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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

☐ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2020
Or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from TO
Commission File Number: 001-36046

AXOGEN, INC.

(Exact name of registrant as specified in its charter)

Minnesota	**41-1301878**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
13631 Progress Blvd., Suite 400 Alachua, FL	**32615**
(Address of principal executive offices)	(Zip Code)

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

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

None
(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☐

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☐ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☐ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☐
	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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☐

As of June 30, 2020, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant was approximately $ 216,633,232 based upon the last reported sale price of our common stock on the Nasdaq Capital Market.

The number of shares outstanding of the Registrant's common stock as of February 22, 2021 was 40,736,714 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant’s definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the Registrant’s fiscal year are incorporated by reference into Part III of this Form 10-K.

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FORWARD-LOOKING STATEMENTS

From time to time, in reports filed with the U.S. Securities and Exchange Commission (the "SEC") (including this Annual Report on Form 10-K), in press releases, and in other communications to shareholders or the investment community, Axogen, Inc. (including Axogen, Inc.'s wholly owned subsidiaries, Axogen Corporation, Axogen Processing Corporation and Axogen Europe GmbH, the "Company", "Axogen", "we", "our", or "us") may provide forward-looking statements, as defined in the Private Securities Litigation Reform Act of 1995, concerning possible or anticipated future results of operations or business developments. Words such as "expects", "anticipates", "intends", "plans", "believes", "seeks", "estimates", "projects", "forecasts", "continue", "may", "should", "will", "goals", 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 assessment of our internal controls over financial reporting, our growth, the impact of COVID-19, product development, product potential, financial performance, sales growth, product adoption, market awareness of our products, data validation, and 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 Form 10-K should be evaluated together with the many uncertainties that affect the Company's business and its market, particularly those discussed in the risk factors and cautionary statements set forth in the Company's filings with the SEC, including as described in "Risk Factors" included in Item 1A of this Form 10-K and "Risk Factor Summary" included on this Form 10-K. Forward-looking statements are not guarantees 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, the Company assumes no responsibility to publicly update or revise any forward-looking statements, whether as a result of new information, future events, changed circumstances or otherwise.

RISK FACTOR SUMMARY

Below is a summary of our risk factors. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Form 10-K and our other filings with the SEC before making an investment decision regarding our common stock.

Risks Related To The Company

- *Our revenue growth depends on our ability to increase distribution and sales to existing customers and develop new customers, domestically and abroad, and expand our sales force, and there can be no assurance that these efforts will result in significant increases in sales.*
- *Our revenue depends primarily on five products.*
- *Our success will be dependent on continued acceptance of our products by the medical community.*
- *We have not consistently experienced positive cash flow from our operations, and the ability to achieve consistent, positive cash flow from operations will depend on increasing revenue from distribution of our products, which may not be achievable.*
- *We are highly dependent on the continued availability of our facilities and could be harmed if the facilities are unavailable for any prolonged period of time.*
- *Technological change and competition for newly developed products could reduce demand for our products.*
- *We must maintain high quality processing of our products.*
- *Our revenue depends upon prompt and adequate reimbursement from public and private insurers and national health systems.*
- *Negative publicity concerning methods of donating human tissue and screening of donated tissue may reduce demand for our products and negatively impact the supply of available donor tissue.*
- *Delays, interruptions or the cessation of production by our third-party suppliers of important materials or delays in qualifying new materials may prevent or delay our ability to manufacture or process the final products.*
- *The failure of third parties to perform many necessary services for the commercialization of our products would impair our ability to meet commercial demand.*
- *We are dependent on our relationships with independent agencies to generate a material portion of our revenue.*
- *If we do not manage product inventory in an effective and efficient manner, it could adversely affect profitability.*
- *There may be significant fluctuations in our operating results.*
- *We may be unsuccessful in commercializing our products outside the U.S.*
- *We incur costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives.*
- *The COVID-19 pandemic has and could continue to materially and adversely affect our ability to operate, results of operations, financial condition, liquidity, and capital investments.*

Risks Related to the Regulatory Environment in which the Company Operates

- *Our business is subject to continuing regulatory compliance by the FDA and other authorities, which could result in negative effects on our business.*
- *The use, misuse or off-label use of our products may harm our reputation, the image of our products, result in injuries leading to product liability suits, which could be costly to our business, or result in FDA sanctions.*
- *Our Avance Nerve Graft product is currently allowed to be distributed pursuant to a transition plan with the FDA and a change in position by the FDA would have a material adverse effect on us.*
- *Our business is subject to continuing compliance to standards by various accreditation and registration bodies.*
- *Our Axoguard and Avive products are subject to FDA and other regulatory requirements.*
- *Defective products could lead to recall or other negative business conditions.*
- *Our operations must comply with FDA and other governmental requirements.*
- *Clinical trials can be long, expensive and results are ultimately uncertain which could jeopardize our ability to obtain regulatory approval.*
- *We will rely on third parties to conduct our clinical trials and they may not perform as required or expected.*
- *U.S. governmental regulation could restrict the use of our Avance Nerve Graft and Avive Soft Tissue Membrane product, restrict our procurement of tissue or increase costs.*
- *Our Axotouch product is subject to FDA and other regulatory requirements.*
- *Healthcare law and policy changes may have a material adverse effect on us.*
- *We could be subject to civil or criminal penalties if we are found to have violated laws protecting the confidentiality of health information.*

Risks Related to Our Intellectual Property

- *Failure to protect our intellectual property rights could result in litigation and our loss of any potential competitive advantage.*
- *Future protection for our proprietary rights is uncertain.*
- *The patent protection for our products may expire before we are able to maximize their commercial value.*
- *Others may claim an ownership interest in our IP which could expose us to litigation and have a significant adverse effect on our prospects.*
- *We depend on the maintenance of exclusive licenses.*
- *Our trademarks are valuable, and our business may be adversely affected if not adequately protected.*

Risks Related to Our Common Stock

- *An active trading market in our common stock may not be maintained.*
- *The price of our common stock could be highly volatile due to a number of factors.*
- *We do not anticipate paying any cash dividends in the foreseeable future.*
- *Anti-takeover provisions in Minnesota law may deter acquisition bids for us that you might consider favorable.*

Risks Related to Financing Our Business

- *Our credit facility with Oberland Capital contains operating and financial covenants that restrict our business and financing activities, requires cash payments over an extended period of time, and is subject to acceleration in specified circumstances.*
- *We may need to raise additional funds to finance our future capital or operating needs, which could have adverse impacts on our business, results of operations, and the interests of our shareholders.*

General Risk Factors

- *Legal proceedings could adversely affect our business operations or financial condition.*
- *We may be subject to future product liability litigation which could be expensive, and our insurance coverage may not be adequate.*
- *Loss of key members of management, could adversely affect our business.*
- *Our business and financial performance could be adversely affected by natural or man-made disasters or other similar events.*
- *Changes in U.S trade policy, threats of international tariffs, and changes to the U.S. political landscape may adversely affect our business.*
- *Our results of operations could be negatively affected by potential fluctuations in foreign currency exchange rates.*
- *Our failure to protect our technology systems and comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our business, results of operations, financial condition and prospects.*
- *We are dependent on internal information and telecommunications systems, and any failure of these systems, including system security breaches, data protection breaches or other cybersecurity attacks, may negatively impact our business and results of operations.*
- *Our management has broad discretion in the use of our cash and cash equivalents and, despite management's efforts, cash and cash equivalents may be used in a manner that does not increase the value of shareholders' investments.*
- *Our business and stock price may be adversely affected if our internal controls are not effective.*
- *Our operating results could be adversely impacted if we are unable to effectively manage and sustain our future growth or scale our operations.*

PART I

ITEM 1. BUSINESS

General

Axogen is the leading company focused specifically on the science, development, and commercialization of technologies for peripheral nerve regeneration and repair. We are passionate about providing the opportunity to restore nerve function and quality of life for patients with peripheral nerve injuries. We provide 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 conduit. Along with these core surgical products, Axogen also offers Axotouch® Two-Point Discriminator, used to measure the innervation density of any surface area of the skin. The Axogen portfolio of products is available in the United States, Canada, Germany, United Kingdom, Spain, South Korea, and several other countries.

Nerves can be damaged in several ways. When a nerve is cut due to a traumatic injury or inadvertently during a surgical procedure, functionality of the nerve may be compromised, causing the nerve to no longer carry the signals to and from the brain to the muscles and skin thereby reducing or eliminating functionality. The loss of function can impact a person's ability to work and perform daily tasks, their ability to properly be aware and respond to their environment (e.g., heat, cold or other dangers), and negatively impact their ability to experience and enjoy life.

Nerve damage or transection of this type generally requires a surgical repair. Traditionally, the standard has been to either suture the nerve ends together directly without tension or to bridge the gap between the nerve ends with a less important nerve surgically removed from elsewhere in the patient's own body, referred to as nerve autograft. Nerves that are not repaired or heal abnormally may result in a permanent loss of function and/or sensation. Additionally, abnormal healing can form a neuroma which may send altered signals to the brain that may result in the sensation of pain. This abnormal section of the nerve can, under certain circumstances, be surgically cut out and the resulting gap repaired.

In addition, compression on a nerve, blunt force trauma or other physical irritations to a nerve can cause nerve damage that may alter the signal conduction of the nerve, result in pain, and may, in some instances, require surgical intervention to address the resulting nerve compression. Finally, when a patient undergoes a mastectomy due to breast cancer or prophylactically due to a genetic predisposition for breast cancer, the nerves are cut to allow the removal of the breast tissue. This can result in a loss of sensation, the potential risk of a symptomatic neuroma, as well as negatively impact the patient's quality of life. When a patient chooses an autologous breast reconstruction after a mastectomy, sensation and quality of life can, in certain cases, be returned through surgical nerve repair.

In order to improve the options available for the surgical repair and regeneration of peripheral nerves, Axogen has developed and licensed regenerative medicine technologies. Axogen's innovative approach to regenerative medicine has resulted in first-in-class products that it believes are redefining the peripheral nerve repair market. Axogen's products are used by surgeons during surgical interventions to repair a wide variety of physical nerve damage or transection throughout the body, which can range from a simple laceration of a finger to a complex brachial plexus injury (an injury to the network of nerves that control the movement and sensation of the shoulder, arm, and hand) as well as nerve injuries caused by dental, orthopedic, and other surgical procedures.

Avance Nerve Graft is processed from donated human nerve tissue and provides surgeons an implant that retains the natural micro-architecture, and biologic cues of the human nerve. The Avance Processing technique preserves this natural structure and removes inhibitors, which allow for bridging nerve gaps or transections up to 70mm in length. Additionally, Avance Nerve Graft has product and distribution synergies with Axoguard Nerve Protector, Axoguard Nerve Connector, Axoguard Nerve Cap, and Avive Soft Tissue Membrane. Axoguard products provide the unique features of pliability, suturability, and semi-translucence for visualization of the underlying nerve, while also allowing the extracellular matrix to

remodel utilizing the patient's own cells. Avive Soft Tissue Membrane is a processed human umbilical cord intended for surgical use as a resorbable soft tissue conduit.

Regenerative Medical Products Industry

Regenerative medical products enable the repair, restoration, replacement or regeneration of tissue or organ systems of the body. Regenerative medical products are becoming common in various medical arenas because they have been shown to be effective repairing injured or defective tissues, such as bone, tendons, dermis, and other tissues of the body. Surgeons utilize regenerative medical products because they can provide the complex structure required for implant integration and regeneration in the body.

Axogen believes the primary driver of sustained growth in the regenerative medical product market is continued favorable efficacy as compared to autograft tissue and synthetic medical products, and a wider understanding of this advantage by practitioners. Repair with nerve autograft requires a secondary recovery procedure to remove tissue from another location of the patient's body to repair the injured area and results in loss of function at the site of donation. Further, nerve autograft may also be costly and time consuming and may result in complications at the second surgical site such as infection. In addition to processed nerve allograft (Avance Nerve Graft), alternatives to nerve autograft include hollow-tube synthetic or collagen-based medical products that are designed to provide a protective channel to allow for nerve fiber regeneration, but may be limited by mechanisms of action and/or biocompatibility with the body. Regenerative medical products often provide more desirable conditions for reconstruction and regeneration of tissue, creating a superior solution for patients and physicians. Axogen follows this trend, providing regenerative medical products for peripheral nerve repair.

Regenerative medicine products typically consist of and rely on:

i. A scaffold or ECM to support the cells and/or provide the architecture of the tissue;
ii. Cells to regenerate or remodel the scaffold; and/or
iii. Biologic mechanisms to support regeneration.

Axogen's Avance Nerve Graft, Axoguard Nerve Protector, Axoguard Nerve Connector, and Axoguard Nerve Cap are ECM scaffolds, and utilize the patient's own cells to remodel or regenerate these scaffolds.

Peripheral Nerves and Their Regeneration

The peripheral nervous system, or PNS, consists of nerves that either extend outside of, or reside outside of, the central nervous system (primarily the brain and spinal cord). Peripheral nerves provide the pathway for signals between the central nervous system and target organs, regulating movement (motor nerves) and touch (sensory nerves). Therefore, if a peripheral nerve is crushed, severed, or otherwise physically damaged, its ability to deliver signals to or from the target organs is eliminated, or significantly reduced, and could result in a loss of sensation and/or motor functionality. The axon portion of the nerve cell, consisting of cell cytoplasm and resembling a hair-like fiber, carries signals between the cell body and the target organ. Axons can be quite long, even exceeding one meter, but are only a few micrometers in diameter. A typical nerve consists of hundreds of axons that lie within long, thin tubes (endoneurial tubes). Analogous to a wiring cable, these endoneurial tubes are bundled together in groups called fascicles, and each nerve may contain numerous fascicles. This sheath structure provides protection for the axons and support for regeneration in the event of damage or transection. Nerve damage or transection occurs when a sufficient number of axons have been crushed or transected (severed), thereby disrupting signals to or from the target motor or sensory organ.

Given the right conditions, peripheral nerves have the ability to regenerate. Regenerating axons require the proper environmental conditions, including structure and guidance of axons in a tension and compression free environment. In an untreated severe crush injury or transected nerve, errant axons that are not guided by the nerve sheath structure or other mechanism can form painful and ineffective nerve proliferation (neuromas). This condition can require revision surgery to relieve pain or bring back sensory and/or motor functionality. Therefore, the surgical treatment of peripheral nerves due to damage or transection is typically focused on restoring nerve functionality by providing guidance to regenerating axons, minimizing the formation of neuromas and protecting the nerve to alleviate compression.

Peripheral Nerve Regeneration Market Overview

Peripheral nerve injury ("PNI") through damage or transection is a major source of physical disability impairing the ability to move muscles or to feel normal sensations. Failure to treat peripheral nerve damage or transection can, in severe cases, lead to full loss of sensation and/or function, pain and, sometimes, amputation. Many peripheral nerve patients who receive

treatment do not optimally recover. They may suffer from both reduced, or no, muscle strength, and reduced, or no, sensitivity and pain.

Patients suffer traumatic bodily injuries every day that may result in damage or transection to peripheral nerves severe enough to require surgical treatment, including injuries from motor vehicle accidents, power tool injuries, gunshot wounds, dislocations, fractures, lacerations, or other forms of penetrating trauma. The peripheral nerves commonly damaged or transected from these traumas include the digital, median, ulnar, radial, facial, spinal accessory, and brachial plexus nerves. The "Trauma" portion of the Total Addressable Market (as defined below) encompasses the traumatic PNI described above, but excludes the Oral Maxillofacial, ("OMF"), Upper Extremity Compressions, and Breast (as such terms are defined below) portions of the Total Addressable Market.

Beyond the physical damage or transection to peripheral nerves resulting from traumatic bodily injuries described above, peripheral nerve damage or transection also occurs due to surgical intervention. For example, nerve damage or transection can occur during dental and oral Maxillofacial surgery procedures, such as third molar extractions, placement of dental implants, removal of tumors, orthognathic surgery, and mandibular resection during which one or more sections of the trigeminal nerve can be damaged or transected. This can result in numbness in certain areas of the face and mouth.

Breast reconstruction neurotization ("Breast") is another portion of the Total Addressable Market. Currently, when a patient undergoes autologous breast reconstruction after a mastectomy, the patient receives the shape of a natural breast, but oftentimes experiencing little to no return of sensory feeling. This forfeiture of sensation can have a profound effect on the patient's quality of life. In certain cases, sensation can be returned to the breast area with the use of the Company's products through an innovative surgical technique we call Resensation®. The Company believes that the ideal breast reconstruction should restore breast size, shape, symmetry, and softness as well as sensation, without the potential risks and co-morbidity associated with autograft. The Company believes the Resensation technique incorporates a patient's desire for the opportunity to return sensation in their breasts with a reproducible and efficient surgical approach for reconstructive plastic surgeons.

Peripheral nerves are also damaged due to compression injuries. For instance, severe and recurrent carpal and cubital tunnel cases may result in complications and damage to the peripheral nerve that requires surgical intervention and protection of the peripheral nerve. PNI caused by recurrent carpal tunnel syndrome and cubital tunnel syndrome constitutes the "Upper Extremity Compression" portion of the Total Addressable Market.

Peripheral nerves are also a source of chronic pain. One of the causes of neuropathic pain is called a neuroma, a tangled mass of disorganized nerve and fibrous tissue resulting in aberrant nerve signals which the brain interprets as pain. Traditionally these neuromas have been treated using pain management methods, including pharmacological agents which do not address the anatomical cause of the pain. The surgical treatment of such pain involves a procedure to remove the painful neuroma and repair of the resulting nerve gap or termination of the nerve end.

In the cases where a peripheral nerve is severed and the gap between its two ends is extremely small, the surgeon may be able to reconnect the peripheral nerve without tension through direct suturing as a coaptation aid ("Primary Repair"). When the gap in the nerve tissue is more than a few millimeters in length, the surgeon typically needs to use material to bridge the gap between the peripheral nerve ends to ensure a tension-free repair ("Gap Repair"). Historically for a Gap Repair surgeons have relied on a nerve autotransplantation (autologous nerve grafting or nerve autograft). In nerve autograft procedures, surgeons remove peripheral nerve from another part of the patient's body, frequently the sural nerve from the back of the lower leg, to repair the damaged nerve. Nerve autografting is often effective in repairing a damaged peripheral nerve, but it presents a tradeoff as the surgeon can attempt to fix the damaged nerve, but must create an additional nerve deficit at another location in the body. For example, a patient may opt to get movement and feeling back in their finger while losing some sensation in their foot. Additionally, Axogen believes the secondary surgery to obtain the needed nerve autograft may increase operating time by ~90 minutes based upon literature and the CMS 2020 Physician Fee Schedule reports autograft intra service work time to be 61-147 minutes longer than allograft (Capek L, Clarke H M, Zuker R M. Endoscopic sural nerve harvest in the pediatric patient. Plast Reconstr Surg. 1996 Oct; 98(5): 884–888; 2020 Physician Fee Schedule, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1715-F; and 2017 RUC recommendations, https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/rbrvs/feb-2017-RUC-recommendations-FINAL.pdf). Operating room expenses associated with longer procedure times are estimated to increase $2 thousand to $4 thousand, depending on case complexity, for each additional 30 minutes of operating time based on Cleveland Clinic 2019 Patient Price Information List (https://my.clevelandclinic.org/-/scassets/files/org/locations/price-lists/main-campus-hospital-patient-price-list.ashx). The nerve harvest necessary in autograft nerve repair may also result in a 27% complication rate due to surgical site infection, delayed wound healing, and chronic pain (Rappaport WD, Valente J, Hunter GC, Rance NE,et al. Clinical utilization and complications of sural nerve biopsy. Am J Surg. 1993 Sep; 166(3): 252-256). Further, in the case of extreme trauma where multiple peripheral nerves need to be repaired, it may not be possible to recover enough nerve

from the patient to complete the Gap Repair; and nerve autograft tissue may not provide an appropriate diameter match with the diameter of the injured nerve stump, an important factor in a successful repair outcome.

Drawbacks of repair with autograft nerve eventually led to the development of hollow tube conduits, or hollow tube nerve cuffs for Primary Repair and Gap Repair made of, for instance, bovine collagen or polyglycolic acid. The hollow tube nerve cuff is typically an absorbable hollow tube that, unlike natural peripheral nerve, does not have internal microarchitecture and endoneurial tubes to support and guide regenerating axons; as a result, it is deficient in the qualities that natural peripheral nerve possesses to support nerve regeneration across a gap. Hollow-tubes may also lack pliability and structural integrity needed when used around joints and may be difficult to use in a confined space. Clinical data has demonstrated that hollow tubes are most effective when used in very short gaps, what Axogen defines as Primary Repair, and the reliability of successful nerve recovery diminishes as gap length increases with a 34% to 57% failure rate for hollow tube conduits in repairs with a greater than 5mm gap (Weber RA, Breidenbach WC, Brown RE, Jabaley ME, Mass DP. A randomized prospective study of polyglycolic acid conduits for digital nerve reconstruction in humans. Plast Reconstr Surg. 2000 Oct;106(5):1036-45; discussion 1046-8 and Wangensteen KJ, Kalliainen LK. Collagen tube conduits in peripheral nerve repair: a retrospective analysis. Hand (N Y). 2010 Sep;5(3):273-7. doi: 10.1007/s11552-009-9245-0. Epub 2009 Nov 24).

Conduits filled with an inner matrix have been announced by competitors. The availability of such filled tube conduits for purchase in the United States is not clear at this time. These filled conduits are purported to have greater ability to regenerate after peripheral nerve injury than a hollow tube conduit, but we believe there is very limited data supporting this position. See - “Competition”.

The shortcomings of hollow-tubes for peripheral nerve repair limit where they may be used effectively. Thus, Axogen believes the peripheral nerve repair market needs an alternative off-the-shelf product that offers other features such as a natural ECM scaffold and three-dimensional structure of a typical nerve for bridging nerve transections without the comorbidities of an additional surgical site required for harvest of autograft nerve tissue. Axogen believes its Avance Nerve Graft and Axoguard Nerve Connector products address the market needs for both Gap Repair and Primary Repair.

Compression on a peripheral nerve or blunt force trauma can also cause nerve damage that may require surgical intervention. In these cases, the peripheral nerve is not severed and thus does not create the need for a Primary Repair or Gap Repair. However, the surgeon may want to protect and isolate the peripheral nerve during the healing process. In these situations, peripheral nerve protection is provided by wrapping the nerve (“Nerve Protection”).

Axoguard Nerve Protector is a porcine submucosa extracellular matrix used for Nerve Protection and Avive Soft Tissue Membrane is a processed human umbilical cord used as a resorbable soft tissue conduit. Other Nerve Protection products are usually made from bovine collagen or polyglycolic acid and are typically absorbable. Axoguard Nerve Protector provides the unique features of pliability, suturability, and translucence for visualization of the underlying peripheral nerve, while also allowing the patient’s own cells to incorporate into the extracellular matrix to remodel and separate the peripheral nerve from the surrounding tissue.

We estimate the United States PNI has a potential total addressable market for our current product portfolio in Trauma, OMF, Breast and Upper Extremity Compression of $2.7 billion (the “Total Addressable Market”). Estimating the Total Addressable Market for nerve repair is challenging as there is not a simple data source for the incidence of peripheral nerve issues. This is further complicated by the fact that nerves can be injured in many traumatic and surgical injuries and can be impacted from the head to the toe of a patient. In addition, we believe nerves are often one of many structures injured in a trauma (i.e. amputation) or in surgery and the incidence of these nerve injuries are often not coded or tracked. Quantifying the procedures involving nerve repair may also be challenging. While selected trauma and surgical procedures are dedicated to the repair of nerves (i.e. a pediatric brachial plexus procedure), most of the incidence of nerve repair is a step in a larger trauma (i.e. digital replant) or surgical procedure (i.e. mandible reconstruction). CPT codes exist for surgeons to code for nerve repair; however, we believe the data substantially underestimates the total number of nerves repaired. Physicians are encouraged to document all steps of procedures. Open trauma often involves many surgical steps, including wound debridement, skin closure and one or more repairs of tendons, bone or joints, nerves, veins, and arteries. CPT codes may be inclusive of each other and may not be documented or reported in billing records. As a result, we believe CPT coding underrepresents the total number of nerve repairs performed in trauma. Because we believe CPT claims are not fully representative of the true volumes of nerve repair surgery, we follow an “empirical” methodology to estimate the Total Addressable Market – using published clinical literature and procedure databases to make what we believe are the most objective assumptions.

We estimate that the Trauma portion of the Total Addressable Market is approximately $1.9 billion based upon epidemiological studies regarding the general number of trauma patients, clinical literature review reporting PNI incidence, and physician interviews. There are almost 137 million emergency department visits in the U.S. each year of which approximately 30 million are related to traumatic injuries (2015 National Hospital Ambulatory Medical Care Survey, Publication of U.S.

Department of Health & Human Services). We believe that this injury population includes more than 1.4 million patients suffering damage or transection to peripheral nerves resulting in over 700,000 nerve repair procedures (Noble, et al. J of Trauma Injury Infection and Critical Care 1998; Portincasa et al: Microsurgery 27:455-462, 2007). We have estimated the portion of these nerve repair procedures due to trauma that would require Gap Repair, Primary Repair and/or Nerve Protection and applied, as we believed was appropriate in each procedure segment, the number of units and average sales price of Avance Nerve Graft and the average market price for nerve connectors, nerve protectors, and soft tissue membrane products to determine the probable Total Addressable Market.

We estimate that the OMF portion of the Total Addressable Market is approximately $300 million annually, based upon research indicating that approximately 56,000 PNI occur in the U.S. each year related to third molar surgeries, anesthetic injections, dental implants, orthognathic surgery, and mandibular resection procedures. (Shih-Yun Wu, et al.: Systematic Review and Meta-Analysis on Incidence of Altered Sensation of Mandibular Implant Surgery - PLoS ONE 11(4): e0154082; Nguyen., et al.: Risk Factors for Permanent Injury of Inferior Alveolar and Lingual Nerves During Third Molar Surgery; J. Oral Maxillofac Surg. 2014 Dec;72(12); Cheung LK, Leung YY, Chow LK, 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;39:320–6.; Transparency Market Research: Dental Implant Market - Global Industry Analysis and Forecast 2016 – 2024; Cha. et al., Maxillofacial Plastic and Reconstructive surgery (2016) 38:19 - Frequency of bone graft in implant surgery; Miloro ed. 2012: Text Book on trigeminal nerve injuries; Pogrel, et al.: J Am Dent Assoc. 2000 Jul;131(7):901-7: Permanent nerve involvement resulting from inferior alveolar nerve blocks; Agbaje, et al.: Int. J. Oral Maxillofac. Surg. 2015; 44: 447-451, J.O Systematic review of the incidence of inferior alveolar nerve injury in bilateral sagittal split osteotomy (BSSO) and the assessment of neurosensory disturbance). We have applied the average sales price of the Avance Nerve Graft, Axoguard Nerve Connector, and Axoguard Nerve Protector that address such PNI in order to derive the OMF portion of the Total Addressable Market.

In 2017, there were 106,295 breast reconstruction procedures in the U.S. as reported in the 2017 plastic surgery statistic report published by the American Society of Plastic Surgery. The report details 19,316 of these reconstructions procedures were autologous flap reconstruction, and that 66.2% of the reconstructions were bilateral. Removing those procedures that are not appropriate for neurotization, and based upon the Company's assumption that approximately 50% of women may elect to have a dual neurotization for each flap, we estimate that the Breast portion of the Total Addressable Market is approximately $250 million. (2017 ASPS Plastic Surgery Statistics Reports, Includes TRAM, DIEP, and "Other Flaps", Distribution based on 2017 ASPS Data).

We estimate that the carpal and cubital tunnel revision portion of the Total Addressable Market is approximately $270 million, or 130,000 procedures Extrapolating the 2016 Medicare National HCPCS Aggregate Summary Table to the total U.S. population, we estimate that there are approximately 488,000 primary carpal tunnel and 95,000 primary cubital tunnel relief surgeries performed annually in the U.S. For carpal tunnel, we believe that our addressable procedure is the estimated 20% of carpal tunnel surgeries that require a revision procedure to address the recurrence of symptoms (Sotereanos, et al., Techniques in hand and Upper extremity surgery 1(1):35-40, 1997). From the 95,000 primary cubital tunnel surgeries, we estimate that our addressable procedure potential comprises a small proportion of primary interventions and all revisions (J. Seradge, et al., Hand Surg. 1998; 23A:483-491; Papatheodorou, et al., J. Hand Surg. Am. 2015;40(5):987e992). As a result, we estimate that approximately 97,500 carpal tunnel revision surgeries and 32,400 total cubital tunnel procedures are addressable each year in the U.S. to mitigate the recurrence of symptoms. These revision and primary surgeries are required due to compression of the peripheral nerve associated with soft tissue attachments from the surrounding tissue or tissue infiltration entrapping the nerve. To prevent additional recurrences, surgeons will opt for a Nerve Protection which includes a product such as the Axoguard Nerve Protector. In order to derive the carpal and cubital tunnel revision portion of the Total Addressable Market, we multiplied the average market sales price of Axoguard Nerve Protectors by the number of estimated procedures.

Although distribution and sales of products in the Trauma, OMF, Breast and Extremity Compression portions of the Total Addressable Market constitute our primary revenue sources today, market expansion opportunities in lower extremity surgery, head and neck surgery, urology and the surgical treatment of pain offer us expanded revenue opportunities. The Company has begun an expansion into the surgical treatment of pain with an initial focus on traumatic injuries, including amputation and orthopedic surgeries such as total hip arthroplasty, total knee arthroplasty, knee arthroscopy, Morton's neuroma, foot and ankle procedures, and wrist arthroscopy. The size of the pain market opportunity is challenging to identify as the cause of the chronic pain is often not diagnosed and there has not historically been a surgical treatment to resolve the cause of the pain. The Company believes the market opportunity is sufficient to apply selected resources to the opportunity and there is a significant patient and societal need to reduce the use of pharmacologic solutions, including opioids. Axogen developed Axoguard® Nerve Cap to protect a peripheral nerve end and separate the nerve end from the surrounding environment to reduce the development of symptomatic or painful neuromas ("Neuroma Management"). An example application for Axoguard Nerve Cap is in a digital amputation whereby the severed nerves may form a painful neuroma if the nerve end is not properly terminated or capped. We conducted user evaluations and a post-market clinical study of neuroma revision using Axoguard Nerve Cap and launched the product in February of 2020.

Axogen's Product Portfolio

Overview of Axogen's Products

The Axogen surgical solution product portfolio provides surgeons off-the-shelf products for a wide variety of peripheral nerve damage or transection. The Company's proprietary products and technologies are designed to overcome fundamental challenges in peripheral nerve repair. Axogen's Avance Nerve Graft is the alternative to autografts and other off-the-shelf peripheral nerve repair products for nerve gaps up to 70mm in length. Axoguard Nerve Connector is a coaptation aid for transected peripheral nerves. Axoguard Nerve Protector is a protective wrap for peripheral nerves damaged by compression, or where the surgeon wants to protect and isolate the peripheral nerve during the healing process after surgery. Avive Soft Tissue Membrane provides a resorbable covering to keep tissue structures apart while providing the beneficial properties of a placental membrane. Axoguard Nerve Cap is a uniquely designed nerve termination device which provides a protective environment for the nerve end to reduce the development of painful neuroma.

Functional measurements play an important role in the evaluation of peripheral nerve function by assisting the healthcare professionals in detecting changes in sensation or muscle strength, assessing return of sensory or motor function, establishing effective treatment interventions, and providing feedback to the patients. Evaluation and measurement of peripheral nerve function is also an important part of identifying nerve damage or transection and determining treatment outcomes. Axogen's functional measurement product is the Axotouch Two-Point Discriminator tool for sensory function.

Avance Nerve Graft

Avance Nerve Graft is a biologically active nerve implant with more than ten years of comprehensive clinical evidence and more than 50,000 implants since launch. Avance Nerve Graft is intended for the surgical repair of peripheral nerve transections to support regeneration across the defect (a gap created when the nerve is severed). It is intended to act as a structural bridge in order to guide and support axonal regeneration across a peripheral nerve gap caused by traumatic injury or surgical intervention. Avance Nerve Graft is decellularized and sterile processed human peripheral nerve tissue. Axogen developed the Avance Nerve Graft by following the guiding principle that the human body created the optimal peripheral nerve structure. Axogen, through its licensing efforts and research, developed the Avanceprocess, a proprietary method for processing recovered human peripheral nerve tissue in a manner that preserves the essential structure of the ECM while cleansing away cellular and noncellular debris. Avance Nerve Graft provides the natural peripheral nerve structure of a nerve, including the native laminin to guide the regenerating nerve fibers. The nerve ECM is additionally processed to remove a natural inhibitor to regeneration called chondroitin sulphate proteoglycan ("CSPG").

Axogen believes that Avance Nerve Graft is the first off-the-shelf human nerve allograft for bridging nerve transections. Avance Nerve Graft is comprised of bundles of small diameter endoneurial tubes that are held together by an outer sheath called the epineurium. Avance Nerve Graft has been processed to remove cellular and noncellular factors such as cells, fat, blood, and axonal debris, while preserving the three-dimensional laminin lined tubular bioscaffold (i.e. microarchitecture), epineurium and microvasculature of the peripheral nerve. After processing, Avance Nerve Graft is flexible and pliable, and its epineurium can be sutured in place allowing for tension-free approximation of the proximal and distal peripheral nerve stumps. During the healing process, the body revascularizes and gradually remodels the graft into the patient's own tissue while allowing the processed peripheral nerve allograft to physically support axonal regeneration across the peripheral nerve transection. Avance Nerve Graft does not require immunosuppression for use.

With lengths up to 70 mm and diameters up to 5 mm, Avance Nerve Graft allows surgeons to choose and trim the implant to the correct length for repairing the relevant peripheral nerve gap, as well as to match the diameter to the proximal and distal end of the severed peripheral nerve. Avance Nerve Graft is stored frozen and utilizes packaging that maintains the graft in a sterile condition. The packaging is typical for medical products so the surgical staff is familiar with opening the package for transfer of Avance Nerve Graft into the sterile surgical field. Such packaging also provides protection during shipment and storage and a reservoir for the addition of sterile fluid to aid in thawing the product. Avance Nerve Graft thaws in less than 10 minutes, and once thawed, it is ready for implantation.

Avance Nerve Graft provides the following key advantages:

- A three-dimensional bioscaffold for bridging a peripheral nerve gap;
- A biologically active nerve therapy with more than 10 years of comprehensive clinical evidence;
- No patient donor-nerve surgery, therefore no comorbidities associated with a secondary surgical site;
- Available in a variety of diameters up to 5mm to meet a range of anatomical needs;
- Available in a variety of lengths up to 70mm, to meet a range of gap lengths;
- Decellularized and cleansed extracellular matrix;

- Implanted without the need for immunosuppression, remodels into patient's own tissue;
- Structurally supports the body's own regeneration process;
- Handles similar to an autograft, and is flexible and pliable;
- Alleviates tension at the repair site;
- Three-year shelf life; and
- Supplied sterile.

Axoguard Nerve Connector

Axoguard Nerve Connector is a coaptation aid used to align and connect severed peripheral nerve ends in a tensionless repair. The product is in a tubular shape with an open lumen on each end where the severed peripheral nerve ends are placed. It is typically used when the gap between the peripheral nerve ends is 5mm or less in length. Axoguard Nerve Connector is made from a processed porcine ECM which allows the body's natural healing process to repair the peripheral nerve while its tube shape isolates and protects the transected nerves during the healing process. During healing, the patient's own cells incorporate into the extracellular matrix product to remodel and form a tissue similar to the outermost layer of the peripheral nerve (nerve epineurium). Axoguard Nerve Connector is provided sterile, for single use only, and in a variety of sizes to meet the surgeon's needs.

Axoguard Nerve Connector can be used:

- As an alternative to direct suture repair;
- As a peripheral nerve coaptation; Connector-Assisted Repair®;
- To aid coaptation in direct repair, grafting, or cable grafting repairs; and
- To reinforce the coaptation site.

Axoguard Nerve Connector has the following advantages:

- Processed intact porcine extracellular matrix with an open, porous structure that allows for cell infiltration and remodeling;
- Designed as a coaptation aid for tensionless repair of transected or severed peripheral nerves;
- Alleviates tension at the repair site;
- Remodels into the patient's own tissue;
- Reduces the number of required sutures (versus direct repair with suture) (Boeckstyns, Jhand Surg. 2013;38:2405-2411);
- Allows surgeon to move sutures away from the repair site which may minimize inflammation and aid nerve regeneration;
- Reduces potential for fascicular mismatch;
- Allows visualization of underlying peripheral nerve ends;
- Available in seven different diameters and two different lengths to address a variety of nerve repair situations;
- Strong and flexible, easy to suture; and
- Stored at room temperature with a minimum of 18-month shelf life.

Axoguard Nerve Protector

Axoguard Nerve Protector is a product used to protect and wrap damaged peripheral nerves and reinforce reconstructed nerve gaps while preventing soft tissue attachments. It is designed to protect and isolate the peripheral nerve during the healing process after surgery by creating a barrier between the nerve tissue and the surrounding tissue bed. The product is delivered in a slit tube format allowing it to be wrapped around peripheral nerve structures. Axoguard Nerve Protector is made from a processed porcine ECM. During healing, the ECM remodels allowing the protector to separate the peripheral nerve from the surrounding tissue. Axoguard Nerve Protector competes against off-the-shelf biomaterials such as reconstituted collagen as well as the use of the patient's own tissue such as vein and hypothenar fat pad wrapping. Axoguard Nerve Protector is provided sterile, for single use only, and in a variety of sizes to meet the surgeon's needs.

Axoguard Nerve Protector can be used to:

- Separates and protects the nerve from the surrounding tissue during the healing process;
- Minimize risk of soft tissue attachments and entrapment in compressed peripheral nerves;
- Protect peripheral nerves in a traumatized wound bed; and
- Reinforce a coaptation site.

Axoguard Nerve Protector has the following advantages:

- Processed porcine submucosa extracellular matrix used to reinforce a coaptation site, wrap a partially severed peripheral nerve or protect peripheral nerve tissue;
- Creates a protective layer that isolates and protects the peripheral nerve in a traumatized wound bed;
- Remodels into the patient's own tissue;
- Easily conforms and provides 360 degree wrapping of damaged peripheral nerve tissue;
- Allows the body's natural healing process to repair the nerve;
- Minimizes the potential for soft tissue attachments and peripheral nerve entrapment by physically isolating the nerve during the healing process;
- Allows peripheral nerve gliding;
- Strong and flexible, plus easy to suture;
- Is available in five different widths and two different lengths to address a variety of peripheral nerve repair situations; and
- Stored at room temperature with a minimum of 24-month shelf life.

Avive Soft Tissue Membrane

Avive Soft Tissue Membrane is processed human umbilical cord membrane that may be used as a resorbable soft tissue covering to separate tissues in the surgical bed.

We believe, the medical community has for decades realized the beneficial qualities of human amniotic membrane and continues to utilize this natural tissue in applications across the body. Avive Soft Tissue Membrane offers a resorbable anatomical covering separate tissues. Avive Soft Tissue Membrane is provided sterile and in a variety of sizes to meet the surgeon's surgical needs.

Avive Soft Tissue Membrane can be used to separate tissues in the surgical bed as a permeable membrane.

Avive Soft Tissue Membrane has the following advantages:

- Umbilical cord amniotic membrane that is naturally resorbable;
- Is non-immunogenic;
- Processed to preserve the natural properties of umbilical cord amniotic membrane;
- Comprised of umbilical cord amniotic membrane which is up to eight times thicker than placental amniotic membrane alone;
- Long lasting (in animal studies, stays in place for at least 16 weeks);
- Easy to handle, suture or secure during a surgical procedure;
- Conforms and stays in place at the application site;
- Chorion free (reducing the likelihood of immune response); and
- Room temperature storage with a two-year shelf life.

Axoguard Nerve Cap

Axoguard Nerve Cap is a proprietary 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.

Nerves are often cut in a variety of surgeries, including orthopedic procedures to repair or replace joints, hernia and other thoracic cavity procedures, and bone fracture revisions. Every nerve that is cut and not reconstructed forms an entangled mass of disorganized nerve and fibrous tissue that could cause debilitating pain called a symptomatic neuroma. Neuromas are the main cause of pain for those patients who complain of post-surgical pain, including in amputees which may lead to an inability to use their prosthesis. Despite more than 30 different treatment methods, it is our belief that neuromas continue to be an unresolved problem in microsurgery. We believe the Axoguard Nerve Cap can address these painful neuroma and better address nerve pain than other methods, including pharmacotherapy and chemical injections, among others.

Axoguard Nerve Cap can be used to reduces the development of symptomatic or painful neuroma formation.

Axoguard Nerve Cap has the following advantages:

- Separates the nerve end from surrounding tissue, neurotrophic factors and mechanical stimulation;
- Reduces painful neuroma formation;
- Allows for anchoring of a nerve end or stump to nearby tissue structure;
- Material gradually remodels into the patient's own tissue to protect the nerve end; and
- Semi-translucence allows for visualization of nerve ends or stumps and easy visualization for suture placement.

Acroval Neurosensory and Motor Testing System

To pursue our mission most effectively, we have made a strategic decision to place our full focus on innovations within our surgical solutions portfolio. Effective November 2019, Axogen discontinued all sales of the Acroval Neurosensory and Motor Testing System. We continue to provide service and support for the existing systems in the marketplace.

Axotouch Two Point Discriminator

The Axotouch Two-Point Discriminator tool can be used to measure the innervation density of any surface area of the skin. The discs are useful for determining sensation after damage to a peripheral nerve, following the progression of a repaired peripheral nerve, and during the evaluation of a person with possible peripheral nerve damage, such as compression. The Axotouch Two-Point Discriminator is a Class 1 510(k) exempt medical device.

The Axotouch Two-Point Discriminator tool is a set of two aluminum discs each containing a series of prongs spaced between two to 15 millimeters apart. Additionally, 20 and 25 millimeter spacing is provided. A circular depression on either side of the disc allows ease of rotation. The discs can be rotated between a single prong for testing one-point and any of the other spaced prongs for testing two-point intervals.

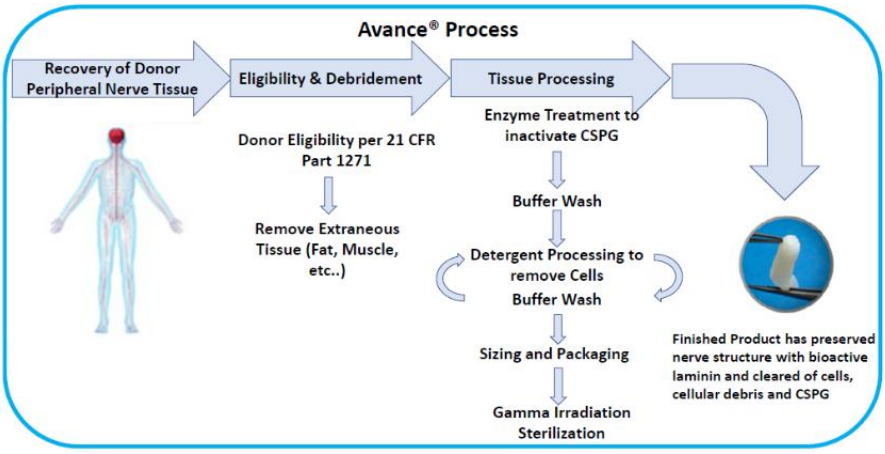
Axotouch Two-Point Discriminator has the following advantages:

- Capable of measuring the innervation density of any skin surface;
- Portable and easy to use;
- Strong aluminum design is resistant to bending;
- Bright colors allow for clear discrimination between discs;
- Clear numbering allows users to interpret results; and
- Reusable carry case protects discs.

Tissue Recovery and Processing for Avance Nerve Graft and Avive Soft Tissue Membrane

Avance Nerve Graft Processing Overview

Axogen has developed the Avance Process, an advanced and proprietary technique to process Avance Nerve Graft from donated human peripheral nerve tissue.The Avance Process requires special training over several months for each manufacturing associate who processes Avance Nerve Grafts. The processing and manufacturing system for Avance Nerve Graft has required significant capital investment, and we seek to continually improve our manufacturing and quality assurance processes and systems. Axogen's Avance Process is depicted as follows:



Avance Nerve Graft and Avive Soft Tissue Membrane Processing

Axogen's Avance process and processing of Avive Soft Tissue Membrane consists of several steps, including peripheral nerve tissue, in the case of Avance, and umbilical cord, in case of Avive, recovery/acquisition and testing, donor medical review and release, processing, packaging, and sterilization to meet or exceed all applicable U.S. Food and Drug Administration (the "FDA"), state, and international regulations and American Association of Tissue Banks ("AATB") standards. We have a number of contracts with recovery and acquisition agencies to supply peripheral nerve tissue and umbilical cord and believe these contracts, and the ability to enter into additional contracts, will provide us with the tissues we require for our Avance and Avive implants. As an FDA registered tissue establishment, Axogen utilizes both its own personnel and a variety of subcontractors for recovery/acquisition, storage, testing, processing and sterilization of the donated peripheral nerve and umbilical cord tissue. Additionally, independent GMP and GLP complaint laboratories have been contracted by Axogen and its subcontractors to perform testing from donor eligibility through release. The safety of Avance Nerve Graft and Avive Soft Tissue Membrane is supported by donor screening, process validation, process controls, and validated terminal sterilization methods. The Axogen Quality System has built in redundancies that are meant to control the release of each product for implantation only after such product meets our stringent quality control and product requirements.

