

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

Form 8-K

Current Report  
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 5, 2024

**AXOGEN, INC.**

(Exact Name of Registrant as Specified in Charter)

**Minnesota**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**001-36046**  
(Commission File Number)

**41-1301878**  
(I.R.S. Employer Identification No.)

**13631 Progress Boulevard, Suite 400 Alachua, Florida**  
(Address of principal executive offices)

**32615**  
(Zip Code)

**(386) 462-6800**  
(Registrant's telephone number, including area code)

N/A  
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, \$0.01 par value	AXGN	The Nasdaq Stock Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 7.01 Regulation FD Disclosure.**

On March 5, 2024, the Company posted an updated corporate presentation to its website at <https://ir.axogeninc.com/news-events>. The Company may use the investor presentation from time to time in conversation with analysts, investors and others. A copy of the investor update is furnished as Exhibit 99.1.

The information in this Item 7.01, including Exhibit 99.1, is being furnished and shall not be deemed to be “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section and shall not be deemed incorporated by reference into any filing under the Securities Act or Exchange Act, except as shall be expressly set forth by specific reference in such filing.

**Item 9.01. Financial Statements and Exhibits**

(d) Exhibits See the Exhibit index below, which is incorporated herein by reference.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Axogen, Inc. Corporate Presentation, dated March 5, 2024</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**SIGNATURES**

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AXOGEN, INC.

Dated: March 5, 2024

By: /s/ Marc Began

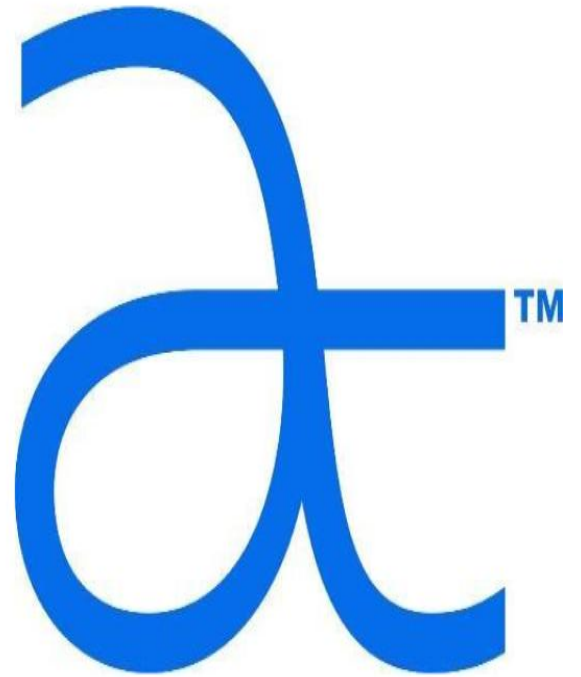
Marc Began

Executive Vice President, General Counsel and Chief Compliance Officer

# Corporate presentation

March 5, 2024

nasdaq: axgn



**axogen<sup>®</sup>**

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# 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,” “goals,” and variations of such words and similar expressions are intended to identify such forward-looking statements. Forward-looking statements include (1) the TAM for the targeted nerve markets, (2) 2024 financial guidance, including revenue range and gross margins, (3) growth drivers for the business, (4) expectations regarding the timing of the roll-out of Avive+ Soft Tissue Matrix, (5) the expectation that the Axogen Processing Center will support our BLA filing, (6) the timing of filing the BLA and our expectation that the rolling BLA submission will be completed in the third quarter 2024, (7) the expectation that a new (non-biosimilar) competitive processed nerve allograft would need to complete clinical testing and obtain BLA approval prior to clinical release, and that it would likely take 8 years to achieve this, and (8) the expectation that RECONSM study topline results will support our BLA filing to be completed by the third quarter of 2024.

Actual results or events could differ materially from those described in any forward-looking statements as a result of various factors, including, without limitation, statements related to potential disruptions caused by leadership transitions, global supply chain issues, record inflation, hospital staffing issues, product development, product potential, expected clinical enrollment timing and outcomes, regulatory process and approvals, financial performance, sales growth, surgeon and product adoption, market awareness of our products, data validation, our visibility at and sponsorship of conferences and educational events, global business disruption caused by Russia’s invasion of Ukraine and related sanctions, recent geopolitical conflicts in the Middle East, potential disruptions due to management transitions, as well as those risk factors described under Part I, Item 1A., “Risk Factors,” of our Annual Report on Form 10-K for the most recently ended fiscal year. Forward-looking statements are not a guarantee 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 applicable law, we assume no responsibility to publicly update or revise any forward-looking statements.

# The Axogen platform for nerve repair

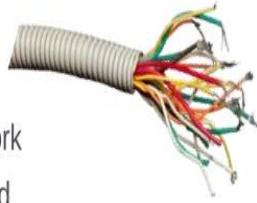


- Exclusively focused on peripheral nerve repair with a differentiated platform
- 10+ years of demonstrated clinical outcome consistency
- 245 peer-reviewed clinical publications
- Over 100,000 Avance® nerve grafts implanted
- Significant barriers to competitive entry
- 116 U.S. sales reps
- Patient activation and surgeon education capabilities

# The function of nerves and injury types

Nerves are like wires

- Transfer signals across a network
- If cut, data cannot be transferred
- If crushed, short circuits and data corruption may occur



The peripheral nervous system is a vast network from every organ to and from the brain

- Sensory
- Motor
- Mixed













Nerves can be injured in three ways:

1. **Transection**  
Traumatic nerve injuries e.g., motor vehicle accidents, power tool accidents, battlefield injuries, gunshot wounds, surgical injuries, neuroma-in-continuity
2. **Compression**  
Carpal, cubital, tarsal tunnel revisions, blunt trauma, previous surgeries
3. **Stump Neuroma**  
Amputations, mastectomies, previous surgeries



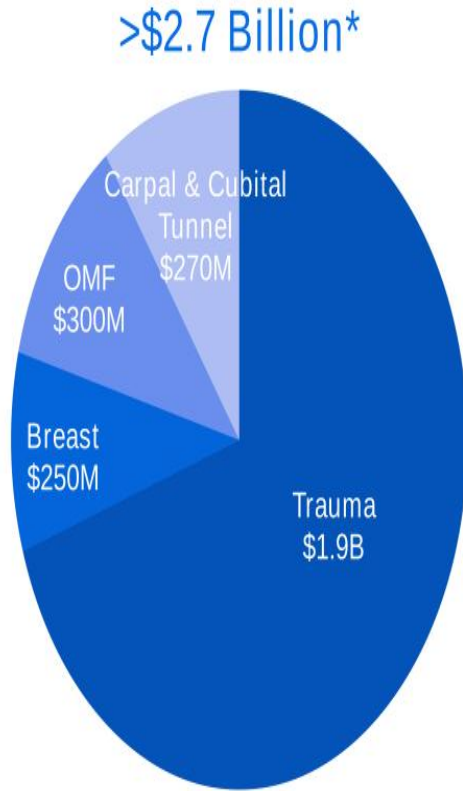
# A comprehensive platform for addressing nerve injuries

one company for all your surgical nerve repair solutions

<p> <b>avance</b> nerve graft</p>  <p>Biologically active, processed human nerve allograft developed for bridging nerve discontinuities up to 70 mm</p>	<p> <b>axoguard</b> nerve connector*</p>  <p>Semi-translucent coaptation aid for nerve transections up to 5 mm</p>	<p> <b>axoguard</b> nerve protector*</p>  <p>Extracellular matrix that remodels to protect injured nerves and reinforce nerve reconstructions</p>	<p> <b>axoguard HA+</b> nerve protector</p>  <p>Extracellular matrix base layer with a hyaluronate-alginate gel coating to facilitate enhanced nerve gliding, aid in minimizing soft tissue attachments, and remodeling of the base layer to provide long-term protection.</p>	<p> <b>axoguard</b> nerve cap*</p>  <p>Separates nerve end from surrounding environment to protect from mechanical stimulation and reduce painful neuroma formation</p>
<p>Connection</p>		<p>Protection</p>		<p>Termination</p>



# Targeted nerve markets (U.S.)



U.S. potential procedural estimates  
>900,000\*\*

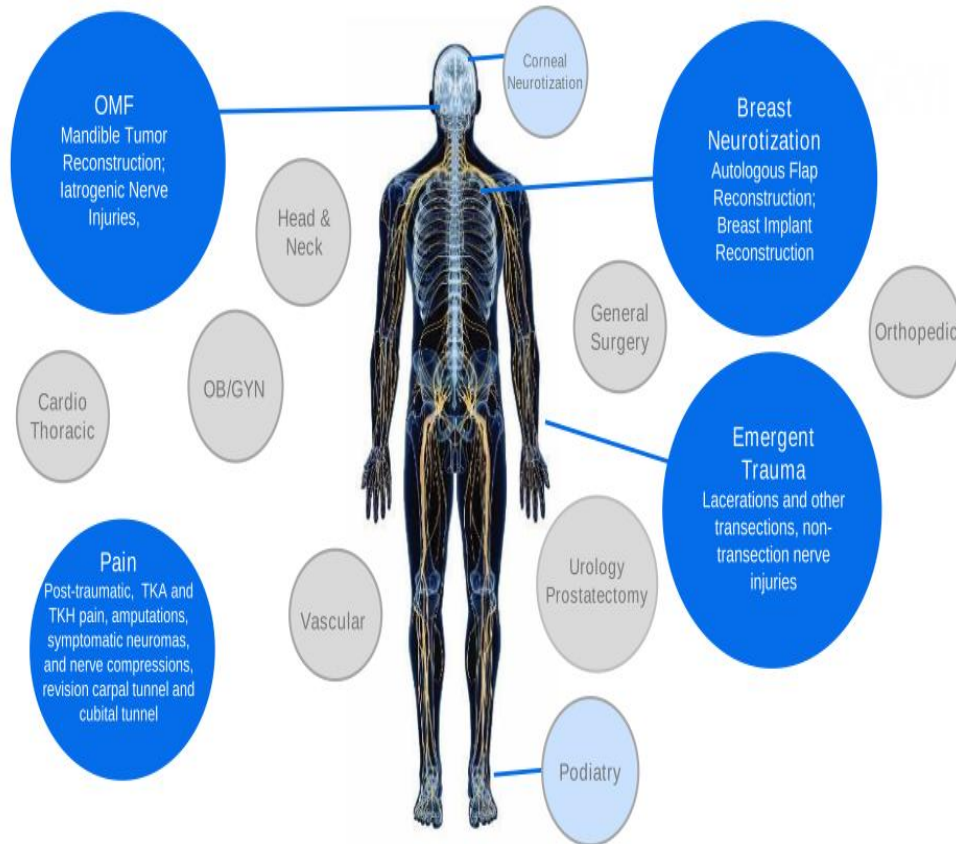
- Trauma: > 700,000
- Carpal and Cubital Tunnel Revisions: 130,000
- Oral Maxillofacial (OMF): 56,000
- Breast Neurotization Procedures: 15,000

\*\$2.7B estimate does not include pain market

\*\*Referenced papers were used to derive specific assumptions in the procedure potential estimates. Papers used include both U.S. and OUS databases and studies. See Appendix for data sources.

