

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): August 7, 2023

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 2.02 Results of Operations and Financial Condition

On July 26, 2023, Axogen, Inc. (the "Company") issued a press release announcing its three and six months ended June 30, 2023 financial results. 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 August 7, 2023, 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. A copy of the investor update is furnished as Exhibit 99.2.

The information in the 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	Press release, dated August 7, 2023
99.2	Axogen, Inc Corporate Presentation, dated August 7, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: August 4, 2023

By: /s/ Marc Began

Marc Began

Executive Vice President, General Counsel and Chief Compliance Officer



Axogen, Inc Reports 2023 Second Quarter Financial Results

ALACHUA and TAMPA, FL – August 7, 2023 – Axogen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for peripheral nerve injuries, today reported financial results and business highlights for the second quarter ended June 30, 2023.

Second Quarter Financial Results and Business Highlights

- Revenue was \$38.2 million during the second quarter, an increase of approximately 11% over the second quarter of 2022.
 - The Company estimates that revenues from scheduled non-trauma procedures represented approximately half of total revenues during the second quarter and grew over 20% from the second quarter of 2022.
 - The Company estimates that revenues from emergent trauma procedures represented approximately half of total revenues during the second quarter and grew in the low single digit range versus the second quarter of 2022.
 - Gross margin was 81.1% for the quarter, compared to 81.8% in the second quarter of 2022.
 - Net loss of \$6.7 million, or \$0.16 per share, compared to net loss of \$7.7 million, or \$0.18 per share in the second quarter of 2022.
 - Adjusted net loss of \$1.3 million, or \$0.03 per share, compared to adjusted net loss of \$2.6 million, or \$0.05 per share, in the second quarter of 2022.
 - Adjusted EBITDA loss of \$0.2 million, compared to an adjusted EBITDA loss of \$1.6 million in the second quarter of 2022.
 - The balance of all cash and cash equivalents and investments on June 30, 2023, was \$40.8 million, as compared to \$44.1 million on March 31, 2023. The net change includes capital expenditures of \$3.6 million related to the construction of the Company's new processing facility in Dayton, OH, partially offset by \$0.3 million of net positive other operating cash flow in the quarter.
 - The Company successfully initiated the pilot launch of the Axoguard HA+ Nerve Protector™ in the second quarter and will fully launch this extension of its nerve protection platform later this month.
 - On August 2nd the Phase 3 RECON study was published online in *The Journal of Hand Surgery*. The Company had previously announced in May of 2022 that RECON had met its primary endpoint. The publication includes the authors analysis of the results, which found that Avance
-

returned a greater degree of functional recovery than conduits and superiority was demonstrated as gap lengths increased.

"We are encouraged by the continued momentum of our overall business, which was led by over 20% growth of scheduled procedures," stated Karen Zaderej, AxoGen's Chairman, CEO, and President. "The strength of our scheduled procedures category is delivering on the Company's underlying goal of gaining deeper surgeon adoption and expanded use cases of our products across our core and active accounts."

"Emergent trauma procedures continue to experience headwinds as hospitals prioritize resources and address operating challenges particularly with routine trauma procedures. We believe that these challenges are transient and that recent clinical publications, demonstrating the clinical effectiveness, cost, and surgical time efficiencies of allograft nerve repairs, will support continued surgeon adoption and expansion of the trauma category," continued Zaderej.

- Core Accounts totaled 347, an increase of 16% over an adjusted* prior-year level of 299, and a decrease of 1% sequentially. Revenue from Core Accounts continued to represent approximately 60% of total revenue.
- Active Accounts totaled 974, an increase of 4% over an adjusted* prior-year level of 941, and a decrease of 1% sequentially. Revenue from the top 10% of Active Accounts represents approximately 35% of total revenue.
- Ended the quarter with over 200 peer-reviewed clinical publications featuring Axogen's nerve repair product portfolio.
- We ended the quarter with 115 direct sales representatives compared to 116 on March 31, 2023 and a year ago.

Update on Axogen Processing Center (APC) and BLA Submission

The Company completed construction of the APC and in the second quarter placed into service the warehouse and office spaces, and now expects to begin processing tissue in the new facility later this month. The Company will include tissue processing information from the APC in its submission of the BLA for Avance Nerve Graft. Additionally, the Company will be requesting to utilize a rolling submission process with the FDA at a pre-BLA meeting that is expected to occur early first quarter of 2024. If the FDA agrees, the Company expects to begin the submission in the first quarter of 2024 and complete the submission in the second quarter of 2024. The company believes this process will support BLA approval in the first half 2025.

Axoguard HA+ Nerve Protector Launch

The Company successfully initiated the pilot launch of the Axoguard HA+ Nerve Protector™ in the second quarter and will fully launch this extension of its nerve protection platform later this month. Axoguard HA+ Nerve Protector is a proprietary nerve protection device designed to provide short- and long-term protection for peripheral nerve injuries. The device is comprised of a processed porcine submucosa extracellular matrix (ECM) base layer with a hyaluronate-alginate gel coating. The gel layer facilitates enhanced nerve gliding to aid in minimizing soft tissue attachments, while the base layer is remodeled into a long-term protective tissue layer. It is available in a variety of sizes to meet patients' and surgeons' needs.

2023 Financial Guidance

Management is maintaining full-year 2023 revenue guidance in the range of \$154 million to \$159 million, which represents annual growth of 11% - 15%. The Company anticipates that gross margin will be reduced with the transition to the new processing facility in the third and fourth quarters and that gross margins for the full year 2023 will be approximately 80%.

*The Company voluntarily suspended market availability of Avive® Soft Tissue Membrane on June 1, 2021; and therefore, no Avive revenue was recorded in 2022. Core and Active Account metrics for prior periods were adjusted for Avive revenue. For a reconciliation of adjusted Core and Active Account numbers, please see our Corporate Presentation on the investors page on www.axogeninc.com.

Conference Call

The Company will host a conference call and webcast for the investment community today at 4:00 p.m. ET. Investors interested in participating in the conference call by phone may do so by dialing toll free at (877) 407-0993 or use the direct dial-in number at (201) 689-8795. Those interested in listening to the conference call live via the Internet may do so by visiting the Investors page of the Company's website at www.axogeninc.com and clicking on the webcast link.

Following the conference call, a replay will be available in the Investors section of the Company's website at www.axogeninc.com under Investors.

About RECON

RECON is a multicenter, prospective, randomized, subject and evaluator blinded comparative clinical study of nerve cuffs (manufactured conduits) and Avance® Nerve Graft, evaluating recovery outcomes for the repair of nerve discontinuities. The phase 3 pivotal study is designed to provide clinical evidence for the Company's BLA filing to transition the Company's Avance Nerve Graft from a section 361 tissue product to a section 351 biologic product; and, as such was designed to test for non-inferiority between static two-point discrimination outcomes for Avance Nerve Graft and manufactured conduit. The study design also allows for a sequential test for superiority of Avance Nerve Graft, following the non-inferiority analysis.

About Avance Nerve Graft

Avance Nerve Graft is a biologically active off-the-shelf processed human nerve allograft for bridging severed peripheral nerves without the comorbidities associated with a second surgical site. Avance provides structural guidance for regenerating axons, and revascularizes and remodels into the patient's own tissue. It is available in a variety of lengths and diameters.

A 2010 written agreement between the FDA and Axogen allows the company to continue marketing Avance as a section 361 Human Cells, Tissues and Cellular and Tissue Based Product (HCT/P) while taking the necessary steps to file a Biologics License Application (BLA) under section 351.

In 2018 the FDA granted a Regenerative Medicine Advance Therapy (RMAT) designation for Avance Nerve Graft. A regenerative medicine therapy is eligible for the designation if it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product has the potential to address unmet medical needs for such a disease or condition. The RMAT designation provides access to a streamlined approval process for

regenerative medicine technologies and ensures continued informal meetings with the FDA in support of the BLA for Avance Nerve Graft.

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 that are used across two primary application categories: scheduled, non-trauma procedures and emergent trauma procedures. Scheduled procedures are generally characterized as those where a patient is seeking relief from conditions caused by a nerve defect or surgical procedure. These procedures include providing sensation for women seeking breast reconstruction following a mastectomy, nerve reconstruction following the surgical removal of painful neuromas, oral and maxillofacial procedures, and nerve decompression. Emergent procedures are generally characterized as procedures resulting from injuries that initially present in an ER. These procedures are typically referred to and completed by a specialist either immediately or within a few days following the initial injury.

Axogen's product portfolio includes 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 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 HA+ Nerve Protector[™], a porcine submucosa ECM base layer coated with a proprietary hyaluronate-alginate gel, a next-generation technology designed to provide short- and long-term protection for peripheral nerve injuries; and 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. The Axogen portfolio of products is available in the United States, Canada, Germany, the United Kingdom, Spain, South Korea, and several other 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. Forward-looking statements include statements about (i) fully launching Axoguard HA+ later this month, (ii) anticipated timetable for seeking approval of the rolling BLA submission in early first quarter of 2024, (iii) subject to approval of the rolling submission, anticipated timetable for the initial BLA submission in the first quarter of 2024 and completion in the second quarter of 2024, (iv) potential BLA approval in the first half of 2025, and

(v) initial processing of tissue in the new facility later this month, as well as statements under the subheading "2023 Financial Guidance." 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 the continued impact of COVID-19, global supply chain issues, record inflation, hospital staffing issues, product development, product potential, expected clinical enrollment timing and outcomes, regulatory process and approvals, APC renovation timing and expense, 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, 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.

About Non-GAAP Financial Measures

To supplement our consolidated financial statements, we use the non-GAAP financial measures of EBITDA, which measures earnings before interest, income taxes, and depreciation and amortization, and Adjusted EBITDA which further excludes non-cash stock compensation expense and litigation and related expenses. We also use the non-GAAP financial measures of Adjusted Net Loss and Adjusted Net Loss Per Common Share - basic and diluted which excludes non-cash stock compensation expense and litigation and related expenses from Net Loss and Net Loss Per Common Share - basic and diluted, respectively. These non-GAAP measures are not based on any comprehensive set of accounting rules or principles and should not be considered a substitute for, or superior to, financial measures calculated in accordance with GAAP, and may be different from non-GAAP measures used by other companies. In addition, these non-GAAP measures should be read in conjunction with our financial statements prepared in accordance with GAAP. The reconciliations of the non-GAAP measures to the most directly comparable financial measures calculated and presented in accordance with GAAP should be carefully evaluated.

We use these non-GAAP financial measures for financial and operational decision-making and as a means to evaluate period-to-period comparisons. We believe that these non-GAAP financial measures provide meaningful supplemental information regarding our performance and that both management and investors benefit from referring to these non-GAAP financial measures in assessing our performance and when planning, forecasting, and analyzing future periods. We believe these non-GAAP financial measures are useful to investors because (1) they allow for greater transparency with respect to key metrics used by management in its financial and operational decision-making and (2) they are used by our institutional investors and the analyst community to help them analyze the performance of our business, the Company's cash available for operations, and the Company's ability to meet future capital expenditure and working capital requirements.