Avance Nerve Graft and Avive Soft Tissue Membrane Tissue Recovery/Acquisition and Processing Facility

Axogen partners with other FDA registered tissue establishments and AATB accredited recovery/acquisition agencies or recovery/acquisition agencies in compliance with AATB standards for human tissue recovery. After consent for donation is obtained, donations are screened and tested in detail for safety in compliance with the federal regulations and AATB standards on communicable disease transmission. Axogen processes and packages Avance Nerve Graft and Avive Soft Tissue Membrane using its employees and equipment pursuant to a License and Services Agreement, as amended (the "CTS Agreement") with Community Blood Center (d/b/a Community Tissue Services) ("CTS"), Dayton, Ohio. CTS is an FDA registered tissue establishment and an AATB accredited organization.

The current CTS Agreement terminates December 31, 2022, subject to earlier termination by either party at any time for cause (subject to the non-terminating party's right to cure, in certain circumstances), or without cause upon 6 months prior notice whereby notice cannot be provided prior to March 1, 2021. Under the CTS Agreement, Axogen pays CTS a facility fee for clean room/manufacturing, storage and office space. CTS also provides services in support of Axogen's manufacturing such

as routine sterilization of daily supplies, providing disposable supplies, microbial services and office support. The service fee is based on a per donor batch rate. The CTS facility provides a cost effective, quality controlled and licensed facility. Axogen's processing methods and process controls have been developed and validated to ensure product uniformity and quality. Pursuant to the CTS Agreement, Axogen pays license fees on a monthly basis to CTS. See – Item 8. Financial Statements and Supplementary Data – Notes to Consolidated Financial Statements - Footnote 15 - Commitments and Contingencies - Service Agreements.

Axogen is renovating a property located near the CTS facility and comprised of an 107,000 square foot building on approximately 8.6 acres of land. It is expected that renovations will be completed by the termination date of the CTS Agreement to provide a new processing facility that can be included in our Biologics License Application ("BLA") for Avance Nerve Graft. The capacity of the property once operational, along with the ability for expansion, is expected to provide processing capabilities that will meet our intended sales growth. Axogen believes it can obtain certain economic incentives from state and local authorities associated with the renovations and additional employment at the facility; however, such incentives are not expected to be a material offset to the cost of the project as a whole. See – Item 8. Financial Statements and Supplementary Data – Notes to Consolidated Financial Statements - Footnote 15 - Commitments and Contingencies - Service Agreements.

Avance Nerve Graft and Avive Soft Tissue Membrane Packaging

After processing, the packaging operation is performed in a controlled environment at CTS. Each Avance Nerve Graft and Avive Soft Tissue Membrane is visually inspected and organized by size into finished product codes. The tissue implant is then packaged in primary packaging. The outer pouch acts as the primary sterility and moisture barrier.

Avance Nerve Graft and Avive Soft Tissue Membrane Sterilization and Labeling

After being processed and packaged, Avance Nerve Graft and Avive Soft Tissue Membrane are then terminally sterilized and shipped to Axogen's Burleson, Texas distribution facility (the "Distribution Facility"). There the products receive their final labels and are released following a final stringent technical and quality review. Orders for Avance Nerve Graft and Avive Soft Tissue Membrane are placed with Axogen's customer care team and the products are packaged and shipped from the Distribution Facility.

Avance Nerve Graft and Avive Soft Tissue Membrane Product Release

Axogen has established quality procedures for review of tissue recovery, relevant donor medical record review and release to processing that meet or exceed FDA requirements as defined in 21 CFR Part 1271, state regulations, international regulations and AATB standards. The Axogen Quality System meets the requirements set forth under 21 CFR Part 1271 for Human Cells, Tissues and Cellular and Tissue-Based Products, including Good Tissue Practices ("GTP") and is compliant with the 21 CFR Part 820 Quality System Regulations ("QSR"). Furthermore, Axogen utilizes validated processes for the handling of raw material components, environmental control, processing, packaging, and terminal sterilization. In addition to ongoing monitoring activities for product conformity to specifications and sterility, shipping methods have been validated in accordance with applicable industry standards.

Manufacturing of Axogen Products Other Than Avance Nerve Graft and Avive Soft Tissue Membrane

Manufacturing for the Axoguard Product Line

The Axoguard product line is manufactured by Cook Biotech Incorporated, West Lafayette, Indiana ("Cook Biotech"), which was established in 1995 to develop and manufacture implants utilizing porcine extracellular matrix technology ("ECM"). Axogen decided to expand its portfolio of products and felt that the unique ECM material offered by Cook Biotech provided the combination of properties needed in nerve reconstruction. Cook Biotech's ECM material is pliable, capable of being sutured, translucent and allows the patient's own cells to incorporate into the extracellular matrix to remodel and form a tissue similar to the nerve's epineurium. Cook Biotech has its own source of the raw material for the ECM material and manufactures Axoguard products from such sources.

In August 2008, Cook Biotech entered into an agreement, amended in March 2012 and February 26, 2018 (the "Distribution Agreement"), with Axogen to distribute its ECM technology in the form of the Surgisis® Nerve Cuff, the form of a nerve wrap or patch, or the form of any other mutually agreed to configuration. The Surgisis products were rebranded under Axogen's Axoguard name and consist of the Axoguard Nerve Connector and Axoguard Nerve Protector. Axogen's distribution rights are worldwide in the field of the peripheral and central nervous system, but excluding use of the products in the oral cavity for endodontic and periodontal applications and OMF surgery solely as they relate to dental, soft or hard tissue repair, or

reconstruction. We believe the exclusion does not limit our identified OMF market, but expansion into certain additional OMF market areas could be limited to the Avance Nerve Graft.

Axogen developed, patented, and obtained regulatory approval on the Axoguard Nerve Cap which in its current configuration is made with Cook Biotech's ECM material. Pursuant to the Nerve End Cap Supply Agreement dated June 27, 2017 (the "Supply Agreement"), Cook Biotech is the exclusive contract manufacturer of the Axoguard Nerve Cap and both parties have provided the other party the necessarily licenses to their technologies for operation of the Supply Agreement. With respect to the license from Cook Biotech, Axogen is able to sell the Axoguard Nerve Cap worldwide in the field of the peripheral and central nervous system, but subject to the same exclusions as Axoguard Nerve Connector and Protector.

The Distribution Agreement terminates on June 30, 2027. Although the agreement requires certain minimum purchases, through mutual agreement, the parties have not established such minimums and to date have not enforced such provision, and also establishes a formula for the transfer cost of the Axoguard Nerve Connector and Axoguard Nerve Protector. The Supply Agreement has a term through August 27, 2027, provided, however, that after June 27, 2022, either party may terminate the Supply Agreement upon 90 days written notice. Under both the Distribution and Supply Agreements, Axogen provides purchase orders to Cook Biotech, and Cook Biotech fulfills the purchase orders.

Manufacturing for the Axotouch Two Point Discriminator

The Axotouch Two Point Discriminator is contract manufactured by Viron Technologies, doing business as Cybernetics Research Laboratories ("CRL"), Tucson, Arizona. CRL supplies the Axotouch unpackaged and they are packaged at Axogen's distribution facility in Burleson, Texas. We believe CRL has capacity to support any future volumes of Axotouch.

Sales and Marketing

Overview

Axogen is focused on developing the peripheral nerve repair and regeneration market, is committed to improving awareness of new surgical peripheral nerve repair options and is building additional scientific and clinical data to assist surgeons and patients in making informed choices with respect to the repair of peripheral nerve injuries. Axogen believes that there is an opportunity to improve current approaches to peripheral nerve repair and that its approach will solidify its position as a leader in the field of peripheral nerve repair products. The following provides the key elements of Axogen's sales and marketing strategy.

Increase Awareness of Axogen's Products

Prior to the introduction of Axogen's portfolio of peripheral nerve repair products, surgeons had a limited number of options available to surgically repair damaged or transected peripheral nerves. Axogen entered the market to improve the standard of care for nerve injury patients. Axogen intends to increase market penetration and share by increasing awareness of the impact of nerve damage on quality of life, and improving the adoption of nerve repair techniques and Axogen's products through the continued use of educational conferences and presentations, surgical resident and fellow training, scientific publications, digital communication, and a knowledgeable and professional sales team. Axogen works to increase the use of its products within active accounts as well as expand the overall customer base by adding new active accounts. Axogen defines an "active account" as an account that has typically gone through the committee approval process, has at least one surgeon who has converted a portion of his or her treatment algorithms for peripheral nerve repair to the Axogen portfolio and has ordered Axogen products at least six times in the last 12 months. Axogen is focused on plastic reconstructive surgeons and orthopedic and plastic hand surgeons who perform surgeries on patients suffering traumatic nerve damage or transection, on oral and maxillofacial surgeons who repair damaged oral nerves, and on plastic reconstructive surgeons who perform autologous flap breast neurotization.

Expand Clinical and Scientific Data Regarding the Performance of Axogen Products

Generating clinical data is an important component of Axogen's marketing strategy. As of December 31, 2020, Axogen had over one hundred and forty five peer reviewed clinical papers. Certain of these publications contain data on multiple products. Axogen will continue to accept patients, for which there are more than 2,300 Avance nerve repairs enrolled to date, in its RANGER® clinical study (defined below in "Government Regulations"), a utilization registry of Avance Nerve Graft. An additional arm of the RANGER study has been initiated tracking neurotization outcomes in breast reconstruction (Sensation-NOW®). Eight of the above mentioned publications and more than 70 scientific conference presentations have been generated to date from the registry. A multicenter prospective randomized comparative pilot study of hollow tube conduits and Avance Nerve Graft has completed subject enrollment and outcome follow-up and has been published (Means, et al.). Case series in digital nerve repair have been published from the Mayo Clinic, Georgetown University Medical Center and Philadelphia Hand

Center and a case series in OMF have been published from UT Southwestern and University of Illinois-Chicago. A number of additional investigator initiated case reports, studies, and publications have been completed, including breast neurotization, mandible reconstruction, compressive neuropathies, and the surgical treatment of pain. Case series in brachial plexus, neurotization of breast reconstruction and the surgical treatment of pain are also being developed. Axogen also supports outside research and will continue to work with investigators working on grants with a translational focus.

Commitment to the Education of Best Practices in Peripheral Nerve Repair

Axogen has established educational conferences and presentations and surgical resident and fellow training that we believe has positioned us as a leader in providing peripheral nerve repair best practices. In 2020, we trained more than three-quarters of hand and microsurgery surgeon fellows in the U.S. through such courses and training, including the use of virtual education programs necessitated by the COVID-19 pandemic. The Company has historically provided education on peripheral nerve repair through in person national programs ("National Programs"), including its "Advances and Best Practices in Nerve Repair" as well as local and regional educational events. In calendar years 2017, 2018, and 2019, we conducted 15, 18, and 26 National Programs, respectively. Due to the COVID-19 pandemic, we transitioned in April 2020 largely to a virtual platform for surgeon education offering multiple educational webinars. In 2021, we expect to again offer multiple educational webinars with the possibility of returning to in person surgeon education programs later in the year. Our education efforts also continue to include online tools and discussion forums such as Nerve Matters, an online community of peripheral nerve surgeons where the surgeons can ask questions, present cases and share findings in the area of peripheral nerve repair.

Focused on developing deeper penetration with our existing surgeon customers through development of long-term users of the Avance Nerve Graft in our largest market opportunity of extremity trauma

Axogen provides full sales and distribution services through both a direct sales force and independent sales agencies. As of December 31, 2020, Axogen had 111 direct sales professionals and 23 independent sales agencies in the U.S. In 2020, approximately 87% of global product revenue came from the direct channel. In late 2019, we adjusted our commercial strategy to focus on deeper penetration of our existing surgeon customers through the development of long-term users of Avance in our largest market opportunity of extremity trauma. Throughout the pandemic, we kept the sales team and broader commercial organization intact and took the opportunity to provide extensive sales training. The team developed new skills and shared best practices around remote case support where hospital access has been restricted. We believe this remote support has been appreciated by customers and has expanded the sales team's ability to support surgeons during COVID-19 and beyond. We believe that near-term growth can be supported first through expanded productivity of our existing sales force as they go deeper with existing surgeons and accounts and then by adding additional surgeons and accounts. We expect the number of direct sales professionals to increase over time. Additionally, we have successfully utilized a hybrid commercial approach that includes the use of independent agencies in more remote geographies in order to provide appropriate local support for surgeons, without the travel time required of a direct sales representative. We anticipate that it will continue to add to the number of independent sales agencies as it continues to drive higher productivity and efficiency with its direct sales force.

Our products are available and sold in 16 countries outside the U.S. through a number of independent in-country distributors. We provide support and resources for independent agencies and distributors both within and outside the U.S. We provide our products to hospitals, surgery centers and military hospitals, calling on surgeons, including plastic reconstructive surgeons, orthopedic and plastic hand surgeons, and certain oral and maxillofacial surgeons to review the benefits of our products. While surgeons make the decision to implant our products in appropriate patients, hospitals make the decision to purchase the products from us. In today's budget constrained environment, hospital committees review new technologies for cost effectiveness as well as quality. We believe that we have been successful in meeting the needs of these hospital committees by demonstrating the cost/benefit of its products and providing a fair value to the hospital.

Expand the Product Pipeline and Applications in Peripheral Nerve Repair

Axogen has developed and continues to develop new and next generation products to support surgeons in their needs for repairing damaged or transected peripheral nerves. Axogen believes additional opportunities exist to develop or acquire complementary products in peripheral nerve repair. In addition, there are opportunities to expand the existing portfolio of products in new applications of peripheral nerve repair in lower extremity surgery, head and neck surgery, urology, and the surgical treatment of pain.

Axogen Strengths

Axogen believes that it has the following strengths in the field of peripheral nerve repair and regeneration:

Established Peripheral Nerve Repair Expertise

Axogen has made a significant investment in understanding peripheral nerve anatomy and surgical peripheral nerve repair and regeneration. This has been accomplished through interaction with leading academic centers throughout the U.S. and by striving to build an outstanding internal team of technical and clinical experts.

Tissue collection, processing, and controls

Axogen's Avance process and processing of Avive Soft Tissue Membrane consists of several steps, including peripheral nerve tissue, in the case of Avance, and umbilical cord, in case of Avive, recovery/acquisition and testing, donor medical review and release, processing, packaging, and sterilization to meet or exceed all applicable U.S. Food and Drug Administration (the "FDA"), state, and international regulations and American Association of Tissue Banks ("AATB") standards.

Commitment to the Promotion and Education of Best Practices in Peripheral Nerve Repair

Axogen has established surgeon educational conferences, presentations, webinars, and surgical resident and fellow training that we believe has positioned us as the leader in providing peripheral nerve repair best practices. Axogen has developed the programs and speakers to train surgeons currently in practice as well as surgical fellows.

Clinical Data

Axogen is developing a body of clinical evidence of its implants in real world situations that surgeons face when treating their patients with peripheral nerve injuries. This data provides support for surgeons in their clinical decision making and providing treatment options to their patients.

A pivotal multicenter prospective randomized comparative study (RECON[SM]) of hollow tube conduits and Avance Nerve Graft to support the transition of Avance to a biological product has completed enrollment and is in follow-up See "Government Regulations – Clinical Trials". A multicenter, prospective, randomized and subject blinded study of Axoguard Nerve Cap as compared to neurectomy for the treatment of symptomatic neuroma (REPOSE[SM]) is currently enrolling. A registry study of Avive Soft Tissue Membrane in acute trauma (ASSIST[SM]) has completed follow-up of all enrolled subjects. Sensation-NOW[SM], a RANGER[SM] expansion study arm for breast neurotization continues to enroll as does the additional expansion arm RANGER (MATCH[SM]), a contemporary cohort control which provides reference controls for nerve autograft and manufactured conduits from participating registry centers.

Surgical Implant Commercialization Experience

The Axogen commercialization team consists of sales, marketing, and customer care professionals with backgrounds in the medical device and biotechnology industries. The team has strong experience in the introduction of technologies and has been instrumental in beginning to establish Avance Nerve Graft, Axoguard product lines, and Avive Soft Tissue Membrane as a new standard of care for the surgical treatment of peripheral nerve damage or transections in our core markets. Axogen believes it can leverage these capabilities to expand the commercial success of the current Axogen products, future peripheral nerve products and opportunities in new peripheral nerve surgical applications.

Avance Nerve Graft Performance

Axogen has worked with leading institutions, researchers, and surgeons to support innovation in the field of surgical peripheral nerve repair. We believe Axogen's RANGER study (defined below in the section entitled "Government Regulations") is the largest multi-center clinical study conducted in peripheral nerve gap repair. Axogen is also conducting a Multicenter, Prospective, Randomized, Subject, and Evaluator Blinded Comparative Study of Nerve Cuffs and Avance Nerve Graft Evaluating Recovery Outcomes for the Repair of Nerve Discontinuities ("RECON"). This study is a phase 3 trial to support its BLA for the Avance Nerve Graft. See "Government Regulations". The January 2012 edition of Microsurgery and November 2012 edition of The Journal of Hand Surgery, June 2015 edition of Journal of Reconstructive Microsurgery and January 2017 edition of HAND each contain an article summarizing the RANGER study results. The Brooks, et al. publication reported on 55 Avance Nerve Graft nerve repairs and resulted in meaningful motor and sensory recovery in 87% of nerve transections between 5 and 50 mm. Additionally, no implant related adverse events were reported. (Brooks, D. N., Weber, R. V., Chao, J. D., Rinker, B. D., Zoldos, J., Robichaux, M. R., Ruggeri, S. B., Anderson, K. A., Bonatz, E. E., Wisotsky, S. M.,

Cho, M. S., Wilson, C., Cooper, E. O., Ingari, J. V., Safa, B., Parrett, B. M. and Buncke, G. M. (2012), Processed nerve allografts for peripheral nerve reconstruction: A multicenter study of utilization and outcomes in sensory, mixed, and motor nerve reconstructions. Microsurgery, 32: 1—14. doi: 10.1002/micr.20975 and Cho, et al. 2012, J. Hand Surg. Am 37(11):2340-9). In the March 2019 the Journal, Plastic and Reconstructive Surgery Global Open, Safa, et al. reported on a cohort of the RANGER Registry focused functional motor recovery after repair with Avance Nerve Graft. In the 22 repairs, the authors found that meaningful motor recovery was observed in 73% of the repairs and no safety concerns were identified. (Safa, Bauback MD; Shores, Jaimie T. MD; Ingari, John V. M; Weber, Renata V. MD; Cho, Mickey MD; Zoldos, Jozef MD; Niacaras, Timothy R. MD, PhD; Nesti, Leon J. MD, PhD; Thayer, Wesley P. MD, PhD; Buncke, Gregory M. MD. (2019)), Recovery of Motor Function after Mixed and Motor Nerve Repair with Processed Nerve Allograft. Plastic and Reconstructive Surgery – Global Open: March 2019 - Volume 7 - Issue 3 - p e2163 doi: 10.1097/GOX.0000000000002216. In the February 2020 edition of the journal Microsurgery, Safa, et al. published updated results from the RANGER registry. The publication included 385 subjects with 624 nerve repairs. Overall, 82% meaningful recovery (MR) was achieved across sensory, mixed, and motor nerve repairs up to gaps of 70 mm. No related adverse events were reported. Safa B., Jain S., Desai MJ, Greenberg JA, Niacaris TR, Nydick JA, Leversedge FJ, Megee DM, Zoldos J., Rinker BD, McKee DM, MacKay BJ, Ingari JV, Nesti LJ, Cho M, Valerio IL, Kao DS, El-Sheikh Y, Weber RV, Shores JT, Styron JF, Thayer WP, Przylecki WH, Hoyen HA, Buncke GM. Peripheral nerve repair throughout the body with processed nerve allografts: Results from a large multicenter study. Microsurgery. 2020 Jul;40(5):527-537. doi: 10.1002/micr.30574. Epub 2020 Feb 26. PMID: 32101338 The Journal of Hand Surgery published in their December 2020 edition the findings from the MATCH Conduit arm of RANGER. The study included 113 Avance Nerve Graft repairs and 49 conduit repairs. Meaningful recovery was reported in 61% of the conduit group, compared with 88% in the PNA group. In the group with a 14-mm or less gap, conduit and PNA outcomes were 67% and 92% meaningful recovery, respectively. In the 15- to 25-mm gap length group, conduit and PNA outcomes were 45% and 85% meaningful recovery, respectively (Fraser J Leversedge, Jozef Zoldos, Jason Nydick, Dennis S. Kao, Wesley Thayer, Brendan MacKay, Desirae McKee, Harry Hoyen, Bauback Safa, Gregory M Buncke 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. doi: 10.1016/j.jhsa.2020.07.016. Epub 2020 Oct 1). At the 2020 American Society for Surgery of the Hand Annual Conference, the RANGER Investigator Team presented on the preliminary findings from the MATCH Autograft arm of RANGER. The team reported that allograft sensory and motor meaningful recovery rates were found to be comparable to those for nerve autograft.
Additionally, at the American Society for Surgery of the Hand Annual Conference, Styron and colleagues presented on the Hospital Index Procedure Costs for nerve allograft and nerve autograft. The study found that costs for nerve allograft and autograft were comparable.

International Opportunity for Revenue

Axogen currently focuses primarily on the U.S. market, with additional foreign distribution and sales in Canada, Germany, United Kingdom, Spain, South Korea, and certain other countries. The need for the surgical repair of damaged or transected nerves is a global opportunity. Through its revenue outside the U.S., Axogen has demonstrated the capability to take its current peripheral nerve repair surgical portfolio into new geographical markets. Axogen does not currently have European Union (“E.U.”) wide approval for Avance Nerve Graft as human tissue is approved in each individual country. Cook Biotech received the renewal of the CE Mark for Axoguard Nerve Connector and Axoguard Nerve Protector in March 2020. Avance Nerve Graft has been granted marketing authorization in Germany and commercial operations will begin in 2021. Currently, Avive Soft Tissue Membrane, Axoguard Nerve Cap and Axotouch Two Point Discriminator are only available in the U.S., but Axogen is taking action to introduce Avive Soft Tissue Membrane internationally, which introduction is subject to meeting the appropriate regulatory standards of a particular country and any appropriate E.U. wide regulation or directive. In addition to regulatory approval, reimbursement approval is necessary to achieve material product adoption in most countries. Avance Nerve graft has achieved NICE approval in the UK for digital nerve repair and reimbursement approval in South Korea for repairs up to 50mm in length. To date, revenue from international distribution and sales have not been material, there are no material risks associated with foreign operations and we do not have dependencies as to international revenue. See Risk Factors – Our operations must comply with FDA and other governmental requirements.

Research and Development

Axogen believes it provides the most extensive product portfolio for peripheral nerve injuries available. Our current development focus is to expand clinical data in both traumatic peripheral nerve repair and other surgical applications and to develop product line extensions of the Avance and Axoguard products. Other peripheral nerve repair technologies may also be developed. In this regard, Axogen introduced: (1) an Axoguard Connector line extension in winter 2014 by providing a new longer 15mm product; (2) Axotouch in the fall of 2014; (3) Avive Soft Tissue Membrane launched in November 2016; and (4) Axoguard Nerve Cap fully released in the U.S. in February 2020.

Axogen works with academic institutions in the expansion of treatments for peripheral nerve and is involved in a number of grants from government agencies related to nerve repair or use of our products and/or technologies. For the years ended

December 31, 2020, 2019, and 2018, Axogen recognized grant revenue of approximately $390,000, $301,000, and $195,000, respectively. For the years ended December 31, 2020, 2019 and 2018, Axogen spent approximately $17.8 million, $17.5 million, and $11.8 million, respectively, on total research and development expenses for product and clinical development.

Competition

The medical device and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. As such, Axogen cannot predict what products may be offered in the future that may compete with Axogen's products. In the peripheral nerve repair market, Axogen competes primarily against all transected and non-transected peripheral nerve repair approaches, including direct suture repair, autograft, and hollow-tube nerve conduits and materials used to wrap and protect damaged peripheral nerve tissue. Finally, there are numerous companies that offer amnion products in a variety of formats, primarily in the area of wound care, which could be competitive with Axogen's Avive product.

Because the requirements of the biomaterials used in peripheral nerve repair can vary based on the severity and location of the damaged nerve, the size and function of the nerve, surgical technique and patient preference, Axogen's peripheral nerve repair products compete against both autograft materials (nerve in the case of a bridging repair and vein or fat in the case of a nerve protection repair), and a limited number of off-the-shelf alternatives for grafting and protecting. Competitive aspects of our products focus on the overall value proposition of our products and their suitability for specific applications and can include composition and structure of the material, ease of use, clinical evidence, handling, and price. Axogen's major competitor for off-the-shelf repair options in hollow-tube conduits and bio-absorbable wraps are:

- Integra LifeSciences Holding Corporation (Nasdaq: IART) ("Integra"). Integra offers NeuraGen®, a hollow tube product made from reconstituted bovine collagen and NeuraWrap™, a reconstituted bovine collagen biomaterial used for nerve wrapping and has announced they will launch NeuraGen 3D Nerve Guide Matrix which we believe is the NeuraGen hollow tube collagen conduit filled with a porous inner matrix comprised of collagen and glycosaminoglycan (chondroitin-6-sulfate);
- Baxter International, Inc. (NYSE: BAX) ("Baxter"). Baxter acquired Synovis which offers Neurotube, a hollow tube made of polyglycolic acid and announced distribution of Nerbridge, a hollow tube filled with porous collagen that according to "A Clinical Multi-Center Registry Study On Digital Nerve Repair Using A Biodegradable Nerve Conduit Of PGA With External And Internal Collagen Scaffolding Hirohisa Kusuhara, Md, Phd; Yu Sueyoshi, Md; Noritaka Isogai, Md, Phd Kindai University, Osaka-Sayama, Japan" the conduit and inner collagen had the greater ability to regenerate after peripheral nerve injury than hollow Nerbridge®". In 2018, Synovis licensed Neurocap Nerve Capping Device and Vivosorb Polymer Film from Polyganics; and
- Stryker Corporation (NYSE: SYK) ("Stryker"). Stryker offers the NeuroMatrix and Neuroflex products, both of which are hollow tubes derived from reconstituted bovine collagen and NeuroMend, a reconstituted bovine collagen biomaterial used for nerve wrapping. All of these products are manufactured by Collagen Matrix Inc.

Axogen believes that surgeons use Avance Nerve Graft because it provides them an off-the-shelf solution with the natural three-dimensional structure and familiar handling characteristics of a typical peripheral nerve for bridging peripheral nerve transections (severed peripheral nerves) without the comorbidities and additional surgical site of an autograft as well as confidence in the performance of the product as a result of the growing body of clinical literature. Axoguard Nerve Protector and Axoguard Nerve Connector provide the unique features of pliability, suturability and translucence for visualization of the underlying nerve while also allowing the patient's own cells to incorporate into the extracellular matrix to remodel. Axogen believes its Avive Soft Tissue Membrane, a resorbable soft tissue covering to separate tissues has favorable handling and absorption properties, and Axoguard Nerve Cap is a uniquely designed nerve termination device which provides a protective environment for the nerve ends to reduce the development of painful neuroma.

Axogen believes any current or future competitors face the following important barriers to market entry as it relates to its peripheral nerve repair products. Axogen's intellectual property ("IP"), and that of its partners, including patents, patents-pending, trade secrets, and know how, is believed to be an important barrier for its Avance Nerve Graft and Axoguard products. Axogen has developed knowledge and experience in understanding and meeting FDA regulatory requirements for Avance Nerve Graft, including having made a substantial investment in conducting the preclinical and clinical testing necessary to support a submission for an FDA BLA. Additionally, Axogen believes the ability to offer a portfolio of products focused on peripheral nerve repair provides a unique competitive position versus other entities that do not have this breadth of product offering. However, due to its limited resources, its smaller size and its relatively early stage, Axogen believes it may face competitive challenges from larger entities and market factors that could negatively impact Axogen's growth, including competitors' introduction of new products and competitors' bundling of products to achieve pricing benefits.

Intellectual Property

Overview

Axogen protects its IP through a combination of patents, trademarks, trade secrets, and copyrights. In addition, Axogen safeguards its trade secrets and other confidential know-how, and carefully protects these and other IP rights when engaging with third parties. For example, Axogen requires vendors, contract organizations, consultants, advisors, and employees to execute confidentiality and nondisclosure agreements, and to appropriately protect any information disclosed to them by Axogen so as to preserve its confidential and/or trade secret status. Axogen also requires consultants, advisors, and employees to assign to Axogen their rights to any IP arising out of their relationship with Axogen.

License Agreements

Axogen has entered into license agreements with University of Florida Research Foundation (the "UFRF") and the University of Texas at Austin ("UTA"). Under the terms of these license agreements, Axogen holds exclusive worldwide licenses to underlying technologies used by Axogen in its Avance Nerve Graft. The license agreements include both the right to issued patents and patents pending in the U.S. and international markets. The effective term of the license agreements extends through the term of the related patents. Currently, Axogen pays royalties to UFRF and UTA specific to the licensed technologies related to the Avance Nerve Graft.

Patents

As of the date of this Form 10-K, Axogen owns or is the exclusive licensee of about thirty issued U.S. patents, more than twenty pending U.S. patent applications (including those for which Axogen has received a notice of allowance) and more than ninety five international patents and patent applications with regard to its peripheral nerve products and other related technologies.

With respect to our Avance Nerve Graft, we have patent protection through at least September 2023 in the U.S. In addition we also expect Avance Nerve Graft will receive Biosimilar Protection that would provide 12 years of data exclusivity. Finally, Axogen has Enforcement Discretion from FDA allowing continued distribution under controls applicable to Human Cellular and Tissue-based Products ("HCT/P") with an agreed transition plan to a Biologic Product under a BLA. We believe a competitive processed peripheral nerve allograft would need to successfully complete BLA Phase I, II and III clinical studies prior to clinical release, the completion of which we believe would take at least 8 years.

Because of the length of time and expense associated with bringing new products through development and the governmental approval process, medical technology companies have traditionally placed considerable importance on obtaining and maintaining patent protection for significant new technologies, products, and processes. Axogen's policy is to seek patent protection for, or where strategically preferable, maintain as trade secret, the inventions that it considers important to its products and the development of its business. Axogen has sought, and will continue to seek, patent protection for select proprietary technologies and other inventions emanating from its R&D, including with respect to uses, methods, and compositions, in an effort to further fortify its IP stronghold in areas of importance to the company and its growing product portfolio. In instances that patent protection is not possible, product value to Axogen's portfolio can still be derived.

Trademarks, Trade Secrets and Copyrights

Axogen holds a significant portfolio of hundreds of registered and applied-for trademarks in the U.S. and worldwide. Protection of our trademarks allows Axogen to prevent competitors from, for example, using the same or a confusingly similar company name, or the same or confusingly similar product names within identified classes of goods which could otherwise wrongfully allow such competitors to capitalize on the Axogen brand, reputation, and goodwill, and thereby improperly bolster their sales or reputations through, for example, consumer confusion, a false indication of Axogen's endorsement, or of a false indication of corporate or contractual relationship with Axogen. Axogen polices and enforces its marks.

Axogen possesses trade secrets and material know-how in the following general subject matters: nerve and tissue processing, nerve repair, product testing methods, and pre-clinical and clinical expertise. Axogen has registered copyrights for training tools and artistic renderings.

Additionally, Axogen entered into the Cook Biotech Distribution Agreement and Supply Agreement for the Axoguard products. Cook Biotech believes it has know-how and trade secrets with respect to its ECM technology that provides certain competitive obstacles.

Government Regulations

U.S. Government Regulation Overview

Axogen's products are subject to regulation by the FDA, as well as other federal and state regulatory bodies in the U.S. and comparable authorities in other countries. In addition, its Avance Nerve Graft and Avive Soft Tissue Membrane must comply with the standards of the tissue bank industry's accrediting organization, the AATB.

Axogen distributes for Cook Biotech the Axoguard Nerve Connector and Axoguard Nerve Protector and Cook Biotech is the contract manufacturer for our Axoguard Nerve Cap. Cook Biotech is responsible for the regulatory compliance of the Axoguard Nerve Connector and Axoguard Nerve Protector and Axogen is responsible for the regulatory compliance of Axoguard Nerve Cap. Axoguard products are regulated as medical devices and subject to premarket notification requirements under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the "FD&C Act"), 21 CFR Part 820 ("Quality System Regulation"), and related laws and regulations. Cook Biotech has obtained a 510(k) premarket clearance for Axoguard Nerve Connector from the FDA for the use of porcine (pig) small intestine submucosa for the repair of peripheral nerve transections where gap closure can be achieved by flexion of the extremity. Cook Biotech has also obtained a 510(k) premarket clearance for Axoguard Nerve Protector for the repair of peripheral nerve damage in which there is no gap or where a gap closure is achieved by flexion of the extremity. We sell the 510(k) cleared device under the trade names Axoguard Nerve Protector and Axoguard Nerve Connector.

Axogen also sells the Axoguard Nerve Cap. This device, manufactured for Axogen by Cook Biotech and distributed from our Burleson facility, is a Class II device. The Axoguard Nerve Cap was cleared for market under 510(k) K163446. It is classified by FDA under 21 CFR 882.5275 (Nerve Cuff, product code: JXI).

Axogen is responsible for the regulatory compliance of Avive Soft Tissue Membrane. Avive Soft Tissue Membrane is processed and distributed in accordance with FDA requirements for Human Cellular and Tissue-based Products (361 HCT/P) under 21 CFR Part 1271 regulations, U.S. regulations and the guidelines of the AATB. The FDA guidance Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use (issued July 2020) could have potential implications on the regulatory status of Avive. Enforcement discretion described in the guidance effectively ends on May 31, 2021. Axogen is in discussions with FDA on the regulatory classification for Avive Soft Tissue Membrane and we believe Avive will meet the requirement to remain a 361 HCT/P. We are prepared to move forward to transitioning Avive to a 351 HCT/P if required by the FDA.

Axogen also distributes Axotouch Two-Point Discriminator. This device is manufactured for Axogen and distributed from the Burleson Facility is a Class I device (general controls) that is exempt from premarket notification and the Quality System Regulation requirements except for the Recordkeeping and Complaint file requirements. It is classified by FDA under 21 CFR 882.1200 (Two-point discriminator, product code: GWI).

In 2007, Axogen began to process and distribute its Avance Nerve Graft pursuant to Section 361 of the PHS Act and 21 CFR Part 1271 Human Cells, Tissues, and Cellular and Tissue Based Products controls. Such action was based on Axogen's good faith belief that Avance Nerve Graft product was an HCT/P tissue product regulated solely under Section 361. From October 2008 through early 2010, Axogen was in communication with the FDA concerning the regulatory status of the Avance Nerve Graft product. In April 2010, in response to a Request For Designation filed by Axogen, the FDA determined that Avance Nerve Graft was a biological product that would be reviewed and regulated by the U.S. FDA Center for Biologics Evaluation and Research ("CBER") under the requirements of Section 351 of the PHS Act. Section 351 requires, among other things, an approved license to market a biological product.

Axogen met with CBER in July 2010 and, between July 2010 and November 2010, provided information to CBER that resulted in the FDA issuing a letter stating the agency's intent to exercise enforcement discretion with respect to the continued introduction or delivery for introduction into interstate commerce of Avance Nerve Graft assuming that certain conditions are met relating to the transition of Avance Nerve Graft from regulation as an HCT/P under Section 361 to a biological product under section 351 of the PHS Act. Specifically, the FDA is permitting Avance Nerve Graft to be distributed, subject to FDA enforcement discretion, provided that:

- Axogen transitions to compliance with Section 501(a)(2)(B) of the FD&C Act, the current Good Manufacturing Practice, or cGMP, regulations in 21 CFR Parts 210 and 211 and the applicable regulations and standards in 21 CFR Parts 600-610 prior to initiation of a phase 3 clinical trial designed to demonstrate the safety, purity, and potency of Avance Nerve Graft.

- Axogen has performed several gap analyses of its quality system for compliance with 21 CFR Parts 210/211 and 600-610 regulations. The gap analyses have identified areas in which our quality system could improve with respect to compliance to the regulations. The transition is in process and we periodically review the 21 CFR Parts 210/211 and 600-610 regulations to ensure that we create and implement appropriate changes, including new quality procedures. Through our internal auditing process, we periodically assess our compliance to the regulations. As Axogen completes the phase 3 clinical trial and eventual BLA submission, we will retain an external audit firm with experience in auditing to 21 CFR Parts 210/211 and 600-610 regulations to verify quality system compliance to the regulations.

- Axogen conducts a phase 3 clinical trial to demonstrate safety, purity, and potency of Avance Nerve Graft under a Special Protocol Assessment ("SPA").
  - Axogen and the FDA agreed to the SPA in August 2011 and in accordance with FDA regulations in 21 CFR Part 312, Axogen submitted an Investigational New Drug Application ("IND") to the FDA in April 2013. The IND was approved and became effective in March 2015 and the phase 3 clinical trial was initiated in the second quarter of 2015. The study completed initial enrollment in January 2019. As required by the SPA and agreed to by FDA and Axogen, an independent statistical analysis was conducted to determine if greater study enrollment is appropriate to maintain the planned statistical power of the trial. As part of that review, the targeted enrollment was increased to 220 subjects, and the number of participating centers was increased to up to 25. The study completed initial subject enrollment in July 2020. No outcome data is available at this time.

- Axogen continues to comply with the regulations and standards under 21 CFR Part 1271.
  - Axogen was audited by the FDA at its processing facility in March 2013, March 2015 and October 2016, and its Distribution Facility in October 2015. The quality system was found to be in compliance with 21 CFR Part 1271 and no FDA Form 483 observations were issued.
  - In February 2018. Axogen was audited by the FDA with respect to its Medical Device Quality System under 21 CFR Part 820 and its Human Tissue Quality System under 21 CFR Part 1271. Such audit resulted in two Form 483 observations on general procedures on the Medical Device regulations and no Form 483 observations as to the Human Tissue Quality System. Axogen has taken corrective action to correct these observations and the FDA has accepted the corrective action plan.
  - In November 2018, Axogen was audited by the FDA with respect to its Human Tissue Quality System under 21 CFR Part 1271. Such audit resulted in one Form 483 observation on tissue tracking. Axogen has taken corrective action to correct this observation and the FDA has accepted the corrective action plan.

- Axogen continues to exercise due diligence in executing its requirements under the transition program.

Axogen is working to ensure compliance with the applicable regulations through ongoing discussions with the FDA regarding the transition of the quality system to 21 CFR Parts 210/211 and 600-610 compliance with the FDA and through audits for compliance to 21 CFR Part 1271 and amendments to the IND providing updates to the phase III clinical trial. The final determination of regulatory compliance will be made by the FDA during the pre-license inspection as part of the BLA review. If the FDA does not find Axogen to be in compliance, or if Axogen is unable to meet the required standards for preclinical studies, clinical studies and Chemistry, Manufacturing, and Controls ("CMC"), the approval of the BLA would be delayed or denied.

The FDA will end the period of enforcement discretion upon a final determination of Axogen's future BLA submission or if prior to the BLA submission, the FDA finds that Axogen does not meet the conditions for the transition plan, or is not exercising due diligence in executing the transition (e.g., study completion, or BLA submission is neither timely nor adequate). If final action on the BLA is negative or Axogen is found to not meet the conditions for the transition plan or its execution, Axogen will not be able to continue to distribute the Avance Nerve Graft. Axogen continues to work diligently to execute the transition plan, including maintaining regular communication with the FDA, and, in this context, continues to distribute Avance Nerve Graft.

The BLA application of Avance Nerve Graft, if approved, will require a potentially substantial user fee payment to the FDA, although certain exemptions, waivers and discounts of the user fees may apply, including certain waivers or discounts for small businesses.

FDA Reauthorization Act, referred to herein as FDARA (Public Law 115-52), which was signed into law on August 18, 2017, amended the FD&C Act. FDARA includes the Prescription Drug User Fee Amendments of 2017, amended the FD&C Act. FDASIA includes the Prescription Drug User Fee Amendments of 2012 which authorizes the FDA to continue to collect the following user fees from applicants who submit certain new drug and biological product applications and supplements:

- *Application Fee:* Each new BLA has a fee required at the time of submission. For Axogen fiscal year 2021 (through September 2021 – FDA resets the fee starting in October of each year), this fee for a BLA requiring clinical data is approximately $2.9 million. The fee is adjusted each year so we cannot provide an accurate estimate of what our fee will be upon submission of our BLA. For small companies (fewer than 500 employees and no other approved biologic product on the market) submitting its first application, a waiver of the application fee is available.

- *Axogen Program Fee:* A program fee is assessed for each strength or potency in which the approved (non-revoked, non-suspended) product is manufactured in final dosage form. The program fee is based on an estimate of the number of products that would be subject to, and for which the companies would pay, program fees. The program fee is determined by dividing the adjusted total fee revenue from program fees by the number of estimated products (based on previous year's program fees) subject to the program fee (excluding program fee waivers and reductions granted by the FDA). For Axogen fiscal year 2021 (through September 2021– FDA resets the fee starting in October of each year), the program fee has been established at $0.3 million. Axogen may have to pay a program fee after BLA approval.

The current version of PDUFA expires October 1, 2022. New user fee amounts could be negotiated during the reauthorization process expected to take place starting in 2020. The future version of PDUFA is unknown at this time
and we cannot provide an accurate description on how the future version of PDUFA will have on our BLA submission.

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

The Company believes that any future, competitive peripheral nerve allograft would be required to follow the standard pathway for biologic licensing, which typically entails multiple clinical trials and takes many years. The FDA provided updated guidance, Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use in November 2017 (revised in July 2020), which made clear that any processing that alters the biological characteristics of peripheral nerve tissue would be considered more than minimal manipulation, and therefore require a BLA prior to marketing.

The Company has maintained a collaborative dialogue with the FDA and will continue to work closely with the FDA as it progresses towards its BLA submission. Upon BLA approval, Avance Nerve Graft we believe we will have 12 years of data exclusivity with regard to potential biosimilars with Avance Nerve Graft being designated as the Reference Product.

FDA — General

FDA regulations govern nearly all the activities that Axogen performs, or that are performed on its behalf, to ensure that medical products distributed domestically or exported internationally are safe and effective for their intended uses. The activities the FDA regulates include the following:

- product design, development, and manufacture;
- product safety, testing, labeling, and storage;
- pre-clinical testing in animals and in the laboratory;
- clinical investigations in humans;
- premarketing clearance, approval, or licensing;
- record-keeping and document-retention procedures;
- advertising and promotion;
- the import and export of products;
- product marketing, sales, and distribution;
- post-marketing surveillance and medical device reporting, including reporting of deaths, serious injuries, communicable diseases, device malfunctions, or other adverse events; and
- corrective actions, removals and recalls.

Failure to comply with applicable FDA regulatory requirements may subject Axogen to a variety of administrative or judicially-imposed penalties or sanctions and/or prevent it from obtaining or maintaining required approvals, clearances or licenses to manufacture and market its products. Such failure to comply with the applicable FDA requirements may subject Axogen to stringent administrative or judicial actions or sanctions, such as agency refusal to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution of products, injunctions, or civil or criminal prosecution.

FDA's Premarket Clearance and Approval Requirements - Medical Devices

Unless an exemption applies, each medical device distributed commercially in the U.S. requires either a 510(k) premarket notification submission or a Pre-Market Approval ("PMA") Application to the FDA. Medical devices are classified into one of three classes—Class I, Class II, or Class III—depending on the degree of risk, the level of control necessary to assure the safety and effectiveness of each medical device and how much is known about the type of device. For devices first intended for marketing after May 28, 1976, pre-market review and clearance by the FDA for Class I and II medical devices is accomplished through the 510(k) pre-market notification procedure by finding a device substantially equivalent to a legally marketed Class I or II device, unless the device is exempt. The majority of Class I medical devices are exempt from the 510(k) premarket notification requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices for which Class II controls are inadequate to assure safety or effectiveness, and novel devices, including devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in Class III. Class III devices generally require an approved PMA prior to marketing.

A PMA must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction, and the safety and effectiveness of the device.

FDA's Premarket Approval Requirements - Biologic Products

Biological Product License Application (BLA) Pathway

Biological products subject to BLA requirements are approved under the Public Health Service Act. Biological products require FDA approval of a BLA to be marketed. In order to be approved, a BLA must demonstrate the safety, purity, and potency of the product candidate based on results of preclinical studies and clinical trials. A BLA must also contain extensive CMC and other manufacturing information, and the applicant must pass an FDA pre-approval inspection of the manufacturing facility or facilities at which the biologic product is produced to assess compliance with the FDA's cGMP. Satisfaction of FDA approval requirements for biologics typically takes several years and the actual time required may vary substantially based on the type, complexity, and novelty of the product. Axogen cannot be certain that any BLA approvals for its products will be granted on a timely basis, or at all.

