



**AxoGen**<sup>®</sup>  
Nerve Regeneration

SURGICAL SOLUTIONS FOR  
NERVE RECONSTRUCTION

As of June 24, 2014

# AXOGEN PRESENTATION

NASDAQ: **AXGN**

*It's time to rethink nerve repair!*



**AxoGen**<sup>®</sup>

# Safe Harbor Statement

This Presentation contains “forward-looking” statements as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management’s current expectations or predictions of future conditions, events or results based on various assumptions and management’s estimates of trends and economic factors in the markets in which we are active, as well as our business plans. Words such as “expects”, “anticipates”, “intends”, “plans”, “believes”, “seeks”, “estimates”, “projects”, “forecasts”, “may”, “should”, variations of such words and similar expressions are intended to identify such forward-looking statements. The forward-looking statements may include, without limitation, statements regarding product development, product potential, regulatory environment, sales and marketing strategies, capital resources or operating performance.

The forward-looking statements are subject to risks and uncertainties, which may cause results to differ materially from those set forth herein. Forward-looking statements in this presentation should be evaluated together with the many uncertainties that affect the Company’s business and its market, particularly those discussed in the risk factors and cautionary statements in the Company’s filings with the Securities and Exchange Commission. Forward-looking statements are not guarantees of future performance, and actual results may differ materially from those projected. The forward-looking statements are representative only as of the date they are made, and the Company assumes no responsibility to update any forward-looking statements, whether as a result of new information, future events or otherwise.

# AxoGen Overview

## *Focus on Executing Sales & Marketing Strategy To Drive Shareholder Value*

- Only company focused on peripheral nerve repair solutions
- Addressing a \$1.6B+ current market opportunity
- Comprehensive product portfolio addresses all surgical peripheral nerve reconstruction needs
- Pioneering sales and market strategy, solid execution plan
- Poised for strong growth in 2014
- High gross margins: 78% in 1st Quarter 2014
- Barriers to competitive entry & growing body of clinical data
- Long term expansion potential beyond current market

# Need for Options in Nerve Repair

## *Nerve injuries can happen to anyone*

- More than 1.4 million Americans will experience a nerve injury in 2014
- More than 900,000 will require a surgical intervention
- Causes of nerve injuries
  - Lacerations, power tool / saw accidents, motor vehicle accidents, gunshot wounds
  - Surgical injuries
  - Nerve compression: Carpal tunnel revision, cubital tunnel

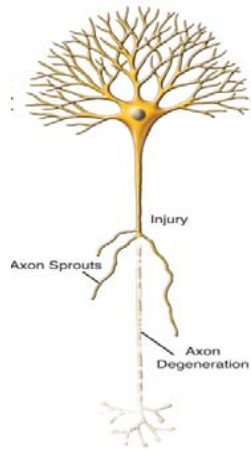


### ***AxoGen Patient Story: Edward***

- Navy Corpsman, shot while serving in Afghanistan
- 5 cm gap of sciatic nerve
- Family sought repair options other than amputation
- Repaired with Avance® Nerve Graft at Bethesda Naval (now Walter Reed National Military Hospital)
- Walking again on his own legs, attending Penn State

# Peripheral Nerves & Goals of Repair

## *Peripheral Nerves are Capable of Regeneration with Appropriate Guidance & Protection*



Example of axonal regeneration  
after injury



Cross section of a peripheral nerve  
illustrating the nerve bundles  
containing individual axons

Peripheral Nerves provide the pathways for both motor and sensory signals between the central nervous system and target organs, regulating movement and sensation.

### Goals of repair

- Restore muscle function and sensation
- Prevent neuroma / chronic pain

### Successful nerve regeneration requires

- Scaffold to direct, support growth
- No tension on the repair site
- Protection from scarring

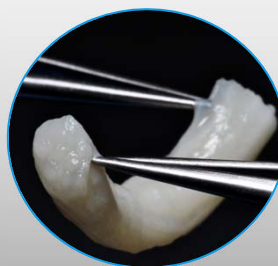
# The AxoGen Family of Products

*Complete line of products, Strong unmet need*

- Thousands of implants to date
- Currently distributed in the US, Austria, Canada, Israel, Netherlands, Sweden, Switzerland, and the United Kingdom