Contact:
Axogen, Inc.
InvestorRelations@axogeninc.com

Axogen, Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands, except share and per share amounts)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 23,219	\$ 15,284
Restricted cash	6,252	6,251
Investments	11,312	33,505
Accounts receivable, net of allowance for doubtful accounts of \$595 and \$650, respectively	21,573	22,186
Inventory	21,237	18,905
Prepaid expenses and other	2,583	1,944
Total current assets	86,176	98,075
Property and equipment, net	87,459	79,294
Operating lease right-of-use assets	13,958	14,369
Intangible assets, net	4,048	3,649
Total assets	\$ 191,641	\$ 195,387
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 22,893	\$ 22,443
Current maturities of long-term lease obligations	1,040	1,310
Total current liabilities	23,933	23,753
Long-term debt, net of debt discount and financing fees	46,154	45,712
Long-term lease obligations	20,131	20,405
Debt derivative liabilities	4,271	4,518
Total liabilities	94,489	94,388
Commitments and contingencies - see Note 12		
Shareholders' equity:		
Common stock, \$0.01 par value per share; 100,000,000 shares authorized; 42,979,541 and 42,445,517 shares issued and outstanding	430	424
Additional paid-in capital	370,036	360,155
Accumulated deficit	(273,314)	(259,580)
Total shareholders' equity	97,152	100,999
Total liabilities and shareholders' equity	\$ 191,641	\$ 195,387

Axogen, Inc.
Condensed Consolidated Statements of Operation
(unaudited)
(In thousands, except per share amounts)

	Three Months Ended		Six Months Ended	
	June 30, 2023	June 30, 2022	June 30, 2023	June 30, 2022
Revenues	\$ 38,155	\$ 34,454	\$ 74,819	\$ 65,461
Cost of goods sold	7,228	6,284	13,937	11,830
Gross profit	30,927	28,170	60,882	53,631
Costs and expenses:				
Sales and marketing	20,838	19,669	42,456	40,557
Research and development	7,363	7,022	14,043	13,296
General and administrative	9,628	9,403	18,627	19,021
Total costs and expenses	37,829	36,094	75,126	72,874
Loss from operations	(6,902)	(7,924)	(14,244)	(19,243)
Other income (expense):				
Investment income (loss)	235	32	784	(15)
Interest expense	(148)	(249)	(164)	(603)
Change in fair value of derivatives	432	434	247	686
Other expense	(277)	(33)	(357)	(40)
Total other income, net	242	184	510	28
Net loss	\$ (6,660)	\$ (7,740)	\$ (13,734)	\$ (19,215)
Weighted average common shares outstanding — basic and diluted	42,862,384	41,994,618	42,719,096	41,900,000
Loss per common share — basic and diluted	\$ (0.16)	\$ (0.18)	\$ (0.32)	\$ (0.46)

Axogen, Inc.
RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES
Three Months Ended March 31, 2023 and 2022
(unaudited)
(In thousands, except per share amounts)

	Three Months Ended		Six Months Ended	
	June 30, 2023	June 30, 2022	June 30, 2023	June 30, 2022
Net loss	\$ (6,660)	\$ (7,740)	\$ (13,734)	\$ (19,215)
Depreciation and amortization expense	871	777	1,650	1,550
Investment (income) loss	(235)	(32)	(784)	15
Income tax expense	240	33	318	33
Interest expense	148	249	164	603
EBITDA - non GAAP	\$ (5,636)	\$ (6,713)	\$ (12,386)	\$ (17,014)
Non cash stock-based compensation expense	5,390	4,910	8,344	7,588
Litigation and related costs	—	216	—	483
Adjusted EBITDA - non GAAP	\$ (246)	\$ (1,587)	\$ (4,042)	\$ (8,943)
Net loss	\$ (6,660)	\$ (7,740)	\$ (13,734)	\$ (19,215)
Non cash stock-based compensation expense	5,390	4,910	8,344	7,588
Litigation and related costs	—	216	—	483
Adjusted net loss - non GAAP	\$ (1,270)	\$ (2,614)	\$ (5,390)	\$ (11,144)
Weighted average common shares outstanding — basic and diluted	42,862,384	41,994,618	42,719,096	41,900,000
Loss per common share — basic and diluted	\$ (0.16)	\$ (0.18)	\$ (0.32)	\$ (0.46)
Non cash stock-based compensation expense	0.13	0.12	0.20	0.18
Litigation and related costs	—	0.01	—	0.01
Adjusted net loss per common share — basic and diluted - non GAAP	\$ (0.03)	\$ (0.05)	\$ (0.12)	\$ (0.27)

Axogen, Inc.
Condensed Consolidated Statements of Changes in Shareholders' Equity
(unaudited)
(In thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount			
Three Months Ended June 30, 2023					
Balance at March 31, 2023	42,809,994	\$ 428	\$ 363,739	\$ (266,654)	\$ 97,513
Net loss	—	—	—	(6,660)	(6,660)
Stock-based compensation	—	—	5,390	—	5,390
Issuance of restricted and performance stock units	57,659	1	(1)	—	—
Exercise of stock options and employee stock purchase plan	111,888	1	908	—	909
Balance at June 30, 2023	<u>42,979,541</u>	<u>\$ 430</u>	<u>\$ 370,036</u>	<u>\$ (273,314)</u>	<u>\$ 97,152</u>
Six Months Ended June 30, 2023					
Balance at December 31, 2022	42,445,517	\$ 424	\$ 360,155	\$ (259,580)	\$ 100,999
Net loss	—	—	—	(13,734)	(13,734)
Stock-based compensation	—	—	8,344	—	8,344
Issuance of restricted and performance stock units	296,378	4	(4)	—	—
Exercise of stock options and employee stock purchase plan	237,646	2	1,541	—	1,543
Balance at June 30, 2023	<u>42,979,541</u>	<u>\$ 430</u>	<u>\$ 370,036</u>	<u>\$ (273,314)</u>	<u>\$ 97,152</u>
Three Months Ended June 30, 2022					
Balance at March 31, 2022	41,972,987	\$ 420	\$ 345,538	\$ (242,107)	\$ 103,851
Net loss	—	—	—	(7,740)	(7,740)
Stock-based compensation	—	—	4,910	—	4,910
Issuance of restricted and performance stock units	44,054	—	—	—	—
Exercise of stock options and employee stock purchase plan	117,463	—	669	—	669
Balance at June 30, 2022	<u>42,134,504</u>	<u>\$ 420</u>	<u>\$ 351,117</u>	<u>\$ (249,847)</u>	<u>\$ 101,690</u>
Six Months Ended June 30, 2022					
Balance at December 31, 2021	41,736,950	\$ 417	\$ 342,765	\$ (230,632)	\$ 112,550
Net loss	—	—	—	(19,215)	(19,215)
Stock-based compensation	—	—	7,588	—	7,588
Issuance of restricted and performance stock units	259,341	2	(2)	—	—
Exercise of stock options and employee stock purchase plan	138,213	1	766	—	767
Balance at June 30, 2022	<u>42,134,504</u>	<u>\$ 420</u>	<u>\$ 351,117</u>	<u>\$ (249,847)</u>	<u>\$ 101,690</u>

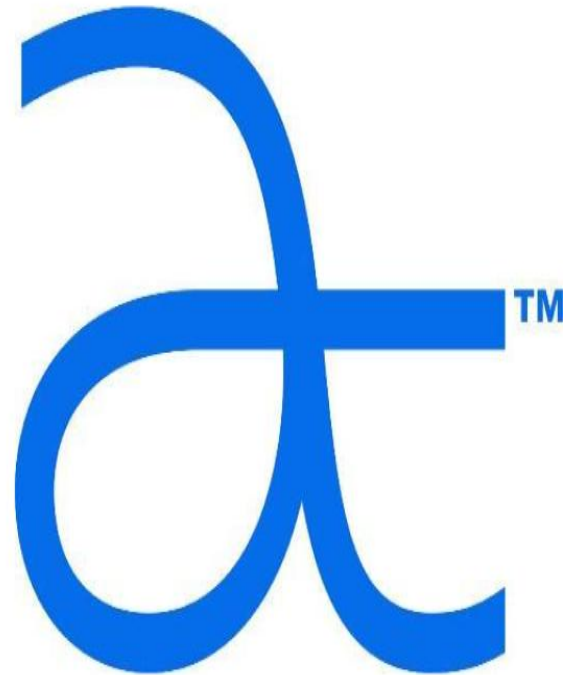
Axogen, Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(In Thousands)

	Six Months Ended	
	June 30, 2023	June 30, 2022
Cash flows from operating activities:		
Adjustments to reconcile net loss to net cash used in operating activities:	\$ (13,734)	\$ (19,215)
Depreciation	1,506	1,418
Amortization of right-of-use assets	642	859
Amortization of intangible assets	144	132
Amortization of debt discount and deferred financing fees	442	442
Provision for bad debt	(37)	550
Provision for inventory write-down	1,052	928
Change in fair value of derivatives	(247)	(686)
Investment (income) loss	(578)	145
Stock-based compensation	8,344	7,588
Change in operating assets and liabilities:		
Accounts receivable	650	(2,719)
Inventory	(3,384)	(3,458)
Prepaid expenses and other	(639)	(1,081)
Accounts payable and accrued expenses	(529)	(786)
Operating lease obligations	(762)	(856)
Cash paid for interest portion of finance leases	(1)	—
Net cash used in operating activities	(7,131)	(16,739)
Cash flows from investing activities:		
Purchase of property and equipment	(8,719)	(9,086)
Purchase of investments	(10,203)	(6,024)
Proceeds from sale of investments	32,974	11,000
Cash payments for intangible assets	(516)	(852)
Net cash from (used in) investing activities	13,536	(4,962)
Cash flows from financing activities:		
Cash paid for debt portion of finance leases	(12)	(1)
Proceeds from exercise of stock options and ESPP stock purchases	1,543	767
Net cash provided by financing activities	1,531	766
Net increase (decrease) in cash, cash equivalents, and restricted cash	7,936	(20,935)
Cash, cash equivalents, and restricted cash, beginning of period	21,535	39,007
Cash, cash equivalents, and restricted cash, end of period	\$ 29,471	\$ 18,073
Supplemental disclosures of cash flow activity:		
Cash paid for interest, net of capitalized interest	\$ —	\$ —
Supplemental disclosure of non-cash investing and financing activities:		
Acquisition of fixed assets in accounts payable and accrued expenses	\$ 1,818	\$ 1,817
Obtaining a right-of-use asset in exchange for a lease liability	\$ 268	\$ 700
Acquisition of intangible assets in accounts payable and accrued expenses	\$ 326	\$ 186

Corporate presentation

August 7, 2023

nasdaq: axgn



axogen[®]

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) foundation for long-term sustainable growth, (2) TAM for the targeted nerve markets, (3) 2023 financial guidance, including revenue range and gross margins, (4) anticipated growth of scheduled and emergent revenue categories, (5) growth drivers for the business, (6) preliminary topline results from Recon study, (7) timing of filing of the BLA, (8) timing of transition of the APC facility, and (9) opportunities in the full peripheral nerve injury trauma market. 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 the continued impact of COVID-19, global supply chain issues, record inflation, hospital staffing issues, product development, product potential, expected clinical enrollment timing and outcomes, regulatory process and approvals, APC renovation timing and expense, 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, 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
- Over 200 peer-reviewed clinical publications
- Over 75,000 Avance® Nerve Grafts implanted
- Significant barriers to competitive entry
- 115 U.S. sales reps
- Patient activation and surgeon education capabilities



