

THE WALL STREET TRANSCRIPT

Questioning Market Leaders For Long Term Investors

Healionics Corporation



ROBERT BROWN, President, CEO and a Director of Healionics Corporation, possesses a unique understanding of the technical development, and the financial and business requirements necessary for companies to succeed. He has over 14 years of experience in technology companies, primarily in management roles, including over nine years at Microsoft. Mr. Brown has helped lead companies to success in all phases of product development from concept through design, production and launch. He received his Bachelor of Science degree in Management from BYU and an MBA from the University of Washington.

TWST: Please start with a short history and overview of your company.

Mr. Brown: Healionics is a biomaterials company, meaning that we supply medical device manufacturers with the materials they need to make their devices more compatible with the body. Our primary technology, known as STAR material, was created at the University of Washington over a period of about nine years using \$30 million of NIH federal grant funds under the direction of Dr. Buddy Ratner, a luminary in the field of tissue engineering. I first encountered STAR Material in 2006, and by March 2007 I was so impressed with the technology and its potential that I left Microsoft to start Healionics together with Max Maginness, our Chief Technology Officer. This biomaterial has such a vast array of potential applications that we've been referring to it as the "Gore-Tex™ of biomaterials."

TWST: What is the science behind the concept?

Mr. Brown: It's quite amazing actually. At a high level, it's simple to understand, yet the science behind the concept has evaded some of the brightest minds in this field and taken years to refine. STAR material is a synthetic, three-dimensional scaffold similar in many ways to a sponge. The key to this scaffold is that the pores are interconnected and have a consistent size and geometry throughout.

The "ah ha" moment for this technology came when Dr. Ratner and his fellow researchers found that by tuning the size of the pore to be equivalent to the size of a cell (about 35 microns) they saw a dramatic increase in the amount of tissue ingrowth. In addition, they found this tissue was vascularized. In effect, this synthetic scaffold promotes the growth of living tissue. As you can imagine, the potential applications for STAR material are vast.

TWST: What does STAR stand for?

Mr. Brown: Sphere-Templated Angiogenic Regenerative material.

TWST: What are the applications that you believe you will be able to enable with STAR material?

Mr. Brown: At a very high level, anything you want to put into the body that needs to interact with the body for an extended period of time will benefit from the material. For example, the body has a natural defense system called the Foreign Body Response that tries to protect the body from any foreign object inserted or implanted. The body doesn't know the difference between a sensor and a bullet, so it surrounds and isolates the device with a thick fibrous shell known as the Foreign Body Response. As a result, any type of sensor or other implanted device that needs to interact with the body

will fail between three to seven days. Wrapping the device with STAR material can potentially lengthen that period to the equal of the functional life of the device; from three days to three months, six months, even a year or longer. This opens the door to a new generation of devices. In addition to devices, STAR Material can be used to enhance applications in other areas such as wound healing, cosmetics and so on.

TWST: What is your current focus as far as the applications? Has this been tested on humans?

Mr. Brown: Currently this material has been tested in mice, rats, rabbits and dogs and human foreskin. In 2008 we have several more large animal trials planned both by ourselves and through our partners. One partnership in particular has plans for human trials in the latter half of the year. However, rather than wait for FDA approval in the human market, we're currently exploring opportunities in the veterinary market. Our first partnership, in fact, is to treat glaucoma in dogs. Trials have been underway for five months and the results have been impressive. There is no other long-term solution for canine glaucoma, so this is a great potential market we can address quickly. In addition, we have give other research agreements signed that we're currently working on, for a total of six, ranging from dog glaucoma to implantable glucose sensors.

TWST: Which one of them is the farthest along?

Mr. Brown: The applications that are closest to market are the veterinary applications. The one application I just mentioned, the dog glaucoma application, consists of a material implanted into the eye to wick the moisture out of the chambers of the eye and help reduce the intraocular pressure. As I mentioned, trials are going very well and the product could potentially be on the market by the end of the year.

