An Unheralded Story of Medtech Success – How Sapheon Went from an Idea on the Back of a Napkin to a $240 Million Exit to Covidien

I'll be candid. This is an interview I've wanted to do for quite some time.

During my time at Covidien, I considered myself fortunate to be involved with the acquisition of Sapheon, a startup company that manufactured a disruptive therapy for venous reflux.

The more I learned about Sapheon through the diligence process (as well as the post-acquisition activities), the more enamored I became with their story. Great idea. Huge market. Really solid execution by people like Don Crawford, Dr. Rod Raabe, Gary McCord, and Monte Madsen. To this day, I still think it's one of the more unheralded examples of success within medtech.

In this interview with Don Crawford, current President of Analytics 4 Life and former CEO of Sapheon, we learn how they went from an idea on the back of a napkin to a $240 million exit to Covidien through unconventional financing, disciplined compliance, and much more.

Scott Nelson: Let's start with Sapheon first. Covidien acquired your company in 2014 for a reported $240 million. I think this is one of the more unheralded stories within med tech. So when you finally got that deal done after spending almost six years with Sapheon, do you recall how you and your team celebrated that win?

Don Crawford: We were really going through a process over the last six months of diligence, working towards a final deal and transition with Covidien. In the last month before the deal was finally done, we had a third quarter management meeting and we took the entire management team back to Sonoma County where the company originally was started. We held these meetings on a regular basis, but we did something special and we invited to a dinner meeting anyone who had ever had anything to do with Sapheon – consultants, past employees, etc. And we more or less held a celebration dinner at the Fairmont in Sonoma. We probably had 50 or 75 people attend and it was really a great celebration. Even my teammates today, that are now scattered, always mention that weekend when we revisit.

Scott Nelson: That's a great story. A well-deserved celebration. Regarding Sapheon, it seems like your team was able to get a lot done on a light budget. When you think about the course of those five-and-a-half, six years from when you joined Sapheon to the eventual acquisition by Covidien, are there one or two things that really stand out?

Don Crawford: You've probably heard stories before of people meeting and writing something on the back of the napkin and it becoming an idea or a patent. Well, I remember one of the first meetings I had with the cofounder, Dr. Rod Raabe, who really had the original clinical idea to glue a leg vein together. We met in a hotel in his hometown and we had dinner, and on the back of the placemat at the dinner, he wrote out some drawings and a thought process of what we could do. So we took that from the back of a napkin to the three clinical trials, launching a global operation, and ultimately a successful PMA trial. And then exited the company from start to finish with the two cofounders involved. So I think that, in and of itself, is a very, very unique story.

Scott Nelson: Without a doubt. And I fortunately have been able to meet some of those members of the team, Dr. Raabe, as well as guys like Monte Madsen and Gary McCord. You had a fantastic team. Really, really good people and a very cool story.

Going back to that napkin story, when you're sitting down with Dr. Raabe at that dinner table, and when he first presented that idea to you, what were your initial thoughts?

Don Crawford: Well, initially, I took the project on as a consultant. I was just doing the very basic thing that I would do in the corporate medical world. If you come up with a new idea, the first thing you do, which you'd learn at business school, is that you've got to lay out a business plan. Does it make sense? Is there a need? Well, the market was huge – 25% of the world's population has venous disease. So boom, that's an early checkmark. Huge market. Next, the proposed technology, Dr. Raabe's idea, seemed like a big improvement over vein stripping as well as the ablation methods that are used today. So we saw an unmet that could be solved with a great idea. And then I looked at the economics. First and foremost, there were a lot of companies that were interested in the venous arena. But really, at that time, none of the companies were owned by major giant corporations. They were really small or midsized companies like Angiodynamics and VNUS. So the competition was still kind of young, and I thought that a company like ours had a place to enter the market. And then lastly, we looked at the basics – is this something that could be manufactured in a low-cost way? Is there an established market that pays a reimbursement that makes sense? And so there you go. We were able to check the box on five or six items on the list. So we thought it would be a great idea to pursue.

Scott Nelson: You make it sound very easy, but I'm sure it wasn't that way. How many ideas do you come across that don't check all those boxes?

Don Crawford: Well, there are a lot of ideas out there. But sometimes they're so innovative and so new that you're really ahead of the market. I typically look at the economics first. Is it being used and is it being reimbursed? And if those boxes are checked, well, you could almost fit anything into

those two. But without the reimbursement or an established market, then you're really fighting a 10-year battle.

