

Third Annual Analyst and Investor Day November 19, 2018

**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," "continue," "may," "should," "will," and 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 our assessment on our internal control over financial reporting, our growth, our 2018 and 2019 guidance, product development, product potential, financial performance, sales growth, product adoption, market awareness of our products, data validation, our visibility at and sponsorship of conferences and educational events.

The forward-looking statements are subject to risks and uncertainties, which may cause results to differ materially from those set forth in the statements. Forward-looking statements in this release should be evaluated together with the many uncertainties that affect AxoGen's business and its market, particularly those discussed in the risk factors and cautionary statements in AxoGen'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, except as required by law, AxoGen assumes no responsibility to update any forward-looking statements, whether as a result of new information, future events, or otherwise.



### **Event Agenda**

Introduction - Kaila Krum, Vice President Investor Relations and Corporate Development

Company Overview and Update - Karen Zaderej, Chairman, CEO, and President

Clinical Review - Erick DeVinney, Vice President of Clinical and Translational Science

Surgeon Panel - Ivica Ducic, MD, PhD - Medical Director, AxoGen Inc. (Washington Nerve Institute)

• Upper Extremity - Brendan MacKay, MD (University Medical Center, Lubbock, TX)

• Surgical Treatment of Pain - Robert Hagan, MD (Neuropax Clinic, St. Louis, MO)

Breast Neurotization - Suhail Kanchwala, MD (Penn Medicine, Philadelphia, PA)

OMF - Ramzey Tursun, DDS, FACS (University of Miami, Miami, FL)

Guidance & Closing Comments – Pete Mariani, Chief Financial Officer

Panel Q&A and Discussion



### The AxoGen Platform for Nerve Repair





### **AxoGen is the Preeminent Nerve Repair Company**

- ✓ Exclusive focus on peripheral nerve repair and protection solutions
- ✓ Comprehensive product portfolio addresses large and untapped market opportunity
- ✓ "Five Pillar" Market Development Strategy delivered 31 consecutive quarters of YOY double-digit growth

Q3 2018 Revenue

2017 Revenue

**High Gross Margins** 

Cash, Cash Equivalents, and Investments as of September 30, 2018

\$22.7M, 41% growth vs Q3 2017

\$60.4M, 47% growth vs 2016

84.7% as of September 30, 2018

\$126.4M

- ✓ Solid balance sheet provides resources to execute business plan
- ✓ Significant barriers to competitive entry including a growing body of clinical data
- ✓ Management team with deep expertise and strong track record of success
- Expansion opportunities beyond current markets



## **Building for Long-term Sustainable Growth**



### **Breadth and Depth of Talent**



Karen Zaderej, MBA Chairman, CEO, & President J&J (Ethicon)



Peter Mariani **Chief Financial Officer** Lensar, Hansen, Guidant



Greg Freitag, JD, CPA **General Counsel** Pfizer, Guidant



Jon Gingrich Chief Commercial Officer Hologic, Boston Scientific



Maria Martinez **Chief Human Resources Officer** HSNi, Bausch + Lomb



Isabelle Billet **Chief Strategy & Business Development Officer** J&J, C.R. Bard, Cardinal



Stacy Arnold VP, Program Management CryoLife



Gregory Davault VP of Marketing Ekso Bionics. Given Imaging



Erick DeVinney VP. Clinical & **Translational Sciences** Angiotech, PRA Intl



Mike Donovan VP. Operations Zimmer



Ivica Ducic, M.D., Ph.D. Medical Director Washington Nerve Institute



Mark Friedman, Ph.D. VP, Regulatory & Quality Assurance AtriCure, Enable Medical



John Glueck, JD **Chief Compliance Officer** Medtronic. Covidien



David Hansen VP, Finance and Treasurer Perma-Fix, Kraft It's time to rethink nerve repair.



Kaila Krum VP. Investor Relations & **Corporate Development** William Blair



Shawn McCarrey SVP. Sales Baver, Medrad, Possis



Angelo Scopelianos, Ph.D. VP, Research & Development 18.1



### Infrastructure to Support Long-term Scale





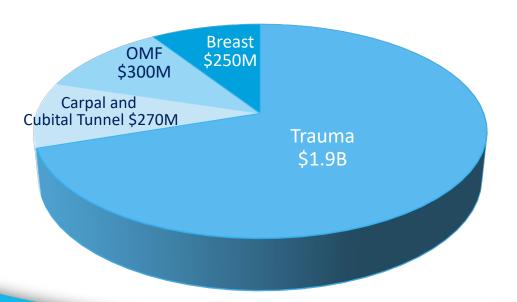
AxoGen
Processing
Center
Dayton, OH



AxoGen Second Corporate Campus
Tampa, FL

AxoGen.

