

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): January 13, 2020

AXOGEN, INC.

(Exact name of registrant as specified in its charter)

Minnesota (State or other jurisdiction of incorporation)	001-36046 (Commission File Number)	41-1301878 (IRS Employer Identification No.)
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13631 Progress Boulevard, Suite 400, Alachua, Florida (Address of Principal Executive Offices)	32615 (Zip Code)
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Registrant's telephone number, including area code

(386) 462-6800 (Former name or former address if changed since last report,)
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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ 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 January 13, 2020, Axogen, Inc. (the “Company”) issued a press release announcing its estimated fourth quarter and full year 2019 revenue. 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 January 13, 2020, the Company also released a corporate update related to the estimated fourth quarter and full year 2019 revenue, among other items to be presented in San Francisco, California at the Solebury Trout Management Access SF 2020 Event and JP Morgan 38th Annual Healthcare Conference on January 13–15, 2020 and January 16, 2020, respectively. 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

Exhibit No.	Description
99.1	<u>Axogen, Inc. Press Release, dated January 13, 2020.</u>
99.2	<u>Axogen, Inc. Corporate Presentation, dated January 13, 2020.</u>

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: January 13, 2020

By: /s/ Gregory G. Freitag
Gregory G. Freitag
General Counsel



Axogen Reports Preliminary Unaudited Revenue for Fourth Quarter and Full-Year 2019 and Provides 2020 Annual Guidance

ALACHUA, FL – January 13, 2020 –Axogen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for peripheral nerve injuries, today announced preliminary unaudited fourth quarter and full-year 2019 revenue.

Preliminary Unaudited Fourth Quarter and Year-End Performance Highlights

- Fourth quarter revenue is expected to be at least \$28.1 million, up 20% compared to fourth quarter 2018 revenue of \$23.4 million
- Full-year 2019 revenue is expected to be at least \$106.6 million, up 27% compared to 2018 revenue of \$83.9 million
- Ended the fourth quarter with 109 direct sales representatives, including 8 former OMF sales roles that were converted to full line territory reps during the quarter. This represents a net increase of 4 representatives during the quarter and 24 representatives in 2019
- Revenue from our direct sales channel represented approximately 90% of total revenue in the fourth quarter, compared to approximately 85% in the fourth quarter of 2018
- Increased active accounts in the fourth quarter to 797, up 12% from 712 in the fourth quarter a year ago

"We delivered solid revenue growth in both the fourth quarter and the full year, and I am pleased with the progress we continue to make in rebalancing and refocusing our commercial efforts towards extremity trauma, our largest market opportunity," commented Karen Zaderej, chairman, CEO, and president of Axogen. "New market development requires persistence and hard work, and I am confident that we have the right team and commercial strategy in place to continue driving strong surgeon adoption of our technology over the next several years."

Updated 2019 Financial Guidance

Management has updated its 2019 revenue guidance and now expects 2019 revenue to be at least \$106.6 million. Management reiterates its expectation of full-year 2019 gross margin above 80%.

2020 Financial Guidance

Management anticipates that 2020 revenue will be approximately \$124 million to \$128 million and expects that the number of direct sales representatives will increase to approximately 126 to 131. Additionally, management expects gross margin to remain above 80% and that operating margin will see moderate improvement year over year.

The results disclosed in this press release are preliminary and unaudited. The Company will report full, audited results for the fourth quarter and year ended December 31, 2019 on February 24, 2020.

Previously Scheduled Investor Meetings to be Held This Week

Members of the Axogen senior management team will participate in the Solebury Trout Management Access SF 2020 Event in San Francisco, January 13 –15, 2020. These annual meetings provide an opportunity for management to meet individually with investors to address Axogen's differentiated platform for nerve repair in an expanding set of applications.

Presentation at JP Morgan Healthcare Conference

As previously announced, Karen Zaderej will present at the JP Morgan 38th Annual Healthcare Conference in San Francisco. The presentation is scheduled for Thursday, January 16, 2020 at 10:30 a.m. PST (1:30 p.m. EST). The presentation will be webcast live and will be accessible through the Investors page at www.axogeninc.com. For those not available to listen to the live broadcast, a replay will be archived for 90 days and will be available through the Investors page on www.axogeninc.com.

The company's updated corporate presentation is available through the investors page on www.axogeninc.com.

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 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, the United Kingdom, 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 regarding our growth, our 2019 and 2020 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, 2018, 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.

