THE WALL STREET TRANSCRIPT
Connecting Market Leaders with Investors

IsoRay, Inc. (NYSEMKT:ISR)

THOMAS LAVOY is Chairman of the board and Chief Executive Officer of IsoRay, Inc. Mr. LaVoy has served as a Director of the company since 2005 and was appointed Chairman of the board effective January 7, 2016. He was subsequently appointed Chief Executive Officer effective February 15, 2016. Mr. LaVoy brings more than 35 years of experience leading and building successful, publicly traded businesses. With SuperShuttle International, a leader in the transportation industry, Mr. LaVoy served as Deputy Chief Operating Officer, President of Corporate Services and Chief Financial Officer. He was instrumental in developing SuperShuttle International's strategic growth plans which included revenue growth from $35 million in 1997 to more than $340 million in 2015, acquiring more than 30 businesses, expanding operations to more than 50 locations and spearheading the acquisition of the business by a large international partner, Veolia Transportation Inc., in 2006. Prior to his tenure at SuperShuttle International, Mr. LaVoy served as CFO of Photocomm, Inc., a leader in solar electric manufacturing, engineering and distribution, from 1987 to 1997. During his term with this small public company, he was responsible for taking the company public in 1988, and growing revenue from $5 million to over $25 million in under 10 years.

SECTOR — HEALTH SERVICES

TWST: You became the CEO of IsoRay last February. Can I ask what attracted you to the position?

Mr. LaVoy: I had been on the board since 2005, and had been the financial expert and the Audit Committee Chairman. I had also been with a number of other larger companies over the years and believed that IsoRay had a great deal of potential. At the point I joined the management team, the company needed stronger leadership, and I felt that IsoRay had an excellent opportunity for success because it had the best product in the brachytherapy industry.

IsoRay had not taken advantage of Cesium-131 from a marketing and sales standpoint, and the isotope was developing new opportunities in critical new applications for cancer treatment. I believed then, and still do, that if the product could be marketed and sold well, IsoRay has a very good opportunity for significant growth going forward

TWST: Now you are the only manufacturer in the world of Cesium-131 brachytherapy seeds. Is there any competition on the horizon?

Mr. LaVoy: IsoRay is not aware of any competition on the near term horizon for Cesium-131. Cesium-131 was the last developed low-dose rate — LDR — isotope for the treatment of cancer through brachytherapy. IsoRay holds several patents related to purification of Cesium-131 and also a seed construction patent and a number of other support patents to protect the propriety of our intellectual property. In terms of competition, there is a high barrier to entry because of the significant amount of time that would be required for someone to develop a process patent, a seed patent as well as get a radiation facility licensed and in place.

The other factor is the market. The prostate brachytherapy market has been disrupted over the past 10 years by robotic surgery and better external beam technologies. I do not believe large companies view the brachytherapy market as a big market opportunity. It is considered a niche market and also considered disrupted, so we do not see any large competitors in the short or midterm trying to come in and produce Cesium-131. We see this as our opportunity over the next three to four years.

Our growth strategy includes our dual goals of continuing to gain acceptance for Cesium-131 in existing markets and also to be first to market with our new applications before any major players recognize the need and opportunity for the product.

TWST: You mentioned a little bit about the patient experience with Cesium-131 versus the other isotopes. Can you talk about any other clinical outcomes that you think significantly differentiates Cesium-131 from the other isotopes?

Mr. LaVoy: IsoRay is very excited about our increasing ability to treat more aggressive and faster-growing cancers. Over the last five years, there have been numerous clinical activities going on in major institutions that have published very good results from the use of Cesium-131 in new therapy applications. The first series came out of Weill Cornell in New York City. There are five to seven publications that have been published on the treatment of brain, head and neck, and lung cancers. These applications all involve treating very difficult reoccurring cases of cancer.

The current standard of care for treatment of brain cancer and other aggressive cancers is to perform a craniotomy, or surgery to remove the tumor, and wait approximately 30 days before radiation therapy is started. When external beam treatment is performed, it can take three to four weeks to treat. Current standard of care treatment for brain cancer is approximately a two-month process. The GammaTile brachytherapy application is done at the time of surgery, adding just a few minutes to the procedure and sparing the patient significant additional treatment time, thereby providing improvement in quality of life from the Cesium-131 radiation treatment.

Additional clinical studies have been performed at the Barrow Neurological Institute for the treatment of brain cancer with a new device that was developed by a group of physicians called the GammaTile device. The device has been used in a prototype form over the past four years in multiple brain cancer treatments. Multiple clinical series have reported 85% to 95% local control of the treated cancers with little radiation injury.

