

THE WALL STREET TRANSCRIPT

Connecting Market Leaders with Investors

Isoray, Inc. (NYSEAMERICAN:ISR)



LORI WOODS is CEO of Isoray and is a member of the board of directors. Ms. Woods has more than 30 years of experience in the medical device technology and health care services industries and is particularly well-known and respected in the brachytherapy community. Her distinguished career includes her position as a Principal of Medvio, LLC, where she worked with large public and international medical device companies and was also involved in the development of proprietary technologies for the colo-rectal and liver treatment markets. She has also served as Chief Executive Officer of Pro-Qura, Inc., a privately-owned cancer treatment management company focused on the quality delivery of brachytherapy treatments for prostate cancer. Ms. Woods' previous experience also includes her role as Director of Business Development for the Tumor Institute Radiation Oncology Group and the Seattle Prostate Institute (SPI) in Seattle, Washington, an early innovator in prostate brachytherapy treatments. Ms. Woods' appointment as CEO marked her return to Isoray after having previously served as Vice President in July 2006, Acting Chief Operating Officer in February 2008, and Chief Operating Officer from February 2009 through January 2010. At the time of her appointment, she was a consultant to the company.

SECTOR — HEALTH SERVICES

TWST: Could you please start with an overview and brief history of Isoray?

Ms. Woods: Isoray is a medical technology company and seed brachytherapy innovator. Brachytherapy is internal radiation therapy and it is a powerful weapon in treating prostate cancer as well as cancers like brain, lung, and head and neck cancer. We have been innovating since about 2004 when we introduced Cesium-131, our proprietary radioactive isotope for internal radiation therapy. We have a strong history of providing focused internal radiation therapy treatment for prostate cancer.

We have also created state-of-the-art personalized products that allow us to provide patients and physicians with very specific treatment for a patient at the time they need treatment. Recently, the company has been expanding our product and service offerings as we continue innovating in developing new and exciting ways to treat cancer patients.

Isoray holds the distinction of being the world's sole manufacturer and supplier of Cesium-131, which is our proprietary radioactive isotope that we use in our targeted treatment for cancer. We're really excited about this particular isotope, because we believe it has the combination of two things that are really unique and important when you're using a radioisotope to treat cancer. One is that it has a short half-life. And what that means is

that the radiation comes into your body, it treats your cancer, and then it dissipates very quickly and leaves your body, which is a good thing. You don't want it to stay in your body too long.

The other part of that is its high energy. You need to have the right level of energy, so the treatment dosage can actually get in there and kill the cancer. So, the combination of having a short half-life where it leaves your body quickly and the high energy where it's getting in there and killing the cancer is really important in what we do.

In short, Cesium-131 internal radiation therapy is able to deliver a targeted treatment dose quickly with precise placement of Cesium-131 seeds, leaving healthy tissues and organs undamaged, and leaving the body quickly so it avoids prolonged radiation exposure. And that's why we're so excited about Cesium-131's important place as a powerful cancer treatment.

TWST: Give us a closer look at Cesium-131 and its development. Are these seeds implanted into the patient?

Ms. Woods: Yes, brachytherapy, or internal radiation therapy, has been around really since the mid-1990s in various forms with other isotopes. Cesium-131 was the last entrant into this market. Two other isotopes in this market are iodine and palladium. They both have some good properties, but Cesium-131's entrance into the market was a breakthrough because it has the combination of the two most important treatment features, which is the short half-life and higher energy.

We're very excited about the impact in treating our core prostate cancer market, where about 80% of our revenue comes from. But we're also increasingly growing Cesium-131's role in the treatment of other cancers including brain, lung, head and neck, and GYN — to name a few.

TWST: Has Cesium-131 received full FDA approval? And what's the level of insurance reimbursement for these products and devices?

Ms. Woods: We have a unique approval. We have a 510(k) clearance to treat any cancer from head to toe that a physician would deem appropriate to treat with Cesium-131. So that is an important advantage. Where we may need to seek new FDA approvals is as we innovate and if, for example, we were combining Cesium-131 with a new delivery device then we might need regulatory approval. But we have very broad regulatory approval, as well as reimbursement through Medicare and reimbursement through normal insurance carriers for our Cesium-131 seeds, as they are known.