The steps for obtaining FDA approval of a BLA to market a biologic product in the U.S. include:

- completion of preclinical laboratory tests, animal studies, and formulation studies under the FDA's good laboratory practices regulations;
- submission to the FDA of an IND, for human clinical testing, which must become effective before human clinical trials may begin and which must include independent Institutional Review Board, or IRB, approval at each clinical site before the trials may be initiated;
- performance of an adequate and well-controlled clinical trial in accordance with Good Clinical Practices to establish the safety and efficacy of the product for each indication;
- submission to the FDA of a BLA, which contains detailed information about the CMC for the product, reports of the outcomes and full data sets of the clinical trials, and proposed labeling and packaging for the product;
- satisfactory review of the contents of the BLA by the FDA, including the satisfactory resolution of any questions raised during the review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP regulations, to assure that the facilities, methods, and controls are adequate to ensure the product's identity, strength, quality, and purity; and
- FDA approval of the BLA, including agreement on post-marketing commitments, if applicable.

Preclinical tests include laboratory evaluations of product chemistry, toxicity, and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. Some preclinical testing may continue after the IND is submitted. The IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless

before that time the FDA raises concerns or questions about issues such as the conduct of the trials and or supporting preclinical data as outlined in the IND. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. In other words, submission of an IND may not result in the FDA allowing clinical trials to commence.

Biosimilar Biological Products

A regulatory approval pathway for biosimilars was established by The Biologics Price Competition and Innovation Act ("BPCIA"), as part of the Patient Protection and Affordable Care Act of 2010. An important component of the legislation specified that a manufacturer of a reference biological product would be granted 12 years of non-patent data exclusivity before a biosimilar could be approved for marketing in the U.S. An application for a biosimilar product may not be submitted to FDA until four years after the approval date of the BLA for the reference biological product. BPCIA provides for an abbreviated licensure process for a biosimilar, *i.e.*, a biological product that is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences compared to the reference product in terms of safety, purity, and potency. At its discretion, the FDA can waive a requirement for any required element in an application for a biosimilar product. In addition, the legislation distinguished approval of a biosimilar from approval of such a product as a substitute for the reference biological products. Where a product is approved as a biosimilar and additionally approved as a substitute for the reference biologic, it is considered an interchangeable product. Approval as interchangeable requires that the product is biosimilar and can be expected to produce the same clinical results as the reference product in any given patient, and if intended for repeat dosing, a demonstration that the risk in terms of safety or diminished efficacy of alternating or switching between the use of the interchangeable and reference product is not greater than the risk of using the reference product without such alternating or switching. Interchangeable products can be substituted for a reference product without intervention of the prescribing healthcare provider. Most states have enacted or are considering laws that regulate the use and substitution of biosimilar and interchangeable products. For example, Virginia requires licensure as interchangeable by the FDA for a pharmacist to dispense a biosimilar in place of a prescribed biological product (Virginia § 54.1-3408.04).

FDA's Pre-Approval and Pre-Licensing Requirements

Before approving a BLA, the FDA generally inspects the facility or the facilities at which the product is manufactured. The FDA will not approve the product if it finds that the facility does not appear to be in cGMP compliance. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it will either not approve the application or issue a complete response letter to indicate that the review cycle for an application is complete and that the application is not ready for approval. The letter will describe specific deficiencies and, when possible, will outline recommended actions the applicant might take to get the application ready for approval. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process requires substantial time, effort, and financial resources, and each may take several years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. Axogen may encounter difficulties or unanticipated costs in its efforts to secure necessary governmental approvals, which could delay or preclude it from marketing its products. The FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of the products. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

After regulatory approval of a product is obtained, Axogen will be required to comply with a number of post-approval requirements. For example, as a condition of approval of a BLA, the FDA may require post marketing testing and surveillance to monitor the product's continued safety or efficacy. In addition, holders of an approved BLA are required to keep extensive records, to report certain adverse reactions and production problems such as biologic deviation reports to the FDA, to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP regulations as well as the manufacturing conditions of approval set forth in the BLA. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP regulations, which impose certain procedural, substantive, and recordkeeping requirements. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Future FDA inspections may identify compliance issues at Axogen's facilities or at the facilities of its contract manufacturers that may disrupt production or distribution, or require substantial resources to correct and prevent recurrence of

any deficiencies. In addition, discovery of problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications. Finally, new government requirements, including those resulting from new legislation, may be established that could delay or prevent regulatory approval of Axogen products that are currently under development or regulatory activity.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that Axogen failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, such as issuing a FDA Form 483 notice of inspectional observations, warning letter, or untitled letter, imposing civil money penalties, suspending or delaying issuance of approvals, requiring product recall, imposing a total or partial shutdown of production, withdrawal of approvals or clearances already granted, and pursuing product seizures, consent decrees or other injunctive relief, and criminal prosecution through the U.S. Department of Justice (the "DOJ"). The FDA can also require Axogen to repair, replace or refund the cost of devices that it manufactured or distributed. If any of these events were to occur, it could materially adversely affect Axogen's business.

Clinical Trials

Clinical trials are required to support a BLA or PMA and are sometimes required for 510(k) clearance. Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators. Clinical trials are conducted under strict requirements to ensure the protection of human subjects participating in the trial and under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring and safety, and the effectiveness criteria to be evaluated. Clinical trials for biological products require the submission and FDA acceptance of an IND and clinical trials for medical devices require the submission and FDA approval of an Investigational Device Exemption application, or IDE, unless the device regulations provide for an exemption from the IDE requirement. Clinical trials for significant risk devices may not begin until the IDE is approved by the FDA and the Institutional Review Board (IRB) overseeing the particular clinical trial. If the product is considered a non-significant risk device under FDA regulations, the trial must only be approved by an IRB prior to its initiation. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND or IDE, for significant risk devices. In addition, for these studies, an IRB at each site at which the study is conducted must approve the protocol, subject consent form and any amendments for each site at which the study is conducted. All research subjects must be informed, among other things, about the risks and benefits of the investigational product and provide their informed consent in writing.

Clinical trials under an IND typically are conducted in three sequential phases, but the phases may overlap or be combined. In Axogen's case, Axogen believes that the Phase 3 clinical trial study for the Avance Nerve Graft represents the only new clinical data that will be required to evaluate safety and effectiveness. Phase 1 clinical trials usually involve the initial introduction of the investigational product into a small group of healthy volunteers (e.g., 10 to 20) to evaluate the product's safety (dosage tolerance and pharmacokinetics if a biologic product) and, if possible, to gain an early indication of its effectiveness. Phase 2 clinical trials usually involve controlled trials in a larger but limited patient population (e.g., a few hundred) to:

- evaluate dosage tolerance and appropriate dosage;
- identify possible adverse effects and safety risks; and
- provide a preliminary evaluation of the efficacy of the product for specific indications.

Phase 3 clinical trials usually further evaluate clinical efficacy and test further for safety in an expanded patient population (e.g., a hundred to several thousand). Phase 3 clinical trials usually involve comparison with placebo, standard treatments, or other comparators. Usually at least one well-controlled large Phase 3 or pivotal clinical trial demonstrating safety and efficacy is required to support a BLA. These trials are intended to establish the overall risk-benefit profile of the product and provide an adequate basis for physician labeling. Phase 3 trials are almost always larger, more time consuming, complex and costly than Phase 1 and Phase 2 clinical trials. Phase 1, Phase 2, and Phase 3 clinical testing may not be completed successfully within any specified period, if at all. Furthermore, the FDA or Axogen may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk, have experienced a serious and unexpected adverse event, or that continued use in an investigational setting may be unethical. Similarly, an IRB can suspend or terminate approval of research if the research is not being conducted in accordance with the IRB's requirements or if the research has been associated with unexpected serious harm to patients.

Investigational New Drug Application

For a biologic product, an IND must be submitted prior to the initiation of the clinical study. The IND application must contain information in three broad areas:

- Animal Pharmacology and Toxicology Studies - Preclinical data to permit an assessment as to whether the product is reasonably safe for initial testing in humans. Also included are any previous experiences with the product in humans (often foreign use).
- Manufacturing Information - Information pertaining to the composition, manufacturer, stability, and controls used for manufacturing of the drug substance and the drug product. This information is assessed to ensure that the company can adequately produce and supply consistent batches of the drug.
- Clinical Protocols and Investigator Information - Detailed protocols for proposed clinical studies to assess whether the initial-phase trials will expose subjects to unnecessary risks. Also, information on the qualifications of clinical investigators—professionals (generally physicians) who oversee the administration of the experimental compound—to assess whether they are qualified to fulfill their clinical trial duties. Finally, commitments to obtain informed consent from the research subjects, to obtain review of the study by an IRB, and to adhere to the investigational new drug regulations.

Once the IND is submitted, the sponsor must wait 30 calendar days before initiating any clinical trials. During this time, the FDA has an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk.

Axogen Clinical Trials

Axogen has an active clinical research program to gather data on Avance Nerve Graft. Axogen has completed two clinical studies and is performing two ongoing clinical studies and has plans to initiate further clinical studies. The ongoing studies are "A Multicenter Retrospective Study of Avance Nerve Graft Utilization, Evaluations, and Outcomes in Peripheral Nerve Injury Repair ("RANGER")" and "A Multicenter, Prospective, Randomized, Patient and Evaluator Blinded Comparative Study of Nerve Cuffs and Avance Nerve Graft Evaluating Recovery Outcomes for the Repair of Nerve Discontinuities ("RECON")". Completed studies are "A Multicenter, Prospective, Randomized, Comparative Study of Hollow Nerve Conduit and Avance Nerve Graft Evaluation Recovery Outcomes of the Nerve Repair in the Hand ("CHANGE")" and a pilot study to evaluate the use of Avance Nerve Graft in the reconstruction of nerves following prostatectomy.

Axogen will continue to accept patients in the RANGER clinical study, a utilization registry of Avance Nerve Graft. As of December 31, 2020, eight publications and more than 70 scientific conference presentations have been generated to date from the registry. The RANGER Study is an observational study currently in enrollment. RANGER is designed to allow up to 2500 subjects. An additional 500 subjects are allowed to be enrolled in Addendum 1 ("MATCH^{SM}") and 2000 enrolled in Addendum 2 ("Sensation-NOW^{SM}").

The follow-up for the RANGER Study is standard of care with a target of up to 36 months post peripheral nerve repair. At the time of BLA submission for Avance Nerve Graft, Axogen will provide Real World Evidence ("RWE") based primarily on Real World Data ("RWD") from the RANGER study data for the enrolled subjects. In 2013, a Matched Autograft and Tube Conduit Case Control Cohort Arm of RANGER ("MATCH^{SM}") comparative arm was added. Subjects treated with Avance Nerve Graft were matched to the peripheral nerve autograft or tube conduit treated groups based on size of gap length. This study is designed to enroll up to 500 repairs with peripheral nerve autograft and/or tube conduit in the comparative arm.

Axogen created an additional RANGER Study arm called Sensation Neurotization Outcomes for Women ("Sensation-NOW"). This registry cohort is designed to assess breast sensation following reconstruction with or without neurotization. Axogen placed the study on an enrollment hold in 2020 as part of its COVID response plan. Subject follow-up continued during this time. Axogen intends to restart enrollment in 2021 at select centers. The study is designed to enroll up to 2,000 subjects who have undergone mastectomy and breast reconstruction.

The RANGER Study database is also utilized to monitor different nerve repair techniques. As part of this, Axogen utilizes the database to support additional clinical evidence submissions for Axoguard products and Avance Nerve Graft.

Axogen has worked with leading institutions, researchers, and surgeons to support innovation in the field of surgical peripheral nerve repair. Axogen believes that RANGER is currently the largest multi-center observational clinical study conducted in peripheral nerve gap repair. Axogen's ongoing RECON study will also continue our clinical work, providing a new multi-center, prospective, randomized, clinical study on Avance Nerve Graft. The January 2012 edition of Microsurgery, November 2012 edition of The Journal of Hand Surgery June 2015 edition of Journal of Reconstructive Microsurgery, the January 2017 edition of HAND, and the March 2019 edition of Plastic and Reconstructive Surgery Global, each contain an

article summarizing RANGER study results (Brooks, et al. Processed nerve allografts for peripheral nerve reconstruction: A multicenter study of utilization and outcomes in sensory, mixed, and motor nerve reconstructions. Microsurgery, 2012 Jan; 32(1): 1-14; and Cho, et al. Functional outcome following nerve repair in the upper extremity using processed nerve allograft. J Hand Surg. Am. 2012 Nov; 37(11):2340-9 and Rinker, et al. Outcomes of short-gap sensory nerve injuries reconstructed with processed nerve allografts from a multicenter registry study. J. Reconstr. Microsurg. 2015 Jun; 31(5):384-90). Brooks, et al. reported on 55 Avance Nerve Graft nerve repairs and resulted in meaningful motor and sensory recovery in 87% of nerve transections between 5 and 50 mm and no safety concerns were identified. Cho, et al. showed that Avance Nerve Graft provided 89% meaningful recovery for digital nerve injuries, and 80% meaningful recovery for motor function in mixed and motor nerve injuries and no safety concerns were identified. An expanded data milestone was presented at the 5th Vienna Symposium on Surgery of Peripheral Nerves in June 2014 and such expanded RANGER data provides that of the injuries repaired with the Avance Nerve Graft 90%, 80%, and 87% achieved meaningful recovery for gap lengths of 5-14 mm, 15-29 mm and 30-65 mm, respectively. Rinker, et al. reported on a subgroup from the RANGER registry on sensory recovery of short-gap digital nerve repairs between 5-15 mm using Avance Nerve Graft. The study cohort included 24 subjects with 37 digital nerve repairs. Outcomes analysis demonstrated meaningful levels of sensory recovery. No implant related adverse experiences were reported in any of such reports. In a second publication, Rinker, et al. reported on a subgroup from RANGER with nerve gaps >25 mm. They found that in the population of 28 subjects, meaningful sensory recovery was reported in 86% of the repairs and no safety concerns were reported. Isaacs and Safa reported on a subgroup of subjects with large diameter nerve injuries repaired with Avance Nerve Graft. The study included 15 nerve repairs with 4-5 mm diameter Avance Nerve Grafts. Outcomes analysis found that meaningful levels of sensory and motor function were achieved and no safety concerns were reported. Safa, et al. 2019., reported on functional motor recovery after repair with Avance Nerve Graft. The study is a cohort of the RANGER Registry Program, and included 22 nerve repairs with sufficient follow up time to assess the motor function associated with the injured nerve. The authors found that 73% of the repairs returned meaningful motor function and no safety concerns were identified. In the February 2020 edition of the journal Microsurgery, Safa, et al. published updated results from the RANGER registry. The publication included 385 subjects with 624 nerve repairs. Overall, 82% meaningful recovery (MR) was achieved across sensory, mixed, and motor nerve repairs up to gaps of 70 mm. No related adverse events were reported. Safa B, Jain S, Desai MJ, Greenberg JA, Niacaris TR, Nydick JA, Leversedge FJ, Megee DM, Zoldos J, Rinker BD, McKee DM, MacKay BJ, Ingari JV, Nesti LJ, Cho M, Valerio IL, Kao DS, El-Sheikh Y, Weber RV, Shores JT, Styron JF, Thayer WP, Przylecki WH, Hoyen HA, Buncke GM. Peripheral nerve repair throughout the body with processed nerve allografts: Results from a large multicenter study. Microsurgery. 2020 Jul;40(5):527-537. doi: 10.1002/micr.30574. Epub 2020 Feb 26. PMID: 32101338. At the 2020 American Society for Surgery of the Hand, Safa and colleagues presented on the preliminary findings from the MATCH Autograft study. The study of 156 nerve repairs found meaningful recovery rates for Avance Nerve Graft were comparable to autograft for both sensory and motor function.

The Journal of Hand Surgery published in their December 2020 edition the findings from the MATCH Conduit arm of RANGER. The study included 113 Avance Nerve Graft repairs and 49 conduit repairs. Meaningful recovery was reported in 61% of the conduit group, compared with 88% in the PNA group. In the group with a 14-mm or less gap, conduit and PNA outcomes were 67% and 92% meaningful recovery, respectively. In the 15- to 25-mm gap length group, conduit and PNA outcomes were 45% and 85% meaningful recovery.

The following describes available clinical outcomes data from published papers on the leading synthetic and collagen conduit. Published papers on the leading synthetic collagen conduit by Weber, et al., 2000 and Wangensteen and Kalliainen, 2009, showed meaningful improvement: 74% in sensory nerves and 43% in sensory, mixed and motor nerves, respectively, of cases bridging a gap in the particular type of nerve. A paper published by Haug, et al., 2013 on the leading synthetic and collagen conduit showed meaningful improvement in 40% sensory nerves using the static 2-point discrimination test. Autograft studies where autograft and direct repair or direct suture were tested by Weber, et al., 2000, Kim and Kline 2001-2006, Frykman and Gramyk, 1991, Frykman and Gramyk, 1991 and Kallio, 1993, as interpreted by Brooks, et al. 2012, reported meaningful recovery: 86% in sensory nerves, 67-86% in sensory and mixed nerves, 80% in sensory nerves, 75-78% mixed nerves and 70% sensory nerves, respectively, of cases bridging a gap in the particular type of nerve. Published papers by Kim and Kline 2001-2006 and Frykman and Gramyk, 1991 reported successful recovery in 75% and 78% of mixed and motor nerves, respectively. A study by Kallio, et al., 1993 showed recovery in 67% of mixed and motor nerves where recovery was defined as results indicating a classification of useful or better motor and sensory recovery.

The RECON study is a prospective, randomized, controlled, patient and evaluator blinded, comparative study of Avance Nerve Graft and Collagen Nerve Cuffs in the repair of peripheral nerve transections. The study is a non-inferiority study designed to assess the outcome of peripheral nerve repair originally in approximately 170 subjects in up to 20 centers. Subjects will be followed over the course of 12 months to assess safety and efficacy outcomes with assessments being performed at various defined intervals up to 12 months. The study completed initial subject enrollment in January 2019. As required by the SPA and agreed to by FDA and Axogen, an independent statistical analysis was conducted to determine if greater study enrollment is appropriate to maintain the planned statistical power of the study. As part of that review, the targeted enrollment

was increased to 220 subjects, and the number of participating centers was increased to up to 25. Enrollment was completed in July of 2020. Subject follow-up is anticipated to be complete in October of 2021.

CHANGE was a prospective randomized controlled pilot study of nerve cuffs and Avance Nerve Graft for the reconstruction of peripheral nerve transections in male and female subjects that sustained injury to at least one nerve in the hand, distal to the superficial palmar arch that after resection resulted in a nerve gap of >5 mm and ≤20 mm. The study results were published by Means, et al. in the June 2016 edition of HAND. The authors randomized 23 participants with 31 digital nerve injuries. Sixteen participants with 20 repairs had at least six months of follow-up while 12-month follow-up was available for 15 repairs. There were no significant differences in participant and baseline characteristics between treatment groups. The average static two-point discrimination (s2PD) for the Avance Nerve Graft was 5 ± 1 mm (n = 6) compared with 8 ± 5 mm (n = 9) for hollow conduits. All injuries randomized to processed nerve allograft returned some degree of s2PD as compared with 75% of the repairs in the conduit group. The authors concluded that in this pilot study, patients whose digital nerve reconstructions were performed with processed nerve allografts had significantly improved and more consistent functional sensory outcomes compared with hollow conduits.

A pilot study on the repair of the cavernous nerves in prostate cancer patients at Vanderbilt with 24-month follow-up has been completed. A total of 12 subjects were enrolled in this single center study. The primary objective of this study was to assess the technical feasibility of using Avance Nerve Graft for neurovascular bundle (NVB) reconstruction during Robotic Assisted Laparoscopic Prostatectomy (RALP). The secondary objective of the study was to assess the long-term safety and efficacy of NVB reconstruction by assessing quality of life and erectile function through validated questionnaires 24 months post-repair.

ASM-CP-001 is a registry study to evaluate the role of Avive Soft Tissue Membrane in the management of nerve injury following acute trauma. The study is designed to collect safety, functional and healthcare economic outcomes data in a select set of acute trauma injuries. The study is designed to enroll up to 200 subjects has enrolled an initial tranche of the planned subjects. All initial pilot subjects completed follow-up in December 2020.

Axogen is conducting a multicenter, prospective, randomized and subject blinded study of Axoguard Nerve Cap as compared to neurectomy for the treatment of systematic neuroma (REPOSE). REPOSE is a two-phase study comparing standard neurectomy to Axoguard Nerve Cap, a porcine small intestine submucosa-based nerve termination cap, which leverages Axogen's chambered technology to aid in the management of symptomatic neuromas. The first phase, a non-randomized pilot has completed enrollment and one-year follow-up. The second phase, a prospective, randomized controlled study, is actively enrolling. Overall enrollment is designed to target 101 subjects with 15 in the first pilot phase followed by up to 86 in the randomized, comparative phase. The study will assess pain scores, quality of life and health outcomes over a 12-month follow-up period.

In addition to these clinical research programs, Axogen is developing additional clinical trials in peripheral nerve repair, including mixed and motor nerve repair, breast neurotization and pain.

Clinical trials are subject to extensive recordkeeping and reporting requirements. Axogen's clinical trials must be conducted under the oversight of an IRB for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to, those relating to good clinical practices. Axogen is also required to obtain the patients' written informed consent in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. Axogen, the FDA or the IRB may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the biological product or device, or may otherwise not be sufficient to obtain FDA approval to market the product in the U.S. Similarly, in Europe, the clinical study for a medicine product must be authorized by the Competent Authority in each Member State in which the clinical trial is to be conducted, and must receive a favorable opinion from an ethics committee. See Risk Factors - Clinical trials can be long, expensive and results are ultimately uncertain, which could jeopardize our ability to obtain regulatory approval and continue to market our Avance Nerve Graft product.

Pervasive and Continuing Regulation

There are numerous regulatory requirements that apply after a product is cleared or approved. For medical devices, these include, but are not limited to: the FDA's regulations for device labeling (21 CFR Part 801), medical device reporting (21 CFR Part 803), reporting of corrections and removals (21 CFR Part 806), establishment registration and device listing requirements (21 C.F.R. Part 807); and compliance with the Quality System Regulation ("QSR") per 21 CFR Part 820. Distribution of medical devices is also subject to license/registration requirements in some states. For tissue and biologic products, the regulatory requirements include: the FDA's registration and listing requirements, donor eligibility requirements and compliance

with Good Tissue Practices ("GTP") in 21 CFR Part 1271 for human tissue products, compliance with the FDA's cGMP in 21 CFR Parts 210, 211, and 600 for licensed biological products, and post-market BLA requirements (21 CFR Part 601). Among other things, these regulations require manufacturers, including third party manufacturers to:

- follow stringent design, testing, control, documentation, and other quality assurance procedures during all aspects of the manufacturing process;
- comply with labeling regulations and FDA prohibitions against the false or misleading promotion or the promotion of products for uncleared, unapproved or off-label uses, or indications;
- comply with requirements to obtain clearance or approval for certain changes affecting the product, including changes to the product's manufacturing, labeling, or intended use;
- report to the FDA certain adverse events, adverse reactions, and deviations: (a) for medical devices, a report to FDA is required if the device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur; (b) for biologics, a deviation from current GMP or an unexpected or unforeseeable event that may affect the safety, purity, or potency of the product must be reported; and (c) for human tissue products, FDA requires reporting of certain adverse reactions involving a communicable disease related to an HCT/P that the company made available for distribution;
- comply with post-approval restrictions or conditions, including post-approval study commitments and post-market safety and annual reporting requirements;
- follow post-market surveillance regulations that may apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device; and
- follow requirements to issue notices of correction or removal, or conduct market withdrawals, or recalls where quality or other issues arise.

Axogen has not received any reports of adverse events where the event was determined to be product related for Avance Nerve Graft or Avive Soft Tissue Membrane products. Nine adverse events have been reported by Cook Biotech for the Axoguard products (one each in 2013, 2014, 2015, 2016, and 2020; and two each in 2017 and 2019). Axogen reported three (3) biological deviations (two in 2018 and one in 2019) for quality system issues related to human tissue distribution (no patient safety issues were involved). In December 2020, a Medwatch report was presented by the user facility for Avance Nerve Graft for a sizing issue and potential delay in procedure. Axogen follow up indicated that there was no delay in procedure and Axogen is filing subsequent information to the FDA on this event. Axogen has not had to submit any Medical Device Reports ("MDRs") or tissue adverse reaction reports to the FDA. Although Axogen's Axoguard products have had just nine adverse events reported to date, there may have been other incidents, including patient deaths, which may have occurred during procedures utilizing Axogen's products without Axogen being aware of any such incidents. In addition, there can be no assurance that in the future Axogen's products will not cause or contribute to an adverse event that would require Axogen to submit MDRs, biological deviation reports, or tissue adverse reaction reports to the FDA.

The advertising and promotion of medical products are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, some promotional activities for FDA-regulated products have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the Federal Lanham Act and similar state laws, competitors, and others can initiate litigation relating to advertising claims.

Axogen is registered with the FDA as a tissue establishment for Avance Nerve Graft and Avive Soft Tissue Membrane. The FDA has broad post-market and regulatory enforcement powers. Axogen is subject to unannounced inspections by the FDA to determine compliance with the GTP, GMP, and other regulations, and these inspections may also include the manufacturing facilities of suppliers.

Failure by Axogen or by Axogen's suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other federal or state authorities, which may include any of the following sanctions, among others:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications, repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- suspension or termination of our clinical trials;
- refusing our PMA or BLA for new products, new intended uses or modifications to existing products;
- withdrawing or spending premarket approvals that have already been granted; and
- criminal prosecution.

Education Grants, U.S. Anti-kickback, False Claims and Other Healthcare Fraud and Abuse Laws

Educational Grants

A medical product manufacturer may provide financial or in-kind support, including support by way of grants, to third-parties for the purpose of conducting medical educational activities. If these supported activities are considered by the FDA to be independent of the manufacturer, then the activities fall outside the FDA restrictions on promotion to which the manufacturer is subject.

The FDA considers several factors in determining whether an educational event or activity is independent from the substantive influence of the product manufacturer and therefore non-promotional, including but not limited to, the following: whether the intent of the funded activity is to present clearly defined educational content, free from commercial influence or bias;

- whether the third-party grant recipient and not the manufacturer has maintained control over selecting the faculty, speakers, audience, program content, and materials;
- whether the program focuses on a single product of the manufacturer without a discussion of other relevant existing competitive products or treatment options;
- whether there was meaningful disclosure to the audience, at the time of the program, regarding the manufacturer's funding or other support of the program, any significant relationships between the provider, presenters, or speakers and the supporting manufacturer; and whether any unapproved uses will be discussed;
- whether there are legal, business, or other relationships between the supporting manufacturer and provider or its employees that could enable the supporting manufacturer to exert influence over the content of the program;
- whether the individuals employed by the provider and involved in designing or conducting the educational activities are also involved in advising or assisting the company with respect to sales or marketing;
- whether the information about the company's products is further disseminated after the initial program, by or at the direction of the company, other than in response to an unsolicited request or through an independent provider; and
- whether the provider is compliant with standards for independence, balance, objectivity, and scientific rigor when putting on ostensibly independent educational programs.

Axogen seeks to ensure that the educational activities it supports through its grants program are in accordance with these criteria for independent educational activities. However, Axogen cannot provide assurance that the FDA or other government authorities would view the programs supported as being independent.

Fraud, Abuse and False Claims

Axogen is directly and indirectly subject to various federal and state laws governing relationships with healthcare providers and pertaining to healthcare fraud and abuse, including anti-kickback laws. In particular, the U.S. Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending a good or service for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs. Penalties for violations could include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. In implementing the statute, the Office of Inspector General of the U.S. Department of Health and Human Services ("OIG") has issued a series of regulations, known as "safe harbors." These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute for activities that fit within a safe harbor. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable element of a safe harbor may result in increased scrutiny by government enforcement authorities, such as the OIG, and may be "at risk" activities unless a favorable advisory opinion is obtained from the OIG.

The Federal False Claims Act ("FCA") imposes civil liability on any person or entity that submits, or causes the submission of, a false or fraudulent claim to the U.S. government. Damages under the FCA can be significant and consist of the imposition of fines and penalties. The FCA also allows a private individual or entity with knowledge of past or present fraud against the federal government to sue on behalf of the government to recover the civil penalties and treble damages. The DOJ has previously alleged that the marketing and promotional practices of pharmaceutical and medical device manufacturers included the off-label promotion of products or the payment of prohibited kickbacks to doctors violated the FCA resulting in the submission of improper claims to federal and state healthcare entitlement programs such as Medicaid. In certain cases, manufacturers have entered into criminal and civil settlements with the federal government under which they entered into plea

agreements, paid substantial monetary amounts and entered into corporate integrity agreements that require, among other things, substantial reporting and remedial actions going forward.

AdvaMed is one of the primary voluntary U.S. trade associations for medical device manufacturers. This association has established guidelines and protocols for medical device manufacturers in their relationships with healthcare professionals on matters, including research and development, product training and education, grants and charitable contributions, support of third-party educational conferences, and consulting arrangements. Adoption of the AdvaMed Code by a medical device manufacturer is voluntary, and while the OIG and other federal and state healthcare regulatory agencies encourage its adoption, they do not view adoption of the AdvaMed Code as proof of compliance with applicable laws. Axogen has incorporated the principles of the AdvaMed Code in its standard operating procedures, sales force training programs, and relationships with doctors. Key to the underlying principles of the AdvaMed Code is the need to focus the relationships between manufacturers and healthcare professionals on matters of training, education and scientific research, and limit payments between manufacturers and healthcare professionals to fair market value for legitimate services provided and payment of modest meal, travel and other expenses for a healthcare professional under limited circumstances. Axogen has incorporated these principles into its relationships with healthcare professionals under its consulting agreements, payment of travel and lodging expenses, research and educational grant procedures and sponsorship of third-party conferences. In addition, Axogen has conducted and will continue to conduct training sessions on these principles. Finally, the Sunshine Act, as defined below, imposes additional reporting and disclosure requirements on Axogen for any "transfer of value" made or distributed to physicians and teaching hospitals, as well as reporting of certain physician ownership interests. Axogen cannot provide any assurance that regulatory or enforcement authorities will view its relationships with physicians or policies as being in compliance with applicable regulations and laws.

Regulation Outside of the United States

Distribution and sales of medical products outside of the U.S. are subject to foreign governmental regulations that vary substantially from country to country. The time required to obtain certification or approval by a foreign country may be longer or shorter than that required for FDA clearance or approval and the requirements may be different.

There are restrictions under U.S. law on the export from the U.S. of medical devices and biological product that cannot be legally distributed in the U.S. If a Class I or Class II device does not have 510(k) clearance and the manufacturer reasonably believes that the device could obtain 510(k) clearance in the U.S., then the device can be exported to a foreign country for commercial marketing without the submission of any type of export request or prior FDA approval if: (i) the device is not sold or offered for sale in the U.S., (ii) is labeled for export only and (iii) satisfies certain criteria relating primarily to specifications of the foreign purchaser and compliance with the laws of the country to which it is being exported, known as Importing Country Criteria. An unapproved Class III device can be exported if it: (i) complies with the criteria discussed above for devices that could obtain 510(k) clearance, (ii) meets certain other quality and labeling requirements, and (iii) has a valid marketing authorization from one of a list of countries listed in the FD&C Act. If an unapproved Class III device does not have a valid marketing authorization from one of the listed countries, an export permit from the FDA is required in order to export it. An unapproved biological product can be exported without submitting an export request to FDA if the product has received a marketing authorization in one of a list of countries listed in the FD&C Act and it meets applicable requirements of the FD&C Act and the laws of the country to which it is exported. An investigational biological product may also be exported under an IND if a listed investigator is in a foreign country and certain requirements specified in FDA's regulations are met. Axogen currently believes it complies with applicable regulations when exporting its products and Axogen intends to continue such compliance in the event there are any regulatory changes regarding its products in the United States.

The primary regulatory body in Europe is the E.U. which has adopted numerous directives and promulgated voluntary standards regulating the design, manufacture and labeling of, and clinical trials and adverse event reporting for, medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear CE marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the member states of the E.U. and other countries that comply with these directives. The method for assessing conformity varies depending on the type and class of the device, but normally involves an assessment by the manufacturer and a third-party assessment by a notified body, an independent and neutral institution appointed by a country to conduct the conformity assessment. This third-party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's device. Such an assessment is required for a manufacturer to commercially distribute the product throughout these countries. In the second quarter of 2014, Axogen's Quality System became registered to ISO 13485 for Receipt, Handling, Storage and Distribution of Axoguard Nerve Connector and Axoguard Nerve Protector and Axogen has maintained the registration through 2023.

Cook Biotech is responsible for all regulatory filings for the Axoguard Connector and Protector products, including international registrations. Axogen works with Cook Biotech by providing the countries for Cook to register or get approval for

these Axoguard products. Cook Biotech prepares the product filing documentation and submits this documentation to the Ministry of Health ("MOH") for the country. Each country or region has its own regulations and the documentation required for submission varies. It typically takes less than nine months from the initiation of the project to obtain clearance in a given country or region. To date, the Axoguard Connector and Protector product lines were registered in May 2013 in Canada for distribution and in April 2013 the product lines were awarded the CE Mark allowing distribution into the E.U. and other countries that accept the CE Mark. Cook Biotech received the renewal of the CE Mark for Axoguard Nerve Connector and Axoguard Nerve Protector in March 2020.

In addition, the new European Medical Device Regulation ("EU MDR") passed in the European Parliament on April 5, 2017 and went into effect on May 25, 2017, replacing the Medical Device Directive. The EU MDR is an extensive reform of the rules that govern the medical device industry in Europe. Under this regulation, manufacturers will have through May 2021 to comply with a broad set of new rules for almost every kind of medical device. The EU MDR will require changes in the clinical evidence required for medical devices, post-market clinical follow-up evidence, annual reporting of safety information for Class III products, and bi-annual reporting for Class II products, Unique Device Identification ("UDI") for all products, submission of core data elements to a European UDI database prior to placement of a device on the market, reclassification of medical devices, and multiple other labeling changes.

Under the new EU MDR rules, medical device companies will have to, among other things. do the following:

- provide significantly more clinical evidence to get new products to market and even to keep existing products on the market;
- make changes to product labeling and make certain product data available to the public; and
- conduct product portfolio assessments to determine the impact of the EU MDR on the Company's margins.

Overall, medical device companies can expect longer lead times to obtain product registrations (CE Mark Certification) in the EU and a substantially costlier pathway to compliance in the EU. We are not yet able to determine the costs of complying with these regulations, how the EU will interpret and enforce them, what the timelines for approvals of products will be and the overall effect of the EU MDR on the marketplace. Given the significant additional pre-market and post-market requirements imposed by the EU MDR, the overall impact of these new rules could have a material, adverse effect on the Company's revenue and expenses.

The UK left the E.U. in January 2020. From January 2020 to until December 31, 2020, E.U. Law remained applicable thus the placement on the market of medical devices continued uninterrupted on both sides of the English Channel and the notified body certificates remained valid while the UK and E.U. negotiated new arrangements. Axogen registers its human tissue products in each individual E.U. country and each distributor in the UK has import authority for Axogen's human tissue product. It is expected that licensed UK establishments that import or export tissues or cells will need written agreements with the relevant E.U. licensed establishments to continue importing and exporting with the E.U. As Axogen ships directly to the UK from the U.S., we expect no delays in shipment of human tissue products into the UK in 2021. Further, the RANGER clinical trial being performed at select hospitals in the UK would not be affected by Brexit as long as the products continue to come directly from the U.S. Beginning January 1, 2021, new changes became effective as the transition period for the UK's exit from the E.U. ended. Specifically, all medical devices placed into the UK market will need to be registered, subject to applicable grace periods, with the Medicines and Healthcare products Regulatory Agency, will need to appoint a UK Responsible Person, and comply with additional product marking and conformity assessment requirements. Medical devices must be registered with the MHRA if they are being placed on the Great Britain market after May 1, 2021. Cook Biotech is responsible for appointing the UK Responsible Person and registering Axoguard Nerve Connector and Axoguard Nerve Protector in UK.

Tissue products are not currently regulated under the CE Mark

Axogen is responsible for all regulatory filings for Avance Nerve Graft and Avive Soft Tissue Membrane including international registrations. To obtain approvals Axogen will prepare the product filing documentation and submit this documentation to the Ministry of Health ("MOH") for a country.

Although some standards of harmonization exist, each country in which Axogen conducts business has its own specific regulatory requirements. Axogen procures and processes its tissue for the Avance Nerve Graft and Avive Soft Tissue Membrane in the U.S., and markets the Avance Nerve Graft in Canada, the United Kingdom, and certain other countries under compliance with the individual country regulations. These requirements are dynamic in nature and, as such, are continually changing. New regulations may be promulgated at any time and with limited notice. Axogen will review the regulations at the time of submission of the product dossier for regulatory review. This review involves reviewing the appropriate MOH regulations, discussion with in-country distributors and use of consultants. It typically takes less than nine months from the initiation of the product to develop a product dossier (specific for that country), submission of the documentation and MOH review of the product filing. While Axogen believes that it is in compliance with all existing pertinent international and

domestic laws and regulations, there can be no assurance that changes in governmental administrations and regulations will not negatively impact Axogen's operations. Avive Soft Tissue Membrane is currently available in the U.S. and has received regulatory registration allowing for distribution in Canada, UK and Austria.

The FDA and international regulatory bodies conduct periodic compliance inspections of Axogen's U.S. processing facilities. Axogen's operations are registered with FDA CBER, as a tissue establishment. Axogen is also accredited by the AATB and is licensed in the states of Florida, New York, California, Maryland, Delaware, Oregon and Illinois. Axogen believes that worldwide regulation of tissue products is likely to intensify as the international regulatory community focuses on the growing demand for these implant products and the attendant safety and efficacy issues of recipients. Changes in governing laws and regulations could have a material adverse effect on Axogen's financial condition and results of operations. Axogen management further believes that it can help to mitigate this exposure by continuing to work closely with government and industry regulators.

Environmental

Axogen's products, as well as the chemicals used in processing, are handled and disposed of in accordance with country-specific, federal, state and local environmental regulations. Since 2007, Axogen has used outside third parties to perform all biohazard waste disposal.

Axogen contracts with independent, third parties to perform sterilization of its allografts. Because of the engagement of a third party to perform irradiation services, the requirements for compliance with radiation hazardous waste do not apply, and therefore Axogen does not anticipate that this engagement will have any material adverse effect upon its capital expenditures, results of operations or financial condition. However, Axogen is responsible for assuring that the service is being performed in accordance with applicable regulations. Although Axogen believes it is in compliance with all applicable environmental regulations, the failure to fully comply with any such regulations could result in the imposition of penalties, fines and/or sanctions which could have a material adverse effect on Axogen's business.

Human Capital

At December 31, 2020, we had approximately 368 total employees, including approximately 22 part-time employees and approximately 346 full-time employees.Of these employees, 84 work in corporate, 157 work in sales, 66 work in operations, and 39 work in research and development. As of the date of this annual report on Form 10-K we have not had a work stoppage and no employees are represented by a labor union. In 2020 and in response to the COVID-19 pandemic, we implemented (i) an employee layoff of approximately 10% of our workforce, (ii) implemented a hiring freeze (with very limited exceptions), and (iii) temporary salary reductions across the organization with full salaries being reinstated for most employees in August 2020, and for executive officers and board members in late October. We believe our relationship with our employees is satisfactory. We encourage our employees to be effective stewards of the gift of human tissue. We believe in creating and maintaining a culture that encourages and rewards honesty, openness, and passionate debate among its employees, respect is the foundation for communication and action, and patient safety is our first priority.

Corporate History

On September 30, 2011, Axogen Corporation ("AC"), a Delaware corporation, completed its business combination with LecTec Corporation ("LecTec"), a Minnesota corporation, in accordance with the terms of an Agreement and Plan of Merger, dated as of May 31, 2011, by and among LecTec, Nerve Merger Sub Corp., a subsidiary of LecTec ("Merger Sub"), and AC, which the parties amended on August 9, 2011 and September 30, 2011 (as amended, the "Merger Agreement"). Pursuant to the Merger Agreement, Merger Sub merged with and into AC, with AC continuing after the merger as the surviving corporation and a wholly owned subsidiary of LecTec (the "Merger"). Immediately following the Merger, LecTec changed its name to Axogen, Inc. In October 2011, Axogen Inc. moved its corporate headquarter facilities (principal executive office) from Texarkana, Texas to Alachua, Florida.

Our website address is http://www.Axogeninc.com. We have included our website address as an inactive textual reference only. We make available, free of charge through our website, our annual reports on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material, or furnish it to the SEC. We also similarly make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. Reference to our website, or any other website, does not constitute incorporation by reference of the information contained on the site and should not be considered part of this Annual Report on Form 10-K.

Executive Officers of the Registrant

The following table lists the names and positions of the individuals who are, as of February 24, 2021, executive officers of Axogen:

Name	Title
Karen Zaderej	Chairman, Chief Executive Officer and President
Peter J. Mariani	Chief Financial Officer
Brad Ottinger	General Counsel and Chief Compliance Officer
Eric A. Sandberg	Chief Commercial Officer
Maria Martinez	Chief Human Resources Officer
Isabelle Billet	Chief Strategy and Business Development Officer
Angelo G. Scopelianos, Ph.D.	Chief Research and Development Officer
Erick DeVinney	Vice President of Clinical and Translational Sciences
Mike Donovan	Vice President of Operations
Mark Friedman, Ph.D.	Vice President of Regulatory Affairs and Quality Assurance

Biographical information for each of our executive officers is included below.

Karen Zaderej, Chairman, Chief Executive Officer and President (Age 59)

Ms. Zaderej joined Axogen Corporation in May 2006. Karen has served as President, Chief Executive Officer, and a Member of our board of directors (the "Board of Directors") since September 2011 and became Chairman of the Board of Directors in May 2018. She has served as Chief Executive Officer and as a member of the Board of Directors of Axogen Corporation since May 2010 and as Chief Operating Officer from October 2007 to May 2010 and as Vice President of Marketing and Sales from May 2006 to October 2007. From October 2004 to May 2006, Ms. Zaderej worked for Zaderej Medical Consulting, a consulting firm she founded, which assisted medical device companies build and execute successful commercialization plans. From 1987 to 2004, Ms. Zaderej worked at Ethicon, Inc., a Johnson & Johnson company, where she held senior positions in marketing, business development, research & development, and manufacturing. Ms. Zaderej is a member of the University of Tampa Board of Trustees and the MedExec Women Board of Advisors. She has an MBA from the Kellogg Graduate School of Business and a BS in Chemical Engineering from Purdue University.

Peter Mariani, Chief Financial Officer (Age 57)

Mr. Mariani has been Axogen's Chief Financial Officer since March 2016. He brings more than 25 years of experience as a financial executive in private and public companies. He previously served as Chief Financial Officer of Lensar, Inc, a privately held laser refractive cataract surgery company, from July 2014 through January 2016, following the sale of Lensar in December 2015. From June 2011 to June 2014 he served as Chief Financial Officer of Hansen Medical, a publicly traded medical device company developing robotic solutions for intravascular procedures. From 2007 through 2010 he served as Chief Financial Officer for two privately held companies (Harlan Laboratories: 2007 – 2009; and BMW Constructors: 2009 – 2010). From 1994 through 2006 he served in various senior financial roles with Guidant Corporation, a publicly traded leader in the development and sale of medical devices for the treatment of cardiovascular disease. Mr. Mariani began his career with Guidant as Director of Corporate Financial Reporting where he supported the initial IPO of Guidant and ultimately served as Vice President, Controller and Chief Accounting Officer. His experience at Guidant included two years as Director of Financial Reporting, Guidant Vascular Intervention in Santa Clara, California, and four years in Tokyo, Japan, mostly as Vice President Finance and Administration. While in Japan he helped to facilitate the conversion and scale of the Japan business from a distributor network to a direct sales and marketing organization. Following the 2006 sale of Guidant to Boston Scientific Corporation, he co-led the initial integration of the two companies. From 1987 to 1994 Mr. Mariani worked with Ernst and Young, LLP, where he served a diverse client base as a Certified Public Accountant (CPA). Mr. Mariani received a Bachelor of Science Degree in Accounting from Indiana University.

