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 3, 2022

AXOGEN, INC.

(Exact Name of Registrant as Specified in Charter)

Minnesota	**001-36046**	**41-1301878**
(State or Other Jurisdiction of Incorporation or Organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

13631 Progress Boulevard, Suite 400 Alachua, Florida	**32615**
(Address of principal executive offices)	(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 August 3, 2022, Axogen, Inc. (the "Company") issued a press release announcing its second quarter 2022 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 3, 2022, the Company also posted an updated corporate presentation to its website at https://ir.axogeninc.com/news-events. The Company may use the corporate presentation from time to time in conversation with analysts, investors, and others. A copy of the corporate presentation is furnished as Exhibit 99.2.

The information in this Item 7.01, including Exhibit 99.2, is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section and shall not be deemed incorporated by reference into any filing under the Securities Act or Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated August 3, 2022
99.2	Axogen Inc. corporate Presentation, dated August 3, 2022
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 3, 2022

By: /s/ Bradley L. Ottinger

Bradley L. Ottinger

General Counsel and Chief Compliance Officer

Axogen, Inc Reports 2022 Second Quarter Financial Results

ALACHUA and TAMPA, FL – August 3, 2022 –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, 2022.

Second Quarter 2022 and Business Highlights

- Net revenue was $34.5 million during the second quarter, an increase of 3% over the second quarter of 2021.
- Excluding revenue from Avive® Soft Tissue Membrane of $1.8 million in the second quarter of 2021, revenue in the second quarter of 2022 increased 9%. The company voluntarily suspended market availability of Avive on June 1, 2021.
- Gross margin was 81.8% for the quarter compared to 78.9% in the second quarter of 2021 which includes the impact of a one-time charge of approximately $1.4 million reflecting the write-down of inventory and related production costs related to the suspension of Avive.
- Adjusted net loss for the quarter was $2.6 million, or $0.06 per share, compared to adjusted net loss of $3.7 million, or $0.09 per share, in the second quarter of 2021.
- Adjusted EBITDA loss was $1.6 million for the quarter, compared to an adjusted EBITDA loss of $2.4 million in the second quarter of 2021.
- The balance of all cash and cash equivalents and investments on June 30, 2022 was $64.3 million, as compared to a balance of $73.7 million on March 31, 2022. The net change includes capital expenditures of $3.9 million related to the construction of our new processing facility in Dayton, OH, and $5.5 million net operating cash burn including a $1.8 million increase in inventory primarily related to accelerated purchases of certain production materials and donor inventory.

“We are pleased with our execution in the quarter as procedure volumes improved and hospitals continued to adapt to evolving challenges," commented Karen Zaderej, chairman, CEO, and president of Axogen, Inc. “As we announced in May, we are happy with the positive top-line results of our RECON℠ study, which is a meaningful addition to our growing body of clinical data. We are well positioned as we enter the second half of the year and look forward to leveraging our data and broad commercial capabilities to drive engagement and adoption with surgeons seeking advanced solutions for their peripheral nerve injury patients.”

Additional Operational and Business Highlights

- Core Accounts totaled 299, an increase of 4% sequentially. Excluding the impact of Avive purchases in the second quarter of 2021, Core Accounts grew 1% over an adjusted prior year

level of 294 which excludes the impact of Avive. Revenue from Core Accounts continued to represent approximately 60% of total revenue.

- Active Accounts totaled 941, an increase of 2% sequentially. Excluding the impact of Avive purchases in the second quarter of 2021, Active accounts grew 2% over an adjusted prior year level of 921. Revenue from the top 10% of Active Accounts continued to represent approximately 35% of total revenue.
- Announced positive top-line results from the RECON Phase 3 Study of Avance®, which met its primary endpoint and will provide Level 1 clinical evidence in support of Avance Nerve Graft for peripheral nerve repairs.
- Completed enrollment of 86 subjects in the comparative phase study of REPOSE℠ (Axoguard Nerve Cap® compared to standard of care) in July. We anticipate topline data read out from the study in the fourth quarter of 2023.
- Ended the quarter with eight new peer-reviewed clinical publications featuring Axogen's nerve repair product portfolio, which now totals 196.
- Ended the quarter with 116 direct sales representatives, consistent with the first quarter of 2022, and compared to 109 one year ago.

2022 Financial Guidance

The Company continues to expect 2022 revenue will be in the range of $135.0 million to $142.0 million. This represents approximately 10% to 15% growth over 2021 revenue excluding the impact of $4.1 million of Avive revenue in 2021. Full-year 2022 gross margin is expected to be above 80%.

Conference Call

The Company will host a conference call and webcast for the investment community today at 4:30 p.m. ET. Investors interested in participating in the conference call by phone may do so by dialing toll free at (888) 428-7458 or use the direct dial-in number at (404) 267-0368. 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 test for non-inferiority between the 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 REPOSE

A Multicenter, Prospective, Randomized and Subject Blinded Comparative Study of Axoguard Nerve Cap and Neurectomy for the Treatment of Symptomatic Neuroma and Prevention of Recurrent End-Neuroma Pain (REPOSE) is the company's post-market study comparing placement of Axoguard Nerve

Cap to standard neurectomy alone for subjects with symptomatic neuroma pain. The study design includes a 15-subject open-label pilot phase and up to 86 subjects in a randomized comparative phase. The study requires a one-year follow-up period for all subjects and is designed to assess changes in pain scores as measured by Visual Analog Scale, quality of life outcomes, medication usage, and subject satisfaction.

About Axogen

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

Axogen's platform for peripheral nerve repair features a comprehensive portfolio of products, including Avance Nerve Graft, a biologically active off-the-shelf processed human nerve allograft for bridging severed peripheral nerves without the comorbidities associated with a second surgical site; Axoguard Nerve Connector®, a porcine submucosa extracellular matrix (ECM) coaptation aid for tensionless repair of severed peripheral nerves; Axoguard Nerve Protector®, a porcine submucosa ECM product used to wrap and protect damaged peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments; 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. Actual results or event could differ materially from those described in any forward-looking statements as a result of various factors, including, without limitation, statements related to the impact of COVID-19 on our business, including but not limited to global supply chain issues, hospital staffing challenges and its impact on our business, statements regarding our growth, our financial guidance and performance, product development, product potential, regulatory process and approvals, APC renovation timing and expense, sales growth,

product adoption, market awareness of our products, anticipated capital requirements, including the potential of future financings, data validation, expected clinical study enrollment, timing and outcomes, our visibility at and sponsorship of conferences and our educational events, regulatory process and approvals and other factors, including legislative, regulatory, political, geopolitical, and economic developments, including global business disruption caused by Russia's invasion of Ukraine and related sanctions, not within our control. The forward-looking statements are and will be subject to risks and uncertainties, which may cause actual results to differ materially from those expressed or implied in such forward-looking statements. Forward-looking statements contained in this press release should be evaluated together with the many risks and uncertainties that affect our business and our market, particularly 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, as well as other risks and cautionary statements set forth in our filings with the U.S. Securities and Exchange Commission. Forward-looking statements are not a guarantee of future performance, and actual results may differ materially from those projected. The forward-looking statements are representative only as of the date they are made and, except as required by applicable law, we assume no responsibility to publicly update or revise any forward-looking statements, whether as a result of new information, future events, changed circumstances, or otherwise.

About Non-GAAP Financial Measures

To supplement our condensed consolidated financial statements, we use the non-GAAP financial measures of EBITDA, which measures earnings before interest, income taxes, 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 Income or Loss and Adjusted Net Income or 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 Axogen's GAAP financial measures to the corresponding non-GAAP measures 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.