**AXOGUARD<sup>®</sup>**  
Nerve Connector



**Avance<sup>®</sup>**  
Nerve Graft



**AXOGUARD<sup>®</sup>**  
Nerve Protector

*It's time to rethink nerve repair!*



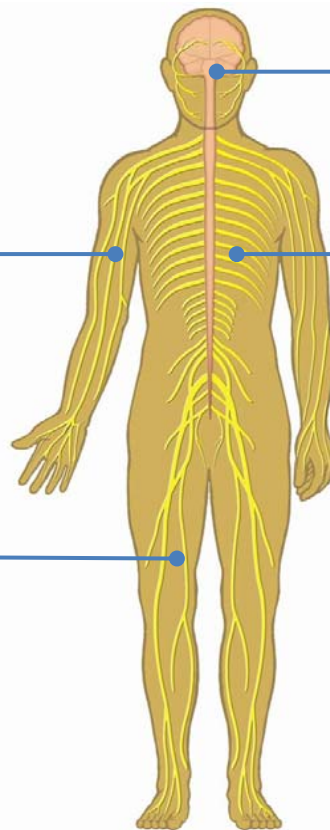
# The Market for Nerve Repair

*The Nerve Repair Market is Large with Opportunity for Expansion*

AxoGen is currently focused on  
Extremity (upper & lower)  
Carpal Tunnel Revision  
Oral Maxillofacial...

Upper Extremity

Lower Extremity



Head and Neck

Torso

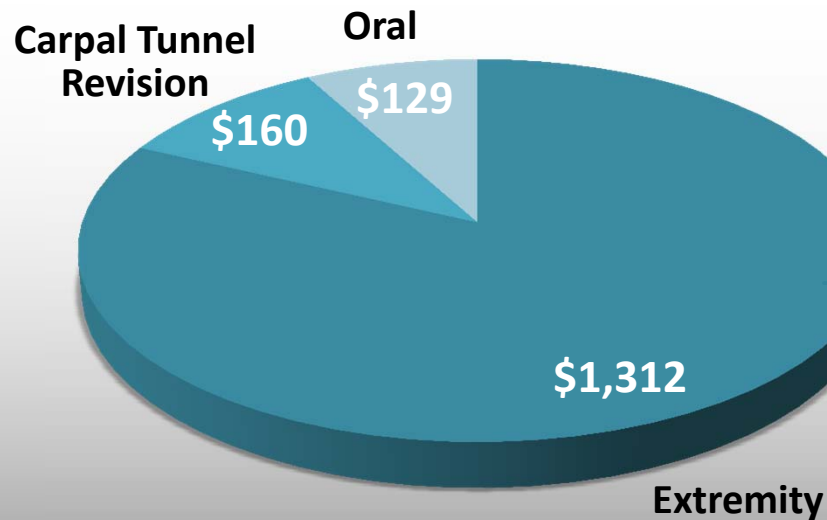
...with future expansion opportunities in  
Facial Reconstruction  
Podiatry  
Breast Reconstruction  
Prostatectomy  
Pain Management

*It's time to rethink nerve repair!*

# Currently Targeted Nerve Market (US): \$1.6B

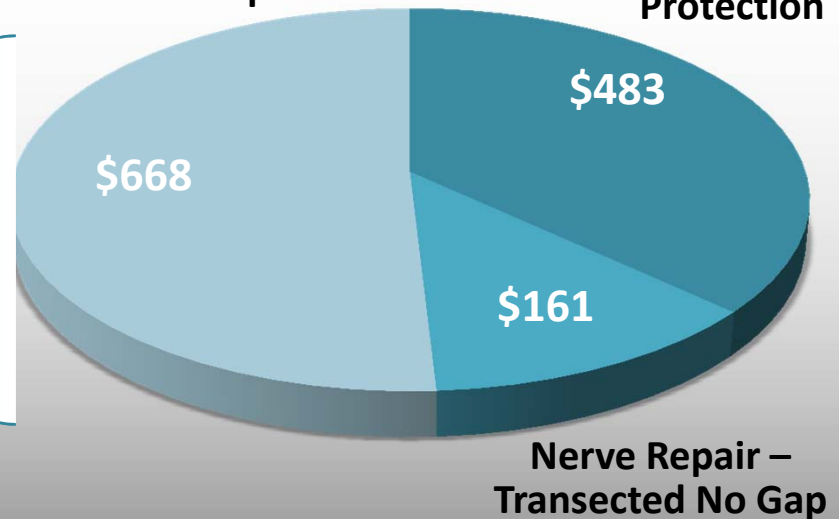
**AxoGen Current Target Market**  
**\$1.6 billion**  
*In millions*

