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Developing Transformative, Intelligent Medical Health Systems

Martin Burns - *CEO*

Founded in 2009 by licensing technology from UCLA, BBI leverages the groundbreaking research conducted at the UCLA Wireless Health Institute, UCLA David Geffen School of Medicine, UCLA School of Nursing, and the UCLA Henry Samueli School of Engineering and Applied Science.

Innovation at BBI is realized through the collaboration of R&D and clinical teams, where every team member is an expert in his or her respective field. BBI applies rigorous scientific, technical and clinical standards to drive product development and address unmet and urgent clinical needs.

BBI's pipeline is comprised of solutions for wound care, orthopedic care and real-time data capture, analytics and reporting. All BBI devices are handheld and portable. Leveraging BBI's passive sensor technology, BBI devices produce actionable data for evidence-based assessments.

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

CEOCFO: ***Mr. Burns, what is Bruin Biometrics?***
Mr. Burns: Bruin Biometrics develops transformative intelligent medical health systems; biometric sensor based medical devices, biometric databanks and data enabled care programs. We are based in Los Angeles and were founded in 2009. We are a fully independent company. However we collaborate with UCLA to perform technology concept development, clinical studies and healthcare services analysis with a number of UCLA schools including the David Geffen School of Medicine, the School of Nursing, the Fielding School of Public Heath, the Anderson School of Management, the Henry Samueli School of Engineering and Applied Science, and the Wireless Health Institute. We develop biometric sensing devices, and we view the body not just as a biological organism but also as a physical mechanism. Our biometric sensing devices detect physical and biomechanical conditions in the body. Why biometric sensors? Because they provide really good clinical data, relatively safely, inexpensively and immediately. Biometric sensors are also used continuously, so we can incorporate them in virtually any professional clinical care setting.

CEOCFO: ***Would you give us an example of what you are working illustrating the way the applications work?***
Mr. Burns: We are currently working on two devices. One has already been approved for sale in Europe; it is called the SEM Scanner™ (Sub Epidural Moisture Scanner). The intent of the device is to provide care practitioners a tool that picks up changes in tissue moisture, which is associated with inflammation and an indication of tissue damage. The first type of damage that we are trying to detect is that of a pressure ulcer, commonly known as a bedsore. Christopher Reeves, for example, sadly died of a pressure ulcer. We developed this product in conjunction with Barbara Bates-Jensen, Ph.D., RN, FAAN, a leading researcher in wound care at UCLA. The SEM Scanner™ aims to detect pressure ulcer formation before practitioners can see the damage at the skin's surface. Our guiding principle here is that with early detection of tissue damage, we can enable practitioners to intervene with existing prevention techniques to decrease the severity of an ulcer. The SEM Scanner™ enables clinicians to move beyond the paradigm in treatment which currently exists – merely treating ulcers – to preventing them. BBI is working to address the void in current healthcare practices to enable clinicians to prevent the worst instances of pressure ulcers.

CEOCFO: ***Would you tell us more about the device and would the patient be using it or the doctor?***
Mr. Burns: No, the patient would not be using it; the SEM Scanner™ is used by nurses or other clinically trained technicians. It scans the anatomical sites on the patient most likely to give develop a pressure ulcer. The device takes a measurement of subepidermal moisture in an area. By tracking changes in the subepidermal moisture over time, the SEM Scanner™ provides an indication of inflammation associated with tissue damage.

CEOCFO: *Are there any methods now that are predictive?*
Mr. Burns: It is a breakthrough technology. In fact, clinicians who used the SEM Scanner™ in our clinical studies actually came up with a powerful phrase: they thought that the SEM Scanner™ reading was the "sixth vital sign" (after body temperature, pulse rate, blood pressure, and respiratory rate). I thought that was just an insightful way of looking at it. The current standard of care is visual inspection of skin together with a series of risk analysis paper and pencil tools; literally a questionnaire and those have been shown to be inadequate and not as effective as an evidence-based measure, like the SEM Scanner™, for example. So there is no other standard other than visual inspections together with these risk questionnaires. What we are trying to do now is provide nurses and clinicians with a device that gives them real evidence about subepidermal moisture buildup which can act as another data point in their assessment of wound development.