Contact:
Axogen, Inc.
Ed Joyce, Director, Investor Relations
ejoyce@axogeninc.com

Axogen, Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(In Thousands, Except Share and Per Share Amounts)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 11,822	$ 32,756
Restricted cash	6,251	6,251
Investments	46,210	51,330
Accounts receivable, net of allowance for doubtful accounts of $595 and $276, respectively	20,370	18,158
Inventory	19,222	16,693
Prepaid expenses and other	2,900	1,861
Total current assets	106,775	127,049
Property and equipment, net	70,988	62,923
Operating lease right-of-use assets	14,975	15,193
Intangible assets, net	3,346	2,859
Total assets	$ 196,084	$ 208,024
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 21,838	$ 22,459
Current maturities of long-term lease obligations	1,762	1,834
Total current liabilities	23,600	24,293
Long-term debt, net of debt discount and financing fees	45,263	44,821
Long-term lease obligations	20,655	20,798
Debt derivative liabilities	4,876	5,562
Total liabilities	94,394	95,474
Commitments and contingencies - see Note 12		
Shareholders' equity:		
Common stock, $0.01 par value per share; 100,000,000 shares authorized; 42,134,504 and 41,736,950 shares issued and outstanding	420	417
Additional paid-in capital	351,117	342,765
Accumulated deficit	(249,847)	(230,632)
Total shareholders' equity	101,690	112,550
Total liabilities and shareholders' equity	$ 196,084	$ 208,024

Axogen, Inc.
Condensed Consolidated Statements of Operations
(unaudited)
(In Thousands, Except Per Share Amounts)

	Three Months Ended		Six Months Ended	
	June 30, 2022	June 30, 2021	June 30, 2022	June 30, 2021
Revenues	$ 34,454	$ 33,580	$ 65,461	$ 64,617
Cost of goods sold	6,284	7,092	11,830	12,264
Gross profit	28,170	26,488	53,631	52,353
Costs and expenses:				
Sales and marketing	19,669	19,250	40,557	37,224
Research and development	7,022	5,723	13,296	11,471
General and administrative	9,403	8,669	19,021	17,032
Total costs and expenses	36,094	33,642	72,874	65,727
Loss from operations	(7,924)	(7,154)	(19,243)	(13,374)
Other (expense) income:				
Investment income	32	29	(15)	63
Interest expense	(249)	(565)	(603)	(1,010)
Change in fair value of derivatives	434	(84)	686	(105)
Other expense	(33)	(124)	(40)	(132)
Total other expense, net	184	(744)	28	(1,184)
Net loss	$ (7,740)	$ (7,898)	$ (19,215)	$ (14,558)
Weighted average common shares outstanding — basic and diluted	41,994,618	41,080,898	41,900,000	40,894,405
Loss per common share — basic and diluted	$ (0.18)	$ (0.19)	$ (0.46)	$ (0.36)

Axogen, Inc.
RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES
Three and Six Months ended June 30, 2022 and 2021
(unaudited)
(In Thousands, Except Per Share Amounts)

	Three Months Ended		Six Months Ended	
	June 30, 2022	**June 30, 2021**	**June 30, 2022**	**June 30, 2021**
Net loss	$ (7,740)	$ (7,898)	$ (19,215)	$ (14,558)
Depreciation and amortization expense	777	682	1,550	1,501
Investment income	(32)	(29)	15	(63)
Income tax expense	33	52	33	47
Interest expense	249	565	(603)	1,009
EBITDA - non GAAP	$ (6,713)	$ (6,628)	$ (17,014)	(12,064)
Non cash stock-based compensation expense	4,910	3,805	7,588	6,499
Litigation and related costs	216	400	483	1,236
Adjusted EBITDA - non GAAP	$ (1,587)	$ (2,423)	(8,943)	(4,329)
Net loss	$ (7,740)	$ (7,898)	$ (19,215)	$ (14,558)
Non cash stock-based compensation expense	4,910	3,805	7,588	6,499
Litigation and related costs	216	400	483	1,236
Adjusted net loss - non GAAP	$ (2,614)	$ (3,693)	(11,143)	(6,823)
Weighted average common shares outstanding basic and diluted	41,994,618	41,080,898	41,900,000	40,894,405
Weighted average common shares outstanding - basis and diluted	$ (0.18)	$ (0.19)	$ (0.46)	$ (0.36)
Non cash stock-based compensation expense	$ 0.12	$ 0.09	$ 0.18	$ 0.16
Litigation and related costs	$ 0.01	$ 0.01	$ 0.01	$ 0.03
Adjusted net loss per common share - basis and diluted - non GAAP	$ (0.06)	$ (0.09)	$ (0.27)	$ (0.17)

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, 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	42,134,504	$ 420	$ 351,117	$ (249,847)	$ 101,690
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	42,134,504	$ 420	$ 351,117	$ (249,847)	$ 101,690
Three Months Ended June 30, 2021					
Balance at March 31, 2021	40,842,717	$ 408	$ 329,603	$ (210,307)	119,704
Net loss	—	$ —	$ —	$ (7,898)	$ (7,898)
Stock-based compensation	—	—	3,804	—	3,804
Issuance of restricted and performance stock units	44,411	$ —	$ —	$ —	$ —
Exercise of stock options and employee stock purchase plan	449,980	5	3,088	—	3,093
Balance at June 30, 2021	41,337,108	$ 413	$ 336,495	$ (218,205)	$ 118,703
Six Months Ended June 30, 2021					
Balance at December 31, 2020	40,618,766	$ 406	$ 326,390	$ (203,647)	123,149
Net loss	—	—	—	(14,558)	(14,558)
Stock-based compensation	—	—	6,499	—	6,499
Issuance of restricted and performance stock units	138,944	1	(1)	—	—
Exercise of stock options and employee stock purchase plan	579,398	6	3,607	—	3,613
Balance at June 30, 2021	41,337,108	$ 413	$ 336,495	$ (218,205)	$ 118,703

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

	Six Months Ended	
	June 30, 2022	**June 30, 2021**
Cash flows from operating activities:		
Net loss	$ (19,215)	$ (14,558)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,418	1,405
Amortization of right-of-use assets	859	960
Amortization of intangible assets	132	96
Amortization of debt discount and deferred financing fees	442	227
Provision for bad debt	550	(65)
Provision for inventory write-down	928	2,455
Change in fair value of derivatives	(686)	105
Investment losses	145	31
Stock-based compensation	7,588	6,499
Change in operating assets and liabilities:		
Accounts receivable	(2,719)	(498)
Inventory	(3,458)	(3,341)
Prepaid expenses and other	(1,081)	199
Accounts payable and accrued expenses	(786)	(5,061)
Operating lease obligations	(856)	35
Cash paid for interest portion of operating and finance leases	—	(1)
Contract and other liabilities	—	(3)
Net cash used in operating activities	(16,739)	(11,515)
Cash flows from investing activities:		
Purchase of property and equipment	(9,086)	(10,924)
Purchase of investments	(6,024)	(23,966)
Proceeds from sale of investments	11,000	32,295
Cash payments for intangible assets	(852)	(692)
Net cash used in investing activities	(4,962)	(3,287)
Cash flows from financing activities:		
Proceeds from the issuance of long-term debt	—	15,000
Cash paid for debt portion of finance leases	(1)	(8)
Proceeds from exercise of stock options and ESPP stock purchases	767	3,612
Net cash provided by financing activities	766	18,604
Net decrease in cash, cash equivalents, and restricted cash	(20,935)	3,802
Cash, cash equivalents, and restricted cash, beginning of period	39,007	55,609
Cash, cash equivalents, and restricted cash, end of period	$ 18,073	$ 59,411
Supplemental disclosures of cash flow activity:		
Cash paid for interest, net of capitalized interest	$ —	$ 739
Supplemental disclosure of non-cash investing and financing activities:		
Acquisition of fixed assets in accounts payable and accrued expenses	$ 1,817	$ 3,035
Obtaining a right-of-use asset in exchange for a lease liability	$ 700	$ 371
Embedded derivative associated with the long-term debt	$ —	$ 1,173
Acquisition of intangible assets in accounts payable and accrued expenses	$ 186	$ 190

