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): February 22, 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 February 22, 2022, Axogen, Inc. (the "Company") issued a press release announcing its fourth quarter and full year 2021 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 February 22, 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	Axogen, Inc. Press Release, dated February 22, 2022.
99.2	Axogen, Inc. Corporate Presentation, dated February 22, 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.

Date: February 22, 2022

By: /s/ Bradley L. Ottinger

Bradley L. Ottinger

General Counsel and Chief Compliance Officer

Axogen, Inc Reports 2021 Fourth Quarter and Full-Year Financial Results

ALACHUA and TAMPA, FL – February 22, 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 fourth quarter and full year ended December 31, 2021.

Fourth Quarter 2021 and Business Highlights

- Net revenue was $31.5 million during the fourth quarter, a 3% decrease compared to fourth-quarter 2020 revenue of $32.5 million.
- Fourth quarter revenue includes $0.5 million from the reversal of a sales return reserve recorded in the second quarter of 2021 for Avive® Soft Tissue Membrane, for which the company voluntarily suspended market availability on June 1, 2021. Avive revenue in the fourth quarter of 2020 was approximately $1.6 million.
- Gross margin was 82.8% for the quarter compared to 83.2% in the fourth quarter of 2020.
- Adjusted net loss was $3.3 million for the quarter, or $0.08 per share, for both the fourth quarter of 2021 and 2020.
- Adjusted EBITDA loss was $1.7 million for the quarter, compared to an adjusted EBITDA loss of $1.3 million in the fourth quarter of 2020.
- The balance of all cash, cash equivalents, and investments on December 31, 2021 was $90.3 million, compared to a balance of $98.1 million on September 30, 2021. The net change includes capital expenditures of $5.8 million related to the construction of our new processing facility in Dayton, OH, and $1.9 million of operating cash burn in the quarter.
- Core Accounts as of December 31, 2021 were 294, a 9% increase compared to 269 as of December 31, 2020. Revenue from Core Accounts continued to represent approximately 60% of total revenue.
- Active Accounts as of December 31, 2021 were 951, a 6% increase from 893 as of December 31, 2020. Revenue from the top 10% of Active Accounts continued to represent approximately 35% of total revenue.

“I am pleased with our full-year results in light of a difficult operating environment in the second half of the year,” commented Karen Zaderej, chairman, CEO, and president of Axogen, Inc. “We believe more surgeons and accounts are recognizing the value Axogen provides, and we enter 2022 with a strong commercial organization and a solid foundation of clinical evidence. We look forward to the release of the topline results of our RECON study in the second quarter and returning to a more normalized growth environment through the year.”

Full-Year 2021 Financial Results and Business Highlights

- Full-year 2021 revenue was $127.4 million, a 13% increase compared to 2020 revenue of $112.3 million.
- Avive revenue totaled approximately $4.1 million and $5.5 million for the years ended 2021 and 2020, respectively.
- Gross margin was 82.0% for the full year, compared to 80.8% in 2020.
- Adjusted net loss was $13.7 million for the full year, or $0.33 per share, compared to $15.3 million, or $0.38 per share, in 2020.
- Adjusted EBITDA loss was $6.7 million for the full year, compared to an adjusted EBITDA loss of $11.1 million in 2020.
- Ended the year with 115 direct sales representatives, compared to 111 at the end of 2020.
- Ended the year with 181 peer-reviewed clinical publications featuring Axogen's nerve repair product portfolio.

2022 Financial Guidance

Management expects 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 by phone are invited to call toll free at 1-877-407-0993 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 the RECON Clinical Study

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 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

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. The forward-looking statements may include, 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 assessment of our internal controls over financial reporting, our visibility at and sponsorship of conferences and our educational events, regulatory process and approvals and other factors, including legislative, regulatory, political and economic developments 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 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.

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

AXOGEN, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(In Thousands, Except Share and Per Share Amounts)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 32,756	$ 48,767
Restricted cash	6,251	6,842
Investments	51,330	55,199
Accounts receivable, net	18,158	17,618
Inventory	16,693	12,529
Prepaid expenses and other	1,861	4,296
Total current assets	127,049	145,251
Property and equipment, net	62,881	38,398
Operating lease right-of-use assets	15,193	15,614
Finance lease right-of-use assets	42	64
Intangible assets, net	2,859	2,054
Total assets	$ 208,024	$ 201,381
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 22,459	$ 21,968
Current maturities of long-term lease obligations	1,834	863
Total current liabilities	24,293	22,831
Long-term debt, net of financing fees	44,821	32,027
Debt derivative liabilities	5,562	2,497
Long-term lease obligations	20,798	20,874
Other long-term liabilities	—	3
Total liabilities	95,474	78,232
Shareholders' equity:		
Common stock, $.01 par value per share; 100,000,000 shares authorized	417	406
Additional paid-in capital	342,765	326,390
Accumulated deficit	(230,632)	(203,647)
Total shareholders' equity	112,550	123,149
Total liabilities and shareholders' equity	$ 208,024	$ 201,381

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
Three Months and Years Ended December 31, 2021 and 2020
(unaudited)
(In Thousands, Except Per Share Amounts)

	Three Months Ended		Year Ended	
	December 31, 2021	December 31, 2020	December 31, 2021	December 31, 2020
Revenues	$ 31,537	$ 32,495	$ 127,358	$ 112,300
Cost of goods sold	5,428	5,463	22,931	21,581
Gross profit	26,109	27,032	104,427	90,719
Costs and expenses:				
Sales and marketing	17,734	19,805	73,328	69,659
Research and development	6,302	4,931	24,177	17,846
General and administrative	7,426	7,670	32,338	26,396
Total costs and expenses	31,462	32,406	129,843	113,901
Loss from operations	(5,353)	(5,374)	(25,416)	(23,182)
Other (expense) income:				
Investment income	13	29	93	605
Interest expense	71	(595)	(1,356)	(1,054)
Change in fair value of derivatives	124	(46)	(28)	(117)
Other expense	(141)	(24)	(278)	(38)
Total other (expense) income, net	67	(636)	(1,569)	(604)
Net loss	$ (5,286)	$ (6,010)	$ (26,985)	$ (23,786)
Weighted average common shares outstanding – basic and diluted	41,593	40,246	41,215	39,967
Loss per common share – basic and diluted	$ (0.13)	$ (0.15)	$ (0.65)	$ (0.60)
Adjusted net loss - non GAAP	$ (3,272)	$ (3,265)	$ (13,697)	$ (15,281)
Adjusted loss per common share – basic and diluted	$ (0.08)	$ (0.08)	$ (0.33)	$ (0.38)

AXOGEN, INC.
RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES
Three Months and Years Ended December 31, 2021 and 2020
(unaudited)
(In Thousands, Except Per Share Amounts)