CEOCFO: *Would you tell us about the wound management market opportunity?*
Mr. Burns: Pressure ulcers cost the US health care system approximately $5 billlion/year. The market opportunity is extremely large. The current wound management market is mostly focused on therapy, such as gels, bandages, dressings and other therapies. There are a number of therapeutic devices, including vacuum dressings for negative pressure wound therapy, which are used on wounds and diabetic foot ulcers. The prevention market is actually relatively undeveloped. We have divided the market that we are seeing for the SEM Scanner™ into three tiers of territories around the world, the first tier being countries that are suffering from chronic pressure ulcer prevalence and where the policy environment has shifted to care quality. We see the total available market for SEM Scanner sale in that first tier as being approximately $2 billion. In total, the wound-care market is tens of billions of dollars and growing.

"In fact, clinicians who used the SEM ScannerTM in our clinical studies actually came up with a powerful phrase: they thought that the SEM ScannerTM reading was the 'sixth vital sign'… BBI provides immediate technology solutions to chronic medical conditions."– Martin Burns

CEOCFO: *Now that you have the CE mark what are your plans in Europe for this device?*
Mr. Burns: We have only just started selling the device in Europe, but we are moving forward aggressively. We launched at the 2013 Medica show, which is the world's biggest medical device conference. We received our first orders already, and are currently in discussions with a number of distributors to sell the device. Our goal is to deploy the SEM Scanner™ in every care setting to every nurse practitioner responsible for patient care. The attractive aspect about Europe for this particular device is that there is a real focus on improving the quality of healthcare services. High pressure ulcer prevalence is seen as an indicator of low healthcare quality; the problem is extremely well-known by policy makers. Last month (November 2013), the United Kingdom's National Health Service said it plans to hire five thousand nurses to focus on improving healthcare quality. In the United States, the Center for Medicare and Medicaid Services (CMS) has classified stage III and IV pressure ulcers as 'never' events; in other words, formation of a pressure ulcer is something that should never occur within a healthcare setting. Pressure ulcers are also extremely expensive; the Joint Commission estimates that the United States spends $15 billion a year on pressure ulcer care, and sixty thousand people die each year because of complications associated with pressure ulcers.

CEOCFO: *Where does this stand in the US?*
Mr. Burns: We are targeting an early 2014 submission to the FDA. We will then go through the approval process with the FDA. We expect selling the SEM Scanner™ in the United States in 2014 pending FDA approval.

CEOCFO: *What is the plan for marketing in the US?*
Mr. Burns: We will not utilize direct sales; all sales will be through distributors. The other type of partnership that we are currently pursuing is with the very large wound-care companies that both have a distributor sales force and internal sales channel, but also have a strategic interest in the prevention market we are pursuing. We are engaged in conversations with both of those groups.

CEOCFO: *What else are you working on at Bruin?*
Mr. Burns: Our common theme is biometric sensing and the information it can provide. Our aim is to put the power of biometric sensing in the hands of every caregiver. We call our second product OrthoSonos™, and it is very exciting. I came across the idea for this product when I was eight years old living in Northern Ireland and heard about an orthopedic surgeon who was implanting artificial knee caps into patients who had been "knee-capped", in other words had had their knee caps shot out by the IRA. He was trying to understand why some of those implants were working well and some of them were not. He was using technology from the aeronautics industry, acoustic emission sensing, to work out what was going on with the joints. He got some insight, but it was pretty basic at that point; he was listening for clicks, clunks and scrapes if you can believe it. His device had some severe data processing issues and some size constraints. BBI has solved these engineering, data processing and classification problems. We have taken the technology of acoustic

emission sensing and developed a spectacular device and "listens" to the structural integrity of joints. The first set of joints we are looking at are knee and hip joints. Why those? Simply because many people experience problems with artificial joints. I'm sure you have seen the reports about prosthetic implant recalls by FDA and other regulatory bodies around the world. This means that patients who have already had a replacement surgery have to go back to their surgeons, the surgeons then have to do an analysis of the joint's health using the current tools available to them -- physical exams, x-ray, radiological scanning and blood-testing – and then the physicians have to make a determination as to whether that joint is actually working properly or not. With the OrthoSonos™, BBI is providing the physician an additional data point and assessment tool: an acoustic emission which is indicative of the joint's structural integrity. We view joint failure as a physics problem and not just a biology problem. Our OrthoSonos™ device can really help patients, physicians and manufacturers have a better understanding of the health of their prosthetic implant, especially while it is in the patient's body and being actively used.

