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): May 4, 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 May 4, 2022, Axogen, Inc. (the "Company") issued a press release announcing its first 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 May 4, 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 8.01 Other Events

On May 4, 2022, the Company issued a press release announcing results from it's Phase 3 RECON^{SM} Study for Avance® Nerve Graft. A copy of the press release is furnished as Exhibit 99.3.

The information in this Item 8.01, including Exhibit 99.3, 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 May 4, 2022.
99.2	Axogen, Inc. Corporate Presentation, dated May 4, 2022.
99.3	Axogen, Inc. Press Release Phase 3 Recon, dated May 4, 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: May 4, 2022

By: /s/ Bradley L. Ottinger

Bradley L. Ottinger

General Counsel and Chief Compliance Officer

Axogen, Inc Reports 2022 First Quarter Financial Results

ALACHUA and TAMPA, FL – May 4, 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 first quarter ended March 31, 2022.

First Quarter 2022 and Business Highlights

- Net revenue was $31.0 million during the first quarter, matching the first quarter of 2021.
- Excluding Avive® revenue of $1.7 million in the first quarter of 2021, revenue in the first quarter of 2022 increased 6%. The company voluntarily suspended market availability of Avive Soft Tissue Membrane on June 1, 2021.
- Gross margin was 82.1% for the quarter compared to 83.3% in the first quarter of 2021.
- First quarter adjusted net loss was $8.5 million, or $0.20 per share, compared with an adjusted net loss of $3.1 million, or $0.08 per share, in the first quarter of 2021.
- Adjusted EBITDA loss was $7.4 million for the quarter, compared to an adjusted EBITDA loss of $1.9 million in the first quarter of 2021.
- The balance of all cash and cash equivalents and investments on March 31, 2022 was $73.7 million, compared to a balance of $90.3 million on December 31, 2021. The net change includes capital expenditures of $5.0 million related to the construction of our new processing facility in Dayton, OH, and $7.6 million related to items which typically occur in the first quarter, including bonuses, sales meeting and awards, and insurance premiums.
- Core Accounts as of March 31, 2022 were 288, a 5% increase compared to 274 as of March 31, 2021. Revenue from Core Accounts continued to represent approximately 60% of total revenue.
- Active Accounts as of March 31, 2022 were 926, a 1% increase from 919 as of March 31, 2021. Revenue from the top 10% of Active Accounts continued to represent approximately 35% of total revenue.

“We are pleased with our progress and execution as procedure trends improved during the quarter. Our outlook for the year remains on track, and we expect continued growth as surgeons adopt the Axogen nerve repair algorithm,” commented Karen Zaderej, chairman, CEO, and president of Axogen, Inc. “We are also pleased to announce today that our RECON℠ study achieved its primary endpoint representing a critical milestone towards transitioning Avance® Nerve Graft to a licensed biologic and further supporting the expanded adoption of Avance.”

Additional Operational and Business Highlights

- Separately announced today, RECON Phase 3 Study of Avance met its primary endpoint. This study will provide the first ever Level 1 clinical evidence in support of Avance Nerve Graft for peripheral nerve repairs.
- REPOSE[SM] Pilot Study results using Axoguard Nerve Cap® for protecting and preserving terminated nerve ends were published in *Foot and Ankle Surgery: Techniques, Reports & Case.*
- Initiated REPOSE-XL[SM], a clinical study of large-diameter Axoguard Nerve Cap.
- Ended the quarter with 188 peer-reviewed clinical publications featuring Axogen's nerve repair product portfolio.
- Published inaugural Environmental, Social, and Governance (ESG) report highlighting the company's corporate responsibility and sustainability initiatives.
- Ended the quarter with 116 direct sales representatives, compared to 115 at year end and 106 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 by phone are invited to call toll free at 1-866-682-6100 or use the direct dial-in number at (862) 298-0702. 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 REPOSE-XL
The 15-subject, multicenter, prospective, single arm pilot safety and feasibility study is intended to evaluate the use of Axoguard Nerve Cap in large-diameter sizes to protect and preserve terminated nerve ends after limb trauma or amputation to optimize subsequent reconstructive procedures. The diameters of the Nerve Cap under investigation range from 5 to 7 millimeters, compared to the current commercially available Axoguard Nerve Cap, which ranges from 2 to 4 millimeters. The aim of the study is to demonstrate the reduction or mitigation of nerve pain with use of the Nerve Cap and its effect on limb function. Patient follow-up is up to 15 months with functional assessments at shorter intervals. This study is supported, in part, with funding by a grant from the United States Department of Defense Peer Reviewed Orthopedic Research Program.

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. The forward-looking statements may include, 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 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, 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 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
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InvestorRelations@axogeninc.com

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

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 14,559	$ 32,756
Restricted cash	6,251	6,251
Investments	52,859	51,330
Accounts receivable, net of allowance for doubtful accounts of $366 and $276, respectively	18,590	18,158
Inventory	17,400	16,693
Prepaid expenses and other	2,816	1,861
Total current assets	112,475	127,049
Property and equipment, net	66,954	62,923
Operating lease right-of-use assets	15,406	15,193
Intangible assets, net	3,190	2,859
Total assets	$ 198,025	$ 208,024
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 20,872	$ 22,459
Current maturities of long-term lease obligations	2,073	1,834
Total current liabilities	22,945	24,293
Long-term debt, net of debt discount and financing fees	45,041	44,821
Long-term lease obligations	20,878	20,798
Debt derivative liabilities	5,310	5,562
Total liabilities	94,174	95,474
Commitments and contingencies - see Note 12		
Shareholders' equity:		
Common stock, $0.01 par value per share; 100,000,000 shares authorized; 41,972,987 and 41,736,950 shares issued and outstanding	420	417
Additional paid-in capital	345,538	342,765
Accumulated deficit	(242,107)	(230,632)
Total shareholders' equity	103,851	112,550
Total liabilities and shareholders' equity	$ 198,025	$ 208,024