	Three Months Ended		Year Ended	
	December 31, 2021	December 31, 2020	December 31, 2021	December 31, 2020
Gross profit	$ 26,109	$ 27,032	$ 104,427	$ 90,719
Avive inventory write-down and production costs	-	-	1,429	-
Adjusted gross profit	$ 26,109	$ 27,032	$ 105,856	$ 90,719
Net loss	$ (5,286)	$ (6,010)	$ (26,985)	$ (23,786)
Depreciation and amortization expense	1,563	1,284 (1)	5,572	3,692 (1)
Investment income	(13)	(29)	(93)	(605)
Income tax expense	138	77	205	77
Interest expense	(71)	595	1,356	1,054
EBITDA - non GAAP	$ (3,669)	$ (4,083) (1)	$ (19,945)	$ (19,568) (1)
Non cash stock-based compensation expense	1,509	2,745	10,919	8,470
Litigation and related costs	505	—	2,369	35
Adjusted EBITDA - non GAAP	$ (1,655)	$ (1,338) (1)	$ (6,657)	$ (11,063) (1)
Net loss	$ (5,286)	$ (6,010)	$ (26,985)	$ (23,786)
Non cash stock-based compensation expense	1,509	2,745	10,919	8,470
Litigation and related costs	505	—	2,369	35
Adjusted net loss - non GAAP	$ (3,272)	$ (3,265)	$ (13,697)	$ (15,281)
Weighted average common shares outstanding – basic and diluted	41,593	40,246	41,215	39,967
Adjusted loss per common share – basic and diluted	$ (0.08)	$ (0.08)	$ (0.33)	$ (0.38)

(1) The Company has revised its definition of EBITDA and Adjusted EBITDA to include amortization of its right-of-use assets and amortization of debt discount

and deferred financing fees. See Reconciliation of Revised EBITDA, Adjusted EBITDA, and Depreciation and Amortization.

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
Three Months and Years Ended December 31, 2021 and 2020
(unaudited)
(In Thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount			
For the Three Months Ended December 31, 2021:					
Balance at September 30, 2021	41,559	$ 415	$ 340,212	$ (225,346)	$ 115,281
Net loss	-	-	-	(5,286)	(5,286)
Stock-based compensation	-	-	1,509	-	1,509
Issuance of restricted and performance stock units	48	-	-	-	-
Exercise of stock options and employee stock purchase plan	130	2	1,044	-	1,046
Balance at December 31, 2021	41,737	$ 417	$ 342,765	$ (230,632)	$ 112,550
For the Year Ended December 31, 2021:					
Balance at December 31, 2020	40,619	$ 406	$ 326,390	$ (203,647)	$ 123,149
Net loss	-	-	-	(26,985)	(26,985)
Stock-based compensation	-	-	10,919	-	10,919
Issuance of restricted and performance stock units	254	2	(2)	-	-
Exercise of stock options and employee stock purchase plan	864	9	5,458	-	5,467
Balance at December 31, 2021	41,737	$ 417	$ 342,765	$ (230,632)	$ 112,550
For the Three Months Ended December 31, 2020:					
Balance at September 30, 2020	40,124	$ 401	$ 318,949	$ (197,637)	$ 121,713
Net loss	-	-	-	(6,010)	(6,010)
Stock-based compensation	-	-	2,745	-	2,745
Issuance of restricted and performance stock units	81	-	-	-	-
Shares surrendered by employees to pay tax withholdings	(2)	1	(6)	-	(5)
Exercise of stock options and employee stock purchase plan	168	2	1,022	-	1,024
Exercise of Oberland option, net of settlement	248	2	3,680	-	3,682
Balance at December 31, 2020	40,619	$ 406	$ 326,390	$ (203,647)	$ 123,149
For the Year Ended December 31, 2020:					
Balance at December 31, 2019	39,590	$ 396	$ 311,618	$ (179,861)	$ 132,153
Net loss	-	-	-	(23,786)	(23,786)
Stock-based compensation	-	-	8,470	-	8,470
Issuance of restricted and performance stock units	249	2	(2)	-	-
Shares surrendered by employees to pay tax withholdings	(40)	-	(670)	-	(670)
Exercise of stock options and employee stock purchase plan	572	6	3,294	-	3,300
Exercise of Oberland option, net of settlement	248	2	3,680	-	3,682
Balance at December 31, 2020	40,619	$ 406	$ 326,390	$ (203,647)	$ 123,149

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
Years Ended December 31, 2021 and 2020
(unaudited)
(In Thousands)

	Year Ended	
	December 31, 2021	December 31, 2020
Cash flows from operating activities:		
Net loss	$ (26,985)	$ (23,786)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,721	1,507
Amortization of right-of-use assets	1,818	1,800
Amortization of intangible assets	202	153
Amortization of debt discount and deferred financing fees	831	232
Loss on disposal of equipment	-	3
Provision for bad debt	(41)	(105)
Provision for inventory write-down	3,314	2,242
Change in fair value of deriviatives	28	117
Investment (gains) losses	68	(47)
Stock-based compensation	10,919	8,470
Change in operating assets and liabilities:		
Accounts receivable	(499)	(635)
Inventory	(7,478)	(910)
Prepaid expenses and other	2,435	(2,524)
Accounts payable and accrued expenses	(270)	4,958
Operating lease obligations	(463)	(1,086)
Cash paid for interest portion of finance leases	(2)	(3)
Contract and other liabilities	(3)	(12)
Net cash used in operating activities	(13,405)	(9,626)
Cash flows from investing activities:		
Purchase of property and equipment	(27,811)	(21,905)
Economic development grant proceeds	950	—
Purchase of investments	(68,699)	(77,806)
Proceeds from sale of investments	72,500	83,440
Cash payments for intangible assets	(589)	(692)
Net cash used in investing activities	(23,649)	(16,963)
Cash flows from financing activities:		
Proceeds from issuance of long-term debt	15,000	35,000
Proceeds from the paycheck protection program loan	—	7,820
Repayment of the paycheck protection program loan	—	(7,820)
Proceeds from issuance of common stock	—	3,500
Payments for debt issuance costs	—	(642)
Payments of employee tax withholding in exchange of common stock awards	—	(670)
Cash paid for debt portion of finance leases	(15)	(14)
Proceeds from exercise of stock options and ESPP stock purchases	5,467	3,300
Net cash provided by financing activities	20,452	40,474
Net (decrease) increase in cash, cash equivalents and restricted cash	(16,602)	13,885
Cash, cash equivalents and restricted cash, beginning of period	55,609	41,724
Cash, cash equivalents and restricted cash, end of period	$ 39,007	$ 55,609
Supplemental disclosures of cash flow activity:		
Cash paid for interest, net of capitalized interest	$ 495	$ 822
Supplemental disclosure of non-cash investing and financing activities		
Acquisition of fixed assets in accounts payable and accrued expenses	$ 1,420	$ 1,077
Obtaining a right-of-use asset in exchange for a lease liability	$ 1,375	$ 14,259
Acquisition of leasehold asset	$ -	$ 5,250
Embedded derivative associated with the long-term debt	$ 3,037	$ 2,563
Acquisition of intangible assets in accounts payable and accrued expenses	$ 418	$ -

