
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 5, 2021

AXOGEN, INC.
(Exact Name of Registrant as Specified in Charter)

Minnesota
(State or Other Jurisdiction of
Incorporation or Organization)

001-36046
(Commission File Number)

41-1301878
(I.R.S. Employer Identification No.)

13631 Progress Boulevard, Suite 400 Alachua, Florida
(Address of principal executive offices)

32615
(Zip Code)

(386) 462-6800
(Registrant's telephone number, including area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, \$0.01 par value	AXGN	The Nasdaq Stock Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition

On May 5, 2021, Axogen, Inc. (the “Company”) issued a press release announcing its financial performance for the quarter ended March 31, 2021. 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 5, 2021, the Company also posted an updated corporate presentation to its website at <https://ir.axogeninc.com/news-events>. The Company may use the investor presentation from time to time in conversation with analysts, investors, and others. A copy of the investor update is furnished as Exhibit 99.2.

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

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Axogen, Inc. Press Release, dated May 5, 2021.
99.2	Axogen, Inc. Corporate Presentation, dated May 5, 2021.
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 5, 2021

By: /s/ Brad Ottinger

Brad Ottinger

General Counsel and Chief Compliance Officer



Axogen, Inc. Reports 2021 First Quarter Financial Results

ALACHUA and TAMPA, FL – May 5, 2021 –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, 2021.

First Quarter 2021 Financial Results and Business Highlights

- Net revenue was \$31.0 million during the quarter, a 28% increase compared to first quarter 2020 revenue of \$24.3 million.
- Gross margin was 83.3% for the quarter, compared to 80.1% in the first quarter of 2020.
- Net loss for the quarter was \$6.7 million, or \$0.16 per share, compared to a net loss of \$8.2 million, or \$0.21 per share, in the first quarter of 2020.
- Adjusted net loss was \$3.1 million for the quarter, or \$0.08 per share, compared with adjusted net loss of \$7.6 million, or \$0.19 per share, in the first quarter of 2020.
- Adjusted EBITDA loss was \$1.9 million for the quarter, compared to an adjusted EBITDA loss of \$7.6 million in the first quarter of 2020.
- The balance of cash, cash equivalents, and investments on March 31, 2021 was \$97.2 million, compared to a balance of \$110.8 million on December 31, 2020.

“I am pleased with our first quarter performance,” commented Karen Zaderej, chairman, CEO, and president of Axogen, Inc. “Surgeon demand for our products remains strong, supported by our substantial investment in clinical studies over the past decade. These studies continue to generate meaningful evidence, driving further surgeon adoption and reinforcing our confidence in the long-term growth potential of our business.”

Additional Operational and Business Highlights

- Active accounts in the first quarter were 919, an 11% increase compared to 825 in the first quarter a year ago, and revenue from the top 10% of our active accounts continued to represent approximately 35% of total revenue in the quarter.
 - Ended the quarter with 106 direct sales representatives, compared to 108 currently, 111 at year end, and 109 one year ago.
 - Ended the quarter with 157 peer-reviewed clinical publications featuring Axogen’s nerve repair product portfolio.
 - Reinitiated clinical study activities for the Rethink Pain™ and Sensation-NOW® registries and are actively engaged in six sponsored studies currently enrolling across our four primary market applications.
-

2021 Financial Guidance

Management is reinitiating financial guidance and believes that full-year 2021 revenue will be in the range of \$133 million to \$136 million. Additionally, full-year 2021 gross margin is expected to remain 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 1-201-689-8795. Those interested in listening to the conference call live via the Internet can do so by visiting the Investors page of the Company's website at www.axogeninc.com and clicking on the webcast link on the Investors home page.

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

About Axogen

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

Axogen's platform for peripheral nerve repair features a comprehensive portfolio of products, including Avance® Nerve Graft, a biologically active off-the-shelf processed human nerve allograft for bridging severed peripheral nerves without the comorbidities associated with a second surgical site; Axoguard Nerve Connector®, a porcine submucosa extracellular matrix (ECM) coaptation aid for tensionless repair of severed peripheral nerves; Axoguard Nerve Protector®, a porcine submucosa ECM product used to wrap and protect damaged peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments; Axoguard Nerve Cap®, a porcine submucosa ECM product used to protect a peripheral nerve end and separate the nerve from the surrounding environment to reduce the development of symptomatic or painful neuroma; and Avive® Soft Tissue Membrane, a processed human umbilical cord intended for surgical use as a resorbable soft tissue barrier. The Axogen portfolio of products is available in the United States, Canada, Germany, 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 expected impact of COVID-19 on our business, statements regarding our growth, our 2021 financial guidance, product development, product potential, financial performance, sales growth, product adoption, market awareness of our products, data validation, our assessment of our internal controls over financial reporting, our visibility at and sponsorship of conferences and educational events. The forward-looking statements are and will be subject to risks and uncertainties, which may cause actual results to differ materially from those expressed or implied in such forward-looking statements. Forward-looking statements contained in this press release should be evaluated together with the many uncertainties that affect our business and our market, particularly those discussed under Part I, Item 1A., “Risk Factors,” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, as well as other risks and cautionary statements set forth in our filings with the U.S. Securities and Exchange Commission. Forward-looking statements are not a guarantee of future performance, and actual results may differ materially from those projected. The forward-looking statements are representative only as of the date they are made and, except as required by applicable law, we assume no responsibility to publicly update or revise any forward-looking statements, whether as a result of new information, future events, changed circumstances, or otherwise.

About Non-GAAP Financial Measures

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

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

Contact:
Axogen, Inc.
Peter J. Mariani, Executive Vice President and Chief Financial Officer InvestorRelations@AxogenInc.com

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

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 39,843	\$ 48,767
Restricted cash	6,333	6,842
Investments	51,062	55,199
Accounts receivable, net	19,825	17,618
Inventory	13,388	12,529
Prepaid expenses and other	4,694	4,296
Total current assets	135,145	145,251
Property and equipment, net	44,395	38,398
Operating lease right-of-use assets	15,442	15,614
Finance lease right-of-use assets	59	64
Intangible assets	2,328	2,054
Total assets	\$ 197,369	\$ 201,381
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 20,831	\$ 21,968
Current maturities of long-term lease obligations	1,442	863
Total current liabilities	22,273	22,831
Long-term debt, net of financing fees	32,140	32,027
Debt derivative liability	2,519	2,497
Long-term lease obligations	20,731	20,874
Other long-term liabilities	2	3
Total liabilities	77,665	78,232
Shareholders' equity:		
Common stock, \$.01 par value per share; 100,000,000 shares authorized; 40,842,717 and 40,618,766 shares issued and outstanding	408	406
Additional paid-in capital	329,603	326,390
Accumulated deficit	(210,307)	(203,647)
Total shareholders' equity	119,704	123,149
Total liabilities and shareholders' equity	\$ 197,369	\$ 201,381

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
Three Months ended March 31, 2021 and 2020
(In Thousands)
(unaudited)

	Three Months Ended	
	Mar 31, 2021	Mar 31, 2020
Revenues	\$ 31,037	\$ 24,261
Cost of goods sold	5,172	4,816
Gross profit	25,865	19,445
Costs and expenses:		
Sales and marketing	17,973	17,838
Research and development	5,748	4,614
General and administrative	8,364	5,502
Total costs and expenses	32,085	27,954
Loss from operations	(6,220)	(8,509)
Other income (expense):		
Interest income	34	311
Interest expense	(444)	(31)
Other income (expense)	(30)	27
Total other income (expense)	(440)	317
Net loss	\$ (6,660)	\$ (8,192)
Weighted average common shares outstanding – basic and diluted	40,706	39,698
Loss per common share – basic and diluted	\$ (0.16)	\$ (0.21)
Adjusted net loss - non GAAP	(3,129)	(7,636)
Adjusted net loss per common share - basic and diluted	\$ (0.08)	\$ (0.19)

AXOGEN, INC.
RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES
Three Months ended March 31, 2021 and 2020
(In Thousands)
(unaudited)

	Three Months Ended	
	Mar 31, 2021	Mar 31, 2020
Net loss	\$ (6,660)	\$ (8,192)
Depreciation and amortization expense	818	343
Investment income	(34)	(311)
Income tax	(5)	(10)
Interest expense	444	31
EBITDA - non GAAP	\$ (5,437)	\$ (8,139)
Non cash stock compensation expense	\$ 2,694	\$ 556
Litigation and related costs	837	—
Adjusted EBITDA - non GAAP	\$ (1,906)	\$ (7,583)
Net loss	\$ (6,660)	\$ (8,192)
Non cash stock compensation expense	2,694	556
Litigation and related costs	837	—
Adjusted Net Loss - non GAAP	\$ (3,129)	\$ (7,636)
Weighted average common shares outstanding – basic and diluted	\$ (0.16)	\$ (0.21)
Non cash stock compensation expense	0.07	0.01
Litigation and related costs	0.02	-
Adjusted net loss per common share - basic and diluted	\$ (0.08)	\$ (0.19)

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
Three Months ended March 31, 2021 and 2020
(unaudited)
(In Thousands, Except Share Amounts)