TWST: So, given that brachytherapy is really a breakthrough treatment, do we know how effective it is?

Ms. Woods: Brachytherapy has been around for a while and is being increasingly recognized as a potent treatment for prostate cancer and other cancers throughout the body. Reimbursement levels for brachytherapy suffered from the competition of higher reimbursement for other competing radiation treatments back then, so it wasn't a level playing field. Now we have some changes coming up with reimbursements to level the playing field and not give one therapy an advantage by reimbursing it at a higher rate.

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But I think it's important to understand that in addition to the treatment advantages we discussed earlier, another very important advantage of brachytherapy is what I call one-and-done treatment. A patient goes in to see their doctor and the doctor decides that brachytherapy is the right option for that patient's cancer. A patient goes to a hospital and usually in an outpatient setting or an ambulatory surgery center and the surgery takes about an hour. Then, the patient moves into the recovery room for a couple of hours and then is free to go home and go about their day.

This is exciting because the cancer is being treated and in many, many cases cured right then and there. It doesn't require the patient having to come back for multiple treatments like some other treatment options where you must return repeatedly for treatment. And that can be day after day after day, or every other day, for a length of time depending on the treatment plan that you have with your physician.

The bottom line is Cesium-131 brachytherapy is very efficient, very effective, and it's important from a quality-of-life consideration as well because people need to be able to get back to their lives. And brachytherapy is a fantastic way to do that and in many prostate cancer cases it can cure your cancer.

TWST: It sounds wonderful. And I can't imagine why anybody with prostate cancer would choose anything else, but yet they do.

Ms. Woods: Yes. It is a fabulous treatment. And unfortunately, I think a lot of people aren't aware of the treatment, how effective it is, and how easy it is. And there are things that drive patients to other therapies, like a physician's choice of what they present to patients. We are making strides in educating clinicians about the important benefits Cesium-131 brachytherapy presents for patients and its ease of use.

I also think there is an important message for patients that really applies to all of us. I believe it behooves us in these times, where you have Google at your fingertips, to do your own research as well and be your own advocate. And get second opinions because it's important to know what all your treatment options are. Sometimes patients don't know all the options that are out there. And that makes it harder for them to get the right treatment.

Think about it. You don't just go out and buy a car or a television. You research your options and, based on your particular needs, you make a decision. Being an informed consumer is very important in deciding a course of action for your health.

TWST: Tell us a little bit about Isoray's corporate structure, your business model, and the corporate culture.

Ms. Woods: Our corporate culture reflects our mission. We are focused on providing patients and physicians the best treatment options with Cesium-131 and that commitment to care permeates our company and extends to our team members.

Starting with our patients, what we do every day is not about mass-produced treatments that get shipped out. We are literally making a specific product for a specific patient at a specific point in time. And so, every day, our team of really dedicated people knows there's a person on the other end of what they're doing who is depending on us, and that's really important to our culture, which is steeped in individual commitment and very people focused.

We're very dedicated to constantly looking at how do we make sure that we're bringing better and better targeted technologies for physicians and patients to be able to treat their cancers quickly, efficiently, and as often in a one-and-done fashion as we possibly can, getting them back to their lives and families; all the things that matter to them.

We also believe very strongly that our team is a critical part of our success. I am very proud to say that our team is a great group of really dedicated people, whether they be in our manufacturing facility in Richland, Washington, or spread out around the country like our sales team is.

And it's very important for all of us to be supportive and communicative and also to be critical thinkers, never wavering from our determination to not ever lose focus on our dedication to making

sure that we are making a difference and improving patients' lives. We don't ever take the importance of what we do for granted and we are constantly looking at how we can be creative to look for ways to make patients' lives better.

TWST: What does the future hold in relation to the development and approvals for brachytherapy to treat other cancers, like brain cancer or lung cancer?

Ms. Woods: So, for prostate cancer, we had to wait 10 years for our clinical data to mature to the level that we could go out and say to everybody, "We have cure rates that are wonderful for low- and intermediate-risk patients. And we also have a great isotope for high-risk prostate cancer in combination with other treatments."