# **Updating Value of Market Opportunity in Existing Applications from \$2.2B to \$2.7B**



#### US procedural estimates remain >900,000

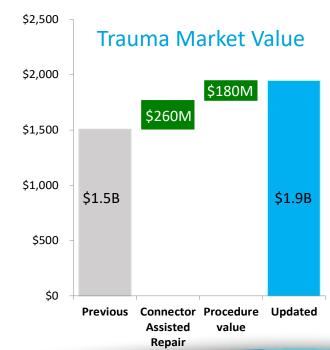
- Trauma: > 700,000 (1,2,3,4)
- Carpal Tunnel Revisions and Cubital Tunnel: 130,000 (5)
- OMF: >55,000 (6,7,8)
- Breast Neurotization Procedures: 15,000 (9)

\$2.7B estimate does not include pain



# Our Trauma Market Increase is Driven by Multiple Product Usage and Price







#### **OMF**

Building momentum toward middle adopters

#### **Breast Neurotization**

Driving market development and clinical efforts

### Trauma

Driving deeper awareness and penetration by sub-segment

# Surgical Treatment of Pain

Establishing the foundation with clinical and market development initiatives



### **Transforming Peripheral Nerve Repair to Create a New Standard of Care**



It's time to rethink nerve repair.™

Focus on Building Awareness Among Surgeons, Patients, and Investors

Participate in Clinical Conferences

■ Exhibits, Podium presentations, KOL panels

Promote Awareness Among Patients

AxoGen Patient Ambassador Program

Garner Positive Media Attention

☐ National, Regional and Local Broadcast,

**Print and Online** 





**Build Market** 

### **Emphasis on Education**

**2017: 15 National Programs** 

2018: 18 National Programs

**2019: 25 National Programs Expected** 

Expect to train three-quarters of hand and microsurgery Fellows in 2019







**Strong Commitment to Developing Clinical Evidence** 



- ☐ The largest multi-center clinical study in peripheral nerve repair, over 1,600 Avance® nerve repairs enrolled to date
- Overall meaningful recovery rates of 84-87%; comparable to autograft outcomes without associated donor site comorbidities

#### **MATCH Registry Study: Enrollment Ongoing**

☐ Autograft and Synthetic Conduit outcomes

#### **RECON Study: Enrollment Ongoing**

- Prospective, randomized study of Avance® Nerve Graft controlled vs
   Synthetic conduits in digital injuries 5 to 25mm
- ☐ IND Pivotal Study to support BLA Submission

#### **SENSATION-NOW Registry Study: Enrollment Ongoing**

Multi-center clinical study in breast neurotization

#### **REPOSE: Initiated**

AxoGuard® Nerve Cap RCT







#### **Sales Execution Focused on Driving Results**

- □ Continue expansion thru driving penetration in active accounts and adding new active accounts
- □ 5,100 potential U.S. accounts performing nerve repair
- ☐ 679 Active accounts as of September 30, 2018