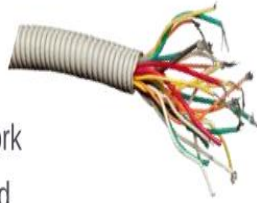
revolutionizing the science of nerve repair®

CONFIDENTIAL

The function of nerves

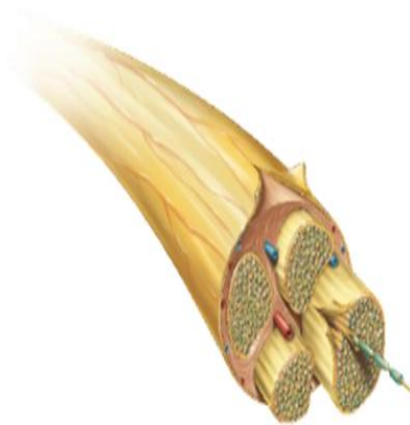
Nerves are like wires

- 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
- Mixed








Nerves can be injured in three ways:

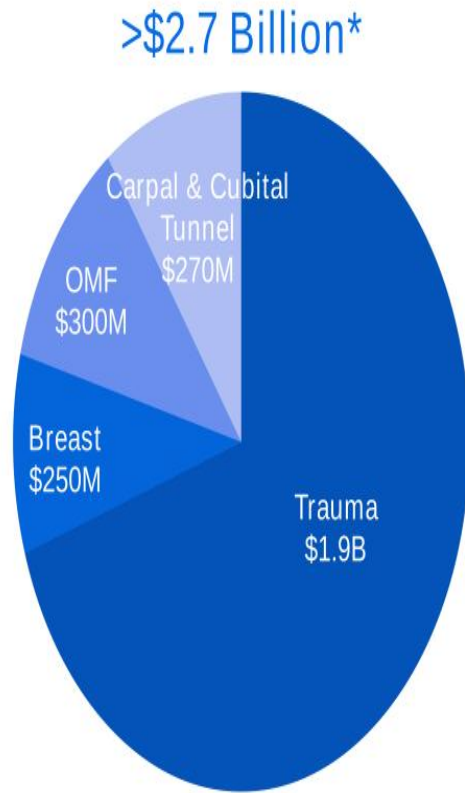
1. **Transection**
Traumatic nerve injuries e.g., motor vehicle accidents, power tool accidents, battlefield injuries, gunshot wounds, surgical injuries, neuroma-in-continuity
2. **Compression**
Carpal, cubital, tarsal tunnel revisions, blunt trauma, previous surgeries
3. **Stump Neuroma**
Amputations,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

A comprehensive platform for addressing nerve injuries

one company for all your surgical nerve repair solutions

<p>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>axoguard HA+ 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>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

Targeted nerve markets (U.S.)



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

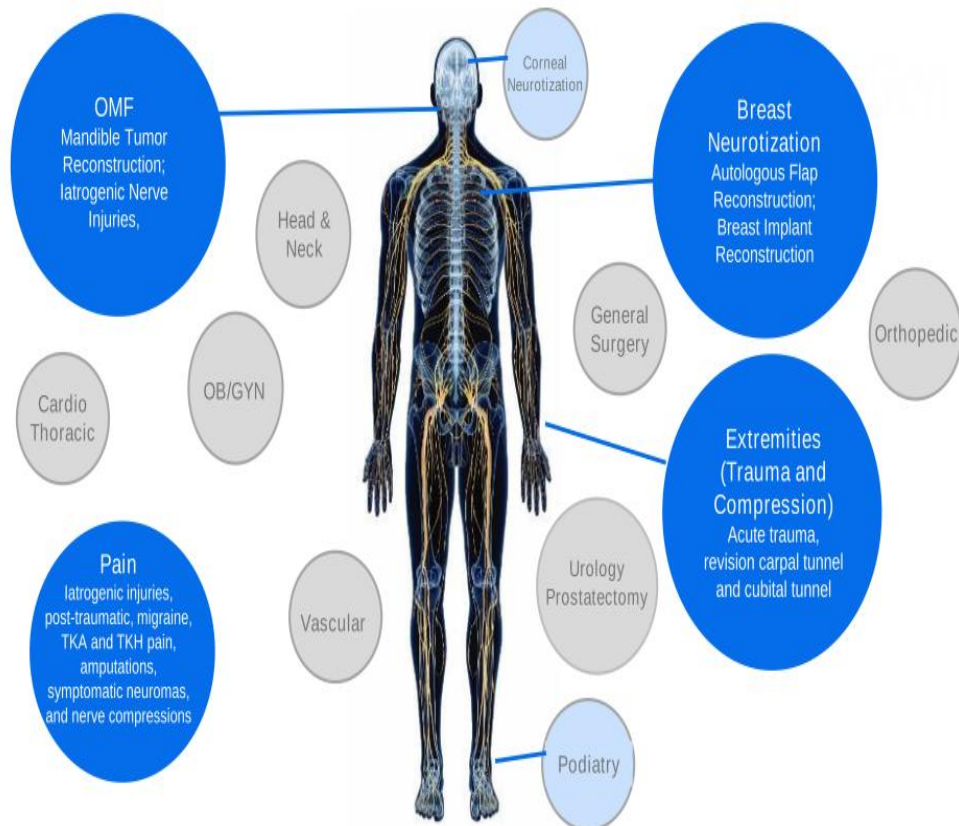
- Trauma: > 700,000
- Carpal Tunnel Revisions & Cubital Tunnel: 130,000
- Oral Maxillofacial (OMF): 56,000
- Breast Neurotization Procedures: 15,000

*\$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.

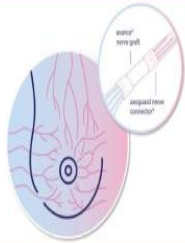
Opportunities in nerve repair

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



As we have introduced new applications, we now think about our business along two primary categories

Scheduled Procedure Examples



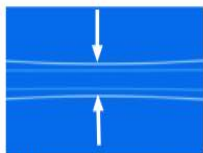
Breast Reconstruction



Mandibular Reconstruction



Neuroma repair



Cubital and Carpal Tunnel Revisions

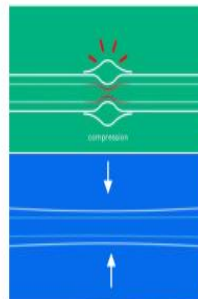
Emergent Trauma Procedure Examples



Transected Sensory nerves



Transected Mixed/Motor nerves



Non-transected nerve injury



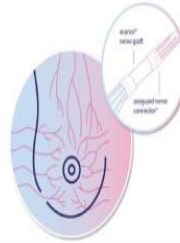
axogen[®] revolutionizing the science of nerve repair[™]

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 on 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.



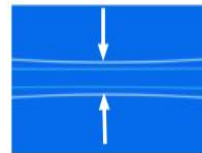
Mandibular Reconstruction

Reconstruction of the inferior alveolar nerve with ablation of the mandible



Neuroma repair

Symptomatic neuroma resection with nerve reconstruction



Cubital and Carpal Tunnel Revisions



revolutionizing the science of nerve repair™

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 Examples



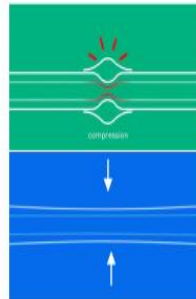
Transected Sensory nerves

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

Delivering strong revenue growth & gross margins

U.S. \$ in millions



81.1% Gross Margin for the quarter ended June 30, 2023

Revenue by Category

- We estimate that revenues from scheduled, non-trauma procedures represented approximately half of total revenues during the second quarter of 2023 and grew over 20% from the second quarter of 2022
- We estimate that revenues from emergent trauma procedures represented approximately half of total revenues during the second quarter of 2023 and grew in the low single digit range versus the second quarter of 2022.
- We estimate that the mix of scheduled and emergent procedures for fiscal 2022 was approximately 45% scheduled and 55% emergent.

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.



revolutionizing the science of nerve repair®

Growth Drivers

- Recent clinical data published within the past year will support increased adoption particularly with middle adopters
 - RECON
 - Meta Analysis of clinical outcomes and Medicare Economic Data
 - Premier Economic Data
- New Product launches in nerve protection
 - HA+ and Avive replacement
- Resensation for breast neurotization, including expansion into implant-based reconstructions
- Surgeon training across our applications
- Improved emergent procedure logistics and economics in more cost-efficient settings (ASCs)
- Patient activation programs for breast neurotization, surgical treatment of pain, and OMF
- New APC facility supports long-term growth

2023 Annual Financial Guidance

The company anticipates:

- Full-year 2023 revenue is expected to be between \$154 million and \$159 million



- Represents ~11% to 15% growth over 2022
- At the mid-point of this range, guidance assumes:
 - Growth of our scheduled procedure revenue in the low-to-mid-20% range
 - Growth in our emergent procedure revenue in the low single digit range

- Gross margin will be reduced with the transition to the new processing facility in the third and fourth quarters
- Expect full year gross margins to be approximately 80%



- Expect to begin processing tissue in the new facility in August 2023



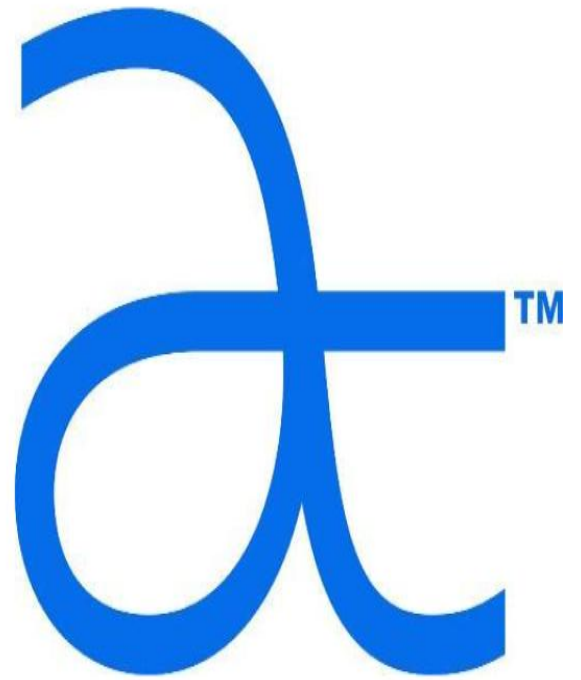
revolutionizing the science of nerve repair®

Axogen Processing Center (APC)

- Completed construction and expect to start processing tissue in August 2023
- Supports BLA requirements for Avance Nerve Graft.
- Provides 3x increase of current capacity; and allows expansion for future growth



