.

CEOCFO: How does that differ from what is currently available?

Dr. Johnson: The CADence Handheld collects eight minutes of data directly from the patient's chest. The patient is in supine position and lying quietly. Data is processed on a cloud-based server and a final report is returned to a doctor via email. Right now CADence is in its FDA pivotal study to prove that non-inferiority to nuclear stress test. A nuclear stress test costs approximately \$1,000, requires a specialized test facility, radiation, and exercise/pharmaceuticals. The value proposition is very clear for our device. We are low cost, non-invasive, fast and easy-to-use test with immediate results.

CEOCFO: Would you explain how the device works, what information you are collecting and how you are able to do so?

Dr. Johnson: CADence collects the acoustic signal associated with turbulence caused by coronary blockage. This is not a new idea. It was actually described in 1967 by a doctor named Dock. He did a case study on a patient who presented with moderate to severe coronary disease and a heart murmur which could be heard with a stethoscope at the third left intercostals space. A number of other doctors have described the same phenomena.

CEOCFO: You said this concept was known years ago. What has been the barrier?

Dr. Johnson: Let me just add one more thing. A group of engineers worked on this technology in the 1990s. They applied advanced statistical methods and microphones. My opinion is at that time, the fidelity of sensors and computing capacity could not deliver what they needed to reliably do the assessment. In 2006 my colleagues and I published an abstract in the journal Circulation where we utilized a stethoscope with reliable sensors and advanced signal processing techniques. The barrier for us was characterizing all of the major coronary vessels. The characterization was challenging and took five years.

CEOCFO: Do you envision a day in the future that this will be part of a routine exam for everyone to have early detection?

Dr. Johnson: At this point, we are only indicated for patients who have chest pain and two or more coronary risk factors. The American Heart Association and the American College of Cardiology indicate that it is not

good clinical practice to broadly screen people for coronary disease. At this point, we are in line with that ideology.

CEO CFO: *Where are you in the process of development, testing and commercialization?*

Dr. Johnson: Right now we have submitted for CE Mark. Pending this regulatory approval, we plan to start selling in Germany. Hopefully this is as early as Q4 of this year. This is very exciting for us. In the United States, we are in the middle of a very large clinical study proving that we are not inferior to a nuclear stress test. This is about a seven hundred patient study. We hope to be done with the study by Q1 2015. At that time we will submit to FDA. Pending FDA approval, we should be on the American Market by the first quarter of 2016.

CEO CFO: *Why is Germany first in Europe?*

Dr. Johnson: Coronary disease afflicts as many Germans as Americans. We think that we can make a big impact.

“Heart disease afflicts one third of Americans and is quickly becoming the #1 killer across the globe. AUM is a company passionate and dedicated to addressing the detection of heart disease in all demographics. CADence is low-cost, fast device that doesn’t make the patient sicker during diagnosis. CADence is a game-changer.” - Marie Johnson

CEO CFO: *What has been the reception from the medical community so far? Are people that should know what you doing aware?*

Dr. Johnson: Out of all the obstacles that we have had to overcome, proving to physicians that the technology works is the toughest. I agree that it seems unbelievable that acoustics are as good as a nuclear stress testing. Think about it; nuclear stress tests require radiation, exercise, and specialized interpretation by a highly trained cardiologist. We are claiming that we can do the same thing within twenty minutes. In the hands of a cardiologist CADence is game changing.

A highly respected scientific advisory board assists in addressing the clinical and scientific questions from the clinical community. We do recognize that larger clinical studies, more patients and broader populations will be required to become a part of the clinical practice guidelines.

CEO CFO: *Do you see the overall atmosphere of cutting costs as being particularly helpful for you?*

Dr. Johnson: Absolutely. The CADence will reduce cost from the system.

CEO CFO: *Do you anticipate patients who have had a nuclear stress test several times being reluctant or receptive?*

Dr. Johnson: We are discovering patients would prefer CADence over nuclear stress test.

CEO CFO: *Are you funded for the next steps you would like to take?*

Dr. Johnson: We are fund raising for the company’s next step, commercialization of CADence.

CEO CFO: *What is the investment community interest these days in this type of a product?*

Dr. Johnson: We have worked with individuals who have the vision for the potential of the device. We have been able to raise enough money to get us to this point.

CEO CFO: *What surprised you as you have working on the product and developed it? What have you learned along the way?*

Dr. Johnson: My surprise is the record-keeping requirements for medical devices. It takes a ton of time and manpower to adhere to requirements. I am happy to say that we are ISO 13485 certified and have proven that we maintain a great quality system.

CEO CFO: *What is the business model?*

Dr. Johnson: We have the razor/razor blade business model. We have a booklet that is a per patient use. This booklet is tied to the test report. The handheld device is the razor.

CEO CFO: *Why does AUM Cardiovascular stand out?*

Dr. Johnson: Heart disease afflicts one third of Americans and is quickly becoming the #1 killer across the globe. AUM is a company passionate and dedicated to addressing the detection of heart disease in all demographics. CADence is low-cost, fast device that doesn't make the patient sicker during diagnosis. CADence is a game-changer.

BIO: Based in Minnesota, but with ties around the globe, Dr. Johnson and the AUM team are developing a truly game-changing wireless diagnostic device that will quickly, easily and more affordably detect coronary obstructive blockage in patients with chest pain and risk factors.

She has (25) years experience in product development and manufacturing in both Fortune 500 companies and university environments in engineering and management positions. Prior to founding AUM Cardiovascular, she created and led the University of Minnesota Medical Device Innovation Fellowship, modeled after the Stanford biodesign program. Over her tenure she trained two classes of post-doctoral engineers and medical doctors who created multiple clinical solutions and two start-up companies in the medical device realm. The core values of this fellowship incorporate not only technology and clinical aspects but also insurance reimbursement, FDA regulatory, intellectual property, marketing and sales.

Dr. Johnson holds a BS in Mechanical Engineering, a MS and PhD in Biomedical Engineering and has completed three post-doctoral fellowships. Dr. Johnson has patents and patents pending in the United States, Europe, China, India and Taiwan in a broad range of disciplines including orthopedic, cardiovascular, ob/gyn, automotive and food safety. Dr. Johnson holds an adjunct faculty position and is the medical device emphasis advisor in Biomedical Engineering department at the University of Minnesota.



AUM Cardiovascular

AUM Cardiovascular, Inc.

6575 145TH St E

Northfield, Minnesota 55057-4617

507-456-4782

aumcardio.com