

amplified impact  
2022 environmental, social,  
and governance report

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## Reporting Framework

This marks Axogen's second ESG report. We have composed these disclosures based on our assessments of our industry, our peer group, and what we believe to be some of the most relevant questions to our long-term success. In doing so we have been inspired by many of the Sustainability Accounting Standards Board (SASB) questions, within the Sustainability Industry Classification System, for both Medical Equipment and Supplies and Biotechnology and Pharmaceuticals.

As we continue along this path, we accept that there will be new discoveries, that additional data will be generated, and that we will need to respond to changing circumstances. As such, we will continue to evaluate these topics in the future and, accordingly, our disclosures may evolve over time.

## Cautionary Statements Concerning Forward-Looking Statements

This ESG report 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 the effectiveness of our protocols in response to potential future cyber security threats, the timing of the Avance production transfer to our new Axogen Processing Center, timing of completion of upgrades in our Burleson Distribution Center, the benefits of the upgrades to the Burleson Distribution Center, our growth, data validation, our ability to attract and retain talent. The forward-looking statements are and will be subject to risks and uncertainties, which may cause actual results to differ materially from those expressed or implied in such forward-looking statements. Forward-looking statements contained in this press release should be evaluated together with the many uncertainties that affect our business and our market, particularly those risk factors described under Part I, Item 1A., "Risk Factors," of our Annual Report on Form 10-K for the most recently ended fiscal year, as well as other risks and cautionary statements set forth in our filings with the U.S. Securities and Exchange Commission. Forward-looking statements are not a guarantee of future performance, and actual results may differ materially from those projected. The forward-looking statements are representative only as of the date they are made and, except as required by applicable law, we assume no responsibility to publicly update or revise any forward-looking statements, whether as a result of new information, future events, changed circumstances, or otherwise.

# letter from the ceo

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Dear Stakeholder,

I am pleased to present Axogen's second annual Environmental, Social, and Governance (ESG) report. We are continuing to identify, refine, and address the ESG efforts that matter to our business and stakeholders, and we are approaching these efforts with diligence while creating long-term value for our stakeholders.

We had a great year in 2022, as we celebrated our company's 20th anniversary by highlighting our unwavering commitment to our mission and our role as the leading company specifically dedicated to improving quality of life for patients suffering from peripheral nerve injuries.

It was also a productive year, as we completed construction of our state-of-the-art biologics processing facility, the Axogen Processing Center (APC), and surpassed 75,000 Avance® Nerve Graft implants since launch. We finished the year with revenue of \$138.6 million and maintained an industry-leading gross margin above 80%, both achieved amid the dynamic COVID-19 pandemic challenges.

Notably, we announced that RECON<sup>SM</sup>, the pivotal study for Avance, achieved its primary endpoint. This milestone is the culmination of tremendous effort over 10 years in the making, and it will be a solid foundation for our biologics license application submission to the U.S. Food and Drug Administration. The RECON achievement furthers our commitment to provide the highest quality data in support of our solutions for peripheral nerve repair.

We also continue to increase patient awareness and education by amplifying voices of patients and activating patients to be good stewards of their health and health priorities. Read more about some of our patient ambassadors starting on page 5.

After releasing our initial ESG assessment last year, we have maintained our focus on our ESG strategy. We have continued to focus on diversity and inclusion and expanded our employee resource groups.

We also concentrated efforts on Axogen employees fostering our "Axogenic" values. We expanded leadership and other career development educational opportunities and launched a mentorship program for our employees. In addition, we provided support and community engagement at our facilities and the communities we serve as outlined throughout this year's report.

We are proud of our achievements and are continually looking to improve upon our ESG efforts in alignment with the Sustainability Accounting Standards Board's (SASB) topics for disclosures and other reporting frameworks. I look forward to continuing to report on our progress as a company.



**Karen Zaderej**

Chairman, CEO, and President

# about axogen

## our promise

Every day, people suffer traumatic injuries or undergo surgical procedures that impact peripheral nerve function, which can result in the loss of muscle or organ function, loss of feeling or pain.

Our comprehensive portfolio of solutions focuses on helping patients touch, run, feel, kiss, smile, and hug—some of the many things healthy peripheral nerves allow us to do.

## our story

Since our founding in 2002, Axogen has been dedicated to improving outcomes and quality of life for patients with peripheral nerve damage. Our mission to provide meaningful surgical solutions to the clinicians who treat these patients is what drives us at every level of the business. Today, this mission continues to fuel our innovative product portfolio, physician education initiatives, clinical research, and patient awareness campaigns.

We have continued to expand applications and increase adoption of our platform for nerve repair, simultaneously growing our business and the market in pursuit of our mission.

In 2022, Axogen celebrated its 20th anniversary of revolutionizing the science of nerve repair and helping to improve quality of life and restore feeling and functionality to patients with damaged peripheral nerves.



After two decades of an unwavering focus on the science, development and commercialization of nerve repair technologies for regeneration, we are still the only company solely dedicated to peripheral nerve repair.

Our comprehensive suite of solutions for nerve repair includes the following:



## Repair Transected Nerves

Repairing transected nerves is critical for the return of sensation and motor function.



### Avance® Nerve Graft

Axogen's 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®

Enables connector-assisted tensionless repair for short-gap nerve injuries.

## Protect Damaged Nerves

Protecting damaged nerves during the healing process is important for more consistent patient outcomes.



### Axoguard Nerve Protector®

Wraps and protects the injured nerve, to reinforce the nerve reconstruction and minimize the potential for soft tissue attachments.

## Terminate Nerves (when repair is not possible)



### Axoguard Nerve Cap®

Protects a nerve end or stump and separates the nerve from the surrounding environment to reduce the development of a symptomatic or painful neuroma.

Our team is built on science and innovation, and our R&D team actively explores potential new technologies and enhancements to our existing portfolio of nerve repair surgical solutions. We continue to expand the adoption of our products in trauma, compression surgeries, oral and maxillofacial applications, breast reconstruction neurotization, and the surgical treatment of pain.