Scott Nelson: Those are two really good points. So let's dive into some of the details specific to Sapheon. This wasn't just a 510(k) device. But instead, it was a PMA device and you were able to navigate those choppy waters. But let's first talk about funding, because based on my research, it looked like you guys were really savvy with the way you approached funding the company. You were able to get a lot done in a short period of time. CE mark, PMA device, commercialized in Europe, getting ready to probably commercialize in the US before the acquisition with Covidien. Talk to us about your approach to the way you funded Sapheon.

Don Crawford: I wish I could say that I was incredibly innovative and brilliant. That we established this new private funding model because I had an amazing vision. But the reality is that we started the company at the worst time in the history of starting medical device companies. It was in the middle of the financial crisis, 2008, the recovery in 2009, and anyone who lived through those days recognizes that any sort of traditional venture capital funding (especially medical) was just not available. There was no institutional money that you could count on at an early stage. You're either too early or you're too late, or every excuse you can imagine from the institutional VC investors about why they wouldn't look at Sapheon. And we did talk with some mainstream, well-known firms, people that we actually knew through our career between Dr. Raabe and myself. But we felt we needed to go to private equity investors. Some people would call them angels, but I just call them credited investors. You've heard of the famous "friends, families and fools". Well, at the time, that's what it was. We would go month by month trying to raise money. That was the way Dr. Raabe and I funded the company. And part of it was investing in the series A ourselves. At the end, management had more than 10% of the invested funds, which turned out to be right at $38 million. That is something you look for when you're looking for private investments. If the managers are investing into their own company, that's usually a pretty good sign.

Scott Nelson: That's such a unique story, especially in regards to the 2008/2009 timeframe. With regard to raising private money, it seems like that would be fairly time-intensive versus the traditional path of having your series A led by one of the well-known VC firms. Instead, you raised it through a network of private investors. How did you balance the necessary day-to-day tasks of running the business versus the time-intensive fundraising efforts across a multitude of different angel investors?

Don Crawford: The balance is what it was. It was a total immersion. That is what my job was 24 hours a day. And even at the very beginning, we had a team of people, Rod, myself, Gary McCord, Monte Madsen, and several others,

we all recognized that fundraising is at the core of the company. So without that, you can't do the other things. Financing was always a part of it and everyone was involved.

Scott Nelson: Before we get into your approach on clinical trials and and the regulatory processes, do you think your fundraising path is one that more early stage device companies should pursue? Versus going the traditional route with well-known venture capital firms?

Don Crawford: I think that we've seen much more of that occur in the last three years. Even in 2011/2012 or so, that started to resonate. And I know a number of companies that have completed their series A and series B along those same lines. So I think that, although it still is fraught with a lot of twists and turns, it can be done. But you have to be well-connected and understand the nuances of how corporate organizations work. It also comes down to setting up the right corporate structure and having the right legal counsel. Your funding documents are critical. The structure is critical. Ultimately, when you get towards the end, or get into later rounds, you'll understand the structure that you started with dictates a lot of things. So you have to put a lot of thought and preparation into the plan.

It's different than if a VC throws some term sheets up. They're the ones who want to have the corporate documents structured in a favorable way. But if you're funding it privately, then really it is the management team that sets the tone, sets the structure, and it has to be something that is attractive to an investor because ultimately your investors are planning on making a multiple return on their investment.

Scott Nelson: Let's now shift to the clinical work and the regulatory pathways that you pursued. I think most people in medtech would agree that the FDA is difficult to work with at times. Even with a 510(k), the clinical burden is a lot heavier than it used to be. Can you give us a little insight into how your team was able to accomplish so much in a short period of time with not a lot of money.

Don Crawford: Well, I had worked 25 years in the implantable device arena. And when you're involved in that space, you learn regulatory and compliance. I've lived through scores of product recalls. You understand, through the knocks of hard life, what a regulated industry requires. And so from the very beginning, I recognized that what we were doing at Sapheon was an implantable device. We were putting something permanently into the body and we needed to treat it from the very beginning with that sort of discipline. And it started from employee number one. In fact, employee number one was a PhD research scientist. Luckily, he had spent a lot of time at Medtronic, so he understood what doing R&D under a process was all about.

And then we hired another employee two weeks later, which was a brand new engineer, right out of Cal Polytech, who was our quality engineer.

She had done some summer intern work in the quality department, and we hired her to document everything our PhD scientist did. We considered ourselves an implantable device company from day one. We documented everything, and as we went through our company processes, it's that discipline in documentation that allowed us to submit some of the work we did in our very first months of the company as part of the PMA application. I've told people that you should do everything under a quality system. Do it right the first time or else you're going to spend a lot more money doing it over again.