	Common Stock		Additional Paid- in Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount			
For the 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)
Issuance of restricted/performance service awards	94,533	1	(1)	-	-
Stock-based compensation	-	-	2,694	-	2,694
Exercise of stock options and employee stock purchase plan	129,418	1	520	-	521
Balance at March 31, 2021	<u>40,842,717</u>	<u>\$ 408</u>	<u>\$ 329,603</u>	<u>\$ (210,307)</u>	<u>\$ 119,704</u>
For the Three Months Ended March 31, 2020:					
Balance at December 31, 2019	39,589,755	\$ 396	\$ 311,618	\$ (179,861)	\$ 132,153
Net Loss	-	-	-	(8,192)	(8,192)
Issuance of restricted/performance service awards	137,634	1	(1)	-	-
Stock-based compensation	-	-	556	-	556
Shares surrendered by employees to pay taxes	(36,963)	-	(639)	-	(639)
Exercise of stock options and employee stock purchase plan	48,341	-	316	-	316
Balance at March 31, 2020	<u>39,738,767</u>	<u>\$ 397</u>	<u>\$ 311,850</u>	<u>\$ (188,053)</u>	<u>\$ 124,194</u>

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
Three Months ended March 31, 2021 and 2020
(In Thousands)
(unaudited)

	Fiscal Year	
	Mar 31, 2021	Mar 31, 2020
Cash flows from operating activities:		
Net loss	\$ (6,660)	\$ (8,192)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	772	307
Amortization of right-of-use assets	500	470
Amortization of intangible assets	47	36
Amortization of deferred financing costs	112	—
Provision for bad debt	(26)	22
Provision for inventory write down	783	924
Change in fair value of derivatives	22	—
Change in investment gains and losses	15	(49)
Share-based compensation	2,694	556
Change in assets and liabilities:		
Accounts receivable	(2,181)	3,902
Inventory	(1,642)	(1,626)
Prepaid expenses and other	(313)	(2,024)
Accounts payable and accrued expenses	(5,061)	(1,903)
Operating Lease Obligations	119	(472)
Contract and other liabilities	(1)	(3)
Net cash used in operating activities	(10,820)	(8,052)
Cash flows from investing activities:		
Purchase of short-term investments	(15,279)	(11,760)
Purchase of property and equipment	(3,095)	(5,021)
Sale/Maturities of short-term investments	19,400	25,450
Cash payments for intangible assets	(156)	(119)
Net cash provided by investing activities	870	8,550
Cash flows from financing activities:		
Payments for repurchase of common stock for employee tax withholding	—	(639)
Cash paid for debt portion of finance leases	(4)	(5)
Proceeds from exercise of stock options and warrants	521	316
Net cash provided by / (used in) financing activities	517	(328)
Net increase in cash, cash equivalents and restricted cash	(9,433)	170
Cash, cash equivalents and restricted cash, beginning of year	55,609	41,724
Cash, cash equivalents and restricted cash, end of period	\$ 46,176	\$ 41,894
Supplemental disclosures of cash flow activity:		
Cash paid for interest	\$ 312	\$ 11
Supplemental disclosure of non-cash investing and financing activities		
Acquisition of fixed assets in accounts payable and accrued expenses	\$ 4,836	\$ 3,674
Right-of-use asset and operating lease liability	\$ 321	\$ 120
Acquisition of intangible assets in accounts payable and accrued expenses	\$ 166	\$ -

Corporate presentation

As of March 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 expected impact of COVID-19 on our business, statements regarding our growth, our 2021 financial guidance, product development, product potential, financial performance, sales growth, product adoption, market awareness of our products, data validation, our assessment of our internal controls over financial reporting, our visibility at and sponsorship of conferences and educational events.

The forward-looking statements are and will be subject to risks and uncertainties, which may cause actual results to differ materially from those expressed or implied in such forward-looking statements. Forward-looking statements contained in this presentation should be evaluated together with the many uncertainties that affect our business and our market, particularly those discussed under Part I, Item 1A., “Risk Factors,” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, as well as other risks and cautionary statements set forth in our filings with the U.S. Securities and Exchange Commission. Forward-looking statements are not a guarantee of future performance, and actual results may differ materially from those projected. The forward-looking statements are representative only as of the date they are made and, except as required by applicable law, we assume no responsibility to publicly update or revise any forward-looking statements, whether as a result of new information, future events, changed circumstances, or otherwise.

The Axogen platform for nerve repair

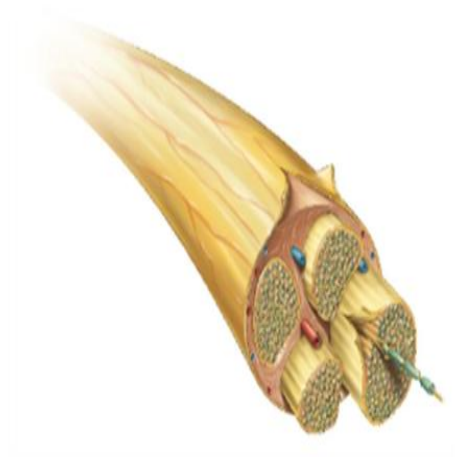
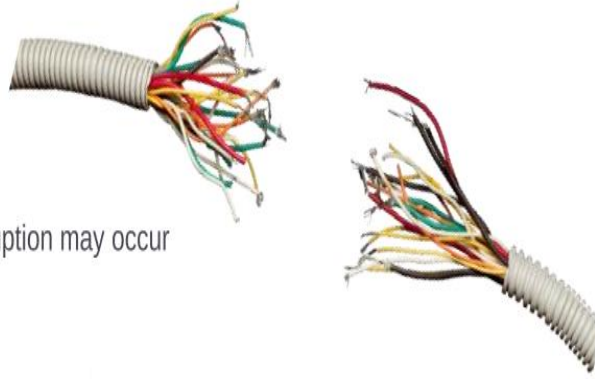


revolutionizing the science of nerve repair™

The function of nerves

Nerves are like wires

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



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

- Sensory
- Motor
- Autonomic

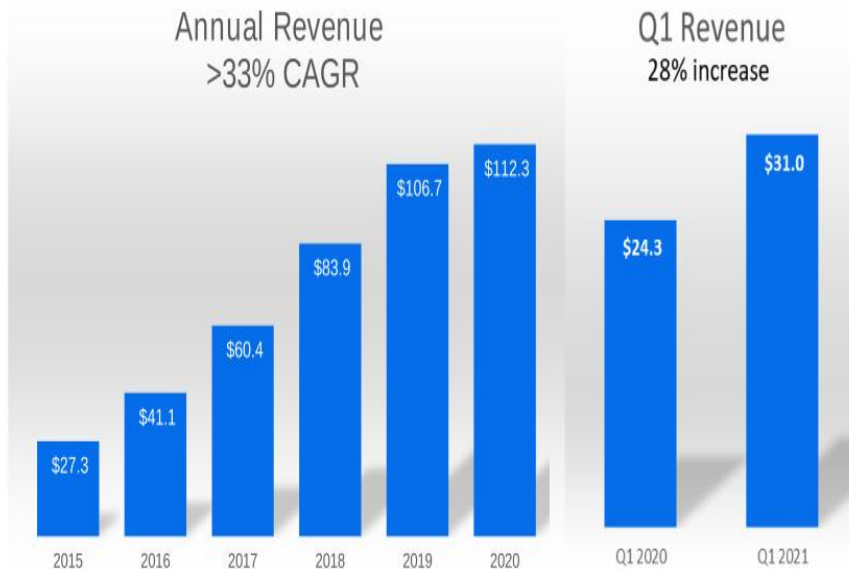
Axogen is the preeminent nerve repair company with a foundation for long-term sustainable growth

- ✓ Exclusively focused on peripheral nerve repair across an expanding set of applications addressing a large market opportunity
- ✓ Differentiated platform for nerve repair, anchored by Avance® Nerve Graft
- ✓ 10+ years of demonstrated clinical consistency and meaningful recovery outcomes
- ✓ 157 peer-reviewed clinical publications featuring the Axogen product portfolio (as of March 31, 2021)
- ✓ More than 50,000 Avance Nerve Grafts have been implanted since launch
- ✓ Avance RMAT designation highlights clinical evidence strength and unmet medical need for improved nerve injury treatments
- ✓ Commercial and Professional Education capability to convert experienced surgeons while training the next generation
- ✓ Significant barriers to competitive entry
- ✓ Solid balance sheet provides resources to execute business plan
- ✓ Experienced management team with strong track record of success



Delivering strong, consistent revenue growth & gross margins

U.S. \$ in millions



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

Operational Highlights

- Revenue growth of 28% for Q1
- Executing our strategy of driving adoption in our largest market opportunity of extremity trauma
- More than 50,000 Avance Nerve Grafts have been implanted since launch
- Reinitiated clinical study activities for the Rethink Pain™ and Sensation-NOW® registries and are actively engaged in six sponsored studies currently enrolling across our four primary market applications



revolutionizing the science of nerve repair™

Guidance Update

May 2021

Reinitiating annual financial guidance

- Full-year 2021 revenue will be in the range of \$133m to \$136m
- Full-year 2021 gross margin is expected to remain above 80%

We expect that the incidence of trauma will increase as communities relax pandemic-related restrictions, which we believe will lead to increasing procedure volumes as we move through the year.