## our patients

Living with nerve damage can have a significant impact on a patient's quality of life. It may involve a loss of function or cause chronic or debilitating pain.

Nerve damage can occur due to a cut or laceration from a traumatic injury or previous surgery, compression, stretching or neuroma.

Surgical nerve repair can help restore lost sensory or motor function or address the source of chronic pain. We are committed to improved patient outcomes and see an opportunity to make a meaningful difference for those who suffer the effects of peripheral nerve damage.

### Meet our patient ambassadors

We believe that the life-changing impact of a nerve injury is best described by those who've lived it. Through our Patient Ambassador Program, we work with and amplify the voices of patients who have experienced the life-changing impact of peripheral nerve repair to increase awareness.



## axogen and donate life: a decade of the rose parade

This year marked the tenth year that Axogen has co-sponsored the Donate Life float at the Rose Parade in Pasadena on New Year's Day. Bri Majsiak was selected to ride on the 2023 Donate Life Rose Parade Float to ring in the new year, and Madie Nicpon was honored through a floragraph that adorned the float.

Madie was an Avance Nerve Graft recipient whose life was improved by the gift of nerve tissue donation. In 2017, she underwent surgery to repair damage to her lingual nerve that occurred when her wisdom teeth were removed. In 2019, Madie rode on the Donate Life Float during the Rose Parade and became a frequent speaker and advocate for tissue donation. Tragically, Madie passed away from an accident in 2021. In the midst of their grief, Madie's parents honored her commitment to tissue donation, and her kindness now lives on through the lives of dozens of organ and tissue recipients. Her parents continued this kindness through the creation of the MN2-Gether Foundation for the advocacy of organ and tissue donation, which Axogen continues to support.



**Chris Brown:** Chris was at work when his hand became entangled in powerful machinery and his right arm was traumatically amputated. Miraculously, he was able to climb down from the machine and his co-worker applied a tourniquet before rushing him to the hospital. Despite the challenge of losing his arm, he was thankful to be alive.

A few months later, Chris began suffering from unrelenting chronic pain that was so intense, he was unable to work, sleep, or function in daily life. Pain medication did little to help and instead caused unbearable side effects.

Fortunately, a local orthopedic surgeon recommended surgical nerve repair. During the procedure, several neuromas that were the source of the pain were surgically removed. Chris's nerves were then reconstructed and reconnected using Avance® Nerve Graft to bridge the resulting nerve gaps and repair nerves without the formation of painful neuromas. After surgical nerve repair, Chris is back to work, spending time with his family, and living pain free.

**Bri Majsiak:** Bri lost her mother to breast cancer when she was just five years old. Growing up, she was concerned about her increased risk of breast cancer. In 2020, at the age of 26, she made a difficult decision to proactively undertake a prophylactic mastectomy followed by immediate breast reconstruction. She knew it would be a significant change to her body; one that she would carry with her for the rest of her life. She was also worried about facing life with a numb chest.

During a mastectomy, the nerves that provide feeling to a patient's breasts are cut when the breast tissue is removed. As a result, the patient can experience a range of partial to complete numbness.

Bri's reconstructive surgical team was able to reconnect the nerves cut during her mastectomy to nerves in her reconstructed breast using Avance® Nerve Graft and the Resensation® surgical technique. Over time, her nerves regenerated and restored feeling to her chest, allowing her to move forward and heal without numbness serving as a constant reminder of what she had lost.

Visit our [website](#) to hear from more patients who were surgically repaired with Axogen products, as they speak from real experience in their own words.

Testimonials from patients regarding our products are not necessarily indicative of the effectiveness or viability of our products. These testimonials are individual experiences, reflecting real life experiences of those that have received surgeries using Axogen products. However, they are individual results and results may vary. We do not claim that they are typical results that patients will generally achieve. The testimonials are not necessarily representative of all of those who will receive surgeries using Axogen products.

These testimonials are applicable to the specific individuals giving such testimony and may not be indicative of future outcomes for prospective patients. Axogen cannot and does not guarantee specific outcome metrics.

# governance

Axogen's Board of Directors includes nine members that offer oversight to the organization with four key committees: Audit; Compensation; Governance, Nominating, and Sustainability; and Quality, Compliance and Portfolio Management. Additionally, the Company founded a scientific advisory board made up of scientists, surgeons, and regulatory experts.

Axogen's ESG commitment lives within the Governance, Nominating and Sustainability Committee and the Compensation Committee.

Visit the website to meet our Axogen Board of Directors and committee members.

Gender balance on  
the Board

22% female

78% male

## ethics

### Responsible Procurement Practices

Axogen values maintaining our legacy of integrity and the role we play as stewards of fair working conditions, basic human rights, and procuring the safest components for our products. Accordingly, we focus on educating our employees, suppliers, and business partners on our expectations as we engage in commerce.

As described in our [Business Code of Conduct](#), it is our expectation that our business partners will conform with [United Nations Universal Declaration of Human Rights](#); [OECD Guidelines](#) and the [Guiding Principles on Business and Human Rights](#). As we engage with our business partners, we will continue to emphasize our expectations as we understand that our choices to source components can have downstream effects, and we want to be a force for positive change. To more closely track how our suppliers are doing, in 2022, we updated our electronic quality management system to facilitate additional monitoring of our suppliers to our high standards.

Furthermore, all of our suppliers and distributors involved in the design, development, manufacturing/processing, and distribution of our products are evaluated and approved via our corporate supplier management process. Supplier management is risk-based, evaluating the potential impact a supplier's activity can have on Axogen operations.

