

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): January 11, 2021

AXOGEN, INC.

(Exact name of registrant as specified in its charter)

Minnesota (State or other jurisdiction of incorporation)	001-36046 (Commission File Number)	41-1301878 (IRS Employer Identification No.)
13631 Progress Boulevard, Suite 400, Alachua, Florida (Address of Principal Executive Offices)		32615 (Zip Code)
Registrant's telephone number, including area code		
(386) 462-6800		
(Former name or former address if changed since last report,)		

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- 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 2.02 Results of Operations and Financial Condition.

On January 11, 2021, Axogen, Inc. (the “Company”) issued a press release announcing its estimated fourth quarter and full year 2020 revenue. A copy of the press release is furnished as Exhibit 99.1.

The information furnished pursuant to Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1 hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of such section, nor shall it be incorporated by reference into future filings by the Company under the Securities Act of 1933, as amended (the “Securities Act”), or under the Exchange Act, unless the Company expressly sets forth in such future filing that such information is to be considered “filed” or incorporated by reference therein.

Item 7.01 Regulation FD Disclosure.

On January 11, 2021, the Company also 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, including while attending the Solebury Trout Virtual Management Access Event on January 11-14, 2021. A copy of the investor update is furnished as Exhibit 99.2.

The information in this Item 7.01, including Exhibit 99.2, 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Axogen, Inc. Press Release, dated January 11, 2021.
99.2	Axogen, Inc. Corporate Presentation, dated January 11, 2021.

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.

Date: January 11, 2021

By: /s/ Brad Ottinger
Brad Ottinger
General Counsel and Chief Compliance Officer



Axogen Reports Preliminary Unaudited Revenue for Fourth Quarter and Full-Year 2020

ALACHUA, FL – January 11, 2021 –Axogen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for peripheral nerve injuries, today announced preliminary unaudited fourth quarter and full-year 2020 revenue.

Preliminary Unaudited Fourth Quarter and Year-End Performance Highlights

- Fourth quarter revenue is expected to be at least \$32.4 million, a 15% increase compared to fourth quarter 2019 revenue of \$28.2 million
- Full-year 2020 revenue is expected to be at least \$112.2 million, a 5% increase compared to 2019 revenue of \$106.7 million
- Ended the fourth quarter with 111 direct sales representatives compared to 110 at the end of the third quarter, and 109 as of December 31, 2019
- Increased active accounts in the fourth quarter to 893, a 12% increase from 797 in the fourth quarter a year ago
- Revenue from the top 10% of our active accounts continued to represent approximately 35% of total revenue in the quarter

"I am pleased with our fourth quarter performance, as we achieved year-over-year revenue growth despite the continued dampening effect of the COVID-19 pandemic," commented Karen Zaderej, chairman, CEO, and president of Axogen, Inc. "While it was a challenging year, our team continued to execute our focused strategy and improved the strength and resilience of our business. I am extremely proud that we achieved an important milestone in 2020, surpassing 50,000 Avance® Nerve Grafts implanted since launch. This accomplishment underscores Axogen's commitment to our mission of restoring nerve function and quality of life to patients with peripheral nerve injuries by providing innovative, clinically proven and economically effective repair solutions for surgeons and health care providers."

Investor meetings scheduled this week

Members of the Axogen senior management team will participate in the Solebury Trout Virtual Management Access Event January 11-14, 2021. These annual meetings provide an opportunity for management to meet individually with investors to discuss Axogen's differentiated platform for nerve repair in an expanding set of applications.

The results disclosed in this press release are preliminary and unaudited. The Company expects to report full, audited results for the fourth quarter and year ended December 31, 2020 on February 22, 2021. The company's updated corporate presentation is available through the investors page on www.axogeninc.com.

About Axogen

Axogen (AXGN) is the leading company focused specifically on the science, development and commercialization of technologies for peripheral nerve regeneration and repair. Axogen employees are passionate about helping to restore peripheral nerve function and quality of life to patients with physical damage or transection to peripheral nerves by providing innovative, clinically proven and economically effective repair solutions for surgeons and health care providers. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body. Every day, people suffer traumatic injuries or undergo surgical procedures that impact the function of their peripheral nerves. Physical damage to a peripheral nerve, or the inability to properly reconnect peripheral nerves, can result in the loss of muscle or organ function, the loss of sensory feeling, or the initiation of pain.

Axogen's platform for peripheral nerve repair features a comprehensive portfolio of products, including Avance[®] Nerve Graft, a biologically active off-the-shelf processed human nerve allograft for bridging severed peripheral nerves without the comorbidities associated with a second surgical site; Axoguard[®] Nerve Connector, a porcine submucosa extracellular matrix (ECM) coaptation aid for tensionless repair of severed peripheral nerves; Axoguard[®] Nerve Protector, a porcine submucosa ECM product used to wrap and protect damaged peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments; Axoguard[®] Nerve Cap, a porcine submucosa ECM product used to protect a peripheral nerve end and separate the nerve from the surrounding environment to reduce the development of symptomatic or painful neuroma; and Avive[®] Soft Tissue Membrane, a processed human umbilical cord intended for surgical use as a resorbable soft tissue barrier. The Axogen portfolio of products is available in the United States, Canada, the United Kingdom, South Korea, and several other European and international countries.

Cautionary Statements Concerning Forward-Looking Statements

This press release 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. The forward-looking statements may include, without limitation, statements related to the expected impact of COVID-19 on our business, statements regarding our growth, 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 press release 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, as

amended on Form 10-K/A, 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.

Contact:

Axogen, Inc.

Peter J. Mariani, Chief Financial Officer

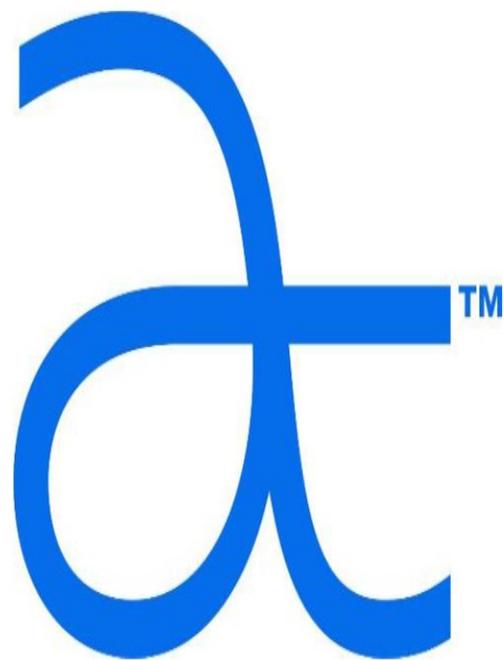
pmariani@axogeninc.com

InvestorRelations@AxogenInc.com

Corporate presentation

As of December 31, 2020

nasdaq: axgn



axogen[®]

Safe harbor statement

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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, as amended on Form 10-K/A, 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