Keep in mind that prostate cancer is a slow-growing cancer. If you look at some of these other cancers, like brain cancers, and how they evolve, they're not slow growing like prostate, and they evolve much quicker. The process with brain cancer was to make sure initially that we did small studies to prove safety and efficacy, and that we were seeing the outcomes that we thought we would see.

Then, it opened the door to being able to roll out our Cesium-131 treatment to a broader set of physicians and patients as an option, along with having clinical studies that they could enroll in and be part of clinical trials, registry trials, and make sure that we're gathering all the data we can on these patients. And as that data is gathered, that then makes the technology more approachable for a community hospital and others outside of some of the research institutions and the groups that do these kinds of earlier testing.

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We have a partner that works with us. They have their own delivery device that uses our Cesium-131 as the power of the treatment therapy. It has ongoing clinical trials right now across the country at places like MD Anderson and other well-known institutions. And that's really given a lot of credibility to the many community-based hospitals and physicians there to go out and use this product and take advantage of its great effectiveness for treating brain cancer.

Right now, we are getting increasingly involved with the treatment of brain cancers and we are treating more and more patients. We're doing the same things with head and neck cancer, and lung cancer, where we're at an earlier stage. Going forward, we're going to continue to expand in these other areas because a lot of these are hard-to-treat cancers that leave the doctors and the patients they treat sometimes facing the reality of having run out of options. What we are doing is building on our drive to make sure that we can give another line of defense for these patients in their battle against their cancer.

TWST: How do you get the word out? Where do you start, and what's your plan and strategy?

Ms. Woods: An important part of getting the word out is the patients themselves. We have found that patient advocacy groups out there are very important in sharing information. We're a small but growing company and so we do, of course, have a website and we also

use social media channels like Twitter, LinkedIn and Facebook and every other place that we can. But being a small company, we don't have the same kinds of abilities to reach out as some of the other bigger companies, so we look to partner with folks. And patient advocacy groups are a wonderful place to do that. We work with those groups because they are able to get key information a lot of patients.

Another important part of the equation are the physicians. We work more from a clinical perspective, getting the word out on how well Cesium-131 works, what its attributes are, how patients respond, and how doctors talk to each other. We have taken a leadership role in supporting training programs that help doctors understand how to use our product and raise awareness that way. We also participate in key conferences that allow us to reach the medical community with the compelling results that demonstrate why Cesium-131 is making a difference.

TWST: Tell us about some of your partners. Are these biopharmas, or patient-based?

Ms. Woods: When I talk about patient advocacy groups, I am referring to organizations like ZERO Cancer, the nation's largest patient advocacy group for prostate cancer. Of course, there's Susan G. Komen, and lots of groups like this. But ZERO Cancer reaches to our core prostate market.

I am using this organization as an example because they have done a fabulous job of putting together a support network in a very aggressive way to help patients navigate through this critical time in their lives. And similar to Susan G. Komen, they reach out to patients, they

help patients understand what their options are, they help patients through this time with emotional support capabilities, all kinds of things. It's a very broad-based, wonderfully dedicated group of people supporting patients and their families nationwide and we're really happy to be working with them.

Of course, there are other groups as well. We try to find as many of those and work with as many of those as we can. And then, as we increasingly work in treating other areas like the brain, we will do the same thing. We will work to raise awareness through social media, and then also to work with the groups that are already out there that patients look to.

But we also recognize that there is more to be done. We have expanded our marketing capabilities to reach a wider audience of patients and clinicians. We are going to continue looking at how we are reaching key constituencies to share what we view as critical information about our important treatment options.

TWST: What have been some of the external impacts that have affected the company? How has the COVID crisis been coloring the surrounding scenario?

Ms. Woods: Prior to COVID, we were growing at a nice clip, well over 25% quarter over quarter for multiple quarters; actually, multiple years, and as high as 45%. Ironically, as we reached that high level of success, it was also the quarter when COVID hit us.

Initially, we thought, it was, “OK, well, COVID is here, but we’re treating cancer patients and that has to go forward.” So our thinking was we’re going to hunker down, make sure our supply chain is well set up, and make sure our employees are all protected. And being based in Washington State, I think we got a little heads up because that first patient was diagnosed with COVID here.