Brad Ottinger, JD, General Counsel (Age 51)

Mr. Ottinger joined Axogen as General Counsel and Chief Compliance Officer on June 1, 2020. Prior to joining Axogen, Mr. Ottinger most recently served as the Vice President, General Counsel, Chief Administrative Officer, and Secretary of MicroPort Orthopedics Inc., a wholly owned subsidiary of Shanghai-based MicroPort Scientific Corporation a manufacturer of total hip and knee implants, from October 2017 to January 2020. From March 2015 until October 2017, Mr. Ottinger served as MicroPort's Vice President, Legal, Compliance, and Human Resources, having joined MicroPort as Associate General Counsel

in January 2014. From March 2015 until his departure, Mr. Ottinger also served as a member of MicroPort Scientific's Intercontinental Executive and Intercontinental Orthopedics Committees. Mr. Ottinger joined MicroPort following his tenure with Buckeye Technologies Inc., where from December 2011 to January 2014 he served as Associate General Counsel, providing a breadth of legal services to the enterprise, with a primary focus on corporate transactions. Prior to joining Buckeye Technologies, Mr. Ottinger concentrated his private practice in securities law/litigation and corporate transactions with both an international and domestic focus and used that foundation to develop expertise in corporate compliance and ethics with which he maintains professional certifications. Prior to attending law school, Mr. Ottinger worked with Accenture (FKA, Andersen Consulting) as a Management Consultant and with First Horizon Bank (FKA/First Tennessee Bank) in Human Resources delivering management development programs and managing succession planning. Mr. Ottinger holds a J.D. from Washington University in St. Louis, an M.Ed. from Vanderbilt University, and a B.A. in Liberal Arts from the Pennsylvania State University.

Eric A. Sandberg, Chief Commercial Officer (Age 56)

Mr. Sandberg has served as Axogen's Chief Commercial Officer since January 2019. Mr. Sandberg has extensive leadership experience in commercializing medical technologies. He held leadership positions across sales, marketing, corporate accounts, and business development during a 12 plus year career at medical device manufacturers Guidant Corporation and Boston Scientific. While at Guidant, Mr. Sandberg built and led commercial teams that challenged the standard of care with innovative new solutions; including the Company's first coronary stent system, which achieved market leadership in three months post launch and generated $700 million in sales within 15 months. He built and led the sales organization for CardioDx, a genomic diagnostic company, spearheading efforts to launch and create market demand for the company's inaugural product. As President and CEO for Tangent Medical Technologies, Mr. Sandberg led all aspects of the company as it commercialized an innovative IV catheter system. Most recently, he served as CEO for Visura Technologies, successfully leading the development, patenting, FDA process, and commercialization of a novel transesophageal echocardiography camera assist device system, and as Chief Business Officer of gene therapy company Rhythm Therapeutics. Mr. Sandberg earned an MBA from Harvard Business School and a Bachelor of Science degree from Bradley University.

Maria Martinez, Chief Human Resources Officer (Age 53)

Ms. Martinez has served as Axogen's Chief Human Resources Officer since October 2018. She brings more than 25 years of human resources leadership experience to the company. From January 2018 until joining AxoGen as Chief Human Resources Officer, Ms. Martinez provided HR consulting and leadership services through her firm MDM Consulting Services, LLC. From June 2014 to December 2017 Ms. Martinez served as Chief Human Resources Officer at HSNi, a $4 billion direct to consumer retail portfolio with more than 7,000 employees in nine locations. She held the SVP Talent Management role at HSNi from July 2010 until June 2014 when she was promoted. Ms. Martinez originally joined HSN as Manager in 1995 and left the company in 2005 as Vice President, Human Resources. From September 2008 to June 2010, Ms. Martinez served as the Vice President, Human Resources for Laser Spine Institute, an organization dedicated to performing minimally invasive spine surgery, where she established the company's human resources function and supported the expansion of the organization's business to multiple sites. She held the role of Human Resources leader for Bausch & Lomb's U.S. Pharmaceutical division from April 2007 to September 2008. From July 2005 to April 2007, she served as Sr. Director Human Resources for Darden Restaurants. Ms. Martinez serves on the Board of Directors of Good360, a national not for profit organization, and on the Board of Managers of MGT Consulting, LLC. Ms. Martinez earned a Master of Science degree in Industrial/Organizational Psychology from Florida Institute of Technology, a B.S. degree in Psychology and a B.A. degree in French from the University of South Florida.

Isabelle Billet, Chief Strategy and Business Development Officer (Age 59)

Ms. Billet has served as Axogen's Chief Strategy and Business Development Officer since October 2018. She brings more than 30 years of global medical device strategy, marketing, and business development experience to the company. From July 2013 until joining the Company as Chief Strategy and Business Development Officer, Ms. Billet worked for IBHC Advisors LLC, a consulting firm she founded. IBHC assisted medical device companies with developing organic and inorganic growth strategies and supported private equity firms on their investment strategy and due diligence. Ms. Billet worked at Cardinal Health, Inc. from 2010-2013, where she served as Senior Vice President of Marketing and Innovation for the Medical segment focusing on their private brand portfolio development. She was Vice President Marketing and New Business Development for C.R. Bard Medical division from 2005-2010. She worked for Johnson & Johnson from 1992 to 2005, splitting her tenure between Advanced Sterilization Products and Ethicon, Inc. in positions of increasing responsibilities in marketing and new business development in France, Europe, and the U.S. Ms. Billet spent the first seven years of her career as the head pharmacist and material manager for a private hospital in France. Ms. Billet is a member of the Clinical Innovations Board of Directors. She earned an MBA from EM Lyon Business School, France and Cranfield School of Management, UK and a Doctorate in Pharmacy from Montpellier University in France.

Angelo G. Scopelianos, Ph.D., Chief Research and Development Officer (66)

Dr. Scopelianos has served as Axogen's Vice President of Research and Development since September 2018 and on January 4, 2021, began serving as the Chief Research and Development Officer. From 2012 until joining Axogen, Dr. Scopelianos was an independent consultant specializing in medical devices. He began consulting after his retirement from a 24-year tenure at Johnson & Johnson (J&J). Angelo began at J&J in 1988 as section manager of R&D and held the escalating positions of manager of R&D, director of R&D, vice president of R&D and finally from October 2010 to September 2012 senior vice president of R&D. He joined J&J after research leadership positions at EI Dupont de Nemours in Wilmington, Delaware, and Pennwalt Corporation. Angelo received his doctorate degree in organic chemistry from Pennsylvania State University, following completion of a Bachelor of Science degree from the State University of New York—Oneonta. He holds over 35 U.S. patents and numerous international patents, and his awards include the Outstanding Science Alumni Award by Penn State University; the Scientific Leadership Award in Biomaterials Science awarded by a consortium of NJ research universities.

Erick DeVinney, Vice President of Clinical and Translational Sciences (Age 45)

Mr. DeVinney has served as Axogen's Vice President of Clinical and Translational Sciences since January 2014. From April 2007 until January 2014, Mr. DeVinney was the Director of Clinical and Translational Sciences for Axogen. Mr. DeVinney has over 18 years of experience in the successful planning and management of clinical trials. He has diverse background, including research at a large academic facility and management of clinical operations for a medical device and pharmaceutical company. Mr. DeVinney has been involved in clinical research at Medical College of Virginia Hospitals, National Clinical Research, PRA International and Angiotech. He has been involved in the successful submission of eight IDE or NDA applications, as well as numerous 510(k)s. He has a B.S. in chemistry from Virginia Commonwealth University.

Mike Donovan, Vice President of Operations (Age 56)

Mr. Donovan has served as Axogen's Vice President of Operations since September 2015. Prior to September 2015, Mr. Donovan was Axogen's Director of Operations from January 2011 until September 2015. From 1988 to 2010, Mr. Donovan held positions at Zimmer Holdings in manufacturing, continuous improvement, quality assurance, and sterilization, including Director of Manufacturing from 2002 to 2010. Mr. Donovan has a BS in Chemical Engineering and an MBA from the University of Akron.

Mark Friedman, Ph.D., Vice President of Regulatory Affairs and Quality Assurance (Age 63)

Dr. Friedman has served as Axogen's Vice President of Regulatory Affairs and Quality Assurance since November 2011. He has also served as Axogen's Director of Quality Assurance and Regulatory Affairs from September 2006 to June 2011. Prior to joining Axogen, Dr. Friedman held several regulatory and quality leadership positions at Enable Medical Corporation, a medical device company, including Director of Quality Assurance from 1997 to 1998 and Vice President of Quality and Regulatory from 1998 to 2001 and from 2004 to 2005. Dr. Friedman also worked for AtriCure, Inc., a company that develops, manufactures and sells surgical ablation systems to treat atrial fibrillation, as Vice President of Quality and Regulatory from 2001 to 2004 and as Vice President of Operations in 2004. AtriCure acquired Enable Medical in 2005. Dr. Friedman has over 24 years of experience in developing and directing regulatory strategy and quality systems for medical products, including 15 years with startup medical product firms. Dr. Friedman has a Ph.D. in Chemistry specializing in protein biochemistry from the University of Cincinnati.

ITEM 1A. RISK FACTORS

Our business involves a number of risks, some of which are beyond our control. The risk and uncertainties described below are not the only ones we face. Set forth below is a discussion of the risks and uncertainties that management believes to be material to us.

Risks Related To The Company

Our revenue growth depends on our ability to increase distribution and sales to existing customers and develop new customers, domestically and abroad, and there can be no assurance that these efforts will result in significant increases in sales.

Beginning in 2020, and in part as response to the COVID-19 pandemic, we adjusted our commercial strategy to focus on deeper penetration of our existing surgeon customers through the development of long-term users of Avance in our largest market opportunity of extremity trauma. Throughout the pandemic, we kept the sales team and broader commercial organization intact and took the opportunity to provide extensive sales training. Our sales team developed new skills and shared best practices for remote case support in hospitals where access was restricted. We believe this remote support has been appreciated by customers and has expanded the sales team's ability to support customers during COVID-19 and beyond. We believe that near-term growth can be supported first through expanded productivity of our existing sales force with existing customers and accounts and second by adding additional customers. We expect the number of direct sales professionals to increase over time. Additionally, we have successfully utilized a hybrid commercial approach that includes the use of independent agencies in more remote geographies in order to provide appropriate local support for customers, without the travel time required of a direct sales representative. We anticipate that we will continue to add to the number of independent sales agencies as it continues to drive higher productivity and efficiency with our direct sales force. We may also need to establish a regional distribution center or centers at some point in the future to account for growth. The incurrence of these expenses may impact our operating results, and there can be no assurance of their effectiveness. If we are unable to increase sales to existing customers and attract new customers, and develop our sales force, there could be a material adverse impact on our business, results of operations, financial condition, and prospects.

Our revenue depends primarily on five products.

Substantially all of our revenue is currently derived from five products, Avance Nerve Graft, Avive Soft Tissue Membrane, Axoguard Nerve Protector, Axoguard Nerve Connector, and Axoguard Nerve Cap for the treatment of peripheral nerve damage. Of these five products, Avance Nerve Graft represents approximately half of the Company's total revenue. Any disruption in our ability to generate revenue from the processing, distribution, and sale of products will have a material adverse impact on our business, results of operations, financial condition, and prospects.

Avance Nerve Graft and Avive Soft Tissue Membrane processing consists of several steps and we use a number of recovery and/or acquisition agencies to supply the human tissue needed for these products. While we believe our current contracts and the ability to enter into future contracts will provide us with the tissues required for the products, we cannot be sure that we will be able to obtain the tissue that we need in the future. Disruptions in the tissue supply may adversely impact both tissue products and our overall business.

Axoguard Nerve Connector and Axoguard Nerve Protector are only available through the Cook Biotech Distribution Agreement. The Distribution Agreement was amended February 26, 2018 to extend the termination date to June 30, 2027. However, there are conditions for continuation of the agreement, including payment terms and minimum purchase requirements, that if breached could result in an earlier termination of the agreement. Through mutual agreement, the parties have not established such minimums and to date have not enforced such minimum purchase provision. Additionally, in the event that we and Cook Biotech were to fail to reach an agreement as to minimum purchase quantities, Cook Biotech could terminate the agreement if it was deemed that we had failed to generate commercially reasonable sales of Axoguard as measured by sales similar to a competitive product at the same stage in its commercial launch as verified by a mutually acceptable third party. We distribute the Axoguard Nerve Connector and Axoguard Nerve Protector for Cook Biotech, and Cook Biotech is the contract manufacturer for our Axoguard Nerve Cap. Although we believe we could develop or obtain products that would replace the Axoguard products obtained through the Cook Biotech agreements, the loss of the ability to sell the Axoguard products could have a material adverse effect on our business, results of operations, financial condition, and prospects.

Our success will be dependent on continued acceptance of our products by the medical community.

Continued market acceptance of our products will depend on our ability to demonstrate that our products are an attractive alternative to existing or new nerve reconstruction treatment options, including both surgical techniques and products. Our ability to do so will depend on surgeons' evaluations of clinical safety, efficacy, ease of use, reliability, and cost-effectiveness, including insurance reimbursement, of our nerve repair products. For example, although our Avance Nerve Graft follows stringent safety standards, including sterilization by gamma irradiation, we believe that a small portion of the medical community has lingering concerns over the risk of disease transmission through the use of allografts in general. If the medical community and patients do not ultimately accept our products as safe and effective or we are unable to raise awareness of our products and processes, our ability to sell the products may be materially and adversely affected, and our business, results of operations, financial condition, and prospects may be adversely affected.

We have not consistently experienced positive cash flow from our operations, and the ability to achieve consistent, positive cash flow from operations will depend on increasing revenue from distribution of our products, which may not be achievable.

We have historically operated with negative cash flow from our operations. As of December 31, 2020, we had an accumulated deficit of approximately $203.6 million. If revenue does not increase as anticipated, then we will continue to experience negative cash flows and adverse operating conditions. In June 2020, we entered into a seven year $70 million debt facility with Oberland Financial, the proceeds of which are expected to be used for working capital and general corporate purposes. As our debt obligations mature or if our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay investments and capital expenditures, or to sell assets, seek additional capital, or restructure or refinance our indebtedness. Our ability to restructure or refinance our debt will depend on the condition of the capital markets and our financial condition at such time. Any refinancing of our debt could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict our business operations. If we raise funds by selling additional equity, such sale would result in dilution to our stockholders. There is no assurance that if we are required to secure funding, we can do so on terms acceptable to us, or at all.

We are highly dependent on the continued availability of our facilities and could be harmed if the facilities are unavailable for any prolonged period of time.

Any failure in the physical infrastructure of our facilities, including the facility we license from CTS, could lead to significant costs and disruptions that could reduce our revenue and harm our business reputation and financial results. Any natural or man-made event that impacts our ability to utilize our facilities could have a material impact on our business, results of operations, financial condition, and prospects. This includes termination of the CTS Agreement, which is set to expire on December 31, 2022, subject to earlier termination by either party at any time for cause (subject to the non-terminating party's right to cure, in certain circumstances), or without cause by us upon 6 months prior notice whereby such notice cannot be provided until March 1, 2021. We believe we can find and make operational a new licensed facility in less than six months, if required. In addition, we acquired property that is located near the CTS facility and it is expected that renovations will be completed by the termination date of the CTS Agreement to provide a new processing facility that can be included in our BLA for the Avance Nerve Graft. However, renovations and the regulatory process for approval of facilities whether licensed or owned is time-consuming and unpredictable. It could cause a significant disruption in service to our customers if we were to lose, even temporarily, the availability of our production or distribution facilities. In addition, we may plan to open additional office, lab or distributions space in the future, and our ability to license, renovate, rebuild or find acceptable service facilities takes a considerable amount of time and expense. Although we have business interruption insurance that would, in instances other than service agreement termination, cover certain costs, it may not cover all costs nor help to regain our standing in the market.

Technological change and competition for newly developed products could reduce demand for our products.

The medical technology industry is intensely competitive. We compete with both U.S. and international entities that engage in the development and production of medical technologies and processes including:

- biotechnology, orthopedic, pharmaceutical, biomaterial, chemical, and other companies;
- academic and scientific institutions; and
- public and private research organizations.

Our products compete with autograft, hollow-tube conduits, commercially available wraps and amnion products, as well as with alternative medical procedures. For the foreseeable future, we believe a significant number of surgeons will continue to choose to perform autograft procedures when feasible, despite the necessity of performing a second operation and its drawbacks. In addition, many members of the medical community will continue to prefer the use of hollow-tube conduits due in

part to their familiarity with these products and the procedures required for their use. Amnion products are widely available and we may not be able to distinguish the Avive Soft Tissue Membrane from such other products so as to produce significant revenue from its distribution. Also, steady improvements have been made in synthetic human tissue substitutes, which could compete with our products in the future. Unlike allografts, synthetic tissue technologies are not dependent on the availability of human or animal tissue. Although our growth strategy contemplates the introduction of new technologies, the development of these technologies is a complex and uncertain process, requiring a high level of innovation, as well as the ability to accurately predict future technology and market trends. We may not be able to respond effectively to technological changes and emerging industry standards, or to successfully identify, develop or support new technologies or enhancements to existing products in a timely and cost-effective manner, if at all. There can be no assurance that in the future our competitors will not develop products that have superior performance or are less expensive relative to our products rendering our products obsolete or noncompetitive. In this regard, Integra and Baxter each have or will commercialize a product consisting of a hollow tube conduit filled with material which they suggest is superior to their current hollow conduit products. Due to our limited resources, our smaller size and our relatively early stage, we may face competitive challenges from these new products or existing products and barriers that are difficult to overcome and could negatively impact our growth. Finally, a Chinese company provides a human peripheral nerve allograft in China, however, such product is not sold in our markets of interest because the protection afforded by our intellectual property.

We must maintain high quality processing of our products.

Our Avance Nerve Graft is processed through our Avance Process, which requires careful calibration and precise, high-quality processing and manufacturing. Our Avive Soft Tissue Membrane is also human tissue that requires skill in its processing. Achieving precision and quality control requires skill and diligence by our personnel. If we fail to achieve and maintain these high levels of quality control and processing standards, including avoidance of processing errors, defects or product failures, we could experience recalls or withdrawals of our product, delays in delivery, cost overruns or other problems that would adversely affect our business. We cannot completely eliminate the risk of errors, defects or failures and could experience quality system issues where corrective actions must be taken. In addition, we may experience difficulties in scaling-up processing of our Avance and Avive products, including problems related to yields, quality control and assurance, tissue availability, adequacy of control policies and procedures, and lack of skilled personnel. If we are unable to process and produce our human tissue products on a timely basis, at acceptable quality and costs, and in sufficient quantities, or if we experiences unanticipated technological problems or delays in production, our business, results of operations, financial condition, and prospects would be adversely affected.

Our revenue depends upon prompt and adequate reimbursement from public and private insurers and national health systems.

Political, societal, economic, and regulatory influences are subjecting the U.S. healthcare industry to fundamental change. The ability of a hospital or an ambulatory surgery center (“ASC”) to pay fees for our products depends in part on the availability of adequate coverage and reimbursement from third-party payors for either our products specifically, the procedures associated with the use of our products, or both. Providers that purchase our products generally rely on third-party payors to reimburse all or part of the costs and fees associated with the procedures performed with our products or the products themselves. Adequate coverage and reimbursement from third-party payors, including governmental payors such as Medicare and Medicaid, therefore, is important for obtaining product acceptance and widespread adoption in the marketplace.

When our products (Avance Nerve Graft, Axoguard Nerve Connector, Axoguard Nerve Cap, Axoguard Nerve Protector, and Avive Soft Tissue Membrane) are used in the operating room of a hospital, they are commonly treated as general supplies utilized in surgery, and the cost is included in payment to the facility for the procedure. When Avance Nerve Graft and Axoguard Connector are used in an outpatient setting where the nerve repair is the primary reason for the procedure, facilities may use a Category I CPT code to facilitate payment.

In January 2018, the American Medical Association created a Category I CPT code (64912) specific to nerve repair with nerve allograft (Avance Nerve Graft) and a separate code (+64913) for each additional strand of allograft used in a procedure. Category I CPT codes are used by providers to facilitate payment to the provider (either hospital or ASC) for outpatient procedures. Additionally, Category I CPT codes are used to facilitate payment to the surgeon, for both time spent in outpatient and inpatient procedures. Prior to January 2018, there was no designated Category I CPT code for nerve repair cases that included nerve allograft. The Category I CPT code specific to nerve repair with nerve allograft, has allowed for nerve allograft repair cases to be uniquely identified in the Medicare claims data. This in turn allowed CMS visibility to nerve allograft nerve procedure costs, and thereby confirm nerve allograft qualified as a device intensive procedure.

Another important change in nerve repair reimbursement occurred in January 2020, when most direct repair procedures were moved to from the higher paying level 2 nerve repair Ambulatory Payment Category (APC) 5432 to the lower paying level 1 APC 5431, thus aligning payment rates more consistently with the lesser costs of a direct repair.

As a result of the allograft device intensive status and direct repair APC realignment, CMS reimbursement rates for nerve repair in the outpatient setting have changed significantly during the last two years. With the new 2021 CMS reimbursement rates for nerve repair in the outpatient setting that were effective January 1st, reimbursement for procedures using Avance have increased 25% in hospital outpatient centers and 97% in ambulatory surgery centers since 2019. During this same timeframe, reimbursement rates for procedures involving conduits and connectors also increased 25% in hospital outpatient centers and 45% in ambulatory surgery centers. While Medicare patients represent a relatively small percentage of trauma cases, CMS' direction often influences commercial payor policies and payments.

The process for securing coding for a product or procedure is separate from the process of securing coverage and establishing a reimbursement payment rate. In the U.S., coverage and reimbursement for medical devices vary among payors. In addition, payors review coverage policies on an ongoing basis and can, without notice, change or deny coverage for these new products and procedures. We estimate that commercial payors covering a significant number of U.S. covered lives have legacy non-coverage policies relating to our Avance Nerve Graft, Avive Soft Tissue Membrane, and our Axoguard product lines, designating these products investigational or experimental. Some commercial payors do not currently cover or reimburse our products because they have determined insufficient evidence of favorable clinical outcomes is available. Although some payors consider Avance Nerve Graft, Avive Soft Tissue Membrane, and our Axoguard product lines investigational or experimental at this time, these payors may in the future determine sufficient evidence has been developed to cover and reimburse our products and related procedures. In partnership with healthcare providers, we are actively working to reverse these non-coverage decisions and were successful with four regional plans in 2020. However, we cannot provide assurance that we will continue to be successful in these efforts. If we are not successful in reversing existing non-coverage policies, or if other third-party payors issue similar policies, this could have a material adverse effect on our business and operations. Further, third-party payors who currently cover and reimburse customers for procedures using our products may in the future choose to decrease current levels of reimbursement or eliminate reimbursement altogether, either of which will cause our business to suffer.

The amount of reimbursement received by our customers from third-party payors is dependent generally on fee schedules established by these payors for the existing CPT codes. For governmental payors, such as Medicare and Medicaid, the fee schedule amount is determined by statutory and regulatory formulas as previously discussed. For commercial payors, the reimbursement amount generally is dependent upon the specific contract terms between the provider and payor. We cannot provide assurance that government or commercial payors will continue to reimburse for procedures with our products using the existing codes, nor can we provide assurance that the payment rates will be adequate. If providers and physicians are unable to obtain reimbursement for the procedure at adequate levels when use of our products is included, this could have a material adverse effect on our business and operations. Hospitals and ASCs may not purchase our products if they do not receive payment sufficient to cover the cost of our products and related procedures. In addition, in the event that the current coding and/or payment methodology for these procedures changes, this could have a material effect on our business, results of operations, financial condition, and prospects.

Negative publicity concerning methods of donating human tissue and screening of donated tissue, in the industry in which we operate, may reduce demand for our products and negatively impact the supply of available donor tissue.

We are highly dependent on our ability to recover human peripheral nerve tissue from tissue donors for our Avance Nerve Graft product and acquire birth tissue for our Avive Soft Tissue Membrane. The availability of acceptable donors is relatively limited, and this availability is impacted by regulatory changes, general public opinion of the donation process and our reputation for our handling of the donation process. Media reports or other negative publicity concerning both improper methods of tissue recovery from donors and disease transmission from donated tissue, including bones and tendons, may limit widespread acceptance of our Avance Nerve Graft and Avive Soft Tissue Membrane. Unfavorable reports of improper or illegal tissue recovery practices, both in the U.S. and internationally, as well as incidents of improperly processed tissue leading to transmission of disease, may broadly affect the rate of future tissue donation and market acceptance of allograft technologies and donated tissue use. Potential patients may not be able to distinguish our products, technologies, and tissue recovery and processing procedures from others engaged in tissue recovery. In addition, unfavorable reports could make families of our potential donors or donors themselves from whom we are required to obtain consent before processing tissue reluctant to agree to donate tissue to for-profit tissue processors. Any disruption in the supply could have a material impact for our business, results of operations, financial condition, and prospects.

Delays, interruptions or the cessation of production by our third-party suppliers of important materials may prevent or delay our ability to manufacture or process the final products.

Most of the raw materials used in the process for Avance Nerve Graft and Avive Soft Tissue Membrane are available from more than one supplier. However, there are materials within the manufacturing and production process that come from single suppliers or certain supplies may be difficult to procure due to supply chain shortages or changes in global trade regulations.

We do not have written contracts that guarantee supply with any of our suppliers, and at any time they could stop supplying our orders. FDA review of a new supplier may be required if these materials become unavailable from our current suppliers. Although there may be other suppliers that have equivalent materials that would be available to us, FDA review, if required, could take several months or years to obtain, if able to be obtained at all. Any delay, interruption or cessation of production by our third-party suppliers of important materials, or any delay in qualifying new materials, if necessary, would prevent or delay our ability to manufacture products. In addition, an uncorrected impurity, a supplier's variation in a raw material or testing, either unknown to us or incompatible with our manufacturing process, or any other problem with our materials, testing or components, would prevent or delay our ability to process tissue. These delays may limit our ability to meet demand for our products and delay our clinical trials, which would have a material adverse impact on our business, results of operations, financial condition, and prospects.

The failure of third parties to perform many necessary services for the commercialization of our products, including services related to recovery/acquisition, distribution and transportation, would impair our ability to meet commercial demand.

We rely upon third parties for certain recovery/acquisition, distribution, and transportation services for our products. If any of the third parties that we rely upon in our recovery/acquisition, distribution or transportation process fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties, experience delays due to the ongoing COVID-19 pandemic, or encounter physical damage or natural disaster at their facilities, our ability to deliver product to meet commercial demand may be significantly impaired, which could have a material adverse impact on our business, results of operations, financial condition or prospects.

We are dependent on our relationships with independent agencies to generate a material portion of our revenue.

We derive material revenue through our relationships with independent agencies. In 2020 approximately 12% of global product revenue was generated through independent agencies. If certain agency relationships were terminated or discontinued for any reason, it could adversely affect our ability to generate revenue and profit. If we require additional agencies, we may not be able to find additional agencies who will agree to market and distribute our products on commercially reasonable terms, if at all. If we are is unable to establish new agency relationships or renew certain current distribution agreements on commercially acceptable terms, our business, results of operations, financial condition, and prospects could be materially and adversely impacted.

If we do not manage product inventory in an effective and efficient manner, it could adversely affect profitability.

Many factors affect the efficient use and planning of product inventory, including donor tissue, such as effectiveness of predicting demand, effectiveness of preparing manufacturing to meet demand, efficiently meeting product mix and product demand requirements and product expiration. We may be unable to manage our inventory efficiently, keep inventory within expected budget goals, keep our work-in-process inventory on hand or manage it efficiently, control expired product or keep sufficient product on hand to meet demand. Finally, we can provide no assurance that we can keep inventory costs within our target levels. Failure to do so may materially and adversely impact our business, results of operations, financial condition, and prospects.

Our operating results could be adversely impacted if we are unable to effectively manage and sustain our future growth or scale our operations.

There can be no assurance that we will be able to manage our future growth efficiently or profitably. Our business is unproven on a large scale, and actual revenue and operating margins, or revenue and margin growth, may be less than expected. If we are unable to scale our production capabilities efficiently or maintain pricing without significant discounting, we may fail to achieve expected operating margins, which would have a material and adverse effect on our operating results. Growth may also stress our ability to adequately manage our operations, quality of products, safety, and regulatory compliance. Failure to implement necessary procedures, equipment or processes or to hire the necessary personnel in a timely and effective manner could result in higher costs or an inability to meet market demand, and could have a material adverse impact on our business, results of operations, financial condition, and prospects. Additionally, our future growth will increase the demands placed on our third-party suppliers and there is no guarantee that our suppliers will be able to support our anticipated growth. If growth significantly decreases it will negatively impact our cash reserves, and we may be required to obtain additional financing, which may increase indebtedness or result in dilution to shareholders. Further, there can be no assurance that we would be able to obtain additional financing on acceptable terms, if at all.

There may be significant fluctuations in our operating results.

Significant quarterly fluctuations in our results of operations may be caused by, among other factors, our volume of revenue, seasonal changes in nerve repair activity, timing of sales force expansion, and general economic conditions. There can be no assurance that the level of revenue and profit, if any, we achieve in any particular fiscal period, will not be significantly lower than in other comparable fiscal periods. Our expense levels are based, in part, on our expectations as to future revenue. As a result, if future revenue is below expectations, net income or loss may be disproportionately affected by a reduction in revenue, as any corresponding reduction in expenses may not be proportionate to the reduction in revenue.

We may be unsuccessful in commercializing our products outside the U.S.

To date, we have focused our commercialization efforts in the U.S., except for minor revenue in certain foreign countries. We intend to expand distribution and sales outside the U.S. and will need to comply with applicable foreign regulatory requirements, including obtaining the requisite approvals to do so. The regulatory environment for our portfolio of products is complex. Avance Nerve Graft is distributed in Canada, the United Kingdom, and certain other countries. We received approval to distribute Avance Nerve Graft in Germany in December 2019. Avance use in Spain currently requires approval for each case to be approved by tissue authorities under an alternative therapies designation. Avive Soft Tissue Membrane is currently available in the U.S. and select other foreign countries. The Axoguard Nerve Connector and Nerve Protector CE has been renewed as of March 2020 by Cook Biotech.

In January 2020, the United Kingdom exited the E.U. (“Brexit”) following a transition period ending on December 31, 2020, which could disrupt trade between the United Kingdom and the E.U. or other nations, as the United Kingdom pursues independent trade regulations. We cannot be sure what changes could occur or the cost of regulatory compliance with both the United Kingdom and the E.U. going forward. Until such time as we can obtain, if at all, the necessary registrations and approvals for our products, material expansion beyond the U.S. will be limited. Finally, the cost of regulatory compliance for sales outside the U.S. can be significant and time consuming.

Further, we will need to either enter into distribution agreements with third parties or develop a direct sales force in foreign markets. If we do not obtain adequate levels of reimbursement from third-party payers outside of the U.S., we may be unable to develop and grow our revenue internationally. Outside of the U.S., reimbursement systems vary significantly by country. Many ex-U.S. markets have government-managed healthcare systems that govern reimbursement for medical devices, implants, and procedures. Some ex-U.S. reimbursement systems provide for limited payments in a given period and therefore result in extended payment periods. If we are unable to successfully commercialize our products internationally, our long-term growth prospects may be limited.

We incur costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives.

As a public company, we incur legal, accounting and other expenses to comply with relevant securities laws and regulations, including without limitation, the requirement of establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management devotes substantial time and financial resources to these compliance initiatives. Failure to comply with public company requirements could have a material adverse effect on our business. In addition, activity by shareholders or others that bring into question aspects of our business, financial reporting or management’s integrity, whether based on facts, beliefs or baseless and contrived for individual economic gain, can have a negative impact on the price of our stock and can result in substantial time and financial resources being expended to address the situation.

The COVID-19 pandemic could have a material adverse effect on our ability to operate, results of operations, financial condition, liquidity, and capital investments.

The World Health Organization has declared the COVID-19 outbreak a pandemic, and the virus continues to spread in areas where we operate and sell our products. COVID-19, or similar extraordinary events in the future, could have a material adverse effect on our ability to operate, results of operations, financial condition, liquidity, and capital investments. While the ultimate economic impact of COVID-19 cannot be reliably quantified or estimated at this time due to the uncertainty of future developments, COVID-19 will materially affect our near-term financial performance and, as a result, we suspended our 2020 financial guidance provided on February 24, 2020.

In response to COVID-19, several public health organizations have recommended, and some local governments have implemented, certain measures to slow and limit the transmission of the virus, including quarantines, “shelter-in-place”, and “stay-at-home” orders, travel restrictions and business curtailments, among other measures. As a result, we believe that the reduced activities of the U.S. population due to the pandemic may reduce the incidence of traumatic nerve injuries. With respect

to the medical industry in particular, COVID-19 has caused some hospitals and clinics to: (1) reallocate their teams and resources to prepare for increased COVID-19 patients; (2) defer or limit elective and non-emergency procedures; (3) restrict hospital access to non-essential personnel, including sales and clinical representatives not directly required for a specific procedure; and (4) limit or pause clinical research activities.

Such measures or others (including future measures implemented by governmental authorities and measures we have put in place or may in the future voluntarily put in place), as well as other effects of COVID-19, have had, and will continue to have, directly and indirectly, a material adverse effect on our business as they result in decreased demand for our product, decreased access to customer channels, slowing or stopping of the development of clinical products or clinical data, decreased employee availability, adverse economic conditions, potential border closures and other disruptions to our business, and the businesses of our business partners and others. Furthermore, COVID-19 may have the effect of heightening many of the other risks described in this Annual Report on Form 10-K.

Risks Related to the Regulatory Environment in which the CompanyOperates

Our business is subject to continuing regulatory compliance by the FDA and other authorities, which is costly and could result in negative effects on our business.

We are subject to extensive regulation by foreign and domestic government entities, including compliance with regulations governing appropriate relationships with healthcare professionals, such as physicians, hospitals and those to whom and through whom we may market our products. We are subject to various federal, state, and territorial laws in the U.S. and other jurisdictions in which we conduct business. These include, for example, anti-kickback laws, false claims laws, health care fraud, waste, and abuse laws, and anti-bribery laws such as the U.S. Foreign Corrupt Practices Act. Violations of these laws can be punishable by criminal and/or civil sanctions, including, in some instances, fines, imprisonment and, within the U.S., exclusion from participation in government healthcare programs, including Medicare, Medicaid, and Veterans Administration health programs. These laws are administered and enforced by, among others, the U.S. Department of Justice ("DOJ"), which issued new compliance guidance in 2020, the Office of Inspector General of the Department of Health and Human Services, state attorneys general, and their respective counterparts in the applicable foreign jurisdictions in which we conduct business. Many of these agencies have increased their enforcement activities with respect to medical device manufacturers in recent years. There can also be changes to the regulations by foreign and domestic government entities that require us to update or upgrade business processes or to perform additional validation activities for product or processes. Compliance with such changes can be costly to implement or result in non-compliance, thus restricting the ability to distribute tissue or sell products, which could have a material adverse effect on our business, results of operations, financial condition, and prospects.

Our products are also subject to regulation by the FDA in the U.S. The FDA regulates the development, preclinical and clinical testing, requirements for commercial marketing abd distribution, manufacturing and quality, safety, labeling, and promotion of human cell and tissue products (HCT/s), medical devices, and biological products. The FDA requires the approval of a biological product, like Avance Nerve Graft, through a BLA prior to marketing. Although the Avance Nerve Graft product has not yet been approved by FDA through a BLA, FDA is permitting the product to be distributed, subject to FDA enforcement discretion, provided that we: (1) transition to compliance with section 501(a)(2)(B) of the FD&C Act, the cGMP regulations in 21 CFR Parts 210 and 211 and the applicable regulations and standards in 21 CFR Parts 600-610 prior to initiation of a phase 3 clinical trial designed to demonstrate the safety, purity, and potency of Avance Nerve Graft; (2) conduct a phase 3 clinical trial to demonstrate safety, purity, and potency of Avance Nerve Graft under an SPA; (3) continue to comply with the requirements of 21 CFR Part 1271; and (4) exercise due diligence in executing the transition plan. See "Business — Government Regulations — U.S. Government Regulation Review."

Avive Soft Tissue Membrane is processed and distributed in accordance with U.S. FDA requirements for Human Cellular and Tissue-based Products (361 HCT/P) and as such, complies with 21 CFR Part 1271 regulations, U.S. State regulations and the guidelines of the American Association of Tissue Banks ("AATB"). FDA could determine that Avive Soft Tissue Membrane should be regulated under Section 351 of the Public Health Service Act and cannot be marketed without a BLA. If so, FDA could take enforcement action including requiring that we remove the product from the market until a BLA is approved. If we fail to comply with applicable regulatory requirements, the FDA could also impose civil penalties, including fines, product seizures or product recalls and, in certain cases, criminal sanctions, which may adversely affect our business, results of operations, financial condition, and prospects.

The FDA also regulates medical devices, for example the Axoguard products, and requires them to be cleared through the 510(k) premarket notification process prior to marketing. The FDA's premarket review process for new and modified existing devices that precedes product marketing can be time consuming and expensive. Some of the future products and enhancements to such products that we expect to develop and market may require marketing clearance or approval from the FDA.

There can be no assurance, however, that clearance or approval will be granted with respect to any of our device products or enhancements of marketed products or that our Avance Nerve Graft will meet FDA's requirements for continued marketing and transition to a BLA or ultimately an approved BLA. FDA review of our devices or biological products may encounter significant delays during FDA's premarket review process that would adversely affect our ability to market our products or enhancements. In addition, there can be no assurance that our products, including the Avance Nerve Graft, or enhancements will not be subject to a lengthy and expensive approval process with the FDA.

It is possible that if regulatory clearances or approvals to market a product are obtained from the FDA, the clearances or approvals may contain limitations on the indicated uses of such product and other uses may be prohibited. Product approvals by the FDA can also be withdrawn due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial approval. Furthermore, the FDA could limit or prevent the distribution of our products, and the FDA has the power to require the recall of such products. FDA regulations depend heavily on administrative interpretation, and there can be no assurance that future interpretations made by the FDA or other regulatory bodies will not adversely affect our business, results of operations, financial condition, and prospects. We, and our facilities, may be inspected by the FDA from time to time to determine whether it is in compliance with various regulations relating to specifications, development, documentation, validation, testing, quality control and product labeling. A determination that we are in violation of such regulations could lead to imposition of civil penalties, including fines, product recalls or product seizures and, in certain cases, criminal sanctions.

The use, misuse or off-label use of our products may harm our reputation, the image of our products, result in injuries leading to product liability suits, which could be costly to our business, or result in FDA sanctions.

If our products are misused or used for off-label purposes, our reputation and our product's reputation may suffer, injuries could occur, which may lead to product liability litigation, or we may be subject to FDA sanctions if we are deemed to have engaged in off-label promotion. We are seeking a biologics license through the BLA process for specific uses of Avance Nerve Graft under specific circumstances. Our promotional materials and training methods must comply with FDA requirements and other applicable laws and regulations, including the prohibition against off-label promotion. Our promotion of the Axoguard products, which are regulated as medical devices, also must comply with FDA's requirements and must only use labeling that is consistent with the specific indication(s) for use included in the FDA substantial equivalence order that results in marketing the devices. Avive Soft Tissue Membrane is processed and distributed in accordance with FDA requirements for (HCT/P) under 21 CFR Part 1271 regulations and is to be dispensed only by or on the order of a licensed physician and is contraindicated for use in any patient in whom soft tissue implants are contraindicated. The FDA does not restrict or regulate a physician's use of a medical product within the practice of medicine, and we cannot prevent a physician from using our products for an off-label use. However, the FD&C Act and the FDA's regulations restrict the kind of promotional communications that may be made about our products and if the FDA determines that our promotional or training materials constitute the unlawful promotion of an off-label use, it could request that we modify training or promotional materials and/or subject the Company to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, civil money penalties, seizure, injunction or criminal fines, and penalties. Other federal, state or foreign governmental authorities might also take action if they consider our promotion or training materials to constitute promotion of an uncleared or unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement, or exclusion from participation in federal health programs. In that event, our reputation could be damaged and our products' use in the marketplace could be impaired.

There may be increased risk of injury if physicians or others attempt to use our products off-label. Furthermore, the use of our product for indications other than those for which our products have been approved, cleared or licensed by the FDA may not effectively treat the conditions not referenced in product indications, which could harm our reputation in the marketplace among physicians and patients. Physicians may also misuse our products or use improper techniques if they are not adequately trained in the particular use, potentially leading to injury and an increased risk of product liability litigation. Product liability claims are expensive to defend and could divert management's attention from our primary business and result in substantial damage awards against us. Any of these events could harm our business, results of operations, financial condition, and prospects.

Our Avance Nerve Graft product is currently allowed to be distributed pursuant to a transition plan with the FDA and a change in position by the FDA regarding its use of enforcement discretion to permit the sale of Avance Nerve Graft would have a material adverse effect on us.

The FDA considers our Avance Nerve Graft product to be a biological product, subject to BLA approval requirements. Although the Avance Nerve Graft product has not yet been approved by FDA through a BLA, it is currently distributed under the controls applicable to a HCT/P pursuant to Section 361 of the Public Health Service Act and 21 CFR Part 1271 of FDA's regulations, subject to FDA's enforcement discretion and our compliance with a transition plan established by the FDA. See "Business — Government Regulations — U.S. Government Regulation Review." We have continued to communicate with the CBER since the acceptance of the transition plan on clinical trial design, preclinical studies, Chemistry, Manufacturing, and

Controls (“CMC”) for Avance Nerve Graft, and other issues related to the effective IND. Subject to the FDA’s enforcement discretion, we can commercially distribute Avance Nerve Graft until the FDA makes a final determination on an Avance Nerve Graft BLA submission, assuming we remain in compliance with the transition plan and exercises due diligence in executing the transition plan. In the event that the FDA becomes dissatisfied with our progress or actions with respect to the transition plan or the FDA changes its position for any reason regarding its use of enforcement discretion to permit us to distribute the Avance Nerve Graft product in accordance with the transition plan, we would no longer be able to distribute Avance Nerve Graft, which would have a material adverse effect on our operations and financial viability. In addition, if we do not meet the conditions of the transition plan, or fail to comply with applicable regulatory requirements, the FDA could impose civil penalties, including fines, product seizures, injunctions or product recalls and, in certain cases, criminal sanctions. These consequences also would have a material adverse effect on our operations and financial viability.

Our business is subject to continuing compliance to standards by various accreditation and registration bodies which is costly, and loss of accreditation or registration could result in negative effects on our business.

We are subject to accreditation such as that by the AATB and as a National Association of Boards of Pharmacy (NABP) Accredited Drug Distributors. We have registration requirements such as that with ISO 13485 registration bodies. These accreditations and regulations can affect distribution and sale of our products on a state-by-state basis, within the U.S. and also affects distribution and sale of our products outside of the U.S. The loss of accreditation or registration could keep us from selling and distributing our products, which may have negative effects on our business, results of operations, financial condition, and prospects.

Our Axoguard products are subject to FDA and international regulatory requirements.

Our Axoguard product line is regulated as a medical device in the US and international countries where we market Axoguard products. In the US, Axoguard product line is regulated under the FD&C Act and subject to premarket notification and clearance requirements under section 510(k) of the FD&C Act, 21 CFR Part 820 (Quality System Regulation) and other FDA regulations. In the rest of the world, each region (such as EU) or country has their independent international regulations such as the Medical Device Regulations (CE Mark) in Europe, UK Medicines and Healthcare products Regulatory Agency (MHRA), and Taiwan Pharmaceutical Affairs Act.

We distribute Axoguard Nerve Connector and Axoguard Nerve Protector products for Cook Biotech, and Cook Biotech is responsible for the regulatory compliance of these products. In the U.S., Cook Biotech has obtained a 510(k) premarket clearance for Axoguard Nerve Connector from the FDA for porcine (pig) small intestine submucosa for the repair of peripheral nerve transections where gap closure can be achieved by flexion of the extremity. Cook Biotech has also obtained a 510(k) premarket clearance for Axoguard Nerve Protector for the repair of peripheral nerve damage in which there is no gap or where a gap closure is achieved by flexion of the extremity. In countries where Axoguard is marketed, Cook Biotech has obtained regulatory clearance with the same indications except for Europe and UK. For the CE Mark, the Axoguard Nerve Protector indication is the same; however for Axoguard Nerve Connector, the indication is more specific - “The Axoguard Nerve Connector is indicated for the repair of peripheral nerve discontinuities with gaps up to 5 mm.”

We are responsible for the regulatory compliance of the Axoguard Nerve Cap. We have obtained a 510(k) premarket clearance for Axoguard Nerve Cap to protect a peripheral nerve end and separate the nerve from the surrounding environment and to prevent or to reduce the development of symptomatic or painful neuroma.

If we or Cook Biotech fail to comply with applicable regulatory requirements, the regulatory bodies in each country could deny or withdraw regulatory clearance/approval for the Axoguard products, or impose civil penalties, including fines, product seizures or product recalls and, in certain cases, criminal sanctions.

Defective products could lead to recall or other negative business conditions.