# Opportunities in nerve repair

Core business anchored in Trauma and Upper Extremity, and expanded to Breast, OMF and Pain. Further Market Expansion in Corneal Neurotization and Podiatry.



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# Applications for our products include two primary categories

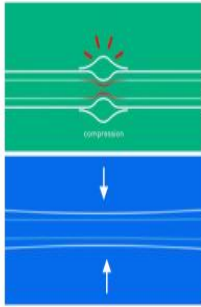
## Emergent Trauma Procedure Examples



Transected sensory nerves

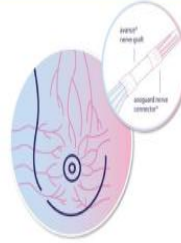


Transected mixed/motor nerves



Non-transected nerve injury

## Scheduled Procedure Examples



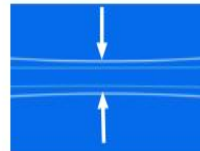
Breast reconstruction



Mandibular reconstruction



Neuroma repair



Cubital and carpal tunnel revisions

# Delivering strong revenue growth and gross margins

U.S. \$ in millions



## Revenue by Category

We estimate that:

- Revenues from emergent trauma procedures represented approximately half of total revenues during the fourth quarter and grew in the mid-single digit range versus the fourth quarter of 2022
- Revenues from scheduled non-trauma procedures represented approximately half of total revenues during the fourth quarter and grew over 25% from the fourth quarter of 2022

## Management expects:

- Full-year 2024 revenue to be in the range of \$177 million to \$181 million, which represents an annual growth rate of approximately of 11% to 14%.
- Additionally, we anticipate gross margin for the full year to be in the range of 76% to 79%.

78.7% gross margin for the quarter ended December 31, 2023

We estimate revenue by application using the information received from hospitals and sales representatives and based upon assumptions regarding specific surgeon practice and account information. Accordingly, the accuracy of our estimates is subject to the limited data we receive and accuracy of those assumptions.

# Growth Drivers

## Clinical Data

- Recent clinical data published within the past year will support increased adoption particularly with middle adopters
  - RECON<sup>SM</sup> 56
  - Meta Analysis of clinical outcomes and Medicare Economic Data<sup>57</sup>
  - Premier Economic Data<sup>58</sup>
  - Cost-effectiveness analysis of Avance<sup>59</sup>

## Innovation

- New product launches in nerve protection: Axoguard HA+ Nerve Protector<sup>TM</sup> launched in August 2023, strategic roll-out of Avive+ Soft Tissue Matrix<sup>TM</sup> in Q2 2024
- Resensation<sup>®</sup> for breast neurotization expansion into implant-based reconstructions
- Improving sales rep productivity
- Patient activation programs for breast neurotization, surgical treatment of pain, and OMF
- Surgeon training across our applications





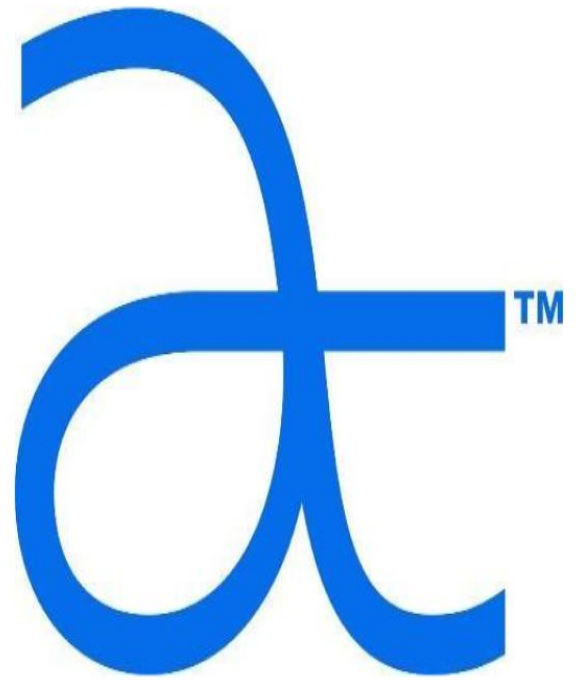
# Axogen Processing Center (APC)

- Began processing tissue in the new facility in August 2023
- Supports BLA requirements for Avance nerve graft
- Provides 3x previous capacity, designed for long-term growth and expansion



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# Product Portfolio



revolutionizing the science of nerve repair®

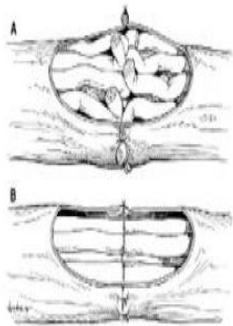


# Traditional TRANSECTION repair options are suboptimal

## 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 method despite several disadvantages

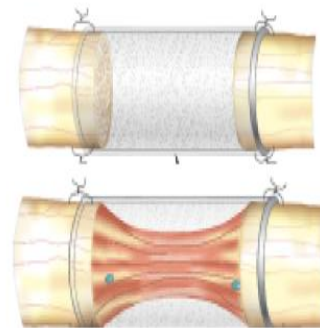
- Secondary surgery
- Loss of function and sensation at harvest site
- 27% complication rate including infection, wound healing and chronic pain<sup>19</sup>
- Limited availability of graft length and diameter



## SYNTHETIC CONDUITS

Convenient off the shelf option; limited efficacy & use

- Provides only gross direction for regrowth
- Limited to small gaps
- 34%-57% failure rate >5mm gaps<sup>20, 21</sup>
- Semi-rigid and opaque material limits use and visualization
- Repair reliant on fibrin clot formation



# Axogen solutions for TRANSECTION repair



**α** **avance**<sup>®</sup>  
nerve graft

Processed human nerve allograft for bridging nerve gaps

Clinically studied off-the-shelf alternative,

- A biologically active nerve therapy with more than ten years of comprehensive clinical evidence
- 82-84% meaningful recovery in sensory, mixed and motor nerve gaps in multi-center study<sup>22</sup>
- Eliminates need for an additional surgical site and risks of donor nerve harvest<sup>22</sup>
- May reduce OR time

Structural support for regenerating axons

- Cleansed and decellularized extracellular matrix (ECM)
- Offers the benefits of human peripheral nerve micro-architecture and handling

Revascularizes and remodels into patient's own tissue similar to autologous nerve<sup>23</sup>

16 size options in a variety of lengths (up to 70mm) and diameters (up to 5mm)

These highlights do not include all the information needed to use Avance<sup>®</sup> Nerve Graft safely and effectively. See full instructions for use (IFU) for Avance<sup>®</sup> Nerve Graft



**α** **axoguard**  
nerve connector<sup>®</sup>

Minimally processed porcine ECM for connector-assisted coaptation

Alternative to direct suture repair

- Reduces the risk of forced fascicular mismatch<sup>24, 25</sup>

Alleviates tension at critical zone of regeneration

- Disperses tension across repair site<sup>26</sup>
- Moves suture inflammation away from coaptation face<sup>27, 28</sup>

Remodels into vascularized patient tissue<sup>28, 29, 30, 31, 32</sup>

14 size options in lengths of 10mm and 15mm, and diameters up to 7mm

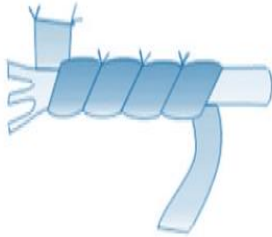
These highlights do not include all the information needed to use Axoguard Nerve Connector<sup>®</sup> safely and effectively. See full instructions for use (IFU) for Axoguard Nerve Connector<sup>®</sup>

# Traditional COMPRESSION repair options are suboptimal

## VEIN WRAPPING

Autologous vein

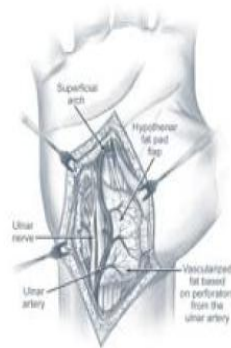
- Barrier to attachment to surrounding tissue
- Requires extra time and skill to perform spiral wrapping technique
- Second surgery site



## HYPOTHENAR FAT PAD

Autologous vascularized flap

- Barrier to attachment to surrounding tissue
- Only wraps part of the nerve circumference
- Increases procedure time



## COLLAGEN WRAPS

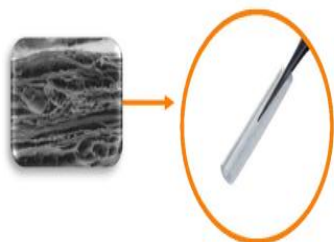
Off-the-shelf

- Semi-rigid material limits use
- Degrades over time and does not provide a lasting barrier to soft tissue attachment



# Axogen solutions for COMPRESSION repair

## axoguard nerve protector®



Minimally processed porcine extracellular matrix for wrapping and protecting injured peripheral nerve

Protects repair site from surrounding tissue

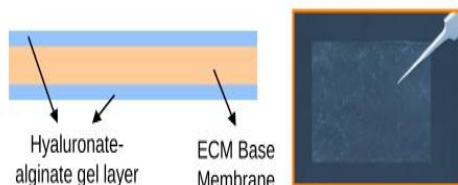
- Processing results in an implant that works with the body's natural healing process<sup>33</sup>
- Minimizes soft tissue attachments<sup>34</sup>

Allows nerve gliding

- Minimizes risk of entrapment<sup>34</sup>
- Creates a barrier between repair and surrounding tissue bed<sup>34</sup>
- ECM revascularizes and remodels into patient's own tissue<sup>29,35</sup>

These highlights do not include all the information needed to use Axoguard Nerve Protector® safely and effectively. See full instructions for use (IFU) for Axoguard Nerve Protector®

## axoguard HA+ nerve protector™



ECM base membrane:

- Processed porcine submucosa extracellular matrix (ECM) base layer
- Vascularizes and remodels to form a new long-term protective tissue layer

Minimally processed porcine extracellular matrix with hyaluronate-alginate gel layer

Lubrication layer:

