

Automated Cerebral Spinal Fluid Drain Monitoring System



Nelson Scharadin - CEO

About BeckerSmith Medical, Inc.

BeckerSmith Medical is a private medical device company developing innovative products in the \$1 billion neurosurgery market for Cerebral Spinal Fluid (CSF) drainage. The Company developed, and is launching the first automated, programmable CSF lumbar drain monitoring system.

BeckerSmith Medical transformed the entire segment of manually operated CSF drainage devices on the market today into a new fully-automated drain monitoring system that dramatically reduces ICU workload and length of stay. The surgeon or ICU nurse programs the flow rate via touch screen and walks away never having to return to open and close, EVERY HOUR, the manually operated valves with current devices that are unreliable and unsafe. Our version 2.0 includes both lumbar and ventricular drainage, expanding the market 5x over lumbar drainage alone.

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

CEOCFO: Mr. Scharadin, would you tell us the concept at BeckerSmith?

Mr. Scharadin: BeckerSmith is transforming an entire medical device market segment where current devices are manually operated, making them unreliable and unsafe, into a fully automated programmable system that reduces complications and increases patient safety. Our device, FlowSafe, is the first automated Cerebral Spinal Fluid (CSF) drain monitoring system.

CEOCFO: What is wrong with the current technology?

Mr. Scharadin: The problem, a long-standing problem with current technology, is human error. Current devices are operated manually, which means the nurse is required to enter the patient's room all day, randomly every few minutes during each and every hour of the day to check on the amount of cerebral spinal fluid that drains from the patient's external catheter. 10ml per hour is the average rate and what the nurse must adhere to each hour so that complications like meningitis and death are avoided. With current devices, two valves that allow CSF to flow properly must be opened and closed manually numerous times per hour. You can imagine how difficult it must be for a nurse in the busy ICU to accomplish this. That's where mistakes are made, errors occur, and patient complications happen. Our device, FlowSafe, simply automates that manual process with a programmable device that accurately measures drain rate, flow and volume, preventing errors and mistakes. The device does all the work, greatly reducing liability for the surgeon and hospital, workload for the nurse and decreasing length of stay in the ICU. In fact, patients in our clinical trial had a 55% reduction in length of stay using FlowSafe because the patients were taken to the step-down unit after connected to the device.

CEOCFO: What was the challenge that you were able to overcome in creating the device?

Mr. Scharadin: The technical challenges were relatively minor, connecting two continuous valves that open and close automatically to a sophisticated flow sensor detecting when certain levels of CS fluid enter a chamber in the device. The challenge was developing an easy to use graphical user interface. It had to be one that nurses feel comfortable with, easily and quickly manipulated to make changes. It had to be visually appealing so that nurses can immediately see from a distance what's happening to the patient, so they can quickly make life-saving changes if necessary. Patients can die from over-drainage when valves are mistakenly left open, and it happens within minutes not hours. It's that quick. Using current manually operated devices dramatically increases the probability of complications, which is why most of these patients are in the ICU and not in the general ward and that costs the hospital \$7,000 per day. A course of therapy can last 8 days and that adds up quickly.

CEOCFO: What is the market opportunity?

Mr. Scharadin: The current market for cerebral spinal fluid drains is approximately \$300 to \$400 million, US and EU combined. There are two segments, lumbar drains and ventricular drains. The ventricular drain market is five times larger than the lumbar market. Using our automated monitoring system and disposable catheter the market grows to over \$1.7 billion, because we're selling a small piece of capital equipment into the hospital ICU instead of just a disposable piece of

plastic like our competitors JNJ and Medtronic. This is the most important part of our strategy for companies interested in acquiring us in the future. We take their existing market that has now growth and single digit CAGR, and quadruple the size of the market with FlowSafe. It's a business development person's dream. We don't just give an acquirer the best and safest product on the market, but we give them top line revenue growth and earnings acceleration with a new market like that. We're already talking with potential strategic partners about EU operations Switzerland and Asian operations in Singapore. In my experience, those are the 3 pillars of the market stool, if you will. Aside from that we have already received calls from medical device distributors in various ROW countries like Turkey who want to license FlowSafe exclusively. We think hospitals will gladly accept a product that increases patient safety, reduces complications, and dramatically reduces workload, allow patients to leave the ICU for the general ward. This transfer from the ICU can save the hospital up to \$40,000 per patient.

CEOCFO: Are you encouraged by the current atmosphere for hospitals to pay more attention to cost?

Mr. Scharadin: It's a very timely question, because under the new ACA guidelines hospitals are penalized for readmissions. Today, in the hospital it's all about decreasing healthcare utilization and preventing readmissions. Now, more than ever before, hospitals are laser focused on using products and/or therapies that reduce the cost of healthcare. In our recently completed clinical trial we saw a reduction in ICU length of stay of 55%. Endpoints that we did not measure, but believe we can also have a positive impact on include, a reduction in the probability of complications, which reduces the liability from lawsuits. One lawsuit due to human error and the hospital can be liable for millions of dollars.

“Using our automated monitoring system and disposable catheter the market grows to over \$1.7 billion, because we’re selling a small piece of capital equipment into the hospital ICU instead of just a disposable piece of plastic like our competitors JNJ and Medtronic... So, when the big public med device companies want something new, something accretive to their bottom line, and something that moves the needle on top line sales, they’ll know who to call. In the meantime, we have a lot of work to do and I don’t like dropping plates.”