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

	Three Months Ended	
	March 31, 2022	March 31, 2021
Revenues	$ 31,007	$ 31,037
Cost of goods sold	5,546	5,172
Gross profit	25,461	25,865
Costs and expenses:		
Sales and marketing	20,888	17,973
Research and development	6,275	5,748
General and administrative	9,618	8,364
Total costs and expenses	36,781	32,085
Loss from operations	(11,320)	(6,220)
Other (expense) income:		
Investment income	(46)	34
Interest expense	(354)	(444)
Change in fair value of derivatives	252	(22)
Other expense	(7)	(8)
Total other (expense) income, net	(155)	(440)
Net loss	$ (11,475)	$ (6,660)
Weighted average common shares outstanding — basic and diluted	41,804,330	40,705,840
Loss per common share — basic and diluted	$ (0.27)	$ (0.16)

Axogen, Inc.
RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES
Three Months ended March 31, 2022 and 2021
(unaudited)
(In Thousands, Except Per Share Amounts)

	Three months ended	
	March 31, 2022	**March 31, 2021**
Net loss	$ (11,475)	$ (6,660)
Depreciation and amortization expense	773	819
Investment income	46	(34)
Income tax expense	—	(5)
Interest expense	354	444
EBITDA - non GAAP	$ (10,302)	$ (5,436)
Non cash stock-based compensation expense	2,678	2,694
Litigation and related costs	267	836
Adjusted EBITDA - non GAAP	$ (7,357)	$ (1,906)
Net loss	$ (11,475)	$ (6,660)
Non cash stock-based compensation expense	2,678	2,694
Litigation and related costs	267	836
Adjusted net loss - non GAAP	$ (8,530)	$ (3,130)
Weighted average common shares outstanding - basis and diluted	$ (0.27)	$ (0.16)
Non cash stock-based compensation expense	0.06	0.07
Litigation and related costs	0.01	0.02
Adjusted net loss per common share - basis and diluted - non GAAP	$ (0.20)	$ (0.08)

Note: In the Press Release dated February 22, 2022, the Company presented a revised calculation of EBITDA and Adjusted EBITDA which included an adjustment for the amortization of the right of use assets. The Company has since reverted to its former presentation which allows investors to more readily assess operating performance among peer companies.

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 March 31, 2022					
Balance at December 31, 2021	41,736,950	$ 417	$ 342,765	$ (230,632)	$ 112,550
Net loss	—	—	—	(11,475)	(11,475)
Stock-based compensation	—	—	2,678	—	2,678
Issuance of restricted and performance stock units	215,287	2	(2)	—	—
Exercise of stock options and employee stock purchase plan	20,750	1	97	—	98
Balance at March 31, 2022	41,972,987	$ 420	$ 345,538	$ (242,107)	$ 103,851
Three Months Ended March 31, 2021					
Balance at December 31, 2020	40,618,766	$ 406	$ 326,390	$ (203,647)	$ 123,149
Net loss	—	—	—	(6,660)	(6,660)
Stock-based compensation	—	—	2,694	—	2,694
Issuance of restricted and performance stock units	94,533	1	(1)	—	—
Exercise of stock options and employee stock purchase plan	129,418	1	520	—	521
Balance at March 31, 2021	40,842,717	$ 408	$ 329,603	$ (210,307)	$ 119,704

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

	Three Months Ended	
	March 31, 2022	March 31, 2021
Cash flows from operating activities:		
Net loss	$ (11,475)	$ (6,660)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	704	772
Amortization of right-of-use assets	427	500
Amortization of intangible assets	69	47
Amortization of debt discount and deferred financing fees	220	112
Provision for bad debt	267	(26)
Provision for inventory write-down	459	783
Change in fair value of derivatives	(252)	22
Investment losses	96	15
Stock-based compensation	2,678	2,694
Change in operating assets and liabilities:		
Accounts receivable	(624)	(2,181)
Inventory	(1,166)	(1,642)
Prepaid expenses and other	(1,030)	(313)
Accounts payable and accrued expenses	(1,104)	(5,061)
Operating lease obligations	(320)	119
Cash paid for interest portion of finance leases	—	—
Contract and other liabilities	—	(1)
Net cash used in operating activities	(11,051)	(10,820)
Cash flows from investing activities:		
Purchase of property and equipment	(5,037)	(3,095)
Purchase of investments	(6,024)	(15,279)
Proceeds from sale of investments	4,400	19,400
Cash payments for intangible assets	(580)	(156)
Net cash (used in) provided by investing activities	(7,241)	870
Cash flows from financing activities:		
Cash paid for debt portion of finance leases	(2)	(4)
Proceeds from exercise of stock options and ESPP stock purchases	97	521
Net cash provided by financing activities	95	517
Net decrease in cash, cash equivalents, and restricted cash	(18,197)	(9,433)
Cash, cash equivalents, and restricted cash, beginning of period	39,007	55,609
Cash, cash equivalents, and restricted cash, end of period	$ 20,810	$ 46,176
Supplemental disclosures of cash flow activity:		
Cash paid for interest, net of capitalized interest	$ —	$ 312
Supplemental disclosure of non-cash investing and financing activities:		
Acquisition of fixed assets in accounts payable and accrued expenses	$ 1,119	$ 4,836
Obtaining a right-of-use asset in exchange for a lease liability	$ 641	$ 321
Acquisition of intangible assets in accounts payable and accrued expenses	$ 239	$ 166

Corporate presentation

As of May 4, 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. 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, 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 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