Peter J. Mariani, Chief Financial Officer

pmariani@axogeninc.com

InvestorRelations@AxogenInc.com

Corporate presentation

As of December 31, 2019

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 regarding our growth, our 2019 and 2020 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, 2018, 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

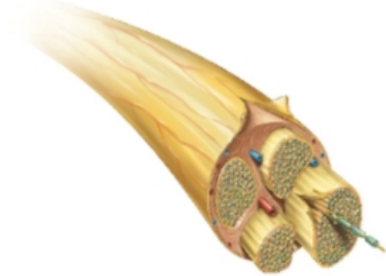


revolutionizing the science of nerve repair™

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

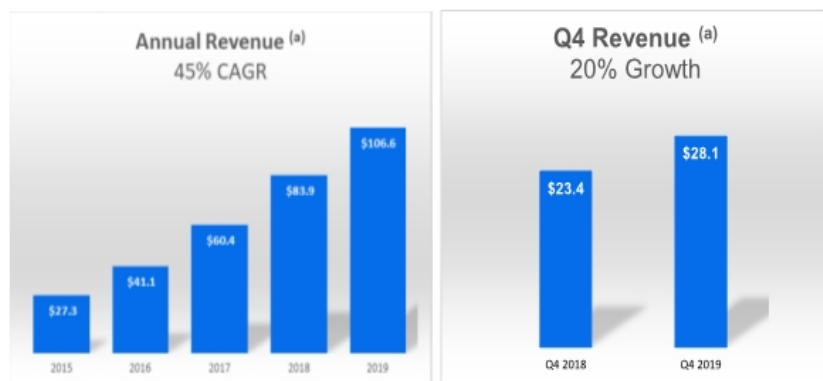
- ✓ **Exclusively focused in peripheral nerve repair** across an expanding set of applications addressing large market opportunity
- ✓ **Differentiated platform** for nerve repair, anchored with Avance® Nerve Graft
- ✓ **10+ years of demonstrated clinical consistency** and meaningful recovery outcomes
- ✓ **105 peer-reviewed clinical publications** featuring the Axogen product portfolio (as of September 30, 2019)
- ✓ **Avance RMAT designation** highlights clinical evidence strength and unmet medical need for improved nerve injury treatments
- ✓ **“Five Pillar” Market Development Strategy** delivered 36 consecutive quarters of YOY double-digit growth
- ✓ **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



revolutionizing the science of nerve repair™

Delivering strong consistent revenue growth & gross margins

U.S. \$ in millions



84.2% Gross Margin for the quarter ended September 30, 2019

Operational Highlights

- Solid revenue growth in Q4 and 2019
- Continuing to rebalance and refocus our commercial efforts toward our largest market opportunity of extremity trauma
- Completed conversion of 8 former OMF sales roles to full line reps in late Q4
- Solid commercial foundation in place to drive strong adoption of our technology over the next several years

a) Unaudited estimate of 2019 year-end and fourth quarter revenue.



revolutionizing the science of nerve repair™

Guidance Update

2019

- Revenue at least \$106.6m
- Gross margin above 80%

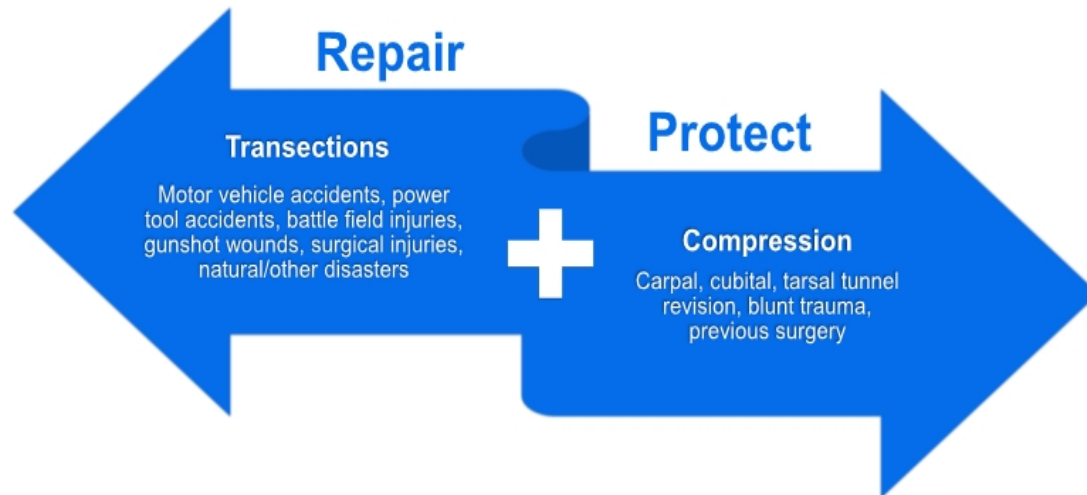
2020

- Revenue approximately \$124m - \$128m
- Direct sales rep increase to approximately 126 - 131
- Gross margin above 80%
- Operating margin will see modest improvement year over year