**Extremity Market**  
**\$1.3 billion**  
*In millions*



**Nerve Repair – Transected with Gap**

**Nerve Protection**



## Approximately 900K Procedures in US:

Extremity	719,000
Carpal Tunnel	100,000
Oral	68,000

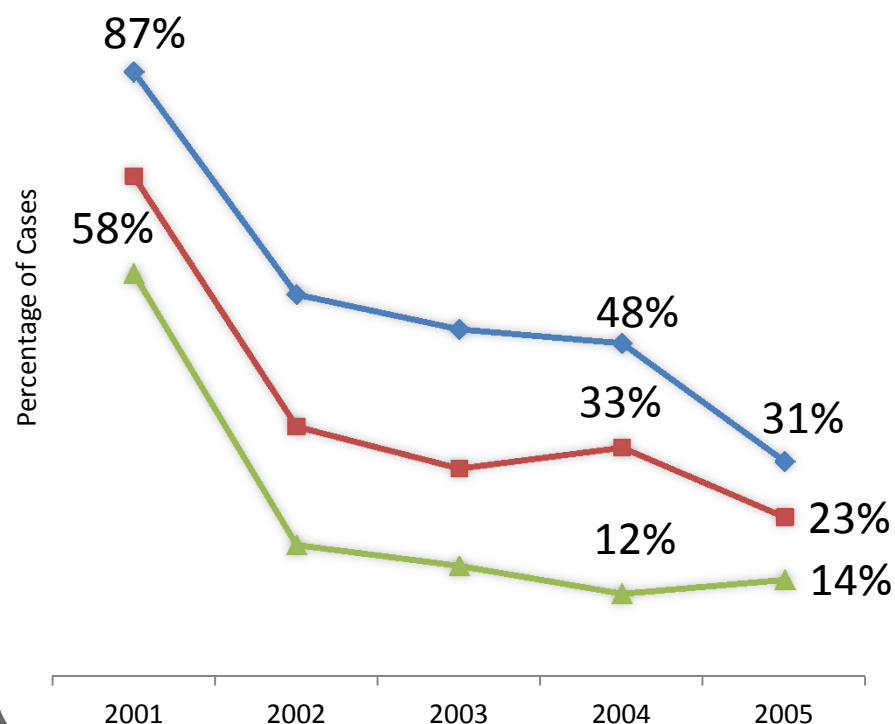
*International opportunity approximately equal to US market*



# Autograft Use Declines with Alternatives

## Trends in autograft use in spinal fusions, 1999-2005

(Source: Orthopedic Research Network, Ann Arbor, Michigan)



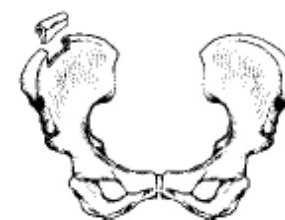
**“Gold Standard”  
autograft usage decreased  
when viable commercial alternatives  
were introduced:**

- Eliminated pain & morbidity of second surgical (harvest) site
- Reduced overall surgical time
- Eliminated costs associated with harvest
- Eliminated risk of poor autograft quality

◆ % lumbar fusions

■ % all fusions

▲ % cervical fusions



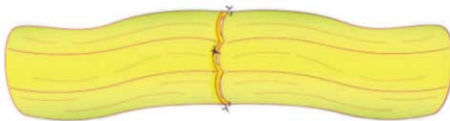
# Traditional Peripheral Nerve Repair Options

## Transected Nerves

### Suture

*Direct suture repair of no-gap injuries*

- Common repair method
- May result in tension to the repair leading to ischemia
- Concentrates sutures at the coaptation site



### Autograft

*Traditional "Gold Standard" despite several disadvantages*

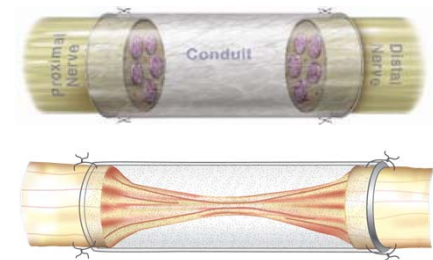
- Secondary surgery
- Loss of function and sensation at harvest site
- 27% complication rate including infection, wound healing and chronic pain<sup>1</sup>
- Limited graft length and diameter



### Hollow-Tube Conduit

*Convenient off the shelf option; limited efficacy and use*

- Provides only gross direction for re-growth
- Limited to small gaps
- 34%-57% failure rate >5mm gaps<sup>2</sup>
- Semi-rigid and opaque material limits use and procedure visualization
- Repair depends on fibrin clot formation