Corporate presentation

As of August 3, 2022

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. Actual results or event could differ materially from those described in any forward-looking statements as a result of various factors, including, without limitation, statements related to the impact of COVID-19 on our business, hospital staffing challenges and its impact on our business, statements regarding our growth, our financial guidance and performance, product development, product potential, regulatory process and approvals, APC renovation timing and expense, sales growth, product adoption, market awareness of our products, anticipated capital requirements, including the potential of future financings, data validation, expected clinical study enrollment, timing and outcomes, , our visibility at and sponsorship of conferences and our educational events, regulatory process and approvals and other factors, including legislative, regulatory, political, geopolitical, and economic developments, including global business disruption caused by Russia’s invasion of Ukraine and related sanctions, not within our control. The forward-looking statements are and will be subject to risks and uncertainties, which may cause actual results to differ materially from those expressed or implied in such forward-looking statements. Forward-looking statements contained in this presentation should be evaluated together with the many risks and uncertainties that affect our business and our market, particularly 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, as well as other risks and cautionary statements set forth in our filings with the U.S. Securities and Exchange Commission. Forward-looking statements are not a guarantee of future performance, and actual results may differ materially from those projected. The forward-looking statements are representative only as of the date they are made and, except as required by applicable law, we assume no responsibility to publicly update or revise any forward-looking statements, whether as a result of new information, future events, changed circumstances, or otherwise.

The Axogen platform for nerve repair

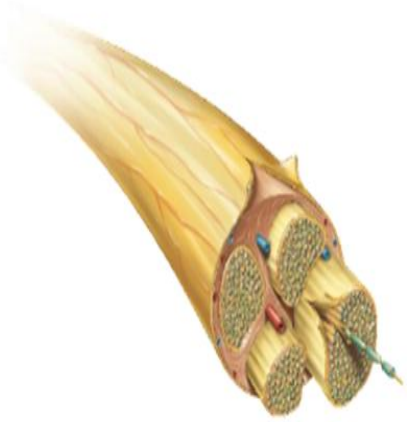
The function of nerves

Nerves are like wires

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

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

- Sensory
- Motor
- Autonomic



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

avance® nerve graft

Biologically active, processed human nerve allograft developed for bridging nerve discontinuities up to 70 mm

axoguard nerve connector®

Semi-translucent coaptation aid for nerve transections

axoguard nerve protector®

Extracellular matrix that remodels to protect injured nerves and reinforce nerve reconstructions

axoguard nerve cap®

Separates nerve end from surrounding environment to protect from mechanical stimulation and reduce painful neuroma formation

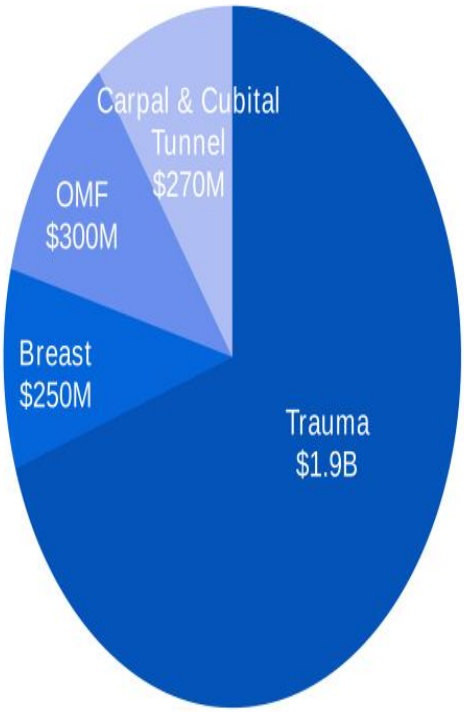
Connection	Protection	Termination

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

- Exclusively focused on peripheral nerve repair with a differentiated platform
- 10+ years of demonstrated clinical outcome consistency
- Featured in 196 peer-reviewed clinical publications
- Over 50,000 Avance® Nerve Grafts implanted
- Significant barriers to competitive entry
- FDA granted Avance Regenerative Medicine Advanced Therapy (RMAT) designation
- Commercial and surgeon education capabilities
- Solid balance sheet provides resources to execute business plan
- Experienced management team with strong track record of success

Targeted nerve markets (U.S.)

>$2.7 Billion*



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

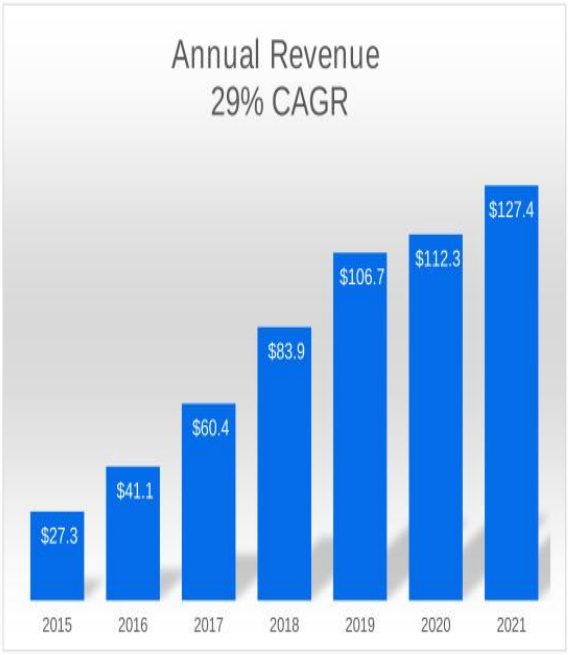
- Trauma: > 700,000
- Carpal Tunnel Revisions & Cubital Tunnel: 130,000
- Oral Maxillofacial (OMF): 56,000
- Breast Neurotization Procedures: 15,000

*$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.

Delivering strong, consistent revenue growth & gross margins

U.S. $ in millions



Operational Highlights

- Q2 growth increased 3% over Q1 2021. Excluding the impact of Avive, growth was approximately 9%*
- Procedure volumes improved as hospitals continued to adapt to evolving challenges
- Total Core accounts of 299 increased 4% sequentially
- Announced positive top-line results of RECON[SM] Trial
- Completed enrollment of comparative phase of REPOSE[SM] Study In July

81.8% Gross Margin for the quarter ended June 30, 2022
78.9% Gross Margin for the quarter ended June 30, 2021

* Axogen voluntarily suspended market availability of Avive® Soft Tissue Membrane on June 1, 2021. Avive revenue in the second quarter of 2021 was approximately $1.8 million and totaled approximately $4.1 million and $5.5 million for the years ended 2021 and 2020 respectively.

Guidance

2022 Annual Financial Guidance

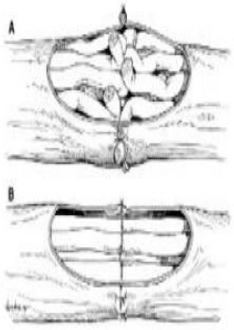
- Full-year 2022 revenue is still expected to be between $135 million and $142 million.
  - Represents approximately 10% to 15% growth over 2021 revenue excluding the impact of $4.1 million of Avive revenue in 2021.
- Full-year 2022 gross margin is still expected to remain above 80%.