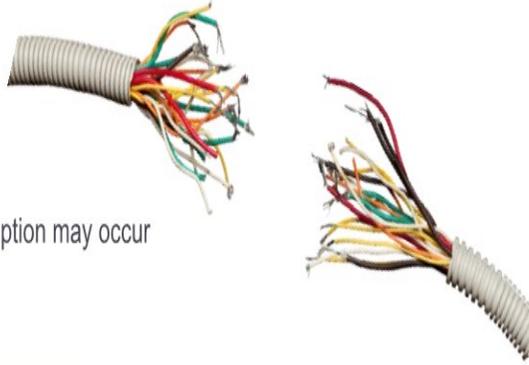


revolutionizing the science of nerve repair™

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

- Sensory
- Motor
- Autonomic

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

- ✓ **Exclusively focused on peripheral nerve repair** across an expanding set of applications addressing large market opportunity
- ✓ **Differentiated platform** for nerve repair, anchored by Avance® Nerve Graft
- ✓ **10+ years of demonstrated clinical consistency** and meaningful recovery outcomes
- ✓ **138 peer-reviewed clinical publications** featuring the Axogen product portfolio
(as of September 30, 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



revolutionizing the science of nerve repair™

Delivering strong, consistent revenue growth & gross margins

U.S. \$ in millions



*Unaudited estimate of 2020 year-end and fourth quarter revenue.

83.0% Gross Margin for the quarter ended September 30, 2020

Operational Highlights

- Revenue growth of 15% for Q4 and 5% for full year 2020, despite the continued dampening effect of COVID-19
- Executing our strategy of driving adoption in our largest market opportunity of extremity trauma
- More than 50,000 Avance Nerve Grafts have been implanted since launch

The company estimates that Q4 revenue includes less than \$1m in revenue from previously deferred procedures.



revolutionizing the science of nerve repair™

How are nerves injured?

Repair

Transections

Traumatic nerve injuries e.g., Motor vehicle accidents, power tool accidents, battlefield injuries, gunshot wounds, surgical injuries, neuromas in continuity

Protect

Compression

Carpal, cubital, tarsal tunnel revision, blunt trauma, previous surgery

Terminate

Stump Neuroma

Amputations, mastectomy, previous surgery

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^(5,6,7,8)
- OMF: > 55,000^(9,10,11,12,13,14,15,16,17)
- Breast Neurotization Procedures: 15,000⁽¹⁸⁾

*\$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 ^(a)	×	Weighted Average Procedure Value	=	Total Addressable Market
Trauma	700,000 ^(b)		\$2,725 ^(c)		\$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	>900,000 (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.



revolutionizing the science of nerve repair™

Trauma total addressable market

Patient Population ^(a)	Source	Adjustments and Rationale
<p style="text-align: center;">136,943,000 Annual emergency department visits in the U.S.</p> <div style="border: 1px solid black; padding: 5px; margin: 10px auto; width: 80%;"> <p style="text-align: center;">30,238,000 Annual emergency department visits <u>due to injury</u> in the U.S.</p> <p style="text-align: center;">✖</p> <p style="text-align: center;">4.76% Percentage of emergency department visits <u>with nerve injury</u></p> <p style="text-align: center;">=</p> </div> <div style="border: 1px solid black; padding: 5px; margin: 10px auto; width: 80%;"> <p style="text-align: center;">1,440,000 Annual emergency department visits with nerve injury in the U.S.</p> <p style="text-align: center;">✖</p> <p style="text-align: center;">46.2% Percentage of ED nerve injuries estimated to be treated surgically</p> <p style="text-align: center;">=</p> <p style="text-align: center;">~665,000</p> <p>Annual ED visits with nerve injury estimated to be treated surgically in the U.S., excluding revisions</p> </div>	<p>2015 National Hospital Ambulatory Medical Care Survey (Table 1)</p> <p>2015 National Hospital Ambulatory Medical Care Survey (Table 18)</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"> 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.) 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%. 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.

a) Patient population figures rounded to the nearest thousandth.



Trauma total addressable market (continued)

Patient Population ^(a)	Source	Adjustments and Rationale
<p style="text-align: center;">~665,000</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;">×</p> <p style="text-align: center;">7.4%</p> <p style="text-align: center;">Revision cases</p> <hr style="width: 10%; margin: 10px auto;"/> <p style="text-align: center;">=</p> <p style="text-align: center;">714,000</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;">↓</p> <p style="text-align: center;">~700,000</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"> <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.

a) Patient population figures rounded to the nearest thousandth.

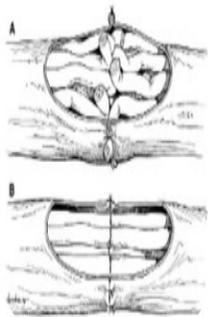


Traditional TRANSECTION repair options are suboptimal

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

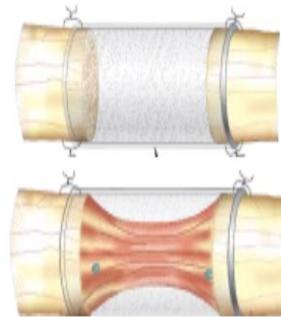
- Secondary surgery
- Loss of function and sensation at harvest site
- 27% complication rate including infection, wound healing and chronic pain¹⁹
- Limited availability of graft length and diameter



SYNTHETIC CONDUITS

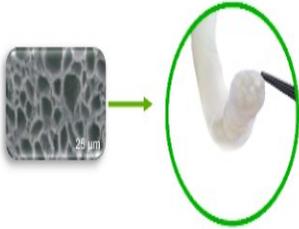
Convenient off the shelf option; limited efficacy & use

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



Axogen solutions for TRANSECTION repair

avance[®] 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 study²²
- Eliminates need for an additional surgical site and risks of donor nerve harvest²²
- May reduce OR time

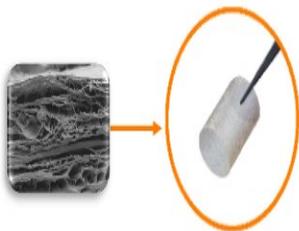
Structural support for regenerating axons

- 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 nerve²³

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

axoguard[®] nerve connector



Only minimally processed porcine ECM for connector-assisted coaptation

Alternative to direct suture repair

- Reduces the risk of forced fascicular mismatch^{24, 25}

Alleviates tension at critical zone of regeneration

- Disperses tension across repair site²⁶
- Moves suture inflammation away from coaptation face^{27, 28}

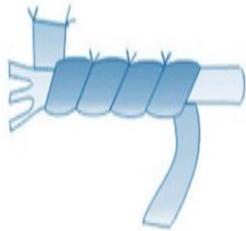
Remodels into vascularized patient tissue^{28, 29, 30, 31}

Traditional COMPRESSION repair options are suboptimal

VEIN WRAPPING

Autologous vein

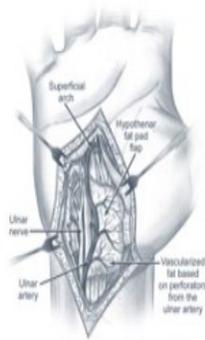
- Barrier to attachment to surrounding tissue
- Requires extra time and skill to perform spiral wrapping technique
- Second surgery site



