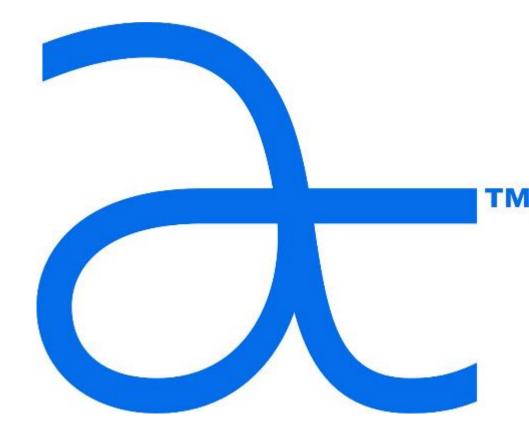
# **Corporate presentation**

As of March 31, 2020

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," "goals," and variations of such words and similar expressions are intended to identify such forwardlooking statements. The forward-looking statements may include, without limitation, statements related to the expected impact of COVID-19 on our business, statements regarding our product development, product potential, financial performance, sales growth, product adoption, market awareness of our products, data validation, our assessment of our internal controls over financial reporting, our visibility at and sponsorship of conferences and educational events.

The forward-looking statements are and will be subject to risks and uncertainties, which may cause actual results to differ materially from those expressed or implied in such forward-looking statements. Forward-looking statements contained in this presentation should be evaluated together with the many uncertainties that affect our business and our market, particularly those discussed under Part I, Item 1A., "Risk Factors," of our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as well as other risks and cautionary statements set forth in our filings with the U.S. Securities and Exchange Commission. 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, whether as a result of new information, future events, changed circumstances, or otherwise.

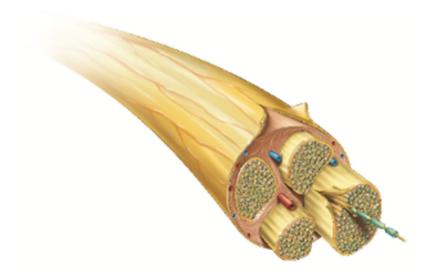
### The Axogen platform for nerve repair



# The function of nerves

#### 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

mary

- Sensory
- Motor
- Autonomic



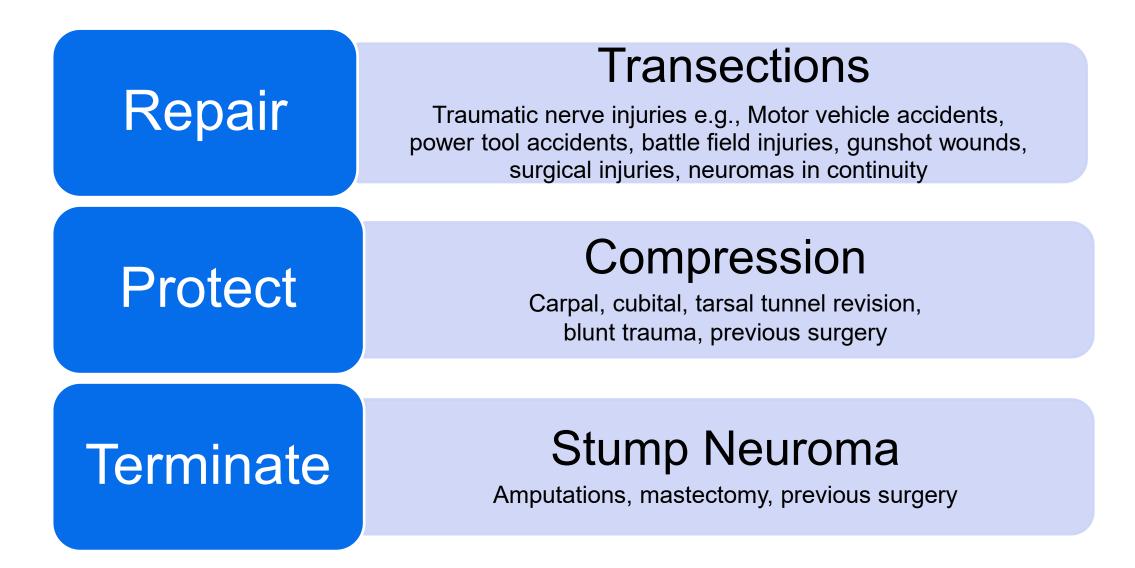
# Axogen is the preeminent nerve repair company

- Exclusive focus on peripheral nerve repair and protection solutions
- Comprehensive product portfolio addresses large and untapped market opportunity

Q1 2020 Revenue 2019 Revenue High Gross Margins Cash, Cash Equivalents, and Investments \$24.3M, 4% growth vs Q1 2019
\$106.7M, 27% growth vs 2018
80.1% for the quarter ended March 31, 2020
\$89.0M as of March 31, 2020