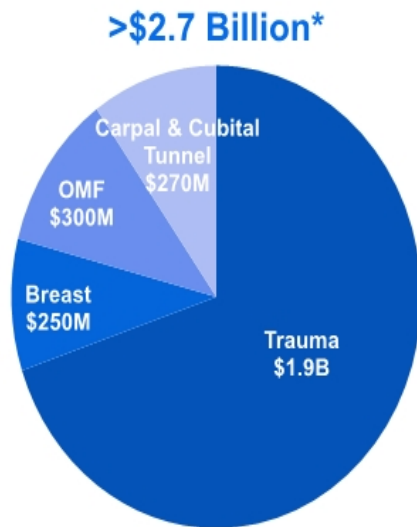
Factors contemplated in 2020 revenue guidance include:

- Continued maturation of expanded sales footprint, offset by near-term effects of efforts to refocus commercial strategy toward extremity trauma
- Measured approach to expanding the commercial organization in 2020 after significant change in 2019
- Net price increase in the low single digit range

How are nerves injured?



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
<p>136,943,000 Annual emergency department visits in the U.S.</p> <div style="border: 1px solid black; padding: 10px; margin: 10px 0;"> <p>30,238,000 Annual emergency department visits <u>due to injury</u> in the U.S.</p> <p style="text-align: center;">✕</p> <p>4.76% Percentage of emergency department visits <u>with nerve injury</u></p> <p style="text-align: center;">=</p> </div> <div style="border: 1px solid black; padding: 10px; margin: 10px 0;"> <p>1,440,000 Annual emergency department visits with nerve injury in the U.S.</p> <p style="text-align: center;">✕</p> <p>46.2% Percentage of ED nerve injuries estimated to be treated surgically</p> <p style="text-align: center;">=</p> <p>~665,000</p> </div> <p>Annual ED visits with nerve injury estimated to be treated surgically in the U.S., excluding revisions</p>	<p>2015 National Hospital Ambulatory Medical Care Survey (Table 1)</p> <p>2015 National Hospital Ambulatory Medical Care Survey (Table 18)</p> <p><i>Noble, et al: J Trauma, Volume 45(1) July 1998:116-122</i></p> <p><i>Noble, et al: J Trauma, Volume 45(1) July 1998:116-122</i></p>	<ul style="list-style-type: none"> Adjusted from 38,959,000 to exclude 8,721,000 injuries that are unlikely to include a nerve injury (i.e., mental disorders, skin conditions, etc.) 2.8% rate cited in <i>Noble, et al</i> study excluded 113 patients coded with nerve injuries outside of the study scope, but that are in the Axogen scope of nerve repair (brachial plexus and digital nerve injuries). Including these injuries increases the rate to 4.76%. Calculated rate based on various rates in <i>Noble et al</i> study for upper and lower extremity and an estimate for other trauma nerves.

Trauma total addressable market (continued)

Patient Population ^{a)}	Source	Adjustments and Rationale
<p>~665,000</p> <p>Annual emergency department visits with nerve injury that can be treated surgically in the U.S., <u>excluding revisions</u></p> <p>✖</p> <p>7.4%</p> <p>Revision cases</p> <hr/> <p>=</p> <p>714,000</p> <p>Annual emergency department visits with nerve injury that can be treated surgically in the U.S., <u>including revisions</u></p> <p>↓</p> <p>~700,000</p> <p>Company estimate of trauma total addressable market</p>	<p>See calculation on previous slide</p> <p><i>Portincasa et al: Microsurgery</i> 27:455-462, 2007</p>	<ul style="list-style-type: none"> <i>Portincasa et al</i> suggests that a revision procedure was necessary in 7.4% of the patients within 6 months of the initial surgery.

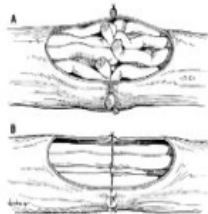
a) Patient population figures rounded to the nearest thousandth.