HYPOTHENAR FAT PAD

Autologous vascularization flap

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



COLLAGEN WRAPS

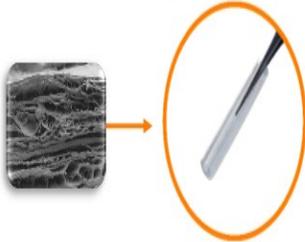
Off-the-shelf

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



Axogen solutions for COMPRESSION repair

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 process³²
- Minimizes soft tissue attachments³³

Allows nerve gliding

- Minimizes risk of entrapment³³
- Creates a barrier between repair and surrounding tissue bed³³
- ECM revascularizes and remodels into patient's own tissue^{29,34}

avive® soft tissue membrane



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

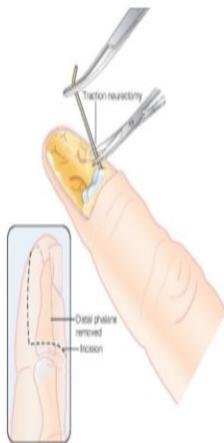
- Easy to handle, suture, or secure during a surgical procedure
- Up to 8x thicker than placental amniotic membrane alone³⁵
- Specifically designed as a resorbable soft tissue barrier to separate the tissue layers for at least 16 weeks³⁶

Traditional STUMP NEUROMA options are suboptimal

TRACTION NEURECTOMY

Nerve placed in traction and cut to allow for retraction

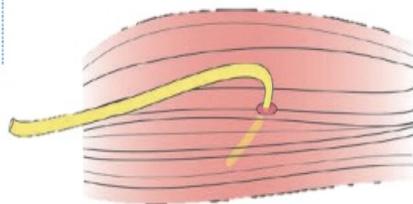
- Simply resecting the nerve results in subsequent neuroma formation
- Causes traction injury
- High risk of recurrence³⁷



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^{38, 39, 40}



INJECTIONS

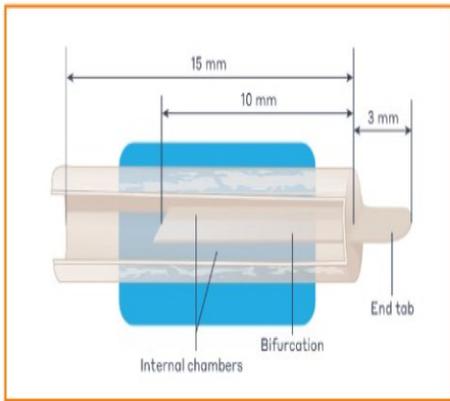
Pharmacologic intervention, typically alcohol or steroids^{41, 42, 43, 44, 45, 46}

- Chemical injections are only successful 40% of the time^{44, 45}
- Temporary solution that has a reduced benefit over time
- May cause considerable side effects



Axogen solution for STUMP NEUROMA

 axoguard®
nerve cap



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)^{47, 48}

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

Intra-operative versatility

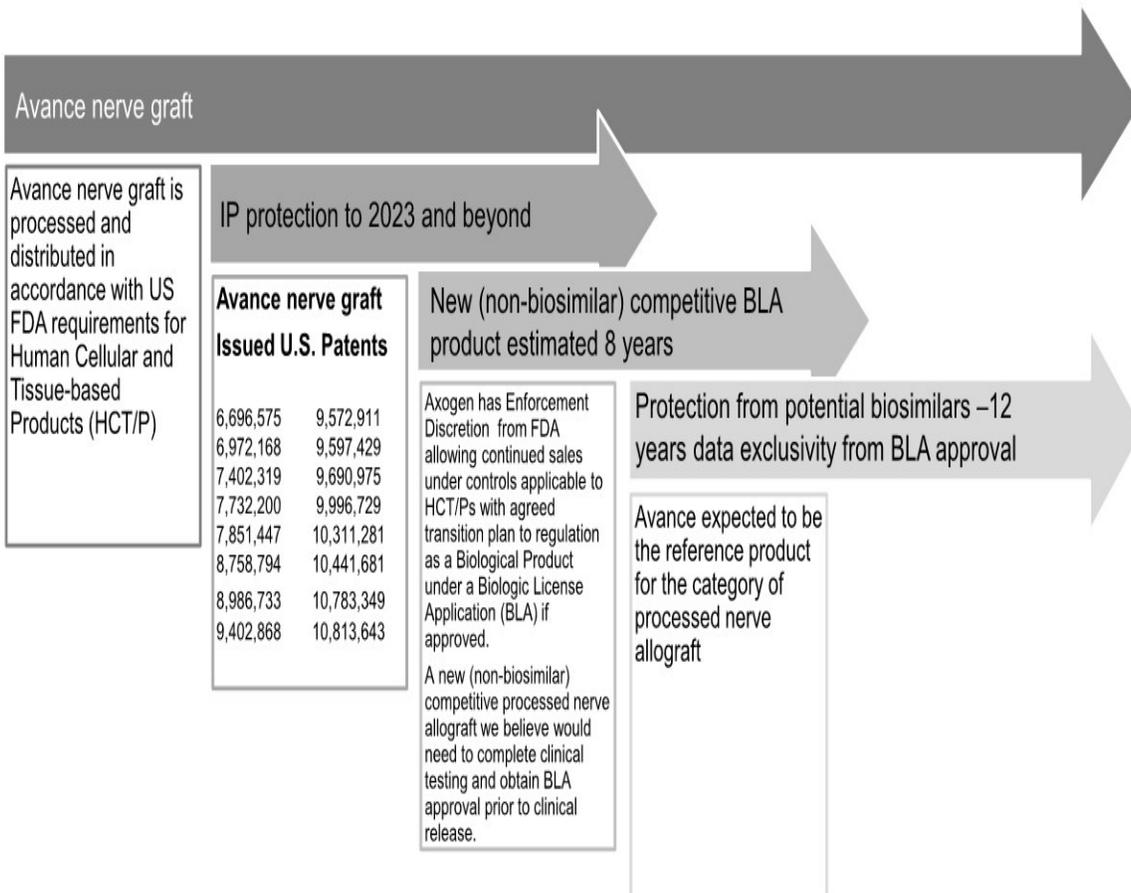
- Ideal for anatomic areas with limited or no musculature
- Alternative to historical techniques such as burying in muscle or bone
- Available in a variety of diameters

Axogen's comprehensive platform for addressing nerve injuries

one company for all your surgical nerve repair solutions

<p>avance[®] nerve graft</p>  <p>Biologically active, processed human nerve allograft developed for bridging nerve discontinuities up to 70 mm</p>	<p>axoguard[®] nerve connector</p>  <p>Semi-translucent coaptation aid for nerve transections up to 5 mm</p>	<p>axoguard[®] nerve protector</p>  <p>Extracellular matrix that remodels to protect injured nerves and reinforce nerve reconstructions</p>	<p>avive[®] soft tissue membrane</p>  <p>Resorbable soft tissue covering to separate tissue layers for at least 16 weeks</p>	<p>axoguard[®] nerve cap</p>  <p>Separates nerve end from surrounding environment to protect from mechanical stimulation and reduce painful neuroma formation</p>
Connection		Protection		Termination