1. Rappaport, et al., Am J Surg 1993

2. Weber, et al., Plas and Recon Surg 2000, Wangenstein et al., Hand 2009

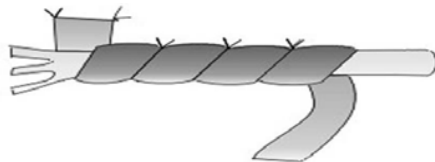
# Traditional Peripheral Nerve Protection Options

## Compressed and Transected Nerves

### Vein Wrapping

*Autologous vein used as a barrier to soft tissue attachments*

- Barrier to attachment to surrounding tissue
- Revascularizes to become a lasting barrier
- Requires extra time and skill to perform spiral wrapping technique
- Additional surgical morbidity due to second surgical site

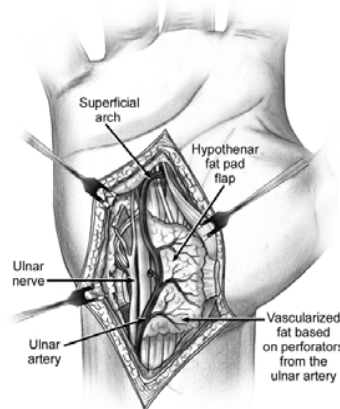


Sotereanos DG, et al., Microsurgery 1995

### Hypothenar Fat Pad Flap

*Vascularized flap used as a barrier to soft tissue attachments*

- Barrier to attachment to surrounding tissue; already vascularized
- Loss of protective hand cushioning
- Only wraps part of the nerve circumference
- Increases procedure time

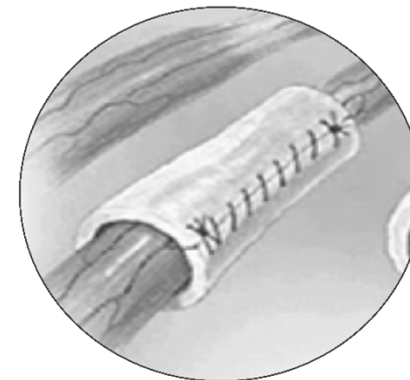


Lippincott and Williams

### Collagen Wraps

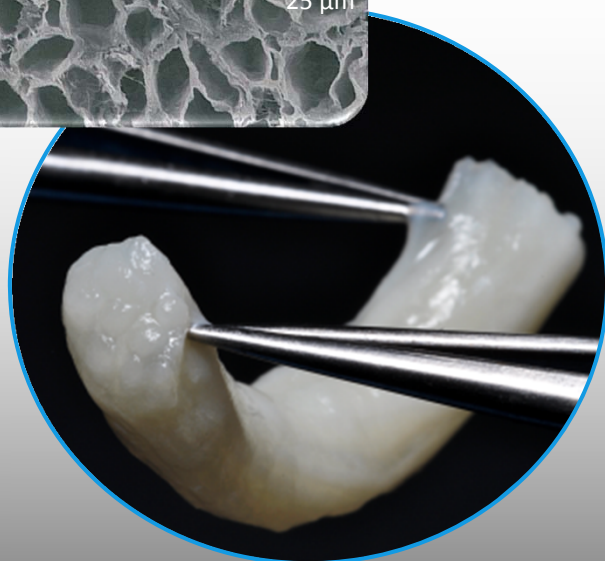
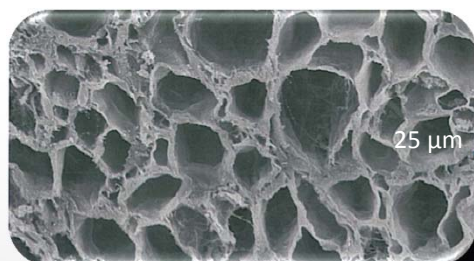
*Off the shelf option; not a lasting option for protection*

- No additional surgical morbidity
- Semi-rigid material limits use
- Degrades over time and does not provide a lasting barrier to soft tissue attachments



# Avance® Nerve Graft

*Only commercially available processed nerve allograft*



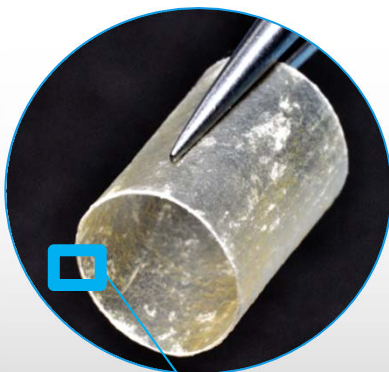
**Avance®**  
Nerve Graft

- Bridges long and short nerve gaps
- Human nerve allograft, decellularized, sterile
- Preserves three dimensional architecture
- Flexible and pliable
- Handles similarly to nerve autograft
- Eliminates risk of loss of donor nerve function
- Available in a variety of lengths (up to 70mm) and diameters (up to 5mm)
- Reduces OR time