Product Portfolio

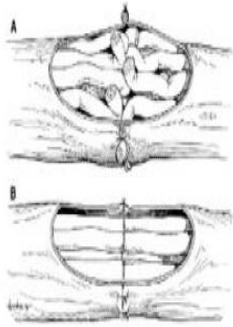


Traditional TRANSECTION repair options are suboptimal

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

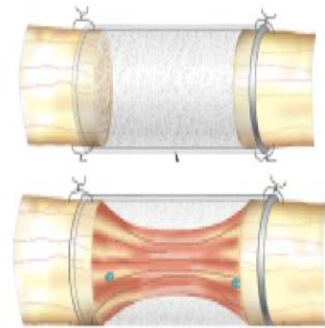
- Secondary surgery
- Loss of function and sensation at harvest site
- 27% complication rate including infection, wound healing and chronic pain¹⁹
- Limited availability of graft length and diameter



SYNTHETIC CONDUITS

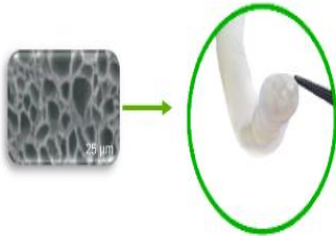
Convenient off the shelf option; limited efficacy & use

- 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, 32}

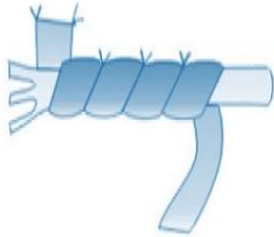
14 size options in lengths of 10mm and 15mm, and diameters up to 7mm

Traditional COMPRESSION repair options are suboptimal

VEIN WRAPPING

Autologous vein

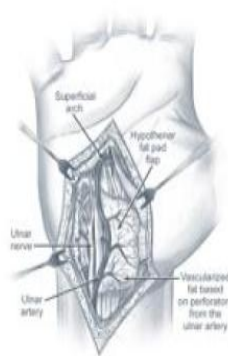
- Barrier to attachment to surrounding tissue
- Requires extra time and skill to perform spiral wrapping technique
- Second surgery site



HYPOTHENAR FAT PAD

Autologous vascularized flap

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



COLLAGEN WRAPS

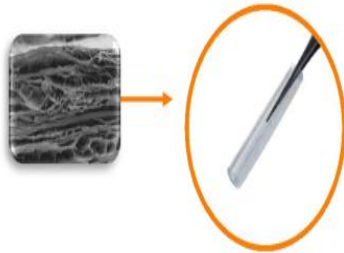
Off-the-shelf

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



Axogen solution for COMPRESSION repair

 **axoguard**
nerve protector[®]



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

Protects repair site from surrounding tissue

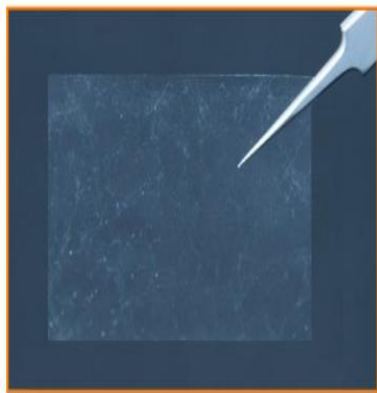
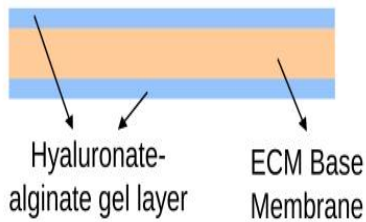
- Processing results in an implant that works with the body's natural healing process³³
- Minimizes soft tissue attachments³⁴

Allows nerve gliding

- Minimizes risk of entrapment³⁴
- Creates a barrier between repair and surrounding tissue bed³⁴
- ECM revascularizes and remodels into patient's own tissue^{29,35}

Axoguard HA+ Nerve Protector™

designed for short and long-term protection



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

ECM Base Membrane:

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

Handling characteristics:

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

Pilot Launch – successfully initiated in Q2 2023

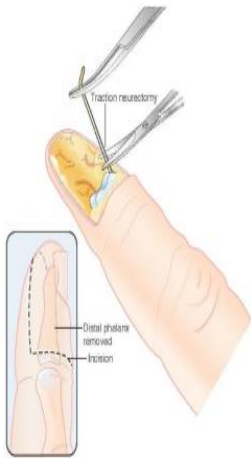
Full Product Launch – anticipated August 2023

Traditional STUMP NEUROMA options are suboptimal

TRACTION NEURECTOMY

Nerve placed in traction and cut to allow for retraction

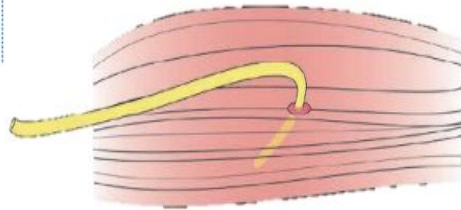
- Simply resecting the nerve results in subsequent neuroma formation and risk of secondary surgery
- Causes traction injury
- High risk of recurrence³⁶



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^{37, 38, 39}



INJECTIONS

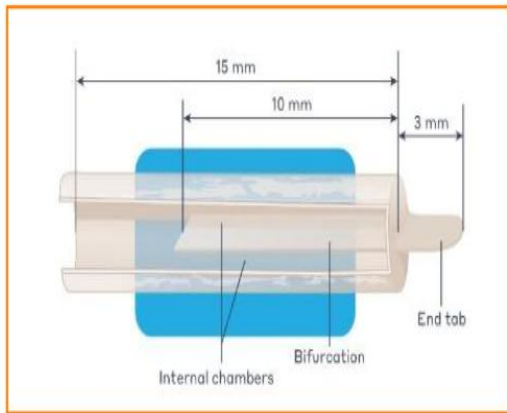
Pharmacologic intervention, typically alcohol or steroids^{40, 41, 42, 43, 44, 45}

- Chemical injections are only successful 40% of the time^{43, 44}
- Temporary solution that has a reduced benefit over time
- May cause considerable side effects



Axogen solution for STUMP NEUROMA

 **axoguard**
nerve cap[®]



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

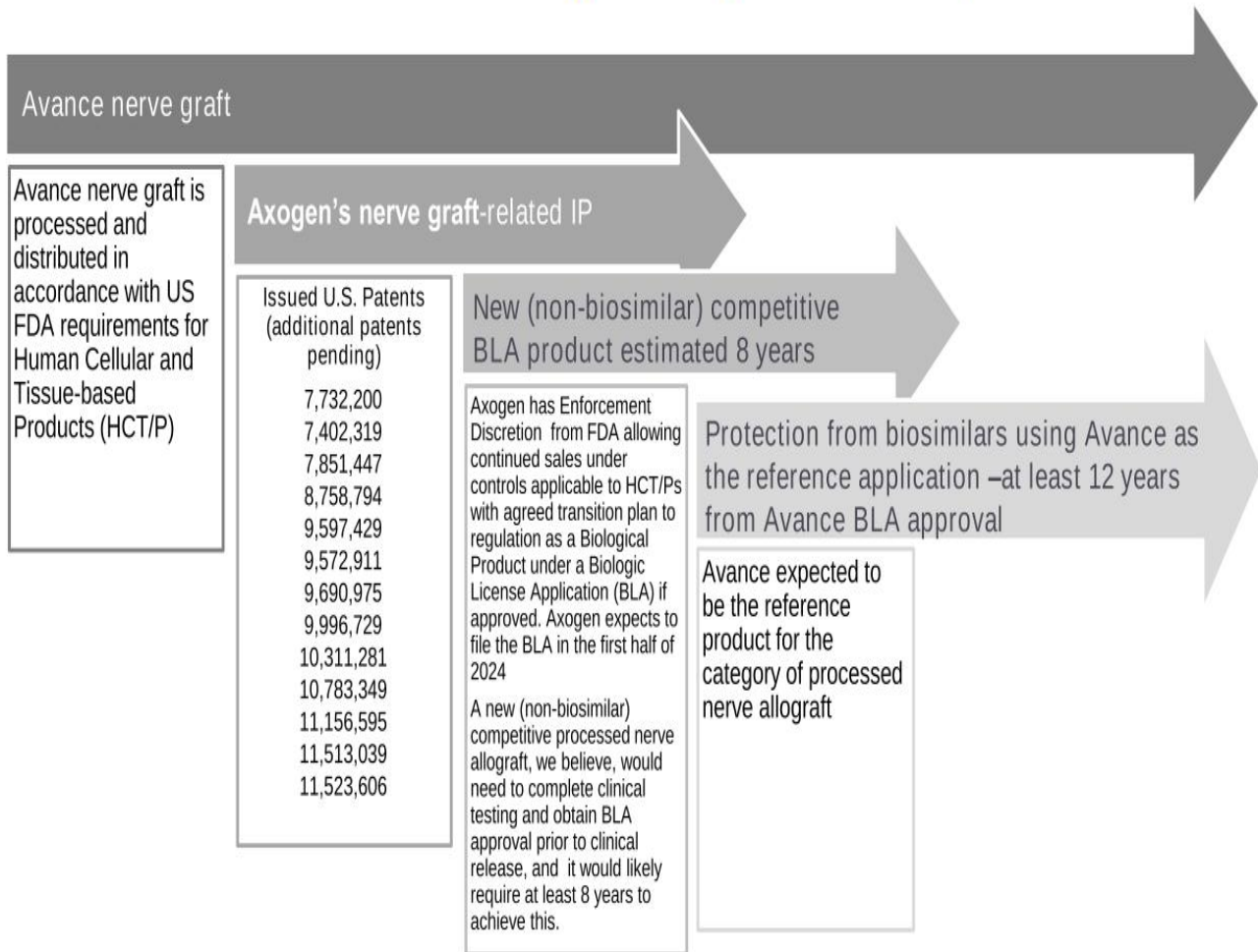
SIS Material allows for vascularization and gradual remodeling (as shown in animal studies)^{46, 47}