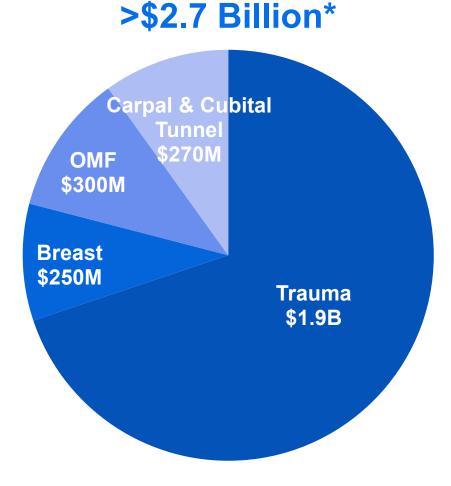
- ✓ Solid balance sheet provides resources to execute business plan
- ✓ Significant barriers to competitive entry including a growing body of clinical data
- ✓ Management team with deep expertise and strong track record of success
- Expansion opportunities beyond current markets

### How are nerves injured?





# Current targeted nerve markets (U.S.)



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

- Trauma: >  $700,000^{(1,2,3,4)}$
- Carpal Tunnel Revisions & Cubital Tunnel: 130,000<sup>(5,6,7,8)</sup>
- OMF: > 55,000<sup>(9,10,11,12,13,14,15,16,17)</sup>
- Breast Neurotization Procedures: 15,000<sup>(18)</sup>

\*\$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.

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

	Annual Incidence <sup>(a)</sup>	Weighted Average Procedure Value	Total Addressable Market
Trauma	700,000 <sup>(b)</sup>	\$2,725 <sup>(c)</sup>	\$1,900M
Carpal and Cubital Tunnel	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	<b>&gt;900,000</b> (potential)		>\$2.7B

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

b) See slides 9 and 10 for further details.

c) Includes factor of 1.22 nerves by procedure based upon data observed in the RANGER® registry



### Trauma total addressable market

Patient Population <sup>(a)</sup>	Source	Adjustments and Rationale
<b>136,943,000</b> Annual emergency department visits in the U.S.	2015 National Hospital Ambulatory Medical Care Survey (Table 1)	
<b>30,238,000</b> Annual emergency department visits <u>due to injury</u> in the U.S.	2015 National Hospital Ambulatory Medical Care Survey (Table 18)	<ul> <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>
<b>4.76%</b> Percentage of emergency department visits <u>with nerve injury</u>	Noble, et al: J Trauma, Volume 45(1) July 1998.116-122	<ul> <li>2.8% rate cited in Noble, et al 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> </ul>
1,440,000 Annual emergency department visits with nerve injury in the U.S. ** 46.2% Percentage of ED nerve injuries estimated to be treated surgically *665,000 Annual ED visits with nerve injury estimated to be treated surgically in the U.S., excluding revisions	Noble, et al: J Trauma, Volume 45(1) July 1998.116-122	<ul> <li>Calculated rate based on various rates in Noble et al 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)



a) Patient population figures rounded to the nearest thousandth.

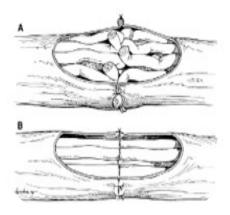
æ axogen<sup>.</sup>

# 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

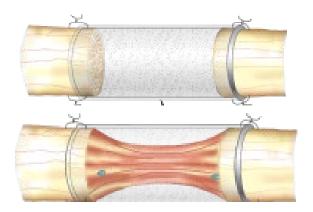
- Secondary surgery
- Loss of function and sensation at harvest site
- 27% complication rate including infection, wound healing and chronic pain <sup>19</sup>
- Limited availability of graft length and diameter



#### 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







#### 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)

#### Only 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>

Revascularizes and remodels into patient's own tissue<sup>28, 29, 30, 31</sup>

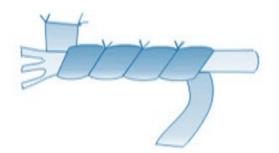


# Traditional COMPRESSION repair options are suboptimal

#### **VEIN WRAPPING**

#### Autologous vein

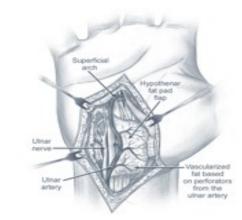
- Barrier to attachment to surrounding tissue
- Requires extra time and skill to perform spiral wrapping technique
- Second surgery site



#### HYPOTHENAR FAT PAD

#### Autologous vascularization flap

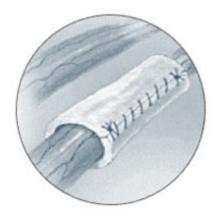
- Barrier to attachment to surrounding tissue
- Only wraps part of the nerve circumference
- Increases procedure time