How are nerves injured?

Connect

Transection

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

Protect

Compression

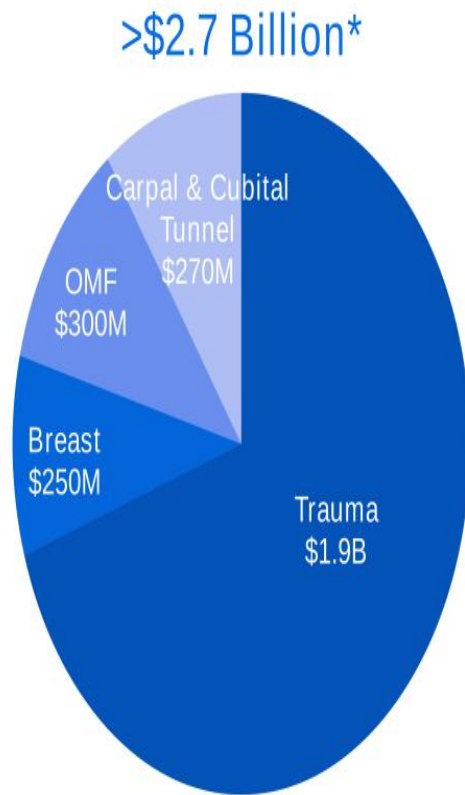
Carpal, cubital, tarsal tunnel revisions, blunt trauma, previous surgeries

Terminate

Stump Neuroma

Amputations, mastectomies, previous surgeries

Current targeted nerve markets (U.S.)



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

- Trauma: > 700,000^(1,2,3,4)
- Carpal Tunnel Revisions & Cubital Tunnel: 130,000^(5,6,7,8)
- OMF: > 55,000^(9,10,11,12,13,14,15,16,17)
- Breast Neurotization Procedures: 15,000⁽¹⁸⁾

*\$2.7B estimate does not include pain market

**Referenced papers were used to derive specific assumptions in the procedure potential estimates. Papers used include both U.S. and OUS databases and studies.

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

	Annual Incidence ^(a)	×	Weighted Average Procedure Value	=	Total Addressable Market
Trauma	700,000 ^(b)		\$2,725 ^(c)		\$1,900M
Carpal and Cubital Tunnel	130,000		\$2,100		\$270M
Oral and Maxillo-Facial (OMF)	56,000		\$5,400		\$300M
Breast Reconstruction Neurotization	24,500 flaps (15,000 patients)		\$10,200		\$250M
Totals	>900,000 (potential)				>\$2.7B

a) Annual incidence of PNI surgery are figures rounded to the nearest thousandth except for Breast Reconstruction Neurotization (rounded to nearest hundredth).

b) See slides 9 and 10 for further details.

c) Includes factor of 1.22 nerves by procedure based upon data observed in the RANGER[®] registry.

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 <u>due to injury</u> in the U.S. ✖ 4.76% Percentage of emergency department visits <u>with nerve injury</u> =	2015 National Hospital Ambulatory Medical Care Survey (Table 1)	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.)
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	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%.
~665,000 Annual ED visits with nerve injury estimated to be treated surgically in the U.S., excluding revisions	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.

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., <u>excluding revisions</u> × 7.4% Revision cases = 714,000 Annual emergency department visits with nerve injury that can be treated surgically in the U.S., <u>including revisions</u> ↓ ~700,000 Company estimate of trauma total addressable market	See calculation on previous slide <i>Portincasa et al: Microsurgery</i> 27:455-462, 2007	<i>Portincasa et al</i> suggests that a revision procedure was necessary in 7.4% of the patients within 6 months of the initial surgery.

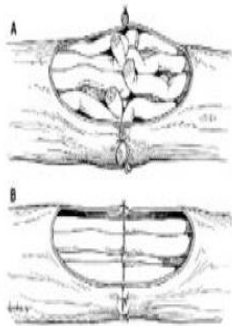
a) Patient population figures rounded to the nearest thousandth.

Traditional TRANSECTION repair options are suboptimal

SUTURE

Direct suture repair of no-gap injuries

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



AUTOGRAFT

Traditional method despite several disadvantages

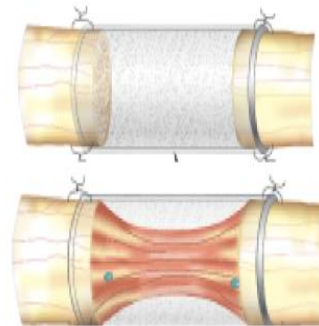
- Secondary surgery
- Loss of function and sensation at harvest site
- 27% complication rate including infection, wound healing and chronic pain¹⁹
- Limited availability of graft length and diameter



SYNTHETIC CONDUITS

Convenient off the shelf option; limited efficacy & use

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



Axogen solutions for TRANSECTION repair



Processed human nerve allograft for bridging nerve gaps

Clinically studied off-the-shelf alternative

- A biologically active nerve therapy with more than ten years of comprehensive clinical evidence
- 82-84% meaningful recovery in sensory, mixed and motor nerve gaps in multi-center study²²
- Eliminates need for an additional surgical site and risks of donor nerve harvest²²
- May reduce OR time

Structural support for regenerating axons

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

Revascularizes and remodels into patient's own tissue similar to autologous nerve²³

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



Only minimally processed porcine ECM for connector-assisted coaptation

Alternative to direct suture repair

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

Alleviates tension at critical zone of regeneration

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

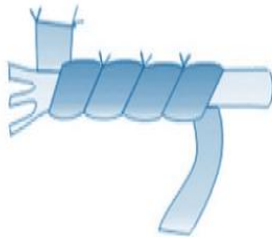
Remodels into vascularized patient tissue^{28, 29, 30, 31}

Traditional COMPRESSION repair options are suboptimal

VEIN WRAPPING

Autologous vein

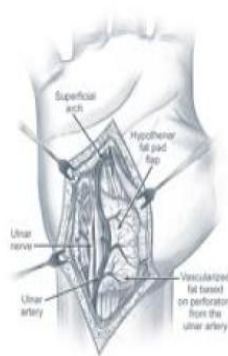
- Barrier to attachment to surrounding tissue
- Requires extra time and skill to perform spiral wrapping technique
- Second surgery site



HYPOTHENAR FAT PAD

Autologous vascularization flap

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



COLLAGEN WRAPS

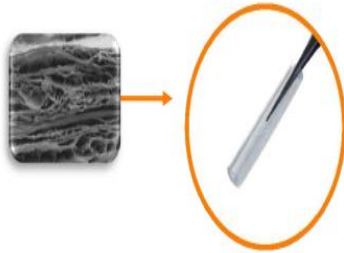
Off-the-shelf

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



Axogen solutions for COMPRESSION repair

axoguard nerve protector[®]



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

Protects repair site from surrounding tissue

- Processing results in an implant that works with the body's natural healing process³²
- Minimizes soft tissue attachments³³

Allows nerve gliding

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

avive[®] soft tissue membrane



Processed human umbilical cord intended for surgical use as a resorbable soft tissue barrier

Smart processing to preserve the natural properties of the umbilical cord amniotic membrane

Designed with the surgeon in mind

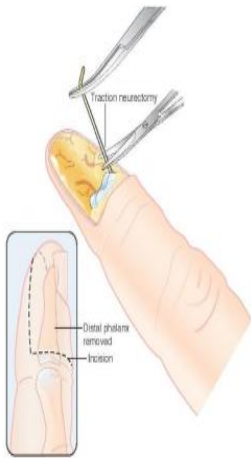
- Easy to handle, suture, or secure during a surgical procedure
- Up to 8x thicker than placental amniotic membrane alone³⁵
- Specifically designed as a resorbable soft tissue barrier to separate the tissue layers for at least 16 weeks³⁶

Traditional STUMP NEUROMA options are suboptimal

TRACTION NEURECTOMY

Nerve placed in traction and cut to allow for retraction

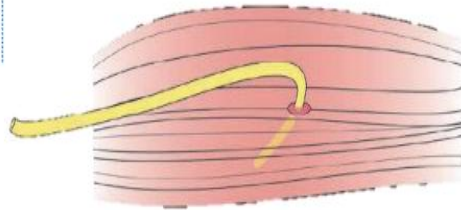
- Simply resecting the nerve results in subsequent neuroma formation and risk of secondary surgery
- Causes traction injury
- High risk of recurrence³⁹



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^{40, 41, 42}



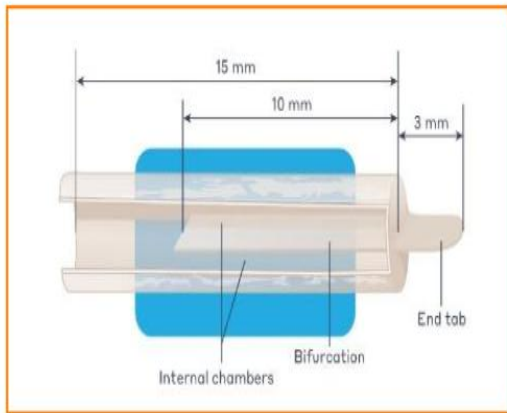
INJECTIONS

Pharmacologic intervention, typically alcohol or steroids^{43, 44, 45, 46, 47, 48}

- Chemical injections are only successful 40% of the time^{46, 47}
- Temporary solution that has a reduced benefit over time
- May cause considerable side effects



Axogen solution for STUMP NEUROMA



Proprietary SIS matrix designed to separate the nerve end from the surrounding environment to protect it from mechanical stimulation and reduce painful neuroma formation.