If our products are defective or otherwise pose safety risks, the FDA could require their recall or we may initiate a voluntary recall of our products. The FDA may require recall of a marketed medical device product, such as the Axoguard products, in the event that it determines the medical device presents a reasonable probability of serious adverse health consequences or death. However, most device recalls do not rise to this level of health significance and result from voluntary action. The FDA has authority to recall biological products when a batch, lot or other quantity of the product presents an imminent or substantial hazard to the public health. However, in such circumstances, the FDA usually initially requests voluntary recalls of biological products, such as the Avance Nerve Graft. If a company does not comply with an FDA request for a recall, the FDA can order one under the above-referenced circumstances or take other enforcement actions, such as product seizure. In addition, manufacturers may, on their own initiative, recall a product to remove or correct a deficiency or to remedy a violation of the FD&C Act that may pose a risk to health. A government-mandated, government-requested or voluntary recall could occur as a result of an unacceptable risk to health, reports of safety issues, failures, manufacturing errors,

design or labeling defects or other deficiencies, and issues. Recalls and other field corrections for any of our products would divert managerial and financial resources and have an adverse effect on our business, results of operations, financial condition, and prospects. A recall could adversely impact our reputation with customers and our sales. If the FDA were to disagree with our internal determinations and decision making relative to potential recalls (including corrections and removal), we could be subject to further regulatory or enforcement action against.

If our products cause or contribute to a death, a serious injury, or any adverse reaction involving a communicable disease, or malfunction in certain ways, we will be subject to reporting regulations, which can result in voluntary corrective actions or agency enforcement actions. See "Business — Regulation — Education Grants, U.S. Anti-kickback, False Claims and Other Healthcare Fraud and Abuse Laws — Pervasive and False Claims." If we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take regulatory or enforcement action against us. Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require the dedication of time and capital, distract management from operating our business, and may adversely impact our reputation, business, results of operations, financial condition, and prospects.

Our operations must comply with FDA and other governmental requirements.

Our operations require us to comply with the FDA's and other governmental authorities' laws and regulations on the topics including the manufacture and production and sales and marketing of medical products, and compliance efforts related to such laws is costly, and failure to comply could subject us to enforcement action. See "Business — Government Regulations — Education Grants, U.S. Anti-kickback, False Claims and Other Healthcare Fraud and Abuse Laws — Fraud, Abuse and False Claims". Enforcement actions could impair our ability to produce products in a cost-effective and timely manner to meet customer demands. We may also be required to bear other costs or take other actions that may have an adverse impact on our future revenue and our ability to generate profits. Furthermore, our key material suppliers, licensors and or other contractors may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce products on a timely basis and in the required quantities, if at all.

Healthcare providers and facilities, and third-party payors, often play a primary role in the recommendation and prescription of any currently marketed products and product candidates for which we may obtain marketing approval. Our current and future arrangements with healthcare providers and facilities, third-party payors and customers, and our sales, marketing and educational activities, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations (at the federal and state level) that may constrain our business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. In addition, our operations are also subject to various federal and state fraud and abuse, and payment transparency.

Payments made to physicians and other healthcare providers, and other financial interests, have been the subject of a range of federal and state laws. The federal physician payment transparency requirements, sometimes referred to as the Physician Payments Sunshine Act, or the Sunshine Act, was created under the Affordable Care Act. The Sunshine Act, among other things, imposes reporting requirements on drug manufacturers for payments or other transfers of value made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians, other healthcare providers, and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an additional aggregate of $1 million per year for "knowing failures," for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. As of 2021, applicable manufacturers are subject to tracking payments and transfers of value to physician assistants, nurse practitioners, and other mid-level HCPs as well as physicians, with reporting relative to these mid-level practitioners beginning in 2022. Additionally, certain states also mandate implementation of compliance programs, impose restrictions on marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians and other HCPs.

In addition to the federal fraud, waste, and abuse laws noted, there are analogous state laws and regulations, such as state anti-kickback and false claims laws, and other state laws addressing the medical product and healthcare industries, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and in some cases may apply regardless of payor, i.e. even if reimbursement is not available. Some state laws require pharmaceutical or device companies to comply with the industry's voluntary compliance guidelines (the PhRMA Code and AdvaMed Code) and the relevant compliance program guidance promulgated by the federal government (HHS-OIG) in addition to other requirements, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Distribution of our human tissue products outside the U.S. are subject to foreign regulatory requirements that vary from country to country. In the E.U., human tissue regulations, if applicable, differ from one E.U. member state to the next. Because

of the absence of a harmonized regulatory framework and the proposed regulation for advanced therapy medicinal products in the E.U., as well as for other countries, the approval process for human derived cell or tissue based medical products may be extensive, lengthy, expensive and unpredictable. Our products are subject to E.U. member states' regulations that govern the donation, procurement, testing, coding, traceability, processing, preservation, storage, and distribution of human tissues and cells and cellular or tissue-based products. In addition, some E.U. member states have their own tissue banking regulations. The inability to meet foreign regulatory requirements could materially affect our future growth and compliance with such requirements could place a significant financial burden on us. As a result of Brexit, we cannot be sure what changes could occur or the cost of regulatory compliance with the United Kingdom. Accordingly, the cost of regulatory compliance for sales outside the U.S. can be significant and time consuming.

Finally, regulations in both the U.S. and other countries are subject to constant change. There can be no assurance that we can meet the requirements of future regulations or that compliance with current regulations assures future capability to distribute and sell our products.

Clinical trials can be long, expensive and results are ultimately uncertain which could jeopardize our ability to obtain regulatory approval and continue to market our Avance Nerve Graft product.

We are required to perform a clinical trial for our Avance Nerve Graft under FDA's statutory requirements to obtain approval of a BLA for the product. This trial is expensive, is expected to take several years to execute, is subject to factors within and outside of our control, and the outcome is uncertain.

We submitted an IND for the RECON study of Avance Nerve Graft in April 2013 and received FDA approval in March 2015. The phase 3 clinical trial was initiated in the second quarter of 2015. The RECON study was designed to assess the outcome of peripheral nerve repair in approximately 170 subjects in up to 20 centers. As required by the SPA and agreed to by FDA and us, an independent statistical analysis was conducted to determine if greater study enrollment was appropriate to maintain the planned statistical power of the study. Based on the results of this analysis, the study's independent biostatistician recommended continuation of the study with a one-time expansion in enrollment according to a pre-defined sample size re-estimation. The recommendation was reviewed with the FDA, and, on April 19, 2019, the FDA provided the company with a Revised Special Protocol Assessment Agreement that confirmed the expanded sample size and allowed the study enrollment target to be increased by 50 subjects, to a total target of 220 subjects and we may add up to five new study centers, for a total of 25 centers, to support enrollment and currently has 25 centers engaged. The study completed subject enrollment in July 2020. No outcome data is available at this time.

We are working to ensure compliance with the applicable regulations by having ongoing discussions on the transition of the quality system to 21 CFR Parts 210/211 and 600-610 regulations with the FDA. Final determination of regulatory compliance with 21 CFR Parts 210/211 and 600-610 will be made during FDA's pre-license inspection as part of the BLA review. The approval of our BLA would not occur or could be delayed, if the FDA is unable to agree with us, or we are unable to meet the standards required by the FDA regarding preclinical studies, clinical studies, and CMC.

We continue to work diligently with the FDA and, in this context, continue to distribute the Avance Nerve Graft products. The FDA will end the period of enforcement discretion upon a final determination of our BLA submission or upon a finding that we do not meet the conditions for the transition plan or are not exercising due diligence in executing the transition (e.g., not progressing toward study completion or BLA submission in a timely or adequate fashion). If final action on the BLA is negative or we are found to not meet the conditions for the transition plan, we will not be able to continue to distribute Avance Nerve Graft, and our business, results of operations, financial condition, and prospects will be materially adversely affected.

The results of non-clinical studies do not necessarily predict future clinical trial results and predecessor clinical trial results may not be repeated in subsequent clinical trials. Additionally, the FDA may disagree with our interpretation of the data from our non-clinical studies and clinical trials and may require the company to pursue additional non-clinical studies or clinical trials, or not approve our BLA. If we are unable to demonstrate the safety and efficacy of our product through our clinical trials, it will be unable to obtain regulatory approval to market the Avance Nerve Graft and will not be able to continue to provide it.

We will rely on third parties to conduct our clinical trials and they may not perform as contractually required or expected.

We will rely on third parties, such as contract research organizations ("CROs"), medical institutions, clinical investigators and contract laboratories to conduct our clinical trials and certain nonclinical studies. We and our CROs are required to comply with all applicable regulations governing clinical research, including good clinical practice ("GCP"). The FDA enforces these regulations through periodic inspections of trial sponsors, principal investigators, CROs and trial sites. If we or our CROs fail to comply with applicable FDA regulations, the data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our applications. We cannot be certain that, upon inspection, the

FDA and similar foreign regulatory authorities will determine that our clinical trial complies or complied with clinical trial regulations, including GCP. In addition, our clinical trial must be conducted with product produced under applicable GCP regulations. Failure to comply with the clinical trial regulations, including GCP, may require us to repeat clinical trials, which would delay the regulatory approval process. Further, if these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, need to be replaced, or the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our non-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we would not be able to obtain regulatory approval for our products on a timely basis, if at all, and our business, results of operations, financial condition, and prospects would be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

U.S. governmental regulation could restrict the use of our Avance Nerve Graft and Avive Soft Tissue Membrane product, restrict our procurement of tissue or increase costs.

In addition to the FDA requirements for biological products, Avance Nerve Graft, and Avive Soft Tissue Membrane will continue to be subject to various requirements for human tissue under 21 CFR Part 1271. Human tissues intended for transplantation have been regulated by the FDA since 1993. In May 2005, three new comprehensive regulations went into effect that address manufacturing activities associated with HCT/P. The first regulation requires that companies that produce and distribute HCT/Ps register with the FDA. The second regulation provides criteria that must be met for donors to be eligible to donate tissues and is referred to as the "Donor Eligibility" rule. The third regulation governs the processing and distribution of the tissues and is often referred to as the "Current Good Tissue Practices" rule. The Current Good Tissue Practices rule covers all stages of allograft processing, from procurement of tissue to distribution of final allografts. Together, the three basic requirements of 21 CFR Part 1271 are designed to ensure that sound, high quality practices are followed to reduce the risk of tissue contamination and of communicable disease transmission to recipients. These regulations increased regulatory scrutiny within the industry in which we operate and have led to increased enforcement actions, which affects the conduct of our business. In addition, guidance was issued by the FDA in November 2017 and revised in July 2020 on Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use which could have potential implications on the regulatory status of Avive and future HCT/P products being evaluated by the Company.

Additional regulations or guidance documents may be implemented by the FDA in the future. These changes may impose new documentation requirements, process changes or testing that could increase costs, and regulatory burden. See "Business — Government Regulations." These regulations can also increase the cost of tissue recovery activities. Finally, Avance Nerve Graft and Avive Soft Tissue Membrane are subject to certain state and local regulations, as well as compliance with the standards of the tissue bank industry's accrediting organization, the AATB.

The procurement and transplantation of allograft nerve tissue is also subject to federal law pursuant to the National Organ Transplant Act ("NOTA"), a criminal statute that prohibits the purchase and sale of human organs used in human transplantation, including nerve and related tissue, for "valuable consideration." NOTA only permits reasonable payments associated with the removal, transportation, processing, preservation, quality control, implantation and storage of human nerve tissue. We make payments to certain of our clients and tissue banks for their services related to recovering allograft nerve and umbilical cord tissue on its behalf. If NOTA is interpreted or enforced in a manner that prevents us from receiving payment for services we render, or prevents us from paying tissue banks or certain of our clients for the services they render for us, our business, results of operations, financial condition, and prospects could be materially and adversely affected.

We have engaged, through marketing employees, independent sales agents and sales representatives, in ongoing efforts designed to educate the medical community as to our products' benefits, and we intend to continue our educational activities. Although we believe that NOTA permits payments in connection with these educational efforts as reasonable payments associated with the processing, transportation and implantation of our products, payments in connection with such education efforts are not exempt from NOTA's restrictions and our inability to make such payments in connection with these education efforts may prevent us from paying our sales representatives and could adversely affect our business, results of operations, financial condition, and prospects. No federal agency or court has determined whether NOTA is, or will be, applicable to every allograft nerve tissue-based material that our processing technologies may generate. Assuming that NOTA applies to our processing of allograft nerve and umbilical cord tissue, we believe that we comply with NOTA, but there can be no assurance that more restrictive interpretations of, or amendments to, NOTA will not be adopted in the future, which would call into question one or more aspects of our method of operations.

Other regulatory entities include state agencies with statutes covering tissue banking. Regulations issued by Florida, New York, California and Maryland, among other states, are particularly relevant to our business. Most states do not currently have tissue banking regulations. However, incidents of allograft related issues in the industry may stimulate the development of regulation in other states. It is possible that third parties may make allegations against us or against donor recovery groups or tissue banks about non-compliance with applicable FDA regulations or other relevant statutes or regulations. Allegations like

these could cause regulators or other authorities to take investigative or other action, or could cause negative publicity for our business and the industry in which we operate.

Our Axotouch product is subject to FDA and other regulatory requirements.

Our Axotouch product is regulated as a Class 1 510(k) exempt medical device under the FD&C Act and not subject to premarket notification and clearance requirements under section 510(k) of the FD&C Act, 21 CFR Part 820 (Quality System Regulation) and other FDA regulations. If we fail to comply with applicable regulatory requirements, the FDA could require a 510(k) for the product, or impose civil penalties, including fines, product seizures or product recalls and, in certain cases, criminal sanctions, which may adversely affect our business, results of operations, financial condition, and prospects.

Healthcare law and policy changes may have a material adverse effect on us.

In the United States there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, and affect our ability, or the ability of our collaborators, to profitably sell any products for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or our collaborators, may receive for any approved products.

Since enactment of the Affordable Care Act (ACA) in 2010 there have been a number of legal challenges as well as other legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. The full effects of the ACA may be unknown until all outstanding legal issues are resolved, the statutory provisions are fully implemented, and CMS, the FDA, and other federal and state agencies issue final applicable regulations or guidance. These developments could potentially alter coverage and marketing requirements, thereby affecting our pricing and market share if individuals lose coverage for certain benefits. The ACA remains subject to pending legal and constitutional challenges in the United States Supreme Court. The Supreme Court heard oral arguments in California v. Texas on November 2, 2020. The Court has yet to issue its opinion, and we cannot say for certain what the decision will be or what impact, if any, it may have on our business.

In the future, there may continue to be additional proposals relating to the reform of the U.S. healthcare system. Executive Orders may be issued in the future that impact the healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products and could also limit the acceptance and availability of our products. The adoption of some or all of these proposals could have a material adverse effect on our business, results of operations, financial condition, and prospects.

Additionally, initiatives sponsored by government agencies, legislative bodies and the private sector in the U.S. and elsewhere to limit the growth of healthcare costs, especially for drugs and biologics, including price regulation and competitive pricing, are ongoing in markets where we do business. We could experience an adverse impact on operating results due to increased pricing pressure in the U.S. and in other markets. Governments, hospitals, pharmacy benefit managers (“PBMs”), and other third-party payors could reduce the amount of approved reimbursement for our products, deny coverage altogether, or impose new requirements on manufacturers to justify their prices. Reductions in reimbursement levels or coverage or other cost-containment measures could unfavorably affect our future operating results.

We could be subject to civil or criminal penalties if we are found to have violated laws protecting the confidentiality of health information, which could increase our liabilities and harm our reputation or our business.

There are a number of federal and state laws protecting the confidentiality of certain health information and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services promulgated privacy rules under the Health Insurance Portability and Accountability Act (“HIPAA”). These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. If we are found to be in violation of the privacy rules under HIPAA, we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, results of operations, financial condition, and prospects.

Risks Related to Our Intellectual Property

Failure to protect our intellectual property rights could result in costly and time-consuming litigation and our loss of any potential competitive advantage.

Our success will depend, to a large extent, on our ability to successfully obtain and maintain patents, prevent misappropriation or infringement of intellectual property ("IP"), maintain trade secret protection, and conduct operations without violating or infringing on the IP rights of third parties. See “Business — Intellectual Property.” There can be no assurance that our patented and patent-pending technologies will provide us with a competitive advantage, that we will be able to develop or acquire additional technology that is patentable, or that third parties will not develop and offer technologies which are similar to ours. Moreover, we can provide no assurance that confidentiality agreements with our employees, consultants and other parties, agreements to protect trade secrets or similar agreements intended to protect unpatented technology or prevent unauthorized use, disclosure, or misappropriation will not be breached by those third parties. IP litigation is extremely expensive and time-consuming, and it is often difficult to predict the outcome of such litigation. A failure by us to protect our IP, or a breach by third parties of agreements aimed at protecting our IP, could have a materially adverse effect on our business, results of operations, financial condition, and prospects.

Future protection for our proprietary rights is uncertain, and may impact our ability to successfully compete in our industry.

The degree of future protection for our proprietary rights is uncertain. We cannot ensure that:

- we, or our licensors, were the first to make the inventions covered by each of our patents;
- we, or our licensors, were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our pending patent applications will result in issued patents;
- any of our issued patents or those of our licensors are valid and enforceable;
- any patents issued to us or our collaborators will provide any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies that are patentable;
- the patents of others will not have a material adverse effect on our business rights; or
- the measures we rely on to protect our IP underlying our products are adequate to prevent third parties from using, disclosing or misappropriating that IP, all of which could harm our ability to compete in the market.

Our commercial success depends in part on our ability and the ability of our collaborators and licensors to avoid infringing patents and proprietary rights of third parties, which could expose it to litigation or commercially unfavorable licensing arrangements. Third parties may accuse us or collaborators and licensors of employing their proprietary technology without authorization in our products, or in the materials or processes used to make our products. Any legal action against our collaborators, licensors or it claiming damages and/or seeking to enjoin our commercial activities relating to the affected products, materials and processes could, in addition to subjecting us to potential liability for damages, require us or our collaborators and licensors to obtain a license to continue to utilize the affected materials or processes or to manufacture or market the affected products. We cannot predict whether we or our collaborators and licensors would prevail in any of these actions or whether any license required under any of these patents would be made available on commercially reasonable terms, if at all. If we were unable to obtain such a license, we and our collaborators and licensors may be unable to continue to utilize the affected materials or processes, or manufacture or market the affected products, or we may be obligated by a court to pay substantial royalties and/or other damages to the patent holder. Even if we were able to obtain such a license, the terms of such a license could substantially reduce the commercial value of the affected product or products and impair our prospects for profitability. Accordingly, we cannot predict whether, or to what extent, the commercial value of the affected product or products or our prospects for profitability may be harmed as a result of any of the liabilities discussed above. Furthermore, infringement and other IP claims, with or without merit, can be expensive and time-consuming to litigate and can divert management’s attention from our core business. We and our licensors may be unable to obtain and enforce IP rights to adequately protect our products and related IP, which could materially and adversely impact our business, results of operations, financial condition or prospects.

The patent protection for our products may expire before we are able to maximize their commercial value which may subject us to increased competition and reduce or eliminate our opportunity to generate product revenue.

The patents for our commercialized products and products in development have varying expiration dates and, when these patents expire, we may be subject to increased competition and we may not be able to recover our development costs. For example, the material U.S. patents covering the formulations used in our Axoguard product line, which are held by Cook Biotech, have expired. Expiration of these patents could adversely affect our ability to successfully execute our business

strategy to maximize the value of Axoguard products and could materially and adversely impact our business, results of operations, financial condition, and prospects.

Others may claim an ownership interest in our IP which could expose us to litigation and have a significant adverse effect on our prospects.

A third party may claim an ownership interest in one or more of our patents or other IP. A third party could bring legal actions against us claiming we infringed their patents or proprietary rights, and seek monetary damages and/or enjoin clinical testing, manufacturing and marketing of the affected product or products. While we believe we own the right, title and interest in the patents for which we or our licensors have applied and our other IP (including that which is licensed from third parties), and is presently unaware of any claims or assertions by third-parties with respect to our patents or IP, we cannot guarantee that a third party will not assert a claim or an interest in any of such patents or IP. If we become involved in any litigation, it could consume a substantial portion of our resources and cause a significant diversion of effort by our technical and management personnel. If any of these actions were successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product, in which case we may be required to pay substantial royalties or grant cross-licenses to our patents. We cannot, however, assure that any such license will be available on acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other IP rights, which could have a material and adverse effect on our business, results of operations, financial condition, and prospects. Further, the outcome of IP litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party. This is especially true in IP cases that may turn on the testimony of experts as to technical facts or the scope or meaning of patent claims upon which experts may reasonably disagree.

We depend on the maintenance of exclusive licenses.

We depend fundamentally on keeping and satisfying the terms of exclusive licenses of our nerve repair technologies from the University of Florida Research Foundation (the "UFRF") and the University of Texas at Austin ("UTA"). Nonetheless, a disagreement between us and either licensor could have a negative impact on our ability to effectively operate our business. In addition, we could learn that the technologies we have licensed do not perform as purported, are not efficacious, or are not the property of the licensor, any of which would have an immediate and negative impact on our business.

Our trademarks are valuable, and our business may be adversely affected if trademarks are not adequately protected.

In the U.S. and other countries, we currently hold trademark registrations and have trademark applications pending, any of which may be the subject of a governmental or third-party objection, which could prevent the maintenance or issuance of the same. As our products mature, our reliance on our trademarks to protect our brand, increase our name recognition and, in part, differentiate us from our competitors increases. As a result, if our trademark applications are not successful and if we are unable to prevent third parties from adopting, registering or using trademarks, including trade dress, that infringe, dilute or otherwise violate our trademark rights, our business, results of operations, financial condition, and prospects could be materially adversely affected.

Risks Related to Our Common Stock

An active trading market in our common stock may not be maintained.

The trading market in our common stock has been extremely volatile. The quotation of our common stock on The Nasdaq Capital Market does not assure that a meaningful, consistent and liquid trading market will exist. We cannot predict whether an active market for our common stock will be maintained in the future. An absence of an active trading market could adversely affect our shareholders' ability to sell our common stock at current market prices in short time periods, or possibly at all. Additionally, market visibility for our common stock may be limited and such lack of visibility may have a depressive effect on the market price for our common stock. As of December 31, 2020, approximately 38.4% of our outstanding shares of common stock was held by our officers, directors, beneficial owners of 5% or more of our securities and their respective affiliates, which adversely affects the liquidity of the trading market for our common stock, in as much as federal securities laws restrict sales of our shares by these shareholders. If our affiliates continue to hold their shares of common stock, there will be limited trading volume in our common stock, which may make it more difficult for investors to sell their shares or increase the volatility of our stock price.

The price of our common stock could be highly volatile due to a number of factors, which could lead to losses by investors and costly securities litigation.

Our common stock is listed on The Nasdaq Capital Market under the symbol "AXGN." The stock market in general, and the market for medical technology companies in particular, have experienced and could in the future experience extreme volatility that has often been unrelated to the operating performance of particular companies. The trading price of our common stock has experienced substantial volatility and is likely to continue to be highly volatile in response to a number of factors including, without limitation, the following:

- fluctuations in price and volume due to investor speculation, including short sales, social media speculation and other factors that may not be tied to our financial performance;
- our performance in the execution of our business plan;
- financial viability;
- actual or anticipated variations in our operating results;
- announcements of developments by us or our competitors;
- market conditions in our industry;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- adoption of new accounting standards affecting our industry;
- additions or departures of key personnel;
- introduction of new products by us or our competitors;
- sales of our common stock or other securities in the open market;
- regulatory developments in both the U.S. and foreign countries;
- performance of products sold and advertised by licensees in the marketplace;
- economic and other external factors;
- period-to-period fluctuations in financial results; and
- other events or factors, including the other factors described in this "Risk Factors" section, many of which are beyond our control.

The stock market is subject to significant price and volume fluctuations. Such fluctuations have and could expose us to securities class action litigation, which could adversely impact our business, results of operations, financial condition, and prospects.

We do not anticipate paying any cash dividends in the foreseeable future.

The operation and expansion of our business will continue to require funding. We do not anticipate that we will pay any cash dividends on our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our Board of Directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law, and other factors our board of directors deems relevant. Accordingly, if any investor purchases shares of common stock, realization of a gain on such investment will depend on the appreciation of the price of our common stock, which may never occur. Investors seeking cash dividends in the foreseeable future should not purchase our common stock.

Anti-takeover provisions in Minnesota law may deter acquisition bids for us that you might consider favorable.

We are governed by the provisions of Sections 302A.671, 302A.673 and 302A.675 of the Minnesota Business Corporation Act (the "MBCA"). These provisions may discourage a negotiated acquisition or unsolicited takeover of us and deprive our shareholders of an opportunity to sell their common stock at a premium over the market price.

In general, Section 302A.671 of the MBCA provides that a corporation's shares acquired in a control share acquisition have no voting rights unless voting rights are approved in a prescribed manner. A "control share acquisition" is a direct or indirect acquisition of beneficial ownership of shares that would, when added to all other shares beneficially owned by the acquiring person, entitle the acquiring person to have voting power of 20% or more in the election of directors.

In general, Section 302A.673 of the MBCA prohibits a public Minnesota corporation from engaging in a business combination with an interested shareholder for a period of four years after the date of the transaction in which the person became an interested shareholder, unless the business combination is approved in a prescribed manner. The term "business combination" includes mergers, asset sales, and other transactions resulting in a financial benefit to the interested shareholder. An "interested shareholder" is a person who is the beneficial owner, directly or indirectly, of 10% or more of a corporation's voting stock or who is an affiliate or associate of the corporation, and who, at any time within four years before the date in question, was the beneficial owner, directly or indirectly, of 10% or more of the corporation's voting stock. Section 302A.673

does not apply if a committee of our Board of Directors consisting of all of its disinterested directors (excluding current and former officers) approves the proposed transaction or the interested shareholder's acquisition of shares before the interested shareholder becomes an interested shareholder.

If a tender offer is made for our common stock, Section 302A.675 of the MBCA precludes the offeror from acquiring additional shares of stock (including in acquisitions pursuant to mergers, consolidations, or statutory share exchanges) within two years following the completion of the tender offer, unless shareholders selling their shares in the later acquisition are given the opportunity to sell their shares on terms that are substantially the same as those contained in the earlier tender offer. Section 302A.675 does not apply if a committee of our Board of Directors consisting of all of its disinterested directors (excluding its current and former officers) approves the proposed acquisition before any shares are acquired pursuant to the earlier tender offer.

Risks Related to Financing Our Business

Our credit facility and payment obligations under the Revenue Participation Agreement with Oberland Capital, contain operating and financial covenants that restrict our business and financing activities, require cash payments over an extended period of time and are subject to acceleration in specified circumstances, which may result in Oberland Capital taking possession and disposing of any collateral.

Our credit facility with TPC Investments II LP and Argo SA LLC, each affiliates of Oberland Capital (collectively, "Oberland Capital"), contains restrictions that limit our flexibility in operating our business. Under the terms of the credit facility, we must maintain, and cause our subsidiaries to maintain, certain covenants, including with respect to limitations on new indebtedness, restrictions on the payment of dividends and maintenance of revenue levels. Our credit facility is collateralized by all of our assets including, among other things, our intellectual property.

If we breach certain of our debt covenants and are unable to cure such breach, revert to the provided liquidity covenant or are not granted waivers in relation to such breach, it may constitute an event of default under the credit facility, giving Oberland Capital the right to require us to repay the then-outstanding debt immediately. If we are unable to pay the outstanding debt immediately, Oberland Capital could, among other things, foreclose on the collateral granted to them to collateralize such indebtedness. A breach of the covenants contained in the credit facility documents and the acceleration of its repayment obligations by Oberland Capital could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In connection with the credit facility, we entered into a Revenue Participation Agreement ("RPA") with Oberland Capital. Pursuant to the RPA, we agreed to pay an additional quarterly royalty payment as a percentage of our net revenue, up to $70 million in any given fiscal year, subject to certain limitations set forth therein, during the period commencing on the later of (i) April 1, 2021 and (ii) the date of funding of a loan under the credit facility, and ending on the date upon which all amounts owed under the Term Loan Agreement have been paid in full. Payments will commence on September 30, 2021 with the royalty structure resulting in approximately 1.0% per year of additional payments on the outstanding principal amount of the loans.

The credit facility and RPA could have important negative consequences to the holders of our securities. For example, a portion of our cash flow from operations will be needed to make payments to Oberland Capital and will not be available to fund future operations. Additionally, we may have increased vulnerability to adverse general economic and industry conditions. Payment requirements under the credit facility and RPA will increase our cash outflows. Our future operating performance is subject to market conditions and business factors that are beyond our control. If our cash inflows and capital resources are insufficient to allow us to make required payments, we may have to reduce or delay capital expenditures, sell assets or seek additional capital. If we raise funds by selling additional equity, such sale would result in dilution to our stockholders. There is no assurance that if we are required to secure funding, we can do so on terms acceptable to us, or at all.

We may need to raise additional funds to finance our future capital or operating needs, which could have adverse impacts on our business, results of operations and the interests of our shareholders.

We may need to seek to raise funds through the issuance of public or private debt or the sale of equity to achieve our business strategy. If we raise funds, this could dilute the interests of our shareholders. Moreover, the availability of additional capital, whether debt or equity from private capital sources (including banks) or the public capital markets, fluctuates as our financial condition and industry or market conditions in general change. There may be times when the private capital markets and the public debt or equity markets lack sufficient liquidity or when our securities cannot be sold at attractive prices, in which case we would not be able to access capital from these sources on favorable terms, if at all. We can give no assurance as to the terms or availability of additional capital.

General Risk Factors

Legal proceedings that we become involved in from time to time could adversely affect our business operations or financial condition.

We are or may become involved in various legal proceedings, including, but not limited to, proceedings related to patent, product liability, shareholder or securities class actions, among other lawsuits. For example, as described in more detail in "Legal Proceedings" included elsewhere in this Annual Report on Form 10-K, we are currently a defendant in several securities class action lawsuits.

Legal proceedings, if decided adversely to or settled by us, and not covered by insurance, could result in liability material to our financial condition, results of operations or cash flows. Likewise, regardless of outcome, legal proceedings could result in substantial costs and expenses, affect the availability or cost of some of our insurance coverage and significantly divert the attention of our management. There can be no assurance that we will be able to prevail in, or achieve a favorable settlement of, any pending or future legal proceedings to which we become subject. Even claims without merit could subject us to adverse publicity and require us to incur significant legal fees.

We may be subject to future product liability litigation which could be expensive, and our insurance coverage may not be adequate.

Although we are not currently subject to any product liability proceedings and have no provision for product liability disbursements, we may incur material liabilities relating to product liability claims in the future, including product liability claims arising out of the usage of our products. Although we currently carry product liability insurance in an amount we believe is consistent with industry averages, our insurance coverage and any provision we may maintain in the future for product related liabilities may not be adequate and our business, results of operations, financial conditions, and prospects could suffer material adverse consequences.

Loss of key members of management, who it needs to succeed, could adversely affect our business.

Our future success depends on the continued efforts of the members of our executive management team. Competition for experienced management personnel in the healthcare industry is intense. If one or more of our executives or other key personnel are unable or unwilling to continue in their present positions, or if we are unable to attract and retain high quality executives or key personnel in the future, our business, results of operations, financial conditions, and prospects may be adversely affected.

Our business and financial performance could be adversely affected, directly or indirectly, by natural or man-made disasters or other similar events.

Neither the occurrence nor the potential impact of natural disasters (such as hurricanes and other natural disasters), civil insurrection and social unrest, public health crises, including COVID-19, nuclear disasters, terrorist activities, international hostilities or other criminal activities can be predicted. However, these occurrences could impact us directly as a result of damage to our facilities or by preventing us from conducting our business in the ordinary course, or indirectly as a result of their impact on our customers, suppliers or other counterparties. We could also suffer adverse consequences to the extent that these disasters affect the financial markets or the economy in general or in any particular region.

Our ability to mitigate the adverse consequences of such occurrences is in part dependent on the quality of our resiliency planning, and our ability, if any, to anticipate the nature of any such event that occurs. The adverse impact of natural or man-made disasters also could be increased to the extent that there is a lack of preparedness on the part of national or regional emergency responders or on the part of other organizations and businesses that we deal with, particularly those that we depend upon but have no control over.

Changes in U.S trade policy, threats of international tariffs, and changes to the U.S. political landscape may adversely affect our business, results of operations, financial condition, and prospects.

Additionally, rising threats of international tariffs, including tariffs applied to goods traded between the U.S. and China, could materially and adversely affect our business, results of operations, financial condition, and prospects. Over the past several years, legislative and executive action from U.S. and foreign leaders has led to both threats of and the imposition of tariffs on certain materials and products. Throughout 2020 and 2019, the U.S. and China imposed tariffs or announced proposed tariffs to be applied in the future to certain of each other's exports. We have not been directly affected by the tariffs implemented by President Trump on the medical technology industry. We cannot be certain, however, if these tariffs will remain following the administration change or what impact, if any they may have on our business. Changes in political

conditions in China and changes in the state of China-U.S. relations, including the current trade tensions, are difficult to predict and could adversely affect the operations or financial condition of the Company. We cannot predict the extent to which the U.S. or other countries will impose quotas, duties, tariffs, taxes or other similar restrictions upon the import or export of our products in the future, nor can we predict future trade policy or the terms of any renegotiated trade agreements and their impact on our business. The adoption and expansion of trade restrictions, the occurrence of a trade war, or other governmental action related to tariffs or trade agreements or policies has the potential to adversely impact demand for our products, our costs, our customers, our suppliers, and the U.S. economy, which in turn could have a material adverse effect on our business, results of operations, financial condition, and prospects.

We may be subject to new and changing legislation, executive orders, and regulations as a result of President Biden. We cannot be certain as to how various policy changes from the Biden administration, including healthcare regulatory changes, may impact our business, results of operation, financial condition, and prospects. Volatile economic, political and market condition, such as social unrest, civil insurrection and political action, could adversely affect our business, results of operation, financial condition, and prospects.

Our results of operations could be negatively affected by potential fluctuations in foreign currency exchange rates.

We are exposed to the effects of changes in foreign currency exchange rates. We are exposed to the risk of an increase or decrease in the value of the foreign currencies relative to the U.S. Dollar, which could increase the value of our expenses and decrease the value of our revenue when measured in U.S. Dollars. As a result, our results of operation may be influenced by the effects of future exchange rate fluctuations and such effects may have an adverse impact on our common stock price. Global markets and foreign currencies, including the Euro and the British Pound, were adversely impacted, as a result of Brexit and volatility in foreign currencies is expected to continue as a result of Brexit. Changes in the relative values of currencies occur regularly and, in some instances, could materially adversely affect our business, results of operations, financial condition or prospects.

Our failure to protect our technology systems and comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our business, results of operations, financial condition, and prospects.

We rely on information technology systems, including technology from third-party vendors, to process, transmit and store electronic information in our day-to-day operations. Similar to other companies, the size and complexity of our information technology systems makes them vulnerable to a cyber-attack, malicious intrusion, breakdown, destruction, loss of data privacy, or other significant disruption. Our information systems require an ongoing commitment of resources to maintain, protect and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving systems and regulatory standards and the increasing need to protect patient and customer information. Any failure by us to maintain or protect our information technology systems and data integrity, including from cyber-attacks, intrusions or other breaches, could result in the unauthorized access to patient data and personally identifiable information, theft of intellectual property or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations, which could adversely impact our business, results of operations, financial condition, and prospects.

In the U.S., federal and state privacy and security laws require certain of our operations to protect the confidentiality of personal information, including patient medical records and other health information. Limiting and/or restricting the use of certain personal data and information, as well as added transparency obligations to data subjects is becoming an increasing focus as evidenced by the implementation of the California Consumer Privacy Act (“CCPA”) which became effective on January 1, 2020. In Europe, E.U. member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Moreover, the collection and use of personal health data in the E.U. is governed by the European Union General Data Protection Regulation (“GDPR”). The GDPR imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the E.U. to the U.S., provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to 4% of the annual global revenue of the noncompliant company. The recent implementation of the GDPR has increased our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management’s attention and increase our cost of doing business.

Compliance with applicable data privacy and security laws and regulations (together with applicable industry standards) may increase our costs of doing business. In this regard and in light of the CCPA’s implementation, we expect that there will be other proposed laws, regulations and industry standards relating to privacy and data protection in the U.S., the E.U. and other

jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business results of operations, financial condition, and prospects.

We are dependent on internal information and telecommunications systems, and any failure of these systems, including system security breaches, data protection breaches or other cybersecurity attacks, may negatively impact our business and results of operations.

Cyber-attacks and other tactics designed to gain access to and exploit sensitive information by breaching mission critical systems of large organizations are constantly evolving and have been increasing in sophistication in recent years. High profile security breaches leading to unauthorized release of sensitive information have occurred with increasing frequency at a number of major U.S. companies, despite widespread recognition of the cyber-attack threat and improved data protection methods. While to date we have not experienced a significant data loss, significant compromise or any material financial losses related to cybersecurity attacks, our systems, those of our customers, and those of our third-party service providers are under constant threat. Cybercrime, including phishing, social engineering, attempts to overload our servers with denial-of-service attacks, or similar disruptions from unauthorized access to our systems, could cause us critical data loss or the disclosure or use of personal or other confidential information. Outside parties may attempt to fraudulently induce employees to disclose personally identifiable information or other confidential information which could expose us to a risk of loss or misuse of this information.

We are dependent on internal information and telecommunications systems, and we are vulnerable to failure of these systems, including through system security breaches, data protection breaches or other cybersecurity attacks. If these events occur, the unauthorized disclosure, loss or unavailability of data and disruption to our business may have a material adverse effect on our reputation and harm our relationships with vendors and customers. Additionally, these events may lead to financial losses from remedial actions, or potential liability from fines, including in relation to noncompliance with the GDPR, as well as possible litigation and punitive damages. Failures of our internal information or telecommunications systems may prevent us from taking customer orders, shipping products and billing customers. Sales may also be impacted if our customers are unable to access our pricing and product availability information. The occurrence of any of these events could have a material adverse impact on our business and results of operations.

Our management has broad discretion in the use of our cash and cash equivalents and, despite management's efforts, cash and cash equivalents may be used in a manner that does not increase the value of shareholders' investments.

Our management has broad discretion in the use of our cash and cash equivalents, and investors must rely on the judgment of management regarding the use of such cash and cash equivalents. Management may invest our cash and cash equivalents in short-term or long-term, investment-grade, interest-bearing securities. These investments may not yield favorable returns to shareholders. If we do not invest or apply our cash and cash equivalents in ways that enhance shareholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

Our business and stock price may be adversely affected if our internal controls are not effective.

Section 404 of the Sarbanes-Oxley Act of 2002 requires that public companies conduct a comprehensive evaluation of their internal control over financial reporting. To comply with this statute, each year we are required to document and test our internal control over financial reporting and our management is required to assess and issue a report concerning it.

Although we have systems in place to strengthen our internal control over financial reporting, we cannot assure you that we will not discover material weaknesses in the future or that no material weakness will result from any difficulties, errors, delays or disruptions while we implement and transition to new internal systems. The existence of one or more material weaknesses could result in errors in our financial statements, and substantial costs and resources may be required to rectify these or other internal control deficiencies. If we cannot produce reliable financial reports, investors could lose confidence in our reported financial information, the market price of our common stock could decline significantly, we may be unable to obtain additional financing to operate and expand our business and our business, results of operations, financial condition, and prospects could be adversely impacted.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We and SNH Medical Office Properties Trust, a Maryland real estate investment trust ("SNH"), are parties to that certain lease dated as of February 6, 2007, as amended, (the "Primary Lease") pursuant to which we lease approximately nineteen thousand square foot corporate headquarters facility in the Progress Center at 13631 Progress Boulevard, Alachua, Florida 32615 (the "Primary Premises").

We have entered into the First Expansion Lease, Second Expansion Lease, Third Expansion Lease, and Fourth Expansion Lease, which relate to properties that are adjacent to the Primary Premises resulting in having approximately eighteen thousand square feet for our corporate headquarters and certain research space in the Progress Center in Alachua, Florida.

On November 30, 2020, we entered into the Fifth Amendment to the Lease (the "Fifth Amendment"), with SNH. The Fifth Amendment provides that the terms attributable to the separate premises demised by the Primary Lease will be co-terminus and will expire on October 31, 2021. We also have the right to extend the term for an additional period of five years commencing on November 1, 2021 (the "Extended Term"). Annual Gross Rent (as defined in the Primary Lease) for each year of the extended term will be equal to 103% of the annual gross rent in effect for each immediately preceding year.

On November 21, 2018, we entered into Commercial Lease Amendment 3 (the "Burleson Amendment"), to the Commercial Lease dated April 21, 2015, as amended, with Ja-Cole L.P. Under the terms of the Burleson Amendment, we leased an additional two thousand five hundred square feet of warehouse/office space in Burleson, Texas (collectively with the space leased under the Commercial Lease with Ja-Cole L.P. prior to the effectiveness of the Burleson Amendment, the "Burleson Facility"). The Burleson Facility will now comprise a total of twelve thousand five hundred square feet, all of which, pursuant to the Burleson Amendment, will be leased until April 30, 2022. The Burleson Facility houses raw material storage and product distribution while allowing same day order fulfillment for both the east and west coasts of the United States. On October 1, 2020, we entered into Commercial Lease with Ja-Cole L.P. for a two thousand five hundred square feet space in Burleson, Texas for 24 months ending on October 31, 2022.

On September 20, 2018, we entered into an agreement with Heights Union, LLC, a Florida limited liability company ("Heights Union"), for the lease of seventy-five thousand square feet of office space (the "Heights Union Premises") in a one hundred and fifty thousand square foot office building that Heights Union on an area of land in Tampa, Florida. Pursuant to the Heights Union lease, we will use the Heights Union Premises for general office, medical laboratory, training and meeting purposes. We believe we can obtain certain economic incentives from state authorities associated with the employment at the facility; but such incentives are not expected to be a material offset to the expenses of the project as a whole.

On August 6, 2015, we entered into the CTS Agreement with CTS, an FDA registered tissue establishment. Processing of the Avance Nerve Graft pursuant to the CTS Agreement began in February 2016. The CTS Agreement initially had a five-year term ending August 31, 2020. On February 22, 2019, the agreement was amended to extend the term through December 31, 2021 and then on April 22, 2020 was further amended to extend the term through December 31, 2022 and provides the Company the right to terminate the agreement after February 28, 2022, with six-months advance written notice and notice cannot be provided prior to March 1, 2021. Under the CTS Agreement, we pay CTS a facility fee for clean room/manufacturing, storage and office space. CTS also provides services in support of our manufacturing such as routine sterilization of daily supplies, providing disposable supplies, microbial services and office support.

Effective June 8, 2018, we entered into an Agreement for Purchase and Sale of Real Property with ARC CRVANOH001, LLC, a Delaware limited liability company ("ARC"), for the acquisition (the "Acquisition") by us of certain real property located in Vandalia, Ohio comprised of a 70,000 square foot building on approximately 8.6 acres of land. We thereafter transferred its rights and obligations under the Agreement to Axogen Processing Corporation, incorporated for purposes of the Acquisition. On July 31, 2018, Axogen Processing Corporation completed the Acquisition pursuant to the terms of the Agreement for Purchase and Sale of Real Property.

In addition, we lease space and maintain records at certain other facilities, including our prior corporate headquarters at 1407 South Kings Highway, Texarkana, Texas 75501.

The aggregate cost of all of our properties is approximately $3 million per year. We believe that our facilities will be sufficient to operate our business for the next 12 months and that current lease obligations will not change materially.

ITEM 3. LEGAL PROCEEDINGS

Except as provided below, Axogen and its subsidiaries do not have any active or pending material legal proceedings:

1. On January 9, 2019, Plaintiff Neil Einhorn, on behalf of himself and others similarly situated, filed a putative class action complaint in the United Stated District Court for the Middle District of Florida alleging violations of the federal securities laws against Axogen, Inc., certain of its directors and officers ("Individual Defendants"), and Axogen's 2017 Offering Underwriters and 2018 Offering Underwriters (collectively, with the Individual Defendants, the "Defendants"), captioned Einhorn v. Axogen, Inc., et al., No. 8:19-cv-00069 (M.D. Fla.). Plaintiff asserts that Defendants made false or misleading statements in connection with the Company's November 2017 registration statement issued regarding its secondary public offering in November 2017 and May 2018 registration statement issued regarding its secondary public offering in May 2018, and during a class period of August 7, 2017 to December 18, 2018. In particular, Plaintiff asserts that Defendants issued false and misleading statements and failed to disclose to investors: (1) that the Company aggressively increased prices to mask lower sales; (2) that the Company's pricing alienated customers and threatened the Company's future growth; (3) that ambulatory surgery centers form a significant part of the market for the Company's products; (4) that such centers were especially sensitive to price increases; (5) that the Company was dependent on a small number of surgeons whom the Company paid to generate sales; (6) that the Company's consignment model for inventory was reasonably likely to lead to channel stuffing; (7) that the Company offered purchase incentives to sales representatives to encourage channel stuffing; (8) that the Company's sales representatives were encouraged to backdate revenue to artificially inflate metrics; (9) that the Company lacked adequate internal controls to prevent such channel stuffing and backdating of revenue; (10) that the Company's key operating metrics, such as number of active accounts, were overstated; and (11) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects, were materially misleading and/or lacked a reasonable basis. Axogen was served on January 15, 2019. On February 4, 2019, the court granted the parties' stipulated motion which provided that Axogen is not required to file a response to the complaint until thirty days after Plaintiff files a consolidated amended complaint. On June 19, 2019, Plaintiff filed an Amended Class Action Complaint, and on July 22, 2019, Defendants filed a motion to dismiss. Plaintiff filed opposing papers on August 12, 2019. The Court held a status hearing on September 11, 2019 and stayed all deadlines regarding the parties' obligations to file a case management report. On December 4, 2019 the parties' presented oral arguments. On April 21, 2020, the Court dismissed the complaint without prejudice, finding the Plaintiff failed to state a claim upon which relief could be granted. The Plaintiff filed a Second Amended Class Action Complaint on June 22, 2020. Axogen filed a motion to dismiss on August 6, 2020. The Plaintiff filed an opposition on September 20, 2020. The Court held oral argument on February 25, 2021. The Company and Individual Defendants dispute the allegations and intend to vigorously defend against the Complaint. The amount of loss, if any, cannot be reasonably estimated at this time.