#### 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



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>32</sup>
- Minimizes soft tissue attachments<sup>33</sup>

Allows nerve gliding

- Minimizes risk of entrapment<sup>33</sup>
- Creates a barrier between repair and surrounding tissue bed<sup>33</sup>
- ECM revascularizes and remodels into patient's own tissue<sup>29,34</sup>

# Processed human umbilical cord intended for surgical use as a resorbable soft tissue barrier

Smart processing to preserve the natural properties of the umbilical cord amniotic membrane

Designed with the surgeon in mind

- Easy to handle, suture, or secure during a surgical procedure
- Up to 8x thicker than placental amniotic membrane alone<sup>35</sup>
- Specifically designed as a resorbable soft tissue barrier to separate the tissue layers for at least 16 weeks<sup>36</sup>

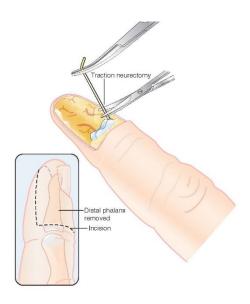
æ axogen.

# Traditional STUMP NEUROMA options are suboptimal

#### TRACTION NEURECTOMY

### Nerve placed in traction and cut to allow for retraction

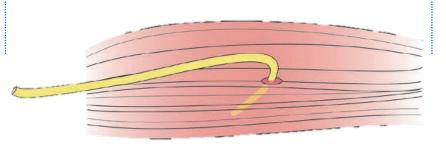
- Simply resecting the nerve results in subsequent neuroma formation
- Causes traction injury
- High risk of recurrence<sup>37</sup>



#### **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>38, 39, 40</sup>



#### INJECTIONS

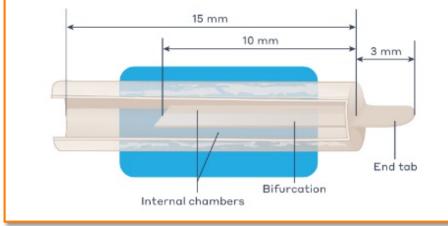
Pharmacologic intervention, typically alcohol or steroids<sup>41, 42, 43, 44, 45, 46</sup>

- Chemical injections are only successful 40% of the time <sup>44, 45</sup>
- Temporary solution that has a reduced benefit over time
- May cause considerable side effects