Traditional TRANSECTION repair options are suboptimal

SUTURE

Direct suture repair of no-gap injuries

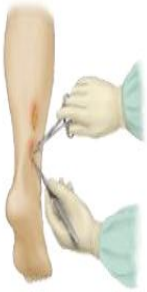
- Common repair method
- May result in tension to the repair leading to ischemia
- Concentrates sutures at the coaptation site



AUTOGRAFT

Traditional method despite several disadvantages

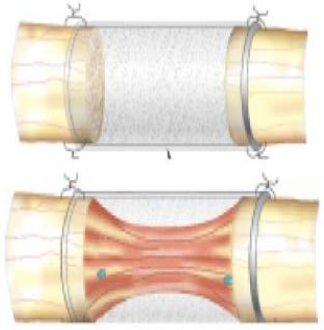
- Secondary surgery
- Loss of function and sensation at harvest site
- 27% complication rate including infection, wound healing and chronic pain [19]
- Limited availability of graft length and diameter



SYNTHETIC CONDUITS

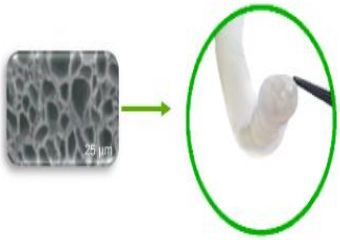
Convenient off the shelf option; limited efficacy & use

- 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 study[22]
- Eliminates need for an additional surgical site and risks of donor nerve harvest[22]
- May reduce OR time

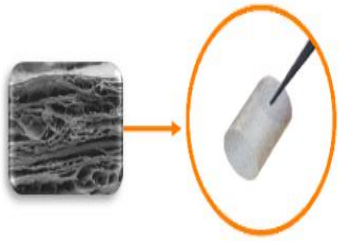
Structural support for regenerating axons

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

Revascularizes and remodels into patient's own tissue similar to autologous nerve[23]

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 site[26]
- Moves suture inflammation away from coaptation face[27, 28]

Remodels into vascularized patient tissue[28, 29, 30, 31, 32]

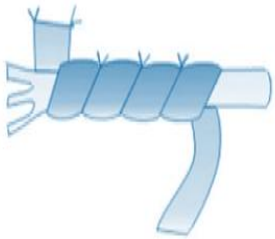
14 size options in lengths of 10mm and 15mm, and diameters up to 7mm

Traditional COMPRESSION repair options are suboptimal

VEIN WRAPPING

Autologous vein

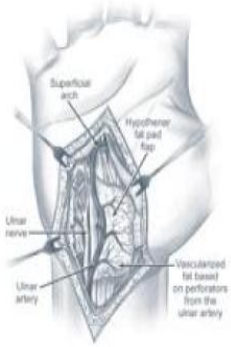
- Barrier to attachment to surrounding tissue
- Requires extra time and skill to perform spiral wrapping technique
- Second surgery site



HYPOTHENAR FAT PAD

Autologous vascularization flap

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



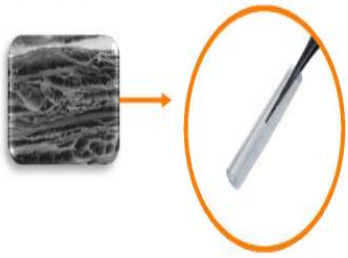
COLLAGEN WRAPS

Off-the-shelf

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

Axogen 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 process[33]
- Minimizes soft tissue attachments[34]

Allows nerve gliding

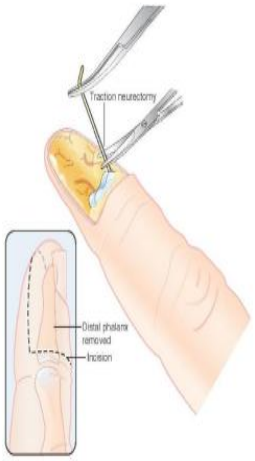
- Minimizes risk of entrapment[34]
- Creates a barrier between repair and surrounding tissue bed[34]
- ECM revascularizes and remodels into patient's own tissue[29,35]

Traditional STUMP NEUROMA options are suboptimal

TRACTION NEURECTOMY

Nerve placed in traction and cut to allow for retraction

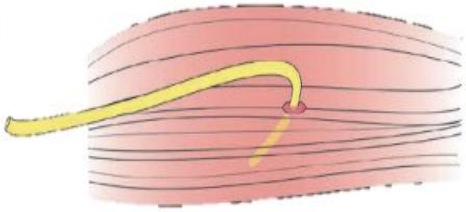
- Simply resecting the nerve results in subsequent neuroma formation and risk of secondary surgery
- Causes traction injury
- High risk of recurrence[36]



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]



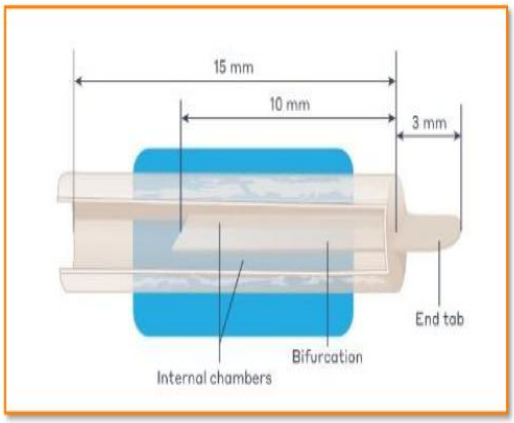
INJECTIONS

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

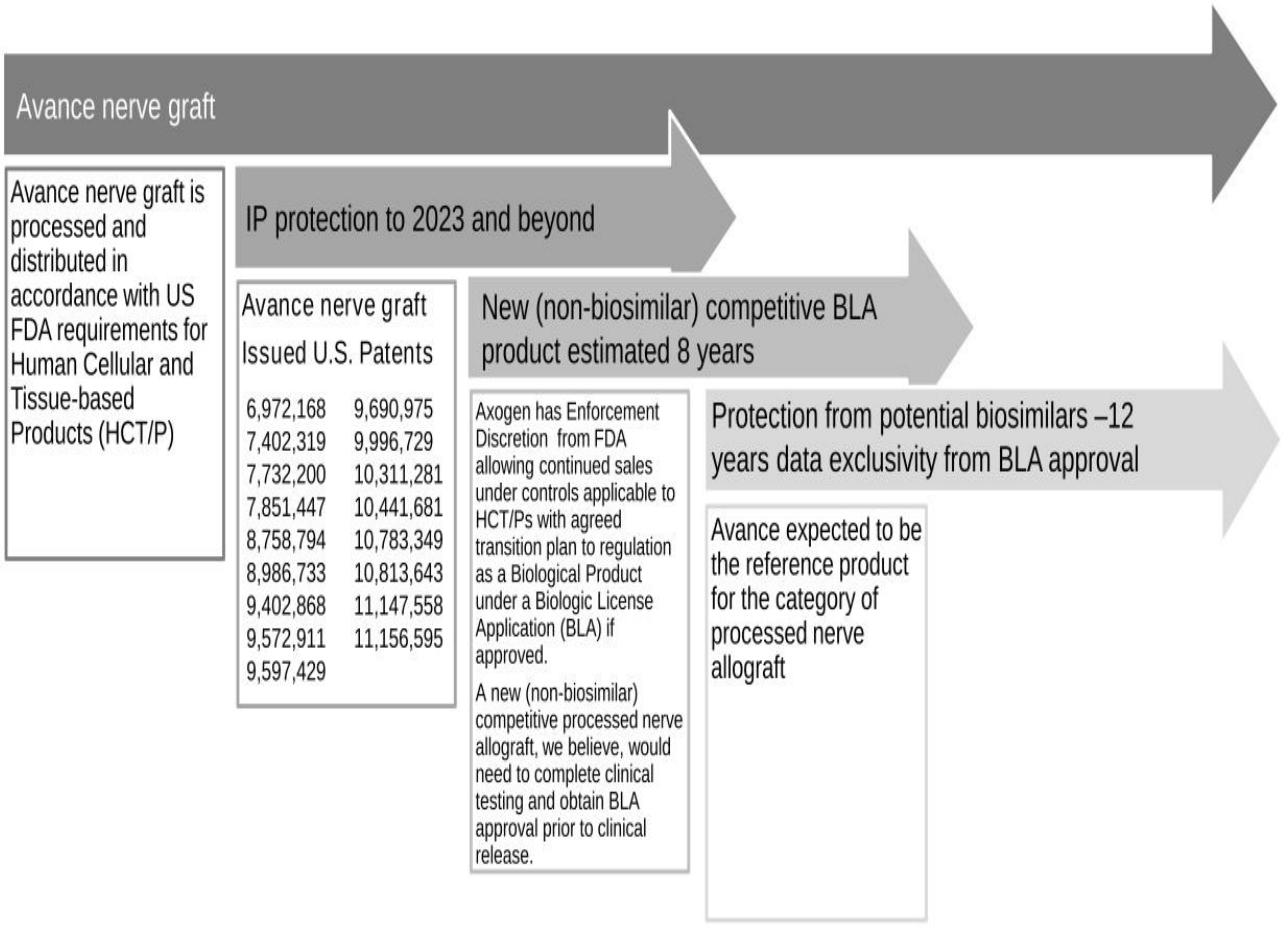
SIS Material allows for vascularization and gradual remodeling (as shown in animal studies)[46, 47]