- Protects nerve in the early critical phase of healing
- Enhance nerve gliding for nerve protection applications where nerve mobility is critical and aids in minimizing soft tissue attachments

Handling characteristics:

- Flat sheet design that easily conforms to tissue
- Coverage of more anatomical locations

Launched August 2023

These highlights do not include all the information needed to use Axoguard HA+ Nerve Protector™ safely and effectively. See full instructions for use (IFU) for Axoguard HA+ Nerve Protector™



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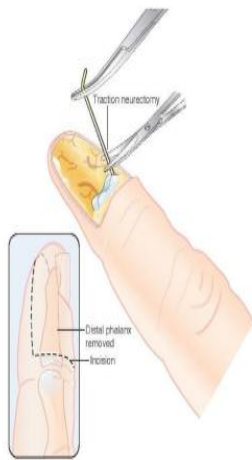


# Traditional STUMP NEUROMA options are suboptimal

## TRACTION NEURECTOMY

Nerve placed in traction and cut to allow for retraction

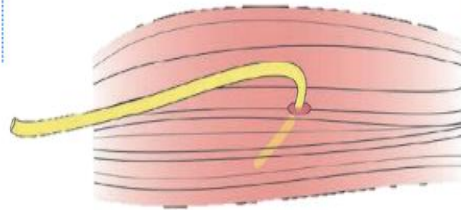
- Simply resecting the nerve results in subsequent neuroma formation and risk of secondary surgery
- Causes traction injury
- High risk of recurrence<sup>36</sup>



## BURYING IN MUSCLE/BONE

Traditional method of neurectomy and neuromyodesis

- Simply resecting the nerve results in subsequent neuroma formation and risk of secondary surgery
- Pain due to muscular contraction or localized pressure
- Larger surgical dissection
- Only 33-40% of patients were satisfied with treatment after burial into bone or muscle<sup>37, 38, 39</sup>



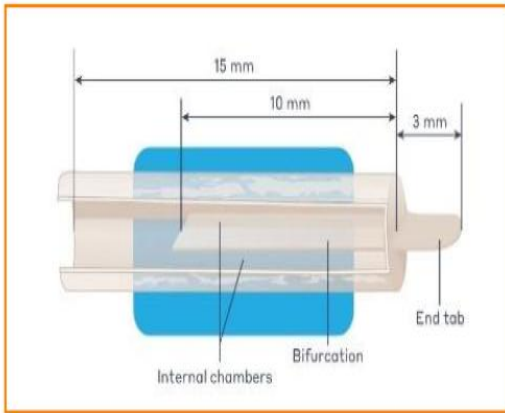
## INJECTIONS

Pharmacologic intervention, typically alcohol or steroids<sup>40, 41, 42, 43, 44, 45</sup>

- Chemical injections are only successful 40% of the time<sup>43, 44</sup>
- Temporary solution that has a reduced benefit over time
- May cause considerable side effects



# Axogen solution for STUMP NEUROMA



Large Diameter Nerve Cap launched in February 2024. 3 larger sizes for larger diameter nerves. Expands addressable procedures in upper and lower extremity.

Proprietary small intestine submucosa (SIS) matrix designed to separate the nerve end from the surrounding environment to protect it from mechanical stimulation and reduce painful neuroma formation\*.

## Protects and isolates

- Reduces the development of symptomatic or painful neuroma formation
- Provides a barrier from neurotrophic factors and mechanical stimulation

SIS Material allows for vascularization and gradual remodeling (as shown in animal studies)<sup>46, 47</sup>

- Material gradually incorporates into patient's own tissue, creating a physical barrier to surrounding soft tissue

## Intra-operative versatility

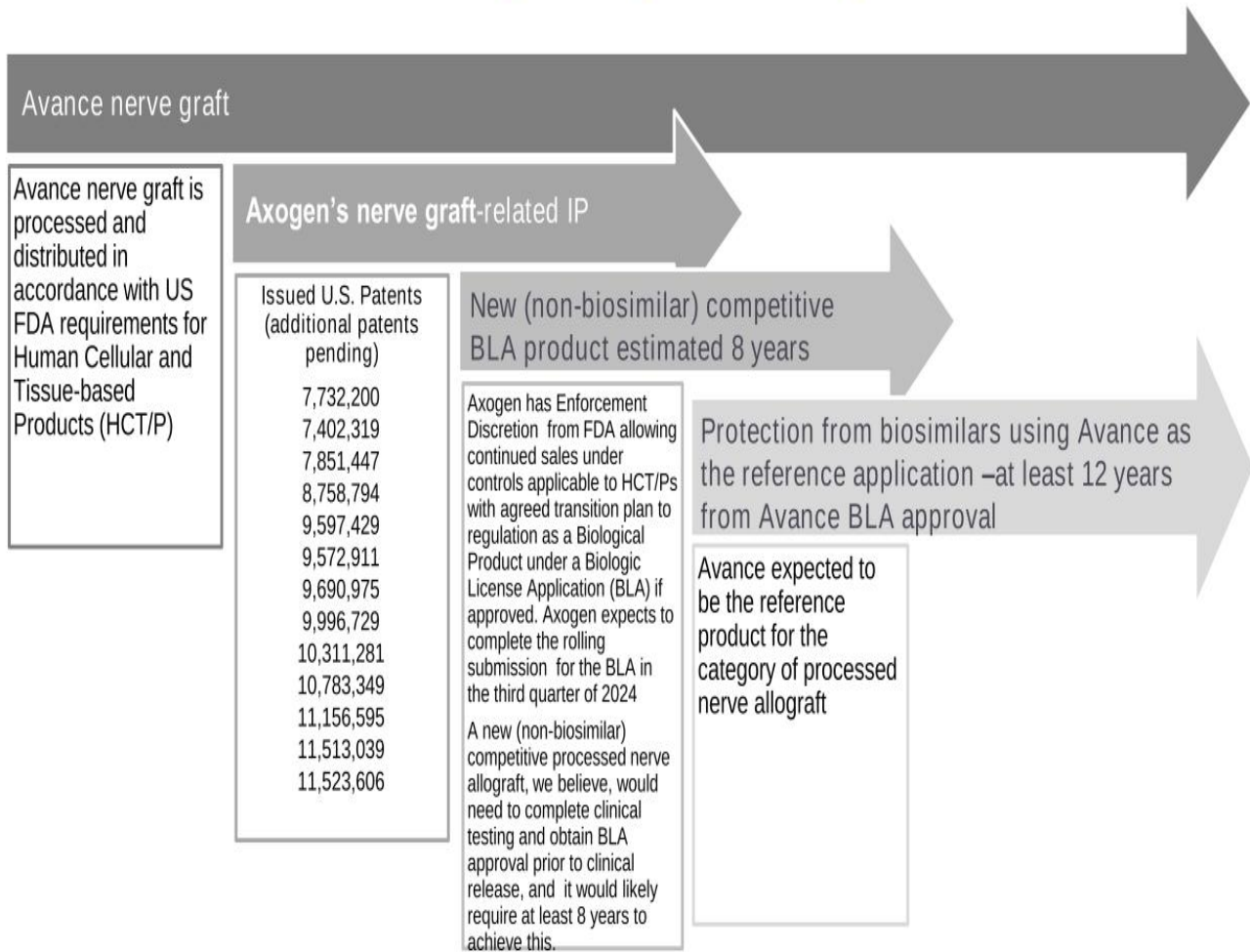
- Ideal for anatomic areas with limited or no musculature
- Alternative to historical techniques such as burying in muscle or bone
- Available in a variety of diameters



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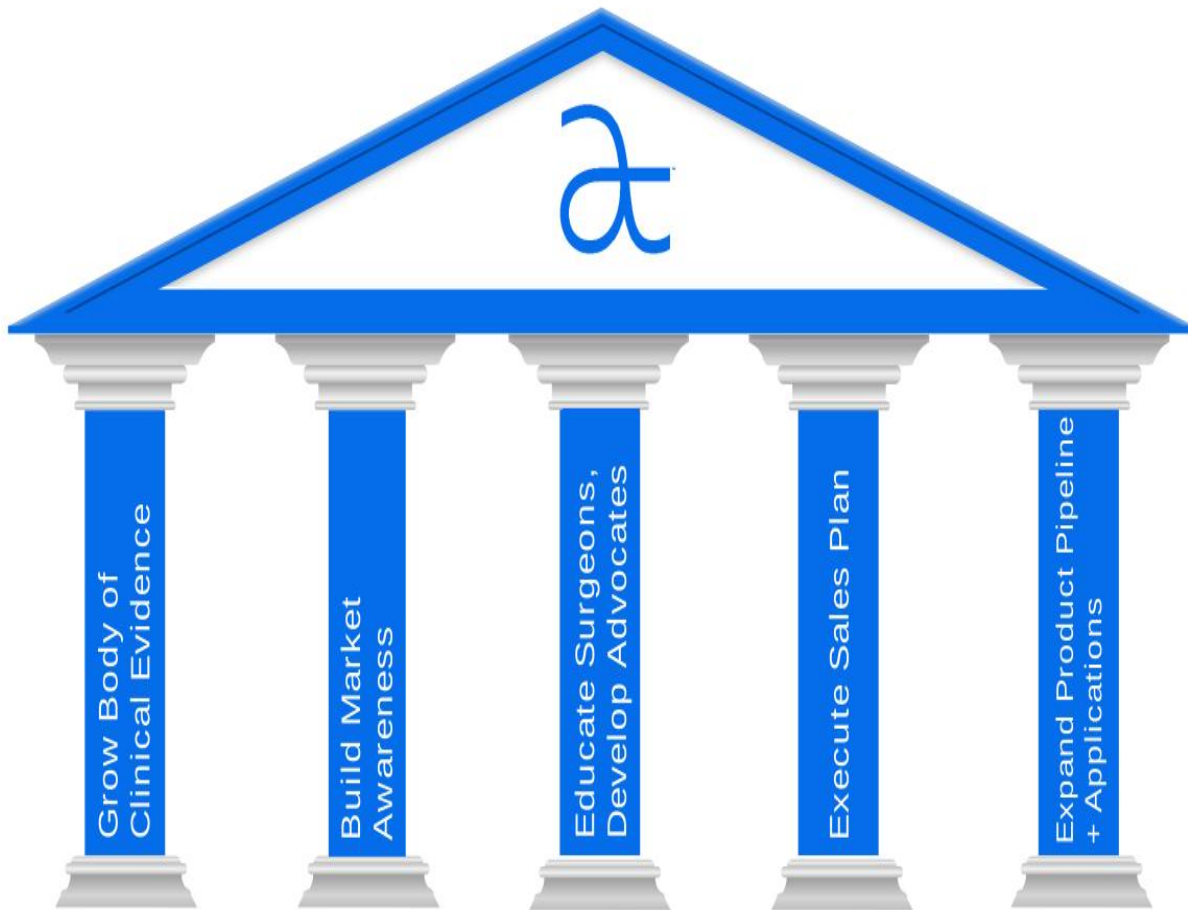
\*These highlights do not include all the information needed to use Axoguard Nerve Cap® safely and effectively. See full instructions for use (IFU) for Axoguard Nerve Cap® [https://www.axogeninc.com/wp-content/uploads/2019/12/LB-580-R04\\_NerveCapIFU.pdf](https://www.axogeninc.com/wp-content/uploads/2019/12/LB-580-R04_NerveCapIFU.pdf) 18