Our Class A (Tier 1) supplies include component, packaging/labeling, contract manufacturing and sterilization, contract laboratory, and tissue agencies due to their significance on tissue processing and product delivery process. The tools used to evaluate and manage these suppliers include quality agreements, questionnaires, audits performed by Axogen to ensure supplier compliance with ISO 13485:2016: Quality Management System Standard and 21 CFR Part 820: Current Good Manufacturing Practice, and the review of third-party certifications. Of the 21 Class A suppliers utilized



by Axogen, 17 (77%) have been audited by a third party (either ISO certified, or FDA registered and inspected). We periodically review available suppliers for additional opportunities and have a preference for those who partake in independent audits of their safety and quality management.

### Cybersecurity and Data Privacy

Axogen recognizes the importance of cybersecurity in our long-term success. We utilize the Center of Internet Security (CIS) framework to evaluate our cybersecurity procedures and target improvements. We continue to implement improvements to maintain our infrastructure, safeguard our corporate data, and promote work stability.

Part of this process includes conducting periodic assessments of our cybersecurity posture and benchmarking that progress by partnering with external experts to report on and compare our cybersecurity position.

In 2022, we continued extending our implementation of Single-Sign-On (SSO) and multi-factor authorization (MFA) to business systems, and now have a majority of our systems utilizing these safeguards. For those systems that are ineligible, additional

safeguards and data segregation has occurred to mitigate potential risk. We exceeded our yearly Center of Internet Security implementations goals in 2022.

Furthermore, we continued implementing cybersecurity trainings and monitoring employee compliance with our information security training program. In 2022, the program included eight all-employee training events and eight additional simulated attempts at data breaches. Any of the users that performed poorly during these tests or trainings were automatically tracked and provided with remedial training. Overall, we have been very pleased with how well Axogen employees have responded to these training events and increased their cybersecurity awareness.

At Axogen, we also understand that cybersecurity is a critical feature of the marketplace and must be integrated into our business model. Accordingly, our cyber team and senior leadership team brief the Board on information security matters every quarter as part of the Audit Committee's corporate review. As a publicly traded company, we have also been monitoring possible disclosure changes in the cybersecurity space and have been working to streamline our response protocols to better align these developments and minimize our risk if such an event were to ever occur. Despite our best efforts at prevention, we are also aware of the gravity of this arena, so we maintain an insurance policy against cybersecurity breaches, should such an event occur.

We also monitor our results. Over the past three years, Axogen has not experienced any known security breaches. Accordingly, Axogen has had zero known impact to the relative revenue and zero penalties or settlement expenses. There are zero known breaches involving personally identifiable information and zero known instances of customers affected by an Axogen security breach.



# operations

## Facilities and Growth

Axogen employs more than 400 professionals across the country, with five physical locations and a remote sales force. Axogen's headquarters is located in Alachua, FL., with a second corporate campus in Tampa, FL., our global distribution facility in Burleson, TX., and our processing centers in Ohio.

In 2022, we completed construction of our state-of-the-art biologics processing facility, the Axogen Processing Center (APC), in Vandalia, OH. As we transition all production to APC, our nearby Dayton, OH, processing center will remain open and operational.



### Axogen Processing Center

APC was designed to accommodate the regulatory transition of Avance® Nerve Graft from a tissue product to a biologic and support our future growth. We plan to consolidate all local staff at APC, with more than 100 employees expected to be onboarded at APC in 2023.

With this in mind, in 2022 we added clean rooms and additional water boilers and chillers for increased capacity, as well as enhanced fire protection and sensing and building security. We also installed ultra-low temperature freezers that deliver the lowest daily energy usage for efficient product storage.

The ISO 14644 processing rooms have redundant HVAC systems running in parallel, so if one of the systems goes offline for either preventive maintenance or an unexpected failure, the backup system will ramp up to carry the load.

Multiple EHS programs were implemented at APC including Fall Protection, Lock-Out/

Tag-Out, Hazard Communication, Wastewater Permit and Sampling, Tier II reporting, and infectious waste large generator registration and removal.

APC has also expanded its sustainability measures. The facility uses hydronics for heating and cooling, utilizing water as the primary fluid to transfer energy throughout the building – a more energy-efficient system that results in tighter control of the temperature/relative humidity. All lighting is LED and operated via motion sensors for energy savings.



### **Burleson Distribution Center**

Axogen's Distribution Center in Burleson, TX., continues to support the distribution of all products to customers globally. Upon completion of processing, Axogen products are shipped to Burleson for storage and distribution.

In 2022, we made several improvements to upgrade the facility. We expanded our lease, growing to occupy eight suites in the building and altered our floor plans to allow for efficient operations flow. Two of these new suites include energy-efficient QTL Series High Bay LED lighting. We are implementing additional upgrades in 2023 that will further improve the efficiency of the facility.



### **Headquarters in Alachua**

Axogen continues to focus on its employee base at our headquarters in Alachua, a growing center of biotech and regenerative medicine adjacent to Gainesville, FL., and the University of Florida, to support ongoing growth. For business continuity, we also have backup distribution capabilities in Alachua.

In 2022, we took steps toward improving the safety and conditions of our facilities in Alachua based on employee suggestions for updates and improvement.



### **Corporate Campus in Tampa**

In 2020, Axogen opened a second corporate campus in Tampa – an important milestone for the company. We continue to expand our presence in the emerging biotech hub of Tampa, supporting innovation, recruitment, and growth in the community.

The facility includes a world-class research center with specific labs for general research, tissue processing, electromechanical development, cell culture, chemistry, and advanced manufacturing.



## Environmental

We understand how important sustainability is, and we are committed to advancing the science of nerve repair in an environmentally friendly way. As such, we regularly evaluate how we can best limit our environmental impact.

In 2022 we took a number of steps in our operations and facilities, as outlined below, to reduce our environmental impact.