Avance IP and regulatory barriers to competitive entry



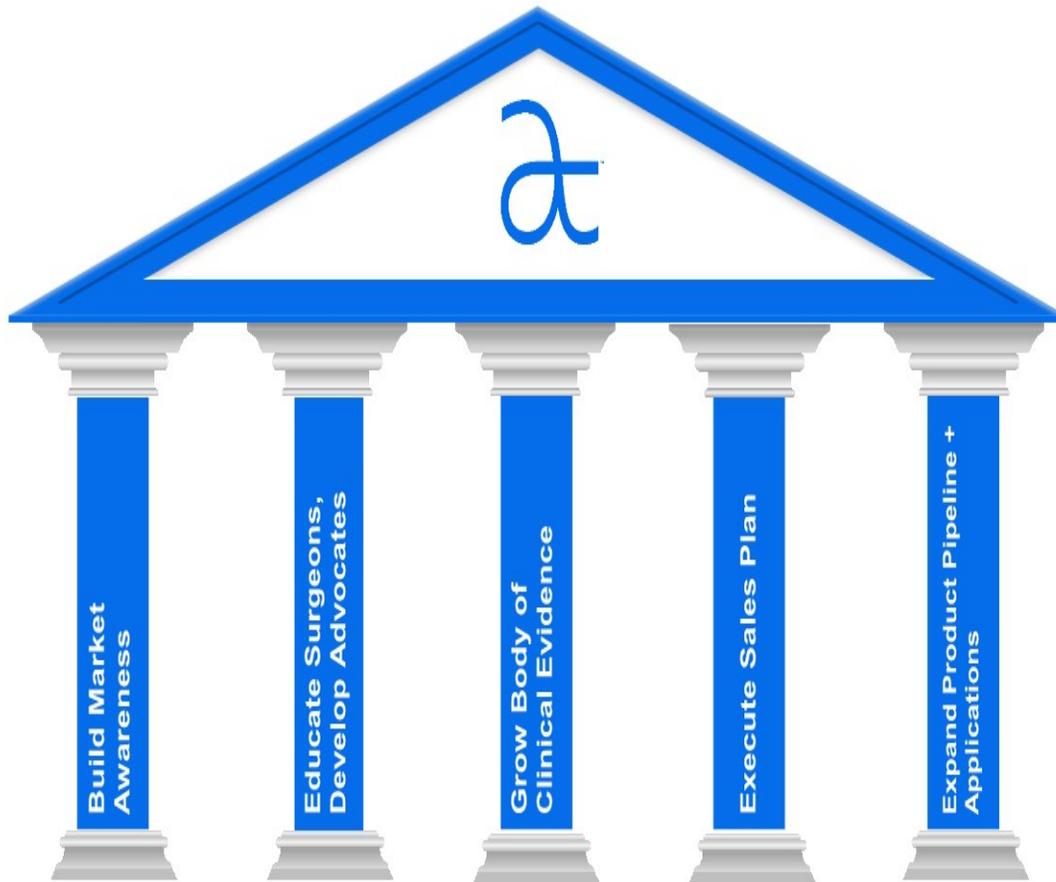
Unique Avance technology creates barriers to competitive entry

Progress toward Biologics 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 target enrollment of 220 subjects was reached in July 2020
 - Prospective randomized controlled double-blinded study compares Avance Nerve Graft to synthetic conduits in digital injuries
 - The study protocol requires a one-year follow-up assessment with an allowance for an additional three-month visit window completing in October 2021
 - Preliminary study data report expected in Q2 2022
 - Expect to file BLA in 2023
- Expected protection from potential biosimilars – 12-year data exclusivity from date of BLA approval
- Building 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
 - Anticipate restarting construction of facility in Q1 2021, after temporary suspension as part of COVID-19 cost mitigation initiative, and transition of tissue processing by late 2022



Market development strategy



axogen[®] revolutionizing the science of nerve repair[™]

Focus on building awareness among clinicians and patients

- Increased multi-channel engagement with clinicians and patients
- Continuing clinical conference participation virtually
- Ongoing patient ambassador program
- Garnering positive media attention
- Growing social media presence



revolutionizing the science of nerve repair™

Emphasis on education

- Converted national education programs to virtual platforms
- Providing customized multimodal learning programs to specific surgeon cohorts for advanced learning
- Interactive webinar series underway covering the principles of nerve repair
- Trained three-quarters of all hand and micro-surgery fellows in 2020



Educate Surgeons,
Develop Advocates



revolutionizing the science of nerve repair™

Strong commitment to developing clinical evidence

RANGER® Registry Study: Enrollment Ongoing

- The largest multi-center clinical study in peripheral nerve repair with >2,200 Avance nerve repairs enrolled to date
- Overall meaningful recovery rates of 82-84%; comparable to autograft outcomes without associated donor site comorbidities

MATCHSM Registry Study: Enrollment Ongoing

- Autograft and Synthetic Conduit outcomes

RECONSM Study: Enrollment Complete

- Prospective, randomized study of Avance Nerve Graft controlled vs synthetic conduits in digital injuries 5 to 25mm
- IND Pivotal Study to support BLA Submission
- Preliminary study data report expected Q2 2022, expect to file BLA in 2023

Sensation-NOW® Registry Study: Enrollment Paused*

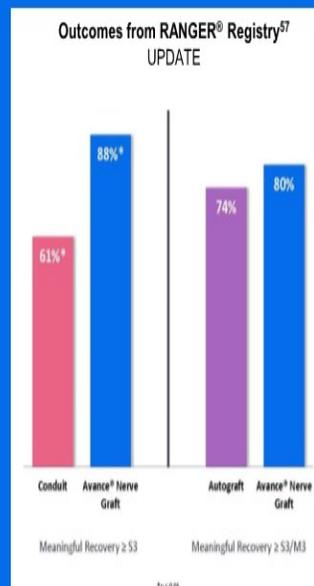
- Multi-center clinical study in breast neurotization