# Axogen solution for STUMP NEUROMA





Proprietary 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>47, 48</sup>

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

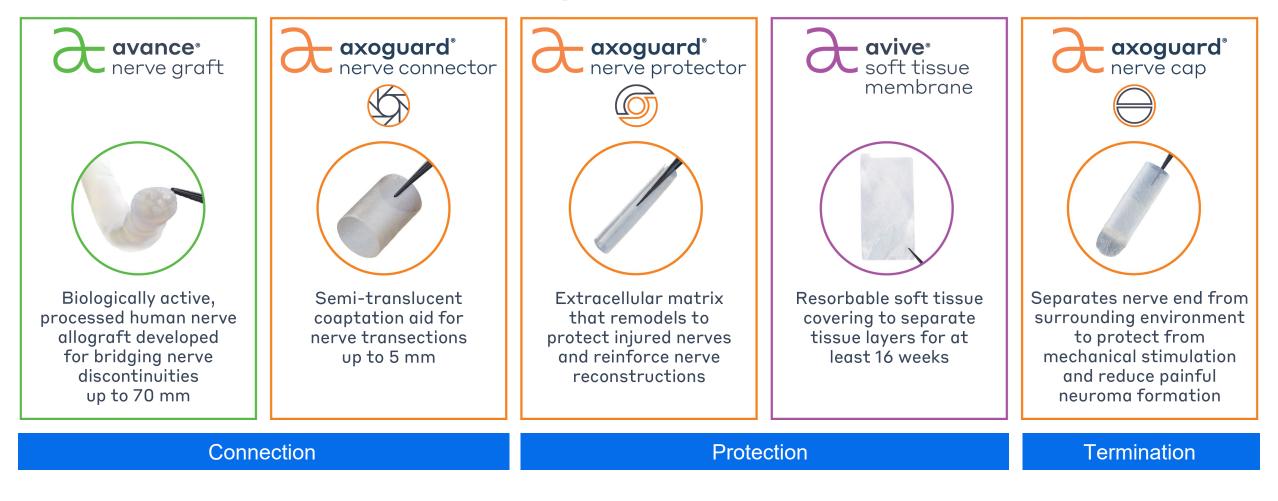
#### Intra-operative versatility

- 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



### Axogen's comprehensive platform for addressing nerve injuries

### one company for all your surgical nerve repair solutions





# Avance IP and regulatory barriers to competitive entry

Avance Nerve Graft is processed and distributed in	IP protection to 202	3 and beyond		
accordance with US FDA requirements for Human Cellular and	Avance Nerve Graft Issued U.S. Patents	New (non-biosimilar product estimated 8		
6,972 7,402 7,732 7,85 8,758 8,986	6,696,575 9,572,911 6,972,168 9,597,429 7,402,319 9,690,975	Axogen has Enforcement Discretion from FDA allowing continued sales under controls applicable to HCT/Ps with agreed transition plan to regulation as a Biological Product under a Biologic License Application (BLA) if approved. A new (non-biosimilar) competitive processed nerve allograft we believe would need to complete clinical testing and obtain BLA approval prior to clinical release.	Protection from potential biosimilars years data exclusivity from BLA app	
	7,732,200 9,996,729 7,851,447 10,311,281 8,758,794 10,441,681 8,986,733 9,402,868		Avance expected to be the reference product for the category of processed nerve allograft	

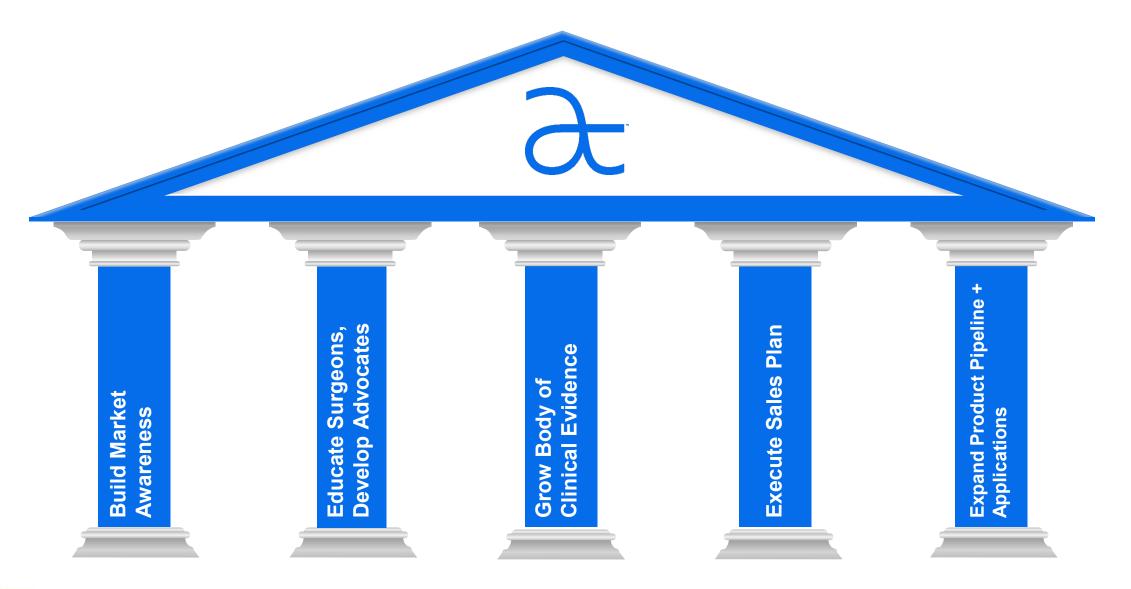
### Unique Avance technology creates barriers to competitive entry

#### **Progress toward Biologic License Application (BLA) for Avance Nerve Graft**

- Received Regenerative Medicine Advanced Therapy (RMAT) designation for Avance Nerve Graft in September 2018
  - Highlights strength of clinical evidence and the unmet medical need for improved therapies to treat nerve injuries
- RECON enrollment of 220 subjects
  - Prospective randomized controlled double-blinded study compares Avance Nerve Graft to synthetic conduits in digital injuries
  - Only a few subjects remain, but enrollment has slowed due to study site restrictions related to COVID-19
  - Any enrollment delay will not negatively impact the trial, or the enforcement discretion provided by the U.S. Food and Drug Administration
- Expected protection from potential biosimilars 12 year data exclusivity from BLA approval
- Initiated the build-out of a new 70,000 square foot, state-of-the-art biologics processing facility
  - Facility being built to cGMP standards under 21 CFR Part 210/211 regulations
  - Supports long term capacity expansion
  - Suspended construction in Q2 2020 for up to 1 year, as a result of COVID19 impact. Anticipate full transition of tissue processing to new facility by early 2023



