

May 7, 2014

# **SEMDA CONFERENCE**

## NASDAQ: AXGN



## 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.



## **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: 77.7% in 1st Quarter 2014
- Barriers to competitive entry & growing body of clinical data
- Long term expansion potential beyond current market



## **Need for Nerve Repair**

### Nerves are Injured in Many Ways

#### **Causes of Nerve Injuries**

- Lacerations, power tool / saw accidents, motor vehicle accidents, battle field injuries, gunshot wounds, natural/other disasters
- 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



## **Need for Nerve Repair**

### Peripheral Nerve Injuries Impact Quality of Life

#### **Impact of Peripheral Nerve Injuries**

- Pain chronic, stabbing, radiating, debilitating
- Numbness and Loss of Sensation
- Partial or Full Loss of Movement



#### AxoGen Patient Story: Frankie

- 12 year old male, injured in an ATV rollover
- 7+cm defect in ulnar nerve
- Parents did not want risk of comorbidities associated with autograft repair
- Repaired with Avance<sup>®</sup> Nerve Graft and 2 AxoGuard<sup>®</sup> Nerve Connectors
- Return of fine motor skills in fingers, planning to join the military



## Peripheral Nerves & Goals of Repair

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



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 Market for Nerve Repair**

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





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



#### Approximately 900K Procedures in US:

 Extremity
 719,000

 Carpal Tunnel
 100,000

 Oral
 68,000

International opportunity approximately equal to US market



## **The AxoGen Family of Products**

### Most Complete Line of Peripheral Nerve Repair Solutions

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



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

only porcine extra-cellular matrix coaptation aid that allows for the close approximation of severed nerves



Avance®

only commercially available decellularized and sterile extra-cellular matrix scaffold processed from human peripheral nerve tissue (i.e. nerve allograft)



AXO GUARD Nerve Protector

only porcine extra-cellular matrix implant designed to wrap and protect injured peripheral nerves



## **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, Wangensteen 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





## **Pioneering Sales & Marketing Strategy**

#### Strong Forward Momentum and Growth

4 PILLAR	Build Market Awareness		
APPROACH	Expand Surgeon Education and Advocacy		
FOR DRIVING			
BUSINESS	Grow Body of Clinical Evidence		
RESULTS	Execute Sales Plan		



## **Build Market Awareness**

#### Building Awareness among Surgeons, Patients & Investors

- Participation in major clinical conferences
  - Educational sales booth
  - Podium presentations
  - Sponsored surgeon panels
- Positive Media Attention
  - Local and National television
  - Wall Street Journal, SF Chronicle





## Educate Surgeons & Develop KOLs

### Educating Surgeons, Developing Advocates

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





## Growing Body of Clinical Evidence

### A strong and broad clinical program

- RANGER<sup>®</sup> Study largest multi-center, on-going registry study in peripheral nerve repair with processed nerve allograft
- CHANGE clinical study multi-center prospective randomized comparative pilot study of hollow tube conduits and Avance<sup>®</sup> Nerve Graft
- RECON clinical study Multicenter prospective randomized comparative pivotal study of hollow tube conduits and Avance<sup>®</sup> Nerve Graft (begin enrollment late 2014)
- Investigator initiated studies and publications



### **Execute Sales Plan**

### Reach, Focus, Geography

- Reach: Growing sales organization
  - 24 direct sales professionals
  - 23 independent distributors
- Focus:
  - Breadth: grow account foot print
  - Depth: utilization of all 3 product lines, increase penetration
  - Quality: High and medium potential accounts
- Geography:
  - US
  - Select countries OUS



## **Strong Competitive Barriers**

### **IP and Unique Regulatory Framework**

#### Avance<sup>®</sup> Nerve Graft

- 6 issued U.S. patents; 3 pending U.S. patent applications; 6 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<sup>®</sup> Nerve Connector & AxoGuard<sup>®</sup> Nerve Protector
  - FDA 510(k) Clearance, CE Mark and Health Canada Approval
  - Patents held by Cook Biotech, AxoGen exclusive WW license for nerve



## **Strong Growth**

### Annual Sales Revenue 42%+

*\$ in millions* 





## 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	2,170,543 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



### **Milestones**

#### Focused on Sales – Positioned For Expansion

 $\mathbf{O}$ 

S С С O L Z ш  $\mathbf{\mathcal{L}}$  $\mathbf{\mathcal{L}}$  $\bigcirc$ 

EXTREMITY (UPPER & LOWER) Nerve Protection

Nerve Repair

CARPAL TUNNEL REVISION

**Nerve Protection** 

OMF

Nerve Repair

Nerve Protection

LOWER EXTREMITY Nerve Protection Nerve Repair

> TORSO – Breast Recon

Nerve Repair

HEAD & NECK
(FACIAL RECONSTRUCTION, TUMOR)

TORSO
 (PROSTATECTOMY)
 PAIN
 MANAGEMENT

 $\square$ 



## **Opportunities**

#### Positioning for the future

#### • Strategic Alliances for New Products

- Development
- Licensing
- Acquisition

#### • Financial Market Awareness

- As of May 1,
  - Market cap \$45 million
    - Approximately 4X 2013 revenue
  - Share price \$2.54



## **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: 77.7% in 1st Quarter 2014
- Barriers to competitive entry & growing body of clinical data
- Long term expansion potential beyond current market





## NASDAQ: AXGN

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 <u>www.AxoGenInc.com</u> Follow us on Twitter @AxoGen