Conversion of the Oberland option	$ -	$ 182

AXOGEN, INC.
RECONCILIATION OF REVISED EBITDA, ADJUSTED EBITDA, and DEPRECIATION AND AMORTIZATION
Three Months Ended September 30, 2021 and 2020; June 30, 2021 and 2020; March 31, 2021 and 2020; December 31, 2020 and
Year Ended December 31, 2020
(unaudited)
(In Thousands)

The Company has revised its definition of EBITDA and Adjusted EBITDA to include amortization of its right-of-use assets and amortization of debt discount and deferred financing fees.

The tables below provide a reconciliation of EBITDA and Adjusted EBITDA as previously reported to the amounts calculated using the new definition.

	Three Months Ended		
	March 31, 2021	June 30, 2021	September 30, 2021
Depreciation and amortization expense, as previously reported	$ 818	$ 661	$ 706
Amortization of ROU assets	500	460	458
Amortization of debt discount and deferred financing fees	112	115	157
Revised depreciation and amortization expense	$ 1,430	$ 1,236	$ 1,321
EBITDA - non GAAP, as previously reported	$ (5,437)	$ (6,639)	$ (6,035)
Amortization of ROU assets	500	460	458
Amortization of debt discount and deferred financing fees	112	115	157
Revised EBITDA - non GAAP	$ (4,825)	$ (6,064)	$ (5,420)
Adjusted EBITDA - non GAAP, as previously reported	$ (1,906)	$ (2,435)	$ (2,496)
Amortization of ROU assets	500	460	458
Amortization of debt discount and deferred financing fees	112	115	157
Revised Adjusted EBITDA - non GAAP	$ (1,294)	$ (1,860)	$ (1,881)

	Three Months Ended				Year Ended
	March 31, 2020	June 30, 2020	September 30, 2020	December 31, 2020	December 31, 2020
Depreciation and amortization expense, as previously reported	$ 343	$ 346	$ 439	$ 556	$ 1,660
Amortization of ROU assets	470	332	480	518	1,800
Amortization of debt discount and deferred financing fees	-	-	22	210	232
Revised depreciation and amortization expense	$ 813	$ 678	$ 941	$ 1,284	$ 3,692
EBITDA - non GAAP, as previously reported	$ (8,139)	$ (7,907)	$ (671)	$ (4,811)	$ (21,600)
Amortization of ROU assets	470	332	480	518	1,800
Amortization of debt discount and deferred financing fees	-	-	22	210	232
Revised EBITDA - non GAAP	$ (7,669)	$ (7,575)	$ (169)	$ (4,083)	$ (19,568)
Adjusted EBITDA - non GAAP, as previously reported	$ (7,583)	$ (5,685)	$ 2,276	$ (2,066)	$ (13,095)
Amortization of ROU assets	470	332	480	518	1,800
Amortization of debt discount and deferred financing fees	-	-	22	210	232
Revised Adjusted EBITDA - non GAAP	$ (7,113)	$ (5,353)	$ 2,778	$ (1,338)	$ (11,063)

Corporate presentation

As of December 31, 2021

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. The forward-looking statements may include, 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 assessment of our internal controls over financial reporting, our visibility at and sponsorship of conferences and our educational events, regulatory process and approvals and other factors, including legislative, regulatory, political and economic developments 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 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

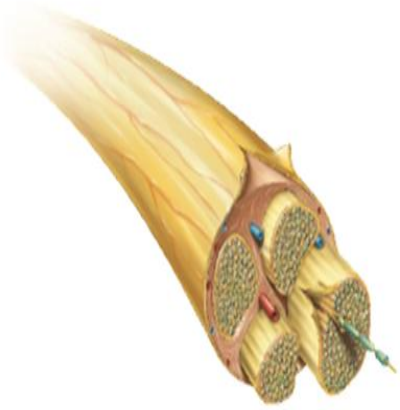
The function of nerves

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 up to 5 mm

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

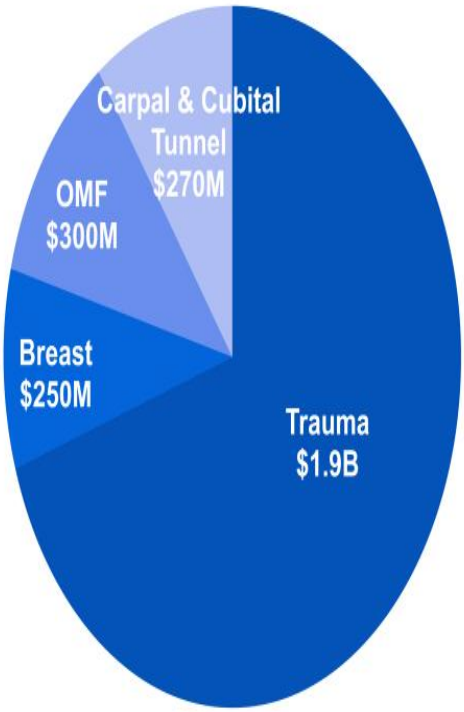
Connection	Protection	Termination

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 181 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

Current targeted nerve markets (U.S.)

>$2.7 Billion*



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

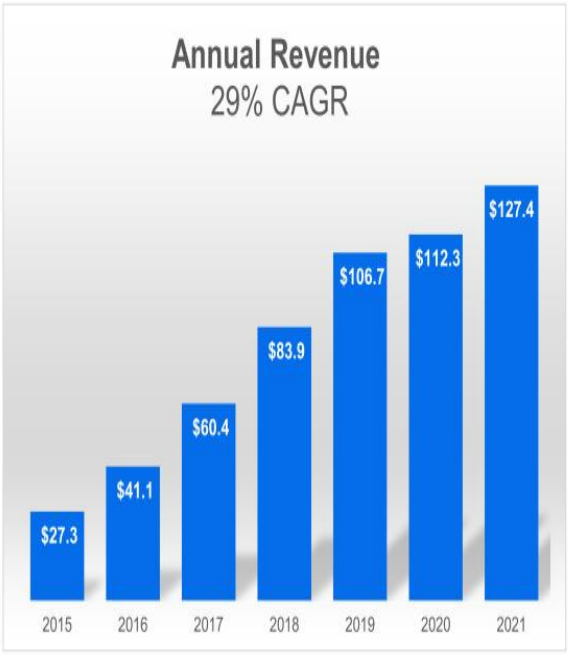
- Trauma: > 700,000
- Carpal Tunnel Revisions & Cubital Tunnel: 130,000
- Oral Maxillofacial (OMF): 56,000
- Breast Neurotization Procedures: 15,000