2. Jackson v. Zaderej, et al., No. 8:19-cv-01976 U.S. District Court (M.D. FL). On August 12, 2019, Plaintiff Harvey Jackson, derivatively on behalf of Axogen, filed a verified shareholder derivative complaint for violations of securities laws, breach of fiduciary duty, waste of corporate assets and unjust enrichment against Quentin S. Blackford, Gregory G. Freitag, Mark Gold, Jamie M. Grooms, Alan M. Levine, Peter J. Mariani, Guido Neels, Robert J. Rudelius, Amy Wendell, and Karen Zaderej (the "Individual Defendants") and Nominal Defendant Axogen, Inc. ("Axogen") (collectively, "Defendants"). Plaintiff asserts that the Individual Defendants, who are current or former Axogen officers or directors, issued a false proxy statement for the election of directors in violation of Section 14(a) of the Securities Exchange Act of 1934, breached their fiduciary duties, wasted corporate assets and were unjustly enriched by allowing Axogen to make false public statements to investors based on the same claims in the report issued December 18, 2018 by Seligman Investments (the same allegations that form the basis for the Einhorn matter and the Bussey shareholder demand). Plaintiff demands judgment in the Company's favor against all Individual Defendants as follows: (A) declaring that Plaintiff may maintain this action on behalf of Axogen, and that Plaintiff is an adequate representative of Company; (B) declaring that the Individual Defendants have breached and/or aided and abetted the breach of their fiduciary duties to Axogen; (C) determining and awarding to Axogen the damages sustained by it because of the violations set forth above from each of the Individual Defendants, jointly and severally, together with pre- and post-judgment interest thereon; (D) directing Axogen and the Individual Defendants to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and protect Axogen and its shareholders from a repeat of the damaging events described therein, including, but not limited to, putting forward for shareholder vote the following resolutions for amendments to the Company's Bylaws or Articles of Incorporation and the following actions as may be necessary to ensure proper corporate governance policies: (i) a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater shareholder input into the policies and guidelines of the Board, (ii) a provision to permit the shareholders of Axogen to nominate at least six candidates for election to the Board; and (iii) a proposal to ensure the establishment of effective oversight of compliance with applicable laws, rules, and regulations; (E) awarding Axogen restitution from Individual Defendants, and each of them; (F) awarding Plaintiff the costs and disbursements of this action, including

reasonable attorneys' and experts' fees, costs, and expenses; and (G) granting such other and further relief as the Court may deem just and proper. The Defendants filed a motion to dismiss on October 22, 2019. In response, Plaintiffs voluntarily withdrew their complaint and the matter was dismissed without prejudice by the court on November 5, 2019.

3. Novitzki v. Zaderej, et al, 19-CA-11745 DIV L (13th Judicial Circuit, Hillsborough Cnty., Fl.). On November 11, 2019, Plaintiff Joseph Novitzki, derivatively on behalf of Axogen, filed a verified stockholder derivative complaint for breach of fiduciary duty, waste of corporate assets and unjust enrichment against Karen Zaderej, Gregory G. Freitag, Peter J. Mariani, Amy Wendell, Robert J. Rudelius, Mark Gold, Guido Neels, and Jamie M. Grooms (the "Individual Defendants") and Nominal Defendant Axogen, Inc. ("Axogen") (collectively, "Defendants"). Plaintiff asserts that the Individual Defendants, who are current or former Axogen officers or directors, breached their fiduciary duties, wasted corporate assets and were unjustly enriched by allowing Axogen to make false public statements to investors based on the same claims in the report issued December 18, 2018 by Seligman Investments (the same allegations that form the basis for the Einhorn matter and the Bussey shareholder demand). Plaintiff demands judgment in the Company's favor against all Individual Defendants as follows: (a) against all of the defendants and in favor of the Company for the amount of damages sustained by the Company as a result of the defendants' breaches of fiduciary duties, waste of corporate assets, and unjust enrichment; (B) directing Axogen to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect Axogen and its stockholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for stockholder vote, resolutions for amendments to the Company's Bylaws or Articles of Incorporation and taking such other action as may be necessary to place before stockholders for a vote of the following corporate governance policies: (1) directing Axogen to employ an independent, third-party expert to calculate the Company's market size (including the dollar values of Axogen's total addressable market and portion of the market relating to extremity trauma and OMF); (2) a provision to control insider selling; (3) a proposal to strengthen Axogen's oversight of its disclosure procedures; (4) a proposal to strengthen the Company's controls over financial reporting; (5) a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater stockholder input into the policies and guidelines of the Board; and (6) a provision to permit the stockholders of Axogen to nominate at least three candidates for election to the Board; (C) extraordinary equitable and/or injunctive relief as permitted by law, equity, and state statutory provisions sued hereunder, including attaching, impounding, imposing a constructive trust on, or otherwise restricting the proceeds of defendants' trading activities or their other assets so as to assure that plaintiff on behalf of Axogen has an effective remedy; (D) Awarding to Axogen restitution from defendants, and each of them, and ordering disgorgement of all profits, benefits, and other compensation obtained by the defendants, including all ill-gotten gains from insider selling by defendants; (E) awarding to plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and (F) granting such other and further relief as the Court deems just and proper. After Defendants' counsel had multiple discussions with Plaintiff's counsel pointing out that it's complaint was deficient for the same reasons argued in Jackson, the Plaintiff agreed to voluntarily dismiss the complaint without prejudice, which the court so-ordered on January 24, 2020.
4. Bach v. Zaderej, et al., 27-cv-20-5997 (Hennepin Cnty., Minn.). On April 21, 2020, Plaintiff Michael Bach, derivatively on behalf of Axogen, filed a verified stockholder derivative complaint for breach of fiduciary duty, insider selling, corporate waste and unjust enrichment against Karen Zaderej, Gregory G. Freitag, Peter J. Mariani, Amy Wendell, Robert J. Rudelius, Mark Gold, Guido Neels, Jamie M. Grooms, Quentin S. Blackford, and Alan M. Levine (the "Individual Defendants") and Nominal Defendant Axogen, Inc. ("Axogen") (collectively, "Defendants"). The Bach Complaint has not yet been served on Defendants and therefore no response is necessary at this time.

ITEM 4. MINE SAFETY DISCLOSURES

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

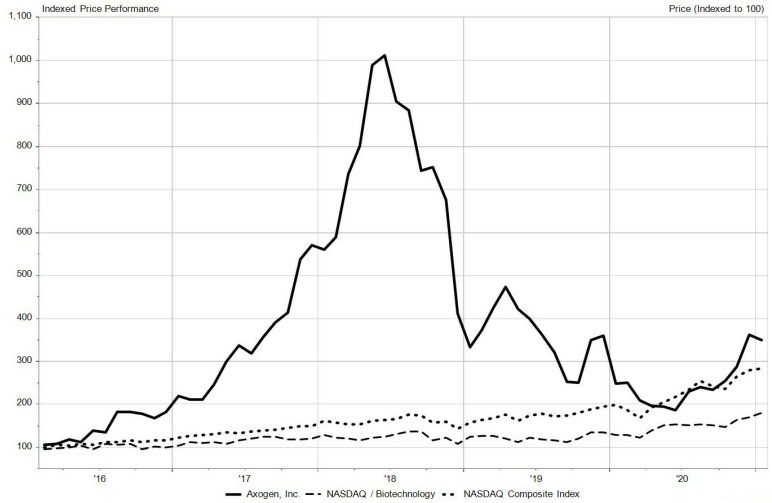
Axogen's common stock is traded on the Nasdaq Capital Market under the symbol "AXGN." On February 22, 2021, the last reported closing sale price of our common stock on the Nasdaq Capital Market was $21.19 per share.

Shareholders

As of February 22, 2021, we had 40,736,714 shares of common stock outstanding, and approximately 234 common shareholders of record, based upon information received from our stock transfer agent. However, this number does not include beneficial owners whose shares were held of record by nominees or broker dealers. We estimate that there are more than 8,934 individual owners. Additional information called for by this item is incorporated herein by reference to the following sections of this Report: Footnote 12 - Equity Compensation Plans of the Notes to Consolidated Financial Statements included in Item 8; and Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters – Equity Compensation Plan Information".

Stock Performance Graph

The following graph compares the cumulative total shareholder return on our common stock for the period from December 31, 2015 to December 31, 2020 with (i) the Nasdaq Stock Market Composite Index; and (ii) the Nasdaq Stock Market Biotechnology Index. The graph assumes an investment of $100 in our common stock and the respective indices for the period of December 31, 2015 to December 31, 2020. The comparisons set forth in the graph are provided pursuant to SEC rules and are not intended to forecast or be indicative of the future performance of our common stock or either of the included indices. The performance graph shall not be deemed incorporated by reference by any general statement incorporating by reference this annual report into any filing under the Securities Act of 1933, as amended, or the Exchange Act of 1934, as amended, except to the extent we specifically incorporate this information by reference, and shall not otherwise be deemed filed under such acts.



Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not repurchase any of our securities in the fourth quarter of 2020.

Recent Sales of Unregistered Securities

We had no sales of unregistered securities in 2020.

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth below has been derived from our audited financial statements. This data should be read in conjunction with the financial statements, the notes thereto and "Management's Discussion and Analysis of Financial

Condition and Results of Operations" included elsewhere in this report. Dollar amounts are in thousands, except per share amounts.

	Year ended December 31,				
	2020	2019	2018	2017	2016
Statement of Operations Data:					
Revenue	$ 112,300	$ 106,712	$ 83,937	$ 60,426	$ 41,108
Cost of goods sold	21,581	17,349	12,923	9,311	6,467
Gross profit	90,719	89,363	71,014	51,115	34,641
Costs and expenses:					
Sales and marketing	69,659	71,950	56,617	37,636	28,426
Research and development	17,846	17,514	11,773	6,699	4,212
General and administrative	26,396	31,305	23,124	14,731	10,133
Total costs and expenses	113,901	120,769	91,514	59,066	42,771
Loss from operations	(23,182)	(31,406)	(20,500)	(7,951)	(8,130)
Other income (expense):					
Investment income	605	2,364	1,525	—	—
Interest expense	(1,054)	(40)	(1,208)	(2,463)	(6,261)
Change in fair value of derivative liabilities	(117)	—	—	—	—
Loss on extinguishment of debt	—	—	(2,186)	—	—
Other (expense)	(38)	(53)	(28)	(31)	(20)
Total other income (expense)	(604)	2,271	(1,897)	(2,494)	(6,281)
Net loss	(23,786)	(29,135)	(22,397)	(10,445)	(14,411)
Loss per common share - basic and diluted	(0.60)	(0.74)	(0.60)	(0.31)	(0.47)

	2020	2019	2018	2017	2016
Balance Sheet Data:					
Total current assets	$ 145,251	$ 135,021	$ 150,953	$ 55,741	$ 44,037
Total assets	201,381	154,643	160,173	58,875	46,360
Total current liabilities	22,831	20,880	13,044	13,719	11,081
Total long-term obligations, net of current maturities and deferred financing fees	55,401	1,610	147	19,974	20,358
Total liabilities	78,232	22,490	13,191	33,693	31,439
Total shareholders' equity	123,149	132,153	146,982	25,182	14,921

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following information should be read in conjunction with "Selected Financial Data" contained in Item 6 of this Form 10-K, our consolidated financial statements and the notes thereto contained in Item 8 of this Form 10-K, the "Cautionary Notice Regarding Forward-Looking Statements" contained in Part 1 of this Form 10-K, "Risk Factors" contained in Item 1A of this Form 10-K, and the other information appearing elsewhere in, or incorporated by reference into, this Form 10-K. Dollar amounts referenced in this Item 7 are in thousands, except per share amounts.

Overview

We are the leading company focused specifically on the science, development and commercialization of technologies for peripheral nerve regeneration and repair. We are passionate about helping to restore peripheral nerve function and quality of life to patients with physical damage or transection to peripheral nerves 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.

Our 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 injured 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. Along with these core surgical products, we also offer the Axotouch® Two-Point Discriminator, used to measure the innervation density of any surface area of the skin. Our product are available in the United States, Canada, Germany, the United Kingdom, South Korea and several European and other international countries.

Revenue from the distribution of Axogen's peripheral nerve repair products, Avance Nerve Graft, Axoguard Nerve Connector, Axoguard Nerve Protector, Axoguard Nerve Cap and Avive Soft Tissue Membrane, in the United States is the main contributor to Axogen's total reported sales and has been the key component of its growth to date.

We have experienced that surgeons initially are cautious adopters for peripheral nerve repair products. Surgeons typically start with a few cases and then wait and see the results of these initial cases. Active accounts are usually past this wait period and have developed some level of product reorder. These active accounts have typically gone through the committee approval process, have at least one surgeon who has converted a portion of his or her treatment algorithms of peripheral nerve repair to the Axogen portfolio and have ordered Axogen products at least six times in the last twelve months. As such, revenue growth primarily occurs from increased purchasing from active accounts, followed by revenue growth from new accounts.

In March 2020, the World Health Organization declared the outbreak of the 2019 novel coronavirus ("COVID-19") a pandemic. The global impact of COVID-19 has had a negative effect on the global economy, disrupting the financial markets and significantly impacting the medical industry. In response to COVID-19, our top priority has been the health and safety of those we serve, including healthcare professionals and their patients, as well as our employees, communities, and suppliers. We ensured employee compliance with state and local mandates as well as implemented certain cost mitigation initiatives such as a reduction in pay levels, temporary suspension of tissue processing and deferral of certain projects, among other efforts.

As we began to experience some recovery from COVID-19, some of our cost mitigation initiatives were lifted such as the restoration of pay levels, which were lifted for most employees in August 2020, and for executive member and board members in late October. We began to gradually restart tissue processing in June and have continued to increase capacity through the end of the fiscal year. We have also begun to slowly increase investment into projects that were previously on hold, including certain clinical trials, product development, and marketing and administrative initiatives, as well as restarting construction of the biologics processing center in Vandelia, Ohio.

Although COVID-19 had significant impact on our revenue growth, the Company was able to increase revenue in 2020 as compared to 2019.Late last year, we rebalanced our commercial organization toward our largest market opportunity, extremity trauma, and refocused our team on driving deeper penetration with our existing surgeon customers. During COVID-19 pandemic, we kept our sales team and broader commercial organization intact and took the opportunity to provide extensive sales training. Our sales team developed skills and shared best practices around remote case support where hospital access has

been restricted. We believe this remote support has been appreciated by customers and has expanded our sales team's ability to support surgeons and their patients during COVID-19 and beyond.

In addition, our professional education group was able to quickly develop a virtual surgeon training program, and combined with our marketing initiatives, was successful in developing new customers and revenue growth through product penetration.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

The following table sets forth, for the periods indicated, our results of operations expressed as dollar amounts and as percentages of total revenue:

	Year Ended December 31,			
	2020		2019	
	Amount	% of Revenue	Amount	% of Revenue
	(dollars in thousands)			
Revenue	$ 112,300	100.0 %	$ 106,712	100.0 %
Cost of goods sold	21,581	19.2	17,349	16.3
Gross profit	90,719	80.8	89,363	83.7
Costs and expenses:				
Sales and marketing	69,659	62.0	71,950	67.4
Research and development	17,846	15.9	17,514	16.4
General and administrative	26,396	23.5	31,305	29.3
Total costs and expenses	113,901	101.4	120,769	113.1
Loss from operations	(23,182)	(20.6)	(31,406)	(29.4)
Other (expense) income:				
Investment income	605	0.5	2,364	2.1
Interest expense	(1,054)	(0.9)	(40)	—
Change in fair value of derivative liabilities	(117)	(0.1)	—	—
Loss on extinguishment of debt	—	—	—	—
Other expense	(38)	—	(53)	—
Total other (expense) income, net	(604)	(0.5)	2,271	2.1
Net Loss	$ (23,786)	(21.1)%	$ (29,135)	(27.3)%

Revenue

Revenue for the year ended December 31, 2020 increased 5.2% to $112,300 as compared to $106,712 for the year ended December 31, 2019. During the on-set of COVID-19, certain hospitals and surgery centers discontinued elective surgeries and our sales force was not allowed to enter the hospitals. This significantly reduced our revenue. Once elective surgeries resumed, hospitals allowed our sales representatives to begin entering their facilities once again. As a result, we began to experience a return in revenue as these facilities began scheduling surgeries, although restrictions continue to limit our access in certain accounts as local communities address resurgences of COVID-19. Revenue growth was driven by an increase in unit volume of approximately 2%, as well as the net impact of changes in prices and product mix of approximately 3%. The growth in unit volume increase was primarily attributed to unit growth in our active accounts. In the fourth quarter of 2020, we had 893 active accounts, an increase of 12% from 797 at the end of 2019.

Gross Profit

Gross profit for the year ended December 31, 2020 increased 1.5% to $90,719 as compared to $89,363 for the year ended December 31, 2019. Gross profit increased during fiscal 2020 due to an increase in revenue, offset by the impact of COVID-19. Gross profit margin in 2020 decreased to 80.8% as compared to 83.7% in 2019. Gross margin was negatively impacted during fiscal year 2020 due to idle facility charges and other increased period costs of approximately $2,000 in the second and third quarters resulting from our temporary suspension of tissue processing, as well as approximately $2,242 of inventory write-downs. Gross margins have continued to improve sequentially in the second half of the year and we expect them to continue to return to historical levels as revenue and nerve processing volumes increase.

Costs and Expenses

Total cost and expenses decreased 5.7% to $113,901 for the year ended December 31, 2020 as compared to $120,769 for the year ended December 31, 2019. The decrease in operating expenses was primarily attributable to the impact of our lower travel and in-person surgeon education program of $9,807 as a result of restrictions associated with COVID-19, as well as a decreased litigation expenses of $2,467 as a result of reaching deductible limits with respect to certain litigation matters. These decreases were slightly offset by higher sales commissions and other compensation related costs of $5,519. As a percentage of revenue, total cost and expenses decreased to 101.4% in 2020 compared to 113.1% in 2019.

Sales and marketing expenses decreased 3.2% to $69,659 for the year ended December 31, 2020 as compared to $71,950 for the year ended December 31, 2019. This decrease was driven by lower travel, surgeon education and conference expenses as we cancelled in-person education programs, and experienced restrictions in hospital access and travel directly related to the impact of COVID-19. The decrease in expenses was slightly offset by salaries and benefits from increased sales commissions. As a percentage of revenue, sales and marketing expenses were 62.0% for the year ended December 31, 2020 compared to 67.4% for the year ended December 31, 2019. We expect sales and marketing expenses will increase as pandemic-related restrictions in hospital access and travel normalize.

General and administrative expenses decreased 15.7% to $26,396 for the year ended December 31, 2020 as compared to $31,305 for the year ended December 31, 2019. The decrease was primarily due to lower litigation expenses as a result of reaching deductible limits with respect to certain litigation matters as well as a decrease in stock compensation. As a percentage of revenue, general and administrative expenses decreased to 23.5% for the year ended December 31, 2020 compared to 29.3% for the year ended December 31, 2019.

Research and development expenses slightly increased to $17,846 for the year ended December 31, 2020, as compared to $17,514 in the prior year ended December 31, 2019. Research and development costs include our product development efforts as well as non-clinical spend in support of our BLA for Avance Nerve Graft, and clinical trials. Product development expenses represented approximately 50% of total research and development expense in the fiscal year ended December 31, 2020 as compared to 52% in the prior year period. It is expected that costs associated with the BLA will continue to increase as we continue to invest in completing the license application. Additionally, we continue to conduct development efforts focused on both new peripheral nerve products and new peripheral nerve applications for our existing products. We pursue research grants to support research and early product development. Clinical trial expenses represented approximately 50% of research and development expense in the fiscal year ended December 31, 2020 as compared to 48% in the prior year period. COVID-19 negatively impacted certain of our clinical study programs as certain study sites restricted access and reallocated their resources to focused on COVID-19 related care; however, we expect activity to recover over the next fiscal year. Included within Clinical trial expenses are clinical trial costs associated with the BLA. Our continued efforts related to the BLA drove the slight increase in research and development expenses year over year. As a percentage of revenue, research and development expenses decreased to 15.9% in 2019 from 16.4% in 2019.

Other Income and Expenses

Interest expense increased to $1,054 as compared to $40 for the year ended December 31, 2019. The change is primarily due to interest expense from our Oberland debt facility, which began on June 30, 2020. We recognized total interest charges of $1,941 in connection with the Oberland debt facility in the current year, but $997 of this interest was capitalized to the construction costs of the APC. For the year ended December 31, 2020, we recognized $605 of investment income from our asset management and cash investment sweep accounts as compared to $2,364 for the year ended December 31, 2019. The decrease is primarily due to lower investment income from our asset management program as a result of lower interest rates from COVID-19 and as we lowered investment balances and increased cash reserves.

Income Taxes

We had no income tax expenses or income tax benefit for 2020 or 2019 due to incurrence of net operating loss for the year, the benefits of which have been fully value allowed. We do not believe that there are any additional tax expenses or benefits currently available.

Comparison of the Years Ended December 31, 2019 and 2018

The following table sets forth, for the periods indicated, our results of operations expressed as dollar amounts and as percentages of total revenue:

	Year Ended December 31,			
	2019		2018	
	Amount	% of Revenue	Amount	% of Revenue
	(dollars in thousands)			
Revenue	$ 106,712	100.0 %	$ 83,937	100.0 %
Cost of goods sold	17,349	16.3	12,923	15.4
Gross profit	89,363	83.7	71,014	84.6
Costs and expenses:				
Sales and marketing	71,950	67.4	56,617	67.5
Research and development	17,514	16.4	11,773	14.0
General and administrative	31,305	29.3	23,124	27.5
Total costs and expenses	120,769	113.1	91,514	109.0
Loss from operations	(31,406)	(29.4)	(20,500)	(24.4)
Other income (expense):				
Investment income	2,364	2.1	1,525	1.8
Interest expense	(40)	—	(1,208)	(1.4)
Loss on extinguishment of debt	—	—	(2,186)	(2.6)
Other expense	(53)	—	(28)	—
Total other income (expense):	2,271	2.1	(1,897)	(2.3)
Net Loss	$ (29,135)	(27.3)%	$ (22,397)	(26.7)%

Revenue

Revenue for the year ended December 31, 2019 increased 27.1% to $106,712 as compared to $83,937 for the year ended December 31, 2018. Revenue growth for the year was primarily the result of increases in unit volume, as well as the net impact of price increases and changes in product mix. Our revenue growth was largely driven by increased revenue in active accounts as well as the addition of new active accounts. In the fourth quarter of 2019, we had 797 active accounts, an increase of 12% from 712 at the end of 2018.

Gross Profit

Gross profit for the year ended December 31, 2019 increased 25.8% to $89,363 as compared to $71,014 for the year ended December 31, 2018. The increase was primarily attributable to the increased revenue, but slightly offset by increased processing costs, inventory write downs and additional inventory reserves. Gross profit margin in 2019 decreased to 83.7% as compared to 84.6% in 2018.

Costs and Expenses

Total cost and expenses increased 32.0% to $120,769 for the year ended December 31, 2019 as compared to $91,514 for the year ended December 31, 2018. The increase was primarily due to variable costs associated with increased sales activity, expansion of our commercial team, expanding product development and clinical study activities, expanded surgeon education programs, and increases in compensation and general expenses associated with ongoing expansions of infrastructure to support

our growth. In addition, general and administrative expenses include approximately $2,467 of litigation expenses and certain expenses associated therewith, as a result of the ongoing litigation described in Legal Proceedings and other litigation that was dismissed during 2019 (the "Litigation") in the period ending December 31, 2019 as compared to $0 in the prior year period. As a percentage of revenue, total cost and expenses increased to 113.1% in 2019 compared to 109.0% in 2018.

Sales and marketing expenses increased 27.1% to $71,950 for the year ended December 31, 2019 as compared to $56,617 for the year ended December 31, 2018. The increase was primarily due to: (a) increased compensation expenses related to Axogen's direct sales force as a result of increased sales and hiring of additional personnel; (b) increased travel expenses to support the commercial team's activities; (c) expansion of our surgeon education program; and (d) increased marketing activity. As a percentage of revenue, sales and marketing expenses were 67.4% for the year ended December 31, 2019 compared to 67.5% for the year ended December 31, 2018.

General and administrative expenses increased 35.4% to $31,305 for the year ended December 31, 2019 as compared to $23,124 for the year ended December 31, 2018. The increase was primarily the result of increased expenses related to infrastructure expansion to support our growth, including professional fees, salaries, and an increase of $1,982 of non-cash stock compensation. As mentioned above, we also recorded $2,467 of legal fees associated the Litigation. As a percentage of revenue, general and administrative expenses increased to 29.3% for the year ended December 31, 2019 compared to 27.5% for the year ended December 31, 2018.

Research and development expenses increased 48.8% to $17,514 in the year ended December 31, 2019 as compared to $11,773 for the year ended December 31, 2018. Research and development costs include our product development and clinical efforts substantially focused on its Biologics License Application, or BLA, for Avance Nerve Graft, the Sensation-NOW and RECON studies and the development of new or next generation products. The increase in expenses for 2019 relate to expenditures for these activities and hiring additional personnel to support clinical and product development activity. It is expected that costs associated with the BLA will continue to increase as we continue to invest in completing the license application. We continue to conduct development efforts focused on both new peripheral nerve products and new peripheral nerve applications for our existing products. We pursue research grants to support research and early product development. Our increased product and clinical pipeline development initiatives contributed to the increase in research and development expenses in 2019. As a result, research and development expenses increased to 16.4% in 2019 from 14.0% in 2018, as a percentage of revenue.

Other Income and Expenses

For the year ended December 31, 2019, we recognized $2,364 of investment income from our asset management and cash investment sweep accounts as compared to $1,525 for the year ended December 31, 2018. Interest expense decreased to $40 as compared to $1,127 for the year ended December 31, 2018 as a result of our paying, in full, the Term Loan and Revolving Loan with MidCap, as defined in "Term and Revolving Loan Agreements in the prior year ended December 31, 2018. For the year ended December 31, 2018, we incurred a loss on the extinguishment of the debt of $2,186 for exit, prepayment fees and the amortization of the remaining balance of the deferred financing costs for which there was no such activity in the current year.

Income Taxes

We had no income tax expenses or income tax benefit for 2019 or 2018 due to incurrence of net operating loss for the year, the benefits of which have been fully value allowed.

Liquidity and Capital Resources

Cash Flow Information

As of December 31, 2020, we had cash, cash equivalents, investments, and restricted cash of $110,808, an increase of $8,298 from $102,510 at December 31, 2019. The increase includes $35,000 of proceeds from our new debt facility, $3,500 of equity proceeds from the Oberland Option, and $2,630 of net proceeds from employee stock option exercises, partially offset by $21,905 of capital expenditures, and $9,626 of cash used in operating activities including favorable changes in working capital.

We have working capital of $122,420 and a current ratio of 6.4 at December 31, 2020, compared to working capital of $114,141 and a current ratio of 6.5 at December 31, 2019. The increase in working capital at December 31, 2020 as compared to December 31, 2019, was primarily proceeds from our new debt facility, which is recorded as a long-term liability and the year over year improvement in the cash collections cycle, as accounts receivable remained relatively flat with revenue growth of 5.2%.

Our future capital requirements depend on a number of factors including, without limitation, revenue increases consistent with our business plan, cost of products and acquisition and/or development of new products. We could face increasing capital needs. Such capital needs could be substantial depending on the extent to which we are unable to increase revenue.

If we need additional capital in the future, we may raise additional funds through public or private equity offerings, debt financings or from other sources. The sale of additional equity would result in dilution to our shareholders. There is no assurance that we will be able to secure funding on terms acceptable to us, or at all. The increasing need for capital could also make it more difficult to obtain funding through either equity or debt. Should additional capital not become available to us as needed, we may be required to take certain action, such as slowing sales and marketing expansion, delaying regulatory approvals or reducing headcount.

	Year Ended		
	December 31, 2020	December 31, 2019	December 31, 2018
	(dollars in thousands)		
Net cash (used in) provided by:			
Operating activities	$ (9,626)	$ (19,872)	$ (17,862)
Investing activities	(16,963)	27,271	(98,193)
Financing activities	40,474	4,031	109,842
Net increase (decrease) in cash and cash equivalents	$ 13,885	$ 11,430	$ (6,213)

Net Cash Used in Operating Activities

We used $9,626 of cash for operating activities in 2020, as compared to using $19,872 and $17,862 of cash for operating activities in 2019 and 2018, respectively. This improvement in cash used in operating activities in 2020 was primarily due to favorable changes in working capital as well as a decrease in the net loss year over year. Net cash used in operations decreased in 2019 as compared to 2018 was the result of a higher net loss for the year offset by improvements in working capital.

Net Cash Provided by/Used in Investing Activities

Investing activities for 2020 used $16,963 of cash as compared to providing $27,271 during 2019 and use of $98,193 in 2018.The increase in outflows of cash in the current year as compared to 2019 primarily related to capital expenditures for APC and our Tampa facilities offset by higher proceeds from the sale of investments in prior year. The improvement in cash flow from investing in 2019 over 2018, was primarily the result of the Company beginning to invest in longer term instruments in 2018.

Net Cash Provided by Financing Activities

Financing activities in 2020 provided $40,474 of cash as compared to providing $4,031 and $109,842 of cash in 2019 and 2018, respectively. The 2020 improvement over 2019 was primarily the result of the borrowings from the Oberland Facility of $35,000 as well as $3,500 of proceeds from the exercise of the stock options related to the Oberland Facility, see Footnote 10 - Long-Term Debt in the Notes to the Consolidated Financial Statements for further discussion. The decrease of cash flows in

2019 as compared to 2018 was the result of the equity financing of $132,964 in 2018. Proceeds from the exercise of stock options, excluding the Oberland stock option exercise, provided $3,300, $4,002, and $3,884 of cash for the years ended December 31, 2020, 2019, and 2018, respectively.

Operating Cash Requirements

On July 9, 2019, we entered into a Standard Form of Agreement Between Owner and Design-Builder (the "Design-Build Agreement") with CRB Builders, L.L.C., a Missouri limited liability company ("CRB"), pursuant to which CRB will renovate and retrofit the APC (See Footnote 15 - Commitments and Contingencies in the Notes to the Consolidated Financial Statements). We anticipate spending up to approximately $25,002 for renovations, equipment and furniture over the next twelve months and up to $26,821 over the next 18 months.

As previously disclosed, we entered into an agreement with Heights Union, LLC, a Florida limited liability company ("Heights Union"), for the lease of seventy-five thousand square feet of office and lab space. Pursuant to the Heights Union lease, we will use the Heights Union Premises for general office, medical laboratory, training and meeting purposes. We expect to spend $1,573 in the first quarter as we complete our furnishing and final touches on our new facility.

As of December 31, 2020, we had cash, cash equivalents, investments and restricted cash totaling $110,808 and total current liabilities of $22,831. Based on current estimates, we believe that our existing cash, cash equivalents and investments will allow us to fund our operations through at least the next 12 months.

Credit Facilities

On October 25, 2016, we entered into Term Loan and a Revolving Loan with MidCap Financial Trust ("MidCap") maturing on May 1, 2021.

We have the option at any time to prepay the Term Loan in whole or in part, subject to payment of a prepayment fee and an exit fee. On May 22, 2018, we exercised our option and paid $22,599 to prepay the Term Loan in full, which included exit and pre-payment fees totaling $1,470. In addition, on May 22, 2018, we charged to interest expense the unamortized deferred financing costs associated with the Term Loan of $473.

We also had the option to terminate or permanently reduce the Revolving Loan prior to the maturity date subject to its payment of a deferred origination fee. On May 22, 2018, we exercised its option to terminate and paid $2,958 to prepay the Revolving Loan in full, which amount included fees of $236.

On June 30, 2020, we entered into a seven-year financing agreement with Oberland Capital (the "Oberland Facility") and obtained the first tranche of $35,000 at closing. The Oberland Facility provides for a total of $75,000 through two additional tranches that can be drawn by December 31, 2021 and requires interest-only payments for the duration of the term. A second tranche of $15,000 may be drawn at our option upon achieving two consecutive quarters with revenue of at least $20,000. Such second tranche may also be put to us at any time by Oberland Capital. A third tranche of $25,000 may be drawn at our option upon achieving two consecutive quarters with revenue of $28,000. The financing costs for this facility are approximately $642 and was recorded as a contra liability to the debt facility.

The Oberland Facility requires quarterly interest payments for seven years. Interest is calculated as 7.5% plus the greater of LIBOR or 2.0% (9.5% as of December 31, 2020). Each tranche of the Oberland Facility, if and when issued, will have a term of seven years from the date of issuance (with the first tranche issued on June 30, 2020 maturing on June 30, 2027). In connection with the Oberland Facility, we entered into a revenue participation agreement with Oberland Capital, which provides that, among other things, an additional quarterly royalty payment as a percentage of our net revenue, up to $70,000 in any given fiscal year, subject to certain limitations set forth therein, during the period commencing on the later of (i) April 1, 2021 and (ii) the date of funding of a tranche of the loan, and ending on the date upon which all amounts owed under the Oberland Facility have been paid in full (the "Revenue Participation Agreement"). Payments will commence on September 30, 2021. This royalty structure results in approximately 1.0% per year of additional interest payments on the outstanding loan amount.

Contractual Obligations and Commitments

The following table summarizes our obligations with regard to our contractual obligations as of December 31, 2020, and the expected timing of maturities of these contractual obligations. This table should be read in conjunction with the notes to consolidated financial statements included elsewhere in this annual report on Form 10-K.

Contractual Obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
			(dollars in thousands)		
Long-term debt	$ 35,000	$ —	$ —	$ —	$ 35,000
APC Commitment	26,976	24,542	2,434	—	—
Tampa Commitment	1,573	1,573	—	—	—
Operating leases	41,279	3,030	6,295	5,277	26,677
Finance Leases	33	19	13	1	—
	$ 104,861	$ 29,164	$ 8,742	$ 5,278	$ 61,677

Service Agreements disclosed in Footnote 15 - Commitments and Contingencies in the Notes to the Consolidated Financial Statements do not have annual firm commitments.

APC Commitment

On July 9, 2019, we entered into the Design-Build Agreement with CRB (which was subsequently amended on October 6, 2020), pursuant to which CRB will renovate and retrofit the APC. The Design-Build Agreement contains several design phase milestones that began in July 2019 and sets the date for Substantial Completion (as defined in the Design-Build Agreement) in the third quarter of 2021, subject to adjustment in accordance with the terms of the Design-Build Agreement. The estimated cost pursuant to the Design-Build Agreement is $28,846. Additional costs associated with the renovation, purchasing of furniture and equipment, validation and certification of the APC are estimated to be $13,600. These capital expenditure costs will be incurred as they arise until the anticipated full transition of material processing to the APC by late 2022. As of December 31, 2020, we have recorded $9,645 in the current year and $15,671 to date related to renovations and design build in construction in progress. These items are recorded as projects in process as part of the property and equipment in our consolidated balance sheet. In addition, we will capitalize interest expense from its debt facility based on the amount of accumulated expenditures of this asset during the period that is required to get the asset ready for its intended use. During fiscal 2020, we capitalized interest of $489 to construction in progress.

As a result of COVID-19, we implemented a cost reduction strategy designed to defer and reduce certain expenses, including deferment of the APC by up to one year. This deferral had the potential to defer approximately $25,000 of expected 2020 capital expenditures to 2021. In addition, the Company extended its current production facility License and Services agreement with Community Tissue Services (“CTS”) by one year to December 31, 2022. During the fourth quarter of 2020, we determined to resume the APC project. We expect expenditures of approximately $26,000 during 2021.

We expect to receive certain economic development grants from state and local authorities totaling up to approximately $2,685 including $1,250 of cash grants to offset costs to acquire and develop the property. These grants have claw back clauses if the Company does not meet these job creation milestones by 2023. We believe despite the delay in the APC that these incentives will continue to be available.

Subsequent Events

On February 22, 2021, we entered into the Seventh Amendment to the Licenses and Services Agreement with Community Tissue Services (the "CTS Agreement"). The amendment extends the term of the agreement until December 31, 2023.

Tampa Commitment

Pursuant to the Heights Agreement, we will use the leased premises in Tampa, Florida for general office, medical laboratory, training and meeting purposes. The lease term includes several months of free rent. We recorded a right of use asset and liability at the commencement of the lease term as discussed in Footnote 15 - Commitments and Contingencies in the Notes to the Consolidated Financial Statements. We began occupying the premises in September of 2020.

Public Offering of Common Stock

On November 16, 2017, Axogen entered into a certain underwriting agreement (the "Leerink Underwriting Agreement") with Leerink Partners LLC, as representative of the several underwriters named therein (collectively, the "2017 Offering Underwriters") and Essex, pursuant to which (i) we agreed to issue and sell 700,000 shares of our common stock pursuant to a registration statement on Form S-3 (File No. 333-207829), filed with the SEC on November 5, 2015, and declared effective by the SEC on December 11, 2015, and the prospectus contained therein, as supplemented by the prospectus supplement dated November 16, 2017, and (ii) Essex agreed to sell 1,000,000 shares of our common stock pursuant to a registration statement on Form S-3 (File No. 333-220770), filed with the SEC on October 2, 2017, and declared effective by the SEC on October 11, 2017, and the prospectus contained therein, as supplemented by the Prospectus Supplement, in an underwritten registered public offering at an offering price of $21.00 per share. We, together with Essex, granted the 2017 Offering Underwriters a 30-day option to purchase up to an aggregate of 255,000 additional shares of common stock, at the public offering price, less the underwriting discounts and commissions, which was exercised in full on November 16, 2017. We received net proceeds of approximately $15,655 after deducting the underwriting discounts and commissions and estimated offering expenses.

On May 8, 2018, we entered into an underwriting agreement with Jefferies LLC and Leerink Partners LLC, as representatives of the several underwriters named therein (collectively, the "2018 Offering Underwriters"), pursuant to which we agreed to issue and sell 3,000,000 shares of our common stock in an underwritten registered public offering at an offering price of $41.00 per share (the "2018 Offering"). We granted the 2018 Offering Underwriters a 30-day option to purchase up to an aggregate of 450,000 additional shares of common stock, at the public offering price, less the underwriting discounts and commissions, which was exercised in full on May 9, 2018. The 2018 Offering closed on May 11, 2018, and we received proceeds of approximately $132,707 from the sale of the shares (including the sale of 450,000 additional shares issued upon exercise of the 2018 Offering Underwriters' overallotment option), after deducting the underwriting discounts and commissions and estimated offering expenses.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Effect of Inflation

Inflation has not had a significant impact on our historical operations, and we do not expect it to have a significant impact on our results of operations or financial condition in the foreseeable future.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements which have been prepared in accordance with accounting principles generally accepted in the United States ("US GAAP"). The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amount of expenses during the period reported. Management bases its estimates and judgments on historical experience, observance of trends in the industry, information provided by outside sources and on various other factors that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. We have described our significant accounting policies in Footnote 3 - Summary of Significant Accounting Policies in the Notes to the Consolidated Financial Statements included in this Form 10-K.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

We enter into contracts to sell and distribute products and services to hospitals and surgical facilities for use in caring for patients with peripheral nerve damage or transection. Revenue is recognized when we have met its performance obligations pursuant to its contracts with its customers in an amount that we expect to be entitled to in exchange for the transfer of control of the products and services to our customers.

In the case of products or services sold to a customer under a distribution or purchase agreement, the distributors are granted exclusive distribution rights to sell the implants internationally in a territory defined by the contract. These international distributor agreements contain provisions that allow us to terminate the distribution agreement with the distributor, and upon termination, the right to repurchase inventory from the distributor at the distributor's cost. We have determined that its

contractual rights to repurchase distributor inventory upon termination of the distributor agreement are not substantive and do not impact the timing of when control transfers; and, therefore, we have determined it is appropriate to recognize revenue when: i) the product is shipped via common carrier; or ii) the product is delivered to the customer or distributor, depending on the terms of the agreement. Determining the timing of revenue recognition for such contracts is subject to judgment, because an evaluation must be made regarding the distributor's ability to direct the use of, and obtain substantially all of the remaining benefits from, the implants received from us. Changes in these assessments could have an impact on the timing of revenue recognition from sales to distributors.

A portion of our product revenue is generated from consigned inventory maintained at hospitals and independent sales agencies, and also from inventory physically held by field sales representatives. For these types of products sales, we retain control until the product has been used or implanted, at which time revenue is recognized.

We elected to account for shipping and handling activities as a fulfillment cost rather than a separate performance obligation. Amounts billed to customers for shipping and handling are included as part of the transaction price and recognized as revenue when control of the underlying products is transferred to the customer. The related shipping and freight charges incurred by us are included in cost of sales.

We operate in a single reportable segment of peripheral nerve repair, offers similar products to its customers, and enters into consistently structured arrangements with similar types of customers. As such,we do not disaggregate revenue from contracts with customers as the nature, amount, timing and uncertainty of revenue and cash flows does not materially differ within and among the contracts with customers.

The contract with the customer states the final terms of the sale, including the description, quantity, and price of each implant distributed. The payment terms and conditions in our contracts vary; however, as a common business practice, payment terms are typically due in full within 30 to 60 days of delivery. Since the customer agrees to a stated price in the contract that does not vary over the contract term, the contracts do not contain any material types of variable consideration, and contractual rights of return are not material. We have several contracts with distributors in international markets which include consideration paid to the customer in exchange for distinct marketing and other services. We record such consideration paid to the customer as a reduction to revenue from the contracts with those distributor customers.

Inventory - Valuation Associated with Excess and Obsolete Inventory

Inventory is comprised of unprocessed tissue, work-in-process, Avance Nerve Graft, Axoguard Nerve Connector, Axoguard Nerve Protector, Axoguard Nerve Cap, Avive Soft Tissue Membrane, Axotouch Two-Point Discriminator and supplies and are valued at the lower of cost (first-in, first-out) or net realizable value.

We monitor the shelf life of our products and historical expiration and spoilage trends, and writes-off inventory based on the estimated amount of inventory that will not be distributed before expiration or spoilage. To estimate the amount of inventory that will expire prior to being sold, we review inventory quantities on hand, historical and projected sales, and historical expiration trends. Our calculation of the amount of inventory that will expire prior to sale has two components: 1) a demand or consumption based component that compares projected sales to inventory quantities on hand; and 2) an expiring inventory component that assesses the risk related to inventory that is near expiration by analyzing historical expiration trends to project inventory that will expire prior to being sold. Our model assumes that inventory will be sold on a first-in-first-out basis. Due to the nature of the inventory (surgical implants with expiration dates) and the fact that a significant portion of our inventory is at medical facility consignment locations, estimating the amount of inventory that will expire and the amount of inventory that should be written-down involves significant judgments and estimates.

Share-Based Compensation

We account for share-based compensation for all share-based payment awards, including stock options, restricted stock units, performance stock units and stock purchases related to an employee stock purchase plan, based on their estimated fair values. We estimate the fair value of time-based options on the date of grant using the multi-point Black-Scholes option pricing model (Black-Scholes model). Our determination of fair value of share-based payment awards is affected by our stock price, as well as assumptions regarding a number of subjective variables. These variables include but are not limited to our expected stock price volatility over the term of the awards. The value of the portion of the awards that are ultimately expected to vest is recognized as expense over the requisite service periods in our Consolidated Statements of Operations.

We estimate the fair value of restricted stock unit and performance stock unit awards based upon the grant date closing market price of our common stock.

We also have an employee stock purchase plan (ESPP), which is available to all eligible employees as defined by the plan document. Under the ESPP, shares of our common stock may be purchased at a discount, currently fifteen percent (15%). We estimate the number of shares to be purchased under the ESPP at the beginning of the purchase period and calculate estimated compensation expense using the Black-Scholes model based upon the fair value of the stock at the beginning of the purchase period. Compensation expense is recognized over each purchase period, and expense is adjusted at the time of stock purchase.