### Market development strategy



axogen

# Focus on building awareness among surgeons and patients

#### Participate in clinical conferences

• Exhibits, podium presentations, KOL panels

Promote awareness among patientsAxogen patient ambassador program

Garner positive media attention

• National, regional and local broadcast, print and online





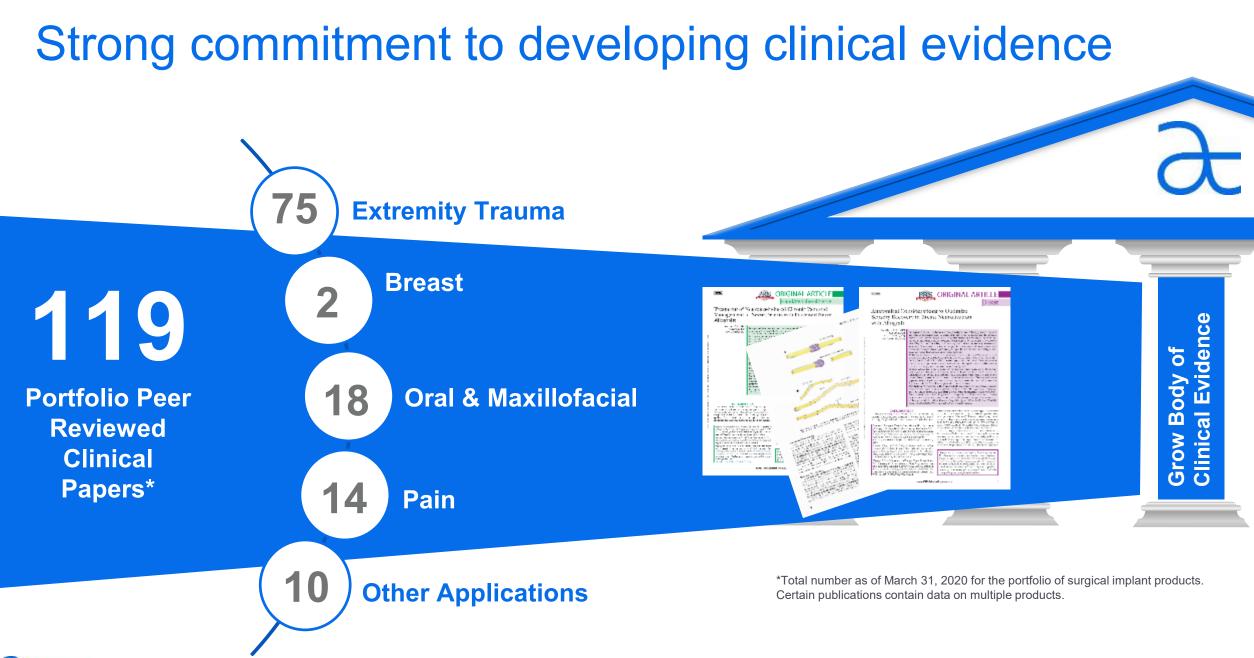
### **Emphasis on education**

National and regional programs

 Expanded offering includes Trauma, Breast, OMF, Pain and Fellows national programs

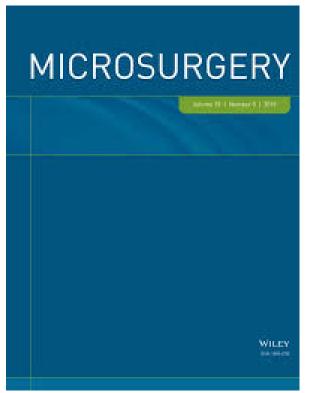
- Trained three-quarters of hand and microsurgery Fellows in 2019
- Current schedule of national and regional programs suspended through July due to travel restrictions
- Developing alternative surgeon led virtual programs and webinars





### New peer reviewed publication from RANGER Registry Comprehensive publication includes more than 10 years of effort and data

"Peripheral Nerve Repair Throughout the Body with Processed Nerve Allografts: Results from a Large Multicenter Study" - *Microsurgery, February 2020* 



.\* Chronic nerve injuries are defined as nerve repairs occurring greater 3 months post injury

- largest dataset from the Registry with quantitative outcomes from 385 subjects and 475 nerve repairs
- study included injuries throughout the body and includes sensory, mixed and motor nerves
- findings show an overall 82 percent meaningful recovery rate in gaps of up to 70mm
- highlights of the Upper Extremity cohort from the paper include:
  - Digital Nerve: 84%, n=381
  - Mixed Nerve: 79%, n=61
  - Chronic Nerve Injuries\*: 90%, n=61
  - Neuroma Resection: 94%, n=36
- results are consistent with prior data for Avance, and comparable to historical literature for nerve autograft, without the known complications of donor site morbidity, and exceed that of conduits
- publication provides important real world data that can help guide health care decisions and strengthen our value proposition with payors and providers

æ axogen<sup>.</sup>

# Strong commitment to developing clinical evidence

#### RANGER<sup>®</sup> Registry Study: Enrollment Ongoing

- The largest multi-center clinical study in peripheral nerve repair; >2,100 Avance nerve repairs enrolled to date
- Overall meaningful recovery rates of 82-84%; comparable to autograft outcomes without associated donor site comorbidities