- 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 IP and regulatory barriers to competitive entry



RECON℠: 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 Demographics: Balanced across both groups

	Conduit	Avance	Overall
Subjects, n	108	112	220
Female (%)	28.7%	30.4%	29.5%
Male (%)	71.3%	69.6%	70.5%
Age, years			
Mean	39.5	36.0	38.5
Min, Max	18, 69	18, 68	18, 69
Nerve Injury Gap Length, mm	12.9	13.4	13.1

RECON Study Topline Results

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 second half of 2023

Statistical superiority demonstrated at increasing gap lengths

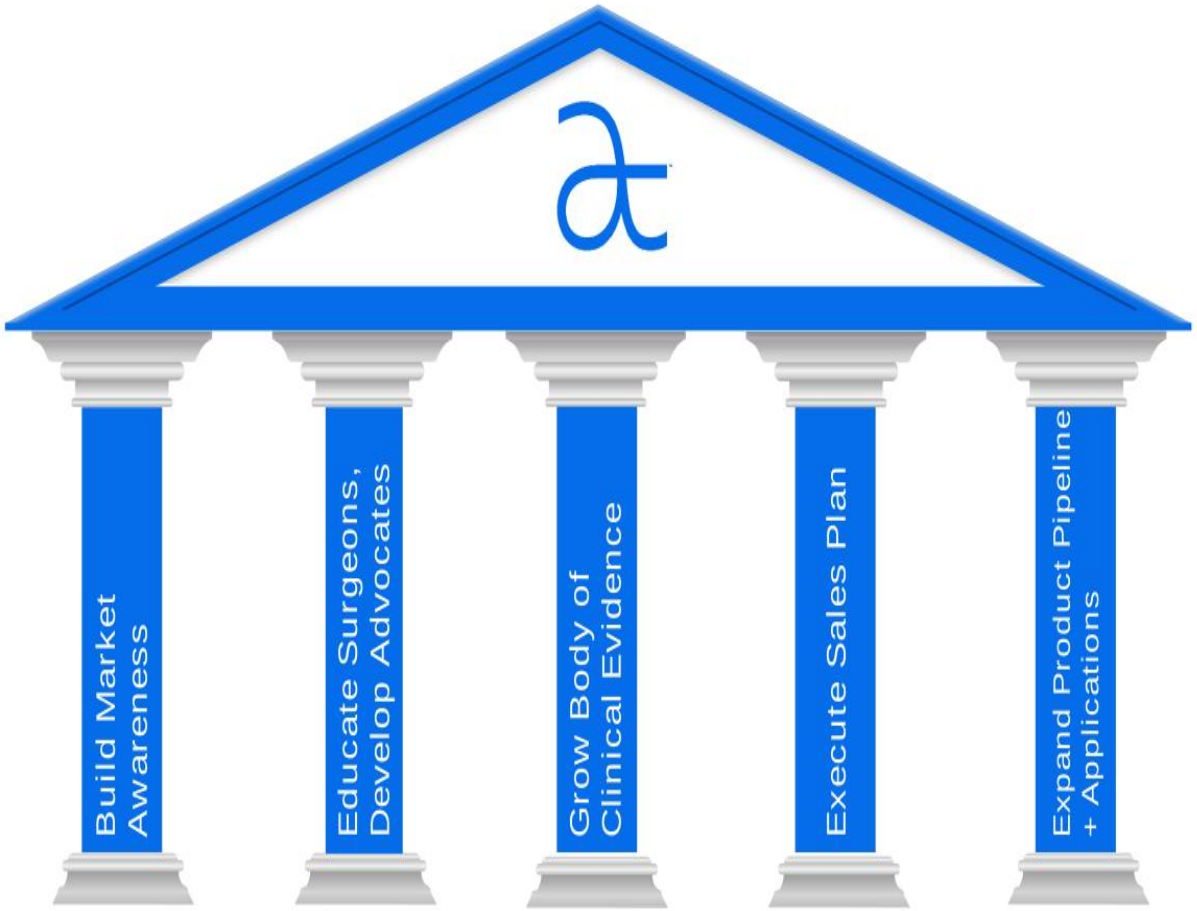
- ✓ Avance demonstrated statistical superiority for return of sensory function (measured by static two-point discrimination) as compared to conduits in gaps greater than 12 mm (p-value 0.021).
- ✓ Avance demonstrated statistical superiority for time to recovery of static two-point discrimination as compared 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 ≤ 6mm.

Market development strategy



Focus on building awareness among clinicians and patients

Build Market Awareness

- 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

Emphasis on education

Educate Surgeons, Develop Advocates

- In-person and virtual national education programs
- Providing customized multimodal learning programs to specific surgeon cohorts for advanced learning
- Ongoing interactive webinar series covering the principles of nerve repair
- Train more than three-quarters of all hand and micro-surgery fellows annually

Strong commitment to developing clinical evidence

Grow Body of 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

RECON℠ 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 in 2023

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

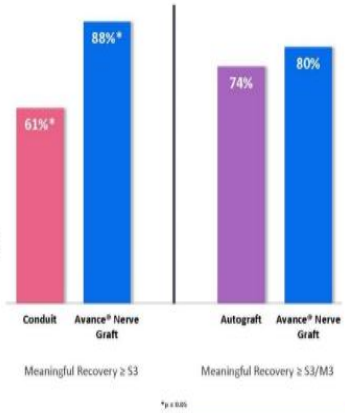
REPOSE-XL℠: Pilot Study Initiated

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

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]



196 Peer Reviewed Clinical Papers*

- 113 Extremity Trauma
- 8 Breast
- 35 Oral and Maxillofacial
- 47 Pain
- 28 Other Applications

*Certain publications contain data on multiple applications.