Protects and isolates

- Reduces the development of symptomatic or painful neuroma formation
- Provides a barrier from neurotrophic factors and mechanical stimulation

SIS Material allows for vascularization and gradual remodeling (as shown in animal studies)^{47, 48}

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

Intra-operative versatility

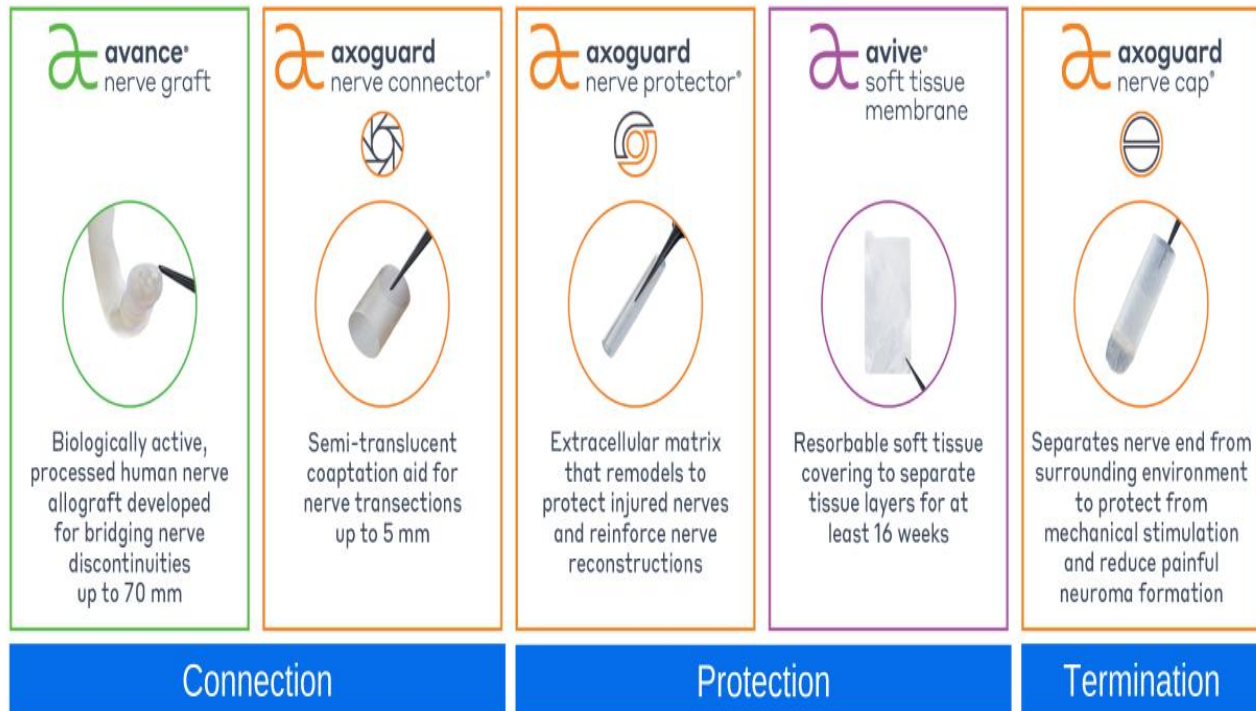
- Ideal for anatomic areas with limited or no musculature
- Alternative to historical techniques such as burying in muscle or bone
- Available in a variety of diameters



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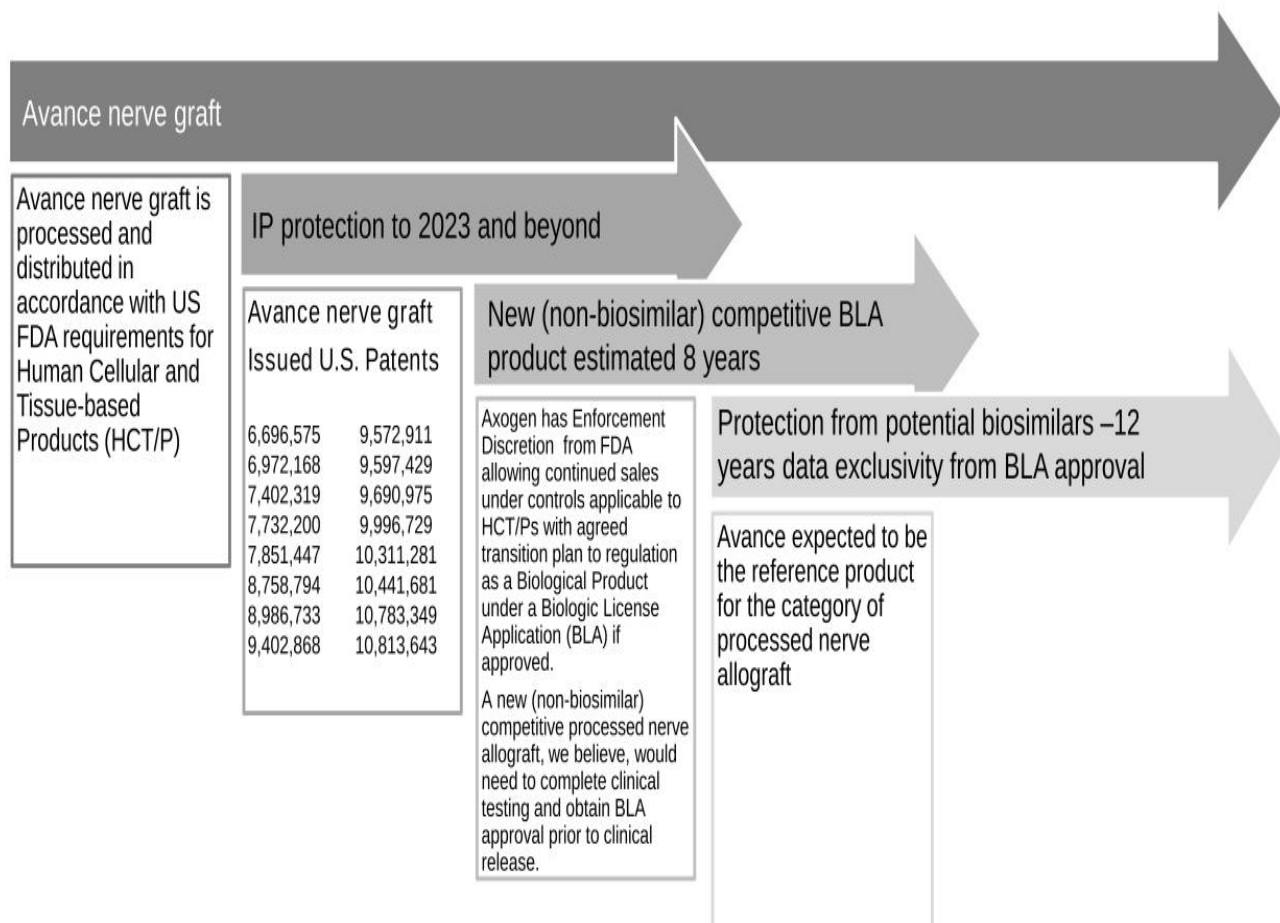
Axogen's comprehensive platform for addressing nerve injuries

one company for all your surgical nerve repair solutions



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Avance IP and regulatory barriers to competitive entry