TWST: What is the market potential?

Mr. Brown: There are about 10,000 surgeries to treat glaucoma in dogs performed every year. Again, because there is no good treatment right now, we expect this to grow from 10,000 and steadily increase. Studies have found that in canines with glaucoma in one eye, the condition usually develops in the second eye within 12 to 18 months, so the trend is to have both eyes treated at the same time.

TWST: What about your other partnerships? When do you expect to start human clinical trials?

Mr. Brown: We currently have one partnership, which will allow us to begin human trials, projected right now in the latter half of 2008. For the other partnerships we're projecting 2009 and 2010.

TWST: How different is the path to FDA clearance with your tissue regeneration as opposed to a therapeutic drug?

Mr. Brown: Actually, it's a much different path. We are considered a device rather than a drug so trials are not quite as intensive. Most of our early applications are focused on improving existing devices. In that case, we expect to fall under the 510K approval process, which is significantly shorter than a pre-market approval process through the FDA. Using the FDA's own statistics,

approximately 80% of 510K submissions are decided within 90 days of application, so most of our efforts will be targeted toward gathering the data necessary for that process. There is also a benefit here as the data from the trials from one application can be used for future applications.

TWST: What are the applications that you would be targeting with these partnerships?

Mr. Brown: As I mentioned previously, a very attractive market is the implantable glucose sensor. Currently diabetics have to stick their fingers several times a day to monitor their glucose levels. An implantable glucose sensor would continuously monitor levels and transmit to an external device, eliminating the need for finger pricks. STAR material would cover that device and reduce or prevent the Foreign Body Response, enabling the device to continue monitoring up to the functional life of the device. Imagine, diabetics changing from a needle stick several times a day to potentially never. That's exciting and just one of the many potential applications.

TWST: Do you have the management team to achieve your goals?

Mr. Brown: Absolutely. We have an excellent management team consisting of a good combination of MBAs, and PhDs. All have entrepreneurial experience and have extensive experience both in large and small companies. Our Chief Technology Officer comes from 25 years at Siemens Medical, the Chief Operating Officer has over 10 years at Medisys as VP of Operations, in charge of opening and operating facilities in the US, Mexico, and Taiwan. Even our CFO has experience managing large teams at HP, giving him the ability to step outside the numbers.

TWST: What is your personal expertise? What occupies most of your time?

Mr. Brown: My personal expertise is actually in product development; that's where I've been for about the last 15 years or so, most recently at Microsoft for almost 10 years. As far as what occupies my time, primarily two things. The first is making sure that the company and the people have the resources they need to fully execute our plan. For that reason, I have been focused on fundraising and structuring partnerships for the last year. Focus is my other priority. As a startup, we cannot afford to be randomized or distracted, so I spend a lot of my time analyzing and evaluating which opportunities to pursue and which markets to target.

TWST: What are your financial plans to take you to FDA approval?

Mr. Brown: One of the benefits of our model is that we position ourselves as a materials supplier. We supply components to the device manufacturers for their devices, allowing them to do the required trials and take their device through FDA approval. That saves us a lot of cost. We will build what they call an FDA master file, so as additional devices are approved, they add to the file. Then, as future devices are submitted for approval, they will be referred back to that file, facilitating approval for that device. In many cases,

we'll be focusing on applications on the veterinary market, which has no FDA approval process, and in the human markets, existing devices, aiming for a more rapid 510K approval process.

TWST: How have you financed the company and will you be seeking additional financing?

Mr. Brown: To this point, we've financed the company all through angel investments. We started with a Seed Round, a convertible note of \$200K which rolled into a Series A round of \$1.7 million. We're just starting a Series B of \$6 million and again focusing strictly on angels at this point. Depending on how well and how quickly we get to market, we may look at a Series C sometime in about two to three years if necessary.

TWST: How are you gauging the current response for raising your B financing?

