

Revolutionary Regenerative Medicine Products providing Plastic and Hand Surgeons with the Tools Necessary to successful Connect and Repair Peripheral Nerve Injuries



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“AxoGen is at the tip of the iceberg in commercializing the over \$1.6B peripheral nerve repair market.”- Karen Zaderej

CEOCFO: Ms. Zaderej, would you tell us about AxoGen and your current focus?

Ms. Zaderej: AxoGen is an emerging global growth company focused in the area of peripheral nerve repair. Our focus is on helping patients, and the surgeons who treat them, with injuries to peripheral nerves. Nerves function as the wires of the body. They carry signals from your brain to tell your muscles to move or to allow you to have sensation. When the nerves are cut, just like when you cut a wire, they do not carry signals anymore. These patients end up with a deficit in function. When a nerve is compressed, it alters the signal carried by the nerve and this change can result in lost sensation or muscle function or can result in pain. Our goal is to work with the surgeons that treat these patients to provide an option to restore the function of the nerve by restoring the continuity of the nerve and protecting the nerve from soft tissue attachments or compression.

CEOCFO: How close is your relationship with the surgeons, and does the surgeon community have an impact on your product focus?

Ms. Zaderej: Absolutely! Our primary customers are surgeons. Hospitals buy medical implants like the AxoGen portfolio of products but it is really the surgeons who determine the course of care for each patient. It is the surgeon who needs to feel comfortable that this is an appropriate treatment for the patient. We work with the surgeons to teach the appropriate techniques for nerve repair and the appropriate applications of the products.

CEOCFO: How big is the market and are you playing only in the US?

Mr. Zaderej: The peripheral nerve market is a large market that has been relatively untapped with off-the-shelf products. Peripheral nerves have been repaired for many years but surgeons repaired them with surgical techniques versus products. Those techniques have some significant drawbacks --they have drawbacks to surgeons in terms of consistency and reliability, there are drawbacks to hospitals in terms of how much those techniques cost and there are drawbacks to the patient in that the traditional techniques always create a deficit to the patient. The patient will have to give up something else in order to get function back in that nerve. If all the procedures that are done today in the U.S. used our off-the-shelf products, the market for nerve repair products would be over a \$1.6 billion opportunity. In addition, injuries can happen all around the world and there are additional global opportunities. From an AxoGen standpoint, while our focus today is predominantly in the US, we are starting to expand globally and we think that the international market opportunity is at least as large as it is in the US.

CEOCFO: How many products do you have currently and are there particular ones that you are focusing on?

Mr. Zaderej: We have three products today in our surgical portfolio that surgeons use to repair nerves. We will be launching a fourth one this year, currently we have three. We really deal with two types of conditions; when a nerve is cut

or when a nerve is compressed. When a nerve is cut, a surgeon needs to go in surgically and align the two nerve ends. The first product we have is called AxoGuard® Nerve Connector. It is used when a nerve is cut in a sharp laceration injury, for example a kitchen knife injury while preparing dinner. That is the sort of repair that a surgeon would repair with an AxoGuard® Nerve Connector. It aligns the two nerve ends and, as all our products are regenerative medicine products, it remodels into the patient's own tissue. The AxoGuard® Nerve Connector remodels into the epineurium or skin of the nerve, keeping the nerve ends aligned and physically seals the nerve connection. The second product we have is Avance® Nerve Graft which is used when a nerve is cut but the surgeon has a gap between the two nerve ends. An example of this type of injury is larger trauma such as an accident while using power tools. In that injury, a small segment of the nerve is removed and there is a gap between the two nerve ends. The surgeon has to do something to bridge that gap. Historically, what they would have done is take a nerve from somewhere else in the patient's own body and move it. That is what I meant when I said that the patient would lose something in the traditional nerve repair techniques. The traditional techniques always involve taking a nerve that is less important to fix one that is more important. With our Avance® Nerve Graft, the surgeons have an off-the-shelf solution for this repair. The third product is focused in the area of protecting nerves. As I mentioned earlier, nerves carry the signals of the body. If you have compression on a nerve either from the surrounding tissues of the body pressing down on it or tethering it, this compression alters the signal conduction of the nerve. This compression can either cause muscle weakness, numbness or pain. People are pretty familiar with carpal tunnel syndrome and this is an example of a compression on a nerve at the wrist causing pain and weakness in the fingers. Our AxoGuard® Nerve Protector is used by a surgeon to wrap and protect the nerve. These are the three products that surgeons will use whenever a patient comes in with a nerve injury. It allows the surgeon to reconstruct a nerve injury to allow restoration and continuity of the nerve and to protect the nerve from the surrounding tissue.

CEOCFO: *You also have a Neurosensory and Motor Testing system. Would you tell us about that?*

Ms. Zaderej: This year we wanted to move into providing surgeons the tools they can use to measure the outcomes of nerve repair. We released the AcroVal™ Neurosensory & Motor Testing System (NSMTS) which is a tool that the surgeons are able to use to measure sensory function as well as grip strength and pinch strength, which are two of the important motor strength measures of the hands. This is a tool that the surgeons will use to monitor their patients as they come back for follow-up to measure and track the progress of the healing of the nerve.