**$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

- Q4 growth was approximately flat, excluding the impact of Avive® Soft Tissue Membrane
- 2021 revenue growth, excluding the impact of Avive, was approximately 15%**
- Revenue was negatively impacted by lower procedure volumes due to the impact of COVID variants and hospital staffing challenges
- Increased Core Accounts by 9%

82.8% Gross Margin for the quarter ended December 31, 2021
82.0% Gross Margin for the year ended December 31, 2021

** Fourth quarter revenue includes $0.5 million from the reversal of a sales return reserve recorded in the second quarter of 2021 for Avive Soft Tissue Membrane, for which the company voluntarily suspended market availability on June 1, 2021. Avive revenue in the fourth quarter 2020 was approximately $1.6 million; and totaled approximately $4.1 million and $5.5 million for the years ended 2021 and 2020, respectively.

Guidance update

February 2022

2022 Annual Financial Guidance

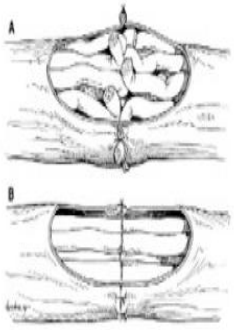
- Full-year 2022 revenue is expected to be between $135 million and $142 million.
  - Represents approximately 10% to 15% growth over 2021 revenue excluding the impact of $4.1 million of Avive revenue in 2021.
- Full-year 2022 gross margin is expected to remain above 80%.

Traditional TRANSECTION repair options are suboptimal

SUTURE

Direct suture repair of no-gap injuries

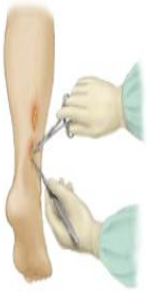
- Common repair method
- May result in tension to the repair leading to ischemia
- Concentrates sutures at the coaptation site



AUTOGRAFT

Traditional method despite several disadvantages

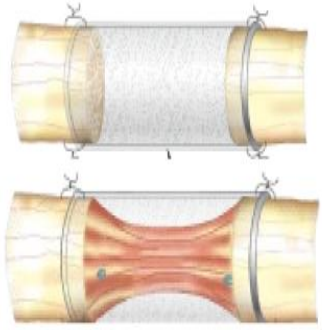
- Secondary surgery
- Loss of function and sensation at harvest site
- 27% complication rate including infection, wound healing and chronic pain [19]
- Limited availability of graft length and diameter



SYNTHETIC CONDUITS

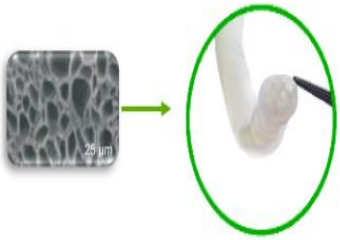
Convenient off the shelf option; limited efficacy & use

- 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

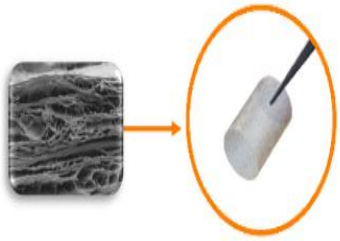
Structural support for regenerating axons

- 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]

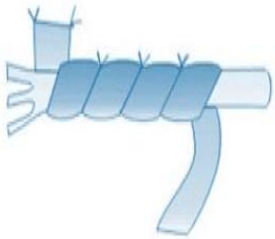
Remodels into vascularized patient tissue[28, 29, 30, 31, 32]

Traditional COMPRESSION repair options are suboptimal

VEIN WRAPPING

Autologous vein

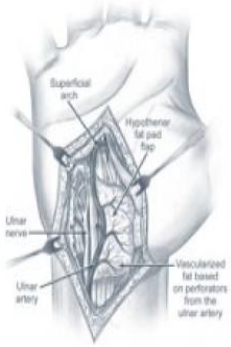
- Barrier to attachment to surrounding tissue
- Requires extra time and skill to perform spiral wrapping technique
- Second surgery site



HYPOTHENAR FAT PAD

Autologous vascularization flap

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



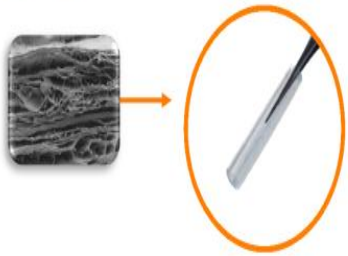
COLLAGEN WRAPS

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

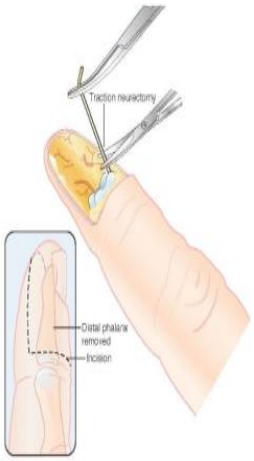
- Minimizes risk of entrapment[34]
- Creates a barrier between repair and surrounding tissue bed[34]
- ECM revascularizes and remodels into patient's own tissue[29,35]

Traditional STUMP NEUROMA options are suboptimal

TRACTION NEURECTOMY

Nerve placed in traction and cut to allow for retraction

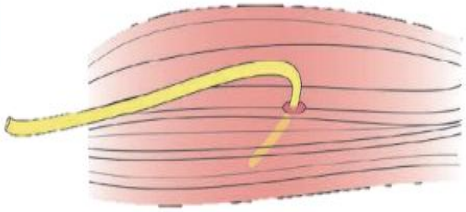
- Simply resecting the nerve results in subsequent neuroma formation and risk of secondary surgery
- Causes traction injury
- High risk of recurrence[36]



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]