Given these results, we are now working on other applications in head and neck cancers, and recurrent gynecological cancer cases. Dr. Jonathan Feddock at the University of Kentucky has presented and published numerous times on results showing excellent local control in recurrent gynecological cancers. At the University of Kentucky, up to 85% local control has been reported in over 30 patients who have been treated with Cesium-131 over the last three or four years. We are really excited about these new applications in these clinical environments.

TWST: In fiscal year 2016, you had $4.7 million in revenue, with close to 90% of that related to prostate cancer treatment. How quickly do you see some of this revenue diverting to some of these new applications?

Mr. LaVoy: The new applications have been a growing percentage of IsoRay's business over the past five years. The prostate treatment market represented over 95% of our business five years ago, and over the last two years we have reported that other applications have grown to approximately 12% of IsoRay's sales. One of the key factors for the surgical applications has been that there has been no reimbursement in place as of yet for these applications. In late 2016, IsoRay collaborated with GammaTile and submitted an application for reimbursement to Medicare for radiation treatment of the brain at the time of surgery. The company also filed for FDA clearance for the device in March 2017.

The GammaTile product was developed by a group of doctors at the highly respected Barrow Neurological Institute. They took a collagen matrix that was developed for brain surgery and inserted our Cesium-131 seeds. In the past radiation was always done after surgery, but with the Cesium-131 application it is performed at the time of surgery. The recurrent brain tumor market is estimated to be approximately 50,000 to 70,000 patients a year. If the reimbursement codes and 510 K clearance is obtained this summer, we will have a new product that could be introduced into the market with significant growth potential over the next one to three years.

TWST: Are you currently selling internationally?

Mr. LaVoy: Right now we don't have a lot of sales in international markets. We believe that Cesium-131 would be very suitable for international markets, because many of those markets don't have the technology and the ability to invest in large radiation external beam equipment such as proton beam or other external radiation therapies. We believe we have the ability to capture international market share with our Cesium-131 isotope in the future although right now there is a lot of competition from Iodine 125 seeds in the international market for prostate treatment.

In the United States we currently we have approximately 3% to 5% market share in prostate cancer treatment. Prostate cancer is typically measured in seven- to 10-year periods of therapy, and since our product was first introduced into the market in the mid-2000s, we are just now starting to get the seven-year data that shows good results for quality of life as well as our long-term survival free performance numbers.

TWST: How do you quantify the number of sites that could be potential customers for you in the U.S., particularly for the prostate applications?

Mr. LaVoy: Right now prostate brachytherapy is a fairly developed market; there are over 500 sites in the U.S. that perform brachytherapy. I would add that there are also approximately 200 to 300 active prostate brachytherapy radiation oncologists providing a good portion of the existing treatments. We currently are serving approximately 30 to 35 sites on a regular basis. Our sales and marketing team is targeting the top 200 active prostate brachytherapy users to adopt the use of Cesium-131 in these practices.

During the past year, we focused our efforts on building a strong sales and marketing staff to address this strategic objective, and we believe that our renewed message of commitment is resonating with the brachytherapy community, as there is a lot of new and renewed interest in Cesium-131 beginning to build.

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TWST: Talk a little bit about what you need to do. This is connected to your sales and marketing effort, but you talked about the prostate cancer treatment market being disrupted, and so where do you see your niche and the type of patient that you think you need to go after?

Mr. LaVoy: We mentioned before that the market had been disrupted. The prostate brachytherapy market had grown very rapidly from the early 1990s to the mid-2000s, going from very few patients to over 50,000 a year. It attracted many large companies, including Bard, GE and Johnson & Johnson, and there were numerous other competitors as well. In the mid-2000s, robotic surgery and external beam treatments improved, and those industries spent a lot of money going after the prostate cancer treatment market. These new products were able to do a pretty good job and capture significant market share over the last eight to 10 years.

Over the last couple of years, the brachytherapy market has stabilized, and the competitive landscape has shrunk to the point

that there are only two or three competitive companies remaining in prostate brachytherapy. Since the other treatments obtained a more significant market share, brachytherapy has stabilized on the treatment side for prostate brachytherapy at approximately 25,000 to 30,000 patients. However, now that good long-term data has been published for brachytherapy, the data continues to support prostate brachytherapy as the most cost-effective treatment with the best quality-of-life statistics and long-term survival rates.