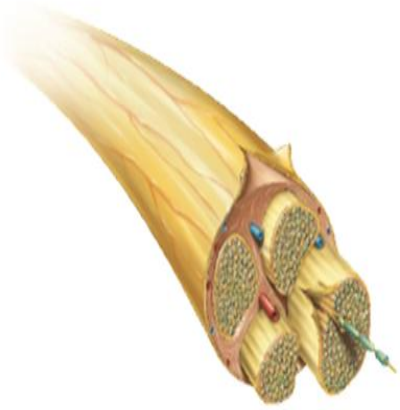
The function of nerves

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

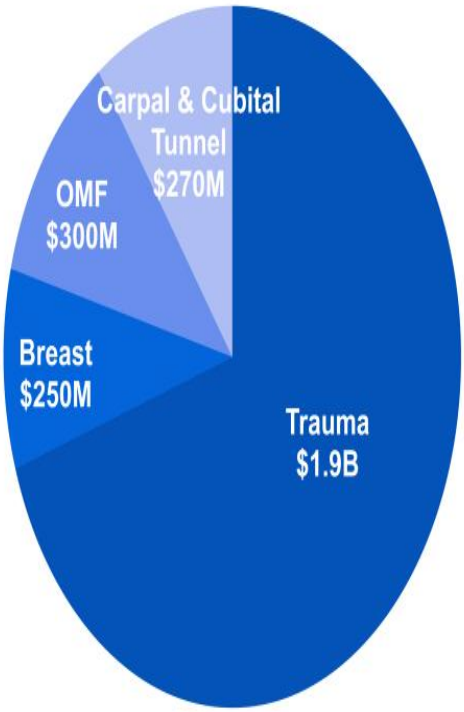
Connection	Protection	Termination

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 188 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**

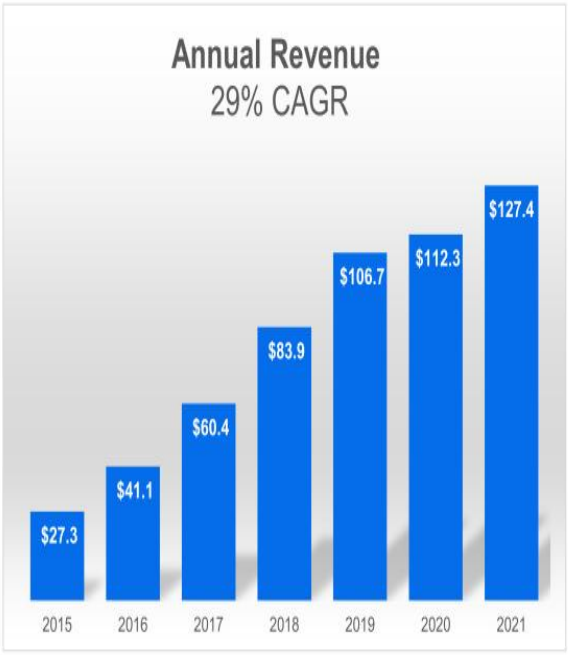
- Trauma: > 700,000
- Carpal Tunnel Revisions & Cubital Tunnel: 130,000
- Oral Maxillofacial (OMF): 56,000
- Breast Neurotization Procedures: 15,000

**$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

- Q1 growth was flat over Q1 2021. Excluding the impact of Avive, growth was approximately 6%*
- Revenue was negatively impacted by COVID headwinds/staffing challenges and partially offset with growth among all products
- Increased Core Accounts by 5%

82.1% Gross Margin for the year ended March 31, 2022
83.3% Gross Margin for the quarter ended March 31, 2021

* Axogen voluntarily suspended market availability of Avive® Soft Tissue Membrane on June 1, 2021. Avive revenue in the first quarter of 2021 was approximately $1.7 million and totaled approximately $4.1 million and $5.5 million for the years ended 2021 and 2020 respectively.

Guidance update

2022 Annual Financial Guidance

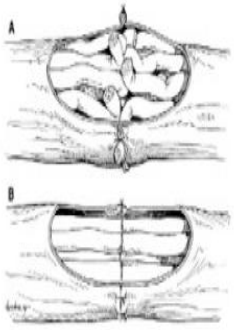
- Full-year 2022 revenue is still expected to be between $135 million and $142 million.
  - Represents approximately 10% to 15% growth over 2021 revenue excluding the impact of $4.1 million of Avive revenue in 2021.
- Full-year 2022 gross margin is still expected to remain above 80%.

Traditional TRANSECTION repair options are suboptimal

SUTURE

Direct suture repair of no-gap injuries

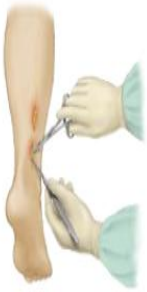
- Common repair method
- May result in tension to the repair leading to ischemia
- Concentrates sutures at the coaptation site



AUTOGRAFT

Traditional method despite several disadvantages

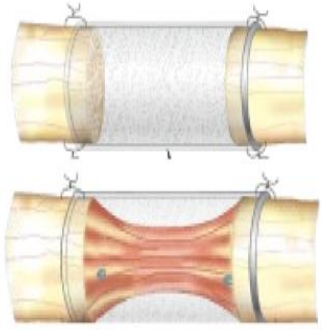
- Secondary surgery
- Loss of function and sensation at harvest site
- 27% complication rate including infection, wound healing and chronic pain [19]
- Limited availability of graft length and diameter



SYNTHETIC CONDUITS

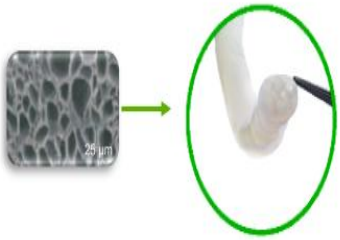
Convenient off the shelf option; limited efficacy & use

- 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

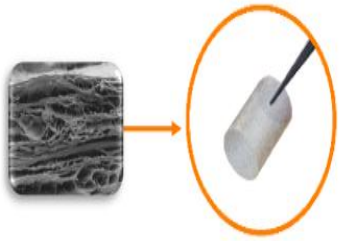
Structural support for regenerating axons

- 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]