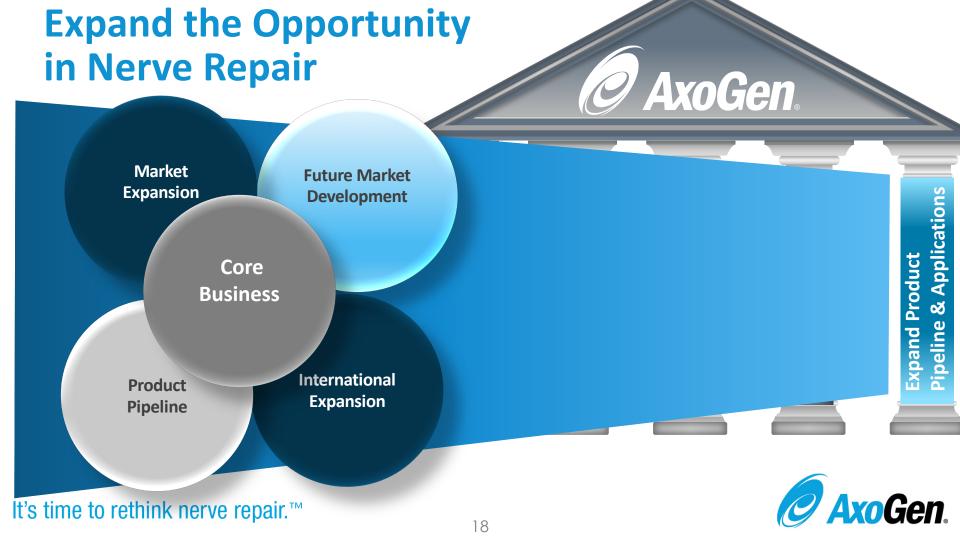
#### **Expanded Sales Reach**

- U.S. direct sales team
  - □ 60 direct sales professionals at end of 2017
  - □ 80+ direct sales professionals by end of 2018
  - □ 115+ direct sales professionals by end of 2019
- Supplemented by independent agencies



**Execute Sales Plan** 





### We Remain Focused on Driving Deeper Penetration in Trauma

#### **Initiatives**

Generate and publish clinical evidence

- Continue to enroll patients in RANGER registry and optimize publications
- Complete MATCH enrollment to provide approximately 100 autograft comparative outcomes
- Continue RECON study and follow up
- Initiate mixed/motor randomized controlled trial (RCT)
- Initiate Avive® soft tissue membrane registry in trauma

Build Market awareness

- Amplify clinical results through podium presentations at clinical conferences and publications
- Targeted PR around patient stories

Emphasize education

- Professional education programs
- Train three quarters of the fellows
- Nerve Matters® forum

Sales force execution

- Grow direct sales team
- Drive penetration in existing active accounts and expand to new active accounts



### **We Expect Continued Momentum in OMF**

#### **Initiatives**

Build Market awareness

- Build the referral channel and patient awareness of iatrogenic injuries
- Grow awareness of the issues and solutions through PR efforts
- Presentations at clinical conferences



**Emphasize** education

- Professional education programs
- Webinar Watch Events
- Nerve Matters® Forum

Sales force execution

- Target 200-300 surgeons in the U.S.
- 5 clinical specialists focused on market development today;
   expect to add 3 additional specialists in 2019

Generate and publish clinical evidence

- Investigator initiated clinical study expanding to malignant tumor mandible reconstruction

The 90-Day Window: Trigeminal Nerve Injuries and the Importance of Prompt Referral

25 Oct 2018 Daniel Petrisor, DMD, MD, FACS Todays Dental News





It's time to rethink nerve repair.™

### We Will Continue to Develop the Breast Neurotization Market

#### **Initiatives**

Generate and publish clinical evidence

- Sensation-NOW™ (Sensation Neurotization Outcomes for Women) Registry
- Single vs Dual Neurotization randomized prospective study
- Breast-Q clinical endpoint

Build Market awareness - Grow awareness of the issues and solutions with patients and referral channel

- Patient-facing tools, including social media and website
- Physician locator
- Partner with advocacy groups

Emphasize education

- Train residents and fellows in specialty centers
- Nerve Matters® Forum
- Referral pathways education

Sales force execution

- 25 ReSensation™ centers now trained on techniques
- 5 clinical specialists focused on market development

Sensation-NOW™ Registry **Thought** Reference Leader Centers Collaborations

It's time to rethink nerve repair.™





Last night I was waiting at the bar for our table to be ready for dinner. As the waitress called our name - I quickly turned and my right Foob legit hit a tray of drinks causing them to all crash on the floor. I'm talking broken glass and mai tais EVERYWHERE - it was a hot mess! 🌹 🤒

Anyone else struggle with spacial awareness and lack of feeling due to their implants?! [ ] I recently heard about @resensation and I feel like having feeling in my foobs would make it so these

905 likes

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Log in to like or comment.

# **Through Social Media and PR Efforts**

**Growing Awareness** 





leslevannemurphy • Follow

leslevannemurphy I've had implants inside my chest for over a year now and have zero regrets. The upside to all of this: I now have a 1% chance of being diagnosed with breast cancer. The downside? I lost all feeling in my breasts and, well, let's just say they aren't the most natural looking things all the time.

