

Disposable Implantable Wireless Sensor for Monitoring The Strain on a Rod during Spine Fusion Surgery



Richard R "Ric" Navarro
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CEOCFO: *Mr. Navarro, what is the concept behind Intellirod Spine™?*

Mr. Navarro: It started out a University of Louisville commercial idea brought to them by a spine surgeon from Louisville by the name of Dr Rolando Puno. He had the idea of being able to implant a wireless sensor into a patient at the time that they are having a spine fusion, to be able to detect the load or strain on the fusion hardware. By knowing that you could tell how the fusion was progressing post operatively using RFID wireless reader technology.

CEOCFO: *That sounds like a reasonable idea. Where are you today with the concept?*

Mr. Navarro: The company was incorporated in 2008 and for the last 7 or 8 years it has been solely focused on a permanently implantable version of this sensor which we have since branded the ACCUVISTA™ sensor. However, about a year ago we actually added a second product called the LOADPRO™, which is a disposable version. It too is used to monitor the strain on a rod, but it is used during surgery. Therefore, we have really accelerated our path toward sales and revenues by having this second product, which is easier to get through the FDA. Therefore, we expect to actually get FDA approval on LOADPRO by the end of the year. LOADPRO is 510 K pending at the FDA now.

CEOCFO: *What is the measurement that is going on during the surgery and how would a surgeon adapt depending on what your device shows them?*

Mr. Navarro: That is a very good question! We have the ability to measure strain on the titanium rod used during fusion. Now, there is a difference between LOADPRO and ACCUVISTA, not in what they measure but how the data is used. Therefore, in LOADPRO; because it is an intra operative measurement and the device is being disposed of we are giving the surgeon the ability, during the surgery, to look at how the load is balanced on the left and the right rod during a scoliosis or a kyphotic deformity correction surgery. That may be important to prevent postoperative complications that frequently happen with these patients. That is because heavy loads are put on the hardware. We see screw loosening or even hardware breakage. Therefore, by better balancing the load in the operating room; which can be done by the surgeon by either adding more screws to the construct or contouring the rods during the surgery to make them more even, he can possibly affect the complication rate post operatively. Now, on ACCUVISTA it is a little bit of a different value proposition. In the case of ACCUVISTA we are looking to use the RFID reader wirelessly at the office visit after the surgery. We will take a baseline reading when the patient is discharged and then compare the subsequent readings to the baseline strain reading. If that strain is dropping we know that new bone must be taking the load off of the hardware. Therefore, we get an indirect but quantitative measure of the progress of the new bone fusion. In this case the surgeon can look at this data and in conjunction with x-rays, determine whether or not this patient is either ready for physical therapy or activities of daily living or even return to work. It is a quantitative way of knowing, biomechanically, how the load is being transferred from the hardware to the bone.

CEO CFO: Are there alternative methods of measurement? Are there other devices or other systems that essentially compete in that measurement area with the ACCUVISTA?

Mr. Navarro: No. The ACCUVISTA's competition is really a CT scan post operatively. Therefore, if surgeons are having difficulty determining the status of a fusion with standard x-rays they will often resort to a CT scan with a three dimensional reconstruction. Now, while that is a better interpretation of what is going on, it is still more of a subjective measure. That is because you cannot tell what is happening with the load bearing by reading that x-ray or CT scan and a CT scan is usually one point in time; because it is a high radiation dose they do not like to do it very frequently and even avoid it post operatively. That is because often patients have had these scans pre operatively. Therefore, the radiation exposure limits the use of the CT, so we are really giving the surgeon a new tool that competes with the CT scan.

CEO CFO: When all the measurements are done and we see how the spine is working that device would remain implanted. Why is it okay to have an extra piece of hardware in your body?

Mr. Navarro: Yes, as does the spine fusion hardware. The titanium screws, the titanium rods; they stay in place ninety five percent of the time. There is a small percentage of patients that have them removed, but usually not routinely. It is due to some ongoing pain or maybe metal allergies. This sensor is quite small and does not add much in the way of any additional material implanted in the patient.

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CEO CFO: Were surgeons looking for a way to be able to measure during the surgery or is it more that they are excited that you found a way to do it?

Mr. Navarro: It is more the latter. What you see in the spine literature is certainly the recognition of the limitations of imaging. There was a paper in the Spine Journal in 2014, done at Yale. It was a review article on the imaging techniques used to assess fusion. Their conclusion was the gold standard CT scan is still only right eighty percent of the time. Therefore, you have this problem that needs solving and I think it is a combination therefore of a problem that exists and a new technology is coming along to help aid in that decision making.

CEO CFO: Is it easy to get attention for the LOADPRO since surgeons are familiar with ACCUVISTA?

Mr. Navarro: We are still pretty young and since we are not out selling surgeons are just becoming exposed to this in the last couple of years, with the exception maybe of a dozen or so surgeons that we have used to help develop the device over the years. Therefore, it is still fairly new to them. What we do find through, is that their reactions are very inquisitive! We do not have the clinical proof yet that our hypothesis will be true, but what we see is that surgeons have a great interest in finding out! Therefore, as we get LOADPRO on the market we will be able to do some post market clinical studies while we are generating revenue. The way that can happen is that LOADPRO will get used with our pedicle screw system and while we may not initially get reimbursed for the sensors in the early going we can get reimbursed for the pedicle screws.