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

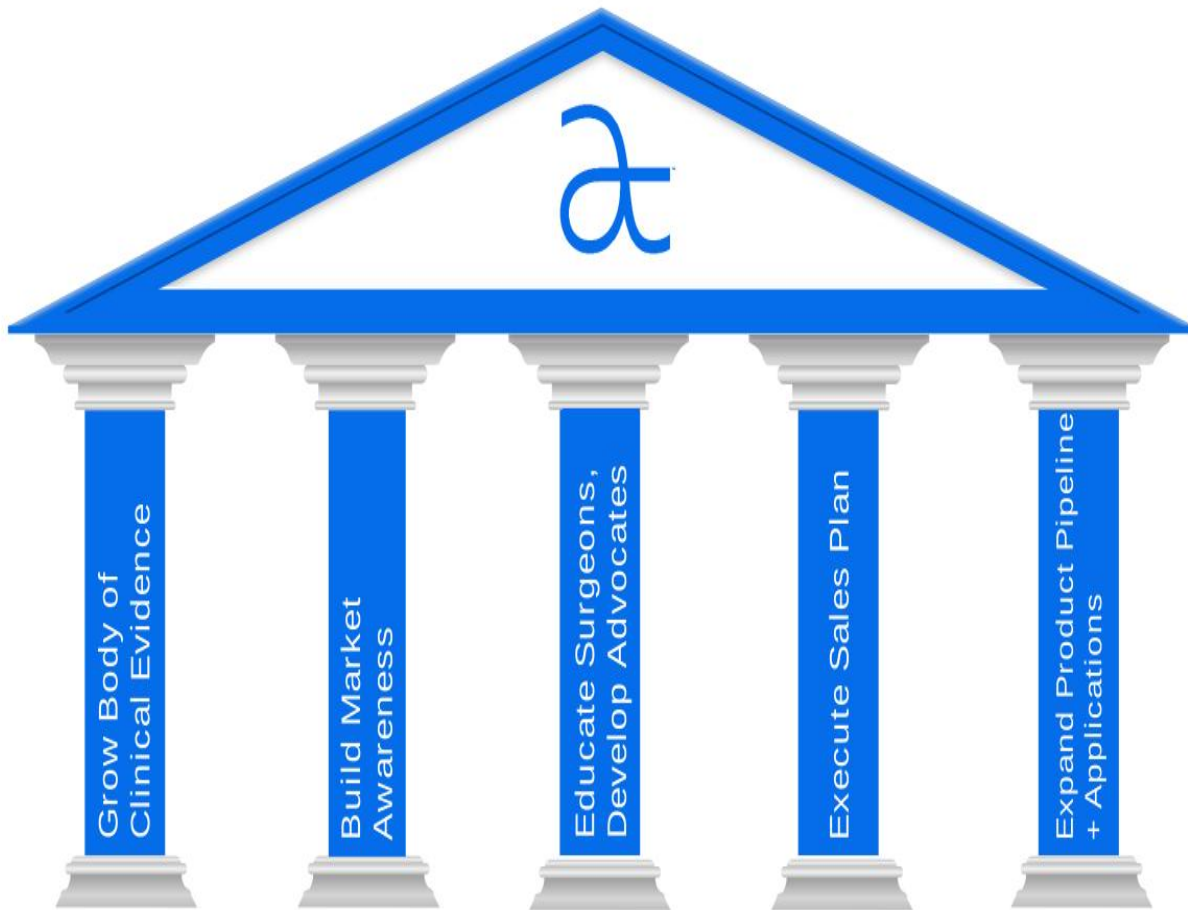
Intra-operative versatility

- 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

Avance Patents and Regulatory Landscape



Market development strategy



Strong commitment to developing clinical evidence



RANGER® Registry Study: Enrollment Ongoing

- 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 Ongoing

- Avance compared to matched cohort of autograft and synthetic conduits

RECONSM Study: Primary Endpoint Achieved

- Prospective, randomized, controlled study of Avance Nerve Graft vs synthetic conduits in digital injuries 5 to 25mm, to support BLA submission

Sensation-NOW® Registry Study: Enrollment Ongoing

- Multi-center clinical study in breast neurotization

REPOSE® : Enrollment Complete

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

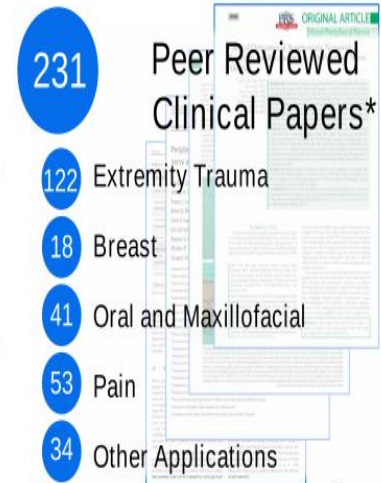
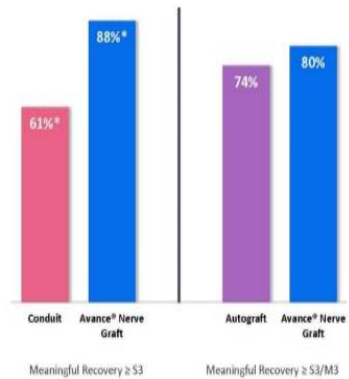
REPOSE-XLSM: Pilot Study Enrollment Ongoing

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

RETHINK PAIN® Registry Study: Enrollment Ongoing

- Designed to capture the patient's pain journey, from onset of chronic pain to nerve repair

Outcomes from RANGER Registry^{48,49}



revolutionizing the science of nerve repair®

*Certain publications contain data on multiple applications.

RECONSM: 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^{1,2}

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 Biologics License Application (BLA) submission in the first quarter of 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 ≤ 6 mm.

¹Axogen Data on File;

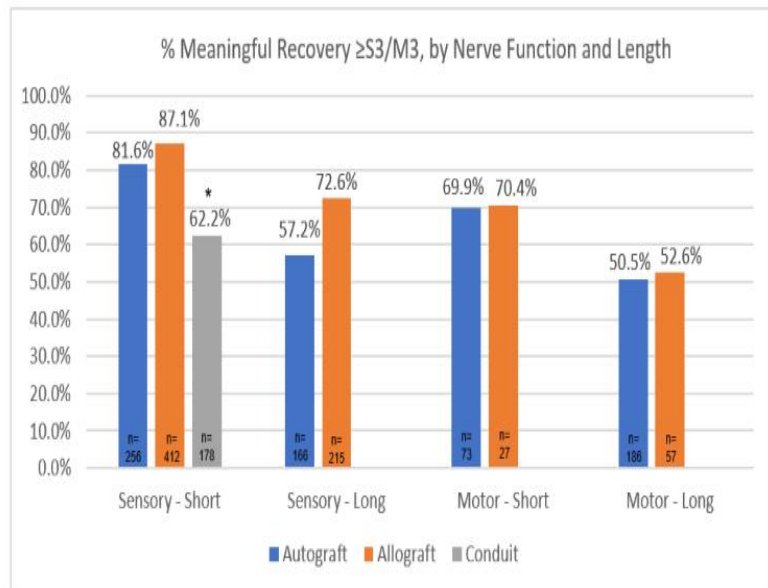


²Isaacs J, Nydick JA, Means KR, Merrell GA, Ilyas A, Levin LS; RECON study group. A Multicenter Prospective Randomized Comparison of Conduits Versus Decellularized Nerve Allograft for Digital Nerve Repairs. *J Hand Surg Am.* 2023 Aug 2:S0363-5023(23)00297-6. doi: 10.1016/j.jhsa.2023.05.020. Online ahead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

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 Surgery¹

- 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



¹Lans J, Eberlin KR, Evans PJ, Mercer D, Greenberg JA, Styron JF. A Systematic Review and Meta-Analysis of Nerve Gap Repair: Comparative Effectiveness of Allografts, Autografts, and Conduits. *Plast Reconstr Surg.* 2023 May 1;151(5):814e-827e. doi: 10.1097/PRS.00000000000010088. Epub 2022 Dec 26.

Procedure Costs of Peripheral Nerve Graft Reconstruction

Raizman et al.
PRSGlobal Open¹



- 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

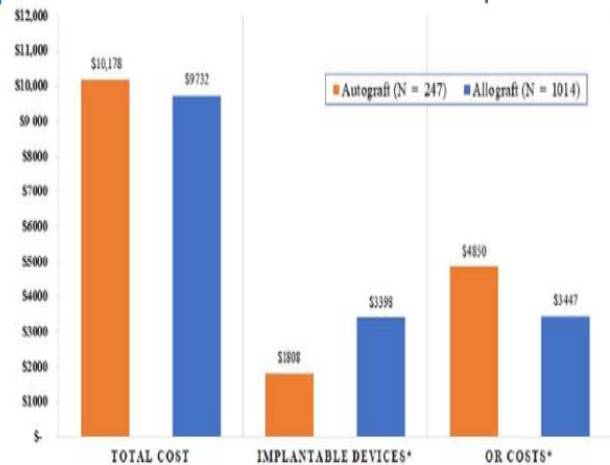
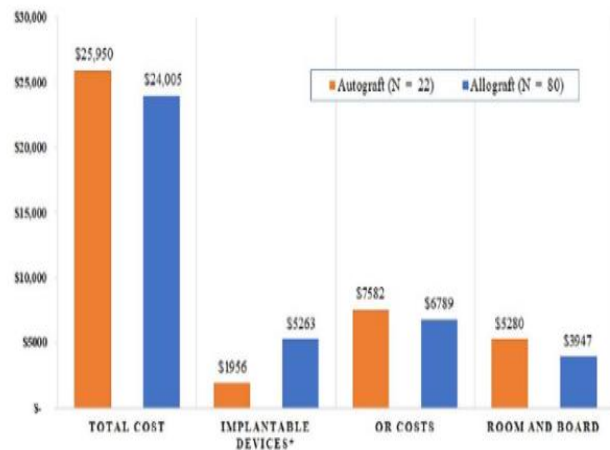


Fig. 2. Outpatient descriptive costs of nerve graft repair type (n = 1261).



¹Raizman NM, Endress RD, Styron JF, Emont SL, Cao Z, Park LI, Greenberg JA. Procedure Costs of Peripheral Nerve Graft Reconstruction. *Plast Reconstr Surg Glob Open*. 2023 Apr 10;11(4):e4908. doi: 10.1097/GOX.0000000000004908. eCollection 2023 Apr.

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



.....
resensation

rethink pain®



revolutionizing the science of nerve repair®

resensation.com

rethink-pain.com

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 20TH anniversary

Cancer Updates, Research & EducationSM

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 improve care 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 the possibility of a new treatment.

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 CATHY BARNES, PhD



MEET All kinds of feeling or sight can fundamentally change a patient's identity as they face a breast of varying size, especially if you are of a certain ethnicity or body type.

SPEAK UP, INVESTIGATE OPTIONS
A patient who underwent a mastectomy may be best left to talk about their numbness. Perhaps the best way to deal with it is to be open to the possibility of a new treatment. It may be a good idea to talk to your doctor about the possibility of a new treatment. It may be a good idea to talk to your doctor about the possibility of a new treatment. It may be a good idea to talk to your doctor about the possibility of a new treatment.