CEOCFO: *Do hospitals tend to buy all three or four of your products?*

Ms. Zaderej: Initially when a surgeon and a hospital start with the AxoGen portfolio, they typically start with one of our three surgical products, depending on what their interest is in nerve repair. What we typically see is, as the surgeon gains confidence with the AxoGen treatment algorithm, he or she will expand the applications and will, ultimately, move to all of our products. A hospital that buys all three of our surgical implants generates, on average, five times the revenue of a hospital buying one of the products.

CEOCFO: *What is your revenue model?*

Ms. Zaderej: We currently have 414 accounts in the U.S. out a potential 5100 accounts that have actively begun using our products. We find surgeons are cautious adopters in new techniques in nerve repair. They typically start slowly and expand as they gain experience and confidence with the products. Our approach is to educate surgeons on the best practices and techniques in nerve repair and to build clinical data to support their patient care decisions. Using these tools, we find surgeons initially begin using our products in a niche of their nerve repair and then they expand over time across the full treatment algorithm.

CEOCFO: *How are you selling your products?*

Mr. Zaderej: We have a hybrid sales team where we have a combination of direct sales associates who are employees of the company as well as independent distributors. We utilize both types of selling models in different territories of the US market.

CEOCFO: *How is the manufacturing done for your product?*

Ms. Zaderej: We process the Avance® Nerve Graft at our processing center in Dayton Ohio. On the AxoGuard products, both the Connect and Protector are manufactured by our partner Cook Biotech in West Lafayette, IN.

CEOCFO: *What are you doing to expand the reach for your product?*

Ms. Zaderej: Our marketing efforts are centered on what we call our five pillars for growth. The first of these pillars focuses on building market awareness with our target surgeons. Our target surgeons are plastic surgeons, hand surgeons and selected oral and maxillofacial surgeons. We actively participate in medical conferences and support panels for discussions on nerve repair. The second pillar is surgeon education. We, as the first company and the preeminent

company in the area of peripheral nerve repair, take our responsibility very seriously about making sure that we provide the best science and data in educational content to support surgeons making good choices for their patients. We do a fairly intense training program on Best Practices in Nerve Repair. This year we will complete thirteen of these two-day intensive courses to help surgeons expand their skills. These courses are taught by some of the most famous surgeons in peripheral nerve repair. The courses go through a rigorous review of the science and techniques of nerve repair as well as hands-on practice on the techniques. The third pillar is building clinical evidence. We focus on building data that surgeons can use to understand and evaluate the outcomes of the product. To date, there are over 39 peer reviewed publications on the AxoGen portfolio of nerve repair products. The fourth pillar is excellence in sales execution. Our sales associates become nerve repair experts and they help the surgeons understand the need for nerve repair and the options available. The sales associate is also responsible to make sure that the accounts have inventory and the surgical staff are prepared for the cases. The fifth pillar is the expansion of nerve repair in even more applications as well as the introduction of new nerve repair products. I talked about the \$1.6 billion opportunity in nerve repair but that is focused predominantly in upper extremity traumatic injuries. We believe we can expand the AxoGen portfolio of products into additional applications where nerves are impacted. For example, in tumor removal many of the complications of the procedures are due to nerve injuries--the erectile dysfunction and incontinence in surgery for prostate cancer are actually nerve injuries, the facial paralysis in surgery for facial tumors is a nerve injury. There are many more surgical areas where we can bring meaningful solutions to clinical challenges. Some initiatives we have in early development are providing sensory restoration in breast reconstruction and the identification and repair of peripheral nerve injuries from total joint replacement.

CEOCFO: Are your R&D efforts focused in new products or expanding on the current?

Ms. Zaderej: Our R&D efforts are focused both in expansions for our current products as well as developing new products for nerve repair. We will be launching another nerve repair implant later this year. We have been actively working on this for the last several years and are excited to release another surgical implant.

CEOCFO: What is your geographic range and your growth strategy?

Ms. Zaderej: We are at the early stages of adoption in nerve repair. Nerve repair is done in many centers across the world but we currently focus predominantly in the U.S. Our primary focus for growth is driving penetration in the centers where we are already active. Even in the accounts we are currently in, we are typically at the early stages of adoption with one surgeon. We have significant opportunities for expansion across the initial surgeon's treatment algorithm and to expand to other surgeons at the account. Our second area for growth is to expand into new accounts in the US. Our third area for growth is to expand geographically across the world. We are currently commercially available in in Canada, Switzerland, Austria, The Netherlands, Spain, UK and several other countries.

CEOCFO: Do you have all the funding necessary or are you looking for investors?

Ms. Zaderej: We are publicly traded on NASDAQ. We just completed a capital raise which provided us net proceeds of \$18.6 million after underwriting discounts and estimated offering expenses. We had enough cash to get us to cash flow break-even but we did not want anybody to be concerned that we were getting skinny on the balance sheet. Therefore, we did an additional capital raise to top off the balance sheet. At this point we have a strong capital position and we are able to execute on our plan to build this market.

CEOCFO: Would you tell investors about your team and why they should consider and have confidence in AxoGen?

Ms. Zaderej: AxoGen is at the tip of the iceberg in commercializing the over \$1.6B peripheral nerve repair market. We are generating revenue with over 52% year-over-year growth. We have given guidance that we will exceed \$40M in revenue this year with gross margins in excess of 80%. We also have barriers to entry that allow us to continue to build this large and relatively untapped market without having significant competition. This allows us to build the market and remain the leader in peripheral nerve repair. And, we have built what I think is a top-notch team with a deep experience in med-tech commercialization and clinical development. We have the skills and experience we need to continue expand the market and deliver revenue results.