# Avance Patents and Regulatory Landscape





# Market development strategy



# Strong commitment to developing clinical evidence



## RANGER® Registry Study: Enrollment Complete

- Multi-center clinical study in PNR with >2,700 enrolled to date
- Overall meaningful recovery rates of 82-84%; comparable to autograft

## MATCH® Registry Study: Enrollment Complete

- Avance compared to matched cohort of autograft and synthetic conduits

## Sensation-NOW® Registry Study: Enrollment Ongoing

- Multi-center clinical study in breast neurotization

## REPOSE®: Top line Data Read Out Complete

- Prospective, randomized, controlled study of Axoguard Nerve Cap® vs neurectomy

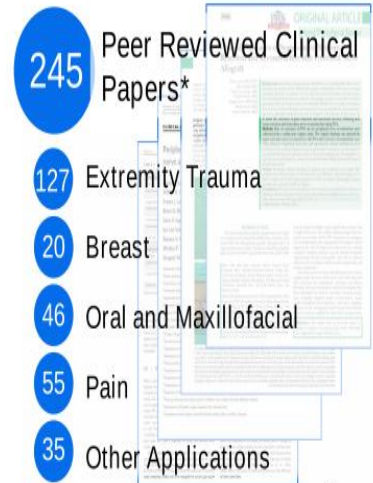
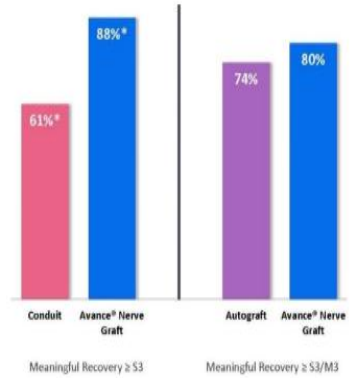
## REPOSE-XL<sup>SM</sup>: Pilot Study Enrollment Ongoing

- Pilot study evaluating the feasibility of large-diameter Axoguard Nerve Cap® for protecting and preserving terminated nerve ends after trauma or amputation

## COVERED<sup>SM</sup>: Now Enrolling

- Prospective, multi-center clinical case series evaluating Axoguard HA+ Nerve Protector™ in first revision cubital tunnel decompression

Outcomes from RANGER Registry<sup>48,49</sup>



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\*Certain publications contain data on multiple applications.

# RECON<sup>SM</sup> : A Multicenter, Prospective, Randomized, Subject & Evaluator Blinded Comparative Study of Nerve Cuffs & Avance Nerve Graft Evaluating Recovery Outcomes for the Repair of Nerve Discontinuities



Safety & efficacy non-inferiority comparison of Avance vs conduit



Evaluated upper extremity digital nerve repair for nerve gaps 5-25mm



220 subjects from up to 25 U.S. centers stratified into gap lengths with two-thirds in the 5-14mm group and one-third in the 15-25mm group

# RECON Study Topline Results<sup>1,2</sup>

## Primary Endpoint Achieved

- This phase three pivotal study met its primary endpoint for the return of sensory function as measured by static two-point discrimination, and the safety profile was consistent with previously published data
- The data will support the company's rolling Biologics License Application (BLA) which we expect to be completed in Q3 2024

### Statistical superiority demonstrated at increasing gap lengths

- ✓ Avance demonstrated statistical superiority for return of sensory function (measured by static two-point discrimination) as compared to conduits in gaps greater than 12 mm (p-value 0.021).
- ✓ Avance demonstrated statistical superiority for time to recovery of static two-point discrimination as compared to conduits, returning normal sensation\* up to 3 months earlier in gaps greater than 10 mm (p-value 0.037).

### The safety profile was consistent with previously published data

- ✓ Conduit repairs were observed to have an increased likelihood of persistent and unresolved nerve pain with an incidence of 9 (8%) conduit subjects as compared to 2 (2%) Avance subjects.

\*Normal Sensation is defined by the Medical Research Council Classification (MRCC) score as S4 or return of static two-point discrimination outcomes of  $\leq 6$ mm.

<sup>1</sup>Axogen Data on File;



<sup>2</sup>Isaacs J, Nydick JA, Means KR, Merrell GA, Ilyas A, Levin LS; RECON study group. A Multicenter Prospective Randomized Comparison of Conduits Versus Decellularized Nerve Allograft for Digital Nerve Repairs. *J Hand Surg Am.* 2023 Aug 2:S0363-5023(23)00297-6. doi: 10.1016/j.jhsa.2023.05.020. Online ahead of print.



# REPOSE Study Top Line Results

## Primary Endpoint Achieved

REPOSE met primary endpoint of non-inferiority between the Month 12 pain visual analog scale scores for neurectomy with Axoguard Nerve Cap vs. standard-of-care neurectomy alone (p-value <0.05).

## Statistical superiority demonstrated in Reduction of Total Pain

- ✓ Axoguard Nerve Cap demonstrated statistical superiority vs. standard-of-care neurectomy in the Reduction of Total Pain reported by participants over the full 12-month course of follow-up (p-value <0.05)

REPOSE is a post-market, randomized, comparative clinical study of standard-of-care neurectomy and standard-of-care neurectomy followed by reconstruction of the nerve end with Axoguard Nerve Cap, evaluating recovery outcomes for the treatment of symptomatic neuroma.

### Study Details:

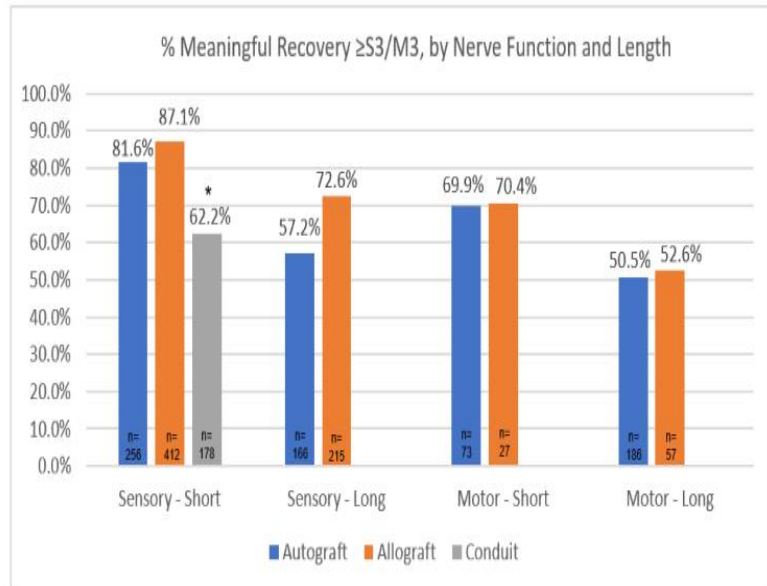
- Multicenter, prospective, randomized, subject blinded trial
- 86 randomized participants
- 12-month follow-up
- Pain, medication, Quality of Life questionnaires, recurrence of neuroma endpoints



# Independent Publication of Nerve Meta-Analysis Provides the Strongest Clinical and Economic Evidence To-Date of the Performance of Avance® Nerve Graft Across All Gap Lengths and Nerve Types

## “Lans et al., A systematic review and meta-analysis of nerve gap repair: Comparative effectiveness of allografts, autografts, and conduits” – Journal of Plastic and Reconstructive Surgery<sup>57</sup>

- Analyzed 35 peer-reviewed studies with 711 allograft, 670 autograft, and 178 conduit repairs, over four decades.
- There were no statistical differences between allograft and autograft outcomes over all gap lengths for both sensory and motor nerve repairs.
- Allograft and autograft repairs delivered significantly better rates of meaningful sensory recovery in short gaps as compared to conduit repairs; 87.1% and 81.6% vs. 62.2%, respectively,  $p < 0.05$ .
- The cost analysis found that allograft does not represent an increased economic burden compared to autograft.



\*statistically significant difference

# Procedure Costs of Peripheral Nerve Graft Reconstruction

Raizman et al.  
PRs Global Open<sup>58</sup>



- Retrospective study of U.S. all-payer data on facility procedure costs from 2018 to 2020. Included over 1,300 nerve repairs.

## Conclusions:

- No significant differences in procedure costs for autograft and allograft repair in either inpatient or outpatient setting.
- OR time was significantly shorter for allograft repairs, in both outpatient and inpatient settings.

## Procedure Costs of Nerve Repair

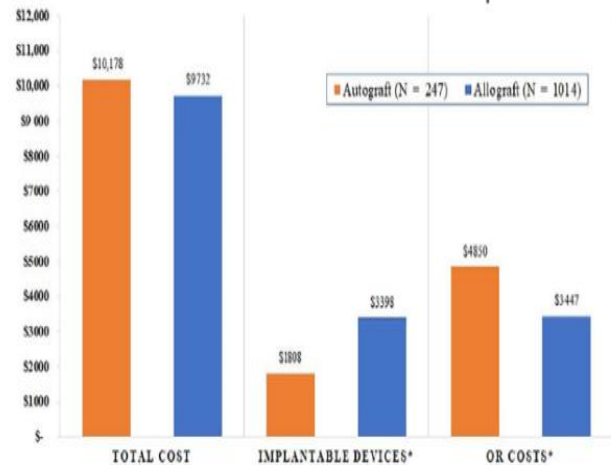


Fig. 2. Outpatient descriptive costs of nerve graft repair type (n = 1261).



Fig. 3. Inpatient descriptive costs of nerve repair graft type (n = 102).



# Focus on building awareness among clinicians and patients



- Increasing omnichannel engagement with clinicians and patients
- Continuing clinical conference participation both virtually and in-person as appropriate
- Ongoing patient ambassador program
- Garnering positive media attention
- Growing social media presence



.....  
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revolutionizing the science of nerve repair®

resensation.com

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Knowledge is power: continued education and advocacy efforts with patients, clinicians and key legislators elevates the problems associated with numbness.