#### MATCH<sup>SM</sup> Registry Study: Enrollment Ongoing

Autograft and Synthetic Conduit outcomes

#### **RECON<sup>SM</sup> Study: Enrollment Ongoing**

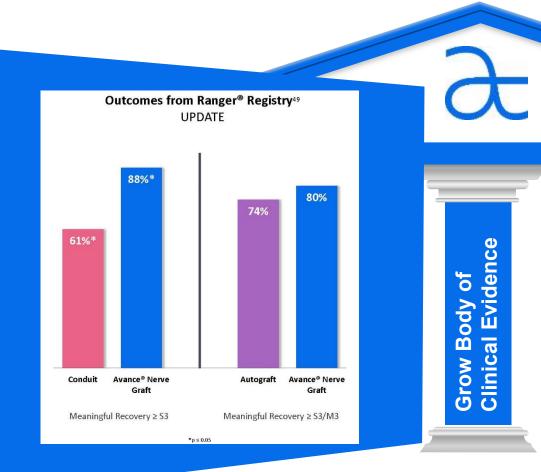
- Prospective, randomized study of Avance Nerve Graft controlled vs Synthetic conduits in digital injuries 5 to 25mm
- IND Pivotal Study to support BLA Submission
- Study enrollment nearing completion of 220 target

#### Sensation-NOW® Registry Study: Enrollment Paused\*

Multi-center clinical study in breast neurotization

#### **REPOSE<sup>SM</sup>: Enrollment Ongoing**

- Prospective, randomized study of Axoguard Nerve Cap controlled vs neurectomy
   RETHINK PAIN Registry Study: Enrollment Paused\*
- Designed to capture the patient's pain journey, from onset of chronic pain to nerve repair



\*Enrollment was paused in Q2 2020 due to study site restrictions resulting from COVID19. We will continue to monitor the recovery of activities at study centers and prioritize the potential restart of these clinical programs to best fit our business needs.



# Focused sales execution, increasing market penetration

#### Sales execution focused on driving results

- Continue expansion by driving penetration in active accounts and adding new active accounts
- 5,100 potential U.S. accounts perform nerve repair
- 825 active accounts as of March 31, 2020, up 13% YoY
  - Top 10% of active accounts represent approximately 35% of total revenue

#### **Expanded sales reach**

- U.S. direct sales team
  - 93 direct sales professionals at end of Q1 2019
  - $\,\circ\,$  109 direct sales professionals at end of Q1 2020
- Supplemented by independent agencies
- Revenue from direct sales channel represented approximately 90% of total revenue in Q1



### CMS outpatient reimbursement rates effective January 1, 2020

Although CMS rates<sup>1</sup> only apply to Medicare cases, which represents a small percentage of traumatic injuries, we believe the increased 2020 rates reflect the positive evolution of nerve repair, and 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)		
	Beschptor		2019	2020	% Change	2019	2020	% Change
64912	Nerve allograft repair	5432	\$4 <i>,</i> 566	\$ 5 <i>,</i> 508	21%	\$1,920	\$3,422	78%
64910	Conduit or vein allograft repair <sup>2</sup>	5432	\$4,566	\$ 5 <i>,</i> 508	21%	\$2,613	\$3,133	20%
64891	Autograft repair (hand and foot>4cm) <sup>3</sup>	5432	\$4,566	\$ 5 <i>,</i> 508	21%	\$1,920	\$2,829	47%
64885-98	Autograft repair (all other nerve type) <sup>4</sup>	5432	\$4,566	\$ 5 <i>,</i> 508	21%	\$1,920 - \$3,575	\$2,170	-39% to +13% <sup>4</sup>
64831, 61, 58	Direct Repair (digital, brachial plexus, sciatic)	5431	\$4,566	\$1,719	-62%	\$1,920	\$793	-59%

1. National average payment rates. Commercial payments are traditionally 1.5-2x higher than Medicare.

2. ASC 2019 and 2020 payment for Conduits received device intensive status for both years.

3. ASC 2020 payment for autograft repair CPT 64891 hand/foot >4cm met device intensive criteria for the first time

4. ASC 2020 payment for autograft repair CPT 64885 - head/neck </4cm, 64886 - head/neck >4cm, and 64890 -hand/foot </4cm, lost device intensive status with a 29%-39% decrease (\$3,575, \$3,172, \$3,075 payment respectively in 2019)

#### Hospital Outpatient and ASC rates:

Allograft, autograft and conduit repair increase

Direct repair for digital, sciatic and brachial plexus rates decrease

(all other direct repairs = allograft and autografts)

Hospital Inpatient rates for nerve repair align to DRGs 040, 041, 042 and range from \$10.5k - \$22.5k