- Nelson Scharadin

CEOCFO: Do you think the fact that it is an easy concept to understand is meaningful?

Mr. Scharadin: Yes, thankfully it's an easy concept to understand for our customers, who are more likely to be the ICU nurses than the neurosurgeons themselves. Getting into the hospital will be an easier proposition for us than most device companies because we priced the device below the capital budget committee cap of, on average \$5,000. This means that FlowSafe doesn't have to be reviewed, which can take 6 to 12 months and many times the review committees only meet every 6 to 12 months. Initial traction should be positive for us because of this, which gets us into the ICU, but doesn't get us market share. To gain market share from the competitors, to be used as the device of choice during procedures, we have to show the nurse that FlowSafe makes their job easier, and we do that in more ways than one. Because FlowSafe simply automates the very same procedure the nurse is used to, they can easily understand why FlowSafe should be the new standard of care in the hospital for ALL lumbar and ventricular drain patients. The device's simplicity is one of its greatest strengths, because the nurse can quickly and immediately change settings using a digital touch screen and redundant visual and audible alarms sound should anything go wrong, unlike any of the current devices which are plastic disposable devices. Our disposable component is just the catheter running from the patient to the device that allows the fluid to be measured.

CEOCFO: What have you learned from your prior ventures that has been most helpful this time around?

Mr. Scharadin: BeckerSmith Medical is my fourth medical device startup, so I have a solid foundation in the space and a fair amount of experience in medical device development and commercialization. Completing FlowSafe's development, working with manufacturing to prepare for launch, and preparing our 510k submission is certainly upstream of marketing and sales and corporate growth planning or exit strategy where my strengths lie, but this has been much more exciting. Rolling up my sleeves and getting my hands dirty is where the rubber meets the road in this business. Helping make team decisions that include all the facts, and collaborating with multiple parties to get from point A to point B and on to point C is what I spend most of my time on. The analogy is spinning multiple plates in the air while riding a bicycle. The goal is not to drop a single plate. My previous experience has taught me time and time again to only work with people you trust, people you like working with, because you're going to spend a lot of time together. A great example is driving from Los Angeles to San Francisco with our Chief Medical Officer, Dr. Jan Eckermann, who just happens to be our Chairman and the Founder of BeckerSmith. Over the 5 hour drive we hashed out some great marketing strategies and tactics we will use against our competitors. On the way back it was less strategy and more comedic relief, and that's the way you want it when working closely in an early-stage company. Another lesson learned and definitely the most important one is persistence and determination. Learning to never, ever give up comes in handy when every other week you're faced with the possibility of this setback or that negative development. Another good lesson I've learned that's been helpful is to focus on creating value. Value for the company, value for shareholders, and value for the customer. Focusing on hitting well thought out milestones adds value to the company and increases shareholder value. Focusing on the best quality product with the

best features we can add adds value for the hospital and will help us hit our top-line revenue numbers. The lessons I've earned as an investment banker have also come in handy, which are essentially 12 to 14 hour days and weekends when needed are the way to solve most problems and get things done.

CEOCFO: *Why should BeckerSmith Medical be of interest the medical and investor communities?*

Mr. Scharadin: BeckerSmith Medical has transformed an entire medical device market segment, the old lumbar and ventricular drainage market, into a new dramatically larger medical device market segment with a safer, more reliable device, expanding the market to over \$1.7 billion dollars. A market that now can change the direction of any large public medical device maker looking to buy revenue and access into the hospital ICU. We think companies like Medtronic and J&J are looking for new products just like FlowSafe and we're here to work with them since they're the experts. Investors in BeckerSmith will be greatly rewarded for investing at this early stage especially when the average revenue multiple for medical devices can be as high as 7x. Putting a 7x multiple on our potential top line revenue in a \$1.7 billion dollar market should be very appealing for investors in my professional opinion as a former investment banker. I believe we can conservatively do \$50 million to \$100 million in revenue two to three years post launch.

CEOCFO: *Final thoughts?*

Mr. Scharadin: Having spent my entire career in healthcare and watching business models change, some dramatically, the one thing I know to be a constant today and in the future is that large public companies need, live and die by, innovative new products to fill the whitespace in their product pipelines. BeckerSmith Medical and FlowSafe are as innovative as it gets in our field. We are on the vanguard of technology when it comes to CSF drainage and monitoring systems, and our IP is bullet proof. So, when the big public med device companies want something new, something accretive to their bottom line, and something that moves the needle on top line sales, they'll know who to call. In the meantime, we have a lot of work to do and I don't like dropping plates.

BIO: Mr. Scharadin began his career in marketing & sales at Abbott where he launched several new products from differing disease states into the hospital market. After grad school, he transitioned to healthcare investment banking on Wall Street with Oppenheimer where he successfully completed numerous M&A and IPO transactions. In 2008, he started his first medical device company, and is now working on his fourth. As CEO of BeckerSmith Medical, he has facilitated the company's financing, product development, and clinical/regulatory process. He is now planning to launch the company's first product into the hospital market in early 2015.



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