FOR PATIENTS, SURVIVORS & THEIR CAREGIVERS

BREAST CANCER

# cure 20<sup>TH</sup> anniversary

Cancer Updates, Research & Education<sup>SM</sup>

SPECIAL ISSUE • 10.2022

## Creating A NEW WAY TO DEFINE BREAST CANCER

THE RECOGNITION OF HER2-LOW STATUS IS RAPIDLY RESHAPING HOW RESEARCHERS AND CARE PROVIDERS THINK ABOUT BREAST CANCER.

**Also in this issue**

**SECONDARY BREAST CANCERS**  
Finding evidence to guide decisions after completing treatment for primary breast.

**FAST FORWARD**  
Researchers identify the method to predict tumor growth in early treatment decisions.

**POST-MASTECTOMY NUMBNESS**  
A new study suggests that the physical effects of breast cancer treatment can last for years.

**Coping With Sensation Loss After Mastectomy**

Chest numbness can be truly daunting, but patients don't have to suffer in silence – and it may not be something they have to live with.

BY CHERYL BERRY, PhD

2022 • 8th Edition • Plastic Surgery News

# Breast Reconstruction

A patient's guide to understanding her treatment options

Q&A: Chicago doctor shares her journey and research efforts to reduce racial disparities in care

Breast Reconstruction: Clearing up common misconceptions Page 5

4 things to consider when finding the right plastic surgeon Page 15

## Helping a patient reclaim her time after mastectomy

HELP WOMEN RECLAIM AFTER MASTECTOMY Page 6

# WILDFIRE

Love & Intimacy

APRIL / MAY 2022

Features  
Regaining Feeling and Restoring Intimacy by Jessica de Paz

Oncology **cure** NURSINGNEWS

Opinion: Post-Mastectomy Chest Numbness: Oncology Nurses Are Key to Patient Education

November 16, 2022  
Jessica de Paz, BSN, Breast Cancer Survivor

Facebook Twitter LinkedIn YouTube Instagram

Oncology nurses are in a unique position to educate patients with breast cancer about post-mastectomy chest numbness.

OCTOBER 2022 • VOL. 8 • NO. 8

# CONQUER

the patient voice

## Breast Cancer Diagnosis & Patient Advocacy

By Cancer Asked Me What I Was Made of

TO BE CANCER-FREE, I Had to Be a Warrior

YOUNG PEOPLE: YOU MAY NOT KNOW IT, BUT YOU ARE BEING WATCHED

VERSUS

ANN

conquer-magazine.com

TODAY

PINK POWER TODAY

NBC'S KRISTEN DAHLGREN ON HER GROUNDBREAKING PROCEDURE

TODAY 8:43 AM

SIDE-EFFECTS MANAGEMENT BREAST CANCER

## Dealing with Chest Numbness After Mastectomy

By Kristen Casey, PsyD

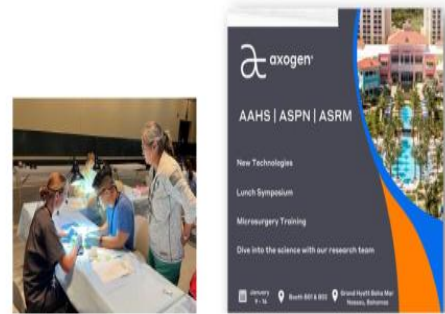
October 2022 Vol 8 No 5

Chest numbness is a side effect often ignored or not discussed in breast cancer, but losing physical sensation in nearly 10% of the body can have a profound impact on a woman's physical and emotional life.

# Emphasis on education



- In-person and virtual national education programs
- Customized multimodal learning programs to specific surgeon groups for advanced learning
- Ongoing interactive webinar series covering the principles of nerve repair
- Emphasis on training hand and micro-surgery fellows



masterminds  
of nerve



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# Focused sales execution, increasing market penetration

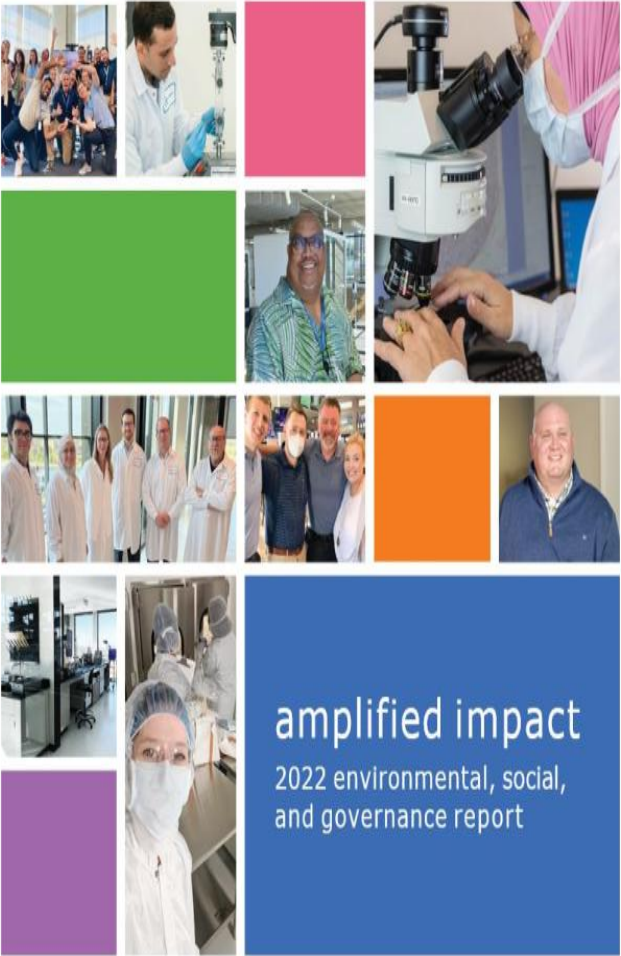


## Sales execution focused on driving results

- Continue driving penetration in Core Accounts
- Approximately 5,100 potential U.S. accounts perform nerve repair
- 376 Core Accounts as of December 31, 2023
- Core Accounts represents approximately 65% of total revenue.

## Broad sales reach

- U.S. direct sales team
  - 116 direct sales professionals at the end of Q4 2023
- Supplemented by independent agencies
- Revenue from direct sales channel represented approximately 90% of total revenue



Committed to our patients, the communities we serve, and our pursuit of advancing the science of nerve repair in ethical and sustainable ways

People Sustainability Business

- Diversity, Equity, and Inclusion - Being the Company where exceptional people want to work
- Cybersecurity – Data Privacy, Training, and Policies
- Compliance – Quality Management System, Regulatory, and Good Manufacturing Practices
- Governance – Framework for Ethics Codes and Accountability
- Environment – Responsible, Sustainable Operations

# Executive team



**Karen Zaderej**  
Chairman, CEO,  
and President  
J&J (Ethicon)



**Marc Began**  
Executive Vice President, General Counsel  
Abiomed, Boehringer Ingelheim, Novo Nordisk



**Nir Naor**  
Chief Financial Officer  
Abar Pharmaceuticals, Mölnlycke  
Healthcare, UCB



**Angelo Scopelianos,  
Ph.D.**  
Chief Research and  
Development Officer  
J&J



**Erick DeVinney**  
Chief Innovation Officer  
Angiotech, PRA Intl



**Jens Schroeder Kemp**  
Chief Marketing Officer  
Ambu, Pera International



**Ivica Ducic, M.D., Ph.D.**  
Chief Medical Officer  
Washington Nerve Institute



**Angela Nelson**  
Vice President, Regulatory Affairs MBA, RAC(GS)  
PPD part of Thermo Fisher Scientific, Cardinal Health,  
UMKC School of Medicine



**Mike Donovan**  
VP, Operations  
Zimmer



**Stacy Arnold**  
VP, Product Development and Clinical  
Research  
Artivion (CryoLife)



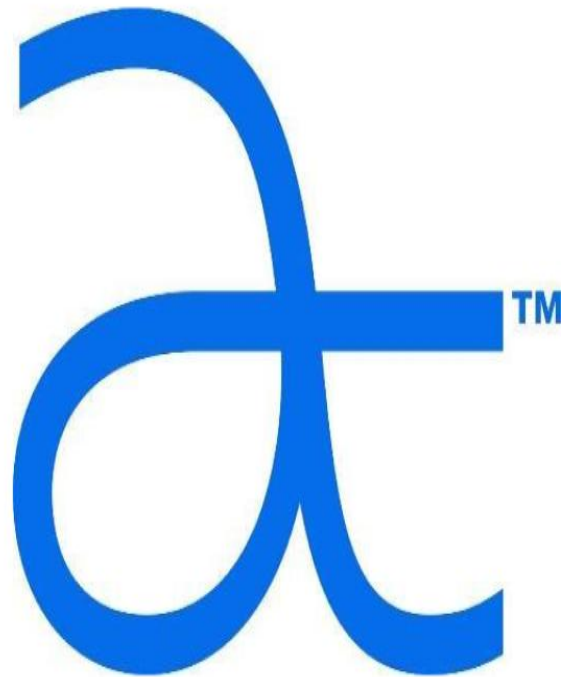
**Al Jacks**  
Vice President, Quality Assurance  
VERO Biotech, Alimera Sciences



**Doris Quackenbush**  
VP, Sales  
Convatec

# Appendix

- Key clinical data
- Historical core and active accounts
- CMS outpatient and ASC reimbursement rates
- Total addressable market
- Cash, debt, and capital structure
- Axogen product portfolio and indications for use