I wrote about it all today on Breast Reconstruction Awareness Day:) I also wrote about what no one talks about what it's really like to be intimate after a double mastectomy. Lastly - I discuss a new technique designed to restore sensation in breasts after surgery (mine are completely numb), Science is so cool, Link in bio. @resensation #resensation

#breastreconstructionawarenessday #breastcancerawareness #mastectomy #partner

11.436 likes

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#### **People**

The Bachelor's Lesley Murphy Gets Candid About Intimacy Following Double Mastectomy





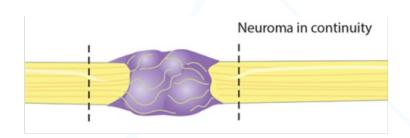
### We Will Establish a Strong Foundation to Expand into the Surgical Treatment of Pain

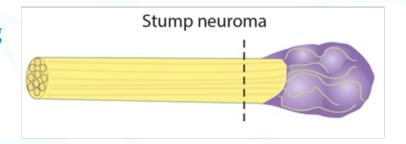


#### Focus on Neuroma Pain

 A neuroma is a tangled mass of disorganized nerve and fibrous tissue

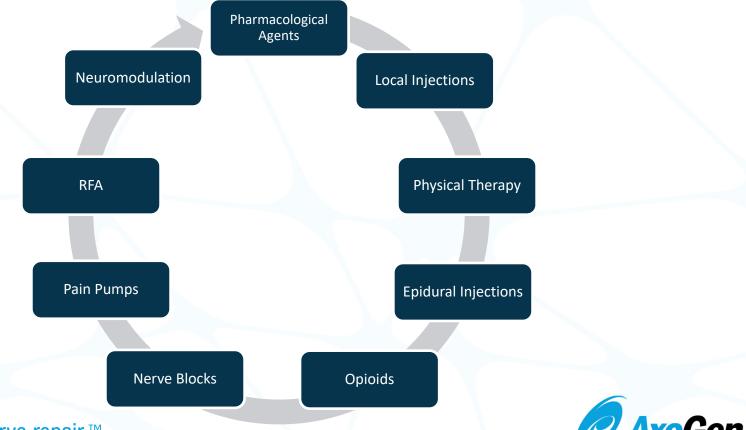
 If not properly diagnosed and addressed, the management of these injuries may require long term pharmacologic treatment and pain management







### **Historical Management Options for Chronic Neuropathic Pain**



It's time to rethink nerve repair.™

### **Drugs are Not the Answer for Neuropathic Pain**

**HEALTH NEWS** 

SEPT. 25, 2018 / 9:48 AM

# Lyrica ineffective for chronic pain from traumatic nerve injury

The drug effectively curbs pain immediately after surgery, and works against other forms of chronic pain, but researchers found it is no better than a placebo for traumatic nerve injury patients.

Roughly one-third of patients with chronic pain after surgery are believed to have neuropathic pain, or ongoing pain related to nerve injury, the study's writers noted.

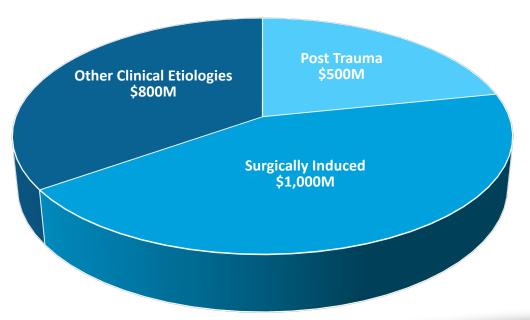
groundwork for future studies in these post-surgical syndromes where there is so much need for non-opioid treatments," Markman said.

- Many modalities manage pain symptoms without addressing the anatomical cause
- Recent study<sup>10</sup> shows Lyrica ineffective for chronic pain from traumatic nerve injury
- Study highlights high prevalence of postsurgical neuropathic pain
- Acknowledges significant need for nonopioid treatments in post-surgical syndromes



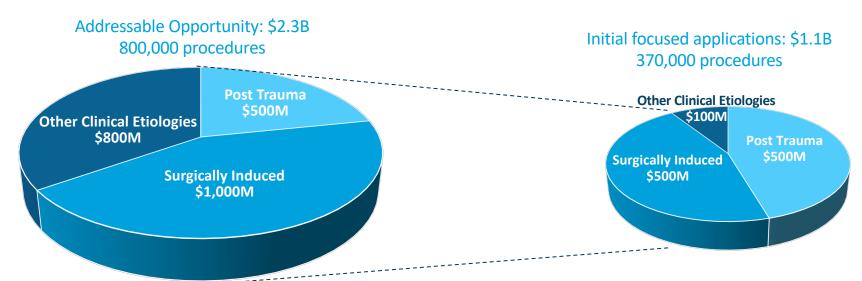
# We Estimate There are 20+ Potential Applications in Chronic Neuropathic Pain, with an Addressable Opportunity of \$2.3B+







