

Having received FDA approval for their Noninvasive, Long-term Cerebral Flow Monitor, the Presto-1000, Physio Sonics is enabling Brain and Cardiac Surgery to be performed Without a Trained Sonographer – providing Multiple Readings while Lowering Costs

**Healthcare
Medical Devices**

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**Brad Harlow
CEO**

BIO:

Brad Harlow has over 25 years experience in medical technology. From 1991-1997 he was VP of sales/marketing for Instromedix, a cardiac technology firm. From 1997-2001 he was SVP of Sales/Marketing for Data Critical, a wires ECG company purchased by GE in 2002. Mr. Harlow worked in M&A for Guidant Corporation, now Boston Scientific. Since 2001, he has led more than \$250 Million of transactions including mergers, financings and joint ventures as Managing Partner of B.Harlow & Associates, LLC.

About PhysioSonics:

PhysioSonics developed and has approval from the FDA to market a non-invasive, long-term cerebral flow monitor. PhysioSonics has developed a non-invasive, long-term cerebral blood flow (CBF) Platform. Utilizing novel ultrasound technology, the company has developed a new method that enables the device to locate and hold on the cerebral artery without a trained sonographer. This auto-locating ultrasound technology thus enables an easy-to-use method for the continuous monitoring of CBF. Future uses of this Platform may include Emboli detection and non-

invasive intracranial pressure monitoring, both of which will require additional FDA submissions.



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

CEOCFO: Mr. Harlow, would you tell us the focus at PhysioSonic?

Mr. Harlow: PhysioSonic was set up to develop a brain monitor to use in cardiology and neurology to help lower the cost of medicine and to increase the opportunity for physicians to do more with less.

CEOCFO: How has the situation been addressed until now? Is there a product that you would be improving on, or is this a totally new area?

Mr. Harlow: Currently, our product uses ultrasound, which is used today where a sonographer or trained ultrasound technician holds a device next to a patient's head right near their temple on one side and then the other in order to get blood flow measure-

ments. This gives the physician an opportunity to know how well the brain is regulating which we call auto-regulating. That is manually, even during surgery they will call in a sonographer or technician from ultrasound to do that. It might have to wait an hour between surgery start and finish to see that patient's ultrasound measurements of the flow in the brain. We came up with an idea to automate this with technology from the University of Washington. We automated it by providing a halo that the patient wears that automatically locks on to the arteries on both sides and gives bilateral information. We simplified and made it faster but it does exactly the same thing. We did not change the physics; we did reduce the cost structure.

CEOCFO: Where are you in the development and commercialization process?

Mr. Harlow: This is an exciting time. We just received approval from the Food and Drug Administration for our product the Presto-1000. Two weeks ago, we received our approval to sell and market the device in the United States this is after a number of years and almost \$18 million dollars invested, plus thirty patents filed. It has been a very rewarding road but a long road that we have just completed and now we are looking to find a partner or distributor for that product.

CEOCFO: What is the market opportunity and how often is this procedure?

Mr. Harlow: It is done hundreds of times a day in hospitals around the country and it is about \$1 billion mar-

ket opportunity both in terms of the hardware and the disposable. There is a disposable the patient wears on the halo so that each time it is removed, it can be replaced because obviously when you do surgery on the brain and/or cardiac surgery, you need a sterile field so we make sure to provide a clean new halo every time.

CEO CFO: Would this work for any cardiac procedure?

Mr. Harlow: The most common procedures it would be used for are stents or heart bypass surgeries and many neurosurgeries.

CEO CFO: Has the medical community been looking for a better method or will they be happy to know you have come up with something?

Mr. Harlow: I think they are going to be happy to know. This is a halfway point for our product. We had to develop an automatic flow monitor as we call it, in order to get to the final product which would be the same hardware but with some software changes and could then give the pressure inside the brain automatically, which is called intracranial pressure. In order to get intracranial pressure, you need to have the ultrasound automaticity and you need to have both sides of the brain. We developed this product and did not realize the market was so large for this interim product while we were on our way to the intracranial product. The intracranial product, which was our original design idea, would replace invasive procedure where you actually drill a hole in the skull through the durra and put a transducer right on the brain to see if it is swelling and if so how much. That has never been done to have a noninvasive intracranial pressure, so we were developing the product really just for that. In the interim, we came up with this automatic flow monitor and as we shared with the medical community cardiologists, neurosurgeons and anesthesiologists. They said I would use that product right now the way it is because it is so much more cost effective and so much simpler to be able to see a long-term trend than

simply to have the ultrasound tech come in one or two times during a surgery or after surgery.