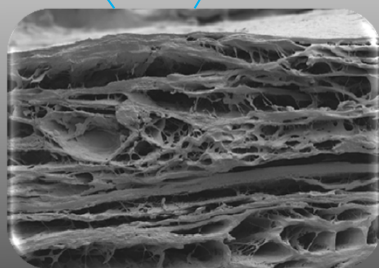
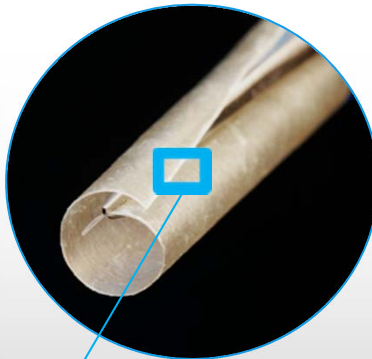
*It's time to rethink nerve repair!*

# AxoGuard® Family of Products

**AXO** **GUARD**<sup>®</sup>  
Nerve Connector



**AXO** **GUARD**<sup>®</sup>  
Nerve Protector



- Only porcine extracellular matrix/scaffold for nerve repair and protection
- ECM preserved to support natural healing response
- Semi-translucent to allow visualization of underlying nerve
- Conforms to nerve
- ECM revascularizes and remodels into patient's own tissue, does not degrade <sup>1, 2, 3, 4</sup>
- Available in tube and wrap forms

1. Badylak, et al., 1998, J Biomater Sci Polym Ed 9(8):863-878.  
2. Hodde, et al., 2007, J Mater Sci Mater Med 18(4):545-550.  
3. Nihsen, et al., 2008, Adv Skin Wound Care 21(10):479-486.  
4. Data on file at AxoGen, Inc.

# Pioneering Sales & Marketing Strategy

*Strong Forward Momentum and Growth*

**4 PILLAR  
APPROACH  
FOR DRIVING  
BUSINESS  
RESULTS**

**Build Market Awareness**

**Educate Surgeons, Develop Advocates**

**Grow Body of Clinical Evidence**

**Execute Sales Plan**



# Build Market Awareness

## *Continuing focus on building awareness among Surgeons, Patients & Investors*

- Participated in in major clinical conferences
  - Technical exhibits
  - Podium presentations
  - Sponsored surgeon panels
- Garnered Positive Media Attention
  - Local and National television
  - Wall Street Journal, SF Chronicle



*It's time to rethink nerve repair!*



# Educate Surgeons & Develop Advocates

## *Increased emphasis on education & hands-on training*

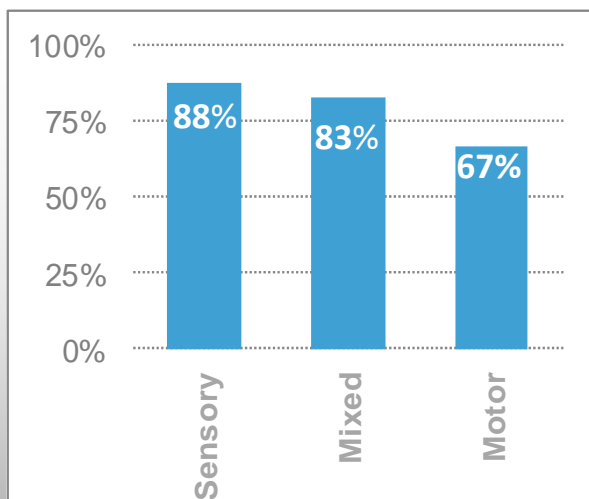
- Launched AxoGen Professional Education Program
  - Educate on “best practices”, science of nerve repair
- Continued Surgeon Advocacy and Speakers’ Bureau
  - National and International Key Opinion Leaders
  - Data presentations, panel events and publications



# Clinical Data - RANGER® Study

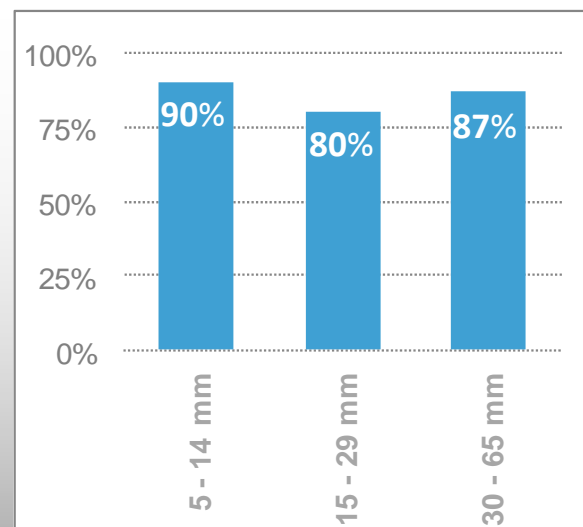
## Largest Multi-center Study in Peripheral Nerve Reconstruction