Focused sales execution, increasing market penetration

Sales execution focused on driving results

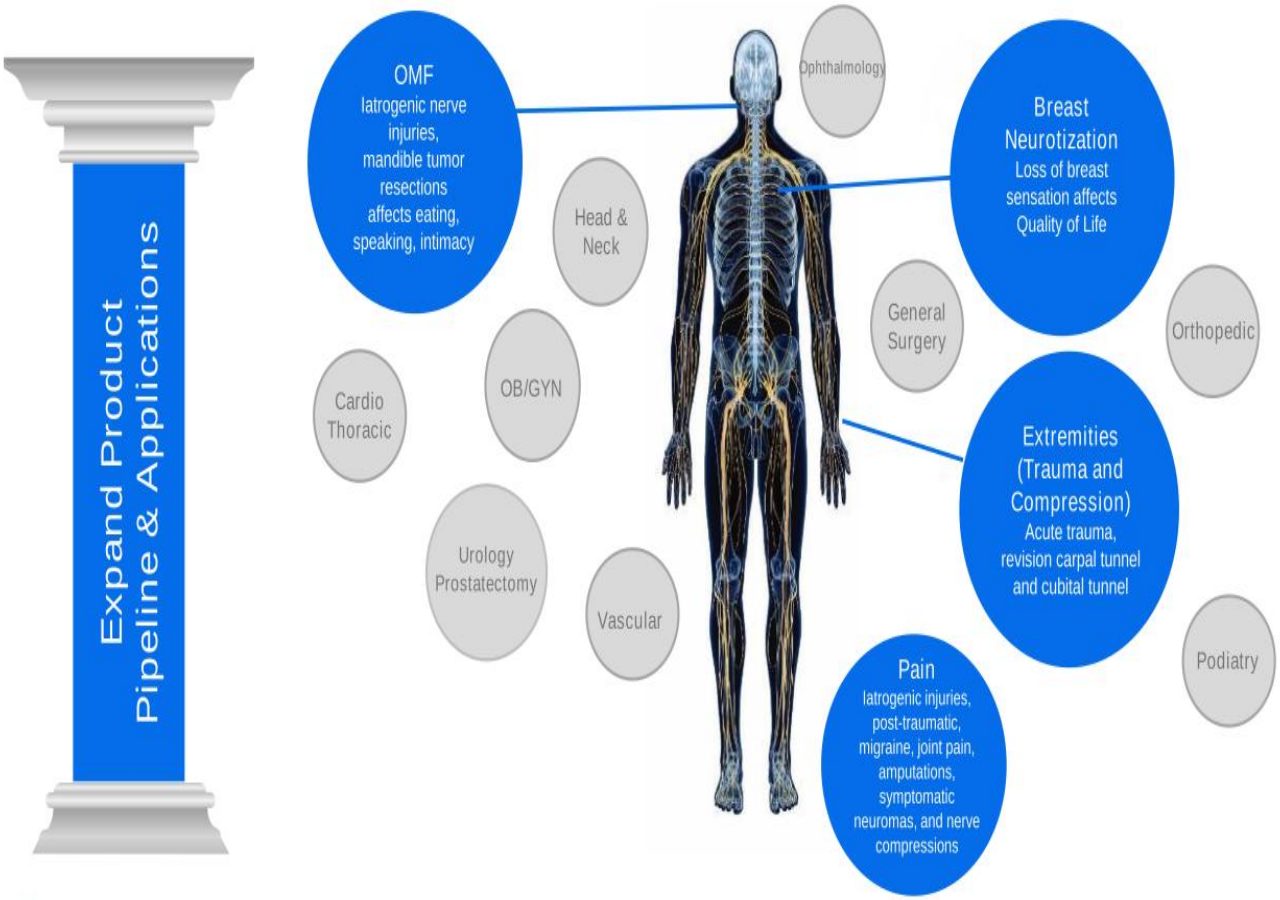
- Continue driving penetration in Active and Core Accounts
- 5,100 potential U.S. accounts perform nerve repair
- 941 Active Accounts as of June 30, 2022
  - Active Accounts represent approximately 85% of total revenue
  - Top 10% of Active Accounts represent approximately 35% of total revenue
- 299 Core Accounts as of June 30, 2022
  - Core Accounts represent approximately 60% of total revenue

Expanded sales reach

- U.S. direct sales team
  - 116 direct sales professionals at end of Q2 2022
- 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



Balance sheet and capital structure

Balance Sheet Highlights	June 30, 2022
Cash, Cash Equivalents, and Investments	$64.3 million
Total Long-term Debt	$50.0 million*

Capital Structure (shares)	June 30, 2022
Common Stock	42,134,504
Common Stock Options, RSUs, PSUs	7,365,177
Common Stock and Common Stock Equivalents	49,499,681

* 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.

Executive team

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

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

Brad Ottinger
General Counsel, Chief Compliance Officer
MicroPort Orthopedics

Maria Martinez
Chief Human Resources Officer
HSNi, Bausch + Lomb

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

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

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

Doris Quackenbush
Vice President of Sales
Convatec

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

- Exclusively focused on peripheral nerve repair with a differentiated platform
- 10+ years of demonstrated clinical outcome consistency
- Featured in 196 peer-reviewed clinical publications
- Over 50,000 Avance® Nerve Grafts implanted
- Significant barriers to competitive entry
- FDA granted Avance Regenerative Medicine Advanced Therapy (RMAT) designation
- Commercial and surgeon education capabilities
- Solid balance sheet provides resources to execute business plan
- Experienced management team with strong track record of success

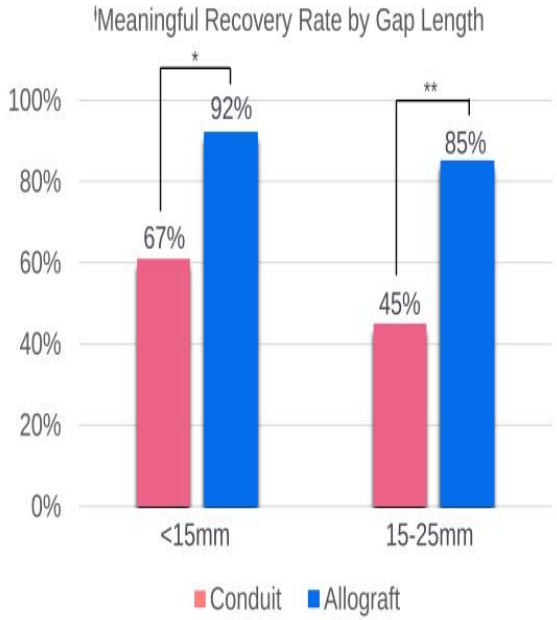
Appendix

- Key Clinical Data
- Historical Core and Active Accounts
- CMS outpatient and ASC reimbursement rates
- Total Addressable Market
- 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 2020[48]

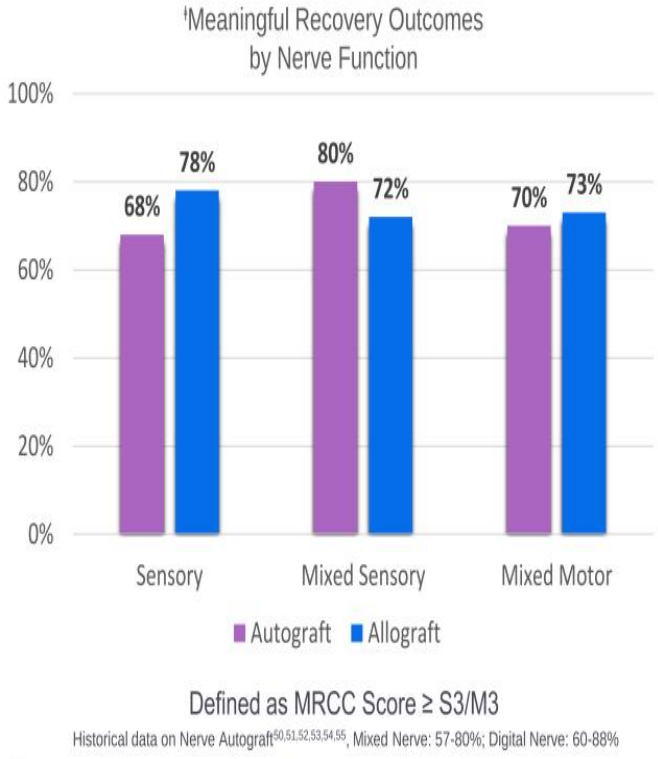
- Peer-reviewed publication from the MATCH cohort of the RANGER Registry
- Includes outcomes from 110 subjects with 162 nerve injuries; 113 were repaired with Avance Nerve Graft and 49 were repaired with manufactured conduit
- Findings show overall meaningful recovery rate was 88% for Avance Nerve Graft 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



[1]Meaningful Recovery = ≥S3 on the MRCC Scale
*p=0.008, **p=0.001

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]



Defined as MRCC Score ≥ S3/M3

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

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

Studies find Avance Nerve Graft performed comparably to nerve autograft for both clinical outcomes and facility procedure costs