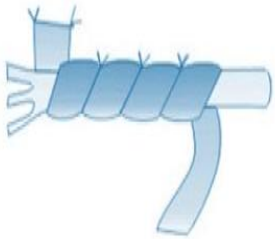
14 size options in lengths of 10mm and 15mm, and diameters up to 7mm

Traditional COMPRESSION repair options are suboptimal

VEIN WRAPPING

Autologous vein

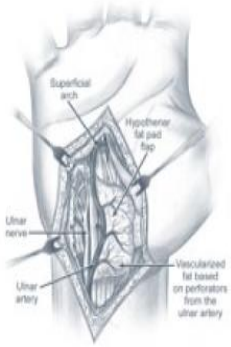
- Barrier to attachment to surrounding tissue
- Requires extra time and skill to perform spiral wrapping technique
- Second surgery site



HYPOTHENAR FAT PAD

Autologous vascularization flap

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



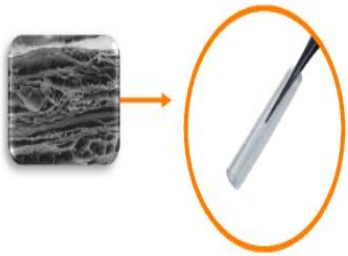
COLLAGEN WRAPS

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

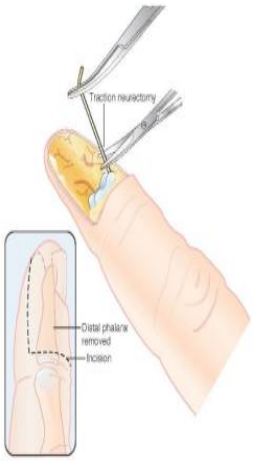
- Minimizes risk of entrapment[34]
- Creates a barrier between repair and surrounding tissue bed[34]
- ECM revascularizes and remodels into patient's own tissue[29,35]

Traditional STUMP NEUROMA options are suboptimal

TRACTION NEURECTOMY

Nerve placed in traction and cut to allow for retraction

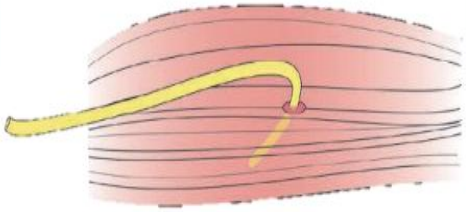
- Simply resecting the nerve results in subsequent neuroma formation and risk of secondary surgery
- Causes traction injury
- High risk of recurrence[36]



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]



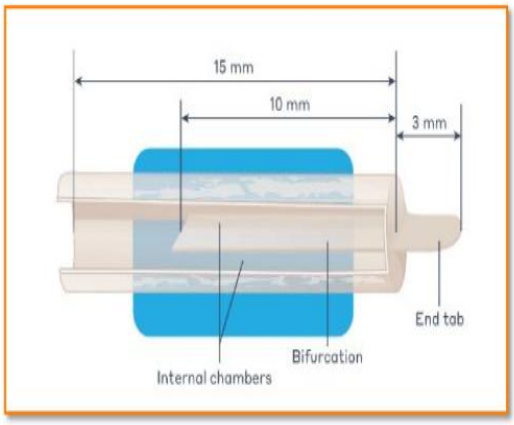
INJECTIONS

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

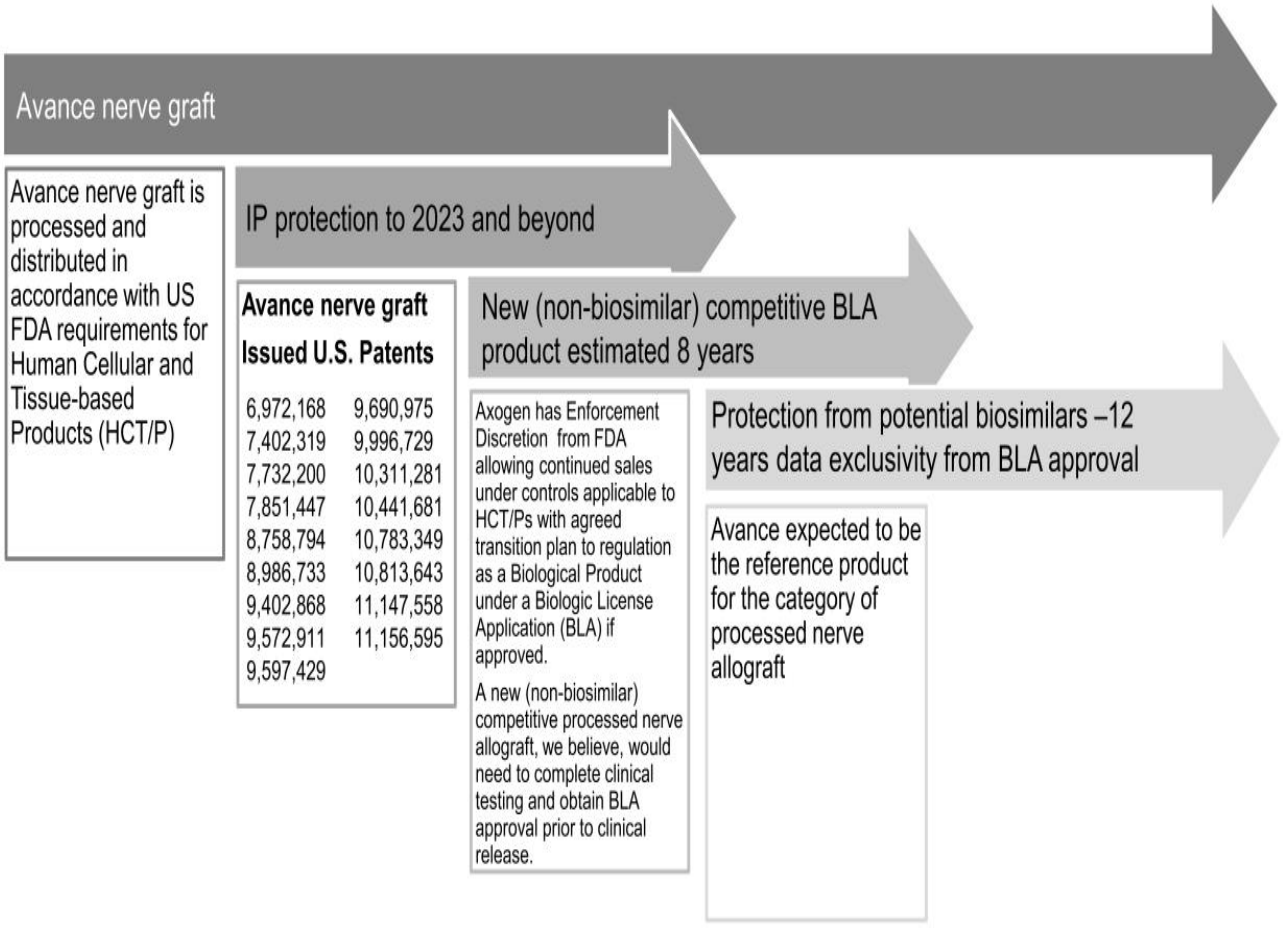
SIS Material allows for vascularization and gradual remodeling (as shown in animal studies)[46, 47]