Injuries Achieving Meaningful Recovery  
by Nerve Type<sup>++</sup>



**87%**  
**Meaningful**  
**Recovery<sup>\*,++</sup>**

Injuries Achieving Meaningful Recovery  
by Gap length<sup>++</sup>



- Open enrollment observational study
- First data milestone
  - 12 centers, 25 surgeons, 132 nerve injuries
  - No graft-related complications
- Peer reviewed publications
  1. Brooks, et al. Microsurgery, January 2012
  2. Cho, et al. Journal of Hand Surgery, November 2012

- Expanded data milestone (presented at 5th Vienna Symposium on Surgery) of Peripheral Nerves, March 2014
  - 18 centers, 36 surgeons, 431 repairs enrolled
  - 85% meaningful recovery <sup>++</sup>

\* Meaningful recovery defined at S3-S4 and M3-M5 from the works of (Kim and Kline), (Frykman and Gramyk) and (Kallio).

++ Includes repairs with qualitative outcomes data.

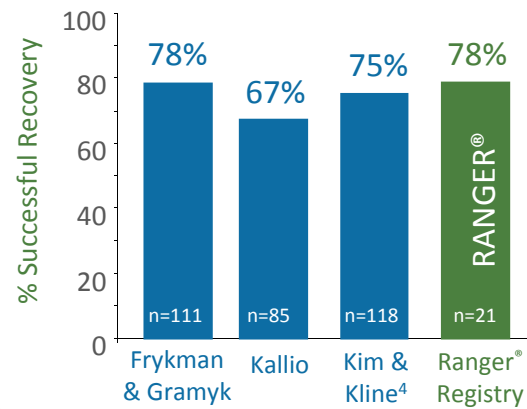
# RANGER® Study Results Compare Favorably to Other Repairs

## Comparison to Historical Reference Literature

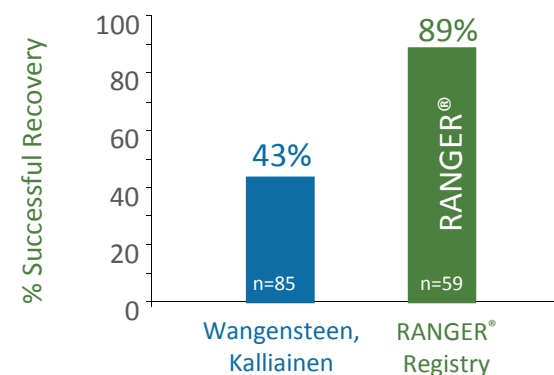
Study	Nerve Injury Types	Test Article	Positive Outcomes*
<b>RANGER® Study</b>			
(Brooks, et al, 2012; Cho, et al, 2012)	Sensory, Mixed and Motor Nerve Injuries	Avance® Nerve Graft	<b>87%</b>
<b>Autograft Studies</b>			
Weber, et al., 2000	Sensory Nerves	Direct Repair and Autograft	<b>86%</b>
Kim and Kline 2001-2006	Sensory and Mixed Nerves	Direct Suture and Autograft	<b>67-86%</b>
Frykman and Gramyk, 1991	Sensory Nerves	Autograft for Digital Nerve Injury under 5 cm	<b>80%</b>
Frykman and Gramyk, 1991	Mixed Nerves	Direct Suture and Autograft	<b>75-78%</b>
Kallio, et al., 1993	Sensory Nerves	Autograft and Direct Repair	<b>70%</b>
<b>Conduit Studies</b>			
Haug, et al., 2013	Sensory Nerves	NeuraGen® Type 1 Bovine Collagen Tube	<b>40%</b>
Weber, et al., 2000	Sensory Nerves	Neurotube® PGA tube	<b>74%</b>
Wangenstein and Kalliainen, 2009	Sensory, Mixed and Motor Nerve Injuries	NeuraGen® Type 1 Bovine Collagen Tube	<b>43%</b>

\* As reported, based on individual study parameters for acceptable recovery: M3-M5, S3-S4 by MRCC