We launched our Environmental and TCFD (Task Force on Climate Related Financial Disclosures) Action Plan in 2022 and we anticipate completion in the next 12-18 months. To date, we have completed the following actions:

- Created Axogen’s Sustainability Advisory Committee (ASAC), which is responsible for monitoring compliance with sustainability policies and efforts, engaging in scenario-based planning to reevaluate Axogen’s roles and opportunities.
  - *Progress: The ASAC Team has been established and completed 13 working meetings since implementation. We anticipate ongoing working meetings as necessary.*
- Determined current levels and setting targets for environmental monitoring and greenhouse gas (GHG) emissions.
  - *Progress: We launched the new environmental monitoring program for each of our locations. The program tracks utilities usage and different waste streams generation. The ASAC Team is analyzing the current data to identify opportunities for improvement in data collection, utility usage, GHG emissions and waste generation.*
  - *Our total 2022 GHG emissions were calculated based on Scope 1 (Natural Gas and Diesel Fuel Usage) and Scope 2 (Electricity Usage).*
- Established an initial assessment of climate-related risks and opportunities for each Axogen location.
  - *Progress: A risk assessment has been created. The risk threats have been identified and evaluated based on relevant impact and probability of occurrence, and a risk rating has been calculated for each threat. The ASAC Team is working on analyzing the current status and creating mitigation plans for all high-risk threats.*



The task force is also working to determine mitigation plans, drafting policies for reviewing, and implementing directions from the Board, standardizing an enterprise risk management system.

### **Evaluating and launching new recycling initiatives and programs**

A recycling program has been implemented in APC and Tampa. We recycle glass, plastic, and cardboard in APC. The Tampa office recycles everything but glass and is recycling approximately 1.2 tons/month of waste. The rest of the waste, approximately 1 ton/month, is sent to the city's waste-to-energy plant located in McKay Bay.

All sites have water fountains equipped with the ability to refill reusable water bottles, reducing the need for plastic bottles and unnecessary waste.

### **Working toward ISO 14001, Environmental Management System Certification**

In 2022, we launched an ISO 14001 Action Plan. We reviewed the organization and determined internal and external issues, interested parties, needs and expectations, and the Scope of Environmental Management System (EMS). In addition, the team drafted the environmental policy and completed ISO 14001 Leadership Training. We anticipate meeting the requirements and having substantial completion of the ISO 14001 milestones in the next 18-24 months.



## Axogen's 2022 Estimated Environmental Figures at a Glance

APC	alachua	BDC	tampa
<b>energy</b>	<b>energy</b>	<b>energy</b>	<b>energy</b>
electricity (kWh) <b>433,760</b>	electricity (kWh) <b>279,206</b>	electricity (kWh) <b>1,215,519</b>	electricity (kWh) <b>896,979</b>
natural gas (ccf) <b>76,896</b>	natural gas (ccf) <b>3</b>	natural gas (ccf) <b>1,207</b>	natural gas (ccf) <b>65</b>
water (1000 gallons) <b>3,373</b>	water (1000 gallons) <b>43,178</b>	water Water is managed by landlord and mixed with other companies.	water (1000 gallons) <b>550</b>
waste (yd)	waste Waste and recycling is managed by landlord and mixed with other companies.	waste Waste and recycling is managed by landlord and mixed with other companies.	waste (tons)
<p>recycling 592.77 trash 433.55</p>			<p>recycling 14.58 trash 13.67</p>

### comments

The facility was under construction through 2022, and therefore these numbers are likely to change in the future once the facility becomes fully operational. This facility is undergoing validation.

### comments

These services are managed by landlord and mixed with other companies. Axogen's usage is calculated by different percentages based on individual meter.

## Axogen's Combined 2022 Estimated GHG Emissions (CO<sub>2</sub>-e metric tons)

• Indirect Emissions   • Direct Emissions



For its first environmental inventory, Axogen used the [EPA Simplified GHG Emissions Calculator](#). The May 2023 revision of the tool was used to calculate our 2022 GHG Emissions.

Axogen's GHG Emissions calculations are currently limited to Scope 1 and Scope 2 emissions, and are our estimates, which are based on invoices from our providers. These calculations are based on electricity purchased and stationary combustion used – such as natural gas and diesel fuel.

This environmental data was gathered as follows:

- APC, BDC, and Alachua: Data was collected from monthly individual invoices.
- Tampa: Data was collected from monthly invoices. However, percentage estimation was calculated because the accounts are shared with other companies/tenants in the same building. In order to improve data collection and monitor our use, individual meters were installed in February 2023.

\* GHG Emissions: These data are for the APC, Alachua, BDC, and Tampa locations only. Although, we believe our DPC use is modest, our landlord does not provide us with separate invoices to monitor or estimate our use there.

# products

## Clinical Studies

Axogen invests in and supports clinical studies and programs to further the understanding and outcomes of peripheral nerve repair. Axogen products are featured in over 215 peer-reviewed clinical publications.

All clinical trials developed and conducted by Axogen are carried out in compliance with applicable domestic and international ethical regulations. We have mechanisms in place to protect the safety and rights of all clinical trial participants when consenting to the research, during the trial, and after completion. Prior to the participation, we gain voluntary informed consent from the subjects who fully understand the risks and benefits involved in the trial.

Clinical Research Organizations (CROs) and vendors selected for use in our clinical trials must meet standards in compliance with the laws and regulations of each country applicable. Continuous feedback is given to CROs to improve clinical study report and service quality.

Onsite monitors are used to oversee study procedures for trials to assure procedures are completed and documented per Good Clinical Practices (GCP).