- 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

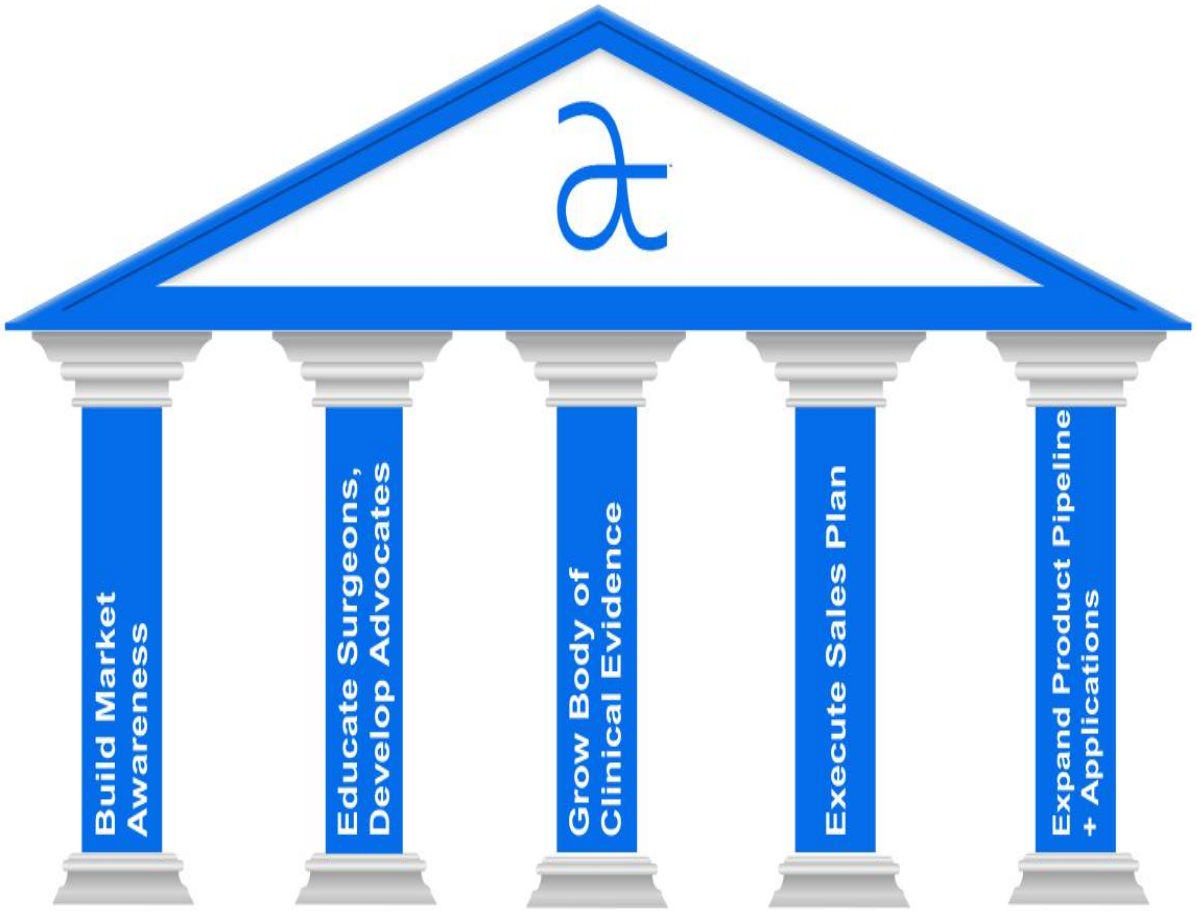
- ✓ Avance demonstrated statistical superiority for return of sensory function (measured by static two-point discrimination) as compared to conduits in gaps greater than 12 mm (p-value 0.021).
- ✓ Avance demonstrated statistical superiority for time to recovery of static two-point discrimination as compared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

- 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

- Multi-center clinical study in PNR with >2,600 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 Ongoing

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

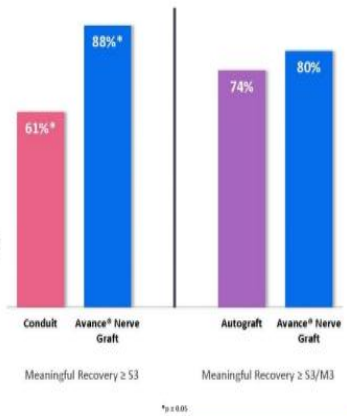
REPOSE-XL℠: Enrollment Initiated

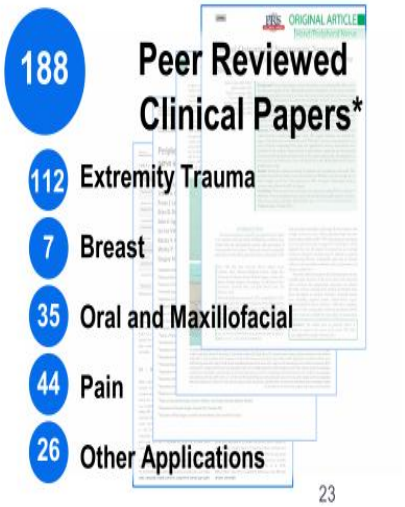
- Prospective, randomized, controlled study of large-diameter Axoguard Nerve Cap® vs neurectomy

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]





*Certain publications contain data on multiple applications.