2022 • 8 • Department of 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 body after mastectomy

HELP WOMEN RECLAIM AFTER MASTECTOMY Page 6



WILDFIRE

Love & Intimacy

APRIL / MAY 2022




Oncology **cure** magazine

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

Survives in Patients

Negative Breast Cancer

BY YOURSELF: ON MY OWN

VERSUS



CONQUER MAGAZINE

CONQUER MAGAZINE

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



axogen[®]

77th annual meeting
of the ASSH

visit Axogen at booth # 815
sponsorship level: elite

"Late-Breaking, State-of-the-Art Nerve Reconstruction Data: The How and Why of Implementing this New Data into Your Clinical Practice"

Friday, September 30 • 7:00 - 8:00 am



masterminds
of nerve



revolutionizing the science of nerve repair[®]

Focused sales execution, increasing market penetration



Sales execution focused on driving results

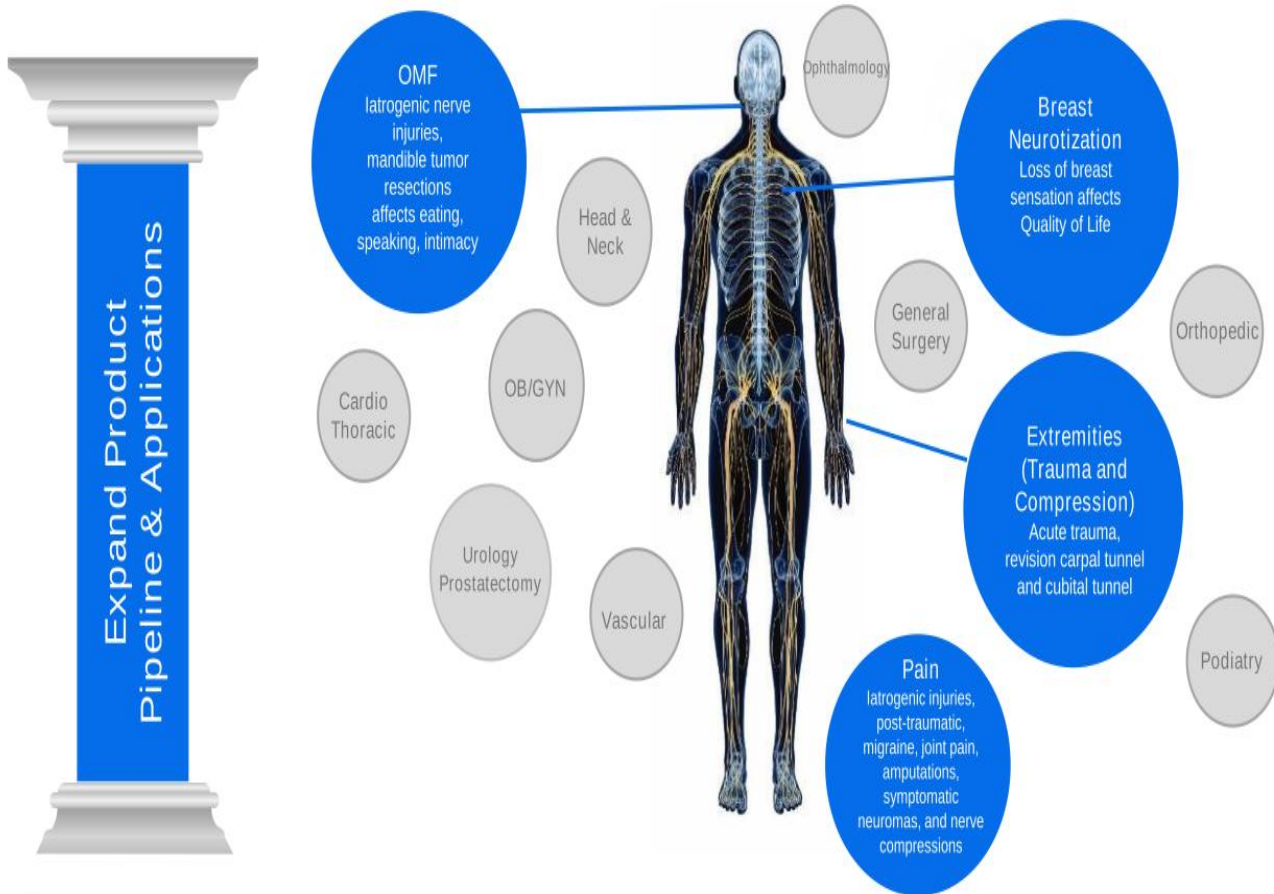
- Continue driving penetration in Active and Core Accounts
- Approximately 5,100 potential U.S. accounts perform nerve repair
- 974 Active Accounts as of June 30, 2023
 - Active Accounts represent approximately 85% of total revenue
 - Top 10% of Active Accounts represent approximately 35% of total revenue
- 347 Core Accounts as of June 30, 2023
 - Core Accounts represent approximately 60% of total revenue

Broad sales reach

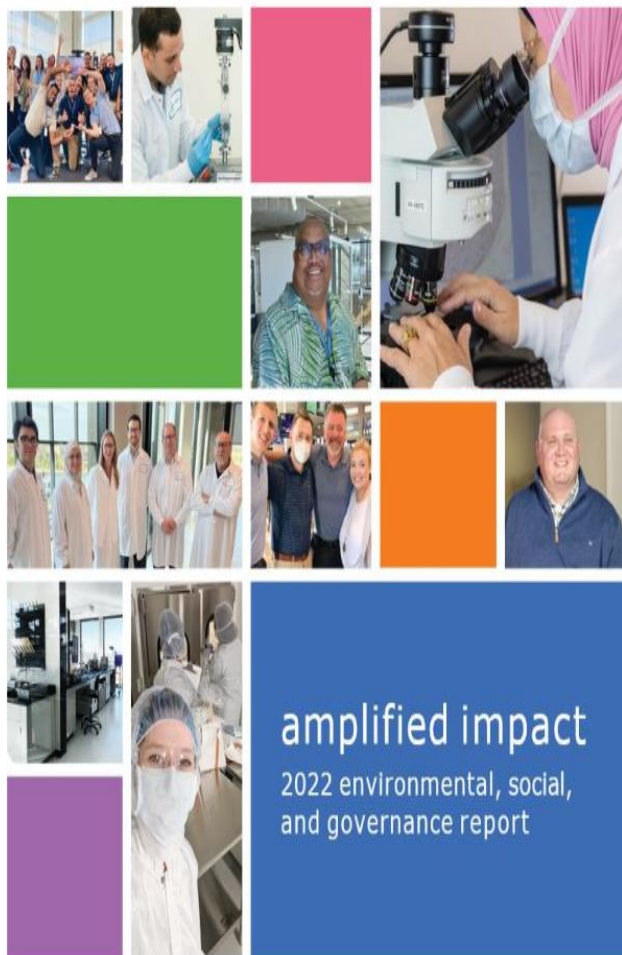
- U.S. direct sales team
 - 115 direct sales professionals at the end of Q2 2023
- Supplemented by independent agencies
- Revenue from direct sales channel represented approximately 90% of total revenue

Expand the opportunity in nerve repair

Expanding Core Business: Market Expansion & Development; Product Pipeline; International



revolutionizing the science of nerve repair®



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,
& President
J&J (Ethicon)



Peter J. Mariani
Executive Vice President
and Chief Financial
Officer
Guidant, Lensar, Hansen



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



Maria Martinez
Chief Human
Resources Officer
HSNi, Bausch + Lomb



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



Erick DeVinney
VP, Peripheral Nerve
Science and Clinical
Innovation
Angiotech, PRA Intl



Mike Donovan
VP, Operations
Zimmer



Jens Schoeder Kemp
Chief Marketing Officer
Ambu, Pera International



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



Doris Quackenbush
Vice President of Sales
Convatec

The Axogen platform for nerve repair



- Exclusively focused on peripheral nerve repair with a differentiated platform
- 10+ years of demonstrated clinical outcome consistency
- Over 200 peer-reviewed clinical publications
- Over 75,000 Avance® Nerve Grafts implanted
- Significant barriers to competitive entry
- 115 U.S. sales reps
- Patient activation and surgeon education capabilities

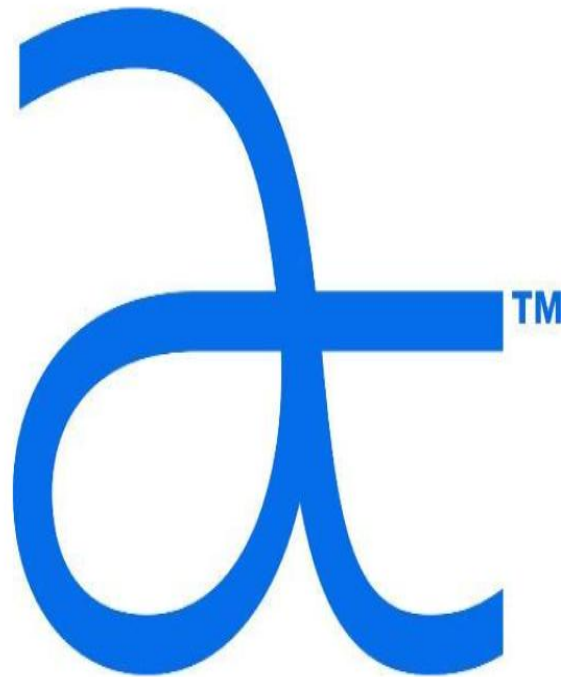


revolutionizing the science of nerve repair®

CONFIDENTIAL

Appendix

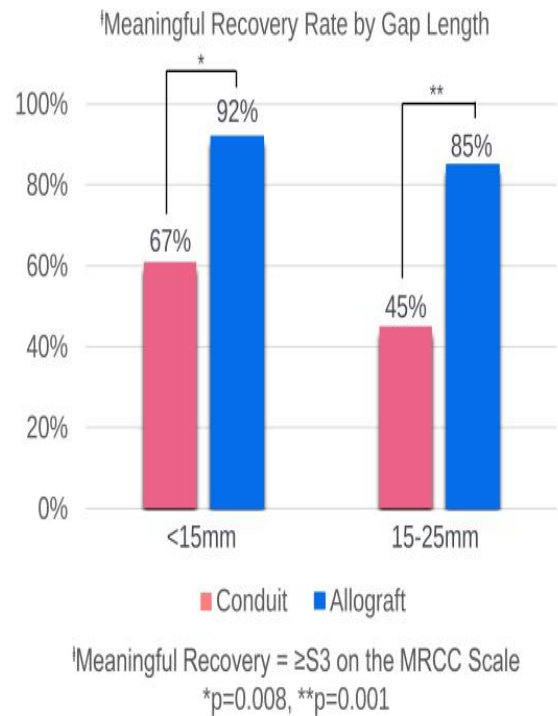
- Key Clinical Data
- Historical Core and Active Accounts
- CMS outpatient and ASC reimbursement rates
- Total Addressable Market
- Cash, debt, and capital structure
- Axogen product portfolio and indications for use



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

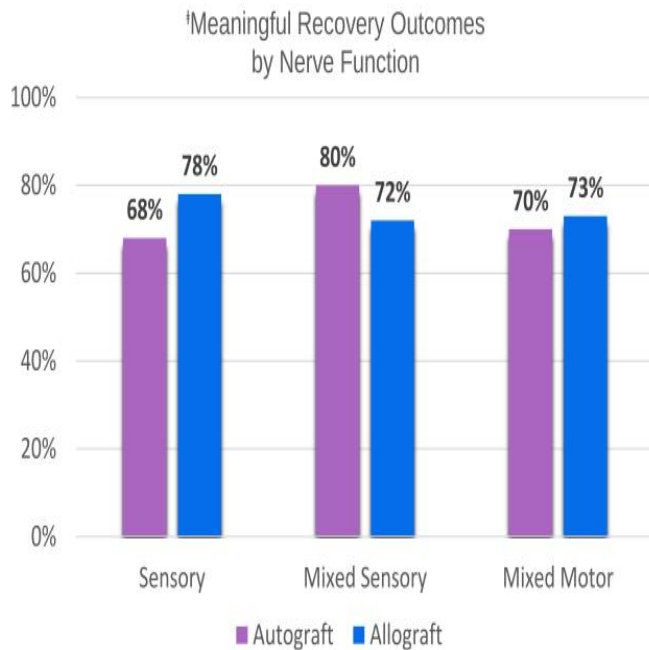
“Leversedge et al., A Multicenter Matched Cohort Study of Processed Nerve Allograft and Conduit in Digital Nerve Reconstruction” – Journal of Hand Surgery, September 2020⁴⁸