CEO CFO: It is an easy-to-understand product.

Mr. Harlow: It is also easy to use. We set it up so that in less than five minutes, a nurse or technician can have the monitor up and running on a patient, so it does not take a large amount of prep and it is very intuitive.

CEO CFO: What are the next steps for you?

Mr. Harlow: We will be at the JP Morgan Healthcare Conference next week in San Francisco and a few other healthcare conferences over the first quarter meeting with potential acquirers or distributors who have either monitoring products or ultrasound products and are looking to add to their portfolio.

“With our monitor, the patient can wear a halo for eight to ten hours to see how their brain blood flow changes and how it is affected by other drugs or therapies. That is much more efficient than having a technician stenographer come in and take their multiple readings over time, and much less costly”. - Brad Harlow

CEO CFO: Is the genre of your medical device in favor these days?

Mr. Harlow: Yes, it is in favor. With the healthcare law and with the cost of medicine increasing you have to sell on both the carpet and the vinyl. The vinyl is to the physicians and the carpet is to the CFO and administrator, so you need to share not only that your product is useful but that it is lower cost and higher value and can save real dollars as well as lives. During this time of uncertainty in healthcare, it is always going to be a larger mountain to go over to get a product into it. We feel very confident we have the right product.

CEO CFO: Would your preference be for partnership or acquisition?

Mr. Harlow: We were a development company that has been very well received in the market. I think an acquisition would be simple for us but we are very open if someone wants to

come in and do a partnership and allow us to distribute procreative time before selling.

CEO CFO: What do you and your team understand about the commercialization process and maybe learn from other vendors, that you bring to the table?

Mr. Harlow: All of our execs have over twenty years in medical product. All of them have background in ultrasound and all of them have done product applications with the FDA, so we have a very deep bench in terms of team to go to when we are developing this product. Certainly the software and hardware engineers are some of the younger people who have the highest new schools but when it comes to actually putting the product together and putting a program together and developing a commercial strategy, I want people that have industry experience and have been there and done that with other companies.

CEO CFO: Do you see the tax on medical devices as being a consideration at this point or as something that will be passed along?

Mr. Harlow: Unfortunately, I think it is just going to occur. I think it is a very poor choice of tax; it will be passed on to the care provider and/or patient. At 2% given that we are trying to price our product at 30% to 40% below current products, it is not going to be a factor in our sales, it is just an unfortunate occurrence for medical devices in general.

CEO CFO: Is reimbursement a consideration, or is that just part of the procedure?

Mr. Harlow: It is both. In some cases, this product would be used and would only be charged as a part of a total procedure, and in others, there is a CPP code for ultrasound monitoring and for Doppler monitoring that we need so that it can go under that code.

CEO CFO: Does PhysioSonics have funding to take you through the next steps?

Mr. Harlow: We have had very generous funding from two strategic partners, Medtronic and Johnson & Johnson and most recently from a group of med tech angels made up primarily of CEOs and financiers of med tech. We have adequate funding for our next step.

CEO CFO: Are you looking outside the US as well at this point or might that be later?

Mr. Harlow: Now we actually think the Asian market for distribution and potential acquisition would be a very good fit for us right now; Korea, Japan and China all have opportunities with distributors and/or acquirers.

CEO CFO: Will you be pursuing conferences that focus there as well or is that more of an ancillary consideration?

Mr. Harlow: I think that would be more ancillary. Many of those partners come here to US to some of the majors.

CEO CFO: Why should the business and investment community pay attention to PhysioSonics?

Mr. Harlow: It is simple, we have a simple low-cost solution to a current medical use and any time you can do a monitor versus a point-in-time, you are helping medicine. Monitor allows you to see a patient change over time versus a specific test, which gives you a single data point at that point in

time. With our monitor, the patient can wear a halo for eight to ten hours to see how their brain blood flow changes and how it is affected by other drugs or therapies. That is much more efficient than having a technician stenographer come in and take their multiple readings over time, and much less costly.

CEO CFO: Do you have any final thoughts?

Mr. Harlow: We are excited to have the product, it has years in the making and we are just looking forward to the next step.



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