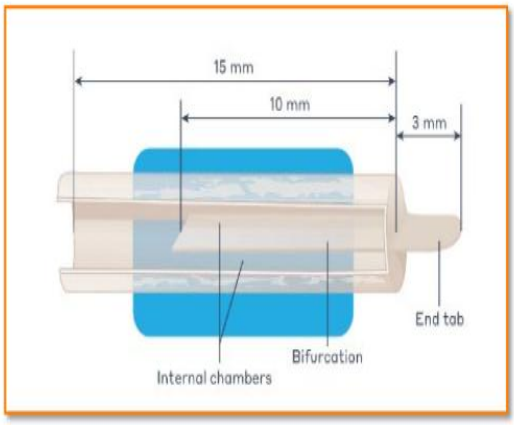
INJECTIONS

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

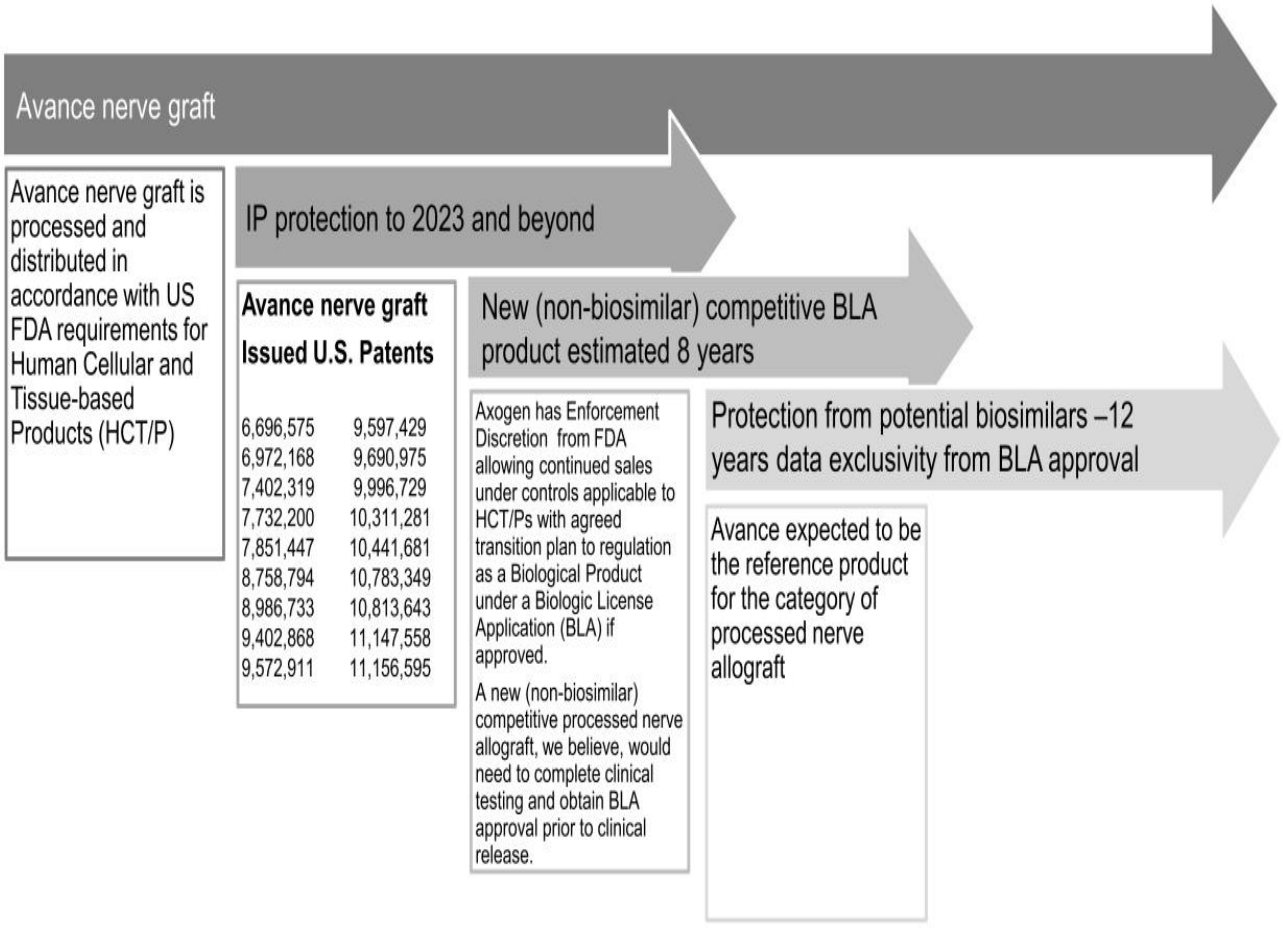
SIS Material allows for vascularization and gradual remodeling (as shown in animal studies)[46, 47]