- 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



Study finds Avance Nerve Graft (allograft) clinical outcomes recovery rates comparable to nerve autograft

“Safa et al., A Propensity Matched Cohort Study on Outcomes from Processed Nerve Allograft and Nerve Autograft in Upper Extremity Nerve Repairs”⁴⁹



Presented at American Society for Surgery of the Hand (ASSH), Oct 2020

- 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

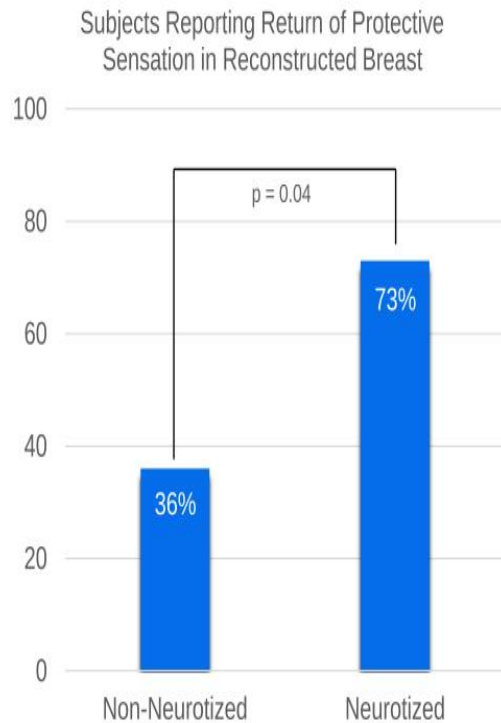
Historical data on Nerve Autograft^{50,51,52,53,54,55}, Mixed Nerve: 57-80%; Digital Nerve: 60-88%



revolutionizing the science of nerve repair®

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 2021⁵⁹

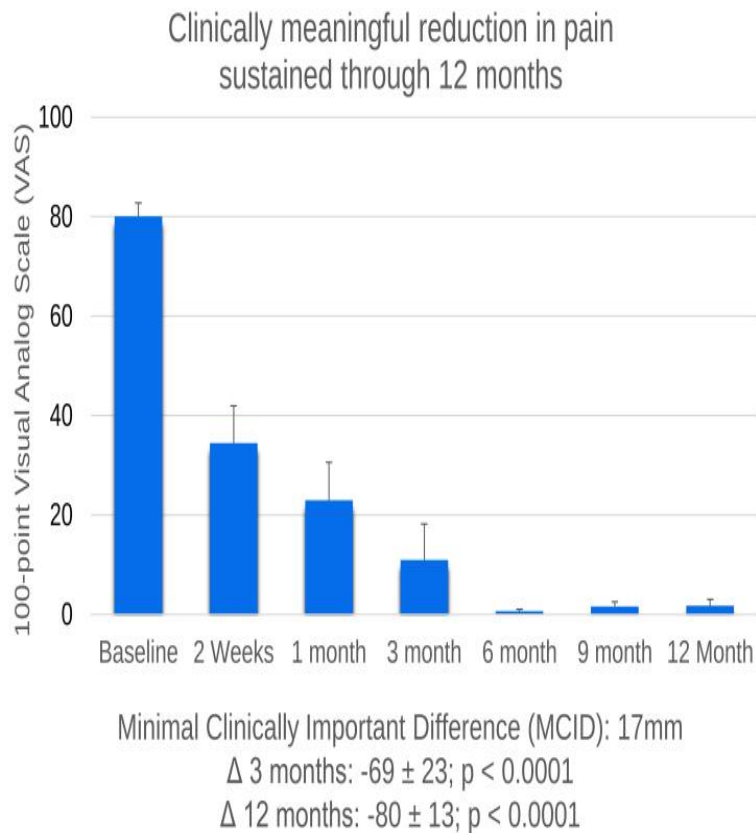


- Early outcomes from a single center study, as part of the Sensation-NOW registry
- 36 breast reconstructions that included:
 - 22 breast reconstructions with Resensation[®]
 - 14 standard non-neurotized breast reconstructions
- Return of Protective Sensation (p=0.04)
 - 73% of the Resensation group
 - 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 REPOSESM pilot study analysis demonstrates clinically significant improvement for subjects with chronic neuropathic pain when using Axoguard Nerve Cap[®] following neurectomy⁶⁰

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

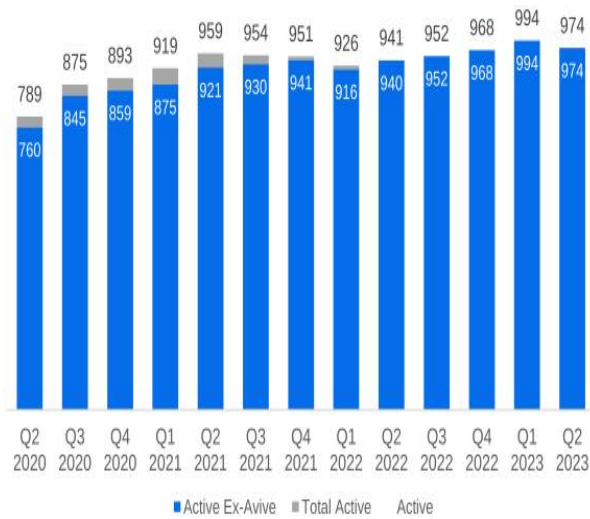
- Significant & clinically meaningful reduction in pain
- Significant and clinically meaningful improvements in Fatigue, Physical Function, Sleep Disturbance, Pain Interference, Pain Intensity, and Pain Behavior as measured by the validated PROMIS[®] measures
- Positive indicators for reduction in pain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



Historical Active and Core Accounts

Active Accounts

6 orders in the last 12 months



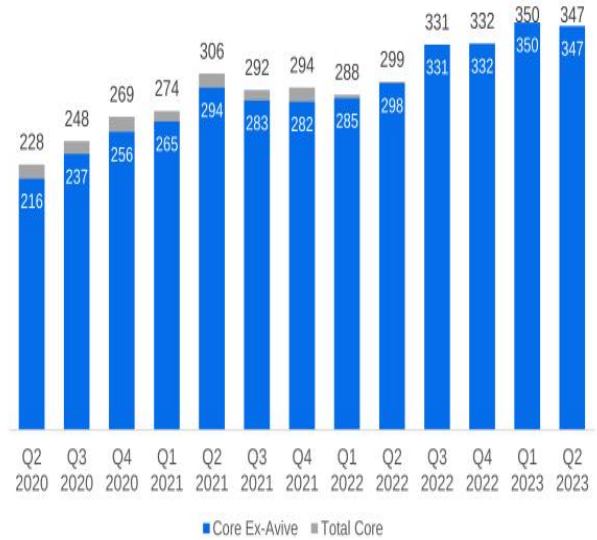
	Q220	Q320	Q420	Q121	Q221	Q321	Q421	Q122	Q222	Q322	Q422	Q123	Q223
Active Accounts	789	875	893	919	959	954	951	926	941	952	968	994	974
*Adjusted Active Acct	760	845	859	875	921	930	941	923	940	952	968	994	974

Active Accounts typically contribute ≈85% of total revenue

Top 10% of Active Accounts typically contribute ≈35% of total revenue

Core Accounts

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



	Q220	Q320	Q420	Q121	Q221	Q321	Q421	Q122	Q222	Q322	Q422	Q123	Q223
Core Accounts	228	248	269	274	306	292	294	288	299	331	332	350	347
*Adjusted Core Accou	216	237	256	265	294	283	282	285	298	331	332	350	347

Core Accounts typically contribute ≈60% of total revenue

* 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.



revolutionizing the science of nerve repair®

2024 CMS Proposed outpatient reimbursement rates - hospital and ASC

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	2023	2024 Proposed	5Y % Change	2019	2023	2024 Proposed	5Y % Change
64912	Nerve allograft repair ²	5432	\$4,566	\$6,179	\$6,504	42.44%	\$1,920	\$4,057	\$4,638	141.56%
64910	Conduit or vein allograft repair ²	5432	\$4,566	\$6,179	\$6,504	42.44%	\$2,613	\$3,805	\$4,416	69.00%
64885	Autograft repair (head and neck ≤4cm) ³	5432	\$4,566	\$6,179	\$6,504	42.44%	\$1,920	\$2,632	\$4,659	142.66%
64886	Autograft repair (head and neck >4cm) ⁶	5432	\$4,566	\$6,179	\$6,504	42.44%	\$3,127	\$4,375	\$3,006	-3.87%
64890	Autograft repair (hand and foot ≤4cm) ³	5432	\$4,566	\$6,179	\$6,504	42.44%	\$3,075	\$2,602	\$4,712	53.24%
64891	Autograft repair (hand and foot >4cm) ²	5432	\$4,566	\$6,179	\$6,504	42.44%	\$1,920	\$3,383	\$3,840	100.00%
64892	Autograft repair (arm and leg ≤4cm) ²	5432	\$4,566	\$6,179	\$6,504	42.44%	\$1,920	\$3,383	\$4,715	145.57%
64893	Autograft repair (arm and leg >4cm) ²	5432	\$4,566	\$6,179	\$6,504	42.44%	\$1,920	\$3,383	\$4,781	149.01%
64897	Autograft repair (arm and leg ≤4cm multiple strands) ³	5432	\$4,566	\$6,179	\$6,504	42.44%	\$1,920	\$3,660	\$4,148	116.04%
64895-96,98	Autograft repair (all other nerve type) ⁵	5432	\$4,566	\$6,179	\$6,504	42.44%	\$1,920	\$2,632	\$3,006	56.56%
64834-36, 40, 56, 57, 62-64	Direct Repair (other hand / foot, arm/leg, repair / transpose, facial, low back), ⁵	5432	\$4,566	\$6,179	\$6,504	42.44%	\$1,920	\$2,632	\$3,006	56.56%
64865	Direct Repair of facial nerve ²	5432	\$4,566	\$6,179	\$6,504	42.44%	\$1,920	\$3,383	\$3,840	100.00%
64831, 61	Direct Repair (digital, brachial plexus/arm) ⁴	5431	\$4,566	\$ 1,798	\$1,845	-59.59%	\$1,920	\$854	\$875	-54.43%
64858	Direct Repair (sciatic) ²	5431	\$4,566	\$ 1,798	\$1,845	-59.59%	\$1,920	\$1,481	\$1,499	-21.93%

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/legs ≤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 Center for Medicare and Medicaid Services (CMS): Proposed Physician Fee Schedule (PFS)

CPT Codes ³	Descriptor	Physician Fee Schedule (PFS)			
		2019	2023	2024 Proposed	5Y % Change
64912	Nerve allograft repair	\$804	\$908	\$883	9.8%
64910	Conduit or vein allograft repair	\$825	\$772	\$751	-9.0%
64885 to 64898*	Autograft repair	\$1,096 to \$1,495	\$1,065 to \$1,444	\$1,035 to \$1,404	-5.6% to -6.1%
64831 to 64861*	Direct Repair	\$713 to \$1,604	\$708 to \$1,560	\$689 to \$1,523	-3.4% to -5.0%

*excludes add-on procedure codes



Estimated Trauma total addressable market

Patient Population ^(a)	Source	Adjustments and Rationale
<p>136,943,000 Annual emergency department visits in the U.S.</p>	<p>2015 National Hospital Ambulatory Medical Care Survey (Table 1)</p>	
<div style="border: 1px solid black; padding: 5px; text-align: center;"> <p>30,238,000 Annual emergency department visits <u>due to injury</u> in the U.S.</p> <p>✖</p> <p>4.76% Percentage of emergency department visits <u>with nerve injury</u></p> <p>⊞</p> </div>	<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>	<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%.
<div style="border: 1px solid black; padding: 5px; text-align: center;"> <p>1,440,000 Annual emergency department visits with nerve injury in the U.S.</p> <p>✖</p> <p>46.2% Percentage of ED nerve injuries estimated to be treated surgically</p> <p>⊞</p> <p>~665,000</p> <p>Annual ED visits with nerve injury estimated to be treated surgically in the U.S., excluding revisions</p> </div>	<p><i>Noble, et al: J Trauma, Volume 45(1) July 1998.116-122</i></p>	<ul style="list-style-type: none"> 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
<div style="border: 1px solid black; padding: 10px; margin-bottom: 10px;"> <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> </div> <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.