And then what we realized was that very quickly, hospitals got overwhelmed. And even the cancer patients weren’t getting treated for a couple of reasons. Some of them didn’t know they had cancer, because they were afraid to leave the house and seek medical care. We were all locked down for a period of time and there were a lot of patients that didn’t get into the system then.

And then, there was an extended period of time where there were hospitals that were overwhelmed. So we initially felt the impact through that. But we’ve been growing back steadily after that first quarter — April, May, June of last year — primarily because physicians really understood that there was a crisis here, but cancer patients still needed to be treated. And they realized that they could do it in an outpatient setting, or an ambulatory surgery center.

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And our treatment, as I described earlier, is a one-and-done treatment. This makes a difference because you didn’t need to have as much PPEs that you were using, you don’t need as much staff, you’re not taking up bed space and they could get patients treated very effectively, quickly, and without having them come back multiple times that would have further complicated the demand on supplies, occupancy availability and staff.

Fast forward to today and we are very encouraged with what we’re seeing happening now. As patients get vaccinated, they are coming back out into the system to get diagnosed, which is very encouraging to us.

I would also point you to the American Cancer Society’s statistics that really tell the story of what can be expected in prostate cancer. The American Cancer Society is suggesting that over the next two years, we’re going to see a 30% increase in the number of people diagnosed with prostate cancer. Where it’s been in the 180,000 cases a year range, they’re projecting 250,000 patients because people stayed at home and didn’t get diagnosed.

And now, because prostate cancer is slow growing, I think for the majority of those patients, they’ll come in with a little bit more advanced disease, but not something we can’t handle for them. So we expect to see growth pick up and continue certainly for the next couple of years to be able to catch up and help those patients out.

TWST: Is this a good time to invest in Isoray? Can you share a look at your balance sheet — the best and the worst?

Ms. Woods: Yes. I think it’s a great time to invest in Isoray. And the reason for that is we are looking to the future of cancer care and

how we can be part of that mix. We are already actively pursuing some really exciting opportunities for Cesium-131 going forward. You can see from the increasing types of cancer for which we are providing treatment options, we don’t intend to be focused as a solely prostate cancer treatment company in the future.

We are looking at and have recently launched clinical trials for combining Cesium-131 with PD-1 inhibitors, so immuno-oncology. And if you look out there right now, immuno-oncology is being researched very thoroughly right now because there are many researchers and leading institutions that believe it’s the future of cancer care. And that is taking a couple of different approaches on how to rev the body up and have its own immune system help fight the battle against cancer.

We recently started a recurrent head and neck study, combined with Keytruda, to look and see how Cesium-131 can go in and really identify and light up the main tumor, and that Keytruda can follow and help train the body on how to identify the cancer and really go after it aggressively. We’re involved in a metastatic melanoma clinical trial with Optivo. In short, these are some really exciting times for Isoray.

It is that vision for the future that was an important motivation for the action we took in February when we raised a substantial amount of money. We had done a smaller raise the previous October in the middle of COVID. The first raise really was to get us to breakeven with our core prostate business.

The money we raised in February, which was a significantly larger amount of just over \$45 million, really was earmarked for where we’re going in the future, and for our R&D efforts, and what we’re going to work on to bring more options to physicians and patients along the lines of what I just described as combination therapies.

Our strategic plan includes the proper investment of this money and we’ve got four different buckets we’re looking at. Certainly, as I touched on earlier, we’re going to do some investment in our sales and marketing efforts for our current core prostate business. That’s important to continue to get the word out, because there continues to be a significant number of patients that need that word to get to them.

Then, we have our growing surgical applications for brain, head and neck, and lung cancers, where we’re doing clinical trials and data research to gather the data for physicians to make informed decisions on our products. So we’re going to continue our efforts in that area.

And then, we’re going to continue these trials with the immuno-oncology. And these are larger volume studies. They’re more expensive studies, but they are definitely where we see the industry is going in terms of new options for better patient treatments. We’re going to be very much involved in that.

And then, the last bucket we’re looking at is based on the incremental opportunities we have right now through maybe a potential

acquisition or a partnership. We're looking at what are the opportunities that are out there right now, either to develop technology that we are excited about and believe in, or to bring technology in that's already been started by someone else and folding that into our company.