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

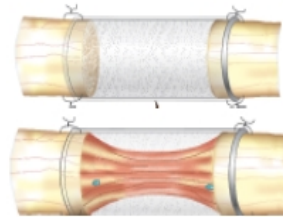
- Secondary surgery
- Loss of function and sensation at harvest site
- 27% complication rate including infection, wound healing and chronic pain¹⁹
- Limited availability of graft length and diameter



HOLLOW-TUBES

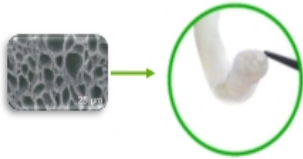
Convenient off the shelf option; limited efficacy & use

- 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
- 84% meaningful recovery in sensory, mixed and motor nerve gaps in multi-center study²²
- Eliminates need for an additional surgical site and risks of donor nerve harvest²²
- May reduce OR time

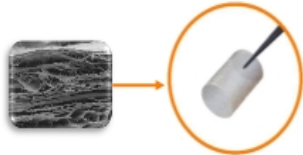
Structural support for regenerating axons

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

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

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

 **axoguard[®]**
nerve connector



Only minimally processed porcine ECM for connector-assisted coaptation

Alternative to direct suture repair

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

Alleviates tension at critical zone of regeneration

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

Revascularizes and remodels into patient's own tissue^{28, 29, 30, 31}

Traditional COMPRESSION repair options are suboptimal

VEIN WRAPPING

Autologous vein

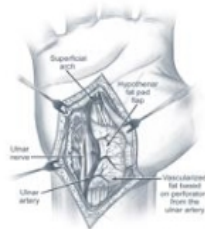
- Barrier to attachment to surrounding tissue
- Requires extra time and skill to perform spiral wrapping technique
- Second surgery site



HYPOTHENAR FAT PAD

Autologous vascularization flap

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



COLLAGEN WRAPS

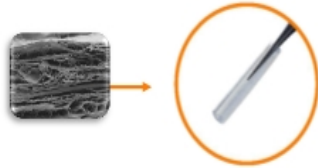
Off-the-shelf

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



Axogen 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 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}

Easy to use

- Semi-translucent to allow visualization of underlying nerve
- Conforms to nerve

Axogen resorbable solution to protect from the surrounding environment

 **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

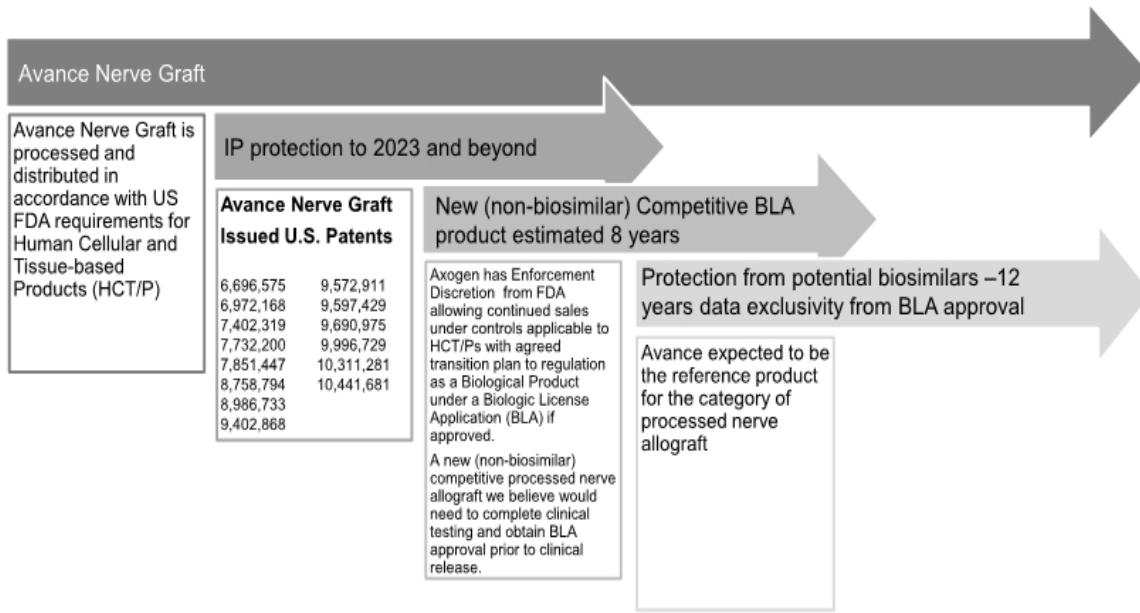
Designed with the surgeon in mind

- 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

Axogen platform for nerve repair

Connection		Protection	
			
			
Repair peripheral nerve discontinuities.	Repair transected or severed peripheral nerves.	Protect injured nerves and reinforce nerve reconstruction while preventing soft tissue attachments.	Surgical use as a resorbable soft tissue barrier.
Transected nerve (5mm-70mm)	Transected nerve (\leq 5mm)		