- 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

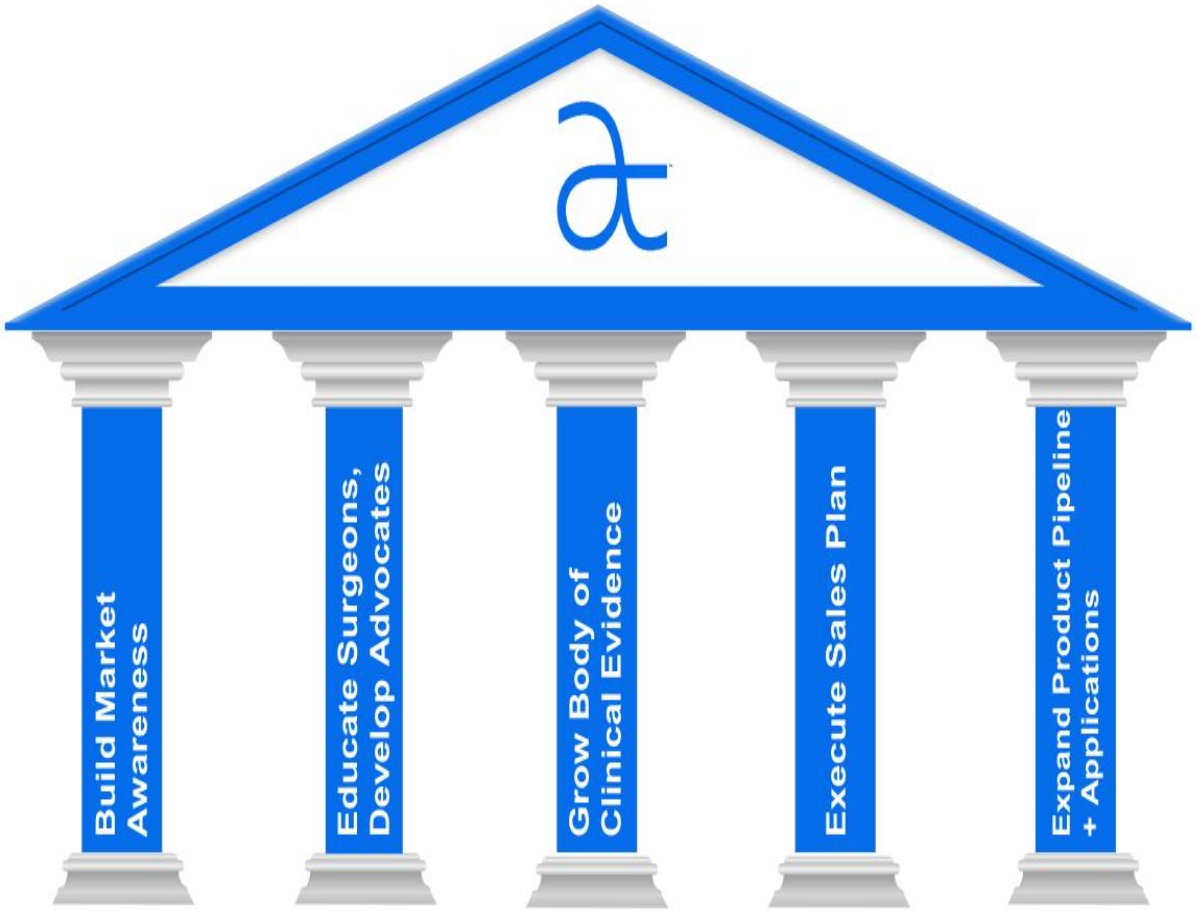


Unique Avance technology creates barriers to competitive entry

Progress toward Biologics License Application (BLA) for Avance Nerve Graft

- ✓ Obtaining reference product designation will provide 12 years of data exclusivity protection from biosimilars
- ✓ Received RMAT Designation from FDA in 2018
- ✓ Top-line results of RECON℠ Study anticipated in Q2 2022
  - Prospective, randomized, controlled double-blinded study compares Avance Nerve Graft to synthetic conduits in digital injuries
  - Non-inferiority study with an adaptive trial design to allow for adequate power
  - Adding level 1 evidence to extensive portfolio of clinical evidence
  - Expect to file BLA in 2023

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

- Returned to in-person national education programs in September 2021
- 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

- The largest multi-center clinical study in peripheral nerve repair with >2,600 Avance nerve repairs enrolled to date
- Overall meaningful recovery rates of 82-84%; comparable to autograft outcomes without associated donor site comorbidities

MATCH® Registry Study: Enrollment Ongoing

- Avance outcomes compared to matched cohort of autograft and synthetic conduits

RECON℠ Study: Enrollment and Follow-up Complete

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

Sensation-NOW® Registry Study: Enrollment Ongoing

- Multi-center clinical study in breast neurotization

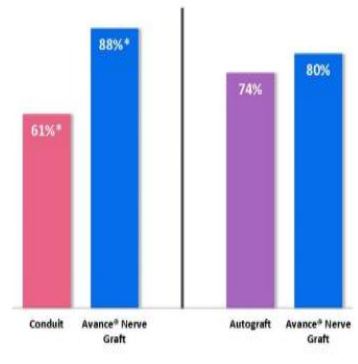
REPOSE℠: Enrollment Ongoing

- Prospective, randomized, controlled study of 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]



*p ≤ 0.05

181 Peer Reviewed Clinical Papers*

- 105 Extremity Trauma
- 6 Breast
- 35 Oral and Maxillofacial
- 43 Pain
- 23 Other Applications

*Certain publications contain data on multiple applications.

Focused sales execution, increasing market penetration

Sales execution focused on driving results

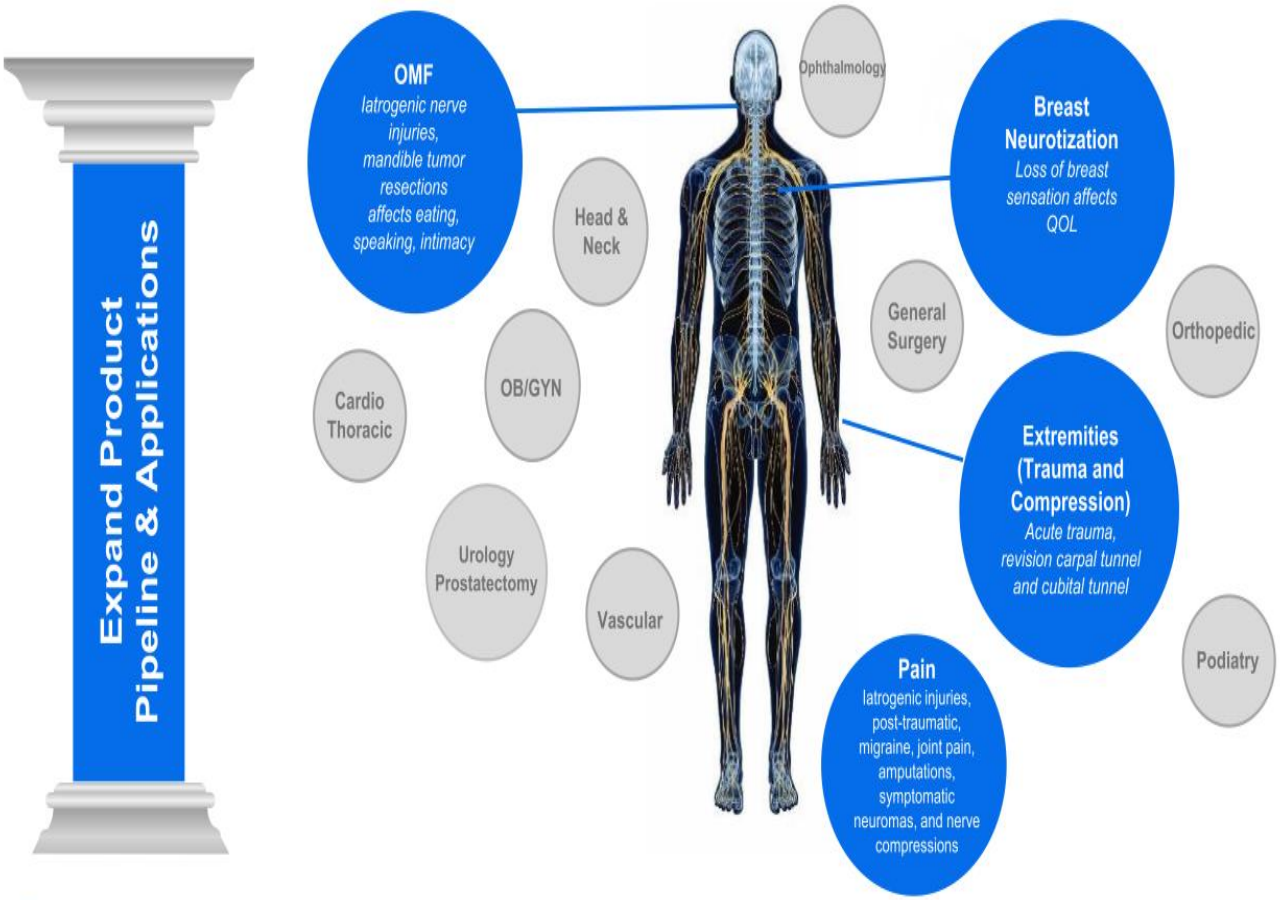
- Continue driving penetration in Active and Core Accounts
- 5,100 potential U.S. accounts perform nerve repair
- 951 Active Accounts as of December 31, 2021, up 6% vs prior year
  - Active Accounts represent approximately 85% of total revenue
  - Top 10% of Active Accounts represent approximately 35% of total revenue
- 294 Core Accounts as of December 31, 2021, up 9% vs prior year
  - Core Accounts represent approximately 60% of total revenue