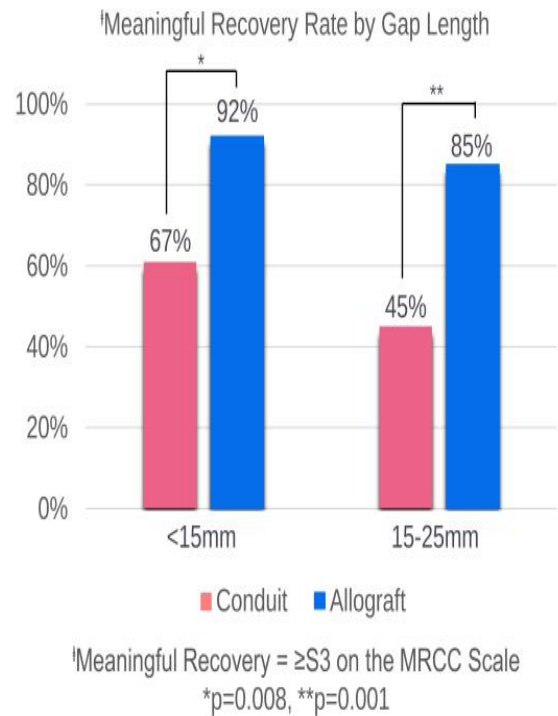




# Avance nerve graft repairs found to be significantly better than conduit repairs

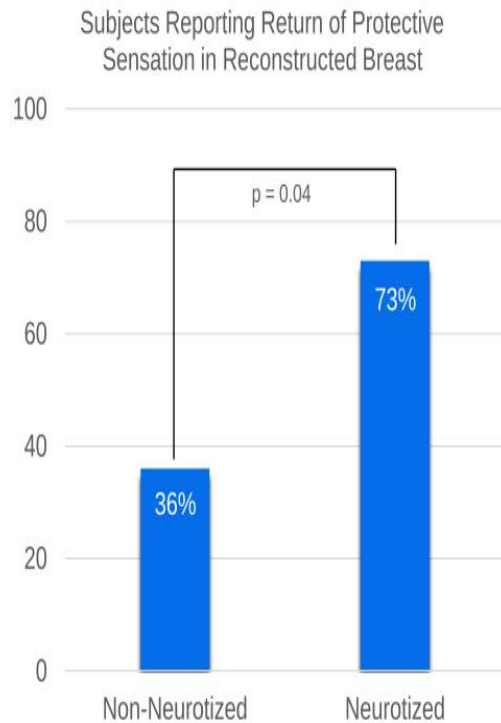
“Liversedge et al., A Multicenter Matched Cohort Study of Processed Nerve Allograft and Conduit in Digital Nerve Reconstruction” – Journal of Hand Surgery, September 2020<sup>48</sup>

- Peer-reviewed publication from the MATCH cohort of the RANGER Registry
- Includes outcomes from 110 subjects with 162 nerve injuries; 113 were repaired with Avance nerve graft and 49 were repaired with manufactured conduit
- Findings show overall meaningful recovery rate was 88% for Avance nerve graft and 61% for conduit (p=0.001) for gaps up to 25mm
- Average static two-point discrimination improved to 9.7mm for Avance nerve graft as compared to 12.2mm for conduit (p=0.018)
  - Note: lower measurement is reflective of improved discrimination and a better outcome
- As gap length increased, Avance nerve graft outcome rates remained consistent while conduit rates declined significantly



# First publication on breast neurotization outcomes with Avance Nerve Graft demonstrated greater return of protective sensation

**“Momeni et al., Flap Neurotization in Breast Reconstruction with Nerve Allografts: 1-year Clinical Outcomes”** – Plastic and Reconstructive Microsurgery Global Open, January 2021<sup>60</sup>

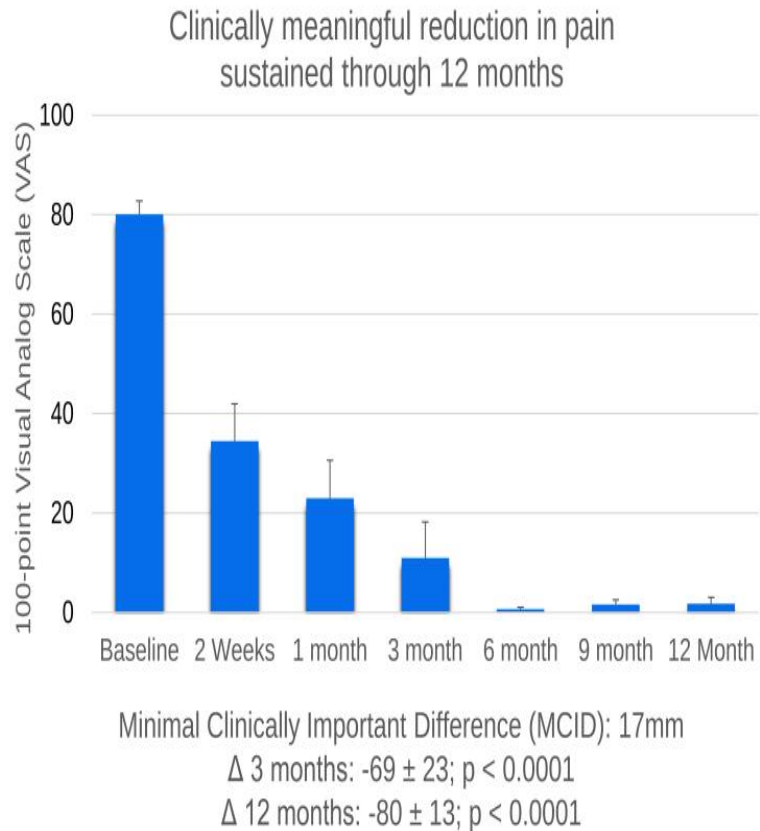


- Early outcomes from a single center study, as part of the Sensation-NOW<sup>®</sup> registry
- 36 breast reconstructions that included:
  - 22 breast reconstructions with Resensation<sup>®</sup>
  - 14 standard non-neurotized breast reconstructions
- Return of Protective Sensation (p=0.04)
  - 73% of the Resensation group
  - 36% of the non-neurotized group
- Neurotization with Avance Nerve Graft resulted in greater return of sensation and return of sensation in more of the breast as compared to standard reconstruction without nerve repair.

# Axogen sponsored REPOSE<sup>SM</sup> pilot study analysis demonstrates clinically significant improvement for subjects with chronic neuropathic pain when using Axoguard Nerve Cap<sup>®</sup> following neurectomy<sup>61</sup>

15-subject, single arm pilot phase evaluating reduction in pain from baseline following surgical excision of the neuroma and placement of the Axoguard Nerve Cap

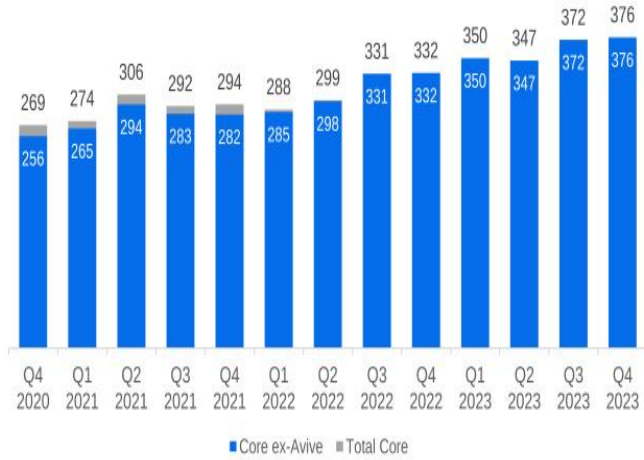
- Significant & clinically meaningful reduction in pain
- Significant and clinically meaningful improvements in Fatigue, Physical Function, Sleep Disturbance, Pain Interference, Pain Intensity, and Pain Behavior as measured by the validated PROMIS<sup>®</sup> measures
- Positive indicators for reduction in pain medication burden, including opioids
- No recurrence of neuroma



# Historical Core and Active Accounts

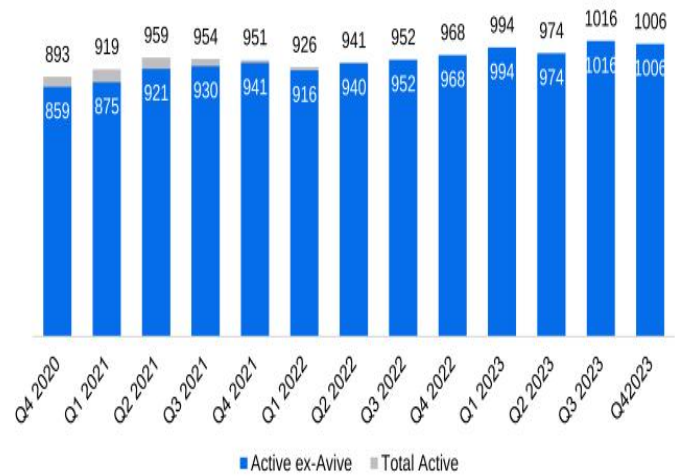
## Core Accounts

≥\$100,000 revenue in the last 12 months



## Active Accounts

6 orders in the last 12 months



	Q420	Q121	Q221	Q321	Q421	Q122	Q222	Q322	Q422	Q123	Q223	Q323	Q423
Core Accounts	269	274	306	292	294	288	299	331	332	350	347	372	376
*Adjusted Core Accounts	256	265	294	283	282	285	298	331	332	350	347	372	376

	Q420	Q121	Q221	Q321	Q421	Q122	Q222	Q322	Q422	Q123	Q223	Q323	Q423
Active Accounts	893	919	959	954	951	926	941	952	968	994	974	1016	1006
*Adjusted Active Account	859	875	921	930	941	923	940	952	968	994	974	1016	1006

Core Accounts represents ~65% of revenue and grew 13.3% vs the prior year.



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\* Axogen voluntarily suspended market availability of Avive® Soft Tissue Membrane on June 1, 2021. Active and Core Account metrics are Adjusted for past Avive revenue. 37



# 2024 Center for Medicare and Medicaid Services (CMS) Final outpatient reimbursement rates - hospital and ASC

Although CMS rates<sup>1</sup> only apply to Medicare cases, which represents a small percentage of traumatic injuries, private payors are often influenced by the analysis and decisions made by CMS