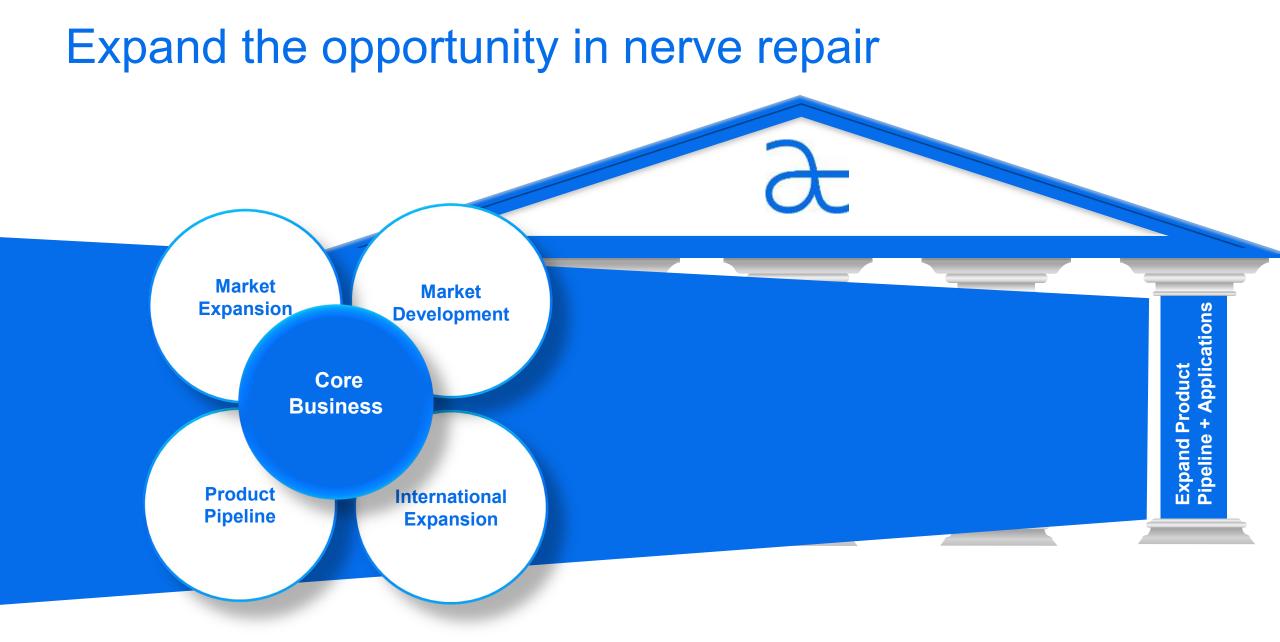
### 2020 Center for Medicare and Medicaid Services (CMS): Physician Fee Schedule (PFS)

- In 2020, physician fees for allograft procedures increased 18% from 2019
  - Traditionally CMS payments for physician services do not vary significantly from year to year.

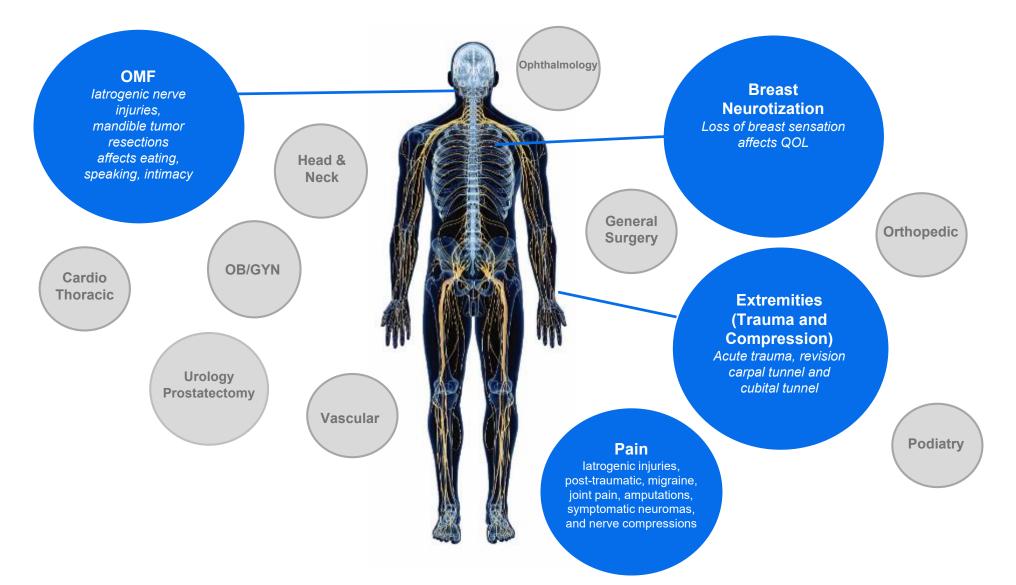
CPT Codes	Descriptor	Physician Fee Schedule (PFS)			
		2019	2020	% Change	
64912	Nerve allograft repair	\$804	\$ 951	18%	
64910	Conduit or vein allograft repair	\$825	\$820	-1%	
64885 to 64898*	Autograft repair	\$1,096 to \$1,495	\$1,096 to \$1,495	-1% to 0%	
64831 to 64868*	Direct Repair	\$713 to \$1,604	\$717 to \$1,578	-2% to 1%	