Expanded sales reach

- U.S. direct sales team
  - 115 direct sales professionals at end of Q4 2021
- 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	December 31, 2021
Cash, Cash Equivalents, and Investments	$90.3 million
Total Long-term Debt	$50.0 million*

Capital Structure (shares)	December 31, 2021
Common Stock	41,736,950
Common Stock Options, RSUs, PSUs	4,825,413
Common Stock and Common Stock Equivalents	46,662,363

** 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

Eric A. Sandberg
Chief Commercial Officer
Guidant

Maria Martinez
Chief Human Resources Officer
HSNi, Bausch + Lomb

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

Brad Ottinger
General Counsel, Chief Compliance Officer
MicroPort Orthopedics

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

Erick DeVinney
VP, 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

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

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 181 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

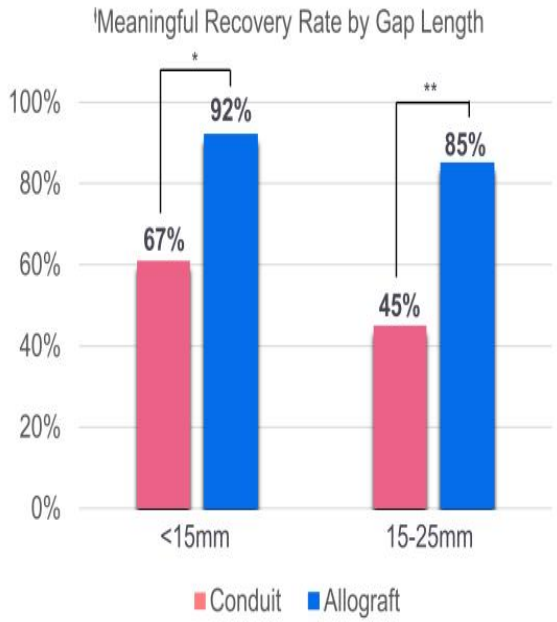
Appendix

- 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]

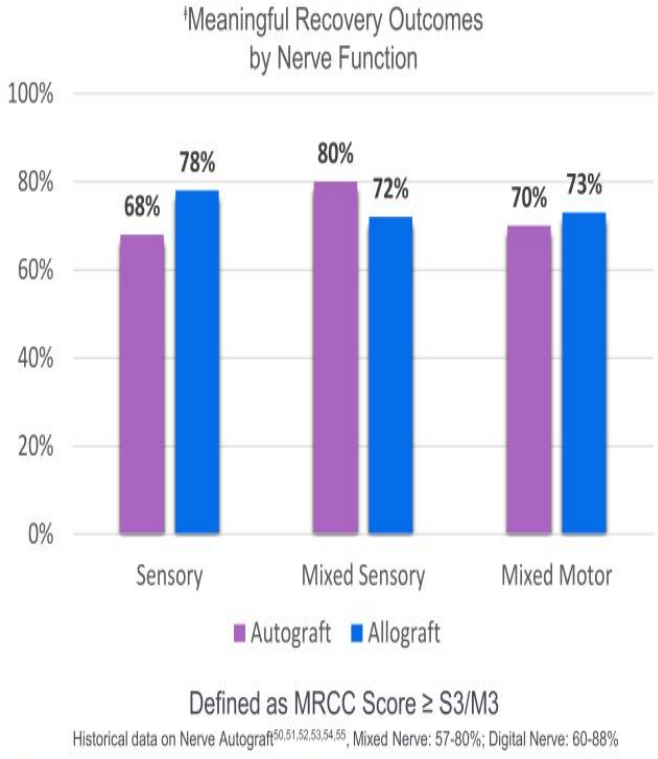
- Peer-reviewed publication from the MATCH cohort of the RANGER Registry
- Includes outcomes from 110 subjects with 162 nerve injuries; 113 were repaired with Avance Nerve Graft and 49 were repaired with manufactured conduit
- Findings show overall meaningful recovery rate was 88% for Avance Nerve Graft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



[I]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"

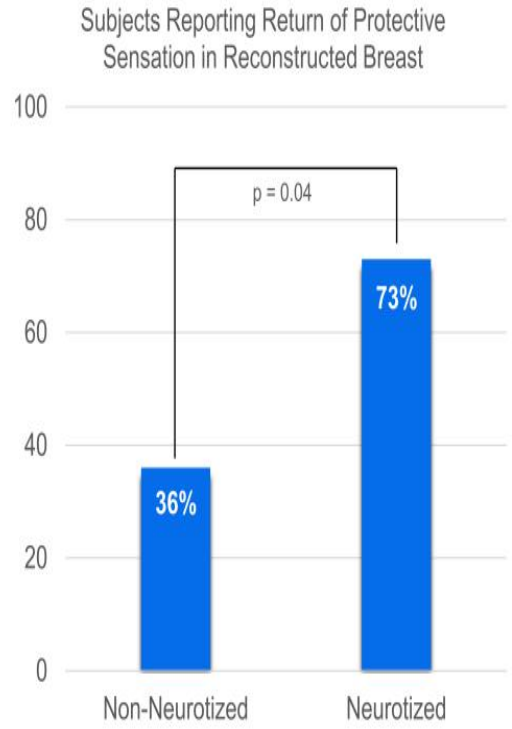
Presented at the American Association for Hand Surgery (AAHS), January 2021[58]

- 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]

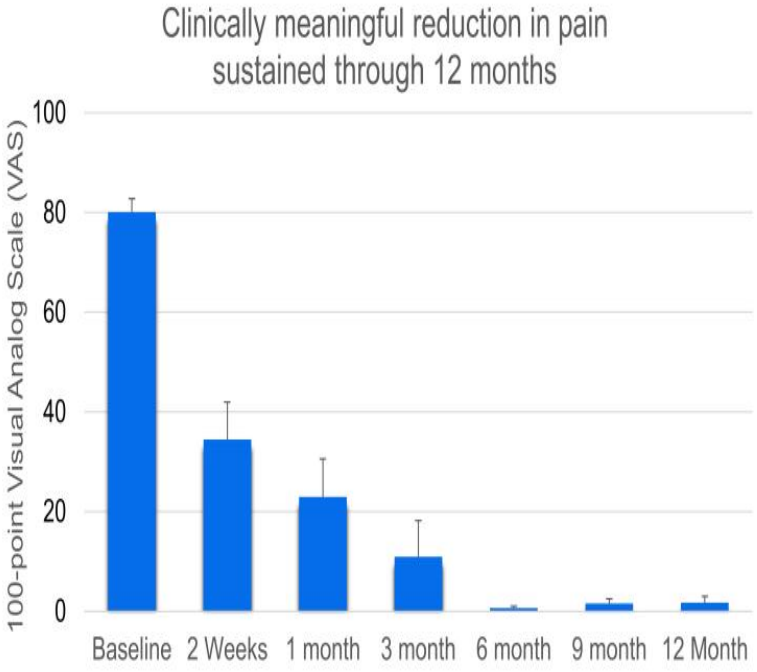


- Early outcomes from a single center study, as part of the Sensation-NOW registry
- 36 breast reconstructions that included:
  - 22 breast reconstructions with Resensation®
  - 14 standard non-neurotized breast reconstructions
- Return of Protective Sensation (p=0.04)
  - 73% of the Resensation group
  - 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