REPOSESM: 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



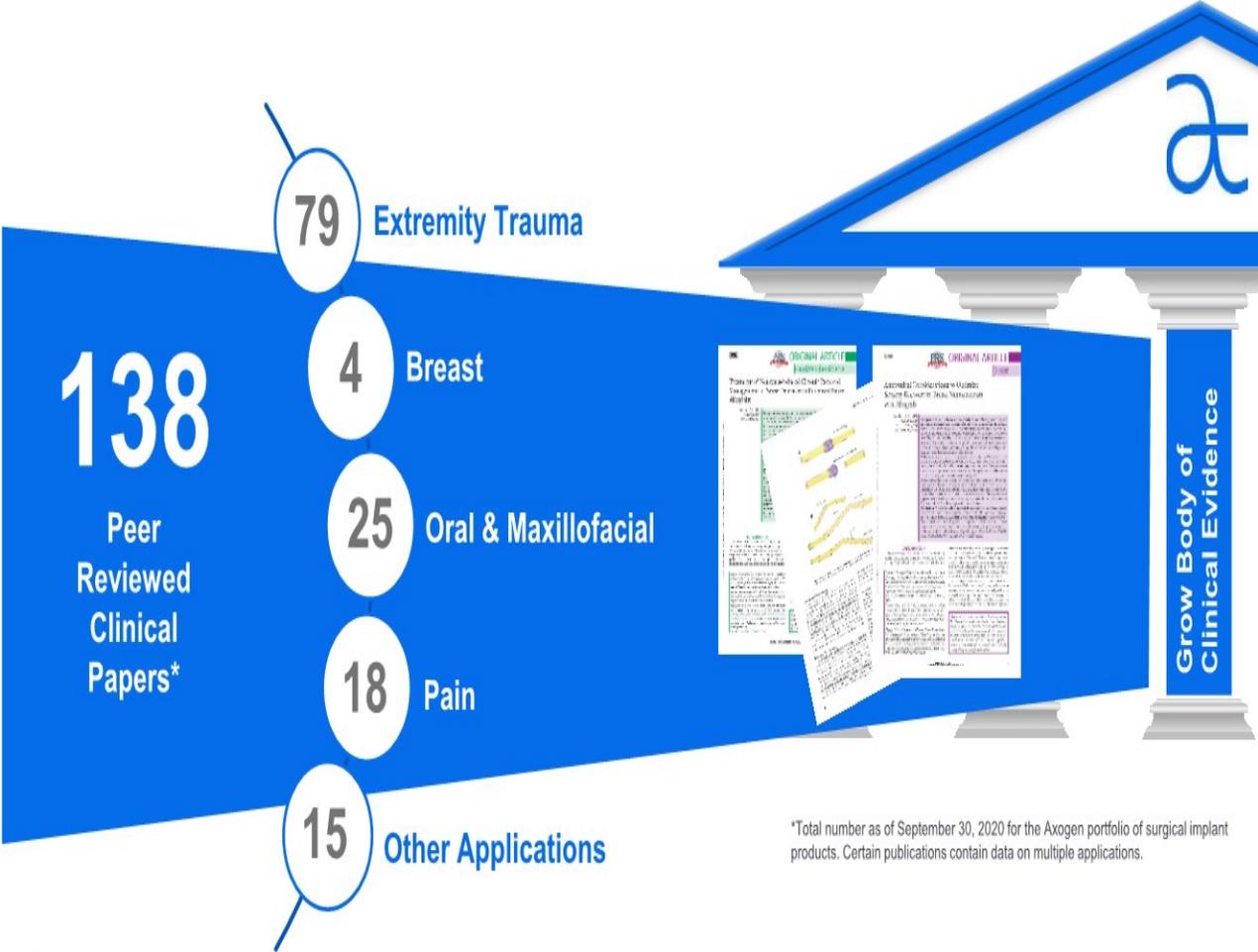
Grow Body of
Clinical Evidence

*Enrollment was paused in Q2 2020 due to study site restrictions resulting from COVID-19. 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.



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Growing body of clinical evidence

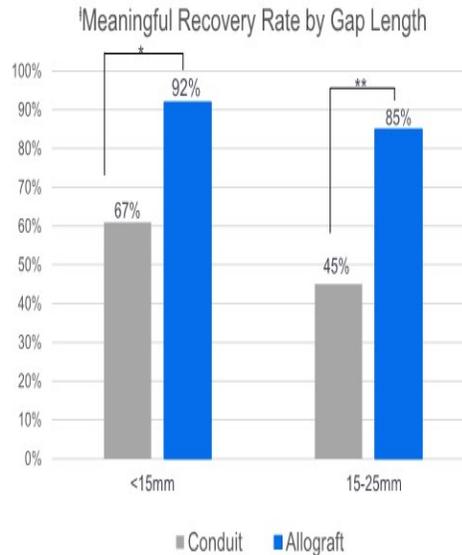


*Total number as of September 30, 2020 for the Axogen portfolio of surgical implant products. Certain publications contain data on multiple applications.

Avance Nerve Graft repairs found to be significantly better than conduit repairs

“A Multicenter Matched Cohort Study of Processed Nerve Allograft and Conduit in Digital Nerve Reconstruction” – *Journal of Hand Surgery, September 2020*

- Peer-reviewed publication from the MATCH cohort of the RANGER Registry
- Includes outcomes from 110 subjects with 162 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 had a significant decline.



Meaningful Recovery = \geq S3 on the MRCC Scale
*p=0.008, **p=0.001

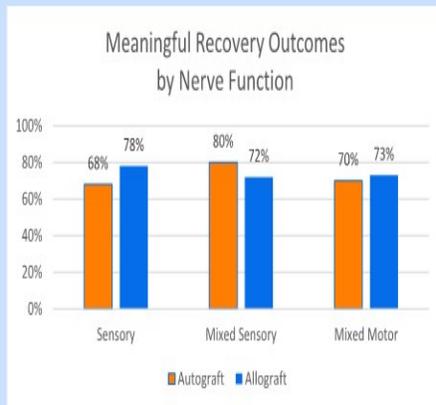


Recent study presentations find Avance Nerve Graft (allograft) rates comparable to nerve autograft for both clinical outcomes and facility procedure costs

“A propensity Matched Cohort Study on Outcomes from Processed Nerve Allograft and Nerve Autograft in Upper Extremity Nerve Repairs”

Presented at American Society for Surgery of the Hand (ASSH), Oct 2020⁴⁹

- Study of 156 nerve repairs found meaningful recovery rates for Avance Nerve Graft were comparable to autograft for both sensory and motor function



Defined as MRCC Score \geq S3/M3
Historical data on Nerve Autograft^{50,51,52,53,54}, Mixed Nerve: 57-80%; Digital Nerve: 60-88%

“Nerve Repair Hospital Index Procedure Costs – Allograft vs. Autograft Repair Type”

Presented at the American Society for Surgery of the Hand (ASSH), October 2020⁵⁵

- Data from the 2018 Medicare Standard Analytic File⁵⁶
- 340 claims reviewed for autograft and allograft, included inpatient and outpatient procedures
- Found hospital facility procedure cost for Avance Nerve Graft was comparable to that of traditional nerve autograft
- Did not evaluate the potential additional costs associated with managing the autograft donor site and subsequent morbidities

Focused sales execution, increasing market penetration



Sales execution focused on driving results

- Continue driving penetration in active accounts and developing new active accounts
- 5,100 potential U.S. accounts perform nerve repair
- 893 active accounts as of December 31, 2020, up 12% YoY
 - Top 10% of active accounts represent approximately 35% of total revenue