Avance IP and regulatory barriers to competitive entry

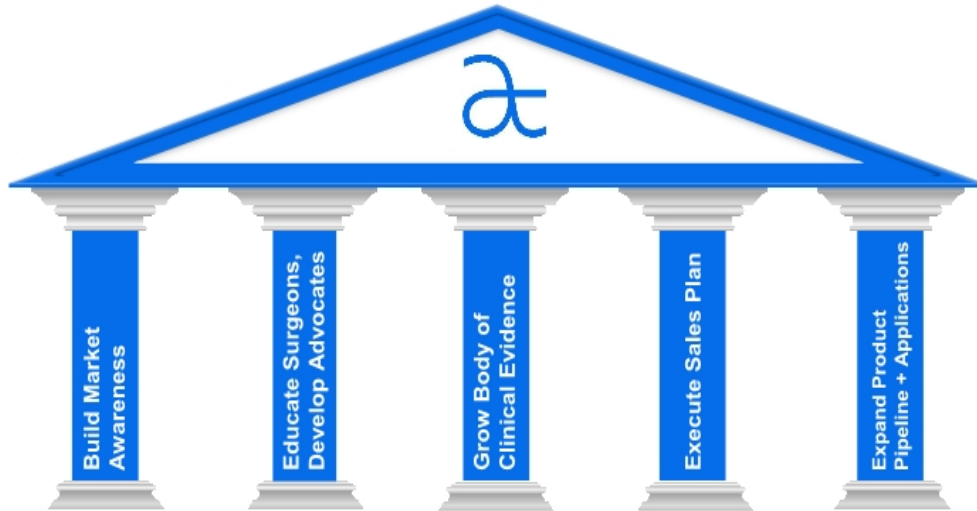


Unique Avance technology creates barriers to competitive entry

Progress toward Biologic 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
- On track to reach RECON enrollment of 220 subjects by end of Q2 2020
 - Prospective randomized controlled double-blinded study compares Avance Nerve Graft to synthetic conduits in digital injuries
- Expected protection from potential biosimilars –12 years data exclusivity from BLA approval
- Began the build-out of our new 70,000 square foot, state-of-the-art biologics processing facility
 - Facility being built to cGMP standards under 21 CFR Part 210/211 regulations
 - Anticipate full transition of tissue processing by early 2022
 - Supports long term capacity expansion

Market development strategy



Focus on building awareness among surgeons, patients, and investors

Participate in clinical conferences

- Exhibits, podium presentations, KOL panels

Promote awareness among patients

- Axogen patient ambassador program

Garner positive media attention

- National, regional and local broadcast, print and online



Build Market Awareness



revolutionizing the science of nerve repair™

Emphasis on education

- During the last 3 years, held 58 national programs including 25 in 2019
- Trained three-quarters of hand and microsurgery Fellows in 2019
- Expanded offering includes trauma, Breast, OMF, Pain and Fellows national programs as well as targeted regional programs
- Expect to train three-quarters of hand and microsurgery Fellows in 2020



Educate Surgeons,
Develop Advocates

Strong commitment to developing clinical evidence



revolutionizing the science of nerve repair™

Strong commitment to developing clinical evidence

RANGER® Registry Study: Enrollment Ongoing

- The largest multi-center clinical study in peripheral nerve repair; >2,000 Avance nerve repairs enrolled to date
- Overall meaningful recovery rates of 82-84%; comparable to autograft outcomes without associated donor site comorbidities

MATCHSM Registry Study: Enrollment Ongoing

- Autograft and Synthetic Conduit outcomes

RECONSM Study: Enrollment Ongoing

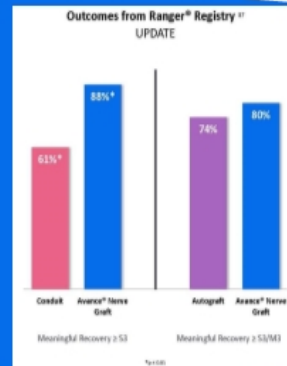
- Prospective, randomized study of Avance Nerve Graft controlled vs Synthetic conduits in digital injuries 5 to 25mm
- IND Pivotal Study to support BLA Submission
- Study enrollment target of 220 expected to be completed by the end of Q2 2020

Sensation-NOW® Registry Study: Enrollment Ongoing

- Multi-center clinical study in breast neurotization

REPOSESM: Enrollment Ongoing

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



Grow Body of
Clinical Evidence



revolutionizing the science of nerve repair™

Focused sales execution, increasing market penetration



Sales execution focused on driving results

- Continue expansion by driving penetration in active accounts and adding new active accounts
- 5,100 potential U.S. accounts perform nerve repair
- 797 active accounts as of December 31, 2019
 - Top 10% of active accounts represent approximately 35% of total revenue

Expanded sales reach

- U.S. direct sales team
 - 85 direct sales professionals at end of 2018
 - 109 direct sales professionals at end of 2019
 - 126 - 131 direct sales professionals expected by end of 2020
- Supplemented by independent agencies
- Revenue from direct sales channel represented approximately 90% of total revenue in Q4

Execute Sales
Plan



revolutionizing the science of nerve repair™

What are the new CMS outpatient reimbursement rates?