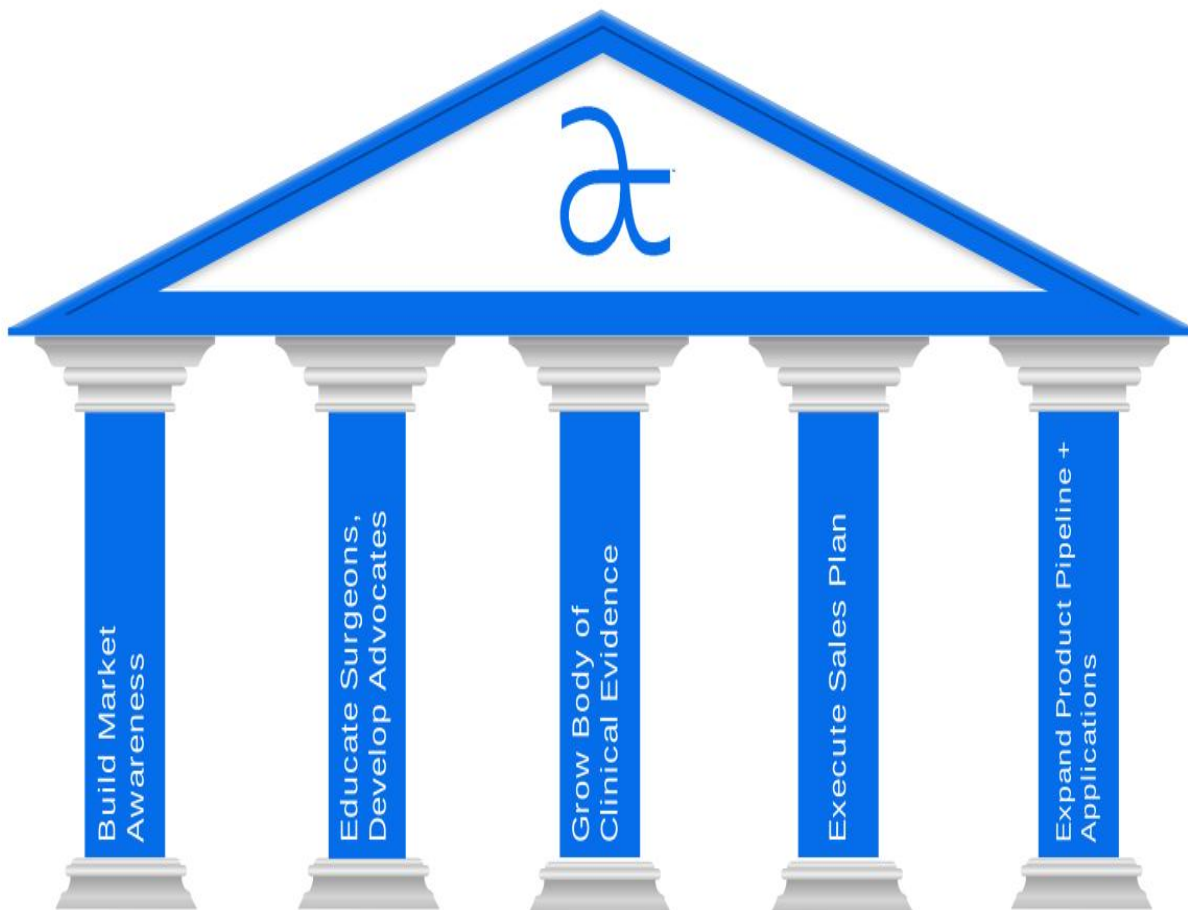


Unique Avance technology creates barriers to competitive entry

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

- Received Regenerative Medicine Advanced Therapy (RMAT) designation for Avance Nerve Graft in September 2018
 - Highlights strength of clinical evidence and the unmet medical need for improved therapies to treat nerve injuries
- RECONSM target enrollment of 220 subjects was reached in July 2020
 - Prospective, randomized, controlled double-blinded study compares Avance Nerve Graft to synthetic conduits in digital injuries
 - The protocol includes a 12-month follow-up visit for all subjects; and, given the impact of COVID-19, our plans allow for an additional three months for the subjects to complete their final visit. We anticipate the final visit to occur no later than October of 2021
 - Preliminary study data report expected in Q2 2022
 - Expect to file BLA in 2023
- Expected protection from potential biosimilars – 12-year data exclusivity from date of BLA approval
- Building a new 107,000 square foot, state-of-the-art biologics processing facility
 - Facility being built to cGMP standards under 21 CFR Part 210/211 regulations
 - Supports long term capacity expansion
 - Restarted construction of facility in January 2021, after temporary suspension as part of COVID-19 cost mitigation initiatives, and anticipate transition of tissue processing by late 2022

Market development strategy



Focus on building awareness among clinicians and patients

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



Build Market Awareness



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Emphasis on education

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



Educate Surgeons,
Develop Advocates



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Strong commitment to developing clinical evidence

RANGER® Registry Study: Enrollment Ongoing

- The largest multi-center clinical study in peripheral nerve repair with >2,400 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

RECONSM Study: Enrollment 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
- Preliminary study data report expected Q2 2022, expect to file BLA in 2023

Sensation-NOW® Registry Study: Enrollment Reinitiated

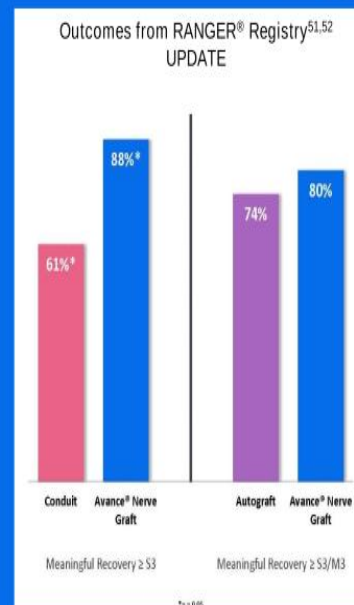
- Multi-center clinical study in breast neurotization

REPOSESM: Enrollment Ongoing

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

RETHINK PAIN™ Registry Study: Enrollment Reinitiated

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



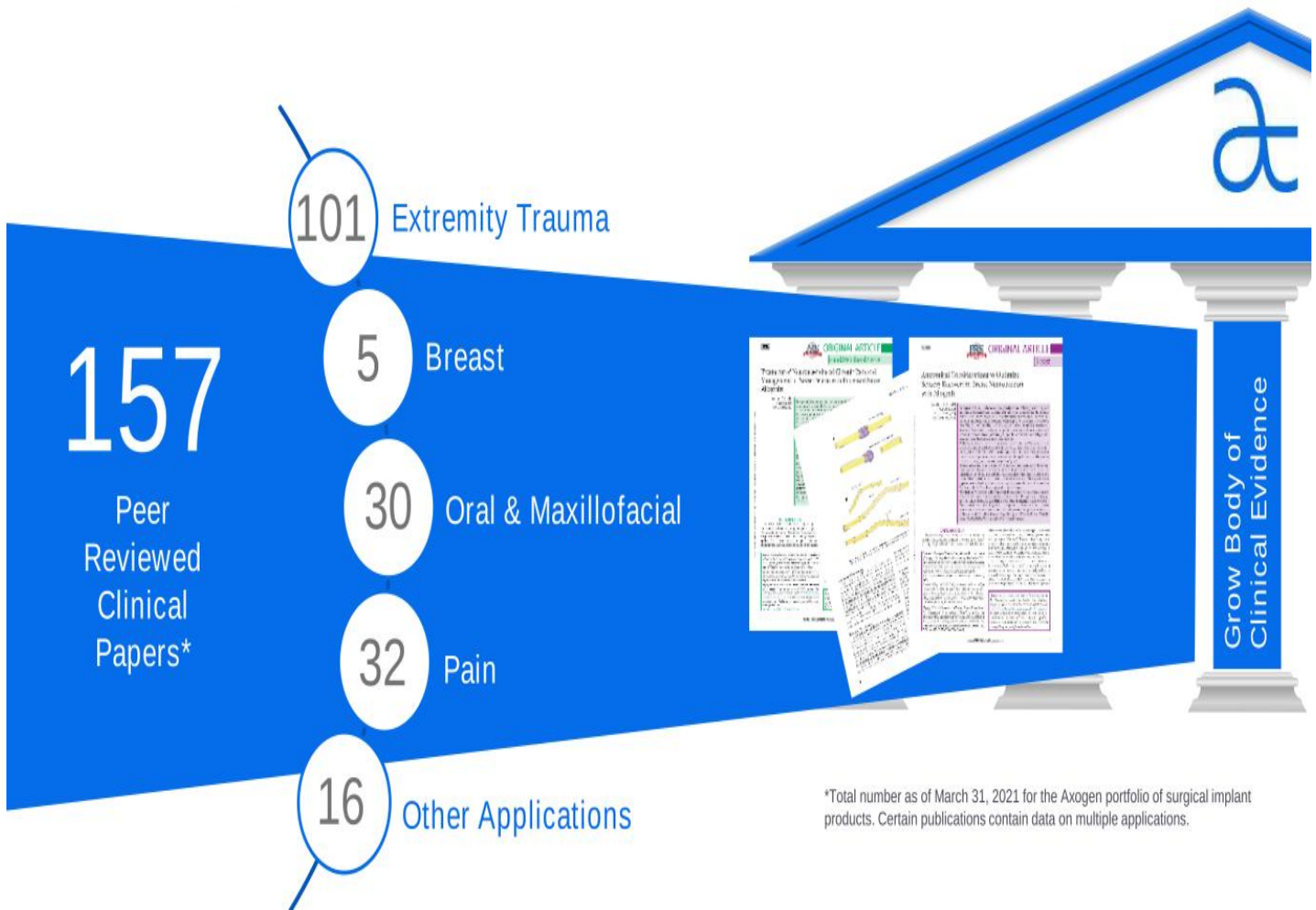
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Grow Body of
Clinical Evidence



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Growing body of clinical evidence



*Total number as of March 31, 2021 for the Axogen portfolio of surgical implant products. Certain publications contain data on multiple applications.