### Our Initial Focus Will be in Orthopedic and Trauma Applications



#### **Nerve reconstruction applications:**

 Trauma, orthopedic procedures, hernia, hysterectomy, C-section, laparoscopic procedures, meralgia paresthetica, CABG donor site, nerve tumor excision

#### **Nerve Termination applications**

 Amputation, mastectomy, hernia, laparoscopic procedures, TKA, knee arthroscopy, Morton neuroma, wrist arthroscopy, CABG donor site

#### **Nerve decompression applications**

Post trauma compressions, occipital neuralgia, meralgia paresthetica

- Orthopedic procedures including THA, TKA, Knee arthroscopy, Morton neuroma, Foot and Ankle procedures, wrist arthroscopy, nerve tumors
- Post traumatic pain including amputation

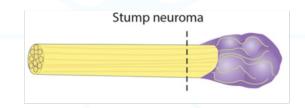


### **Creating Surgical Solutions for Chronic Neuropathic Pain**

#### **Objectives Examples of initiatives** Establish pilot referral pathways with three Develop Create the most efficient model for reference centers **Business** model clinicians and AxoGen Standardize algorithm for patient selection Initiate a pain registry Build evidence with defined Generate and publish Enroll REPOSE<sup>™</sup> – AxoGuard® Nerve Cap RCT algorithm in selected applications clinical evidence Initiate RCT on neuroma treatment Educate physician referral base through Establish the surgical treatment of Build a physician podium presentation and papers across pain as a valid treatment option referral pathway disciplines Add Medical Science Liaisons to educate referral community Gain awareness of the surgical Build Expand our KOL advisory board treatment of pain as a viable option Market awareness Pilot patient awareness program



#### **AxoGuard® Nerve Cap for Neuroma Pain**





- Completed clinical evaluation and user preference study
- Initiated a randomized controlled study of neuroma revision
- Commercial launch in 2<sup>nd</sup> half of 2019



- US FDA Clearance K163446
  - > Indicated to protect a peripheral nerve end and separate the nerve from the surrounding environment to reduce the development of symptomatic or painful neuroma



### Foundation for Long-term Sustainable Growth

- Exclusively focused in nerve repair across an expanding set of applications
- Differentiated platform for nerve repair, anchored with Avance® Nerve Graft, a biologically active nerve therapy
- 10+ years of demonstrated clinical consistency and meaningful recovery outcomes
- Avance® RMAT designation highlights strength of clinical evidence and the unmet medical need for improved therapies to treat nerve injuries
- Converting experienced surgeons while training the next generation on best practices
- Leadership team with depth and breadth of expertise





**NASDAQ: AXGN** 

Deloitte Technology Fast 500: 2014, 2015, 2016, 2017, 2018

Russell 2000 Index: June 2016

It's time to rethink nerve repair.™

#### **Footnotes**

- (1) National Hospital Ambulatory Medical Care Survey: 2015 Emergency Department Summary Tables Table 18
- (2) Noble, et al: J Trauma, Volume 45(1).July 1998.116-122
- (3) Uzun, et al: J Clin Neuromusc Dis 2006;7:97–103
- (4) Portincasa et al: Microsurgery 27:455–462, 2007
- (5) Medicare\_National\_HCPS\_Aggregate\_Summary\_Table\_CY2016.xls
- (6) Shih-Yun Wu et al: Systematic Review and Meta-Analysis on Incidence of Altered Sensation of Mandibular Implant Surgery PLoS ONE 11(4): e0154082
- (7) Souheil Hussaini, Procedure frequency in the jaws related to implant location, Dent Oral Craniofac Res, 2016 Volume 2(2): 230-233
- (8) Nguyen. Et al: Risk Factors for Permanent Injury of Inferior Alveolar and Lingual Nerves DuringThird Molar Surgery; J Oral Maxillofac Surg. 2014 Dec;72(12
- (9) ASPS statistics Annual comprehensive report 2017 www.plasticsurgery.org/documents/News/Statistics/2017/plastic-surgery-statistics-full-report-2017.pdf
- (10) www.upi.com/Lyrica-ineffective-for-chronic-pain-from-traumatic-nerve-injury/5131537877458/