Although CMS rates¹ only apply to Medicare cases, which represents a small percentage of traumatic injuries, the increased 2020 rates reflect the positive evolution of nerve repair, and 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	% Change	2019	2020	% Change
64912	Nerve allograft repair	5432	\$4,566	\$ 5,508	21%	\$1,920	\$3,422	78%
64910	Conduit or vein allograft repair ²	5432	\$4,566	\$ 5,508	21%	\$2,613	\$3,133	20%
64891	Autograft repair (hand and foot>4cm) ³	5432	\$4,566	\$ 5,508	21%	\$1,920	\$2,829	47%
64885-98	Autograft repair (all other nerve type) ⁴	5432	\$4,566	\$ 5,508	21%	\$1,920 - \$3,575	\$2,170	-39% to +13% ⁴
64831, 61, 58	Direct Repair (digital, brachial plexus, sciatic)	5431	\$4,566	\$1,719	-62%	\$1,920	\$793	-59%

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

2. ASC 2019 and 2020 payment for Conduits received device intensive status for both years.

3. ASC 2020 payment for autograft repair CPT 64891 hand/foot >4cm met device intensive criteria for the first time

4. ASC 2020 payment for autograft repair CPT 64885 - head/neck <4cm, 64886 - head/neck >4cm, and 64890 -hand/foot <4cm, lost device intensive status with a 29%-39% decrease (\$3,575, \$3,172, \$3,075 payment respectively in 2019)

Hospital Outpatient and ASC rates:

Allograft, autograft and conduit repair increase

Direct repair for digital, sciatic and brachial plexus rates decrease

(all other direct repairs = allograft and autografts)

2020 Center for Medicare and Medicaid Services (CMS): Physician Fee Schedule (PFS)

- In 2020 physician fees for allograft procedures increased 18% from 2019
 - Traditionally CMS payments for physician services do not vary significantly from year to year.

CPT Codes	Descriptor	Physician Fee Schedule (PFS)		
		2019	2020	% Change
64912	Nerve allograft repair	\$804	\$ 951	18%
64910	Conduit or vein allograft repair	\$825	\$820	-1%
64885 to 64898*	Autograft repair	\$1,096 to \$1,495	\$1,096 to \$1,495	-1% to 0%
64831 to 64868*	Direct Repair	\$713 to \$1,604	\$717 to \$1,578	-2% to 1%