Mr. Brown: In a word, overwhelming. The Series A was wrapped up in January, and we closed about 75% of the round in about two weeks. Series B of \$6 million hasn't quite opened yet and we already have about a third of it committed.

And to remain focused, we are pursuing the right opportunities that are most likely to succeed and offer the best return, enabling sustainable revenue streams before funds run out. For that reason we have a laser focus on costs as well as analyzing and evaluating partnership opportunities.

TWST: Of the applications that you mentioned earlier, does any one of them strike you as a home run opportunity?

Mr. Brown: Oh, there are many of them. The implantable glucose sensor is something that device companies have been working on for over 15 years. There are at least 20 devices that are in development and not a single implantable glucose sensor on the market. Most of these companies are well financed by VCs. The one major obstacle they all need to solve is the Foreign Body Response, which encapsulates and isolates the device, preventing it from monitoring glucose levels. Our STAR material is a potential solution for that issue. That market will be a home run. Cosmetics are another area we're currently working on. The proposed solution is a permanent, degradable, dermal filler potentially replacing collagen and

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TWST: Is there enough appetite to fund your company through FDA approval, to take you to commercialization?

Mr. Brown: We believe so. As I mentioned, we have a great facility, which allows us to do our own manufacturing in house for the foreseeable future at a very reasonable rate. We have a stellar management team consisting of high quality, experienced and passionate executives. And we have an incredible technology that represents a disruptive force in many different markets, but yet is fairly easy to understand at a high level and seems to resonate with investors.

TWST: What could possibly go wrong?

Mr. Brown: The strength of this technology is that the benefits are largely independent of the substrate material. The secret to this technology is the pore size and geometry. This means you can literally make it out of any material that that is compatible with the body, whether it is silicone, a biodegradable polymer or other types of materials. I believe the two main risks are: not receiving FDA approval on a certain application and losing focus. We have largely mitigated the first risk by pursuing a number of potential applica-

other current dermal fillers. STAR material once injected will induce tissue growth naturally and slowly degrade, leaving a permanent, natural filler consisting of the patient's own tissue. This will also be a huge home run and there are several more in the pipeline.

TWST: Are you planning on increasing the staff at Healionics?

Mr. Brown: As a startup, we need to be very careful to balance growth with controlling costs. Right now we have seven employees and we will be looking at bringing on another four this year and then another five next year. We are also contracting out, where appropriate, to help stretch our funds.

TWST: Would you sketch a realistic picture of your company a couple of years down the road?

Mr. Brown: The goal for the company this year is to build data supporting the claims that we can take to the FDA. Once we have that and we have these partnerships in place, the next big step for us is to bring the manufacturing of this material in large quantities in-house. We manufacture small quantities in the low 100s right now, but our goal is to continue to develop the process so we can handle

the manufacturing ourselves. More than likely we should have at least two products on the market within three years and well on the way, with FDA approval for several more in human applications.

TWST: Are you content with the way the partnership is progressing with the trials?

Mr. Brown: Absolutely. The results we're seeing from the trials are very encouraging. It's been wonderful to see our partners' progress from cautiously optimistic to being passionate about the technology and the potential applications as results come in.

TWST: When do you expect meaningful revenue streams?

Mr. Brown: Our first revenue streams focused around R&D have already begun. We expect our first product to hit the market early in 2009, with significant streams occurring around 2010 once we receive FDA 510K approval for the human applications we're currently working on.

TWST: Is there anything you would like to add?

Mr. Brown: We're really looking forward to the future. We refer to our technology as the "Gore-Tex™ of biomaterials" due to the many potential opportunities that exist for this material. We are continually finding new applications and markets to pursue and there appears to be no end in sight for those possibilities. The three things that really attracted me to this company are the technology, the ability to dramatically impact and improve people's lives and the revenue structure that allows for multiple, continually increasing revenue streams. This is a very exciting opportunity and I'm privileged to be a part of bringing it to fruition.

TWST: Thank you.

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