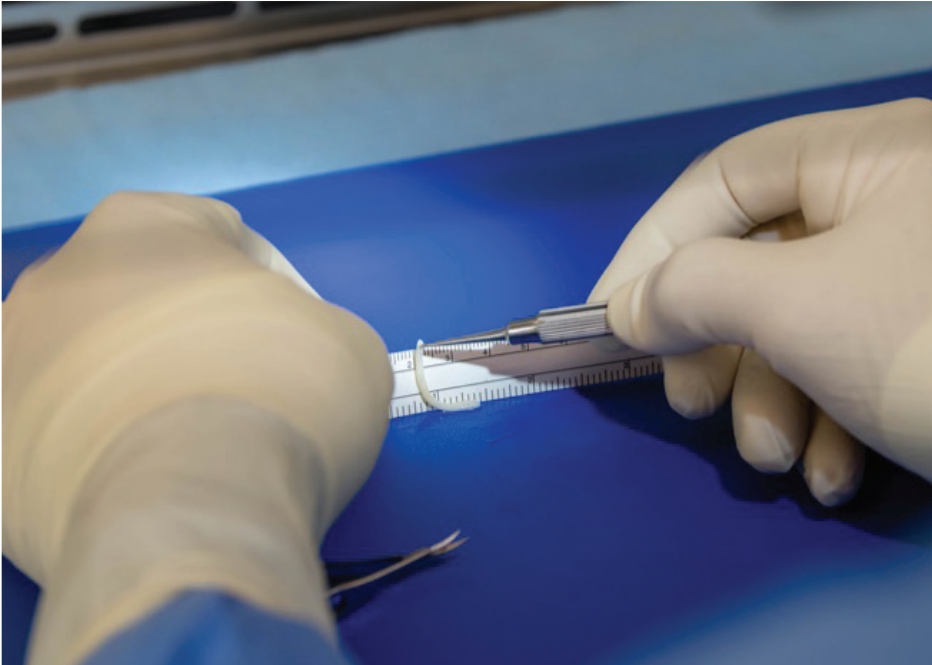
Axogen strives to collect data from participants of various ethnicities, ages, and genders through clinical trials in pursuit of diversity in our clinical trials and product development. All our enrolling clinical studies are based in the U.S. or U.K.

## Clinical Studies at a Glance

### In 2022, we had zero:

- FDA-sponsored inspections related to clinical trial management and pharmacovigilance that resulted in Voluntary Action Indicated (VAI) or Official Action Indicated (OAI).
- Monetary losses as a result of legal proceedings associated with clinical trials in developing countries.





In 2022, we had six enrolling clinical studies:

- RANGER® Registry, the largest multi-center clinical study in peripheral nerve repair with more than 2,600 repairs.
- MATCH® Registry, comparing Avance outcomes to autograft and synthetic conduits.
- SensationNOW®, a multi-center registry study in breast neurotization.
- REPOSE<sup>SM</sup>, a prospective, randomized, controlled study of Axoguard Nerve Cap vs neurectomy.
- RETHINK PAIN™, a study designed to capture the patient's pain journey from onset of chronic pain to nerve repair.
- REPOSE-XL<sup>SM</sup>, a multicenter, prospective single cohort pilot study intended to evaluate the use of Axoguard Nerve Cap® in large diameter sizes to protect and preserve terminated nerve ends.

### Announcing Topline Results for RECON<sup>SM</sup>

In May 2022, we completed subject follow-up for RECON<sup>SM</sup>, the pivotal study supporting the BLA (Biologics License Application) submission for Avance Nerve Graft.

The Phase 3 pivotal study met its primary endpoint for the return of sensory function as measured by static two-

point discrimination, and the safety profile was consistent with previously published data. The FDA granted Avance Nerve Graft a Regenerative Medicine Advanced Therapy (RMAT) designation. The data will support our BLA submission.

Additional analysis of the RECON study data found:

- Avance demonstrated statistical superiority for return of sensory function (measured by static two-point discrimination) as compared to conduits in gaps greater than 12 mm (p-value 0.021).
- Avance demonstrated statistical superiority for time to recovery of static two-point discrimination as compared to conduits, returning normal sensation\* up to 3 months earlier in gaps greater than 10 mm (p-value 0.037).
- Conduit repairs were observed to have an increased likelihood of persistent and unresolved nerve pain with an incidence of 9 (8%) conduit subjects as compared to 2 (2%) Avance subjects.

This is a critical milestone toward transitioning Avance Nerve Graft to a licensed biologic and further supports the expanded adoption of Avance.

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



## Product Safety

As a company with more than 75,000 implants of Avance Nerve Graft in patients across the country, we understand the importance of regularly monitoring quality and safety throughout the product lifecycle. To do this, we provide effective training, meticulous reviews, and detailed audits and inspections of our products to review how we are tracking against our specifications.

This includes a Quality Management System that is accredited to American Association of Tissue Banks (AATB) and National Association of Boards of Pharmacy (NAPB) standards, registered to ISO 13485 standard and complies with U.S. regulations under 21 CFR 1271 (Good Tissue Practices) and 21 CFR 820 (Quality System Regulations).

To ensure effective and safe delivery to the patient, products are labeled and traced from their inception. They continue through transportation to the health care facility and conclude with the end recipient. Moreover, Axogen has a robust Corrective Action and Preventative Action Program (CAPA) and complaint/feedback system that is critical to our commitment to patient safety.

## Product Safety at a Glance

### In 2022, we had zero:

- **Recalls issued or units recalled.**
- **Products listed in the FDA's MedWatch Safety Alerts for Human Medical Products Database.**
- **Fatalities related to products as reported in the FDA Manufacturer and User Facility Device Experience.**
- **FDA enforcement actions taken in response to violations of current Good Manufacturing Practices (cGMP) by type.**
- **Products accepted for takeback, reuse, or disposal.**
- **Fatalities associated with products as reported in the FDA Adverse Event Reporting System.**
- **Products listed in the FDA's MedWatch Safety Alerts for Human Medical Products database.**

## Product Lifecycle

Products are tracked by lot serialized number from donors through processing, shipping, storage or sale, implantation, demonstration, or destruction. This tracking occurs via an electronic records system and tissue utilization record system. Our inventory specialists work closely with our sales representatives and distribution partners to ensure product allocation is carefully monitored. Furthermore, product supplies are audited, and the results reviewed. We also implement initiatives to ensure a safe product supply is available and to prevent abuse, introduction of expired products into a black market, or release into the environment. We are aware of no instances of counterfeiting of our products.