Expanded sales reach

- U.S. direct sales team
 - 111 direct sales professionals at end of Q4 2020
- Supplemented by independent agencies
- Revenue from direct sales channel represented approximately 87% of total revenue in Q4

Execute Sales
Plan



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CMS outpatient reimbursement rates improving for nerve repair with the Axogen portfolio

Although CMS rates¹ 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	2020	2021	2Y % Change	2019	2020	2021	2Y % Change
64912	Nerve allograft repair ²	5432	\$4,566	\$5,508	\$5,700	25%	\$1,920	\$3,422	\$3,788	97%
64910	Conduit or vein allograft repair ²	5432	\$4,566	\$5,508	\$5,700	25%	\$2,613	\$3,133	\$3,802	45%
64885	Autograft repair (head and neck ≤4cm)	5432	\$4,566	\$5,508	\$5,700	25%	\$3,575	\$2,170	\$2,449	-31%
64886	Autograft repair (head and neck >4cm) ³	5432	\$4,566	\$5,508	\$5,700	25%	\$3,172	\$2,170	\$4,157	31%
64890	Autograft repair (hand and foot≤4cm)	5432	\$4,566	\$5,508	\$5,700	25%	\$3,075	\$2,170	\$2,449	-20%
64891	Autograft repair (hand and foot>4cm) ²	5432	\$4,566	\$5,508	\$5,700	25%	\$1,920	\$2,829	\$3,185	66%
64892-98	Autograft repair (all other nerve type) ⁴	5432	\$4,566	\$5,508	\$5,700	25%	\$1,920	\$2,170	\$2,449	28%
64831, 61	Direct Repair (digital, brachial plexus) ⁴	5431	\$4,566	\$1,719	\$1,754	-62%	\$1,920	\$797	\$809	-58%
64858	Direct Repair (sciatic) ³	5431	\$4,566	\$1,719	\$1,754	-62%	\$1,920	\$797	\$1,434	-25%

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 and autograft repair hand/foot >4cm CPT 64891 continue to meet ASC device intensive criteria
3. Autograft repair CPT 64886 head/neck >4cm and direct repair sciatic CPT 64858 meet ASC device intensive criteria
4. Direct repair digital and brachial plexus (64831, 64861) and autograft repair all other nerve type CPT 64892-98 do not meet ASC device intensive criteria. (excludes autograft add-on procedure codes)



Hospital Inpatient rates for nerve repair align to DRGs 040, 041, 042 and range from \$11.1k - \$23.3k

CMS physician fee adjustments continue to favor nerve allograft repair

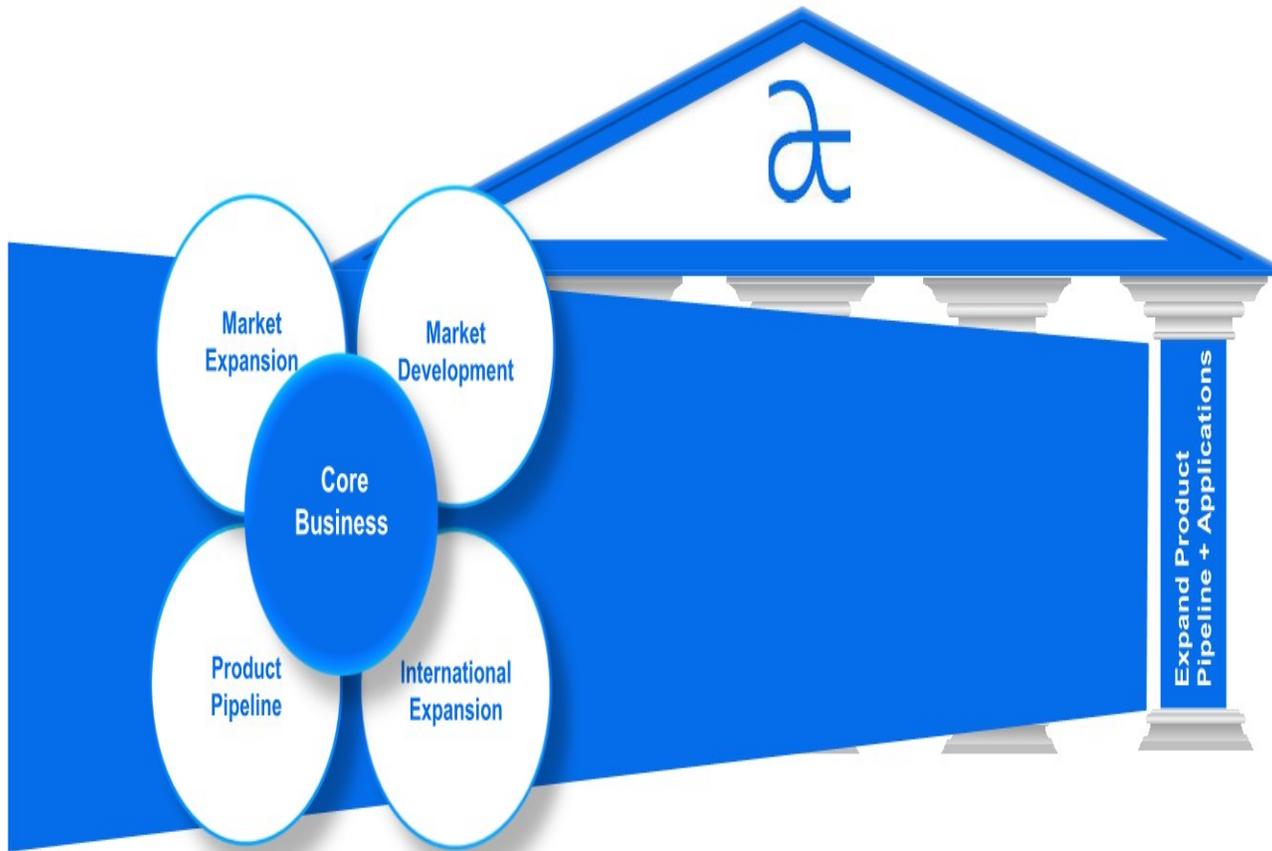
CPT Codes	Descriptor	Physician Fee Schedule (PFS)			
		2019	2020	2021	2Y % Change
64912	Nerve allograft repair	\$804	\$ 951	\$904	12.4%
64910	Conduit or vein allograft repair	\$825	\$820	\$803	-3%
64885 to 64898*	Autograft repair	\$1,096 to \$1,495	\$1,096 to \$1,495	\$1,080 to \$1,468	-2%
64831 to 64868*	Direct Repair	\$713 to \$1,604	\$717 to \$1,578	\$710 to \$1,565	-1 to -2%