"Styron et al., Nerve Repair Hospital Index Procedure Costs – Allograft vs. Autograft Repair Type"

Presented at the American Society for Surgery of the Hand (ASSH), October 2020[56]

- Data from the 2018 Medicare Standard Analytic File[57]
- 340 claims reviewed for autograft and allograft, included inpatient and outpatient procedures
- Found hospital facility procedure cost for Avance Nerve Graft was comparable to that of traditional nerve autograft
- Did not evaluate the potential additional costs associated with managing the autograft donor site and subsequent morbidities

"Styron et al., Comparative Effectiveness Evaluating Allograft, Autograft and Conduit Nerve Repairs: A **Systematic Review"**

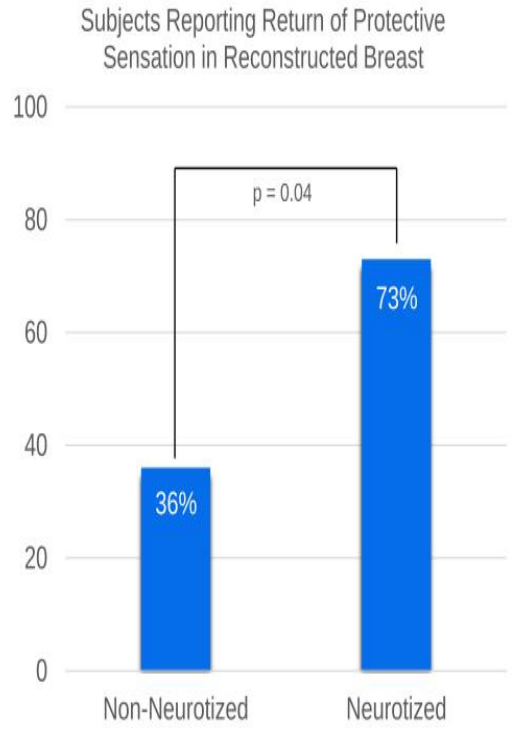
Presented at the American Association for Hand Surgery (AAHS), January 2021[58]

- Systematic review of recovery outcomes from over 35 clinical studies and 1,500 nerve repairs with autograft, allograft and conduit repairs
- Evaluated short and long gaps for both sensory and motor outcomes
- Autograft and allograft outcome rates were found to be statistically better than conduit repairs*
- Autograft and allograft outcome rates were found to be similar, regardless of gap length or nerve function
- Cost comparison conducted with Medicare data on Hospital Index Procedure Costs for autograft and allograft were found to be similar

*Conduits only had available data for short gap sensory nerve group

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

"Momeni et al., Flap Neurotization in Breast Reconstruction with Nerve Allografts: 1-year Clinical Outcomes" – Plastic and Reconstructive Microsurgery Global Open, January 2021[59]

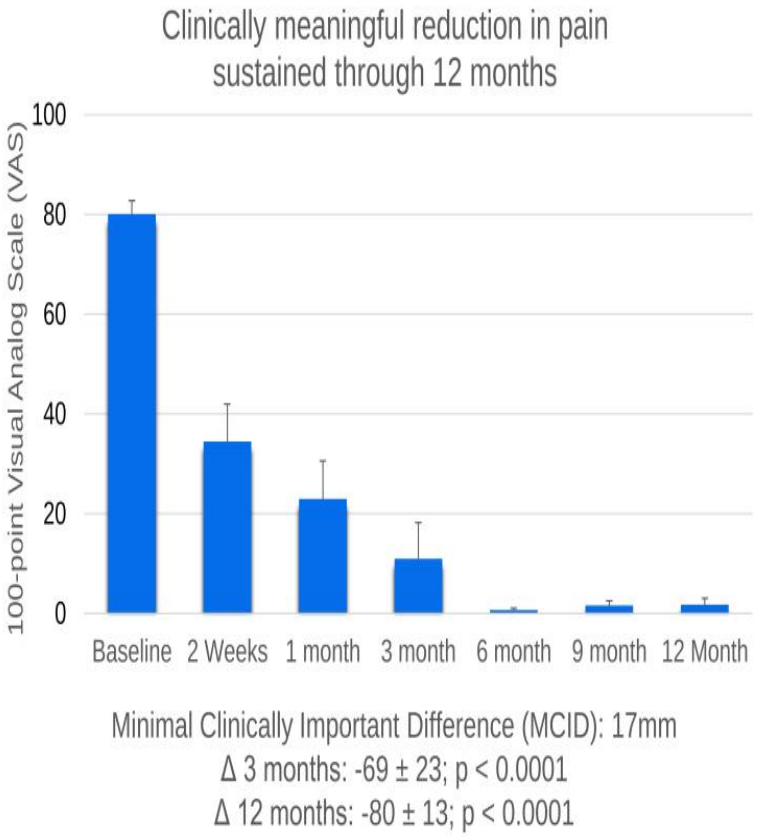


- Early outcomes from a single center study, as part of the Sensation-NOW registry
- 36 breast reconstructions that included:
  - 22 breast reconstructions with Resensation®
  - 14 standard non-neurotized breast reconstructions
- Return of Protective Sensation (p=0.04)
  - 73% of the Resensation group
  - 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 REPOSE℠ pilot study analysis demonstrates clinically significant improvement for subjects with chronic neuropathic pain when using Axoguard Nerve Cap® following neurectomy[60]

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

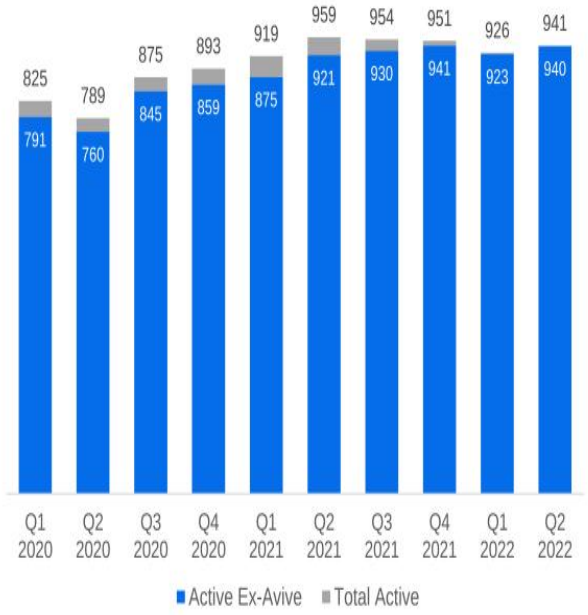
- Significant & clinically meaningful reduction in pain
- Significant and clinically meaningful improvements in Fatigue, Physical Function, Sleep Disturbance, Pain Interference, Pain Intensity, and Pain Behavior as measured by the validated PROMIS® measures
- Positive indicators for reduction in pain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