CEO CFO: What is the market potential in general? How prevalent is spine surgery?

Mr. Navarro: It is quite a prevalent condition that results in the second highest reason for lost work in the United States; next to the common cold it is back pain. Therefore, we are dealing with a big problem, while LOADPRO is intended for more of a niche market. I had mentioned earlier, for kyphotic deformities or scoliosis that might be five to ten percent of the total spine market. However, the ACCUVISTA is targeted more toward your routine degenerative disk disease fusion patients. Therefore, it is lumbar fusion between L1 and S1 and it would commonly be one or two levels. Those are numbering four hundred thousand plus per year. Therefore, a total addressable market for the ACCUVISTA is in the billion dollars a year range.

CEO CFO: Are you going international or is it too early?

Mr. Navarro: We are approaching it. The reason that I say that is because we recently got our ISO 13485 certification. We were audited in the spring and received our ISO certification in June. That positions us to be able to apply for the CE Mark on LOADPRO, which is a prerequisite for selling in the EU. Therefore, we are excited about that; to have our application pending by the end of the third quarter. We could receive approval by the end of the year or the first quarter next year. That would set up the possibility of international distribution through a strategic spine company partner or on our own in a limited engagement with a couple of surgeons.

CEOCFO: *Development and commercialization are always expensive. How are you with funding as you go forward?*

Mr. Navarro: We just finished a round of equity financing which came from our internal investors, so we call it more of a bridge round that was part of our B round of preferred equity. That sets us up for about the next year and yet my job is to go out and find the C round of funding, which we are doing and we think that will be about in the four million dollar range. That would take us all the way to break even in 2018. Therefore, we are running a pretty lean enterprise here with six employees. We would add a few more, but we would stay lean while we conduct the clinical trials of ACCUVISTA and we would be selling LOADPRO and reach a level of three to four million in sales in 2018.

CEOCFO: *Is spine an area where investors are focused? Does it make it easier to get traction with an easily understood concept?*

Mr. Navarro: Yes. Since I have been in spine for over twenty years I have watched it come up through a craze period during the early 2000s where M & A deals were being made and many new products were coming out, but a lot of them did not reach their potential in the late 2000s where hundreds and millions were invested. There was kind of a heyday followed by a bit of a maturing cycle, as I call it, where many of the fusion products had become passé or more like commodities and we are starting to see what has happened in the hip and knee industry, where the prices are being forced down by healthcare reform. However, countering that is the demographic. We have the Baby Boomers reaching their elder years and wanting to stay active. Therefore, you have reasons to do these surgeries to keep people out of debilitating pain. While the investment community; I am mainly talking of the venture capitalist, are a little wary of spinal implant products, we are a spinal implant product but we are not a therapeutic. We are more along the lines of the diagnostics. However, what we see is this need to explain that we are different than a spinal implant, which many investors perceive as maybe evolutionary and not revolutionary. Our device provides new data and helps differentiate a pedicle screw system. What we are seeing is that payers or insurance companies want more evidence based medicine. That is what we are providing is a new form of evidence of fusion.

CEOCFO: *It seems that the accountability that doctors are going to have rather than pay by visit will be helpful to you as well!*

Mr. Navarro: You are right! I was talking to a surgeon in Columbus who said that a few years ago he might not have been interested in this device and now these payers are asking for evidence that he has achieved a fusion if what they are paying for is a fusion. Therefore, that result is difficult to interpret using standard imaging and if we can bring a new piece of information or data to augment that imaging data it helps makes that decision and takes some of the subjectivity out of that decision we think that is going to lead to our success.

CEOCFO: *So, timing is right for Intellirod?*

Mr. Navarro: It very well could be; the forces of healthcare reform are playing in our favor, we think. There are some pure sales reasons that we think the devices will both be successful and then the fact that they help to differentiate a pedicle screw system. The FDA has approved over one hundred and fifty pedicle screw systems, which makes them a commodity. Yet, by packaging our sensor with the screw system, that system becomes high tech; it becomes set apart from its competitors. Therefore, we are anxious to show that ourselves as we have a pedicle screw system to distribute. We are starting in Louisville and Columbus and hope to follow that with Cleveland and Cincinnati. Then from there we may attract the interest of a spine partner.

CEOCFO: *Why take a look at Intellirod Spine today?*

Mr. Navarro: That is a good question and I touched on it earlier. Each spine, if you look at the North American Spine Society and you see the hundreds of booths there and you walk the floor, you will see the usually incremental improvements in products, but you see very few revolutionary products; especially a product that helps set apart and differentiates a pedicle screw system. That is very, very important, because pedicle screw systems and related implants and biologics are forty percent of the lumbar fusion market and represent about three to four billion in sales in total per year. Therefore, we think that the interest will come and it has come from some of the strategic spine companies in wanting to be the first to market with a revolutionary product that differentiates their product.

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



For more information visit:

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