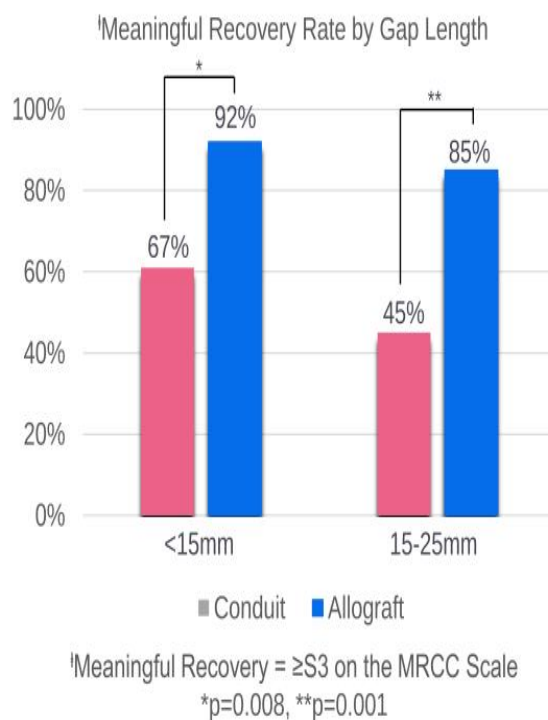


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Avance Nerve Graft repairs found to be significantly better than conduit repairs

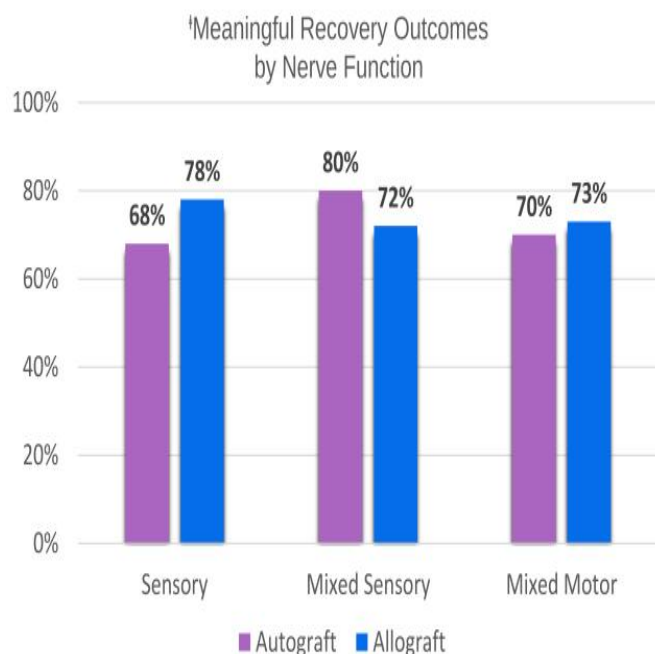
“Leversedge et al., A Multicenter Matched Cohort Study of Processed Nerve Allograft and Conduit in Digital Nerve Reconstruction” – Journal of Hand Surgery, September 2020⁵¹

- 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



Recent 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”⁵²



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

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

Defined as MRCC Score $\geq$ S3/M3

Historical data on Nerve Autograft^{53,54,55,56,57,58}, Mixed Nerve: 57-80%; Digital Nerve: 60-88%



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Recent 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 2020²³

- Data from the 2018 Medicare Standard Analytic File⁵⁹
- 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 2021²⁴

- 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

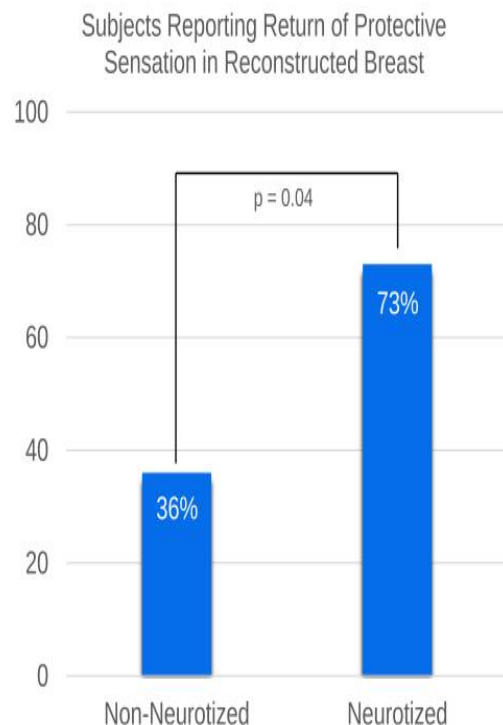
*Conduits only had available data for short gap sensory nerve group



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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 2021⁶⁰

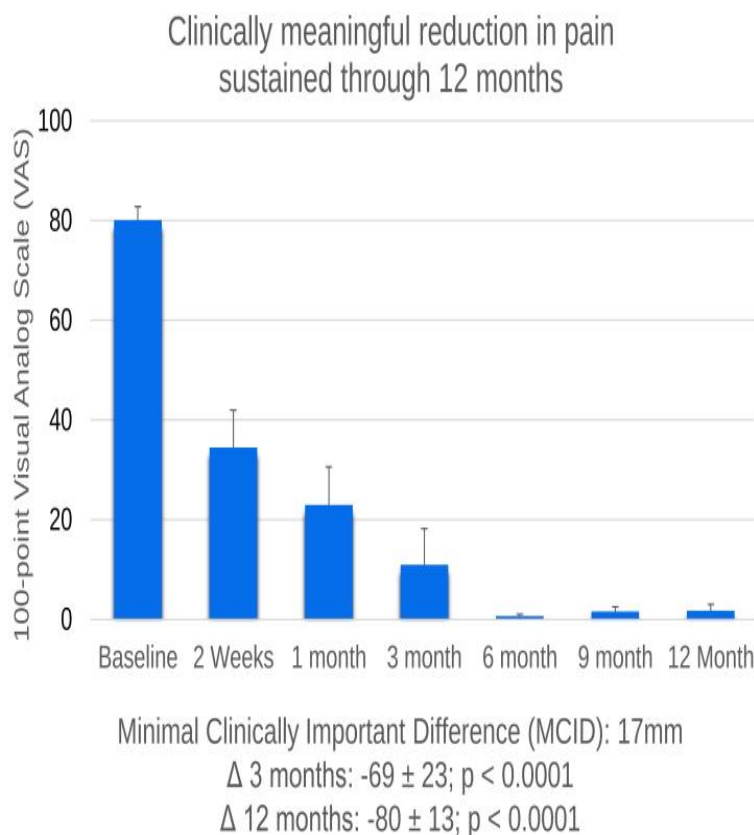


- Early outcomes from a single center study, as part of the Sensation-NOW registry
- 36 breast reconstructions that included:
- 22 breast reconstructions with Resensation®
- 14 standard non-neurotized breast reconstructions
- Return of Protective Sensation (p=0.04)
- 73% of the Resensation group
- 36% of the non-neurotized group
- Neurotization with Avance Nerve Graft resulted in greater return of sensation and return of sensation in more of the breast as compared to standard reconstruction without nerve repair.

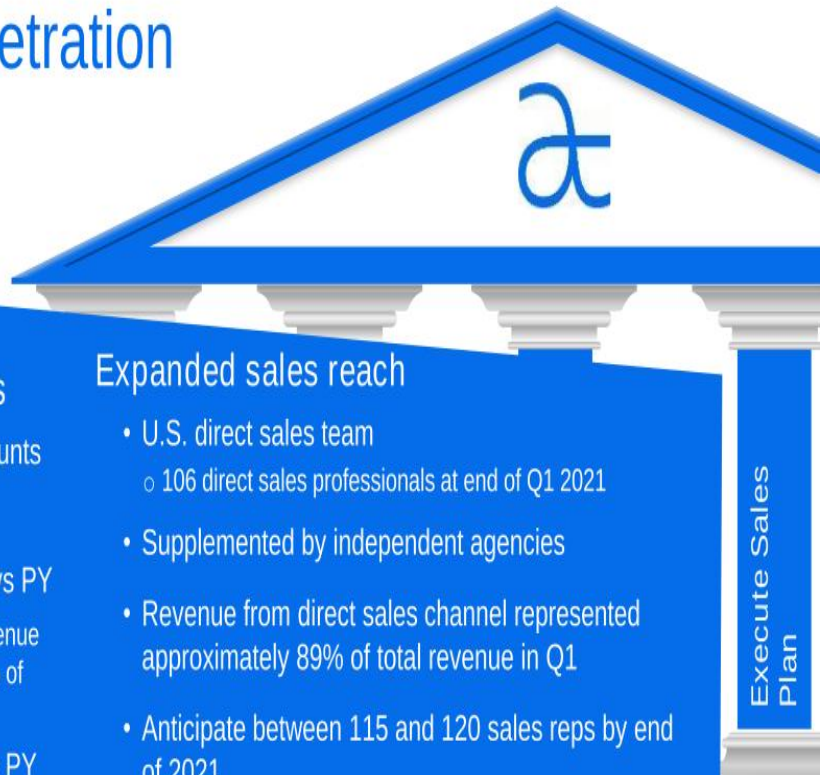
Axogen sponsored REPOSESM pilot study analysis demonstrates clinically significant improvement for subjects with chronic neuropathic pain when using Axoguard Nerve Cap[®] following neurectomy⁶¹