\*excludes add-on procedure codes



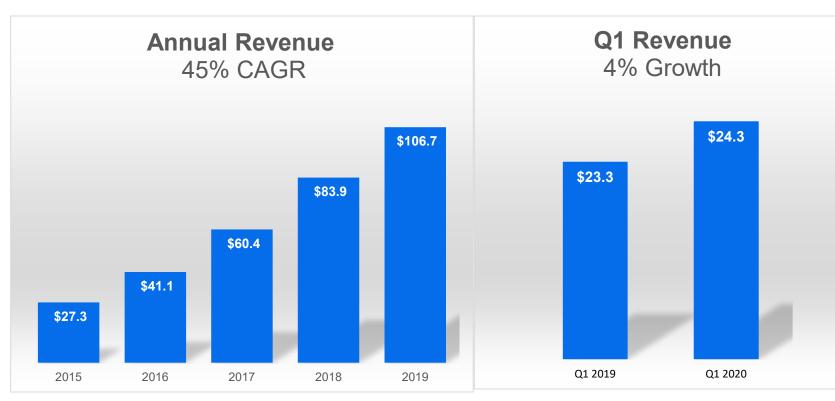


## Platform for nerve repair across multiple applications



# Delivering strong consistent revenue growth & gross margins

U.S. \$ in millions



80.1% Gross Margin for the quarter ended March 31, 2020 83.7% Gross Margin for year ended December 31, 2019

#### **Business Highlights**

- Increased active accounts in the first quarter to 825, up 13% from 731 a year ago
- Ended the quarter with 109 direct sales representatives and 19 independent agencies
- Conducted two national education programs
- Added seven peer reviewed clinical publications to our portfolio for a total of 119
- Dismissal of Class Action
   Lawsuit
- New peer reviewed publication
   from RANGER registry



### 2020 Guidance

On April 1, 2020, the Company suspended its 2020 annual financial guidance as previously provided on February 24, 2020, due to uncertainty associated with COVID-19. At this date, management cannot predict the extent or duration of the impact of the COVID-19 pandemic on its financial results but believes the current environment will continue to negatively impact its revenue in the second quarter of 2020 and potentially beyond.



### Balance sheet and capital structure

Balance Sheet Highlights	March 31, 2020
Cash, Cash Equivalents, and Investments	\$89.0 million
Total Bank Debt	\$0

Capital Structure (shares)	March 31, 2020
Common Stock	39,738,767
Common Stock Options, RSUs, PSUs	5,503,303
Common Stock and Common Stock Equivalents	45,242,070

### **Executive team**



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



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



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



Eric A. Sandberg **Chief Commercial** Officer Guidant



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



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



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



Mike Donovan **VP**, Operations Zimmer



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



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



Angelo Scopelianos, Ph.D. VP, Research & Development 1&1



# Axogen is the preeminent nerve repair company with a foundation for long-term sustainable growth

- Exclusively focused in peripheral nerve repair across an expanding set of applications addressing large market opportunity
- Differentiated platform for nerve repair, anchored with Avance<sup>®</sup> Nerve Graft
- 10+ years of demonstrated clinical consistency and meaningful recovery outcomes
- 119 peer-reviewed clinical publications featuring the Axogen product portfolio (as of March 31, 2020)
- Avance RMAT designation highlights clinical evidence strength and unmet medical need for improved nerve injury treatments

- Commercial and Professional Education capability to convert experienced surgeons while training the next generation
- ✓ Significant barriers to competitive entry
  - **Solid balance sheet** provides resources to execute business plan
  - **Experienced management team** with strong track record of success





Deloitte Technology Fast 500: 2014, 2015, 2016, 2017, 2018, 2019

Russell 2000 Index: June 2016

DecisionWise Intl Employee Engagement Best Practices Award Winner: 2018

### **Footnotes**

- 1. National Hospital Ambulatory Medical Care Survey: 2015 Emergency Department Summary Tables Table 18. https://www.cdc.gov/nchs/data/nhamcs/web\_tables/2015\_ed\_web\_tables.pdf
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- 9. Lin, et al. Systematic Review and Meta-Analysis on Incidence of Altered Sensation of Mandibular Implant Surgery PLoS One. 2016; 11(4): e0154082.
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### **Footnotes**

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