## Autograft vs. Avance® Nerve Graft Motor Recovery Outcomes in Mixed and Motor Nerves

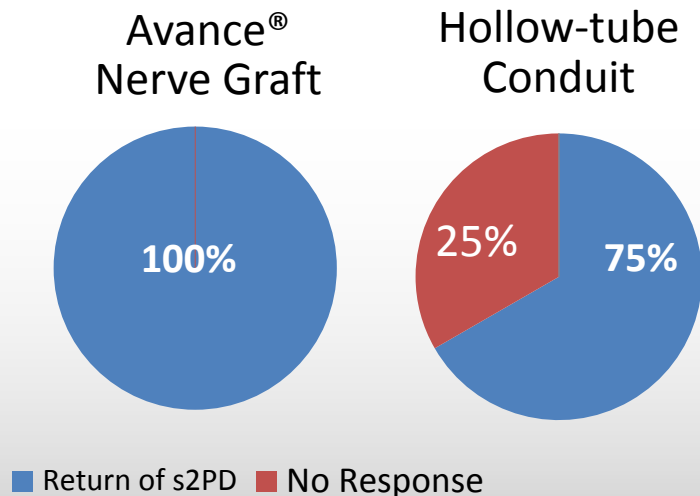


## Conduit vs. Avance® Nerve Graft Overall Recovery Outcomes



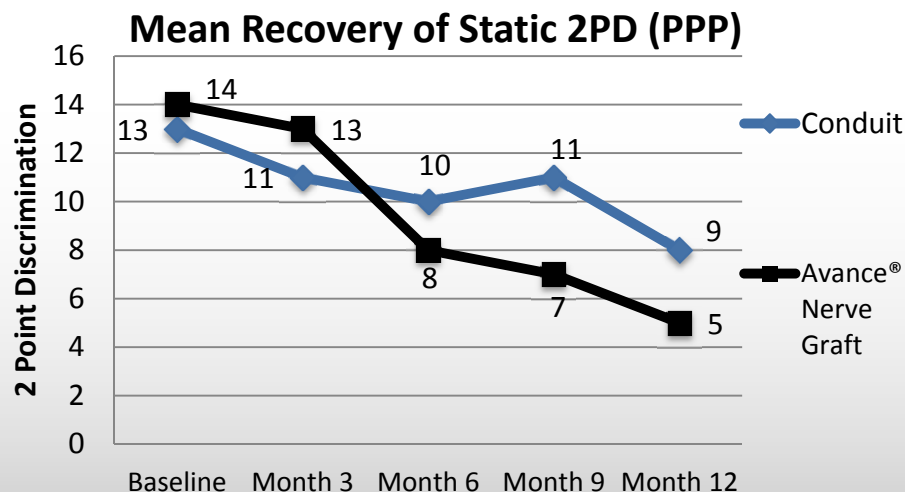
# Clinical Data - CHANGE Clinical Study

## Pilot Comparative Study of Avance® Nerve Graft and Hollow Tubes



### Study Design

- Prospective single-blind, randomized, comparison trial of recovery outcomes between hollow tubes and Avance® Nerve Graft
- Adults; Digital nerve injuries between 5 and 20 mm
- Primary outcome static 2PD- a standardized measure of sensory density (lower is better sensory discrimination)
- 23 subjects with 31 repairs randomized and enrolled in the study



### Outcomes

- Follow-up on 18 subjects
- Treatment groups showed statistically significant difference at month 12 in static 2PD with greater recovery in the Avance® Nerve Graft group
- Avance® Nerve Graft group reported functional sensory outcomes at more consistent levels as compared to hollow -tube conduits.