So I think Isoray is at an inflection point now, growing from a small company that has worked to grow slowly and steadily over the years — and has done a good job of that and treated over 15,000 patients today — to a company that's looking to the future and all the ways that we can be involved in the promising future of disease treatment throughout the body. We are going to be taking all of our expertise and leveraging our knowledge and lessons learned to find new treatments for patients and also working with other companies to bring these new treatments along as well.

TWST: As you look forward into the coming year or two, what are the challenges you might be preparing to meet? Any headwinds that worry you?

Ms. Woods: At this point in time, I think the thing that everybody is thinking about is where is COVID, how long is it going to be here, and are the variants going to become a problem?

At the same time, we are looking at lessons learned. What I will say is that I am very proud of the job we have done over this last year. We had no supply chain disruptions. We didn't have any major outbreaks in our manufacturing facility. We've done a really good job of making sure we're there for our patients. We didn't miss any patient's treatment.

And as we look forward, we always want to make sure we're in a position to provide these targeted personalized treatments. That's why we always look very closely at how we can make sure that we have all the capacity we need and that our supply chains remain robust and dependable.

Looking to the future, we are going to always pose the question: How do we make sure we find something better for these patients than we have today? So these are the considerations that remain in focus going forward.

TWST: Anything else you'd like to share about your specific goals and targets for the second half, and going into 2022?

Ms. Woods: As we look to the next couple of quarters, what we're looking at is really ramping up for those patients that are coming through the system now and making sure that we are ready to support them, while we also are spending a lot of time expanding our R&D team. This is something new to Isoray and marks another important step forward. We haven't had an R&D team really in the past. And so, to make this a reality, we have our Chief Research and Development Officer, Bill Cavanagh, leading that charge to bring in and put together a team who can help execute on the future goals for the company and the future of treatments for patients.

Certainly, these next few quarters we'll see a great deal of activity around helping those patients who are entering the system who need to be treated and who are maybe a little bit behind in the treatment paradigm. We are confident that we have all the resources in place.

And now that we have had this investment from our investors, we won't just sit on that money. Our investors expect us to make good and wise choices on how our capital is invested and we intend to do just that. And so that's where we are really focused in the next couple of quarters;

doing the due diligence we need to do to bring some good opportunities to Isoray that will benefit patients and also benefit our investors.

TWST: What is your competitive moat? How unique are these products?

Ms. Woods: In brachytherapy, there are a couple of other isotopes that compete with us. One is Iodine-125, the other is Palladium-103. And both those isotopes have been around longer than we have. Those isotopes work very well in prostate and there's a lot of data that shows that, but as we discussed earlier, Cesium-131 has definitive strengths in treating prostate cancer.

What we also know, however, is that these other isotopes do not have the same ability as Cesium-131 does to move into other cancer treatment areas. In the past, they've tried those other isotopes in treating other cancers and they've really backed off on that, because they do not have the full complement of characteristics that are needed. They have one of the two things that you need, so they might have high energy, but they would have a long half-life, or they might have a short half-life, but a low energy.

What we see with Cesium-131 is we have that sweet spot. We've got both the key characteristics that are needed. That has allowed us to expand outside of prostate cancer treatment into some of these other crucial areas we've discussed, such as head and neck, lung, brain.

As we look at the current brachytherapy marketplace, we also have to keep in mind that there's radiation that's delivered in other ways. There's external beam radiation, IMRT, a variation of other common external beam therapies and there are other applications as well — protons and other things that are in the marketplace for some of these cancers. But, keep in mind, this is where you have a beam of radiation coming from an outside source through your body, through tissues and organs that maybe don't need that radiation coming through them into the body. Maybe it's a single beam, maybe it's a lot of different beams that come through and focus right at the tumor site, but they're still coming through your other critical structures in the body.

What we think is so important about brachytherapy and about Cesium-131 specifically is that we're delivering a targeted internal radiation dose that is just going to that specific site. The doctor can determine exactly where he wants the radiation to go, and not go and not have it go through other important critical body structures. The doctor also knows exactly the dosage he is delivering when using Cesium-131 brachytherapy. This is another important distinction. So we're delivering our therapeutic isotope right to the tumor, and that's very important.

TWST: Thank you. (VSB)

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