Focused sales execution, increasing market penetration

Sales execution focused on driving results

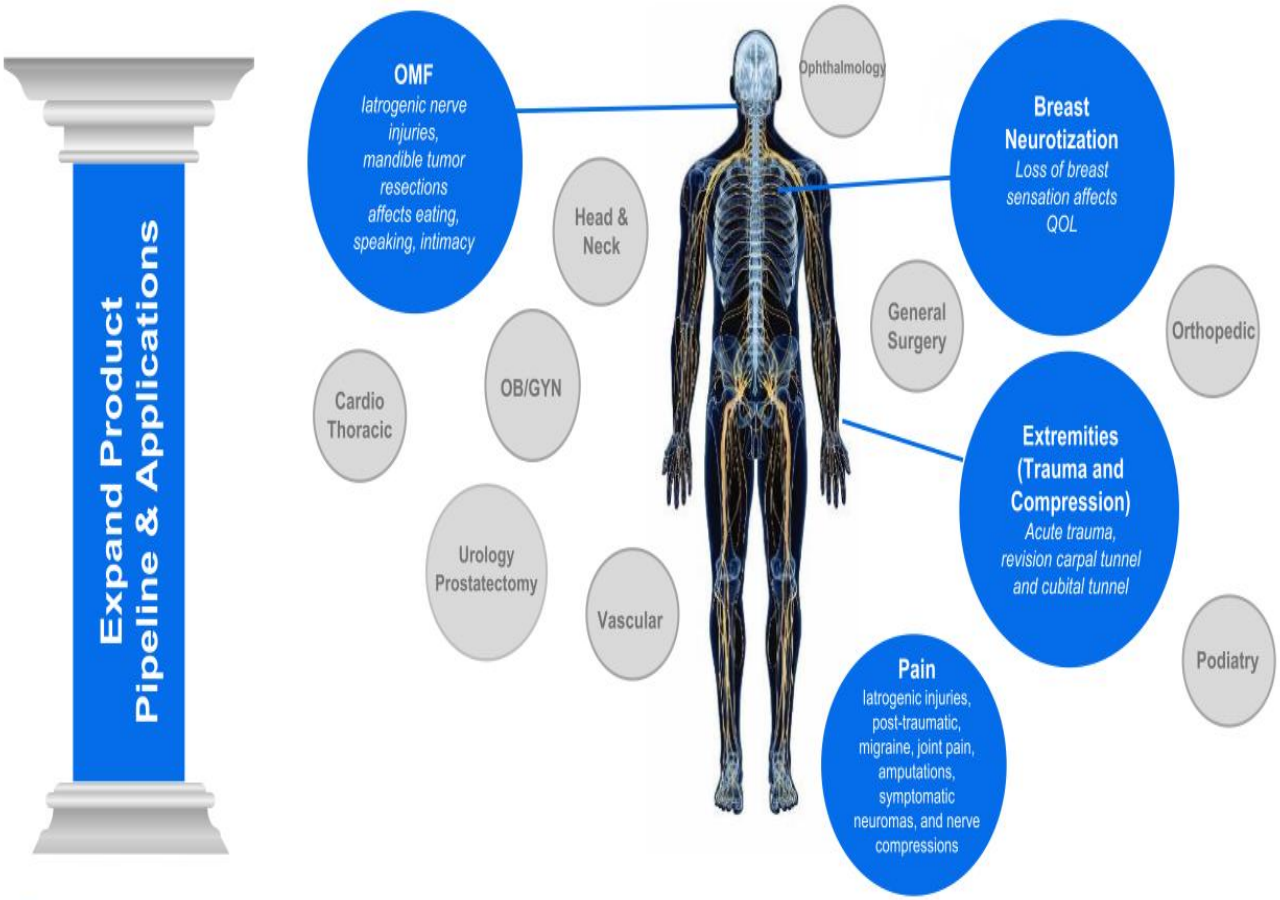
- Continue driving penetration in Active and Core Accounts
- 5,100 potential U.S. accounts perform nerve repair
- 926 Active Accounts as of March 31, 2022, up 1% vs prior year
  - Active Accounts represent approximately 85% of total revenue
  - Top 10% of Active Accounts represent approximately 35% of total revenue
- 288 Core Accounts as of March 31, 2022, up 5% vs prior year
  - Core Accounts represent approximately 60% of total revenue

Expanded sales reach

- U.S. direct sales team
  - 116 direct sales professionals at end of Q1 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	March 31, 2022
Cash, Cash Equivalents, and Investments	$73.7 million
Total Long-term Debt	$50.0 million*

Capital Structure (shares)	March 31, 2022
Common Stock	41,972,775
Common Stock Options, RSUs, PSUs	7,296,910
Common Stock and Common Stock Equivalents	49,269,685

** 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

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 188 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