Axogen does not reuse or recycle product. In 2022, we estimate 1,100 pounds of unused goods (400 pounds of Avance tissue products and 700 pounds of Axoguard medical devices) were repurposed into a pool for surgeon education and demonstration. After this demonstration use, the product is destroyed.

### **1. Direct product/devices/ equipment**

– 80lbs, 0.04 metric tons

### **2. Associated supplies/ packaging**

– 320lbs, 0.16 metric tons

Our products are small and lightweight. However, the packaging required to provide a sterile barrier and reliable storage adds weight and volume. An estimated 80% of the weight is from the product packaging (Tyvek/foil, clamshell, box).

Tissue products are traced via unique identifiers from manufacturing through distribution to customers. Medical devices are lot traced from receipt through distribution.

Axogen's first line of defense against the risks associated with the use of critical materials is to maintain significant safety stock (approximately six months on all supplies and approximately 18 months of a critical component) and secondarily, to avoid sole sourcing on critical materials. We are in the process of adding a second qualified supplier for the last of critical materials.

## Product Lifecycle at a Glance

### In 2022, we had zero:

- Actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products.

# our people

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## Human Resources

In 2022, we prioritized our wellness programs for employees, which are focused on the pillars of mental health, physical well-being, and financial education:

### Mental Health

- Diversity, Equity, and Inclusion (DE&I) monthly meeting discussions
- Employee Assistance Program training sessions
- Emotional well-being coaching webinar series

### Physical Well-Being:

- Mammogram bus on Tampa site
- Virtual primary care visits through Doctors on Demand and AmWell
- Step challenge for Donate Steps to Donate Life
- Hydration challenge during the summer
- Fall into Wellness bingo to promote self-care
- Providing free CDC prediabetes risk tests

### Financial Wellness

- CapTrust financial planning webinars
- Financial coaching webinars

In 2023, we plan to continue expanding our wellness initiatives to focus on the following pillars:

- **Wellness programming:** Implementing a digital health solution through our partnership with Burnalong.
- **Functional fitness:** Partnering with gyms to support improving strength, flexibility, balance, and coordination to help employees achieve fitness goals.
- **Nutrition education:** Partnering with a qualified nutritionist to teach classes and workshops to offer employees credible, science-based information to help them make decisions about their health.
- **Mental health/mindfulness:** Incorporating mindfulness challenges and mental health awareness campaigns for employees.
- **Wellness committee:** Relaunching the committee to drive employee engagement in the wellness program to increase participation at each of our locations and help execute our wellness challenges.
- **Leadership:** Collaborating with our leadership team to highlight the importance of wellness training to help drive employee engagement in wellness events.

Workforce Development

total employees

396

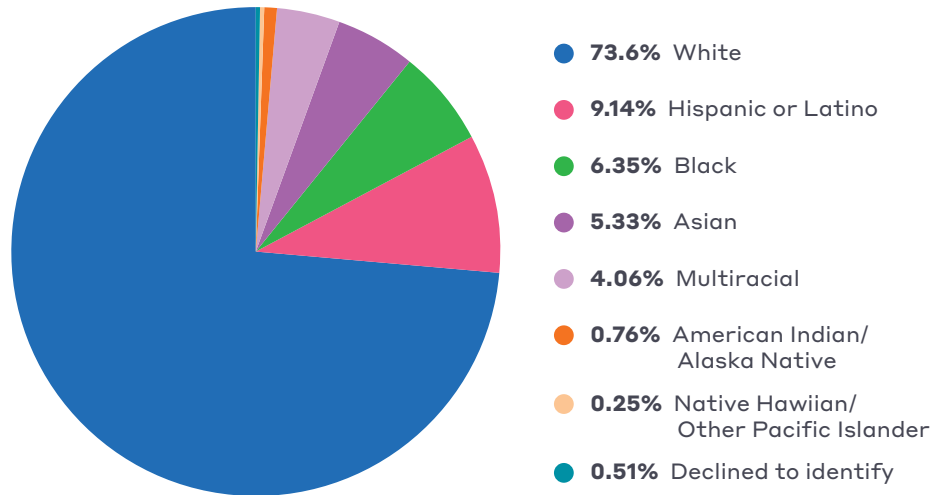
214 sales and marketing

78 corporate

44 research and development

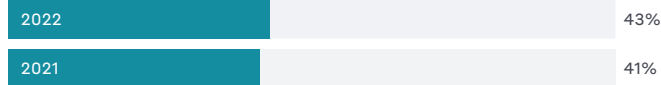
60 operations

ethnicity



gender

Female



Male



## Employee Health and Safety

Axogen is committed to creating a safe and healthy work environment that meets all regulatory requirements. Safety remains a key priority and we are continuously looking at ways to improve the health and safety of our employees. In 2022, we made the following progress:

- Created and executed Environmental, Health, and Safety (EHS) Action Plans and Compliance Calendar, prioritized based on risk.
- Conducted third party Industrial Hygiene testing for high-usage chemicals in DPC, APC, and BDC.
  - All results were within Occupational Safety & Health Administration (OSHA) limits.
- Created and improved multiple safety programs, including Confined Spaces, Lock-Out/Tag-Out, Environmental Health and Safety Management of Change (MOC), Fall Protection, Powered Industrial Truck, Hazard Communication, and Bloodborne Pathogens.
- Upgraded and implemented Emergency Preparedness and Response and Spill Response Procedures.
- Implemented AlertMedia Emergency Notification and Global Threat Intelligence System.



# alertmedia

In 2022, we upgraded to a system called AlertMedia to quickly communicate with our employees during emergency situations. Employees also have access to a unique employee-only emergency number that can be called at any time to hear companywide announcements or to leave a voicemail or text message for emergency coordinator support.