We believe our critical accounting policies regarding revenue recognition, allowance for uncollectible accounts receivable, investments, inventory and share-based employee compensation affect our more significant judgments and estimates used in the preparation of our consolidated financial statements. We base our judgments and estimates on historical experience, current conditions and other reasonable factors.

Recent Accounting Pronouncements

See Note 3 - Summary of Significant Accounting Policies to our Consolidated Financial Statements for further information.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We are exposed to market risk from interest rates. For our cash, cash equivalents and investments, a change in interest rates affects the amount of interest income that can be earned.

With respect to accounts receivable, we perform credit evaluations of our customers and do not require collateral. There have been no material losses on accounts receivables. Concentrations of credit risk with respect to accounts receivable are limited because a large number of geographically diverse customers make up the Company's customer base, thus spreading the trade credit risk. The Company also controls credit risk through credit approvals and monitoring procedures.

We invest our cash primarily in money market accounts, U.S. government agencies and securities, corporate bonds and commercial paper. Although we believe our cash to be invested in a conservative manner, with cash preservation being the primary investment objective, the value of the securities held will fluctuate with changes in the financial markets including, among other things, changes in interest rates, credit quality and general volatility. This risk is managed by investing in high quality investment grade securities with short-term maturities.

Financial instruments that potentially subject the us to credit risk consist of cash and cash equivalent balances and investments in corporate bonds. Certain of our cash and cash equivalents balances exceed FDIC insured limits or are invested in money market accounts with investment banks that are not FDIC-insured. We place our cash and cash equivalents in what we believe to be credit-worthy financial institutions. As of December 31, 2020, $48,267 of the cash and cash equivalents balance was in excess of FDIC limits.

We are subject to market risk from exposure to changes in interest rates based upon our investing and cash management activities. Changes in interest rates affect interest income earned on cash and cash equivalents. We have not entered into derivative transactions related to cash and cash equivalents. We do not expect changes in interest rates to have a material adverse effect on our income or our cash flows in 2020. However, we can give no assurance that interest rates will not significantly change in the future.

We also have interest rate exposure as a result of the Oberland Facility. As of September 30, 2020, the outstanding principal amount of our loans under the Oberland Facility was $35,000. Interest on our loans under the Oberland Facility is payable quarterly during the term of the loans at a rate per annum, subject to certain exceptions, equal to the sum of (a) the greater of (i) LIBOR and (ii) 2% and (b) 7.5% (which percentage is subject to adjustment as described in the Oberland facility); provided that the interest rate shall never be less than 9.5%. Changes in the LIBOR rate may therefore affect our interest expense associated with the loans. An increase of 100 basis points in interest rates would increase expense by approximately $350 annually based on the amounts currently outstanding and would not materially affect our results of operations.

The value of the U.S. dollar compared to the Euro has little to no effect on our financial results. International business transactions are currently invoiced in U.S. dollarsAs a result, the Company has minimal exposure related to exchange rate fluctuations.

In the United States, we sell our products directly to hospitals and clinics in the local currency. Revenue is recognized as disclosed in Footnote 3 - Summary of Significant Accounting Policies - Revenue Recognition in our Notes to the Consolidated Financial Statements.

In all international markets, we distribute our products and services to independent distributors who, in turn, distribute and market to medical clinics. The revenue from the distribution of our products in these countries through independent distributors is denominated in United States dollars.

We do not believe our operations are currently subject to significant market risks for foreign currency exchange rates, commodity prices or other relevant market price risks of a material nature.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Axogen, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Axogen, Inc and subsidiaries (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations, shareholders' equity, and cash flows, for each of the three years in the period ended December 31, 2020, and the related notes and the schedule listed in the Index at Item 15(a)(2) (collectively referred to as the "financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America, Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control — Integrated Framework (2013) issued by COSO.

Basis for Opinion

The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on these financial statements and an opinion on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audit of the financial statements included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures to respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Inventory – Valuation Associated with Excess and Obsolete (E&O) Inventory — Refer to Notes 3 and 4 to the financial statements

Critical Audit Matter Description

Inventories are comprised of unprocessed tissue, work-in-process, Avance Nerve Graft, Axoguard Nerve Connector, Axoguard Nerve Protector, Axoguard Nerve Cap, Avive Soft Tissue Membrane, Axotouch Two-Point Discriminator and supplies and are valued at the lower of cost or net realizable value. The Company monitors the shelf life of its products and historical expiration and spoilage trends, and writes-off inventory based on the estimated amount of inventory that will not be sold before expiration or spoilage. To estimate the amount of inventory that will expire prior to being sold, the Company reviews inventory quantities on hand, historical and projected sales, and historical expiration trends. The Company's calculation of the amount of inventory that will expire prior to sale has two components: 1) a demand or consumption based component that compares projected sales to inventory quantities on hand; and 2) an expiring inventory component that assesses the risk related to inventory that is near expiration by analyzing historical expiration trends to project inventory that will expire prior to being sold. The Company's model assumes that inventory will be sold on a first-in-first-out basis. Due to the nature of the inventory (surgical implants with expiration dates) and the fact that a significant portion of the Company's inventory is at medical facility consignment locations, estimating the amount of inventory that will expire and the amount of inventory that should be written-down involves significant judgments and estimates.

Given the significant judgments associated with evaluating the valuation of E&O inventory, auditing the reasonableness of management's estimates and assumptions involved especially subjective judgment and an increased extent of effort.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the Company's valuation of E&O inventory included the following, among others:

- We tested the effectiveness of controls over the E&O inventory valuation. The controls we tested included those over the calculation and accuracy and completeness of underlying data used in the calculation.
- We performed procedures to evaluate management's ability to accurately forecast by comparing the historical expiring inventory estimates to subsequent inventory destructions and expirations.
- We obtained the Company's E&O calculation and tested the mathematical accuracy.
- We assessed the reasonableness of the assumptions used in the E&O calculation by developing an independent expectation and comparing our independent expectation to the results of the Company's calculation.
- We tested the accuracy and completeness of the underlying data used in the calculation of the Company's expiring inventory model.
- We made inquiries of the Company's employees outside of the accounting department and evaluated other areas of the audit to identify business, product, or industry changes that may impact the inputs in the inventory valuation calculation.

/s/ Deloitte & Touche LLP

Miami, Florida
March 1, 2021

We have served as the Company's auditor since 2018.

AXOGEN, INC.
CONSOLIDATED BALANCE SHEETS
December 31, 2020 and 2019
(In Thousands, Except Share Amounts)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 48,767	$ 35,724
Restricted cash	6,842	6,000
Investments	55,199	60,786
Accounts receivable, net of allowance for doubtful accounts of $416 and $1,092, respectively	17,618	16,944
Inventory	12,529	13,861
Prepaid expenses and other	4,296	1,706
Total current assets	145,251	135,021
Property and equipment, net	38,398	14,887
Operating lease right-of-use assets	15,614	3,133
Finance lease right-of-use assets	64	87
Intangible assets	2,054	1,515
Total assets	$ 201,381	$ 154,643
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	21,968	19,144
Current maturities of lease liabilities	863	1,736
Total current liabilities	22,831	20,880
Long-term debt, net of financing fees	32,027	—
Long-term lease obligations	20,874	1,595
Debt derivative liability	2,497	—
Other long-term liabilities	3	15
Total liabilities	78,232	22,490
Commitments and contingencies - see Note 15		
Shareholders' equity:		
Common stock, $0.01 par value per share; 100,000,000 shares authorized; 40,618,766 and 39,589,755 shares issued and outstanding	406	396
Additional paid-in capital	326,390	311,618
Accumulated deficit	(203,647)	(179,861)
Total shareholders' equity	123,149	132,153
Total liabilities and shareholders' equity	$ 201,381	$ 154,643

The accompanying notes are an integral part of these consolidated financial statements.

AXOGEN, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
Years ended December 31, 2020, 2019 and 2018
(In Thousands, Except Per Share Amounts)

	2020	2019	2018
Revenue	$ 112,300	$ 106,712	$ 83,937
Cost of goods sold	21,581	17,349	12,923
Gross profit	90,719	89,363	71,014
Costs and expenses:			
Sales and marketing	69,659	71,950	56,617
Research and development	17,846	17,514	11,773
General and administrative	26,396	31,305	23,124
Total costs and expenses	113,901	120,769	91,514
Loss from operations	(23,182)	(31,406)	(20,500)
Other (expense) income:			
Investment income	605	2,364	1,525
Interest expense	(1,054)	(40)	(1,208)
Change in fair value of derivative liabilities	(117)	—	—
Loss on extinguishment of debt	—	—	(2,186)
Other expense	(38)	(53)	(28)
Total other (expense) income, net	(604)	2,271	(1,897)
Net Loss	$ (23,786)	$ (29,135)	$ (22,397)
Weighted average common shares outstanding — basic and diluted	39,967	39,235	37,127
Loss per common share — basic and diluted	$ (0.60)	$ (0.74)	$ (0.60)

The accompanying notes are an integral part of these consolidated financial statements.

AXOGEN, INC.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
Years ended December 31, 2020, 2019 and 2018
(In Thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity/(Deficit)
	Shares	Amount			
Balance, December 31, 2017	34,350	$ 343	$ 153,168	$ (128,329)	$ 25,182
Stock-based compensation	—	—	7,606	—	7,606
Exercise of stock options	1,101	11	3,873	—	3,884
Issuance of common shares	3,450	35	132,672	—	132,707
Net loss	—	—	—	(22,397)	(22,397)
Balance, December 31, 2018	38,901	$ 389	$ 297,319	$ (150,726)	$ 146,982
Stock-based compensation	—	—	10,304	—	10,304
Exercise of stock options	689	7	3,995	—	4,002
Net loss	—	—	—	(29,135)	(29,135)
Balance, December 31, 2019	39,590	$ 396	$ 311,618	$ (179,861)	$ 132,153
Stock-based compensation	—	—	8,470	—	8,470
Issuance of restricted and performance stock units	249	2	(2)	—	—
Shares surrendered by employees to pay tax withholdings	(40)	—	(670)	—	(670)
Exercise of stock options and employee stock purchase plan	572	6	3,294	—	3,300
Exercise of Oberland option net of settlement	248	2	3,680	—	3,682
Net loss	—	—	—	(23,786)	(23,786)
Balance, December 31, 2020	40,619	$ 406	$ 326,390	$ (203,647)	$ 123,149

The accompanying notes are an integral part of these consolidated financial statements.

AXOGEN, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years ended December 31, 2020, 2019 and 2018
(In Thousands)

	Year Ended		
	December 31, 2020	December 31, 2019	December 31, 2018
Cash flows from operating activities:			
Net loss	$ (23,786)	$ (29,135)	$ (22,397)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,507	933	774
Amortization of right-of-use assets	1,800	1,821	—
Amortization of intangible assets	153	123	77
Impairment loss on intangible assets	—	104	—
Amortization of deferred financing costs	232	—	81
Loss on disposal of equipment	3	—	1
Loss on extinguishment of debt	—	—	2,186
Provision for bad debt	(105)	514	852
Provision for inventory writedown	2,242	1,887	1,343
Changes in investment gains and losses	(47)	(972)	(721)
Changes in fair value of derivatives	117	—	—
Share-based compensation	8,470	10,304	7,606
Change in operating assets and liabilities:			
Accounts receivable	(635)	(2,136)	(5,108)
Inventory	(910)	(3,767)	(6,009)
Prepaid expenses and other	(2,524)	(661)	(192)
Accounts payable and accrued expenses	4,958	2,920	3,711
Operating lease obligations	(1,086)	(1,773)	—
Cash paid for interest portion of finance leases	(3)	(4)	—
Contract and other liabilities	(12)	(30)	(66)
Net cash used in operating activities	(9,626)	(19,872)	(17,862)
Cash flows from investing activities:			
Purchase of property and equipment	(21,905)	(4,664)	(6,282)
Purchase of investments	(77,806)	(121,074)	(114,736)
Proceeds from sale of investments	83,440	153,571	23,146
Cash payments for intangible assets	(692)	(562)	(321)
Net cash (used for) / provided by investing activities	(16,963)	27,271	(98,193)
Cash flows from financing activities:			
Proceeds from the issuance of long-term debt	35,000	—	—
Proceeds from the paycheck protection program	7,820	—	—
Repayment of paycheck protection program	(7,820)	—	—
Proceeds from issuance of common stock	3,500	—	132,964
Cash paid for equity or debt financing fees	(642)	—	(257)
Borrowing on revolving loan	—	—	26,253
Payments on revolving loan and prepayment penalties	—	—	(30,489)
Repayments of long-term debt and prepayment penalties	—	—	(22,513)
Cash paid for debt portion of finance leases	(14)	29	—
Proceeds from exercise of stock options	3,300	4,002	3,884
Payments of employee tax witholdings in exchange of common stock award	(670)	—	—
Net cash provided by financing activities	40,474	4,031	109,842
Net increase in cash, cash equivalents, and restricted cash	13,885	11,430	(6,213)
Cash, cash equivalents, and restricted cash, beginning of period	41,724	30,294	36,507
Cash, cash equivalents and restricted cash, end of period	$ 55,609	$ 41,724	$ 30,294

The accompanying notes are an integral part of these consolidated financial statements.

AXOGEN, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years ended December 31, 2020, 2019 and 2018
(In Thousands)

	Year Ended		
	December 31, 2020	December 31, 2019	December 31, 2018
Supplemental disclosures of cash flow activity:			
Cash paid for interest, net of capitalized interest	$ 822	$ 34	$ 1,325
Supplemental disclosure of non-cash investing and financing activities:			
Acquisition of fixed assets in accounts payable and accrued expenses	$ 1,077	$ 3,212	$ 335
Acquisition of leasehold asset	$ 5,250	$ —	$ —
Embedded derivative associated with long-term debt	$ 2,563	$ —	$ —
Obtaining a right-of-use asset in exchange for a lease liability	$ 14,259	$ 26	$ —
Conversion of the Oberland Option	$ 182	$ —	$ —

The accompanying notes are an integral part of these consolidated financial statements.

AXOGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2020, 2019 and 2018
(In Thousands, Except Per Share Amounts)

1. Basis of Presentation

The accompanying consolidated financial statements include the accounts of Axogen, Inc. (the "Company" or "Axogen") and its wholly owned subsidiaries, Axogen Corporation ("AC"), Axogen Processing Corporation ("APC") and Axogen Europe GmbH, as of December 31, 2020 and December 31, 2019 and for the three years ended December 31, 2020. The Company's consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. All intercompany accounts and transactions have been eliminated in consolidation.

2. Organization and Business

Axogen is the leading company focused specifically on the science, development, and commercialization of the technologies for peripheral nerve regeneration and repair. Axogen is passionate about providing the opportunity to restore nerve function and quality of life for patients with peripheral nerve injuries. Axogen 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 conduit. Along with these core surgical products, Axogen also offers the Axotouch Two-Point Discriminator, used to measure the innervation density of any surface area of skin. The Company's portfolio of products is available in the United States, Canada, Germany, United Kingdom, Spain, South Korea, and several other countries.

Avance Nerve Graft and Avive Soft Tissue Membrane are processed in the United States by Axogen at its processing facility in Dayton, Ohio. Axoguard Nerve Cap is manufactured by Cook Biotech in the United States for sale by Axogen and Axoguard Nerve Connector and Axoguard Nerve Protector are manufactured in the United States by Cook Biotech and are distributed worldwide exclusively by Axogen. The Axotouch Two Point Discriminator is contract manufactured by Viron Technologies, LLC (doing business as Cybernetics Research Laboratories) ("CLR") Tucson, Arizona. CRL supplies the Axotouch unpackaged and they are packaged at Axogen's distribution facility in Burleson, Texas. Axogen maintains its corporate offices in Alachua, Florida and is the parent company of its wholly owned operating subsidiaries, AC, APC and Axogen Europe GmbH.

3. Summary of Significant Accounting Policies

Cash and Cash Equivalents and Concentration

The Company considers highly liquid investments with maturities of three months or less at the date of acquisition as cash equivalents in the accompanying consolidated financial statements. The Company has not experienced any losses related to these balances; however, as of December 31, 2020, $48,267 of the cash and cash equivalents balance was in excess of FDIC limits. As of December 31, 2020 and 2019, the Company had restricted cash balances of $6,842 and $6,000, respectively. The December 31, 2020 and 2019 balances both include $6,000, which represents collateral for an irrevocable standby letter of credit and the December 31, 2020 balance includes $842 which is the balance of the Heights Union Escrow Account (see Note 15 - Commitments and Contingencies).

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheet that sum to the total of the same amounts shown in the statement of cash flows:

	December 31, 2020	December 31, 2019
Cash and cash equivalents	$ 48,767	$ 35,724
Restricted cash	6,842	6,000
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$ 55,609	$ 41,724

Inventory

Inventory is comprised of unprocessed tissue, work-in-process, Avance Nerve Graft, Axoguard Nerve Connector, Axoguard Nerve Protector, Axoguard Nerve Cap, Avive Soft Tissue Membrane, Acroval Neurosensory and Motor Testing System, Axotouch Two-Point Discriminator and supplies and are valued at the lower of cost (first-in, first-out) or net realizable value.

The Company monitors the shelf life of its products and historical expiration and spoilage trends, and writes-off inventory based on the estimated amount of inventory that will not be sold before expiration or spoilage. To estimate the amount of inventory that will expire prior to being sold, the Company reviews inventory quantities on hand, historical and projected sales, and historical expiration trends. The Company's calculation of the amount of inventory that will expire prior to sale has two components: 1) a demand or consumption based component that compares projected sales to inventory quantities on hand; and 2) an expiring inventory component that assesses the risk related to inventory that is near expiration by analyzing historical expiration trends to project inventory that will expire prior to being sold. The Company's model assumes that inventory will be sold on a first-in-first-out basis. Due to the nature of the inventory (surgical implants with expiration dates) and the fact that a significant portion of the Company's inventory is at medical facility consignment locations, estimating the amount of inventory that will expire and the amount of inventory that should be written-down involves significant judgments and estimates.

Investments

The Company invests primarily in U.S. Government securities, corporate bonds and commercial paper and classifies all investments as available-for-sale. Investments are recorded at fair value. The Company has elected the fair value option (FVO) for all of its available-for-sale investments. The FVO election results in all changes in unrealized gains and losses being included in investment income in the Consolidated Statements of Operations.

Derivative Instruments

The Company analyzes all financial instruments with features under Accounting Standards Codification ("ASC") 480, "Distinguishing Liabilities from Equity" and ASC 815, "Derivatives and Hedging". The Company also reviews debt agreements for embedded features. If these features are not clearly and closely related to the debt host, they meet the definition of a derivative and require bifurcation from the host. All derivative instruments are recorded on the balance sheet at their respective fair values. The Company will adjust the carrying value of the derivative liability to fair value at each subsequent reporting date. The changes in the value of the derivatives are recorded in the consolidated statement of operations in the period in which they occur.

Property and Equipment

Property and equipment is stated at cost. Additions and improvements that extend the lives of the assets are capitalized, while expenditures for repairs and maintenance are expensed as incurred. Leasehold improvements are amortized on a straight-line basis over the shorter of the asset's estimated useful life or the remaining lease term. Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets ranging from three to seven years.

When depreciable assets are retired or sold the cost and related accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized in operations.

Intangible Assets

Intangible assets are recorded at cost and include patents and patent application costs, licenses and trademarks. Intangible assets are amortized on a straight-line basis over their estimated useful lives of seventeen to twenty years. Trademarks are indefinite lived intangible assets.

Revenue Recognition

The Company enters into contracts to sell and distribute products and services to hospitals and surgical facilities for use in caring for patients with peripheral nerve damage or transection. Revenue is recognized when the Company has met its performance obligations pursuant to its contracts with its customers in an amount that the Company expects to be entitled to in exchange for the transfer of control of the products and services to the Company's customers.

In the case of products or services sold to a customer under a distribution or purchase agreement, the customers are granted exclusive distribution rights to sell the implants internationally in a territory defined by the contract. These international distributor agreements contain provisions that allow the Company to terminate the distribution agreement with the distributor, and upon termination, the right to repurchase inventory from the distributor at the distributor's cost. The Company has determined that its contractual rights to repurchase distributor inventory upon termination of the distributor agreement are not substantive and do not impact the timing of when control transfers; and, therefore, the Company has determined it is appropriate to recognize revenue when: i) the product is shipped via common carrier; or ii) the product is delivered to the customer or distributor, depending on the terms of the agreement. Determining the timing of revenue recognition for such contracts is subject to judgment, because an evaluation must be made regarding the distributor's ability to direct the use of, and obtain substantially all of the remaining benefits from, the implants received from the Company. Changes in these assessments could have an impact on the timing of revenue recognition from sales to distributors.

A portion of the Company's product revenue is generated from consigned inventory maintained at hospitals and independent sales agencies, and also from inventory physically held by field sales representatives. For these types of products sales, the Company retains control until the product has been used or implanted, at which time revenue is recognized.

The Company accounts for shipping and handling activities as a fulfillment cost rather than a separate performance obligation. Amounts billed to customers for shipping and handling are included as part of the transaction price and recognized as revenue when control of the underlying products is transferred to the customer. The related shipping and freight charges incurred by the Company are included in cost of sales.

The Company operates in a single reportable segment of peripheral nerve repair, offers similar products to its customers, and enters into consistently structured arrangements with similar types of customers. As such, the Company does not disaggregate revenue from contracts with customers as the nature, amount, timing and uncertainty of revenue and cash flows does not materially differ within and among the contracts with customers.

The contract with the customer states the final terms of the sale, including the description, quantity, and price of each implant distributed. The payment terms and conditions in the Company's contracts vary; however, as a common business practice, payment terms are typically due in full within thirty to sixty days of delivery. Since the customer agrees to a stated price in the contract that does not vary over the contract term, the contracts do not contain any material types of variable consideration, and contractual rights of return are not material. The Company has several contracts with distributors in international markets which include consideration paid to the customer in exchange for distinct marketing and other services. The Company records such consideration paid to the customer as a reduction to revenue from the contracts with those distributor customers.

In connection with the Acroval Neurosensory and Motor Testing System, the Company sold extended warranty and service packages to some of its customers who purchase this evaluation and measurement tool, and the prepayment of these extended warranties represent contract liabilities until the performance obligations are satisfied ratably over the term of the contract. The sale of the aforementioned extended warranty represents the only performance obligation the Company satisfies over time and creates the contract liability disclosed below. The opening and closing balances of the Company's contract receivables and liabilities are as follows:

Contract Balances

	Net Receivables	Contract Liabilities, Current	Contract Liabilities, Long-Term
Opening January 1, 2019	$ 15,321	$ 18	$ 42
Closing, December 31, 2019	16,944	14	15
Increase (decrease)	1,623	(4)	(27)
Opening January 1, 2020	$ 16,944	$ 14	$ 15
Closing, December 31, 2020	17,618	14	3
Increase (decrease)	674	—	(12)

Allowance for Doubtful Accounts Receivable and Concentration of Credit Risk

The Company evaluates the collectability of accounts receivable to determine the appropriate allowance for doubtful accounts. In determining the amount of the allowance, the Company considers aging of account balances, historical credit losses, customer-specific information, the current economic environment, supportable forecasts and other relevant factors. An increase to the allowance for doubtful accounts results in a corresponding increase in general and administrative expense. The Company reviews accounts receivable and adjusts the allowance based on current circumstances and charges off uncollectible receivables against the allowance when all attempts to collect the receivable have failed. The Company's history of write-offs has not been significant. The allowance for doubtful accounts balance was approximately $416 and $1,092 at December 31, 2020 and 2019, respectively.

Concentrations of credit risk with respect to accounts receivable are limited because a large number of geographically diverse customers make up the Company's customer base, thus spreading the trade credit risk. The Company also controls credit risk through credit approvals and monitoring procedures.

Leases

The Company adopted Accounting Standards Update ("ASU") No. 2016-2—Leases (Topic 842) ("ASU 2016.02"), effective January 1, 2019, using the modified retrospective approach. The Company will continue to report financial information for fiscal years prior to 2019 under the previous lease accounting standards.

The Company determines whether or not a contract contains a lease at the inception date and determines the lease classification, recognition and measurement at commencement date. The Company classifies a lease based on whether the arrangement is effectively a purchase of the underlying asset. Leases that transfer the control of the underlying asset are classified as finance leases and all others are classified as an operating lease. Interest and amortization expense are recognized for operating leases on a straight-lined basis. If a change to the lease term leads to a reassessment of the lease classification and remeasurement, assumptions such as the discount rate and variable rents based on a rate or index will be updated as of the remeasurement date. If an arrangement is modified, the Company will reassess whether the arrangement contains a lease. Any subsequent changes in lease payments are recognized when incurred, unless the change requires a remeasurement of the lease liability.

The Company made an accounting policy election to not recognize right-to-use assets and lease liabilities that arise from short term leases, which are defined as leases with a lease term of 12 months or less at the lease commencement date.

Net Loss Per Share

Basic net loss per share is computed by dividing reported net loss by the weighted average number of common shares outstanding for the reported period. Diluted net loss per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock of the Company during the reporting period. Diluted net loss per share is computed by dividing net loss by the sum of the weighted average number of common shares and the number of potential dilutive common share equivalents outstanding during the period. Potential dilutive common share equivalents consist of the incremental common shares issuable upon the exercise of vested share options and the incremental shares issuable upon conversion of the convertible notes. Potential dilutive common share equivalents consist of stock options, restricted stock units ("RSUs"), and performance stock units ("PSUs").

Due to net losses for the years ended December 31, 2020, 2019, and 2018, basic and diluted net loss per share were the same as the effect of potentially dilutive securities would have been anti-dilutive.

Research and Development Costs

Research and development costs are expensed as incurred and were $17,846, $17,514 and $11,773 for the years ended December 31, 2020, 2019 and 2018, respectively.

Stock-Based Compensation

The Company measures all employee stock-based compensation awards using the fair value, including stock options, restricted stock, performance stock and stock purchases related to an employee stock purchase plan. The share-based compensation recognized under ASC 718 for years ended December 31, 2020, 2019 and 2018 was $8,470, $10,304, and $7,606, respectively.

ASC 718 requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in the Company's consolidated statements of operations. The expense has been reduced for forfeitures as they occur.

The Company estimates the fair value of time-based options on the date of grant using the Black-Scholes option-pricing model (Black-Scholes model). The Company's determination of fair value is affected by the Company's stock price, as well as assumptions regarding several subjective variables. These variables include, but are not limited to, the Company's expected stock price volatility over the term of the awards.

The Company estimates the fair value of restricted stock based upon the grant date closing market price of the Company's common stock.

The Company also has an employee stock purchase plan (ESPP) which is available to all eligible employees as defined by the plan document. Under the ESPP, shares of the Company's common stock may be purchased at a discount. The Company estimates the number of shares to be purchased under the ESPP at the beginning of each purchase period based upon the fair value of the stock at the beginning of the purchase period using the Black-Scholes model and records estimated compensation expense during the period. Expense is adjusted at the time of stock purchase.

With respect to performance stock units ("PSUs"), the number of shares that vest and are issued to the recipient is based upon the Company's performance as measured against specified targets over the measurement period. The fair value of the PSUs is based on the Company's closing stock price on the grant date and its estimate of achieving such performance targets. For further discussion and disclosures, see Note 12 - Equity Compensation Plans.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Management believes the critical accounting policies regarding revenue recognition, inventory and share-based employee compensation affect the Company's more significant judgments and estimates used in the preparation of the Company's consolidated financial statements. Actual results could differ materially from those estimates.

Recent Accounting Pronouncements

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740) ("ASU 2019-12"), Simplifying the Accounting for Income Taxes. This amendment simplifies the accounting for income taxes by removing certain exceptions to the general principles and improve consistent application or and simplify accordance with accounting principles generally accepted in the United States for other areas of Topic 740 by clarifying and amending existing guidance. This update is effective for annual and interim reporting periods beginning after December 15, 2020. Early adoption is permitted but requires simultaneous adoption of all provisions of ASU 2019-12. The Company does not expect this standard will have a material impact on the Company's consolidated financial statements.

In October 2020, the FASB issued ASU 2020-08, Codification Improvements to Subtopic 310-20, Receivables-Nonrefundable Fees and Other Costs. The guidance is effective for fiscal years beginning after December 15, 2020. Early adoption is not permitted. The Company is currently evaluating the impact the standard may have on the Company's consolidated financial statements and related disclosures.

Recently Adopted Accounting Pronouncements

On January 1, 2020, the Company adopted Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, which replaces the incurred loss methodology with an expected loss methodology that is referred to as the current expected credit loss ("CECL") methodology. The CECL model utilizes a lifetime expected credit loss measurement objective for the recognition of credit losses for loans and other receivables at the time the financial asset is originated or acquired. The expected credit losses are adjusted each period for changes in expected lifetime credit losses. This model replaces the multiple existing impairment models previously used under U.S. generally accepted accounting principles, which generally require that a loss be incurred before it is recognized. The new standard also applies to financial assets arising from revenue transactions such as contract assets and accounts receivables. The adoption did not have a material impact on the Company's condensed consolidated financial statements.

Credit losses for trade receivables is determined based on historical information, current information and reasonable and supportable forecasts. The Company has concluded that the adoption of the standard was not material as the composition of the trade receivables at the reporting date is consistent with that used in developing the historical credit-loss percentages. Further, the risk characteristics of the Company's customer and composition of the portfolio have not changed significantly over time.

On January 1, 2020, the Company adopted ASU 2018-13, Fair Value Measurements (Topic 820) Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement. ASU 2018-13 changes the fair value measurement disclosure requirements of ASC 820, "Fair Value Measurement" by adding, eliminating, and modifying certain disclosure requirements. The adoption of ASU 2018-13 did not have a material impact on the Company's consolidated financial statements.

On January 1, 2020, the Company adopted ASU No. 2018-15, Guidance on Cloud Computing Arrangements. ASU 2018-15 provides guidance on implementation costs incurred in a cloud computing arrangement ("CCA") that is a service contract and aligns the accounting for such costs with the guidance on capitalizing costs associated with developing or obtaining internal-use software. More specifically, the ASU 2018-15 provides guidance on accounting for implementation, set-up and other upfront costs incurred in a CCA hosted by a vendor. As of January 1, 2020, this standard did not have a material impact on the Company's consolidated financial statements.

On March 12, 2020, the FASB issued ASU 2020-04, Reference Rate Reform (ASC 848). The ASU also establishes (1) a general contract modification principle that entities can apply in other areas that may be affected by reference rate reform and (2) certain elective hedge accounting expedients. The elective contract modification guidance in the ASU applies to "contracts or other transactions that reference [LIBOR] or a reference rate that is expected to be discontinued as a result of reference rate reform" (an "affected rate"). The optional amendments are effective for all entities as of March 12, 2020 through December 31, 2022. The Company adopted the guidance upon issuance on March 12, 2020. There was no impact on the Company's consolidated financial statements.

The Company's management has reviewed and considered all other recent accounting pronouncements and believe there are none that could potentially have a material impact on the Company's consolidated financial condition, results of operations, or disclosures.

Reclassifications

"Contract liabilities, current" of $14 were reported in the Company's consolidated balance sheets as of December 31, 2019 have been combined into "Accounts payable and accrued expenses" in the Company's consolidated balance sheets to conform with the presentation as of December 31, 2020.

4. Inventory

Inventory is comprised of unprocessed tissue, work-in-process, Avance® Nerve Graft, Axoguard® Nerve Connector, Axoguard® Nerve Protector, Axoguard® Nerve Cap, Avive® Soft Tissue Membrane, Acroval® Neurosensory and Motor Testing System, Axotouch® Two-Point Discriminator and supplies and is valued at the lower of cost (first-in, first-out) or net realizable value and consist of the following:

	December 31, 2020	December 31, 2019
Finished goods	$ 8,876	$ 10,403
Work in process	751	730
Raw materials	2,902	2,728
Inventory	$ 12,529	$ 13,861

The Company monitors the shelf life of its products and historical expiration and spoilage trends and writes-down inventory based on the estimated amount of inventory that may not be distributed before expiration or spoilage. For the years ended December 31, 2020, 2019 and 2018, the Company had recorded a provision for inventory write-downs of $2,242, $1,887 and $1,343, respectively, primarily relating to product expiration.

5. Fair Value Measurement

The Company has elected the FVO for all investments in debt securities. Fair value is defined as the price that would be received upon the sale of an asset or paid to transfer a liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy defines a three-level valuation hierarchy for classification and disclosure of fair value measurements as follows:

Level 1 – Quoted prices in active markets for identical assets or liabilities.

Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company classifies cash and investments in U.S. government securities as Level 1 within the fair value hierarchy. Accounts receivable, short-term other assets, accounts payable and accrued liabilities are also classified as Level 1. The carrying amounts of these assets and liabilities approximate their fair values due to their relatively short-term nature. Investments in corporate bonds and commercial paper are classified as Level 2 within the fair value hierarchy. The fair value of long-term debt is estimated by calculating the net present value of future debt payments at current market interest rates and is classified as Level 2.

On June 30, 2020, the Company entered into the Oberland Facility (see Note 10 - Long-Term Debt), concluding that the term debt instrument included certain embedded features that required separate accounting (the “Debt Derivative Liability”) and that the equity contract entered into concurrently was required to be classified as a liability and recorded at its fair value (the “Common Stock Derivative Option Liability”). These instruments were determined to be financial liabilities requiring Level 3 fair value measurements. The Common Stock Derivative Option Liability was physically settled on December 10, 2020 (see Note 10 - Long-Term Debt).

The following table represents the Company's fair value hierarchy for its financial assets measured at fair value on a recurring basis as of December 31, 2020:

	(Level 1)	(Level 2)	(Level 3)	Total
December 31, 2020				
Assets:				
Money market funds	$ 23,044	$ —	$ —	$ 23,044
U.S. government securities	12,123	—	—	12,123
Corporate bonds	—	6,408	—	6,408
Commercial paper	—	36,668	—	36,668
Total assets	$ 35,167	$ 43,076	$ —	$ 78,243
Liabilities:				
Oberland facility	$ —	$ —	$ 36,855	$ 36,855
Debt derivative liability	—	—	2,497	2,497
Total liabilities	$ —	$ —	$ 39,352	$ 39,352

	(Level 1)	(Level 2)	(Level 3)	Total
December 31, 2019				
Assets:				
Money market funds	$ 26,812	$ —	$ —	$ 26,812
U.S. government securities	4,544	—	—	4,544
Corporate bonds	—	17,754	—	17,754
Commercial paper	—	24,679	—	24,679
Asset-backed securities	—	13,808	—	13,808
Total assets	$ 31,356	$ 56,241	$ —	$ 87,597

Oberland Facility

The Company estimates the fair value of long-term debt under the Oberland Facility using a discounted cash flow analysis and rates being offered for similar loans to borrowers with similar credit ratings. The discounted cash flow model uses unobservable inputs, including estimates of discount rates and loan prepayments. The Oberland Facility is classified as Level 3. The estimated fair value of the Company's long-term debt under the Oberland facility was $36,855 at December 31, 2020 (see Note 10 - Long-Term Debt).

Debt Derivative Liability

The debt derivative liability was measured using a 'with and without' valuation model to compare the fair value of the Oberland Facility including the identified embedded derivative features and the fair value of a plain vanilla note with the same terms. The fair value of the Oberland Facility including the embedded derivative features was determined using a probability-weighted expected return model ("PWERM") based on four potential settlement scenarios for the Oberland Facility due to a mandatory prepayment event between January 1, 2024 and June 30, 2027; (a) the prepayment of the Oberland Facility at the Company's option; and (b) the repayment of the Oberland Facility at its maturity in accordance with the terms of the debt agreement. The estimated settlement value of each scenario, which would include any required make-whole payment (see Note 10 - Long-Term Debt) is then discounted to present value using a discount rate that is derived based on the initial terms of the Oberland Facility at issuance and corroborated utilizing a synthetic credit rating analysis. The significant inputs that are included in the valuation of the debt derivative liability include:

	December 31, 2020
Input	
Remaining term (years)	6.5
Maturity date	June 30, 2027
Coupon rate	9.50%
Revenue participation payments	Maximum each year
Discount rate	8.70 %[1]
Probability of mandatory prepayment before 2024	5.0%[1]
Estimated timing of mandatory prepayment event before 2024	December 31, 2023[1]
Probability of mandatory prepayment 2024 or after	15.0%[1]
Estimated timing of mandatory prepayment event 2024 or after	March 31, 2026[1]
Probability of optional prepayment event	5.0%[1]
Estimated timing of optional prepayment event	December 31, 2025[1]

[1] Represents a significant unobservable input

The following represents the rollforward of the fair value of instruments classified as Level 3 measurements for the year ended December 31, 2020:

Year ended December 31, 2020	
Beginning Balance	$ —
Fair Value of Oberland Facility	36,855
Fair Value of Derivative Feature	2,387
Fair Value of Oberland Option	176
Gains (losses) included in earnings	117
Settlement of Oberland Option	(182)
Ending Balance, December 31, 2020	$ 39,352

There were no changes in the levels or methodology of the measurement of financial assets or liabilities during the year ended December 31, 2020 and December 31, 2019. The maturity date of all of the Company's investments is less than one year.

6. Prepaid Expense and Other

Prepaid expense and other consist of the following:

	December 31, 2020	December 31, 2019
Prepaid insurance	$ 2,596	$ —
Stock option receivable	2	244
Litigation receivable	23	98
Prepaid events	203	110
Prepaid marketing	587	227
Prepaid software license	220	207
Prepaid professional fees	251	433
Other prepaid items	414	387
Prepaid Expense and Other	$ 4,296	$ 1,706

Our policy year for the Company's insurance runs on a calendar year and as such a significant portion of the policy payment is made at the beginning of the new year and amortized to expense throughout the remaining year. For the year ended December 31, 2020, the insurance premium was paid prior to year end, resulting in a prepaid balance of $2,596.

7. Property and Equipment

Property and equipment consist of the following:

	December 31, 2020	December 31, 2019
Furniture and equipment	$ 2,334	$ 2,059
Leasehold improvements	12,983	2,203
Processing equipment	2,634	2,772
Land	731	731
Projects in process	24,540	10,886
Property and equipment, at cost	43,223	18,651
Less: accumulated depreciation and amortization	(4,825)	(3,764)
Property and equipment, net	$ 38,398	$ 14,887

Depreciation expense for the years ended December 31, 2020, 2019 and 2018 was $1,507, $933 and $774, respectively. The significant increase in projects in process is related to the Company's Axogen Processing Center ("APC") facility (See Note 15 - Commitments and Contingencies).

On September 20, 2018, the Company entered into an agreement (the "Heights Agreement") with Heights Union, LLC, a Florida limited liability company ("Heights Union"), for the lease of seventy-five thousand square feet of office and lab space (the "Heights Union Premises") in Tampa, Florida (See Note 15 - Commitments and Contingencies). In May 2020, the Company entered into a construction escrow agreement (the "Escrow Agreement") with Heights Union and Commonwealth Land Title Insurance Company ("Escrow Agent") which provided for the establishment of a federally insured escrow bank account (the "Escrow Account") to hold Company funds to be used for tenant improvements in excess of the tenant allowance as provided in the Heights Agreement. The Company deposited $6,289 into the Escrow Account for use in completing construction of the tenant improvements. The Escrow Agent will disburse the funds upon joint written instructions from Heights Union and the Company. During the year ended December 31, 2020, $5,447 was disbursed from the Escrow Account and recorded in property and equipment account of the balance sheet. The Company anticipates depleting the Escrow Account by the end of the first quarter of fiscal 2021. As of December 31, 2020, $842 remained in the Escrow Account and is recorded as restricted cash in the condensed consolidated balance sheet.

8. Intangible Assets

The Company's intangible assets consist of the following:

	December 31, 2020			December 31, 2019		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Amortized intangible assets						
Patents	$ 1,496	$ (139)	$ 1,357	$ 845	$ (84)	$ 761
License agreements	1,093	(745)	348	1,067	(647)	420
Total amortizable intangible assets	2,589	(884)	1,705	1,912	(731)	1,181
Unamortized intangible assets						
Trademarks	349	—	349	334	—	334
Total intangible asset, net	$ 2,938	$ (884)	$ 2,054	$ 2,246	$ (731)	$ 1,515

License agreements are being amortized over periods ranging fromseventeen to twenty years. Patents are being amortized over periods up totwenty years. Amortization expense for 2020, 2019 and 2018 was approximately $153, $123 and $77,

respectively. In January 2019, the Company rebranded its logo and product name designs, as a result the Company recorded a $104 impairment charge related to the previous logo and product design names. This charge is recorded in the "General and Administrative" in the Statement of Operations. As of December 31, 2020, future amortization of patents and license agreements are as follows:

Year Ending December 31,		
2021	$	170
2022		170
2023		164
2024		77
2025		77
Thereafter		1,047
Total	$	1,705

License Agreements

The Company has entered into multiple license agreements with the University of Florida Research Foundation and the University of Texas at Austin (together, the "License Agreements"). Under the terms of the License Agreements, the Company acquired exclusive worldwide licenses for underlying technology used in repairing and regenerating nerves. The licensed technologies include the rights to issued patents and patents pending in the United States and international markets. The effective term of the License Agreements extends through the term of the related patents and the agreements may be terminated by the Company with 60 days prior written notice. Additionally, in the event of default, licensors may terminate an agreement if the Company fails to cure a breach after written notice. The License Agreements contain the key terms listed below:

- Axogen pays royalty fees ranging from 1% to 3% under the License Agreements based on net sales of licensed products. One of the agreements also contains a minimum royalty of $13 per quarter, which may include a credit in future quarters in the same calendar year for the amount the minimum royalty exceeds the royalty fees. Also, when Axogen pays royalties to more than one licensor for sales of the same product, a royalty stack cap applies, capping total royalties at 3.75%;
- If Axogen sublicenses technologies covered by the License Agreements to third parties, Axogen would pay a percentage of sublicense fees received from the third party to the licensor. Currently, Axogen does not sublicense any technologies covered by License Agreements. The Company is not considered a sub-licensee under the License Agreements and does not owe any sub-licensee fees for its own use of the technologies;
- Axogen reimburses the licensors for certain legal expenses incurred for patent prosecution and defense of the technologies covered by the License Agreements; and
- Currently, under the University of Texas at Austin's agreement, Axogen would owe a $15 milestone fee upon receiving a Phase II Small Business Innovation Research or Phase II Small Business Technology Transfer grant involving the licensed technology. The Company has not received either grant and does not owe such a milestone fee. A milestone fee to the University of Florida Research Foundation of $2 is due if Axogen receives FDA approval of its Avance Nerve Graft, a milestone fee of $25 is due upon the first commercial use of certain licensed technology to provide services to manufacture products for third parties and a milestone fee of $10 is due upon the first use to manufacture products that utilize certain technology that is not currently incorporated into Axogen products.

Royalty fees were $2,289, $2,119 and $1,661 for the years ended December 31, 2020, 2019 and 2018, respectively, and are included in sales and marketing expense on the accompanying consolidated statements of operations.

9. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consists of the following:

	December 31, 2020	December 31, 2019
Accounts payable	$ 4,597	$ 8,262
Accrued expenses	3,778	3,251
Accrued compensation	13,593	7,631
Accounts Payable and Accrued Expenses	$ 21,968	$ 19,144

10. Long-Term Debt

The carrying value of the Company's outstanding debt consists of the following:

As of December 31	2020	2019
Oberland Facility	$ 35,000	$ —
Less - unamortized debt discount and deferred financing fees	(2,973)	—
Total long-term debt	$ 32,027	$ —

Oberland Facility

On June 30, 2020, the Company entered into a seven year financing agreement with Oberland Capital (the "Oberland Facility") and obtained the first tranche of $35,000 at closing. The Oberland Facility provides for a total of $75,000 through two additional tranches that can be drawn by December 31, 2021 and requires interest-only payments for the duration of the term. A second tranche of $15,000 may be drawn at the Company's option upon achieving two consecutive quarters with revenue of at least $20,000. Such second tranche may also be put to the Company at any time by Oberland Capital. A third tranche of $25,000 may be drawn at the Company's option upon achieving two consecutive quarters with revenue of $28,000. The financing costs for this facility are approximately $642 and will be recorded as a contra liability to the debt facility. As of December 31, 2020, the Company has paid all of the financing costs.

The Oberland Facility requires quarterly interest payments for seven years. Interest is calculated as 7.5% plus the greater of LIBOR or 2.0% (9.5% as of December 31, 2020). Each tranche of the Oberland Facility, if and when issued, will have a term of seven years from the date of issuance (with the first tranche issued on June 30, 2020 maturing on June 30, 2027). In connection with the Oberland Facility, the Company entered into a revenue participation agreement with Oberland Capital, which provides that, among other things, an additional quarterly royalty payment as a percentage of the Company's net revenue, up to $70,000 in any given fiscal year, subject to certain limitations set forth therein, during the period commencing on the later of (i) April 1, 2021 and (ii) the date of funding of a tranche of the loan, and ending on the date upon which all amounts owed under the Oberland Facility have been paid in full (the "Revenue Participation Agreement"). Payments will commence on September 30, 2021. This royalty structure results in approximately 1.0% per year of additional interest payments on the outstanding loan amount. For the year ended December 31, 2020, the Company paid $1,941 of interest to Oberland for this debt facility. The Company capitalized approximately $997 of the interest towards the costs to construct and retrofit its Axogen Processing Center in Vandalia, OH (See Note 15 - Commitments and Contingencies). The capitalized interest is recorded as part of property and equipment in the consolidated balance sheet.