CPT Code	Descriptor	C-APC	Hospital Outpatient (HOPD)				Ambulatory Surgery Center (ASC)			
			2019	2023	2024	5Y % Change	2019	2023	2024	5Y % Change
64912	Nerve allograft repair <sup>2</sup>	5432	\$4,566	\$6,179	<b>\$6,354</b>	<b>39.15%</b>	\$1,920	\$4,057	<b>\$4,583</b>	<b>138.69%</b>
64910	Conduit or vein allograft repair <sup>2</sup>	5432	\$4,566	\$6,179	<b>\$6,354</b>	<b>39.15%</b>	\$2,613	\$3,805	<b>\$4,291</b>	<b>64.21%</b>
64885	Autograft repair (head and neck ≤4cm) <sup>3</sup>	5432	\$4,566	\$6,179	<b>\$6,354</b>	<b>39.15%</b>	\$1,920	\$2,632	<b>\$4,499</b>	<b>134.33%</b>
64886	Autograft repair (head and neck >4cm) <sup>6</sup>	5432	\$4,566	\$6,179	<b>\$6,354</b>	<b>39.15%</b>	\$3,127	\$4,375	<b>\$3,013</b>	<b>-3.65%</b>
64890	Autograft repair (hand and foot ≤4cm) <sup>3</sup>	5432	\$4,566	\$6,179	<b>\$6,354</b>	<b>39.15%</b>	\$3,075	\$2,602	<b>\$4,586</b>	<b>49.14%</b>
64891	Autograft repair (hand and foot >4cm) <sup>2</sup>	5432	\$4,566	\$6,179	<b>\$6,354</b>	<b>39.15%</b>	\$1,920	\$3,383	<b>\$3,796</b>	<b>97.71%</b>
64892	Autograft repair (arm and leg ≤4cm) <sup>2</sup>	5432	\$4,566	\$6,179	<b>\$6,354</b>	<b>39.15%</b>	\$1,920	\$3,383	<b>\$4,619</b>	<b>140.59%</b>
64893	Autograft repair (arm and leg >4cm) <sup>2</sup>	5432	\$4,566	\$6,179	<b>\$6,354</b>	<b>39.15%</b>	\$1,920	\$3,383	<b>\$4,681</b>	<b>143.79%</b>
64897	Autograft repair (arm and leg ≤4cm multiple strands) <sup>3</sup>	5432	\$4,566	\$6,179	<b>\$6,354</b>	<b>39.15%</b>	\$1,920	\$3,660	<b>\$4,085</b>	<b>112.78%</b>
64895-96,98	Autograft repair (all other nerve type) <sup>5</sup>	5432	\$4,566	\$6,179	<b>\$6,354</b>	<b>39.15%</b>	\$1,920	\$2,632	<b>\$3,013</b>	<b>56.92%</b>
64834-36, 40, 56, 57, 62-64	Direct Repair (other hand / foot, arm/leg, repair / transpose, facial, low back), <sup>5</sup>	5432	\$4,566	\$6,179	<b>\$6,354</b>	<b>39.15%</b>	\$1,920	\$2,632	<b>\$3,013</b>	<b>56.92%</b>
64865	Direct Repair of facial nerve <sup>2</sup>	5432	\$4,566	\$6,179	<b>\$6,354</b>	<b>39.15%</b>	\$1,920	\$3,383	<b>\$3,796</b>	<b>97.71%</b>
64831, 61	Direct Repair (digital, brachial plexus/arm) <sup>4</sup>	5431	\$4,566	\$ 1,798	<b>\$1,842</b>	<b>-59.67%</b>	\$1,920	\$854	<b>\$898</b>	<b>-53.24%</b>
64858	Direct Repair (sciatic) <sup>2</sup>	5431	\$4,566	\$ 1,798	<b>\$1,842</b>	<b>-59.67%</b>	\$1,920	\$1,481	<b>\$1,498</b>	<b>-21.98%</b>

1. National average payment rates. Commercial payments are traditionally 1.5-2x higher than Medicare.
2. Nerve allograft repair CPT 64912, conduit repair CPT 64910, autograft repairs hand/foot >4cm CPT 64891, arm/leg≤4cm CPT 64892, arm and leg >4cm CPT 64893, repair arm/leg ≤4cm multiple strands CPT 64897. direct repair of facial nerve CPT 64865 remain in C-APC 5432 and direct repair sciatic CPT 64858 remains in C-APC 5431 and all continue to meet ASC device intensive criteria
3. Autograft repair head/neck ≤4cm CPT 64885, hand and foot ≤4cm 64890 remains in C-APC 5432 and meets ASC device intensive criteria in 2024
4. Direct repair digital and brachial plexus/arm CPT codes 64831 and 64861 remain in C-APC 5431 and do not meet ASC device intensive criteria.
5. Autograft repair all other nerve type CPT 64895-96,98 and Direct repair other hand/foot CPT 64834-36, leg CPT 64840, repair/transpose CPT 64856, arm/leg CPT 64857, low back CPT 64862-64 remain in C-APC 5432 and do not meet ASC device intensive criteria
6. Autograft repair head/neck >4cm CPT 64886 remains in C-APC 5432 no longer meets ASC device intensive criteria in 2024



Note: Hospital inpatient rates for nerve repair align to DRGs 040, 041, 042 and range from \$11.1k to \$24.6k in the 2024 IPPS Final Rule



# 2024 CMS: Final Physician Fee Schedule (PFS)

CPT Codes <sup>3</sup>	Descriptor	Physician Fee Schedule (PFS)			
		2019	2023	2024	5Y % Change
64912	Nerve allograft repair	\$804	\$908	<b>\$883</b>	<b>9.78%</b>
64910	Conduit or vein allograft repair	\$825	\$772	<b>\$752</b>	<b>-8.80%</b>
64885 to 64898*	Autograft repair	\$1,096 to \$1,495	\$1,065 to \$1,444	<b>\$1,035 to \$1,404</b>	<b>-5.54% to -6.12%</b>
64831 to 64861*	Direct Repair	\$713 to \$1,604	\$708 to \$1,560	<b>\$689 to \$1,522</b>	<b>-3.34% to -5.11%</b>

\*excludes add-on procedure codes



# Emergent trauma cases generally result from injuries that initially present in an ER

## Emergent Procedures:

- Significant number of nerve injuries typically referred to and completed by a specialist either immediately or within a few days following the injury with limited post op follow-up evaluations
- Emergent and diverse nature of injuries result in variable patient pathways from ER to nerve repair specialist and diverse repair algorithms
- Specialist surgeons typically perform nerve repair as a minor portion of their overall practice
- Opportunity to drive care pathways with surgeon education supported by clinical and economic data
- Opportunity to shift site of care for routine traumatic injuries to more cost-efficient settings (ASC)

## Emergent Trauma Procedure Examples



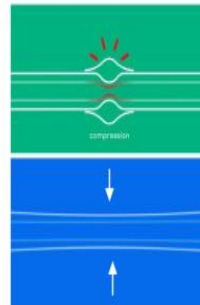
### Transected sensory nerves

Digital nerve injury after sharp lacerations e.g., a knife slipping when cutting an avocado, glass injuries



### Transected mixed/motor nerves

More complex trauma injuries e.g., circular saw injury to hand and wrist resulting in ulnar and median nerve damage



### Non-transected nerve injury

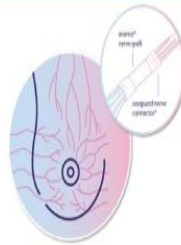
Trauma induced compression and stretch injuries e.g., peroneal nerve compression at the fibular head after knee dislocation, shoulder trauma causing stretching of the brachial plexus

# Scheduled procedures involve a patient seeking relief of a condition caused by a nerve defect or surgical procedure

## Scheduled Procedures:

- Patients seeking a scheduled procedure weeks or months in advance allows patients to advocate for solutions that may improve quality of life outcomes
- Procedures lend themselves to standardized surgical techniques and more consistent repair algorithms, and extended follow-up evaluations
- Completed in specialist centers at regular intervals, typically in existing core accounts
- Concentrated group of surgeon specialists allow for more focused surgeon training and adoption
- Typically involve a higher value of Axogen products per procedure

## Scheduled Procedure Examples



### Breast reconstruction

Neurotization of the breast and/or nipple areolar complex may be possible in many delayed or immediate breast reconstruction settings.



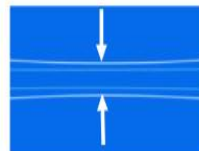
### Mandibular reconstruction

Reconstruction of the inferior alveolar nerve with ablation of the mandible



### Neuroma repair

Symptomatic neuroma resection with nerve reconstruction



### Cubital and carpal tunnel revisions



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# Estimated Trauma total addressable market

Patient Population <sup>(a)</sup>	Source	Adjustments and Rationale
<p><b>136,943,000</b> Annual emergency department visits in the U.S.</p>	2015 National Hospital Ambulatory Medical Care Survey (Table 1)	
<p><b>30,238,000</b> Annual emergency department visits <u>due to injury</u> in the U.S.</p> <p>✕</p> <p><b>4.76%</b> Percentage of emergency department visits <u>with nerve injury</u></p> <p>=</p>	2015 National Hospital Ambulatory Medical Care Survey (Table 1)	<ul style="list-style-type: none"> <li>Adjusted from 38,959,000 to exclude 8,721,000 injuries that are unlikely to include a nerve injury (i.e., mental disorders, skin conditions, etc.)</li> </ul>
<p><b>1,440,000</b> Annual emergency department visits with nerve injury in the U.S.</p> <p>✕</p> <p><b>46.2%</b> Percentage of ED nerve injuries estimated to be treated surgically</p> <p>=</p> <p><b>~665,000</b> Annual ED visits with nerve injury estimated to be treated surgically in the U.S., excluding revisions</p>	<p><i>Noble, et al: J Trauma, Volume 45(1) July 1998.116-122</i></p> <p><i>Noble, et al: J Trauma, Volume 45(1) July 1998.116-122</i></p>	<ul style="list-style-type: none"> <li>2.8% rate cited in <i>Noble, et al</i> study excluded 113 patients coded with nerve injuries outside of the study scope, but that are in the Axogen scope of nerve repair (brachial plexus and digital nerve injuries). Including these injuries increases the rate to 4.76%.</li> <li>Calculated rate based on various rates in <i>Noble et al</i> study for upper and lower extremity and an estimate for other trauma nerves.</li> </ul>

a) Patient population figures rounded to the nearest thousandth.



# Trauma total addressable market (continued)

Patient Population <sup>(a)</sup>	Source	Adjustments and Rationale
<div style="border: 1px solid black; padding: 10px; margin-bottom: 10px;"> <p style="text-align: center;"><b>~665,000</b></p> <p style="text-align: center;">Annual emergency department visits with nerve injury that can be treated surgically in the U.S., <u>excluding revisions</u></p> <p style="text-align: center;"><b>×</b></p> <p style="text-align: center;"><b>7.4%</b></p> <p style="text-align: center;">Revision cases</p> </div> <p style="text-align: center;"><b>=</b></p> <p style="text-align: center;"><b>714,000</b></p> <p style="text-align: center;">Annual emergency department visits with nerve injury that can be treated surgically in the U.S., <u>including revisions</u></p> <p style="text-align: center;"><b>↓</b></p> <p style="text-align: center;"><b>~700,000</b></p> <p style="text-align: center;">Company estimate of trauma total addressable market</p>	<p>See calculation on previous slide</p> <p><i>Portincasa et al: Microsurgery</i> 27:455-462, 2007</p>	<ul style="list-style-type: none"> <li><i>Portincasa et al</i> suggests that a revision procedure was necessary in 7.4% of the patients within 6 months of the initial surgery.</li> </ul>

a) Patient population figures rounded to the nearest thousandth.