Data presented - AAHS meeting  
1/2014

# Execute Sales Plan

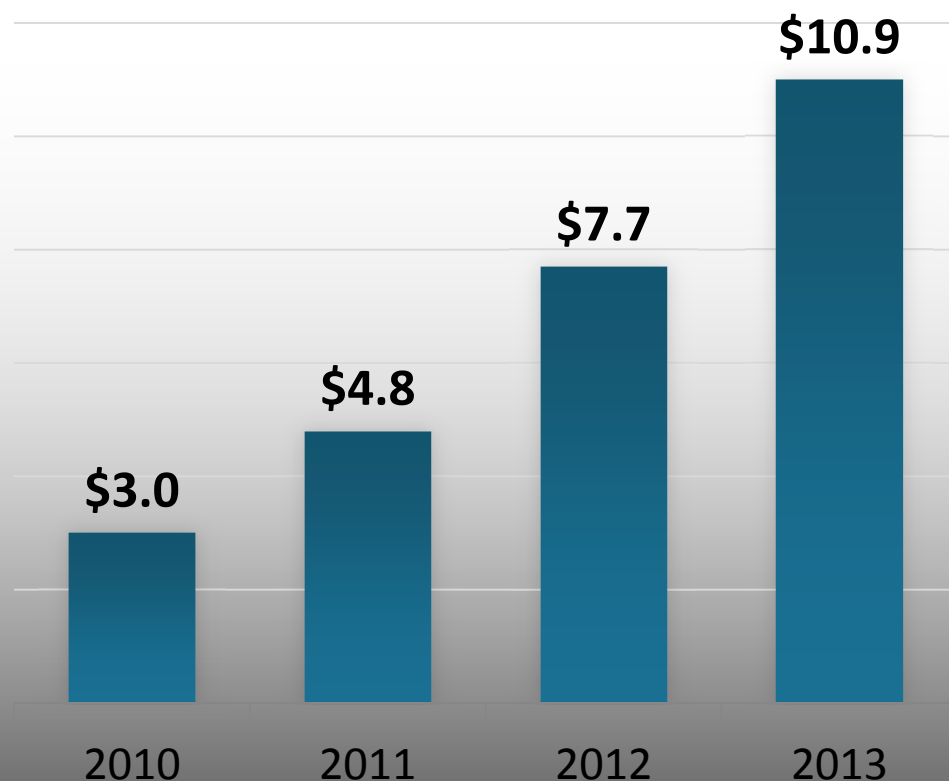
## *Expanded Reach, Focus on Sales Execution*

- Expanded Reach:
  - 24 direct sales professionals
  - 22 independent distributors
  - Available in 8 countries OUS
- Focused Sales Execution:
  - Breadth: grow account foot print
  - Depth: utilization of all 3 product lines, increase penetration
  - Quality: High and medium potential accounts
  - Reorder rate

# Strong Growth

*\$ in millions*

**42%+ Annual Sales Revenue Growth**



**46% Revenue Growth  
Q1 2013 over Q1 2014**



**78% Gross Margin Q1 2014**

*It's time to rethink nerve repair!*

# Strong Competitive Barriers

## *IP and Unique Regulatory Framework*

- **Avance® Nerve Graft**
  - 6 issued U.S. patents; 4 pending U.S. patent applications; 3 issued international patents and 9 pending international patent applications
  - Regulatory path US: Biologic Transition Process
    - November 2010: Enforcement Discretion letter from FDA allowing continued sales under controls applicable to HCT/P with agreed transition plan to Biologic (BLA)
    - BLA requires a phase III clinical trial; SPA approved by FDA
  - Regulatory path ex-US: Country by country
    - Registration completed in Austria, Canada, Israel, Italy, Netherlands, Switzerland and the United Kingdom.
- **AxoGuard® Nerve Connector & AxoGuard® Nerve Protector**
  - FDA 510(k) Clearance, CE Mark and Health Canada Approval
  - Patents held by Cook Biotech, AxoGen exclusive WW license for nerve



# Balance Sheet & Capital Structure

Balance Sheet Highlights	March 31, 2014
Cash and cash equivalents	\$16,807,753
Total current assets	\$22,434,498
Total current liabilities	\$ 1,922,861
Note Payable — Revenue Interest Purchase Agreement**	\$26,255,540

Capital Structure	March 31, 2014
Common Stock	17,445,968 shares
Common Stock Options	2,098,195 shares
Common Stock Warrants	89,686 shares
Fully Diluted	19,633,849 shares

\*\* PDL BioPharma, Inc. \$20.8M Revenue Royalty Agreement:

- Maximum 8 years (10/2020) paying 9.95% on Gross Revenue from current products
- No re-payment after last royalty payment

# Investment Considerations

## *Focus on Executing Sales & Marketing Strategy To Drive Shareholder Value*

- Only company focused on peripheral nerve repair solutions
- Addressing a \$1.6B+ current market opportunity
- Comprehensive product portfolio addresses all surgical peripheral nerve reconstruction needs
- Pioneering sales and market strategy, solid execution plan
- Poised for strong growth in 2014
- High gross margins: 78% in 1st Quarter 2014
- Barriers to competitive entry & growing body of clinical data
- Long term expansion potential beyond current market



### Recognitions

Deloitte & Touche “Fast 500”

Frost & Sullivan 2014 Technology Innovation Award

*It's time to rethink nerve repair!*

AxoGen is the only company dedicated to the  
\$1.6 billion US nerve repair market

Visit us at [www.AxoGenInc.com](http://www.AxoGenInc.com)

Follow us on Twitter @AxoGen