*excludes add-on procedure codes

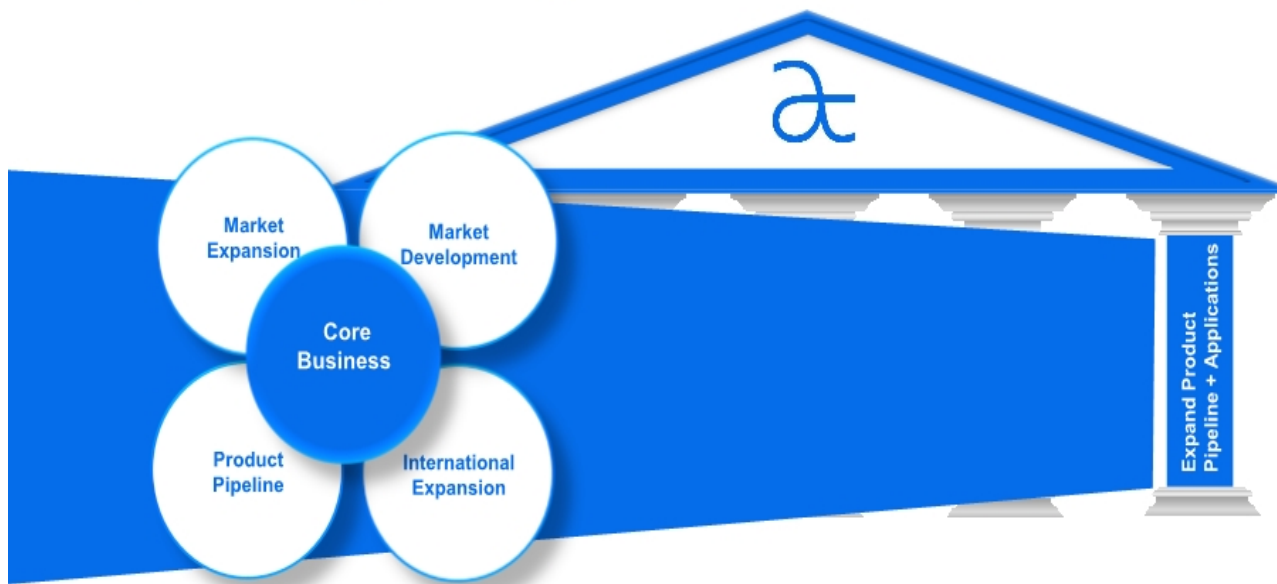


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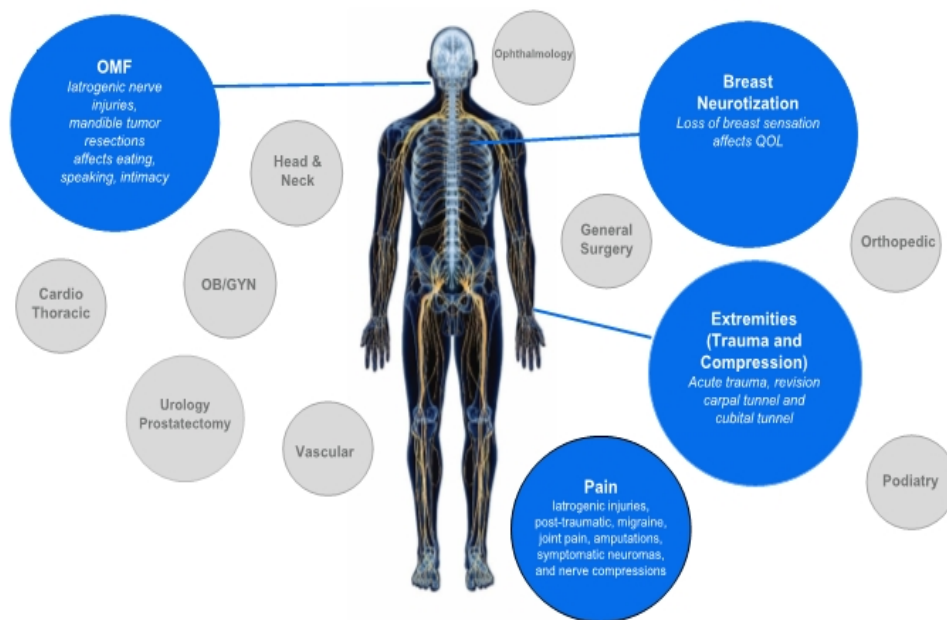
January 12, 2020

28

Expand the opportunity in nerve repair



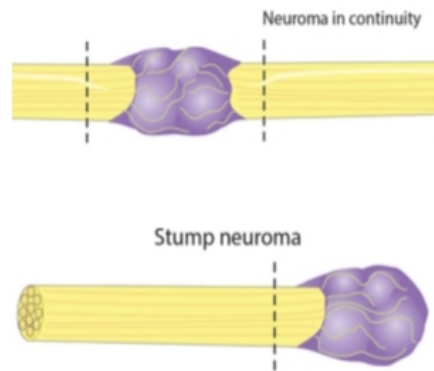
Platform for nerve repair across multiple applications