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

	Projected Incidence ^(a)	×	Weighted Average Procedure Value	=	Estimated Total Addressable Market
Trauma	700,000 100%		\$2,715		\$1,900M 100%
Transection injuries >5mm (b)	203,000 29%		\$5,515		\$1,120M 59%
Transection injuries <5mm	198,000 29%		\$1,200		\$238M 12%
Protection (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).

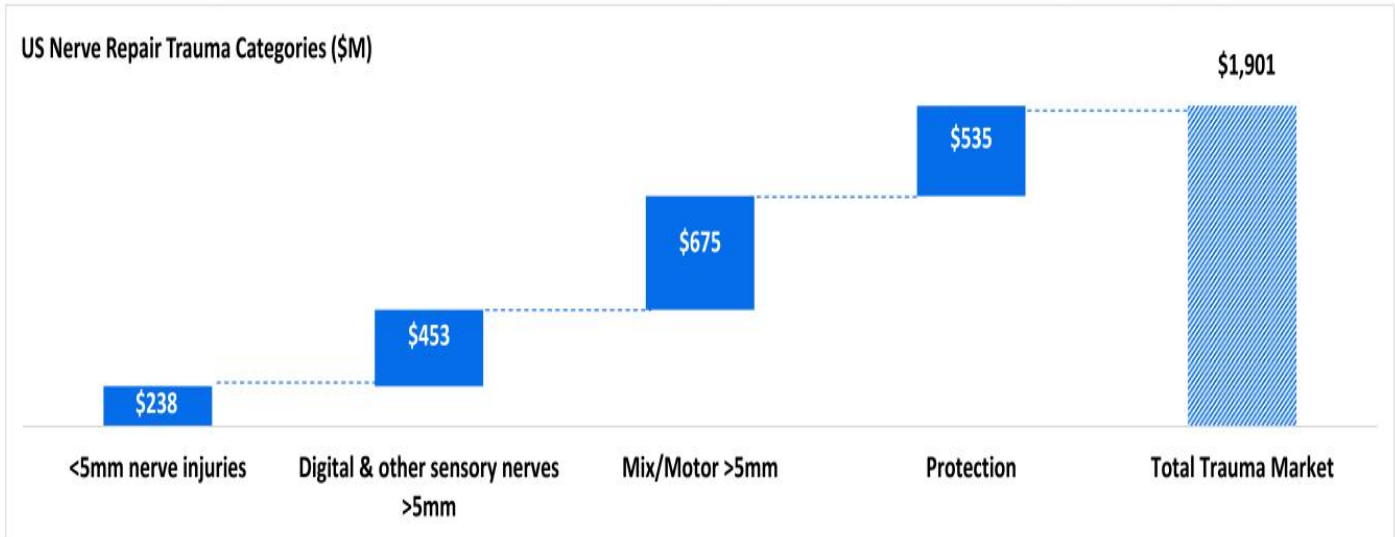
b) Transection injuries > 5mm assumes a factor of 1.22 nerve repairs per procedures, and utilization of the Axogen portfolio of products, based upon data observed in the RANGER® registry.

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



revolutionizing the science of nerve repair®

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



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

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	June 30, 2023
Cash, Cash Equivalents, and Investments	\$40.8 million
Total Long-term Debt	\$50.0 million*

Capital Structure (shares)	June 30, 2023
Common Stock	42,979,541
Common Stock Options, RSUs, PSUs	8,587,824
Common Stock and Common Stock Equivalents	51,567,365

* Total long-term debt includes debt proceeds under the terms of the agreement with Oberland Capital, inclusive of 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, CE Marked
- 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.
- Indications for Use (ROW): Axoguard Nerve Connector is intended 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.
- Contraindications: This device is derived from a porcine source and should not be used for patients with known sensitivity to porcine material.

Axoguard Nerve Protector®

- Regulatory Classifications: Class II Medical Devices - 510(k) cleared, CE Marked
- 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.
- Contraindications: This device is derived from a porcine source and should not be used for patients with known sensitivity to porcine material.

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.
- 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. Note: This device is not intended for use in vascular applications.

Axogen comprehensive portfolio of products (Cont'd)

- Axoguard HA+ Nerve Protector®
 - Regulatory Classifications: Class II Medical Devices - 510(k) cleared
 - Indication for Use: Axoguard HA+ Nerve Protector is indicated for the management of peripheral nerve injuries where there is no gap.
 - 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. NOTE: This device is not intended for use in vascular applications.



nasdaq: axgn



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

Footnotes

Trauma Market Data:

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.

Carpal Tunnel Revisions & Cubital Tunnel Market Data

5. Medicare National HCPCS Aggregate Summary Table CY2016. <https://data.cms.gov/Medicare-Physician-Supplier/Medicare-National-HCPCS-Aggregate-Summary-Table-CY/tra-d83c/data>
6. Sotereanos, 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

OMF Market Data

9. Lin, et al. Systematic Review and Meta-Analysis on Incidence of Altered Sensation of Mandibular Implant Surgery - *PLoS One*. 2016; 11(4): e0154082.
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, Intramucosal 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.

Breast Neurotization Market Data, and Other Clinical References

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. Badyak, 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. Zhukauskas et al., Comparative Study of Porcine Small Intestine Submucosa and Cross-Linked Bovine Type I Collagen as a Nerve Conduit. *JHS GO* 3(5), 282-288 Sep 2021
33. Hodde, et al. Vascular endothelial growth factor in porcine-derived extracellular matrix. *Endothelium*. 2001; 8(1): 11-24.
34. Data on file at Axogen
35. 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.
36. Pet MA, Ko JH, Friedly JL, Smith DG. Traction Neurectomy for Treatment of Painful Residual Limb Neuroma in Lower Extremity Amputees *J Orthop Trauma*. 29 (9), e321-5 Sep 2015.
37. 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.



revolutionizing the science of nerve repair®

Footnotes

38. Galeano M, et al. A free vein graft cap influences neuroma formation after nerve transection. *Microsurgery*. 2009;29(7):568-572.
39. Stokvis A. Surgical management of painful neuromas. Rotterdam, The Netherlands: Optima Grafische Communicatie; 2010.
40. 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.
41. 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.
42. Rajput K, et al. Painful neuromas. *The Clinical Journal of Pain*. 2012;28(7):639-645
43. 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.
44. Fallat L. Cryosurgery or sclerosing injections: which is better for neuromas. *Podiatry Today*. 2004;17(6):58-66.
45. Bradley MD. Plantar neuroma: analysis of results following surgical excision in 145 patients. *South Med J*. 1976;69:853-845.
46. 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.
47. Record RD, Hillegonds D, Simmons C, Tullius R, Rickey FA, Elmore D, Badylak SF. In vivo degradation of 14C-labeled small intestinal submucosa (SIS) when used for urinary bladder repair. *Biomaterials*. 2001 Oct;22(19):2653-9.
48. Leversedge FJ, Zoldos J, Nydick J, Kao DS, Thayer W, MacKay B, McKee D, Hoyen H, Safa B, Buncke GM. A Multicenter Matched Cohort Study of Processed Nerve Allograft and Conduit in Digital Nerve Reconstruction. *J Hand Surg Am*. 2020 Dec;45(12):1148-1156.
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. Safa B, Jain S, Desai MJ, Greenberg JA, Niacaris TR, Nydick JA, Leversedge FJ, Megee DM, Zoldos J, Rinker BD, McKee DM, MacKay BJ, Ingari JV, Nesti LJ, Cho M, Valerio IL, Kao DS, El-Sheikh Y, Weber RV, Shores JT, Styron JF, Thayer WP, Przylecki WH, Hoyen HA, Buncke GM. Peripheral nerve repair throughout the body with processed nerve allografts: Results from a large multicenter study. *Microsurgery*. 2020 Jul;40(5):527-537.
51. 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
52. Roganovic Z, Pavlicevic G. Difference in recovery potential of peripheral nerves after graft repairs. *Neurosurgery*. 2006 Sep;59(3):621-33; discussion 621-33.
53. Frykman G, Gramyk K. Results of nerve grafting. In: Gelberman R, ed. *Operative nerve repair and reconstruction*. Philadelphia: JB Lippincott, 1991:553-567
54. 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.
55. 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.
56. 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.
57. U.S. Centers for Medicare and Medicaid Services. Medicare Claims standard analytic file. 2018.
58. Styron JF, Lans-Valera J. Comparative Effectiveness Evaluating Allograft, Autograft and Conduit Nerve Repairs: A Systematic Review. American Association for Hand Surgery. Virtual Annual Meeting, January 2021
59. Momeni A, Meyer S, Shefren K, Januszky M. Flap Neurotization in Breast Reconstruction with Nerve Allografts: 1-year Clinical Outcomes. *Plast Reconstr Surg Glob Open*. 2021 Jan 12;9(1):e3328
60. to Pereira R, Dauphinee D, Frania S, Garrett A, Martin C, Van Gils C, Thomajan C. Clinical evaluation of an innovative nerve termination cap for treatment and prevention of stump neuroma pain: Results from a prospective pilot clinical study. *Fastrac*. 2022; 2(2): 100179.

© 2022 Axogen Corporation. The stylized "a" logo and Avance Nerve Graft are trademarks of Axogen Corporation. Axoguard is a registered trademark of Axogen Corporation. Axoguard Nerve Connector and Axoguard Nerve Protector are manufactured in the United States by Cook Biotech Incorporated, West Lafayette, Indiana, and are distributed exclusively by Axogen Corporation.



revolutionizing the science of nerve repair®

LB-0588

55

The Axogen platform for nerve repair



- Exclusively focused on peripheral nerve repair with a differentiated platform
- 10+ years of demonstrated clinical outcome consistency
- Over 200 peer-reviewed clinical publications
- Over 75,000 Avance® Nerve Grafts implanted
- Significant barriers to competitive entry
- 115 U.S. sales reps
- Patient activation and surgeon education capabilities



revolutionizing the science of nerve repair®

CONFIDENTIAL