# Estimated \$2.7B value of market opportunity in existing applications

	Projected Incidence <sup>(a)</sup>	×	Weighted Average Procedure Value	=	Estimated Total Addressable Market
Trauma	700,000 100%		\$2,715		\$1,900M 100%
Trasection injuries >5mm (b)	203,000 29%		\$5,515		\$1,120M 59%
Trasection injuries <5mm	198,000 29%		\$1,200		\$238M 12%
Non-Trasected Injuries (c)	293,000 42%		\$1,825		\$535M 28%
Carpal and Cubital Tunnel Protection	130,000		\$2,100		\$270M
Oral and Maxillo-Facial (OMF)	56,000		\$5,400		\$300M
Breast Reconstruction Neurotization	24,500 flaps (15,000 patients)		\$10,200		\$250M
Totals	>900,000 (potential)				>\$2.7B

a) Estimated Annual incidence of PNI surgery are figures rounded to the nearest thousandth except for Breast Reconstruction Neurotization (rounded to nearest hundredth).

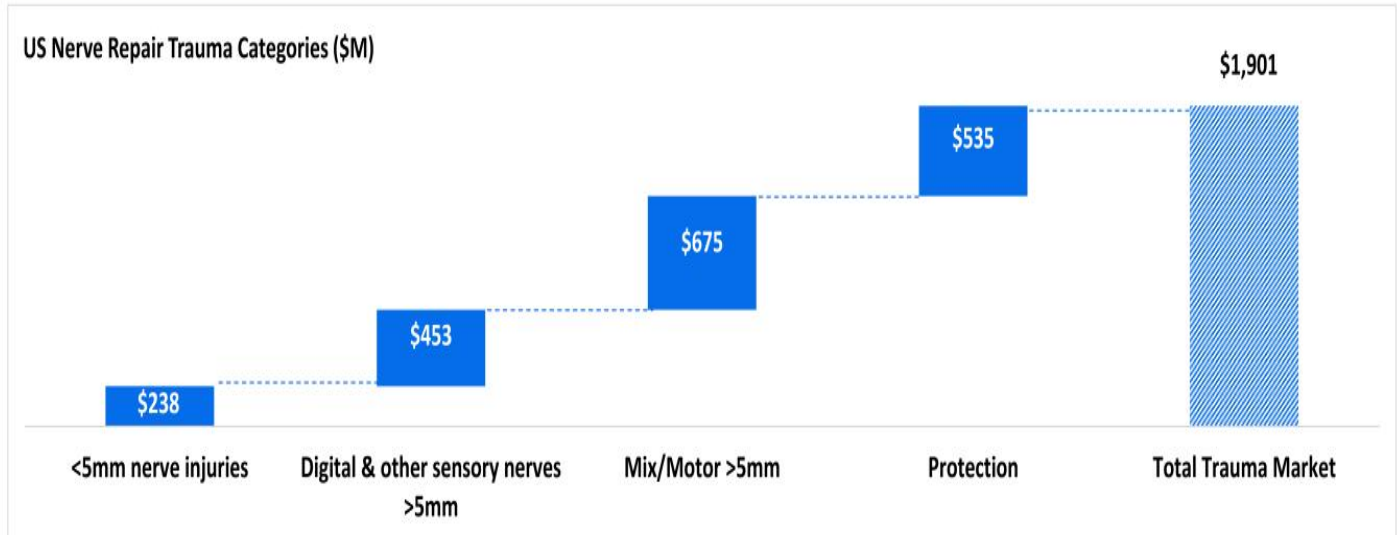
b) Trasection injuries > 5mm assumes a factor of 1.22 nerve repairs per procedures, and utilization of the Axogen portfolio of products, based upon data observed in the RANGER® registry.

c) Protection includes non-trasected compression and crush injuries including protection from surrounding soft tissue attachments.



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We continue to see a significant growth opportunity in the trauma market as we leverage new clinical & health economic data and product launches, by category



Category	Algorithm	Trends and Growth Levers
<ul style="list-style-type: none"> <li>Short gap transected nerve injuries</li> </ul>	Low	<ul style="list-style-type: none"> <li>Routine trauma moving to ASCs and lower cost sites of care</li> <li>Education and awareness of proper nerve repair technique</li> <li>Improve procedure awareness and scheduling across all care settings</li> <li>Private payer adoption of improved CMS reimbursement guidelines</li> </ul>
<ul style="list-style-type: none"> <li>Digital Sensory 5-25mm</li> <li>Digital Sensory &gt;25mm</li> </ul>	Low	<ul style="list-style-type: none"> <li>Routine trauma moving to ASCs and lower cost settings</li> <li>Education and awareness of proper nerve repair technique</li> <li>New Clinical data from Recon/Meta-analysis</li> <li>All Payor Procedural Cost analysis</li> <li>Societal support for standard of care</li> <li>Improved private payer reimbursement</li> <li>Activating middle adopters</li> </ul>
<ul style="list-style-type: none"> <li>Mixed/Motor 5-25mm</li> <li>Mixed/Motor &gt;25mm</li> </ul>	Low	<ul style="list-style-type: none"> <li>Motor clinical outcome data from Meta-analysis</li> <li>Societal support for standard of care</li> <li>Prof ed on appropriate surgical technique &amp; algorithm</li> <li>Improved private payer reimbursement</li> <li>Activating middle adopters</li> </ul>
<ul style="list-style-type: none"> <li>Protection from non transected nerve injuries</li> </ul>	Low	<ul style="list-style-type: none"> <li>New product launches of HA+ and Avive+ to address acute and chronic applications</li> <li>Increased awareness of Non-Transected Nerve Injuries</li> <li>Clinical evidence generation</li> <li>Professional education on appropriate surgical technique &amp; algorithm</li> <li>Reimbursement coding and coverage</li> </ul>

Axogen has, until now, focused primarily in digital and short gap but new evidence and product launches will open full peripheral nerve injury trauma market



# Balance sheet and capital structure

Balance Sheet Highlights	December 31, 2023
Cash, Cash Equivalents, and Investments	\$37.0 million
Total Long-term Debt	\$50.0 million*

Capital Structure (shares)	December 31, 2023
Common Stock	43,124,496
Common Stock Options, RSUs, PSUs	7,964,885
Common Stock and Common Stock Equivalents	51,089,381

\* Total long-term debt includes debt proceeds under the terms of the agreement with Oberland Capital, does not include unamortized debt discount and deferred financing fees.

# Axogen comprehensive portfolio of products

## Avance® Nerve Graft

- Regulatory Classification: Avance Nerve Graft is processed and distributed in accordance with U.S. Food and Drug Administration (FDA) requirements for Human Cellular and Tissue-based Products (HCT/P) under 21 CFR Part 1271 regulations, U.S. State regulations and the guidelines of the American Association of Tissue Banks (AATB). Additionally, international regulations are followed as appropriate.
- Indication for Use: Avance Nerve Graft is processed nerve allograft (human) intended for the surgical repair of peripheral nerve discontinuities to support regeneration across the defect.
- Contraindications: Avance Nerve Graft is contraindicated for use in any patient in whom soft tissue implants are contraindicated. This includes any pathology that would limit the blood supply and compromise healing or evidence of a current infection.

## Axoguard Nerve Connector®

- Regulatory Classifications: Class II Medical Devices - 510(k) cleared, Class III Medical Devices, CE Marked (EU), Class 4 (CA)
- Indications for Use (US): The Axoguard Nerve Connector is indicated for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity. The Axoguard Nerve Connector is supplied sterile and is intended for single use.
- This product is intended for use by trained medical professionals.
- Indications for Use (EU and UK): The Axoguard Nerve Connector is indicated for the repair of peripheral nerve discontinuities with gaps up to 5 mm. The Axoguard Nerve Connector is supplied sterile and is intended for single use.
- This product is intended for use by trained medical professionals.
- Contraindications: This device is derived from a porcine source and should not be used for patients with known sensitivity to porcine material. This device is not intended for use in vascular applications.

## Axoguard Nerve Protector®

- Regulatory Classifications: Class II Medical Devices - 510(k) cleared, Class III Medical Device, CE Marked (EU), Class 4 (CA)
- Indication for Use: Axoguard Nerve Protector is indicated for the repair of peripheral nerve injuries in which there is no gap. The Axoguard Nerve Connector is supplied sterile and is intended for single use.
- This product is intended for use by trained medical professionals.
- Contraindications: This device is derived from a porcine source and should not be used for patients with known sensitivity to porcine material. This device is not intended for use in vascular applications.





# Axogen comprehensive portfolio of products (Cont'd)

## Axoguard Nerve Cap®

- Regulatory Classification: Class II Medical Device – 510(k) cleared
  - Indications for Use: Axoguard Nerve Cap is indicated to protect a peripheral nerve end and to separate the nerve from the surrounding environment to reduce the development of symptomatic or painful neuroma.
  - This product is intended for use by trained medical professionals.
  - Contraindications: Axoguard Nerve Cap is derived from a porcine source and should not be used for patients with known sensitivity to porcine derived materials. Axoguard Nerve Cap is contraindicated for use in any patient for whom soft tissue implants are contraindicated; this includes any pathology that would limit the blood supply and compromise healing, or evidence of a current infection. Axoguard Nerve Cap should not be implanted directly under the skin. This device is not intended for use in vascular applications.
- 
- **Axoguard HA+ Nerve Protector™**
    - Regulatory Classifications: Class II Medical Devices - 510(k) cleared (K223640)
    - Indication for Use: Axoguard HA+ Nerve Protector is indicated for the management of peripheral nerve injuries where there is no gap.
    - This product is intended for use by trained medical professionals.
    - Contraindications: Axoguard HA+ Nerve Protector base membrane is derived from a porcine source and the lubricant coating is composed of sodium hyaluronate and sodium alginate. The Axoguard HA+ Nerve Protector should not be used for patients with known sensitivity to porcine, alginate, or hyaluronate materials. This device is not intended for use in vascular applications.
- 
- **Axoguard HA+ Nerve Protector™**
    - Regulatory Classifications: Class II Medical Devices - 510(k) cleared ( K231708)
    - Indication for Use: Axoguard HA+ Nerve Protector is indicated for the management of peripheral nerve injuries where there is no gap, or following closure of the gap.
    - This product is intended for use by trained medical professionals.
    - Contraindications: Axoguard HA+ Nerve Protector base membrane is derived from a porcine source and the lubricant coating is composed of sodium hyaluronate and sodium alginate. The Axoguard HA+ Nerve Protector should not be used for patients with known sensitivity to porcine, alginate, or hyaluronate materials. This device is not intended for use in vascular applications.



# Footnotes

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