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



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
- 919 active accounts as of March 31, 2021, up 11% vs PY
 - Active accounts represent approximately 85% of total revenue
 - Top 10% of active accounts represent approximately 35% of total revenue
- 274 core accounts as of March 31, 2021, up 13% vs PY
 - Core accounts represent approximately 60% of total revenue

Expanded sales reach

- U.S. direct sales team
 - 106 direct sales professionals at end of Q1 2021
- Supplemented by independent agencies
- Revenue from direct sales channel represented approximately 89% of total revenue in Q1
- Anticipate between 115 and 120 sales reps by end of 2021
- Increasing sales rep productivity



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

Although CMS rates¹ only apply to Medicare cases, which represents a small percentage of traumatic injuries, private payors are often influenced by the analysis and decisions made by CMS

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

1. National average payment rates. Commercial payments are traditionally 1.5-2x higher than Medicare.

2. Nerve allograft repair CPT 64912, conduit repair CPT 64910 and autograft repair hand/foot >4cm CPT 64891 continue to meet ASC device intensive criteria

3. Autograft repair CPT 64886 head/neck >4cm and direct repair sciatic CPT 64858 meet ASC device intensive criteria

4. Direct repair digital and brachial plexus (64831, 64861) and autograft repair all other nerve type CPT 64892-98 do not meet ASC device intensive criteria. (excludes autograft add-on procedure codes)



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

CMS physician fee adjustments continue to favor nerve allograft repair

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

*excludes add-on procedure codes

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

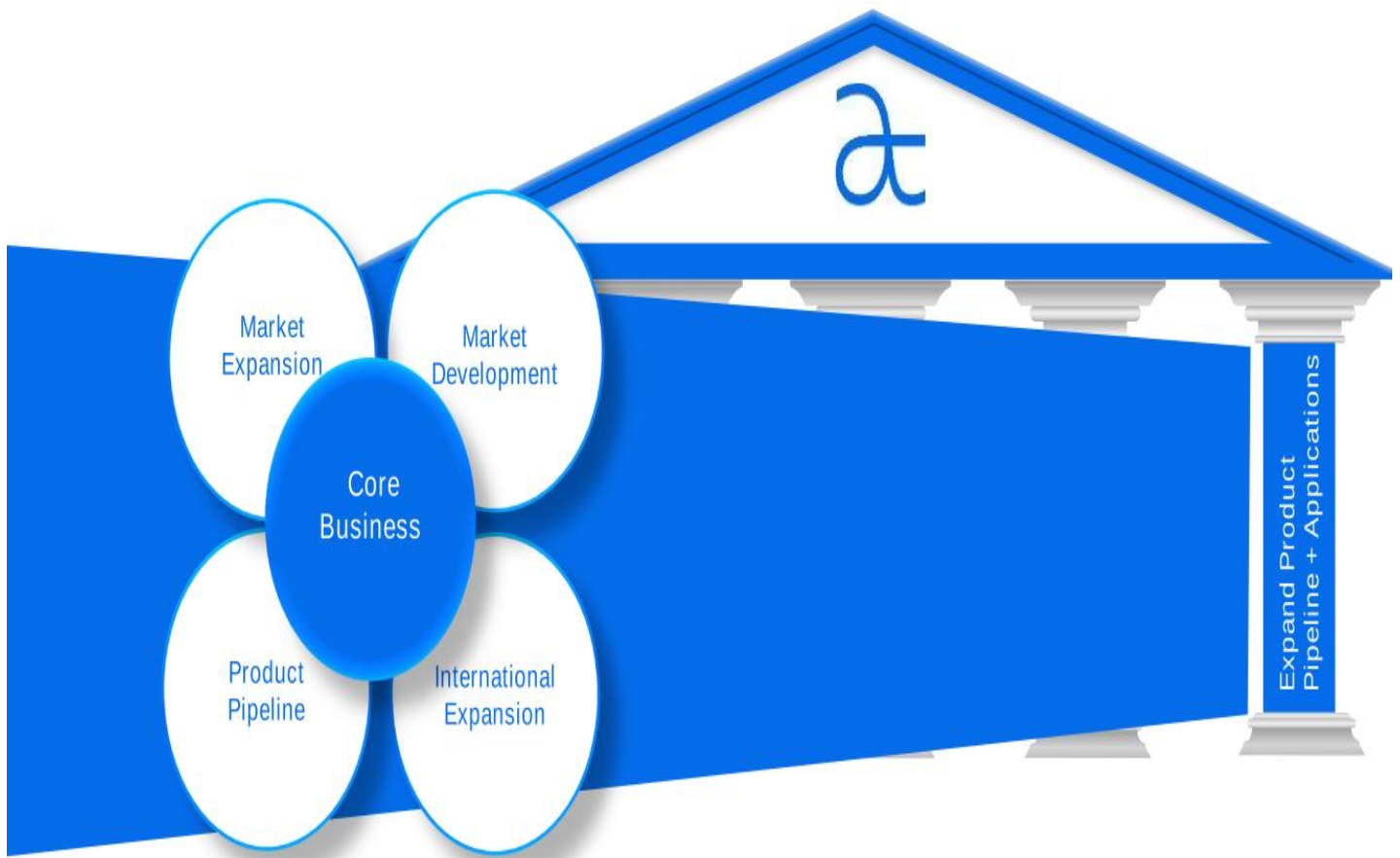


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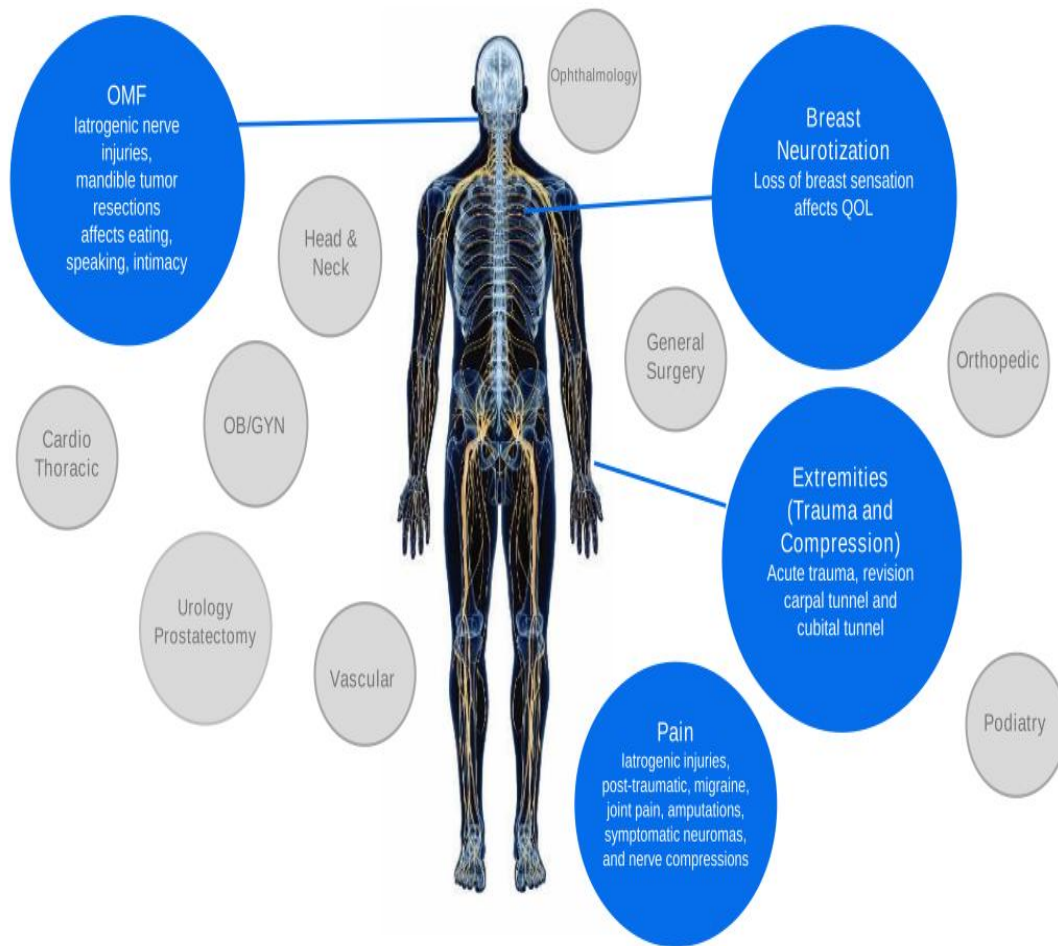
May 5, 2021

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Expand the opportunity in nerve repair



Platform for nerve repair across multiple applications



Balance sheet and capital structure

Balance Sheet Highlights	March 31, 2021
Cash, Cash Equivalents, and Investments	\$97.2 million
Total Long-term Debt	\$35.0 million*

Capital Structure (shares)	March 31, 2020
Common Stock	40,705,840
Common Stock Options, RSUs, PSUs	6,152,283
Common Stock and Common Stock Equivalents	46,858,123