Minimal Clinically Important Difference (MCID): 17mm
Δ 3 months: -69 ± 23; p < 0.0001
Δ 12 months: -80 ± 13; p < 0.0001

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

2022 CMS 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	3Y % Change	2019	2020	2021	2022	3Y % Change
64912	Nerve allograft repair[2]	5432	$4,566	$5,508	$5,700	**$5,824**	27.6%	$1,920	$3,422	$3,788	**$3,868**	101.5%
64910	Conduit or vein allograft repair[2]	5432	$4,566	$5,508	$5,700	**$5,824**	27.6%	$2,613	$3,133	$3,802	**$3,882**	48.6%
64885	Autograft repair (head and neck ≤4cm)	5432	$4,566	$5,508	$5,700	**$5,824**	27.6%	$3,575	$2,170	$2,449	**$2,498**	-30.1%
64886	Autograft repair (head and neck >4cm)[2]	5432	$4,566	$5,508	$5,700	**$5,824**	27.6%	$3,172	$2,170	$4,157	**$4,245**	33.8%
64890	Autograft repair (hand and foot≤4cm)[3]	5432	$4,566	$5,508	$5,700	**$5,824**	27.6%	$3,075	$2,170	$2,499	**$3,251**	5.7%
64891	Autograft repair (hand and foot>4cm)[2]	5432	$4,566	$5,508	$5,700	**$5,824**	27.6%	$1,920	$2,829	$3,185	**$3,251**	69.3%
64892	Autograft repair (arm and leg ≤4cm)[4]	5432	$4,566	$5,508	$5,700	**$5,824**	27.6%	$1,920	$2,170	$2,449	**$3,719**	93.7%
64893-98	Autograft repair (all other nerve type)[4]	5432	$4,566	$5,508	$5,700	**$5,824**	27.6%	$1,920	$2,170	$2,499	**$2,498**	30.1%
64834-36, 40, 56, 57, 62, 64-65	Direct Repair (other hand/foot, arm/leg, repair/transpose, facial, low back,)[5]	5432	$4,566	$5,508	$5,700	**$5,824**	27.6%	$1,920	$2,170	$2,499	**$2,498**	30.1%
64831, 61	Direct Repair (digital, brachial plexus/arm)[4]	5431	$4,566	$1,719	$1,754	**$1,793**	-60.7%	$1,920	$797	$809	**$826**	-57.0%
64858	Direct Repair (sciatic)[2]	5431	$4,566	$1,719	$1,754	**$1,793**	-60.7%	$1,920	$797	$1,434	**$1,474**	-23.2%

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 and head/neck >4cm CPT 64886 and direct repair sciatic CPT 64858 continue to meet ASC device intensive criteria
3. Autograft repairs hand/foot ≤4cm CPT 64890 and arm/leg ≤4cm CPT 64892 meet ASC device intensive criteria in 2022
4. Direct repair digital and brachial plexus/arm (64831, 64861), and autograft repairs head/neck ≤4cm 64855 and all other nerve type CPT 64893-98 do not meet ASC device intensive criteria in 2022.
5. 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 criterianote

axogen

Note:Hospital inpatient rates for nerve repair align to DRGs 040, 041, 042 and range from $11.5k - $23.3k.

2022 Center for Medicare and Medicaid Services (CMS): Physician Fee Schedule (PFS)

CPT Codes3	Descriptor	Physician Fee Schedule (PFS)				
		2019	2020	2021	2022	3Y % Change
64912	Nerve allograft repair	$804	$ 951	$904	**$910**	**13.2%**
64910	Conduit or vein allograft repair	$825	$820	$803	**$790**	**-4.2%**
64885 to 64898*	Autograft repair	$1,096 to $1,495	$1,096 to $1,495	$1,080 to $1,468	**$1,077 to $1,462**	**-1.7% to 2.2%**
64831 to 64868*	Direct Repair	$713 to $1,604	$717 to $1,578	$710 to $1,565	**$712 to $1,567**	**-0.1% to -2.3%**

*excludes add-on procedure codes

Estimated $2.7B value of market opportunity in existing applications

	Annual Incidence[a]	×	Weighted Average Procedure Value	=	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) 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

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

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 HCPS Aggregate Summary Table CY2016. https://data.cms.gov/Medicare-Physician-Supplier/Medicare-National-HCPCS-Aggregate-Summary-Table-CY/jtra-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

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. Wangensteen, 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 neurorrhaphy: 2-year follow-up of a prospective, blinded clinical and electrophysiological multicenter randomized, controlled trial. J hand Surg Am. 2013; 38(12): 2405-2411.
25. Brushart, et al. Selective reinnervation of distal motor stumps by peripheral motor axons. Exp Neurol. 1987; 97(2): 289-300.
26. Schmidhammer, et al. Alleviated tension at the repair site enhances functional regeneration: The effect of full range of motion mobilization on the regeneration of peripheral nerves--histologic, electrophysiologic, and functional results in a rat model. J Trauma. 2004; 56(3): 571-584
27. Tang, et al. The optimal number and location of sutures in conduit-assisted primary digital nerve repair. J Hand Surg Eur Vol. 2018; 43(6): 621-625.
28. Data on file at Axogen
29. Badylak, et al. Small intestinal submucosa: A substrate for in vitro cell growth. J Biomater Sci Polym Ed. 1998; 9(8): 863-878.
30. Hodde, et al. Effects of sterilization on an extracellular matrix scaffold: Part II. Bioactivity and matrix interaction. J Mater Sci Mater Med. 2007; 18(4): 545-550.
31. Nihsen, et al. Bioactivity of small intestinal submucosa and oxidized regenerated cellulose/collagen. Adv Skin Wound Care. 2008; 21(10): 479-486.
32. 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.

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 norephinephrine 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, Januszyk 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. Data on file at Axogen.