Scott Nelson: To be candid, I wouldn't have expected that to be your answer, but it makes a lot of sense now that you explain it. But for a lot of people, obtaining a PMA, especially for an early stage company, seems like a daunting task. However, your team was able to obtain the eventual PMA in an extremely short fashion. Was there anything, besides solid documentation, that you can pinpoint that led to such quick regulatory timelines?

Don Crawford: We had a quality management system from the beginning, which helped with product development. Dr. Raabe and Monte, our early cofounders, were doing the animal work themselves in a university lab that was not GLP. But we conducted the study GLP-like and we kept great records of each and every animal implant. I think there was something like 4,000 days of animal implants that we did ourselves in a university setting that was relatively cheap because it was not GLP. But later along in the process, the only reason that we were able to use that data is because we took the burden ourselves to document it properly and then that became part of the record. And as we went into the clinical trial work with humans, we worked with top-notch investigators. We started off with a group of U.S. physicians that had a research center in the Dominican Republic. We were able to team up with this group of U.S. physicians and do our first in-man work fairly quickly after some very exhaustive benchtop and animal work. I think in one day, we treated eight patients, and then later on, we treated 30 patients in two days. That's almost unheard of in U.S. clinical practice. So those were the sort of things that made it quick. We were able to do offshore work at a lower price point than what you would do in a U.S. clinical trial. That was our pilot work.

Scott Nelson: So in terms of being able to execute quickly, do you attribute that to being really well-organized and working with the right physician partners? Or does it have to do with the disease state and the fact that it's relatively easy to find patients?

Don Crawford: Well, I think that first and foremost, the fact is 25% of the world's population has the disease. So there are just a ton of patients that need treatment. That makes it really easy. Secondly, from an invasive PMA-type class III product, putting something in a diseased vein is really pretty low on the totem pole compared to a heart valve or something like

that. So we were at a pretty low risk. And then, you can't discount the fact that our two founders, Dr. Raabe and Monte did all of the animal work. They worked closely with the engineers. But because they did all of the animal work, they mastered the techniques and were able to transfer that knowledge to the actual physicians who did the human work. There was such good communication between our founders and the customers, which led to easier clinical work. And the fact that we knew the patient population, because of Monte's and Dr. Raabe's background, we were able to really focus in on the right patient populations, which is the key to all clinical trials and regulatory submissions.

Scott Nelson: Yeah, those are some really, really good points, so thanks for kind of outlining that, Don. I didn't, especially in regard to the fact, the point you mentioned about the early animal work that Dr. Raabe and Monty sort of led themselves and because…I mean, it sounds like listening to explain the story that because Rod and Monty were so involved in the animal work that really...and the fact that they had a lot of domain expertise that really translated well at a later stage once you got into the clinical trial work as well as the regulatory submissions.

Scott Nelson: Got it. Makes a ton of sense. So let's transition to what you're doing now with Analytics 4 Life. Based on some research, it looks like you brought your team from Sapheon to this company. Can you provide us with an overview of what you're doing and then cover some of the key learnings you experienced at Sapheon that have translated into your new company, Analytics 4 Life.

Don Crawford: Analytics 4 Life is information technology, first and foremost. So it's different than say a typical single-use medical device product that people are probably more familiar with. We're using information technology to look at biological signals, or biological information, that's coming from the patient. We're able to assess and diagnose disease and then send that information, in a clinically relevant report, back to the physician. So it is more on a per-test basis as opposed to single-use medical device. But the real product is the information that we are gathering and processing. We're using big data sets to compare and predict the outcomes for patients. So it's a different type of technology than catheters and wires. But the discipline is the same. Our product is considered a medical device. The instrument that retrieves the data is a medical device, the cloud storage facility where the information is saved is considered a medical device, the algorithm that analyzes the data is a separate medical device, and the clinical report that goes back to the physician through a portal is considered a medical device. So those four pieces are separate medical devices that make up the system that allows physicians and patients to get treated faster, safer, quicker, and cheaper.

Scott Nelson: So are you owning each part of that supply chain? The data, the reporting, as well as the device that's used to collect the information from the patient?

Don Crawford: We brought on some team members from our Sapheon days. People like Greg Davis, who runs an organization called MedCelerate. One of Greg's key roles within Sapheon was outsourcing our supply chain. Nearly everything that Sapheon created was via a contract manufacturer. We would design and manage the process, but we actually outsourced our manufacturing capabilities. So we're doing the same thing with Analytics 4 Life. The assembly for the device itself is done by a third-party contract manufacturer. One that works for multiple large medical device companies. All we do is manage the quality process of that.