Historical Active and Core Accounts

Active Accounts

6 orders in the last 12 months

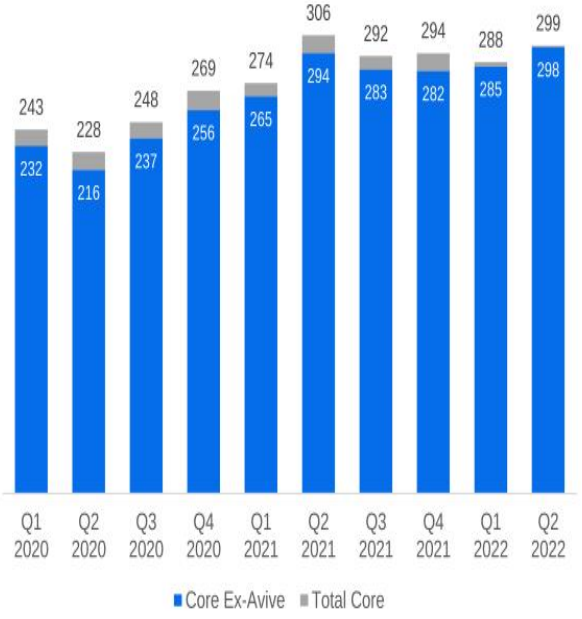


Active Accounts typically contribute ≈85% of total revenue

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

Core Accounts

≥$100,000 revenue in the last 12 months



Core Accounts typically contribute ≈60% of total revenue

2023 CMS proposed outpatient reimbursement rates - hospital and ASC

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

CPT Code	Descriptor	C-APC	Hospital Outpatient (HOPD)						Ambulatory Surgery Center (ASC)					
			2019	2020	2021	2022	2023 Proposed	4Y % Change	2019	2020	2021	2022	2023 Proposed	4Y % Change
64912	Nerve allograft repair[2]	5432	$4,566	$5,508	$5,700	$ 5,824	**$ 6,304**	**38.1%**	$1,920	$3.422	$3,788	$3,868	**$4,125**	**114.8%**
64910	Conduit or vein allograft repair[2]	5432	$4,566	$5,508	$5,700	$ 5,824	**$ 6,304**	**38.1%**	$2,613	$3,133	$3,802	$3,881	**$3,905**	**49.4%**
64886	Autograft repair (head and neck >4cm)[2]	5432	$4,566	$5,508	$5,700	$ 5,824	**$ 6,304**	**38.1%**	$3,127	$2,170	$4,157	$4,245	**$4,467**	**42.8%**
64890	Autograft repair (hand and foot≤4cm)[6]	5432	$4,566	$5,508	$5,700	$ 5,824	**$ 6,304**	**38.1%**	$3,075	$2,170	$2,499	$3,249	**$2,602**	**-15.4%**
64891	Autograft repair (hand and foot>4cm)[2]	5432	$4,566	$5,508	$5,700	$ 5,824	**$ 6,304**	**38.1%**	$1,920	$2,829	$2,499	$3,249	**$3,405**	**77.3%**
64892	Autograft repair (arm and leg ≤4cm)[2]	5432	$4,566	$5,508	$5,700	$5,824	**$ 6,304**	**38.1%**	$1,920	$2,170	$3,185	$3,718	**$3,405**	**77.3%**
64897	Autograft repair (arm and leg ≤4cm multiple strands)[3]	5432	$4,566	$5,508	$5,700	$5,824	**$ 6,304**	**38.1%**	$1,920	$2,170	$2,499	$2,496	**$3,702**	**92.8%**
64885 and 64893-96,98	Autograft repair (all other nerve type)[5]	5432	$4,566	$5,508	$5,700	$5,824	**$ 6,304**	**38.1%**	$1,920	$2,170	$2,499	$2,496	**$2,602**	**35.5%**
64834-36, 40, 56, 57, 62-65	Direct Repair (other hand/foot, arm/leg, repair/transpose, facial, low back,)[5]	5432	$4,566	$5,508	$5,700	$5,824	**$ 6,304**	**38.1%**	$1,920	$2,170	$2,499	$2,496	**$2,602**	**35.5%**
64831, 61	Direct Repair (digital, brachial plexus/arm)[4]	5431	$4,566	$1,719	$1,754	$1,793	**$ 1,830**	**-59.9%**	$1,920	$797	$809	$825	**$838**	**-56.4%**
64858	Direct Repair (sciatic)[2]	5431	$4,566	$1,719	$1,754	$1,793	**$ 1,830**	**-59.9%**	$1,920	$797	$41,434	$1,465	**$1,503**	**-21.7%**

1. National average payment rates. Commercial payments are traditionally 1.5-2x higher than Medicare.
2. Nerve allograft repair CPT 64912, conduit repair CPT 64910, autograft repairs hand/foot >4cm CPT 64891,arm/leg≤4cm CPT code 64892 and head/neck >4cm CPT 64886 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 arm/leg ≤4cm multiple strands CPT 64897 remains in C-APC 5432 and meets ASC device intensive criteria in 2023
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 64885 and 64893-96,98 and Direct repair other hand/foot CPT 64834-36, leg CPT 64840, repair/transpose CPT 64856, arm/leg CPT 64857, low back CPT 64862, facial 64864-65 remain in C-APC 5432 and do not meet ASC device intensive criteria
6. Autograft repair hand/foot ≤4cm remains in C-APC 5432 no longer meets ASC device intensive criteria in 2023

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Note: Hospital inpatient rates for nerve repair align to DRGs 040, 041, 042 and range from $11.5k to $23.7k in the 2023 IPPS Proposed Rule

2023 Center for Medicare and Medicaid Services (CMS): Proposed Physician Fee Schedule (PFS)

CPT Codes3	Descriptor	Physician Fee Schedule (PFS)					
		2019	2020	2021	2022	2023 Proposed	4Y % Change
64912	Nerve allograft repair	$804	$ 951	$904	$910	**$893**	11.1%
64910	Conduit or vein allograft repair	$825	$820	$803	$790	**$759**	-8.0%
64885 to 64898*	Autograft repair	$1,096 to $1,495	$1,096 to $1,495	$1,080 to $1,468	$1,031 to $1,462	**$1003 to $1,422**	-4.9% to -8.5%
64831 to 64861*	Direct Repair	$713 to $1,604	$717 to $1,578	$710 to $1,565	$712 to $1,567	**$695 to $1,546**	-2.5% to -3.6%

*excludes add-on procedure codes

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%
Other trauma injuries (c)	497,000 71%		$1,570		$780M 41%
Carpal and Cubital Tunnel	130,000		$2,100		$270M
Oral and Maxillo-Facial (OMF)	56,000		$5,400		$300M
Breast Reconstruction Neurotization	24,500 flaps (15,000 patients)		$10,200		$250M
Totals	>900,000 (potential)				>$2.7B

a) 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) Other trauma injuries include transections < 5mm and crush injuries utilizing the Axoguard product line based upon literature and data observed in the RANGER® registry

Estimated Trauma total addressable market

Patient Population[a]	Source	Adjustments and Rationale
136,943,000 Annual emergency department visits in the U.S.	2015 National Hospital Ambulatory Medical Care Survey (Table 1)	
30,238,000 Annual emergency department visits due to injury in the U.S. ✖ **4.76%** Percentage of emergency department visits with nerve injury	2015 National Hospital Ambulatory Medical Care Survey (Table 18) *Noble, et al: J Trauma, Volume 45(1) July 1998.116-122*	• 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 *Noble, et al* study excluded 113 patients coded with nerve injuries outside of the study scope, but that are in the Axogen scope of nerve repair (brachial plexus and digital nerve injuries). Including these injuries increases the rate to 4.76%.
1,440,000 Annual emergency department visits with nerve injury in the U.S. ✖ **46.2%** Percentage of ED nerve injuries estimated to be treated surgically	*Noble, et al: J Trauma, Volume 45(1) July 1998.116-122*	• Calculated rate based on various rates in *Noble et al* study for upper and lower extremity and an estimate for other trauma nerves.
~665,000 **Annual ED visits with nerve injury estimated to be treated surgically in the U.S., excluding revisions**		

a) Patient population figures rounded to the nearest thousandth.

Trauma total addressable market (continued)

Patient Population[a]	Source	Adjustments and Rationale
~665,000 Annual emergency department visits with nerve injury that can be treated surgically in the U.S., excluding revisions	See calculation on previous slide	
✖ **7.4%** Revision cases	*Portincasa et al: Microsurgery 27:455-462, 2007*	• *Portincasa et al* suggests that a revision procedure was necessary in 7.4% of the patients within 6 months of the initial surgery.
= **714,000** Annual emergency department visits with nerve injury that can be treated surgically in the U.S., including revisions		
↓ **~700,000** **Company estimate of trauma total addressable market**		

a) Patient population figures rounded to the nearest thousandth.

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.

nasdaq: axgn

Footnotes

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