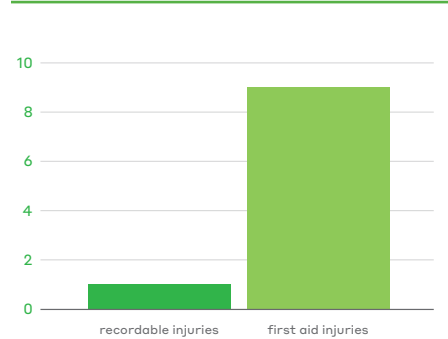
With AlertMedia, we can easily send multi-channel alerts to impacted individuals via email, text, voice call, and app push, helping us to reach employees, no matter where they are, during a critical event.

With AlertMedia, we are able to keep our employees informed, safe, and protected should an emergency situation occur.

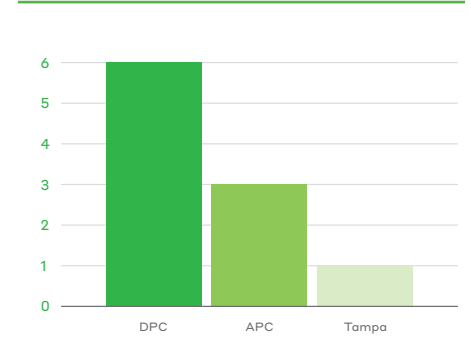
Axogen follows OSHA 29 CFR 1910, and uses a series of company-wide policies, trainings, and procedures to protect all employees' health and safety. Our EHS committee meets monthly to analyze potential issues, review incident data and implement necessary changes to minimize work-related injuries.

In 2022, across all facilities and employees, we had 10 minor first aid injuries, one of which was OSHA reportable, and zero fatalities. Our Recordable Incident Rate (RIR)\* for 2022 is 0.25 and Lost Time Injury Rate is zero.

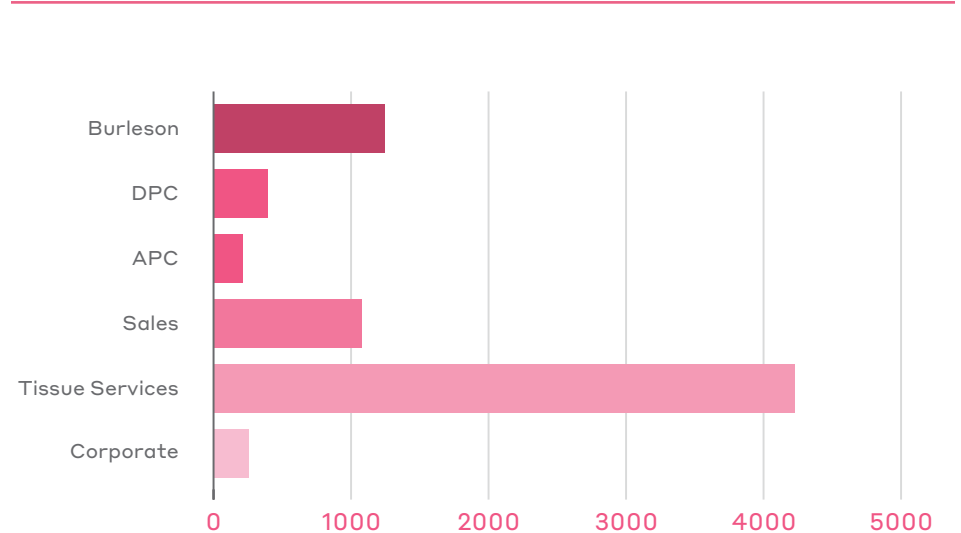
## injuries 2022



## injuries by site 2022



## days since last recordable safety incident



\* RIR = Number of injuries and illnesses X 200,000 / Employee hours worked



Our benefits package includes health and welfare benefits, employee, spouse, and dependent life insurance, 401(k) retirement plan with company match, Employee Stock Purchase Plan, Parental and Family Leave, supplemental disability, adoption assistance, holiday and paid time off, wellness program, educational reimbursement for advanced degrees, and relocation assistance.

We also offer all employees the opportunity to enroll in leadership and career development programs and support external development through continuing education. We provide employees with individual career development plans focused on developing specific skills, including a mix of on-the-job training, advanced external training, stretch assignments, mentoring, and coaching resources. Employees actively participate in annual job performance reviews. Additionally, we encourage external professional networking and participation in industry conferences and trade shows.

All employees are offered the opportunity to contribute to an annual employee engagement survey and, as a result of the survey responses, we believe our relationship with our employees is sound. Targeted action plans are implemented at both the department and company level based on our employees' responses in the survey.

Employee safety is critical to our operations, and we follow OSHA 29 CFR 1910, and use a series of company-wide policies, trainings, and procedures to protect all employees' health and safety. We utilize an Environmental Health and Safety committee that meets monthly to analyze potential issues, review any incident data, and implement necessary process or procedural changes that can minimize the work-related injuries and occupational exposure to chemicals, biohazards, or illnesses, and eliminate any potential from serious injuries and fatalities. See page 19 for more details on employee health and safety.

The Compensation Committee of our Board of Directors has oversight of our culture and human capital management, including diversity, equity, and inclusion with respect to our employees.

### Commitment to DE&I

Axogen is committed to fostering an "Axogen Authentic" culture of DE&I – one that is open and inviting to all who join us on our mission of restoring nerve function and quality of life to patients.

Our corporate values support honest and open communication, mutual support, collaboration, passionate debate, empowerment, and respect. These foundational values are at the core of our culture and, when combined with purposeful DE&I initiatives, help us to create meaningful change and an excellent place to work.

In 2022, we continued to partner with external consultants to support the launch of our initiatives and made significant headway toward our objective of continuing our education efforts, increasing the number of ERGs, and creating teaching opportunities for our leaders. Additionally, our Affirmative Action plan will continue to drive our recruitment and retention efforts and align with our overall principles of creating an inclusive environment.