* 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, Clinical &
Translational
Sciences
Angiotech, PRA Intl



Mike Donovan
VP, Operations
Zimmer



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



Mark Friedman, Ph.D.
VP, Regulatory & 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 across an expanding set of applications addressing a large market opportunity
- ✓ Differentiated platform for nerve repair, anchored by Avance® Nerve Graft
- ✓ 10+ years of demonstrated clinical consistency and meaningful recovery outcomes
- ✓ 157 peer-reviewed clinical publications featuring the Axogen product portfolio (as of March 31, 2021)
- ✓ More than 50,000 Avance Nerve Grafts have been implanted since launch
- ✓ Avance RMAT designation highlights clinical evidence strength and unmet medical need for improved nerve injury treatments
- ✓ Commercial and Professional Education capability to convert experienced surgeons while training the next generation
- ✓ Significant barriers to competitive entry
- ✓ Solid balance sheet provides resources to execute business plan
- ✓ Experienced management team with strong track record of success





nasdaq: axgn

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

Russell 2000 Index: June 2016

DecisionWise Intl Employee Engagement Best Practices Award Winner: 2018

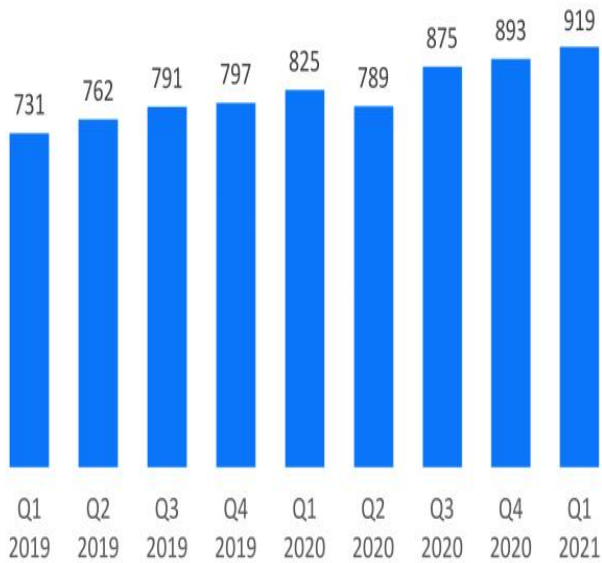


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Historical Active and Growth Accounts

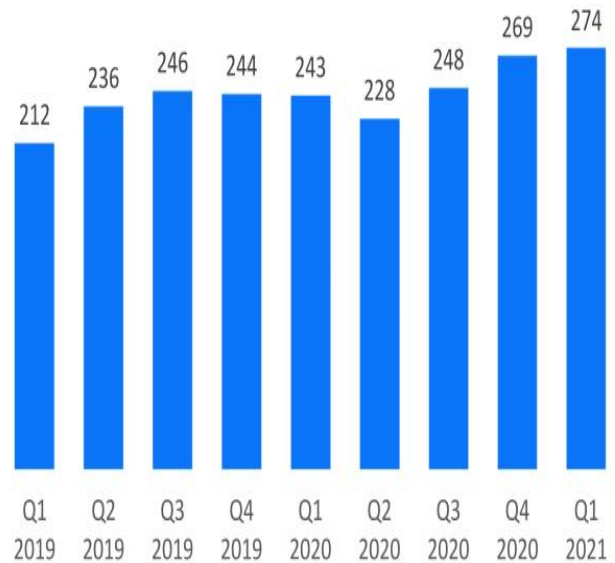
Active Accounts

6 orders in the last 12 months



Core Accounts

≥\$100,000 revenue 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 typically contribute ≈60% of total revenue

Footnotes

1. National Hospital Ambulatory Medical Care Survey: 2015 Emergency Department Summary Tables – Table 18. https://www.cdc.gov/nchs/data/nhamcs/web_tables/2015_ed_web_tables.pdf
2. Noble, et al., Analysis of Upper and Lower Extremity Peripheral Nerve Injuries in a Population of Patients with Multiple Injuries. *J Trauma*. 1998; 45(1): 116-122.
3. Uzun, et al., Traumatic peripheral nerve injuries: demographic and electrophysiologic findings of 802 patients from a developing country. *J Clin Neuromusc Dis*. 2006; 7(3): 97–103.
4. Portincasa, et al. Microsurgical treatment of injury to peripheral nerves in upper and lower limbs: a critical review of the last 8 years. *Microsurgery*. 2007; 27(5): 455–462.
5. Medicare National HCPS Aggregate Summary Table CY2016. <https://data.cms.gov/Medicare-Physician-Supplier/Medicare-National-HCPCS-Aggregate-Summary-Table-CY/tra-d83c/data>
6. 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
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.
18. ASPS 2017– Plastic Surgery Statistics Report. www.plasticsurgery.org/documents/News/Statistics/2017/plastic-surgery-statistics-full-report-2017.pdf
19. Rappaport, et al. Clinical utilization and complications of sural nerve biopsy. *Am J Surg*. 1993; 166(3): 252-256.
20. Weber, et al. A randomized prospective study of polyglycolic acid conduits for digital nerve reconstruction in humans. *Plast Reconstr Surg*. 2000; 106(5): 1036-1045.
21. Wangenstein, et al. Collagen tube conduits in peripheral nerve repair: A retrospective analysis. *Hand*. 2010; 5(3): 273-277.
22. Data on file at Axogen
23. 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.
24. 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
25. 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.
26. Boeckstyns, et al. Collagen conduit versus microsurgical neurotaphy: 2-year follow-up of a prospective, blinded clinical and electrophysiological multicenter randomized, controlled trial. *J hand Surg Am*. 2013; 38(12): 2405-2411.
27. Brushart, et al. Selective reinnervation of distal motor stumps by peripheral motor axons. *Exp Neurol*. 1987; 97(2): 289-300.
28. 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.
29. 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.
30. Data on file at Axogen
31. Badylak, et al. Small intestinal submucosa: A substrate for in vitro cell growth. *J Biomater Sci Polym Ed*. 1998; 9(8): 863-878.
32. 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.
33. Nihsen, et al. Bioactivity of small intestinal submucosa and oxidized regenerated cellulose/collagen. *Adv Skin Wound Care*. 2008; 21(10): 479-486.
34. Kokkalis, et al. Assessment of processed porcine extracellular matrix as a protective barrier in a rabbit nerve wrap model. *J Recon MicroSurg*. 2011; 27(1): 19-28.
35. Hodde, et al. Vascular endothelial growth factor in porcine-derived extracellular matrix. *Endothelium*. 2001; 8(1): 11-24.
36. Data on file at Axogen
37. Data on file at Axogen
38. Data on file at Axogen

Footnotes

39. Mitchell A Pet, Jason H Ko, Janna L Friedly, Douglas G SmithTraction. Neurectomy for Treatment of Painful Residual Limb Neuroma in Lower Extremity Amputees J Orthop Trauma. 29 (9), e321-5 Sep 2015.
40. 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.
41. Galeano M, et al. A free vein graft cap influences neuroma formation after nerve transection. Microsurgery. 2009;29(7):568-572.
42. Stokvis A. Surgical management of painful neuromas. Rotterdam, The Netherlands: Optima Grafische Communicatie; 2010.
43. Lin E, et al. Local administration of norepinephrine in the stump evokes dose-dependent pain in amputees. Clin J Pain. 2006;22(5):482-486.
44. 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.
45. Rajput K, et al. Painful neuromas. The Clinical Journal of Pain. 2012;28(7):639-645
46. 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.
47. Fallat L. Cryosurgery or sclerosing injections: which is better for neuromas. Podiatry Today. 2004;17(6):58-66.
48. Bradley MD. Plantar neuroma: analysis of results following surgical excision in 145 patients. South Med J. 1976;69:853-845.
49. 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.
50. Record RD, Hillegonds D, Simmons C, Tullius R, Rickey FA, Elmore D, Badyak SF. In vivo degradation of 14C-labeled small intestinal submucosa (SIS) when used for urinary bladder repair. Biomaterials. 2001 Oct;22(19):2653-9.
51. Leversedge FJ, Zoldos J, Nydick J, Kao DS, Thayer W, MacKay B, McKee D, Hoyer 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.
52. 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.
53. Safa B, Jain S, Desai MJ, Greenberg JA, Niaccaris 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, Hoyer 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.
54. 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
55. Roganovic Z, Pavlicevic G. Difference in recovery potential of peripheral nerves after graft repairs. Neurosurgery. 2006 Sep;59(3):621-33; discussion 621-33.
56. Frykman G, Gramyk K. Results of nerve grafting. In: Gelberman R, ed. Operative nerve repair and reconstruction. Philadelphia: JB Lippincott, 1991:553-567
57. 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.
58. 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.
59. U.S. Centers for Medicare and Medicaid Services. Medicare Claims standard analytic file. 2018.
60. Momeni A, Meyer S, Shefren K, Januszzyk M. Flap Neurotization in Breast Reconstruction with Nerve Allografts: 1-year Clinical Outcomes. Plast Reconstr Surg Glob Open. 2021 Jan 12;9(1):e3328
61. Data on file at Axogen.

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