

Proton Therapy Technology for Solid Tumor Cancers



Stephen L. Spotts - CEO

ProTom is a privately-held company, developing innovative and affordable solutions for proton radiation therapy. ProTom has offices in Flower Mound, Texas and Wakefield, Massachusetts. Its Engineering, Physics, Clinical, Operational and IT leadership experience collectively spans 150 years in healthcare, with more than 75 years of combined experience in proton therapy. Developing and delivering highly sophisticated proton therapy technology is not only what we do, it is all we do. Our medical device operations are headquartered in the USA — from which all of our design, manufacturing, and service divisions are currently managed and operated. To find out more about the future of proton therapy, visit us at www.protominternational.com.

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

CEOCFO: Mr. Spotts, what is the concept behind ProTom International?

Mr. Spotts: Proton therapy is a technology used in the treatment of cancer, specifically solid tumor cancers. Proton therapy is not new technology. It was conceptualized and developed in the 1950s at the Harvard Medical School. Over a course of probably twenty years the clinical data that emerged from the efficacy of proton therapy led a number of initiatives in which proton therapy was approved by the FDA for clinical use for solid tumor cancer treatment. Ultimately, several proton therapy systems were built in the United States. It has, for the most part, not been available for the community based providers that treat over 85% of cancer patients.

CEOCFO: Why is that?

Mr. Spotts: Proton centers that utilized existing technology were too large and too expensive. The first facility built was in Loma Linda, California. They commercialized proton therapy and started offering it to the public. The project began in the 1980s. Then Massachusetts General Hospital, one of the teaching hospitals for Harvard Medical School, brought the technology to the mainstream and offered it primarily to children's cancer patients and for some of the most complex cancer patients. Many of MGH's patients come from around the world. The MGH project started in the mid 1990s. There were only these two facilities for several years. Then MD Anderson built a facility, the University of Florida built a facility, and so on. These facilities, in today's dollars, cost between two hundred and two hundred and fifty million dollars. Therefore, the average community based provider -- like Texas Health Resources, an integrated health system that treats a tremendous amount of the local cancer patients -- could not cost justify a proton therapy system because it is just too expensive and too large.

CEOCFO: What is your approach at ProTom International? How are you helping to alleviate the problem?

Mr. Spotts: The analogy that I like to use for those of us that are old enough to remember is a comparison between the large IBM mainframe computers in the 1970s and 1980s and today's MacBook Air. Sitting on my desk I have a very small MacBook Air that is connected to our corporate server. Between my MacBook Air and our small corporate server, we have more computing power and speed than a couple of floors of IBM mainframe computers from the 1970s. That is a good analogy of what ProTom International has done with its Radiance 330. We have advanced the technology, made it much smaller, much lighter and much less expensive. In our first facility with McLaren Health Care, the largest provider of cancer services in the state of Michigan and the third or fourth largest in the country, we have a three treatment room facility, which is about one third the total cost of one of the original facilities.

CEOCFO: What was the biggest challenge in getting the technology in place?

Mr. Spotts: It was the integration of a number of subsystems we put together for a fully integrated treatment system that we could take to the FDA. What we had to prove to the FDA is that our system is safe, repeatable and meets the efficacy of proton therapy. This was a multi year process with the FDA with a lot of emphasis, as it should be, on patient safety and repeatability. In recent years the FDA has put a lot of emphasis on testing of computer system interfaces. As you can imagine, in a system of this complexity there are multiple subsystems, each with its own operating software control. For instance, the accelerator has operating system software controls of its own. Our beam line that transports the beam has a

separate set of computer operating controls. The imaging system in the treatment room has separate operating controls. There are literally dozens of separate software systems that we integrated into a precisely controlled system that is treating cancer. That is the difficult part of putting together one of these systems.

CEO CFO: Why is proton therapy more effective? Why is it superior or a better choice than some of the other treatments?

Mr. Spotts: Proton therapy is absolutely a better therapeutic choice for many tumor sites, such as brain tumors. Traditional x-ray therapy is effective at killing solid tumor cells, but it damages surrounding healthy tissue, both on the entrance dose and the exit dose. That is because traditional x-ray therapy goes through the patient and into the shielded treatment room. The result is peripheral damage to healthy tissue. Proton therapy is different, in that you have the effect of the Bragg Peak, where you can stop the energy at the distal edge of the tumor, so there is no exit dose. Our proton therapy system is the first of its kind, which is pencil beam scanning only. Think of a laser beam where we can paint the tumor, left to right, up and down and in the three dimensional, the Z axis. Therefore, we can paint the tumor much more precisely and spare healthy tissue. Think of tumors near critical structures like a brain tumor or tumors near the heart. You do not want to damage a healthy heart by treating a tumor in the lung. Intuitively, even from a layman's prospective, proton therapy is a better option versus traditional x-ray therapy.

CEO CFO: You recently officially received FDA clearance. How long have you been working with the hospital that has it up and running. Has that been a test program? What is the next in terms of who you may be working with?