A recent publication showed the results of a very good randomized trial study based in Canada that did a head-to-head comparison with external beam and hormones versus external beam, hormones and brachytherapy. The data shows that after nine years, in a high-risk patient pool, that the triple-combination therapy using a brachytherapy boost had clearly outperformed external beam and hormone therapy. The data shows approximately a 40% chance of reoccurrence in cancer patients receiving external beam and hormones versus 20% with the triple combination of brachytherapy, external beam and hormones.

High-risk patients represent approximately 15% to 20% of the total of 160,000 patients a year in prostate cancer diagnosis. This large patient base provides a very good opportunity for the prostate brachytherapy industry. IsoRay believes that there will be a growing population of patients over the next few years as this information is publicized in major medical journals.

Another segment that has been drawing a lot of attention in prostate cancer treatment has been focal therapy. Focal therapy is for low-risk patients and accounts for a significant number of patients each year. The current recommendation for treatment of low-risk patients is, in many cases, watchful waiting, meaning to just wait and see what happens. A lot of people don't like waiting; they want to be treated.

The urology community has been looking at multiple ways to treat these cancers focally, and with better MRI guidance and better biopsy technology, this is possible. Many treatment options are being considered for focal therapy, including cryotherapy or high-frequency ultrasound — HIFU. From IsoRay's perspective as well as the industry's perspective, treating it focally with radiation is a very good option. We believe Cesium-131 has a very good opportunity to be part of the treatment of prostate cancer focally in the future.

TWST: When I was looking at your website and some of the clinical results, I wondered whether patients anywhere in the U.S. could find a center that uses Cesium-131?

Mr. LaVoy: At this time Cesium-131 is not as widely distributed as we would like it to be. We currently have 35 or so brachytherapy centers in the U.S. that utilize Cesium-131. These centers are disbursed across the country, so we can direct patients to those centers of excellence that would be convenient to them.

TWST: You have mentioned in some of your news releases that you are rebranding. What does that mean?

Mr. LaVoy: IsoRay was an older brand that was initially introduced in the market back in 2003, 2004, a time when the market was being disrupted. After my appointment as CEO, we took a fresh view of the market and brought in a marketing consultant group to get feedback from patients and doctors to formulate an updated brand. We felt that the company had really not invested much effort in developing the prostate market over the last eight or 10 years. We focused initially on prostate treatment, and then we focused more on the new application opportunities for Cesium-131. We felt that we had an opportunity to improve our brand to create better social media, digital marketing and PR programs to support our sales people in the field.

We also saw an opportunity to come in and have a significant impact because the marketing activities from even our remaining competitors have decreased significantly. The feeling was that we needed to reintroduce IsoRay and the newly available long-term data that supports our product. With our good long-term results now documented, we have an excellent opportunity to redevelop the market and convince physicians that Cesium-131 should have a significant place in the industry. We are also now better able to develop other cancer treatment applications that Cesium-131 has a distinct advantage in, giving us a nice opportunity to develop other new market segments for future growth.

TWST: What do you want a potential investor to know today about IsoRay?

Mr. LaVoy: I want the new potential investor to understand that we have made a major change in our business in the last year. We have assembled a very good executive team and have formulated a strong short-term and long-term strategic plan and growth strategy. We have totally revamped our sales force and have also looked at every part of our business including our production processes and the efficiency of every facet of our business.

Right now I think we've done a good job positioning ourselves for growth in the prostate business, and we have done a good job with new market applications, too, especially the brain. One year ago, we didn't have a near-term opportunity to get to the market because we didn't have a reimbursement strategy nor any FDA clearance for any surgical applications. In the last year, we were able to develop a strategy for the GammaTile product to the point where, potentially this summer, it may be an FDA-cleared product with reimbursement in place. We also have good clinical results that are documented by a world-renowned neurological institution that we can collaborate with to bring the product to market.

The market size of brain treatments with Cesium-131 is potentially 50,000 to 70,000 recurrent patients a year. We believe we have an excellent opportunity in the brain immediately, but we see a lot of other new applications for internal radiation and brachytherapy. Radiation is a proven killer of cancer. Our opportunity is in new as well as existing markets as we have a very special isotope that has treated very aggressive cancers for the last five or six years with very good clinical results.

TWST: Is there anything else you wanted to mention?

Mr. LaVoy: IsoRay is at an inflection point as we now have very good long-term data on the efficacy of Cesium-131 and we believe a really good story. We have $11 million in cash and equivalents on our balance sheet and are listed on the New York Stock Exchange. Please visit our website at www.isoray.com.

TWST: Thank you. (KJL)

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