*excludes add-on procedure codes

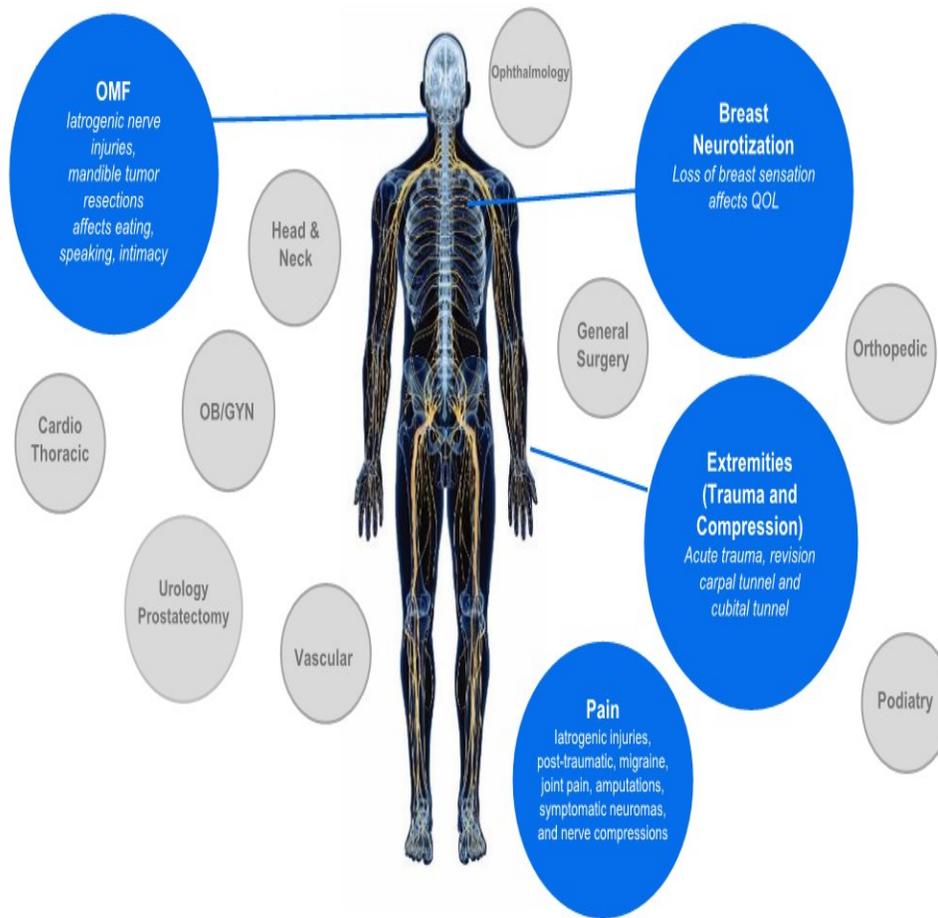
Note: PFS rates updated to reflect the Consolidated Appropriations Act (passed Dec-27, 2020) that modified the Calendar Year (CY) 2021 Medicare Physician Fee Schedule (MPFS).



Expand the opportunity in nerve repair



Platform for nerve repair across multiple applications



Balance sheet and capital structure

Balance Sheet Highlights	September 30, 2020
Cash, Cash Equivalents, and Investments	\$106.7 million
Total Long-term Debt	\$34.4 million*

Capital Structure (shares)	September 30, 2020
Common Stock	40,123,841
Common Stock Options, RSUs, PSUs	5,496,833
Common Stock and Common Stock Equivalents	45,620,674

* Total long-term debt includes debt proceeds under the terms of the agreement with Oberland Capital, net of deferred financing fees, and inclusive of the debt derivative liability, and related common stock derivative option liability recorded under the terms of the financing agreement.



Executive team



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



Peter J. Mariani
Chief Financial
Officer
Guidant, Lensar,
Hansen



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



Brad Ottinger
General Counsel,
Chief Compliance
Officer
MicroPort Orthopedics



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



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 & QA
AtriCure, Enable
Medical



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

- ✓ **Exclusively focused on peripheral nerve repair** across an expanding set of applications addressing large market opportunity
- ✓ **Differentiated platform** for nerve repair, anchored by Avance® Nerve Graft
- ✓ **10+ years of demonstrated clinical consistency** and meaningful recovery outcomes
- ✓ **138 peer-reviewed clinical publications** featuring the Axogen product portfolio
(as of September 30, 2020)
- ✓ **Avance RMA 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