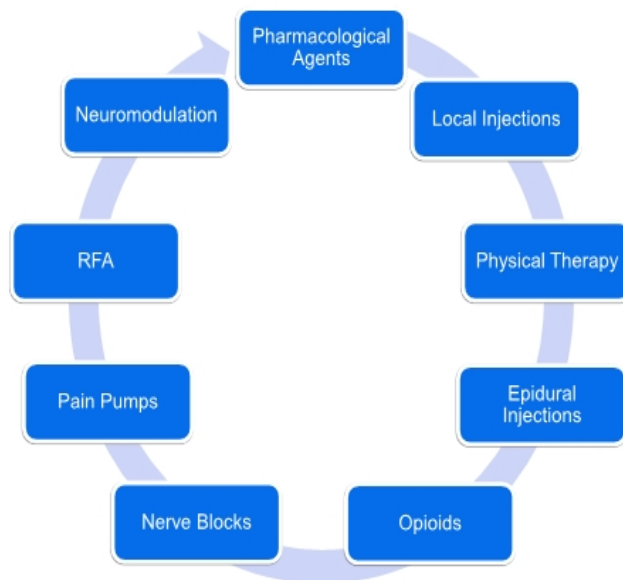
The surgical treatment of pain

Focus on neuroma pain from orthopedic surgeries or trauma

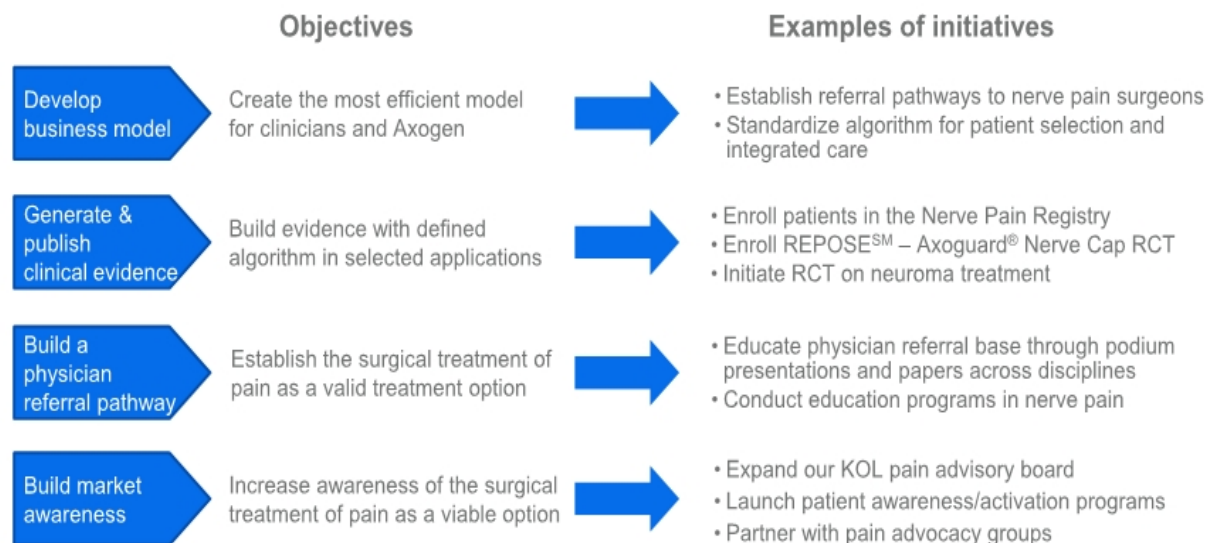
- A neuroma is a tangled mass of disorganized nerve and fibrous tissue that can impair function and cause chronic pain
- If not properly diagnosed and addressed, the management of these injuries may require long-term pharmacologic treatment and pain management



Historical management options for chronic neuropathic pain



Creating solutions for chronic neuropathic pain



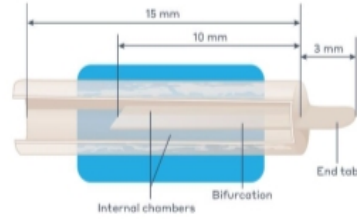
Axoguard nerve cap for stump neuroma pain

 **axoguard®**
nerve cap



US FDA Clearance – K163446

Indicated to protect a peripheral nerve end and separate the nerve from the surrounding environment to reduce the development of symptomatic or painful neuroma.



- Completed clinical evaluation and user preference study
- Enrolling REPOSE, a randomized controlled study of neuroma revision
- Product launch expected in February 2020



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Executive team



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



Peter J. Mariani
Chief Financial Officer
Lensar, Hansen, Guidant



Greg Freitag, JD, CPA
General Counsel
Pfizer, Guidant



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



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 & QA
AtriCure, Enable
Medical



Angelo Scopellanos, Ph.D.
VP, Research & Development
J&J



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Balance sheet and capital structure

Balance Sheet Highlights	September 30, 2019
Cash, Cash Equivalents, and Investments	\$106.1 million
Total Bank Debt	\$0

Capital Structure (shares)	September 30, 2019
Common Stock	39,461,318
Common Stock Options, RSUs, PSUs	4,584,991
Common Stock and Common Stock Equivalents	44,046,309

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

- ✓ **Exclusively focused in peripheral nerve repair** across an expanding set of applications addressing large market opportunity
- ✓ **Differentiated platform** for nerve repair, anchored with Avance® Nerve Graft
- ✓ **10+ years of demonstrated clinical consistency** and meaningful recovery outcomes
- ✓ **105 peer-reviewed clinical publications** featuring the Axogen product portfolio (as of September 30, 2019)
- ✓ **Avance RMAT designation** highlights clinical evidence strength and unmet medical need for improved nerve injury treatments
- ✓ **“Five Pillar” Market Development Strategy** delivered 36 consecutive quarters of YOY double-digit growth
- ✓ **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



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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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Footnotes

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