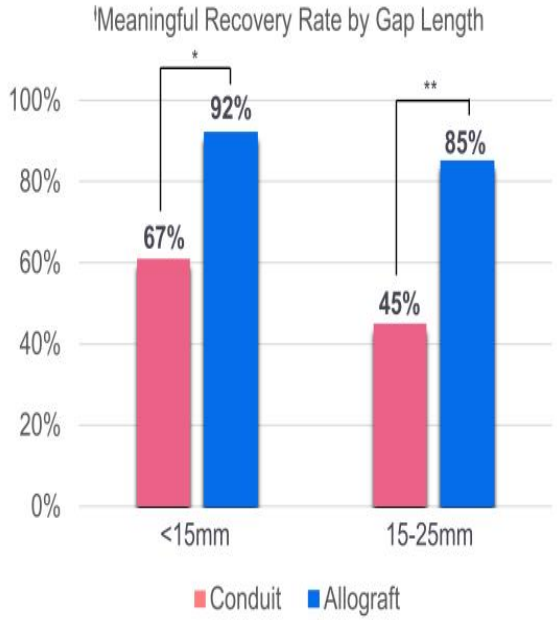
Appendix

- 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]

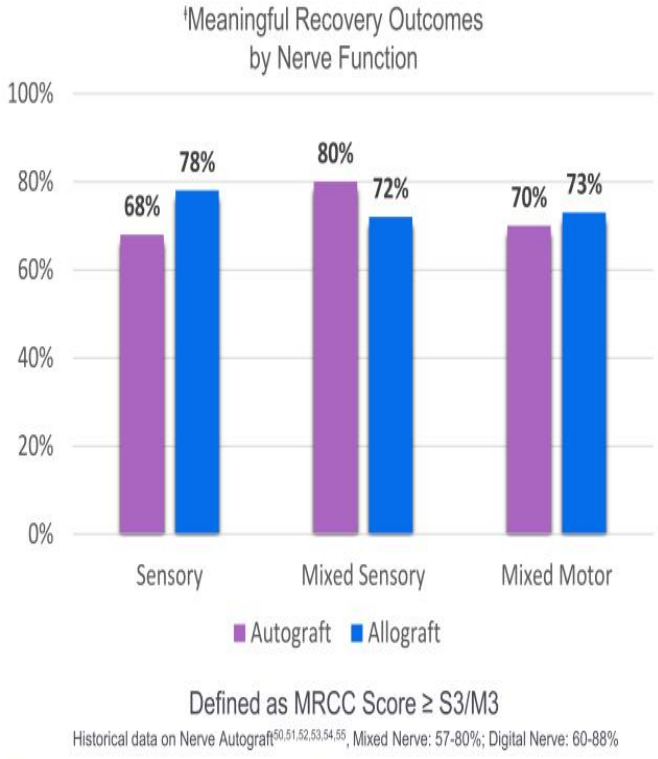
- Peer-reviewed publication from the MATCH cohort of the RANGER Registry
- Includes outcomes from 110 subjects with 162 nerve injuries; 113 were repaired with Avance Nerve Graft and 49 were repaired with manufactured conduit
- Findings show overall meaningful recovery rate was 88% for Avance Nerve Graft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

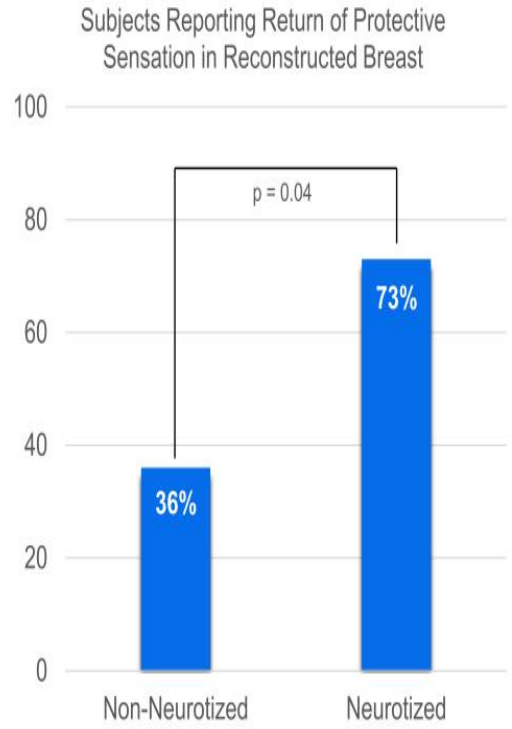
Presented at the American Association for Hand Surgery (AAHS), January 2021[58]

- 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]

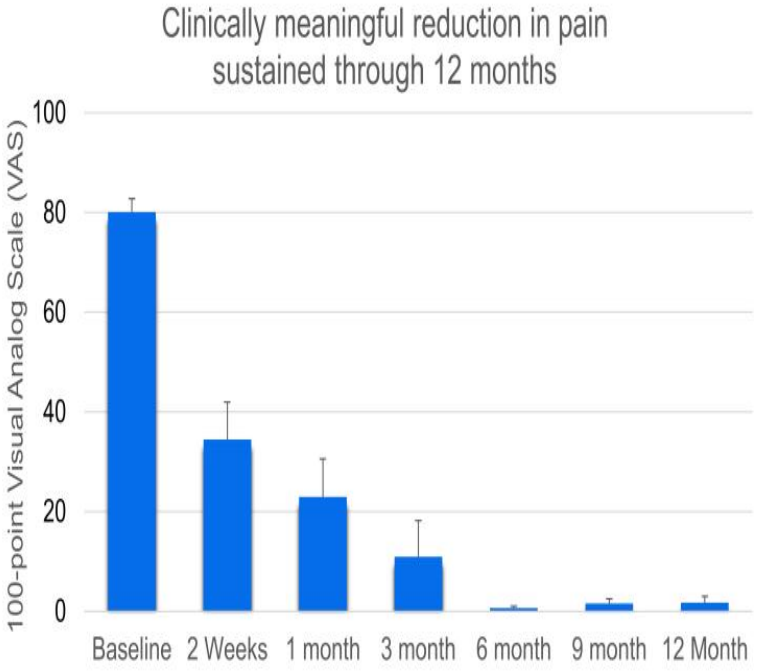


- Early outcomes from a single center study, as part of the Sensation-NOW registry
- 36 breast reconstructions that included:
  - 22 breast reconstructions with Resensation®
  - 14 standard non-neurotized breast reconstructions
- Return of Protective Sensation (p=0.04)
  - 73% of the Resensation group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