Mr. Spotts: We did laboratory testing under a collaborative agreement with MIT, Massachusetts Institute of Technology. We began testing and the integration of subsystems in a laboratory setting at MIT's Bates Accelerator Center five years ago. The McLaren Proton Therapy Center is ProTom's first clinical site. Now that we are FDA cleared, the McLaren Proton Therapy Center will soon be treating patients from throughout Michigan and probably patients from Canada and the upper Mid West. Our second contract is with Atlantic Health System in New Jersey, and that project will soon be under way. Our third contract was signed in mid-March with Massachusetts General Hospital. Therefore, we will be installing our Radiance 330® Proton Therapy System in two additional facilities over the next two years.

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CEO CFO: What is involved in an installation?

Mr. Spotts: First of all, the bunker or the building that houses the treatment room or rooms and the accelerator must be built. We provide what is called the equipment building interface. It is much more complex than blueprint drawings, but from a laymen's perspective, let us just describe it as very, very detailed plans on the treatment room and the accelerator room. The customer hospital system will decide, with our help, on the best location. Because our system is so much smaller than competing technology, the location chosen may be adjacent to the customer's existing cancer treatment facilities, just as McLaren added the proton center to its existing cancer institute. Therefore, the cancer patients come in the front door and if they are getting traditional medical oncology they can go down the hall to the right; if they are getting traditional x-ray therapy they go down the hall to the left ;or if they are getting proton therapy they go down the middle hall. That is literally the way it works. It is so much more efficient for the patients, the doctors and the staff. One of the things that our client hospitals love about our system is that it dramatically reduces the amount of redundancy that you would have to have if you had a totally separate facility, as are most of the other proton facilities. They are so large that they have to be down the street on a separate parcel of property, which increases the operating costs.

CEO CFO: Proton therapy has been around for a while; are doctors on board? Have they been hopeful or looking for a solution like yours?

Mr. Spotts: That is a great question. The one area that radiation oncologists universally agree is that pediatric patients with solid tumor cancers should be treated with proton therapy. However, many children cancer patients with solid tumors have not had access to proton therapy. St Jude's is in the process of building a proton therapy center, which is fantastic for pediatric patients. We believe all children's hospitals around the country should be looking at proton therapy. That is number one. Radiation oncologists also agree that protons are best for solid tumors that are near critical structures, like brain tumors, spinal cord tumors and tumors that are near the heart. There are other treatment sites that doctors do not all agree on. Other tumor sites will continue to emerge for proton therapy. For instance, the doctors and the providers of equipment like ours all generally agree that lung cancer is a type of cancer that should receive proton therapy as an option to other therapies. The challenge, historically, has been motion management. A lung tumor, as you can imagine, is moving because the patient is breathing. Some of the technology that has been evolving, which we will incorporate into our system, is able to track a tumor as it is moving, sparing healthy tissue around it. Treatment for those types of cancers will continue to evolve as the technology becomes more available. MD Anderson, for instance, is doing a lot of testing of

its technology for lung cancer patients and as more clinical data emerges about the efficacy of this in tumor sites that have not traditionally been treated with proton therapy, we will see the utilization of proton therapy grow.

CEO/CFO: Commercialization and development is always costly. Are you funded for the next steps?

Mr. Spotts: If you are a baseball fan, the opening day of baseball season is Monday, here in Texas. The way that we look at it is that we are starting a new season and a new chapter in our company. Some people would call us early stage or developmental. We are generating revenue and expect to achieve profitability in this calendar year. That is a big step in an early stage company. We are poised now, with FDA approval, to really go after the domestic and international markets. We have plans to get CE Mark in Europe, and we have a number of potential international clients. To facilitate this, we are beginning the process of raising growth equity.

CEO/CFO: Therefore, this is the time to pay attention?

Mr. Spotts: This is the time to pay attention. The US market, with the Affordable Care Act and some of the other things going on, continues to be unsettled. The proton market will continue to develop in the United States. What is very interesting to us and other providers of this technology is that the explosive growth is in international markets, specifically in the Pacific Rim and in Europe. Emerging technology, traditionally, has grown more rapidly in the United States. However, with some of the things going on with the Affordable Care Act and the commercial carriers, new technology is not growing as rapidly in the United States as it has historically, and that is a shame.

BIO: Stephen L. Spotts is the President and Chief Executive Officer of ProTom International, Inc., a cancer therapy company, and has served in this position since inception in 2008. He is a founding stockholder of the Company and is a member of its Board of Directors. From April 2000 to 2006, he was president, chief executive officer, and Board of Directors member of Pathology Partners, Inc. (formerly Caris Life Sciences, now Miraca Life Sciences). Previously he served as its chief development officer from 1999 to 2000. Mr. Spotts currently serves on the Board of Directors of Oxford Immunotec (Nasdaq: OXFD), an international medical diagnostics company with innovative T-cell measurement technology. From 2005 through mid-2008, he served on the Board of Directors of Genoptix, Inc., a California-based specialized laboratory service provider focused on delivering personalized and comprehensive diagnostic services to community-based hematologists and oncologists. From 1996 through 1999, Mr. Spotts served as the president of the Hospital Services Group for Mariner Post-Acute Network. Prior to joining Mariner, he served as director of development of Marriott Healthcare Services and as vice president of Valley Management Services. Since inception in 2007 through 2012, Mr. Spotts served as a Trustee of the Southwestern Seminary Foundation. Steve received his bachelor of business administration degree from the University of Mississippi.



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