CEOCFO: ***Where are you in the development process with OrthoSonos™?***
Mr. Burns: We have been developing this device over the last eighteen months. We expect to announce it more broadly and reveal it at the American Academy of Orthopedic Surgeons in March. We are compiling our FDA and CE submissions currently. In fact, I met with the FDA on Monday about this exact product. We expect to file those regulatory approvals in the middle of 2014 and start selling in Europe first and then in the US after FDA approval.

CEOCFO: ***Are you funded for all the steps as the products rollout?***
Mr. Burns: We actually just closed our latest funding round for $10 Million. We are funded by high net-worth individuals and one or two smaller institutional investors. We actually got modestly more funding than we anticipated in this round. In 2014 we will start generating revenue with the SEM Scanner™, and then we will start a second round of funding next year. That will allow us to accelerate the development of the OrthoSonos™ acoustic emissions platform, as well as to accelerate the development of another wound-care product that we have in the R&D phase at the moment.

CEOCFO: ***What have you learned from previous endeavors that you find helpful at Bruin?***
Mr. Burns: Good question! I will be bold and give you two answers. The first is that I came from consulting to the medical device industry. The dynamic that is overriding in the medical device industry is that it is a regulated business. The rules of R&D, market launch and marketing are different in a regulated industry. We aim to be compliant with all of those regulations; it is something that we take incredibly seriously, and the importance of this fact is a big lesson I take from the previous work I have done. The second lesson, which is probably more interesting for your readers, is that I have become a student of "systems thinking." I see systems as large, dispersed organizations in which we all operate on a daily basis. In my previous role, I actually studied a fairly large system, which is the financial services system, for a particular project. What is amazing is that the healthcare system is also very similar. Think about the pressure ulcer problem – why do they develop, particularly when CMS, wound-care academics, and commissions around the world say that the vast majority of pressure ulcers should never occur and are perfectly avoidable? Why is it that in Florida you have an incidence rate of 12% and the same incidence rate exists in Seattle or Los Angeles or the UK or Germany when they are totally disconnected? When one thinks about it, the physicians, the patients, administrators and care protocols are all different, but the outcome is exactly the same. There are obvious themes in patient characteristics, but what is more important is the systems part – that all healthcare practitioners operate within an economic and policy environment and with limited knowledge about what is happening with a patient's tissue. They may try hard to operate with a focus on quality, but are hindered in their ability to be able to execute on that quality the way they may wish to. What you end up with are these amazing dynamics that produce negative health outcomes that are all the result of the setup of the system. My previous role working and studying financial services systems has been incredibly helpful because I think that the pressure ulcer problem is a result of systemic failures that should never happen and can be improved.

CEOCFO: ***How do you decide areas of focus?***
Mr. Burns: Two things fundamentally. First, we focus on biometrics sensing so our aim is to get biometric sensors into the hands of every caregiver in the world. Why? Because they provide great data capable of making evidence-based healthcare possible. So when we are evaluating at technologies, they have to be biometric sensing based technologies. Second, we are seeking to address the most chronic healthcare problems hat we can solve with biometric sensors. That is something we have learned from AL Mann, who is a pioneer in this area of medical devices; a real leader. He always said do not start with technology and try to find the solution for it, rather start with the problem and find the technology that can solve it. And this is what we do.

CEOCFO: ***Why pay attention to Bruin Biometrics?***
Mr. Burns: BBI develops innovative systems devices, and we build healthcare programs around the chronic problems that the healthcare industry trying to solve. Frankly, BBI is a pipeline of innovation. It is hard to innovate in this industry – it is expensive and it takes time. There is a graveyard of medical device companies out there that got it wrong and, so far, we are getting it right. We are providing novel solutions to chronic problems. BBI provides immediate technology solutions to chronic medical conditions, and that is very compelling.

BIO: Martin spent more than 15 years as a management consultant in the US and Europe at Deloitte Consulting and PricewaterhouseCoopers. During the past 6 years, Martin led corporate strategy, innovation, operations, quality and regulatory, M&A and global expansion assignments for medical device and life sciences companies.

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