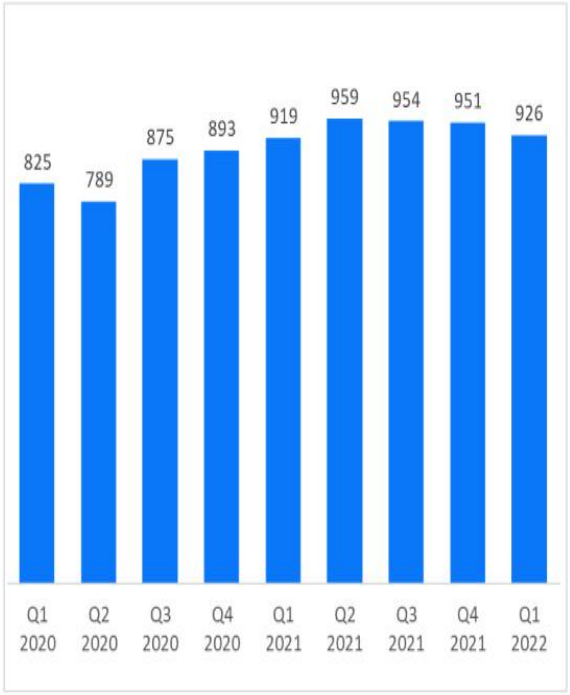


Minimal Clinically Important Difference (MCID): 17mm
Δ 3 months: -69 ± 23; p < 0.0001
Δ 12 months: -80 ± 13; p < 0.0001

Historical Active and Core Accounts

Active Accounts

6 orders in the last 12 months

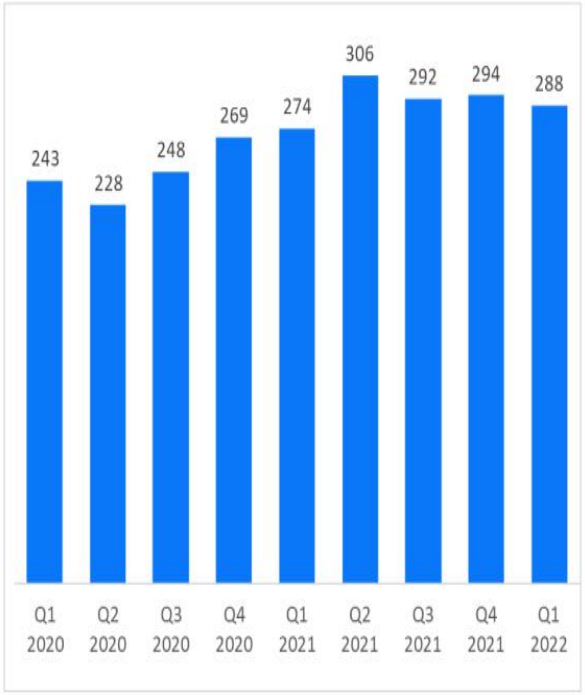


Active Accounts typically contribute ≈85% of total revenue

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 criteria note

Note: Hospital inpatient rates for nerve repair align to DRGs 040, 041, 042 and range from $11.5k - $23.4k.

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 ✖ **7.4%** Revision cases	See calculation on previous slide *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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Axogen, Inc. Announces Positive Topline Results from Phase 3 RECON℠ Study for Avance® Nerve Graft

RECON achieved its Primary Endpoint, a critical milestone toward transitioning Avance Nerve Graft to a licensed biologic and further supporting the expanded adoption of Avance

ALACHUA and TAMPA, FL – May 4, 2022 –Axogen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for peripheral nerve injuries, today announced topline results from its RECON Clinical Study comparing Avance Nerve Graft to conduits in digital nerve injuries. The 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. This data will support the company's Biologics License Application (BLA) submission in the second half of 2023.

Additional analysis of the study data found:

- 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).
- 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.

"I would like to share my appreciation for the RECON investigators and their study teams. Their commitment to the importance of this research was essential in completing a study with this quality of data and rigor of evidence and execution," said Co-Lead Investigator Jonathan Isaacs, MD., Professor and Chair, Division of Hand Surgery Virginia Commonwealth University. "The study data confirmed that as gap lengths increased, Avance returned superior levels of sensation, and this was achieved at earlier time points than those observed for conduits."

"We are thrilled that the RECON study has met its primary endpoint. This is a critical milestone towards transitioning Avance Nerve Graft to a licensed biologic and further supports the expanded adoption of Avance," said Karen Zaderej, chairman, CEO, and president of Axogen, Inc. "This study will provide Level 1 clinical evidence important to surgeons choosing among treatment options for patients with

peripheral nerve injuries. I want to thank all of the participating subjects, clinical sites, investigators, and our Axogen employees who have contributed to this landmark study."

* Normal Sensation is defined by the Medical Research Council Classification (MRCC) score as S4 or return of static two-point discrimination outcomes of ≤ 6mm.

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 Avance Nerve Graft

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

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

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

About Axogen

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

Axogen's platform for peripheral nerve repair features a comprehensive portfolio of products, 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, the United Kingdom, South Korea, and several other European and international countries.

Cautionary Statements Concerning Forward-Looking Statements

This press release contains “forward-looking” statements as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations or predictions of future conditions, events, or results based on various assumptions and management's estimates of trends and economic factors in the markets in which we are active, as well as our business plans. Words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “seeks,” “estimates,” “projects,” “forecasts,” “continue,” “may,” “should,” “will,” “goals,” and variations of such words and similar expressions are intended to identify such forward-looking statements. The forward-looking statements may include, without limitation, statements related to the 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 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, 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 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.

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