Same thing with the cloud. We are designing the cloud data as well as the processes that are used. But we use large, established companies that are cloud-based. For instance, we use IBM to transfer our data to the cloud and IBM equipment to transfer the data in the cloud to the patient. We use cloud-based algorithms. All of it is done by companies like Apple, who is involved with part of our device offering. Amazon was one of our early cloud transfers, but more and more we're looking at IBM as being the gold standard, the trusted name in the business that we're dealing with. And then the instrument is with a third-party manufacturer that ultimately we might outsource to Costa Rica or Ireland as we start building into the hundreds of thousands. But now, it's done at a smaller firm.

Scott Nelson: Most of your experience is in the traditional device space where you've got a hardware-based product that's either implanted or used on a patient. But it seems like you're making a pretty big leap. So how have you overcome that mentally? Transitioning from Sapheon to Analytics 4 Life?

Don Crawford: Well, even though our products are IT-manipulated and IP-delivered, and they are separate devices from a regulatory and a quality standpoint, you're managing those exactly the same way you would any other device. So I do believe the process, the system, the organization that made Sapheon successful is also leading to an incredibly organized and streamlined company at Analytics 4 Life. From a technology standpoint, we still have our legacy team of PhD scientists and computer data engineers that are still with the company. But now they are following very strict and very regulated processes, because, in addition to the normal safety and efficacy concerns, you've also got HIPAA requirements and a lot more of the challenges that come with information technology and cloud-based technologies. But just as we recruited some very top-notch people along the way with Sapheon, we are doing the same things with Analytics 4 Life. We kept our VP of Quality and Regulatory and our

VP of Manufacturing and Business Development from Sapheon. But we recruited our Vice President of Technology, who is an expert in cloud-based medical device delivery. We hired this person out of the Bay Area and he relocated to the Research Triangle where we're headquartered in the U.S. We actually have a Toronto-based technology team and a US-based operational team, and we'll continue to add top-notch people. So that's the key to transitioning the technology bridge per se.

Scott Nelson: So what's next for Analytics 4 Life? Where are you guys at now and what are your plans for the immediate future?

Don Crawford: Well, we have completed our platform instrument, which is a signal collection device, and we are now focusing on cardiac signals. When I say right now, that's what we will focus on for the greater part of 2016. We also have the ability to look at other disease states. But right now, coronary artery disease detection, diagnosis, and guiding treatment for coronary artery disease are the areas that are important for us. We did recruit a Chief Medical Officer last quarter, an electrophysiologist who spent the last three-and-a-half years as a medical reviewer for the FDA, to manage our clinical program. We are going to begin our clinical trial with a well-thought-out protocol and we do expect to do our first human clinical work with our new device in the spring/second quarter/May timeframe. We will collect data for maybe 300 to 500 patients. Once you gather enough patients in your database, you can create the algorithms that allow you to predict what the next patient's going to do and we believe that number is 300 to 500 patients. That's what we plan to do over the course of the summer. And into the fall we'll be prepared to discuss our results with the FDA.

Scott Nelson: Very cool. Sounds really interesting. So I've got the last 3 questions for you. First, what's your favorite non-fiction business book?

Don Crawford: You know, I am so engrossed in the day-to-day aspects of our business. I'm not a bookworm. I guess that comes with my engineering background. I always like to say to everyone, "Give me the Reader's Digest version."

Scott Nelson: Very good. So on that note, is there a business leader that you're following right now that really inspires you?

Don Crawford: Yes, I had the opportunity of attending a luncheon with Ginni Rometty from IBM earlier this fall. And now that we are starting to work a lot with the IBM products, I've read quite a bit about the Watson healthcare system. The future for IBM is in the healthcare arena and they may just be the largest healthcare provider 20 years from now. So the way that she is communicating her vision and turning her vision into real actions, I'm really amazed at what I'm seeing there. The transition at IBM to go from hardware to a pure software play.

Scott Nelson: And the last question, when thinking about your medtech career, if you had to look back and give a piece of advice to your 30-year-old self, what would that be?

Don Crawford: Just be patient. Enjoy the wins along the way. That's another thing that Dr. Raabe and I recognized early on. We made a point to really celebrate the wins along the way and not just focus on the end game, but enjoy it. We always talked about enjoying the journey and Sapheon was a fantastic journey. The people that I was involved with were real friends and true colleagues that will transcend a lifetime. And we're taking that same philosophy with Analytics 4 Life. Remember that it's a journey, not an ending.

Scott Nelson: Yeah, that's great advice. So easy to gloss over the wins and move on to the next thing, but definitely something that I think all of us should take to heart. And with regard to Sapheon, it's really cool to see what you guys were able to do in today's medtech environment. Thanks once again for doing this interview, Don.

Don Crawford: I've enjoyed reminiscing about the Sapheon story.