nasdaq: axgn

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

Russell 2000 Index: June 2016

DecisionWise Intl Employee Engagement Best Practices Award Winner: 2018



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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
2. Noble, et al. Analysis of Upper and Lower Extremity Peripheral Nerve Injuries in a Population of Patients with Multiple Injuries. *J Trauma*. 1998; 45(1): 116-122.
3. Uzun, et al., Traumatic peripheral nerve injuries: demographic and electrophysiologic findings of 802 patients from a developing country. *J Clin Neuromusc Dis*. 2006; 7(3): 97–103.
4. Portincasa, et al. Microsurgical treatment of injury to peripheral nerves in upper and lower limbs: a critical review of the last 8 years. *Microsurgery*. 2007; 27(5): 455–462.
5. Medicare National HCPS Aggregate Summary Table CY2016. <https://data.cms.gov/Medicare-Physician-Supplier/Medicare-National-HCPCS-Aggregate-Summary-Table-CY/tra-d83c/data>
6. Solereanos, et al. Vein wrapping for the treatment of recurrent carpal tunnel syndrome. *Tech Hand Up Extrem Surg*. 1997; 1(1):35-40.
7. Seradge, et al. Cubital tunnel release with medial epicondylectomy factors influencing the outcome. *J Hand Surg Am*. 1998; 23(3): 483-491.
8. Papatheodorou, et al. Preliminary results of recurrent cubital tunnel syndrome treated with neurolysis and porcine extracellular matrix nerve wrap. *J Hand Surg Am*. 2015; 40(5): 987-992
9. Lin, et al. Systematic Review and Meta-Analysis on Incidence of Altered Sensation of Mandibular Implant Surgery - *PLoS One*. 2016; 11(4): e0154062.
10. Hussaini. Procedure frequency in the jaws related to implant location. *Dent Oral Craniofac Res*. 2016; 2(2): 230-233.
11. Nguyen, et al. Risk factors for permanent injury of inferior alveolar and lingual nerves during third molar surgery. *J Oral Maxillofac Surg*. 2014; 72(12): 2394-2401.
12. Cheung, et al. Incidence of neurosensory deficits and recovery after lower third molar surgery: a prospective clinical study of 4338 cases. *Int J Oral Maxillofac Surg*. 2010; 39(4): 320–326.
13. Dental Implants Market (Product - Endosteal Implants, Subperiosteal Implants, Transosteal Implants, Intramuscular Implants; Material - Titanium Implants, Zirconium Implants; End User - Hospitals, Dental Clinics, and Academic & Research Institutes) - Global Industry Analysis, Size, Share, Growth, Trends, and Forecast 2017 – 2025. <https://www.transparencymarketresearch.com/dental-implants-market.html>
14. Cha, et al. Frequency of bone graft in implant surgery. *Maxillofac Plast and Reconstr Surg*. 2016; 38(1): 19.
15. Miloro, M (ed). *Trigeminal Nerve Injuries*. Springer; 2013.
16. Pogrel et al. Permanent nerve involvement resulting: From inferior alveolar nerve blocks. *J Am Dent Assoc*. 2000; 131(7): 901-907.
17. Agbaje, et al. Systematic review of the incidence of inferior alveolar nerve injury in bilateral sagittal split osteotomy and the assessment of neurosensory disturbances. *Int J Oral Maxillofac Surg*. 2015; 44(4): 447-451.
18. ASPS 2017– Plastic Surgery Statistics Report. www.plasticsurgery.org/documents/News/Statistics/2017/plastic-surgery-statistics-full-report-2017.pdf
19. Rappaport, et al. Clinical utilization and complications of sural nerve biopsy. *Am J Surg*. 1993; 166(3): 252-256.
20. Weber, et al. A randomized prospective study of polyglycolic acid conduits for digital nerve reconstruction in humans. *Plast Reconstr Surg*. 2000; 106(5): 1036-1045.
21. Wangenstein, et al. Collagen tube conduits in peripheral nerve repair: A retrospective analysis. *Hand*. 2010; 5(3): 273-277.
22. Data on file at Axogen
23. Karabekmez, et al. Early clinical outcomes with the use of decellularized nerve allograft for repair of sensory defects within the hand. *Hand*. 2009; 4(3): 245-249.
24. Boeckstyns, et al. Collagen conduit versus microsurgical neurotaphy: 2-year follow-up of a prospective, blinded clinical and electrophysiological multicenter randomized, controlled trial. *J hand Surg Am*. 2013; 38(12): 2405-2411.
25. Brushart, et al. Selective reinnervation of distal motor stumps by peripheral motor axons. *Exp Neurol*. 1987; 97(2): 289-300.
26. Schmidhammer, et al. Alleviated tension at the repair site enhances functional regeneration: The effect of full range of motion mobilization on the regeneration of peripheral nerves—histologic, electrophysiologic, and functional results in a rat model. *J Trauma*. 2004; 56(3): 571-584.
27. Tang, et al. The optimal number and location of sutures in conduit-assisted primary digital nerve repair. *J Hand Surg Eur Vol*. 2018; 43(6): 621-625.
28. Data on file at Axogen
29. Badylak, et al. Small intestinal submucosa: A substrate for in vitro cell growth. *J Biomater Sci Polym Ed*. 1998; 9(8): 863-878.
30. Hodde, et al. Effects of sterilization on an extracellular matrix scaffold: Part II. Bioactivity and matrix interaction. *J Mater Sci Mater Med*. 2007; 18(4): 545-550.
31. Nihsen, et al. Bioactivity of small intestinal submucosa and oxidized regenerated cellulose/collagen. *Adv Skin Wound Care*. 2008; 21(10): 479-486.
32. Hodde, et al. Vascular endothelial growth factor in porcine-derived extracellular matrix. *Endothelium*. 2001; 8(1): 11-24.
33. Data on file at Axogen
34. Kokkalis, et al. Assessment of processed porcine extracellular matrix as a protective barrier in a rabbit nerve wrap model. *J Recon MicroSurg*. 2011; 27(1): 19-28.
35. Data on file at Axogen
36. Data on file at Axogen



Footnotes

37. Mitchell A Pej 1, Jason H Ko, Janna L Friedly, Douglas G Smith Traction Neurectomy for Treatment of Painful Residual Limb Neuroma in Lower Extremity Amputees J Orthop Trauma. 29 (9), e321-5 Sep 2015.
38. Laborde K, et al. Results of surgical treatment of painful neuromas of the hand. The Journal of Hand Surgery. March 1981;7(2):190-193.
39. Galeano M, et al. A free vein graft cap influences neuroma formation after nerve transection. Microsurgery. 2009;29(7):568-572.
40. Stokvis A. Surgical management of painful neuromas. Rotterdam, The Netherlands: Optima Grafische Communicatie; 2010.
41. Lin E, et al. Local administration of norepinephrine in the stump evokes dose-dependent pain in amputees. Clin J Pain. 2006;22(5):482-486.
42. O'Reilly MA, et al. Neuromas as the cause of pain in the residual limbs of amputees. An ultrasound study. Clin Radiology. May 1-6, 2016.
43. Rajput K, et al. Painful neuromas. The Clinical Journal of Pain. 2012;28(7):639-645
44. Gruber H, et al. Practical experience with sonographically guided phenol instillation of stump neuroma: predictors of effects, success, and outcome. Am J Roentgenol. 2008;190(5):1263-1269.
45. Fallat L. Cryosurgery or sclerosing injections: which is better for neuromas. Podiatry Today. 2004;17(6):58-66.
46. Bradley MD. Plantar neuroma: analysis of results following surgical excision in 145 patients. South Med J. 1976;69:853-845.
47. Kehoe S, et al. FDA-approved guidance conduits and wraps for peripheral nerve injury: A review of materials and efficacy. Injury. 2012;43:553-572. [Biomaterials](#). 2001 Oct;22(19):2653-9.
48. Record RD¹, Hillemonds D, Simmons C, Tullius R, Rickey FA, Elmore D, Badylek SF. In vivo degradation of 14C-labeled small intestinal submucosa (SIS) when used for urinary bladder repair.
49. Safa B, Power D, Liu A, Thayer WP, et al. A Propensity Matched Cohort Study on Outcomes from Processed Nerve Allograft and Nerve Autograft in Upper Extremity Nerve Repairs. In: *The 75th Annual Meeting of the ASSH. Virtual Annual Meeting*, October 1-2, 2020.
50. Sallam AA, El-Deeb MS, Imam MA. Nerve Transfer Versus Nerve Graft for Reconstruction of High Ulnar Nerve Injuries. J Hand Surg Am. 2017 Apr;42(4):265-273
51. Roganovic Z, Pavlicevic G. Difference in recovery potential of peripheral nerves after graft repairs. Neurosurgery. 2006 Sep;59(3):621-33; discussion 621-33.
52. Frykman G, Gramyk K. Results of nerve grafting. In: Gelberman R, ed. Operative nerve repair and reconstruction. Philadelphia: JB Lippincott. 1991:553-567.
53. Vastamäki M, Kallio PK, Solonen KA. The results of secondary microsurgical repair of ulnar nerve injury. J Hand Surg Br. 1993 Jun;18(3):323-6.
54. Kallio PK, Vastamäki M, Solonen KA. The results of secondary microsurgical repair of radial nerve in 33 patients. J Hand Surg Br. 1993 Jun;18(3):320-2.
55. Styron JF, Thompson AK, Park LI, Watson GJ. Nerve Repair Hospital Index Procedure Costs – Allograft vs. Autograft Repair Type. In: *The 75th Annual Meeting of the ASSH. Virtual Annual Meeting*, October 1-2, 2020.
56. U.S. Centers for Medicare and Medicaid Services. Medicare Claims standard analytic file. 2018.
57. Data on file at Axogen.

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