### Conexión Latinx Employee Resource Group

The group empowers self-identified Latino/a/x/e and/or Hispanic employees at Axogen by providing a space for career development, personal development, and networking opportunities. The group currently has 40 members.

The mission of Conexión Latinx is to cultivate a community of Latinx employees that are inspired, empowered, and equipped to achieve excellence in both their personal and professional lives. The group offers an inclusive space for mutual sharing of ideas, resources, and knowledge.



### EmpowHER WINners Women's Network

The group provides a productive environment for women to network, mentor, collaborate, and educate while redefining the standard of care in peripheral nerve repair. The group's goal is to promote an open communication network and cultivate female leadership across Axogen.

### Community Initiatives

Giving back to the community—from the medical community in which we operate, to local business and education initiatives, to organizations in the communities in which our employees live and work, community involvement continues to be a vital component of Axogen's operations.

## **Nerve Repair and Supporting Patients**

### Donate Life

Axogen recognizes that without the partnership of Donate Life and our tissue procurement partners, our mission of restoring nerve function and quality of life to patients with nerve injuries would not be achievable.



### Surgeon Education

Axogen has a robust surgeon education program. We have several in-person national education programs each year and provide customized multimodal programs to specific surgeon cohorts for advanced learning. We also have an ongoing interactive webinar series on the principles of nerve repair, and we sponsor Nerve Matters, a forum for surgeons to discuss nerve cases and ask advice of experts in a HIPAA-compliant environment.

### American Association of Tissue Banks (AATB)

We are an active member of the AATB, and members of our management team have served in leadership roles with the organization throughout the years. Since its beginning, AATB has been dedicated to saving and improving lives by promoting the safety, quality, and availability of donated human tissue.

### Camp Open Arms

Axogen has been a Camp Open Arms sponsor since its inception in 2015. This program was brought to life by University of Maryland School of Medicine pediatric orthopaedist Dr. Joshua Abzug, who works with patients with limb differences. Camp Open Arms is a place where children can experience a carefree camp experience.

## **MedTech and Education**

### University of Tampa Board of Trustees

Axogen CEO Karen Zaderej has served on the University of Tampa Board of Trustees since 2020. This group of outstanding professionals meets formally four times each year and provides oversight to all areas of the University and works to raise resources.



### Leadership and Innovation Forum of Tampa

Axogen Sr. Director of Regulatory Luis Caveda has served on the Leadership and Innovation Forum of Tampa (LIFT) since 2021. LIFT, powered by USF Health, is designed to unite the innovators and leaders committed to advancing the economic and physical health of the Tampa region.

### BioFlorida

BioFlorida is the voice of Florida's life sciences industry, representing 8,600 establishments and research organizations in BioPharma, MedTech, Digital Health and Health Systems that collectively employ nearly 107,000 Floridians. Mark Freidman, Axogen VP of Regulatory and Policy, joined the BioFlorida Board of Directors in 2021.

### Additional Board Involvement:

- Stacy Arnold, Vice President of Clinical Research, serves as a board member for Mercer University's National Engineering Advisory Board and as a founding member of Life Science Women's Network.
- Maria Martinez, Chief Human Resources Officer, serves as board member of Good360, a leader in product philanthropy that delivers hope for those in need.
- Angelo Scopelianos, Chief Research and Development Officer, serves on the University of Florida Biomedical Engineering advisory board.
- Karen Zaderej, Chairman and CEO, serves as a board member for EyePoint Pharmaceuticals, Inc.

## **Local Philanthropy**

### Food Drives

For the past five years, Axogen has conducted annual food and resource drives to collect non-perishable food items and other necessary supplies to benefit those in need in our communities. In 2022, all locations (Alachua, Burleson, Dayton, and Tampa) participated, collecting needed items for local organizations.

Alachua held a supply drive for Ronald McDonald House and Wish Upon a Star through Partnership for



Strong Families and were able to sponsor 30 children. The Burleson team held a food drive for Harvest House and a toy drive for Cook Children's Hospital in Ft. Worth. The Dayton team held a food drive for the Food Bank of Dayton and a toy drive benefiting For Love of Children. The Tampa team collected school supplies for Hillsborough Education Foundation and held a toy drive for Metropolitan Ministries.

### Humanitarian Aid

Axogen partners with Touching Hands to provide life-changing hand surgeries, rehabilitation, and medical training in the world's underserved communities.

In 2022, we completed mission trips to serve global needs in Algeria, Ecuador, Honduras, and Swaziland, and surgical training support in Mozambique and Ethiopia. We also provided a surgery donation in Barcelona for a patient in need.

We provided monetary and in-kind donations to support the people of Ukraine and the students and families of Uvalde, TX.

### Angel Trees

Axogen has a longstanding tradition with Angel Trees. Across all of our facilities, we partner with the local community to bring holiday cheer and gifts to underprivileged children.



For too many, this time of celebration and gifts is overshadowed by the daily struggle to put food on the table or keep a roof over their heads. Each Angel on the tree represents a child in need from our communities, and each tag represents a simple wish list for each Angel.

### Community Service Days

Axogen employees at each location participate in community service days each year to hold food drives and volunteer with local organizations including Ronald McDonald House and Hillsborough Education Foundation. This year, 18 members of the Axogen senior leadership and executive teams also participated in a community service day at Metropolitan Ministries.

### Global Nerve Foundation

In 2022, we continued to support the Global Nerve Foundation. The non-profit organization focuses on improving the awareness and care of patients with peripheral nerve injuries and includes all perspectives ranging from the public to patients to health care providers.

The Foundation was structured into four strategic pillars of Awareness, Education, Research, and Advocacy. Each committee has specific goals and objectives to bring the Foundation's mission of improving the lives of people with nerve problems and the vision of advancing and promoting excellence in nerve care to life. To learn more, visit [globalnervefoundation.org](http://globalnervefoundation.org).



[www.axogeninc.com](http://www.axogeninc.com)