Additionally, Oberland Capital has the right to purchase up to $3,500 worth of Axogen common stock from Axogen in one transaction at any time after closing of the Oberland Facility until the later of (i) the date all amounts due under the Oberland Facility are repaid and (ii) June 30, 2027 (the "Oberland Option"). The purchase price of the common stock will be calculated based on the 45-day moving average of the closing stock price on the day prior to the purchase. On December 10, 2020, Oberland Capital exercised in full its option under the Oberland Option. The exercise price was determined to be $14.13, resulting in gross proceeds to the Company of approximately $3.5 million for the issuance of 247,699 shares to TPC Investments II LP, a wholly owned subsidiary of Oberland Capital. In conjunction with the issuance, Oberland Capital received certain protective rights (including protection from down-round stock issuances) for a period of one year subsequent to the issuance.

The amounts outstanding under the Oberland Facility may be accelerated upon certain events, including: (a) required mandatory prepayments upon an asset sale; (b) in the event Axogen is subject to (i) any litigation brought by a Governmental Authority (as defined in the Oberland Facility) including intervention after litigation is commenced by a Person (as defined in the Oberland Facility), or (ii) any final administrative action by a Governmental Authority, in each case arising out of or in

connection with any of the Company's registry studies, payments made to doctors or training activities with respect to healthcare professionals (excluding certain final administrative action that have been fully and finally resolved by the parties pursuant to a settlement agreement) or (c) upon the occurrence of an event of default (either automatically or at the option of Oberland Capital depending on the nature of the event). In addition, the Company has the right to prepay any amounts outstanding under the Oberland Facility. Upon maturity or upon such earlier repayment of the Oberland Facility, the Company will repay the principal balance and provide a make-whole payment calculated to generate an internal rate of return ("IRR") to Oberland Capital of at least 11.5%, less the total of all quarterly interest and royalty payments previously paid to Oberland Capital.

Upon the occurrence of an event of default, the interest rate incurred on amounts outstanding under the Oberland Facility will be increased by 4%. The Oberland Facility includes a financial covenant requiring the Company to achieve revenue targets of $8,750 for the third and four quarters of 2020, $17,500 for the first and second quarter of 2021 and $20,000 for each quarter thereafter. In the event of a failure to meet such covenant the Company may avoid a default by electing to be subject to a liquidity covenant and meeting all of the obligations required by such covenant. Specifically, the liquidity covenant provides that the Company must maintain on deposit in a cash collateral account an amount not less than 1.1 times the aggregate outstanding principal balance of all outstanding loan amounts. The borrowings under the Oberland Facility are secured by substantially all of the assets of the Company. As of December 31, 2020, the Company was in compliance with the all covenants.

Accounting Considerations

The Company assessed the accounting impact of the Oberland Facility and the related agreements entered into with Oberland Capital. The Company concluded that the Oberland Facility and the Revenue Participation Agreement should be assessed on a combined unit of account basis (with the Revenue Participation Agreement being considered as an embedded feature with the Oberland Facility), and that the Oberland Option should be considered as a separate freestanding instrument for analysis purposes.

In relation to the Oberland Facility and Revenue Participation Agreement, the Company assessed the identified embedded features to determine if they would require separate accounting. In performing this assessment, the Company concluded the following embedded features met the definition of a derivative and would not be considered clearly and closely related to the debt instrument, requiring separate accounting as bifurcated derivatives:

- Mandatory prepayments upon an asset sale or litigation involving the government, including the make-whole payment (put rights)
- Optional or automatic prepayment upon an event of default (put rights)
- Payments under the Revenue Participation Agreement (contingent interest feature)
- Additional interest upon events of default (contingent interest feature)

The Company considered these separable embedded features on a combined basis as a single derivative feature. The Company estimated the fair value of these features as $2,387 as of the date of issuance of the Oberland Facility (see Note 5 - Fair Value Measurement) and recorded this value as a deduction to the carrying value of the Oberland Facility.

In relation to the Oberland Option, the Company concluded that the equity contract met the definition of a derivative and did not qualify for an exception from derivative accounting. As such, the Company concluded that the Oberland Option should be classified as a liability. The Company estimated the fair value of the Oberland Option as $176 as of the date of issuance of the Oberland Facility and recorded this value as a deduction to the carrying value of the Oberland Facility. As previously discussed, the Oberland Option was physically settled on December 10, 2020.

Other Long-Term Debt

On April 23, 2020, the Company received a Small Business Administration ("SBA") loan under the Paycheck Protection Program ("PPP") in the amount of $7,820. The loan was obtained pursuant to the original guidance of the SBA to preserve positions in the Company by providing necessary economic relief during this period of reduced surgical procedures because of the negative business effects of COVID-19. The Company believed it correctly applied for the loan, met the initial intent of the PPP program to preserve jobs and believed it complied with the representations provided in the loan documents. However, subsequent to obtaining the loan, the United States Treasury Department issued guidance, which the Company believes contradicts the original intent and language of the PPP, providing that public companies are unlikely to be able to meet the standards for receiving the PPP loan. As a result of this change, the Company believed it was in its best business interests to repay the loan and did so on May 5, 2020.

11. Public Offering of Common Stock

Axogen, Inc. Classes of Stock

Axogen, Inc.'s authorized capital stock consists of 100,000,000 shares of common stock, par value $0.01 per share. The authorized capital stock is divisible into the classes and series, has the designation, voting rights, and other rights and preferences and is subject to the restrictions that the Axogen Board of Directors may establish from time to time. Unless otherwise designated by the Axogen Board of Directors, all shares are common stock. Axogen has not designated any shares other than common stock.

12. Equity Compensation Plans

The Company maintains two share-based incentive plans: the Axogen 2017 Stock Incentive Plan, as amended ("2017 Plan"), and the Axogen 2017 Employee Stock Purchase Plan ("2017 ESPP").

Overview of Equity Incentive Plans

At the 2019 Annual Meeting of Shareholders held on August 14, 2019, the shareholders approved the Axogen 2019 Long-Term Incentive Plan (the "New Axogen Plan"), which allows for issuance of incentive stock options, non-qualified stock options, performance stock units ("PSUs") and restricted stock units ("RSUs") to employees, directors and consultants at exercise prices not less than the fair market value at the date of grant. The number of shares of common stock authorized for issuance under the New Axogen Plan is (A) 3,385,482 shares, comprised of (i) 3,000,000 new authorized shares and (ii) 385,482 unallocated shares of common stock available for issuance as of August 14, 2019 pursuant to the Company's 2010 Stock Incentive Plan, as amended and restated (the "Prior Axogen Plan"), that were not then subject to outstanding awards; plus (B) shares under the Prior Axogen Plan and the New Axogen Plan that are cancelled, forfeited, expired, unearned or settled in cash, in any such case that does not result in the issuance of common stock. Following shareholder approval of the New Axogen Plan, no future awards will be made under the Prior Axogen Plan. As of December 31, 2020, 1,793,090 shares of common stock were available for issuance under the New Axogen Plan.

The Company recognized stock-based compensation expense, which consisted of compensation expense related to employee stock options, PSUs, RSUs and the 2017 ESPP based on the value of share-based payment awards that are ultimately expected to vest during the period, of approximately $8,470, $10,304 and $7,606 for the fiscal year ended December 31, 2020, 2019, and 2018, respectively.

As of December 31, 2020, there was $16,568 of unrecognized compensation costs related to non-vested stock options and restricted stock awards. This cost is expected to be recognized over a weighted-average period of 2.11 years for stock options and 2.23 years for restricted stock awards.

Based on the assumptions noted above, the weighted average estimated grant date fair value per share of the stock options and restricted stock granted for the years ended December 31, 2020, 2019 and 2018, respectively, was as follows:

	2020	2019	2018
Stock options	$ 9.29	$ 18.07	$ 15.05
Restricted and performance stock units	9.57	17.60	23.34

Stock Options

The options granted to employees prior to July 1, 2017 typically vest 25% one year after the grant date and 12.50% every six months thereafter for the remaining three years period until fully vested after four years. The options granted to employees after July 1, 2017 typically vest 50% two years after the grant date and 12.5% every six months thereafter for the remaining two years period until fully vested after four years. The options granted to directors and certain options granted from time to time to certain executive officers have vested ratably over three years, 25% per quarter over one year or had no vesting period. Options typically have terms ranging from seven to ten years.

The Company estimates the fair value of each option award issued under such plans on the date of grant using a Black-Scholes option-pricing model which uses a weighted average of historical volatility and peer company volatility. The Company determines the expected life of each award giving consideration to the contractual terms, vesting schedules and post-vesting forfeitures. The Company uses the risk-free interest rate on the implied yield currently available on U.S. Treasury issues with an equivalent remaining term approximately equal to the expected life of the award.

Activity under the Prior Axogen Plan and the New Axogen Plan during 2020 and 2019 was as follows:

Time-Based Stock Options	Number of Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term(Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2018	3,893,171	$ 11.94	5.95	$ 41,020
Granted	344,176	18.07		
Forfeited	(287,609)	22.75		
Exercised	(529,557)	5.21		
Outstanding at December 31, 2019	3,420,181	$ 12.69	5.70	$ 26,074
Granted	663,098	9.29		
Forfeited	(107,541)	19.71		
Exercised	(459,254)	5.36		
Outstanding at December 31, 2020	3,516,484	$ 12.79	5.93	$ 25,717,664
Vested and expected to vest	3,516,484	$ 12.79	5.93	$ 25,717,664
Exercisable at December 31, 2020	2,287,786	$ 11.34	4.49	$ 19,626,780

The exercise price per share of each option is equal to the fair market value of the underlying share on the date of grant. For 2020, 2019 and 2018, $,300, $4,002 and $3,884, respectively, in cash proceeds were included in the Company's Consolidated Statements of Cash Flows as a result of the exercise of stock options. The intrinsic value of equity awards exercised during the years ended December 31, 2020, 2019 and 2018 was $5,595, $9,553 and $34,229, respectively.

The following weighted-average assumptions were used for stock options granted during the year ended December 31:

Year ended December 31,	2020	2019	2018
Expected term (in years)	5.88	5.76	6.22
Expected volatility	58.46 %	54.97 %	50.99 %
Risk free rate	0.49 %	1.71 %	2.70 %
Expected dividends	— %	— %	— %

Restricted and Performance Stock Units

Performance stock units generally have a requisite service period of three years and are subject to graded vesting conditions based on revenue goals of the Company. The Company expenses their fair value over the requisite service period. Restricted stock units have a requisite service period of four years. The Company expenses the fair value of restricted stock awards on a straight-line basis over the requisite service period.

A summary of the Company's RSU and PSU award activity for the fiscal year ended December 31, 2020 is as follows:

Restricted and Performance Stock Units	Outstanding Stock Units			
	Number of Shares Outstanding	Weighted Average Grant Date Fair Value	Weighted Average Remaining Vesting Life	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2018	1,106,363	$ 22.18	2.90	$ 22,603
Granted	217,146	17.60		
Released	(86,405)	16.77		
Forfeited	(123,407)	22.97		
Outstanding at December 31, 2019	1,113,697	21.62	2.26	19,800
Granted	1,008,869	9.57		
Released	(247,333)	19.66		
Forfeited	(92,328)	18.64		
Outstanding at December 31, 2020	1,782,905	$ 15.23	1.83	$ 31,825

The total fair value of restricted stock vested during 2020, 2019 and 2018 was $3,811, $1,467 and $196. The Company issues registered shares of common stock to satisfy stock option exercises and restricted stock grants.

Performance Stock Units

The Company estimates the fair value of the PSUs based on its closing stock price at the time of grant and its estimate of achieving such performance target and records compensation expense as the milestones are achieved. Over the performance period, the number of shares of common stock that will ultimately vest and be issued and the related compensation expense will be adjusted based upon the Company's estimate of achieving such performance target. The number of shares delivered to recipients and the related compensation cost recognized as an expense will be based on the actual performance metrics as set forth in the applicable PSU award agreement. The amount actually awarded will be based upon achievement of the performance measures

On December 27, 2018 and December 17, 2019, the Compensation Committee of the Board of Directors also approved PSU awards to certain employees related to their work on the Company's Biologics License Application "BLA". The PSU awards consist of a targeted total award of 200,000 shares. The number of shares are allocated to certain milestones related to the BLA submission to and approval by the FDA. The performance measure is based upon achieving each of the specific milestones and will vest 50% upon achieving each of the milestones and 50% one year later. In February 2020, the Company issued PSUs relating to the 2017 grant with performance metrics tied to 2019 revenue. The award was issued at 72.3% of achievement and therefore, 27.7% of the stock compensation, or $536 relating to this grant was forfeited or reversed in the first quarter 2020. In addition, as a result of COVID-19 and the expected decline in revenue for 2020, it was determined that the 2018 PSU grant with performance metrics tied to 2020 revenue would not be awarded and therefore stock compensation related to these grants of $1,161 was reversed.

On February 21, 2020, the Compensation Committee of the Board of Directors approved PSUs that were tied to 2021 revenue. The 2020 PSU award consists of a targeted award of 348,000 shares. In June 2020, the Company concluded that the performance metrics relating to the 2020 PSU grant with performance metrics tied to 2021 revenue were no longer probable and therefore stock compensation related to these grants of $340 was also reversed. On July 17, 2020, the Compensation Committee of the Board of Directors approved PSU awards of 144,300. The July 2020 PSU award consists of a targeted award of 114,300 shares. These awards were granted in mid year with certain revenue targets adjusted for the impact of COVID-19. Based on the fiscal 2020 fourth quarter revenue results, it became probable that the Company would achieve 50% of the revenue target for the 2020 PSUs, granted in March. The 2020 PSUs granted in July reached 110% achievement of revenue targets.

The fair value of the common stock on the grant date was $12.00 on July 17, 2020, $8.61 on March 16, 2020, $16.88 on December 17, 2019, and $19.17 on December 27, 2018. The total unrecognized future compensation expense related to PSUs, assuming achievement of 100% of the target award is $7,521. Assuming the minimum of 0% and the maximum of 150% payout opportunity for the PSU, the range of total future compensation expense related to PSU awards is between $0 and $7,521 as of December 31, 2020.

Employee Stock Purchase Plan

The 2017 Employee Stock Purchase Plan (the "ESPP"), which was effective as of January 1, 2018, allows for eligible employees to acquire shares of Axogen common stock through payroll deductions at a discount from market value (currently 15%) of the lesser of the closing price of the Company's common stock on the first day or last day of the offering period. The offering period is currently six months, and the offering prices are subject to change. Participants may not purchase more than $25 of the Company's common stock in a calendar year. As of December 31, 2020 , there were 600,000 shares of common stock authorized for issuance under the 2017 ESPP and323,913 were available for future issuance.

13. Income Taxes

The Company has temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and their respective income tax basis, as measured by enacted state and federal rates as follows:

December 31,	2020	2019	2018
Deferred tax assets:			
Net operating loss carryforwards	$ 42,317	$ 36,250	$ 30,588
Inventory write down	397	317	273
Depreciation	—	136	117
Amortization	—	—	—
Interest limitation	115	—	336
Allowance for doubtful accounts	106	274	285
Lease liability	5,551	837	—
Stock-based compensation	3,218	3,140	2,335
Total deferred tax assets	51,704	40,954	33,934
Deferred tax liabilities:			
Depreciation	(1,145)	—	—
Amortization	(34)	(206)	(43)
Right-of-use asset	(4,004)	(809)	—
Contract liabilities	(4)	(7)	(15)
Net deferred tax assets	46,517	39,932	33,876
Valuation allowance	$ (46,517)	$ (39,932)	$ (33,876)

The difference between the financial statement income tax and the income tax benefit using statutory rates is primarily due to the increase in the valuation allowance.

The Company's effective income tax rate differs from the statutory federal income tax rate as follows for the years ended December 31, 2020 and 2019:

	Year Ended December 31,	
	2020	2019
Federal tax rate	21.0 %	21.0 %
State Taxes - Net of Federal Benefit	7.3	4.1
Permanent items and other deductions	(0.6)	(4.3)
Valuation allowance	(27.7)	(20.8)
Effective income tax rate	— %	— %

As of December 31, 2020 and 2019, management assessed the realizability of deferred tax assets. Management evaluated the need for an amount of any valuation allowance for deferred tax assets on a jurisdictional basis. This evaluation utilizes the framework contained in ASC 740, *Income Taxes*, wherein management analyzes all positive and negative evidence available at the balance sheet date to determine whether all or some portion of the Company's deferred tax assets will not be realized. Under this guidance, a valuation allowance must be established for deferred tax assets when it is more likely than not (a probability

level of more than 50%) that the Company may not realize the benefit of its deferred tax assets. In assessing the realization of the Company's deferred tax assets, the Company considers all available evidence, both positive and negative.

In concluding on the evaluation, management placed significant emphasis on guidance in ASC 740, which states that "a cumulative loss in recent years is a significant piece of negative evidence that is difficult to overcome." Based upon available evidence, it was concluded on a more-likely-than-not basis that all deferred tax assets were not realizable as of December 31, 2020. The valuation allowance increased by $6,585 and $6,056 during 2020 and 2019, respectively, primarily as a result of current year increase in the net operating loss carry forward. During 2018, the valuation allowance decreased by $5,519, primarily due to the remeasurement of the Company's deferred tax assets and liabilities as a result of the Tax Reform enacted on December 22, 2017.

As of December 31, 2020, the Company had tax-effected net operating loss carry forwards of approximately $42,317 to offset future taxable income which expire in various years through 2040. Federal net operating losses incurred in tax years beginning on or after January 1, 2018 are carried forward indefinitely. A portion of the net operating loss carry forwards may expire due to limitations imposed by section 382 of the Internal Revenue Code.

The Company files U.S. federal and state income tax returns in jurisdictions with varying statutes of limitations. In the normal course of business the Company is subject to examination by taxing authorities throughout the country. These audits could include examining the timing and amount of deductions, the allocation of income among various tax jurisdictions and compliance with federal, state and local laws. The Company's tax years since 2017 remain subject to examination by federal, state and foreign tax authorities.

The Company adopted Accounting Standards Codification ("ASC") Topic 842 – Leases, on January 1, 2019. Under Topic 842, the Company is required to recognize the assets and liabilities that arise from most operating leases on the balance sheet. Upon adoption, no change in retained earnings was recorded related to income taxes as the Company maintains a full valuation allowance. As of the implementation date, an adjustment of $951 was recorded as a deferred tax liability and an adjustment of $961 was recorded as a deferred tax asset. See above for more information about the non-income tax impact of the adoption of the new leasing standard.

Legislation enacted in 2018, informally titled the Tax Cuts and Jobs Act of 2017, subjects a U.S. shareholder to tax on global intangible low-taxed income ("GILTI") earned by certain foreign subsidiaries. The FASB Staff Q&A, Topic 740, No. 5, Accounting for Global Intangible Low-Taxed Income, states that an entity can make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. The Company has elected to account for GILTI in the year the tax is incurred.

The Company had no income tax expense or income tax benefit for 2018, 2019 and 2020 due to incurrence of net operating losses. The Company does not believe there are any additional tax refund opportunities currently available.

14. Employee Benefit Plan

The Company sponsors the Axogen 401(k) plan (the 401(k) Plan), a defined contribution plan covering substantially all employees of the Company. All full-time employees who have attained the age of 21 are eligible to participate in the 401(k) Plan. Eligibility is immediate upon employment and enrollment is available any time during employment. Participating employees may make annual pretax contributions to their accounts up to a maximum amount as limited by law. The 401(k) Plan requires the Company to make matching contributions of 3% on the first 3% of the employee's annual salary and 1% of the next 2% of the employee's annual salary as long as the employee participates in the 401(k) Plan. Both employee contributions and Company contributions vest immediately. The Company contributed $1,141, $988 and $650 in matching funds during the years ended December 31, 2020, 2019 and 2018, respectively.

15. Commitments and Contingencies

Leases

The Company leases office space, medical lab and research space, a distribution center, a tissue processing center and equipment. Leases with an initial term of 12 months or less are not recorded on the balance sheet; the Company recognizes lease expense for these leases on a straight-line basis over the lease term.

Certain of the leases include options for the Company to extend the lease term. None of the options were reasonably certain of exercise and therefore are not included in the measure of lease obligations and right-to-use assets.

Certain of the Company's lease agreements include provisions for the Company to reimburse the lessor for common area maintenance, real estate taxes, and insurance, which the Company accounts for as variable lease costs. The Company's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

The Company and Heights Union are parties to the Heights Agreement for the lease ofseventy-five thousand square feet of office space in Tampa, Florida. Pursuant to the Heights Agreement, the Company will use the leased premises for general office, medical laboratory, training and meeting purposes. In September 2020, the Company began occupying the space. The lease includes a $5,250 lessor allowance to be used towards the hard and soft costs of the tenant improvements. The Company will bear the cost of any tenant improvement in excess of this allowance. Total costs of the tenant improvements were approximately $11,450. The Company concluded that it is the accounting owner of the tenant improvements. The lessor's allowance of $5,250 for the construction of tenant improvements will be treated as an incentive. As the Company is the accounting owner of the improvements, the lease incentive is accounted for as a reduction of the right-of-use asset and the total cost of the improvements of $11,539 is recognized on the balance sheet separate from the right-of-use asset as leasehold improvements. The improvements will be amortized over the life of the lease, which was determined to be the shorter of the useful life of the improvements or the lease term. The Company determined the commencement date of the lease was August 28, 2020 and valued the lease using a 10.6% incremental borrowing rate. The Company recorded a right-of-use asset of $13,323 and lease liability of $18,573 for the new office lease as of the commencement date.

The components of total lease expense for the year ended December 31, 2020 were as follows:

	2020	2019
For the Fiscal Year Ended For the fiscal years ended December 31,		
Finance lease costs		
Amortization of right-to-use assets	$ 22	$ 22
Interest on lease liabilities	3	4
Operating lease costs	2,777	1,910
Short term lease costs	116	41
Variable lease costs	18	17
Total lease cost	$ 2,936	$ 1,994

The short-term lease cost shown above reasonably reflects the Company's ongoing short-term lease commitment.

Supplemental balance sheet information related to leases as of December 31, 2020 was as follows:

	2020	2019
Operating Leases		
Operating lease right-of-use assets	$ 15,614	$ 3,133
Current maturities of long-term obligations	$ 846	$ 1,719
Long term obligations	$ 20,864	$ 1,565
Finance Leases		
Finance lease right-of-use assets	$ 64	$ 87
Current maturities of long-term obligations	$ 17	$ 17
Long term obligations	$ 13	$ 30

Other information related to leases was as follows:

	2020	2019
Cash paid for amounts included in the measurement of operating lease liabilities	$ 1,913	$ 1,773
Right-to-use assets obtained in exchange for new finance lease liabilities	$ 16	$ 16
Weighted-average remaining lease term - finance leases	2	3
Weighted-average remaining lease term - operating leases	12	2
Weighted-average discount rate - finance leases	7.28 %	7.28 %
Weighted-average discount rate - operating leases	9.44 %	6.28 %

The weighted-average discount rate for the majority of the Company's leases is based on the Company's estimated incremental borrowing rate since the rates implicit in the leases were not determinable. The Company's incremental borrowing rate is based on Management's estimate of the rate of interest the Company would have to pay to borrow on a fully collateralized basis over a similar term an amount equal to the lease payments.

Future minimum lease payments under non-cancellable leases as of December 31, 2020 were as follows:

Year Ending December 31,	Operating Leases	Finance Leases
2021	$ 3,030	$ 19
2022	3,750	10
2023	2,545	3
2024	2,606	—
2025	2,671	—
Thereafter	26,677	—
Total Future Minimum Lease Payments	$ 41,279	$ 32
Less future payments for leases that have not yet commenced	—	—
Less imputed interest on commenced leases	(19,573)	(2)
Total Lease Liability	$ 21,706	$ 30

Service Agreements

On August 6, 2015, the Company entered into a License and Services Agreement (the "CTS Agreement") with Community Blood Center (d/b/a Community Tissue Services) ("CTS"), Dayton, Ohio, an FDA registered tissue establishment. Processing of the Avance Nerve Graft pursuant to the CTS Agreement began in February 2016. The CTS Agreement initially had a five-year term ending August 31, 2020. On February 22, 2019, the agreement was amended to extend the term through December 31, 2021 and then on April 22, 2020 was further amended to extend the term through December 31, 2022 and provides the Company the right to terminate the agreement after February 28, 2022, with six-months advance written notice. Under the CTS Agreement, the Company pays CTS a facility fee for use of clean room/manufacturing, storage and office space, which the Company accounts for as an embedded lease in accordance with ASC 842, "Leases". The Company also pays CTS for services in support of its manufacturing process such as for routine sterilization of daily supplies, providing disposable supplies, microbial services and office support. Pursuant to the CTS Agreement, Axogen pays license fees and the operating lease amounts, on a monthly basis to CTS which total an annual amount of approximately $1,739, $2,148 and $1,931 for the years ended December 31, 2020, 2019 and 2018, respectively. The CTS Agreement was amended on February 22, 2021 (see further discussion in Note 17 - Subsequent Events.)

In December 2011, the Company entered into a Master Services Agreement for Clinical Research and Related Services. The Company was required to pay $151 upon execution of this agreement and the remainder monthly based on activities associated with the execution of Axogen's phase 3 pivotal clinical trial to support BLA for Avance Nerve Graft. In September 2019, the Company entered into an amendment to this agreement. The amendment extends the end of the study timeline from December 2019 to December 2021. It also increases the total number of subjects enrolled and the number of sites used in the studies. Payments made under this agreement were $1,136 and $1,056 for the years ended December 31, 2020 and 2019, respectively.

In August 2008, the Company entered into an agreement with Cook Biotech to distribute the Axoguard products worldwide in the field of peripheral nerve repair, and the parties subsequently amended the agreement on February 26, 2018. Pursuant to

the February 2018 amendment, the agreement expires on June 30, 2027. The Cook Biotech agreement requires certain minimum purchases, although, through mutual agreement, the parties have not established such minimums; and, to date, have not enforced such provision, and establishes a formula for the transfer cost of the Axoguard products. Under the agreement, Axogen provides purchase orders to Cook Biotech, and Cook Biotech fulfills the purchase orders.

In June 2017, the Company entered into the Nerve End Cap Supply Agreement with Cook Biotech whereby Cook Biotech is the exclusive contract manufacturer of the Axoguard Nerve Cap and both parties have provided the other party the necessarily licenses to their technologies for operation of the Supply Agreement. The Supply Agreement has a term through August 27, 2027, provided, however, that after June 27, 2022, either party may terminate the Supply Agreement upon 90 days written notice. Under the Supply Agreement the Company provides purchase orders to Cook Biotech and Cook Biotech fulfills the purchase orders.

Certain executive officers of the Company are parties to employment contracts. Such contracts have severance payments for certain conditions including change of control.

Concentrations

Vendor

Substantially all of Axogen's revenue is currently derived from five products, Avance Nerve Graft, Axoguard Nerve Protector, Axoguard Nerve Connector, Avive Soft Tissue Membrane and Axoguard Nerve Cap. Axogen has an exclusive distribution agreement with Cook Biotech for the purchase of Axoguard Nerve Connector and Axoguard Nerve Protector which expires June 30, 2027. The Cook Biotech Distribution Agreement also requires certain minimum purchases, although through mutual agreement the parties have not established such minimums and to date have not enforced such provision, and establishes a formula for the transfer cost of the Axoguard Nerve Connector and Axoguard Nerve Protector.

The agreement allows for termination provisions for both parties. Although there are products that Axogen believes it could develop or obtain that would replace the Axoguard products, the loss of the ability to sell the Axoguard products could have a material adverse effect on Axogen's business until other replacement products would be available.

Processor

Axogen is highly dependent on the continued availability of its processing facilities at CTS and could be harmed if the physical infrastructure of this facility is unavailable for any prolonged period of time. In addition, disruptions could lead to significant costs and reductions in revenue, as well as a potential harm to the Axogen's business reputation and financial results. In addition, Axogen acquired property which is located near the CTS facility and it is expected that renovations will be completed by the termination date of the CTS Agreement to provide a new processing facility that can be included in the Company's BLA for the Avance Nerve Graft. However, the regulatory process for approval of facilities whether licensed or owned is time-consuming and unpredictable. Axogen's ability to license, renovate, rebuild or find acceptable service facilities takes a considerable amount of time and expense and could cause a significant disruption in service to its customers if it were to lose the availability of it production or distribution facilities. Although Axogen has business interruption insurance which would, in instances other than lease termination, cover certain costs, it may not cover all costs nor help to regain Axogen's standing in the market.

In July 2018, Axogen purchased a facility (the "APC") in Vandalia, Ohio, located near the CTS processing facility where Avance Nerve Graft and Avive Soft Tissue Membrane are currently processed. The APC, when and if operational, will be the new processing facility for Avance Nerve Graft and Avive Soft Tissue Membrane to provide continued capacity for growth and to support the transition of Avance Nerve Graft from a 361 HCT/P tissue product to a biologic product. The APC is comprised of a 107,000 square foot building on approximately 8.6 acres of land. The Company paid $731 for the land and this is recorded as Land within property and equipment account on the balance sheet. The Company paid $4,300 for the building and this is recorded as projects in process as part of the property and equipment on the balance sheet. As of December 31, 2020, the Company has recorded $15,724 related to renovations and design build, of which were recorded $9,645, $5,819, and $260 in fiscal 2020, fiscal 2019, and fiscal 2018 respectively. These items are recorded as projects in process as part of the property and equipment on the balance sheet.

Axogen expects to receive certain economic development grants from state and local authorities totaling up to $2,685 including $1,250 of cash grants to offset costs to acquire and develop the APC. The economic development grants are subject to certain job creation milestones by 2023 and related contingencies.

Litigation

The Company is subject to various claims, lawsuits and proceedings in the ordinary course of the Company's business, some of which have been dismissed by the Company. In the opinion of management, such claims are either adequately covered by insurance or otherwise indemnified, or are not expected, individually or in the aggregate, to result in a material, adverse effect on the Company's financial condition. However, it is possible that the Company's results of operations, financial position and cash flows in a particular period could be materially affected by these contingencies.

On January 9, 2019, Plaintiff Neil Einhorn, on behalf of himself and others similarly situated, filed a putative class action complaint in the United Stated District Court for the Middle District of Florida alleging violations of the federal securities laws against Axogen, Inc., certain of its directors and officers ("Individual Defendants"), and Axogen's 2017 Offering Underwriters and 2018 Offering Underwriters (collectively, with the Individual Defendants, the "Defendants"), captioned Einhorn v. Axogen, Inc., et al., No. 8:19-cv-00069 (M.D. Fla.). Plaintiff asserts that Defendants made false or misleading statements in connection with the Company's November 2017 registration statement issued regarding its secondary public offering in November 2017 and May 2018 registration statement issued regarding its secondary public offering in May 2018, and during a class period of August 7, 2017 to December 18, 2018. In particular, Plaintiff asserts that Defendants issued false and misleading statements and failed to disclose to investors: (1) that the Company aggressively increased prices to mask lower sales; (2) that the Company's pricing alienated customers and threatened the Company's future growth; (3) that ambulatory surgery centers form a significant part of the market for the Company's products; (4) that such centers were especially sensitive to price increases; (5) that the Company was dependent on a small number of surgeons whom the Company paid to generate sales; (6) that the Company's consignment model for inventory was reasonably likely to lead to channel stuffing; (7) that the Company offered purchase incentives to sales representatives to encourage channel stuffing; (8) that the Company's sales representatives were encouraged to backdate revenue to artificially inflate metrics; (9) that the Company lacked adequate internal controls to prevent such channel stuffing and backdating of revenue; (10) that the Company's key operating metrics, such as number of active accounts, were overstated; and (11) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects, were materially misleading and/or lacked a reasonable basis. Axogen was served on January 15, 2019. On February 4, 2019, the court granted the parties' stipulated motion which provided that Axogen is not required to file a response to the complaint until thirty days after Plaintiff files a consolidated amended complaint. On June 19, 2019, Plaintiff filed an Amended Class Action Complaint, and on July 22, 2019, Defendants filed a motion to dismiss. Plaintiff filed opposing papers on August 12, 2019. The Court held a status hearing on September 11, 2019 and stayed all deadlines regarding the parties' obligations to file a case management report. On December 4, 2019 the parties' presented oral arguments. On April 21, 2020, the Court dismissed the complaint without prejudice, finding the Plaintiff failed to state a claim upon which relief could be granted. The Plaintiff filed a Second Amended Class Action Complaint on June 22, 2020. Axogen filed a motion to dismiss on August 6, 2020. The Plaintiff filed an opposition on September 20, 2020. The Court held oral argument on February 25, 2021. The Company and Individual Defendants dispute the allegations and intend to vigorously defend against the Complaint. The amount of loss, if any, cannot be reasonably estimated at this time.

Jackson v. Zaderej, et al., No. 8:19-cv-01976 U.S. District Court (M.D. FL). On August 12, 2019, Plaintiff Harvey Jackson, derivatively on behalf of Axogen, filed a verified shareholder derivative complaint for violations of securities laws, breach of fiduciary duty, waste of corporate assets and unjust enrichment against Quentin S. Blackford, Gregory G. Freitag, Mark Gold, Jamie M. Grooms, Alan M. Levine, Peter J. Mariani, Guido Neels, Robert J. Rudelius, Amy Wendell, and Karen Zaderej (the "Individual Defendants") and Nominal Defendant Axogen, Inc. ("Axogen") (collectively, "Defendants"). Plaintiff asserts that the Individual Defendants, who are current or former Axogen officers or directors, issued a false proxy statement for the election of directors in violation of Section 14(a) of the Securities Exchange Act of 1934, breached their fiduciary duties, wasted corporate assets and were unjustly enriched by allowing Axogen to make false public statements to investors based on the same claims in the report issued December 18, 2018 by Seligman Investments (the same allegations that form the basis for the Einhorn matter and the Bussey shareholder demand). Plaintiff demands judgment in the Company's favor against all Individual Defendants as follows: (A) declaring that Plaintiff may maintain this action on behalf of Axogen, and that Plaintiff is an adequate representative of Company; (B) declaring that the Individual Defendants have breached and/or aided and abetted the breach of their fiduciary duties to Axogen; (C) determining and awarding to Axogen the damages sustained by it because of the violations set forth above from each of the Individual Defendants, jointly and severally, together with pre- and post-judgment interest thereon; (D) directing Axogen and the Individual Defendants to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and protect Axogen and its shareholders from a repeat of the damaging events described therein, including, but not limited to, putting forward for shareholder vote the following resolutions for amendments to the Company's Bylaws or Articles of Incorporation and the following actions as may be necessary to ensure proper corporate governance policies: (i) a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater shareholder input into the policies and guidelines of the Board, (ii) a provision to permit the shareholders of Axogen to nominate at least six candidates for election to the Board; and (iii) a proposal to ensure the establishment of effective oversight of compliance with applicable laws, rules, and regulations; (E) awarding Axogen restitution from Individual Defendants, and each of them; (F) awarding Plaintiff the costs and disbursements of this action, including reasonable attorneys' and experts' fees, costs, and expenses; and (G) granting such other

and further relief as the Court may deem just and proper. The Defendants filed a motion to dismiss on October 22, 2019. In response, Plaintiffs voluntarily withdrew their complaint and the matter was dismissed without prejudice by the court on November 5, 2019.

Novitzki v. Zaderej, et al, 19-CA-11745 DIV L (13th Judicial Circuit, Hillsborough Cnty., Fl.). On November 11, 2019, Plaintiff Joseph Novitzki, derivatively on behalf of Axogen, filed a verified stockholder derivative complaint for breach of fiduciary duty, waste of corporate assets and unjust enrichment against Karen Zaderej, Gregory G. Freitag, Peter J. Mariani, Amy Wendell, Robert J. Rudelius, Mark Gold, Guido Neels, and Jamie M. Grooms (the "Individual Defendants") and Nominal Defendant Axogen, Inc. ("Axogen") (collectively, "Defendants"). Plaintiff asserts that the Individual Defendants, who are current or former Axogen officers or directors, breached their fiduciary duties, wasted corporate assets and were unjustly enriched by allowing Axogen to make false public statements to investors based on the same claims in the report issued December 18, 2018 by Seligman Investments (the same allegations that form the basis for the Einhorn matter and the Bussey shareholder demand). Plaintiff demands judgment in the Company's favor against all Individual Defendants as follows: (a) against all of the defendants and in favor of the Company for the amount of damages sustained by the Company as a result of the defendants' breaches of fiduciary duties, waste of corporate assets, and unjust enrichment; (B) directing Axogen to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect Axogen and its stockholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for stockholder vote, resolutions for amendments to the Company's Bylaws or Articles of Incorporation and taking such other action as may be necessary to place before stockholders for a vote of the following corporate governance policies: (1) directing Axogen to employ an independent, third-party expert to calculate the Company's market size (including the dollar values of Axogen's total addressable market and portion of the market relating to extremity trauma and OMF); (2) a provision to control insider selling; (3) a proposal to strengthen Axogen's oversight of its disclosure procedures; (4) a proposal to strengthen the Company's controls over financial reporting; (5) a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater stockholder input into the policies and guidelines of the Board; and (6) a provision to permit the stockholders of Axogen to nominate at least three candidates for election to the Board; (C) extraordinary equitable and/or injunctive relief as permitted by law, equity, and state statutory provisions sued hereunder, including attaching, impounding, imposing a constructive trust on, or otherwise restricting the proceeds of defendants' trading activities or their other assets so as to assure that plaintiff on behalf of Axogen has an effective remedy; (D) Awarding to Axogen restitution from defendants, and each of them, and ordering disgorgement of all profits, benefits, and other compensation obtained by the defendants, including all ill-gotten gains from insider selling by defendants; (E) awarding to plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and (F) granting such other and further relief as the Court deems just and proper. After Defendants' counsel had multiple discussions with Plaintiff's counsel pointing out that it's complaint was deficient for the same reasons argued in Jackson, the Plaintiff agreed to voluntarily dismiss the complaint without prejudice, which the court so-ordered on January 24, 2020.

Bach v. Zaderej, et al., 27-cv-20-5997 (Hennepin Cnty., Minn.). On April 21, 2020, Plaintiff Michael Bach, derivatively on behalf of Axogen, filed a verified stockholder derivative complaint for breach of fiduciary duty, insider selling, corporate waste and unjust enrichment against Karen Zaderej, Gregory G. Freitag, Peter J. Mariani, Amy Wendell, Robert J. Rudelius, Mark Gold, Guido Neels, Jamie M. Grooms, Quentin S. Blackford, and Alan M. Levine (the "Individual Defendants") and Nominal Defendant Axogen, Inc. ("Axogen") (collectively, "Defendants"). The Bach Complaint has not yet been served on Defendants and therefore no response is necessary at this time.

These matters are subject to various uncertainties and it is possible that it may be resolved unfavorably to the Company. However, while it in not possible to predict with certainty the outcome of the matter, the Company and the Individual Defendants dispute the allegations and intend to vigorously defend themselves.

16. Quarterly Results of Operations (Unaudited)

The following is a summary of the quarterly results of operations for the years ended December 31, 2020 and 2019:

	Quarter				
	First	Second	Third	Fourth	Total
2020					
Revenue	$ 24,261	$ 22,116	$ 33,428	$ 32,495	$ 112,300
Gross profit	19,445	16,511	27,731	27,032	90,719
Net loss	(8,192)	(8,105)	(1,479)	(6,010)	(23,786)
Loss per common share - basic and diluted	(0.21)	(0.20)	(0.04)	(0.15)	(0.60)
2019					
Revenue	$ 23,285	$ 26,701	$ 28,564	$ 28,162	$ 106,712
Gross profit	19,571	22,457	24,054	23,281	89,363
Net loss	(9,504)	(7,022)	(5,571)	(7,038)	(29,135)
Loss per common share - basic and diluted	(0.24)	(0.18)	(0.14)	(0.18)	(0.74)

17. Subsequent Events

On February 22, 2021, the Company entered into the Seventh Amendment to the Licenses and Services Agreement with Community Tissue Services (the "CTS Agreement"). The amendment extends the term of the agreement until December 31, 2023.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are designed to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, and Board of Directors, as appropriate, to allow timely decisions regarding required disclosure. Our management, including our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2020. Based on this evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable assurance of achieving the desired objectives, and we necessarily are required to apply our judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures.

Changes in Internal Control Over Financial Reporting

In the ordinary course of business, we routinely enhance our information systems by either upgrading current systems or implementing new ones. There were no changes in our internal control over financial reporting that occurred during the three months ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. The Company's internal control system is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of inherent limitations, a system of internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate due to change in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, including our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of our internal control over financial reporting as of December 31, 2020. In making this assessment, the

Company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013). Based on their evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our internal controls over financial reporting were effective.

The Company's independent registered public accounting firm, Deloitte & Touche LLP, who audited the consolidated financial statements included in this Annual Report on Form 10-K, has issued an attestation report on the effectiveness of managements internal control over financial reporting as of December 31, 2020.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Information required by this item concerning our directors will be set forth under the caption "Election of Directors" in our definitive proxy statement for our 2021 annual meeting, and is incorporated herein by reference.

If applicable, information required by this item concerning compliance with Section 16(a) of the Exchange Act, as amended, will be set forth under the caption "Delinquent Section 16(a) Reports" in our definitive proxy statement for our 2021 annual meeting, and is incorporated herein by reference.

Information required by this item concerning the audit committee of the Company, the audit committee financial expert of the Company and any material changes to the way in which security holders may recommend nominees to the Company's Board of Directors will be set forth under the caption "Corporate Governance" in our definitive proxy statement for our 2021 annual meeting, and is incorporated herein by reference.

The Board of Directors adopted a Code of Ethics, which is posted on our website https://ir.axogeninc.com/governance-docs that is applicable to all employees and directors. We will provide copies of our Code of Business Conduct and Ethics without charge upon request. To obtain a copy, please visit our website or send your written request to Investors Relations, 13631 Progress Blvd., Suite 400, Alachua, FL 32615. With respect to any amendments or waivers of this Code of Business Conduct and Ethics (to the extent applicable to the our chief executive officer, principal accounting officer or controller, or persons performing similar functions) we intend to either post such amendments or waivers on its website or disclose such amendments or waivers pursuant to a Current Report on Form 8-K.

ITEM 11. EXECUTIVE COMPENSATION.

Information required by this item will be set forth under the caption "Executive Compensation" in our definitive proxy statement for our 2021 annual meeting, and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS

Information required by this item concerning ownership will be set forth under the caption "Security Ownership of Certain Beneficial Owners", "Security Ownership of Directors and Executive Officers" and "Equity Compensation Plan Information" in our definitive proxy statement for our 2021 annual meeting, and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Information required by this item concerning ownership will be set forth under the caption "Corporate Governance — Director Independence" and "Certain Relationships and Related Transactions" in our definitive proxy statement for our 2021 annual meeting, and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information required by this item concerning ownership will be set forth under the caption "Ratification of Appointment of Independent Registered Public Accounting Firm" in our definitive proxy statement for our 2021 annual meeting, and is incorporated herein by reference.

PART IV

Schedule II – Valuation and Qualifying Accounts

AXOGEN, INC.
SCHEDULE II – VALUATION AND QUALIFYING ACCOUNTS
THREE YEARS ENDED DECEMBER 31, 2020, 2019 AND 2018

	Balance at Beginning of Year	Additions	Deductions (Chargeoffs)	Balance at End of Year
Allowance for doubtful accounts				
2018	$ 461	$ 852	$ (196)	$ 1,117
2019	$ 1,117	$ 514	$ (539)	$ 1,092
2020	$ 1,092	$ —	$ (676)	$ 416
Valuation allowance for deferred tax assets				
2018	$ 28,357	$ 5,519	$ —	$ 33,876
2019	$ 33,876	$ 5,977	$ —	$ 39,853
2020	$ 39,932	$ 6,585	$ —	$ 46,517

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) **Financial Statements and Financial Statement Schedules**

The financial statements required by Item 15(a) are filed in Item 8 of this annual report on Form 10-K. Schedules not included have been omitted because they are not applicable or because the required information is included in the Consolidated Financial Statements and notes thereto.

(b) **Exhibits**

The following exhibits are included in this annual report on Form 10-K or incorporated by reference in the Form 10-K.

Exhibit Number	Description
3.1	Amended and Restated Articles of Incorporation of Axogen, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q, filed on November 6, 2019).
3.2	Axogen, Inc. Amended and Restated Bylaws. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed on May 2, 2019).
4.1	Description of Securities of Axogen, Inc. (incorporated by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed on February 24, 2020).
4.2	Registration Rights Agreement, dated as of August 26, 2015, between Axogen, Inc. and Essex Woodlands Fund IX, L.P. (incorporated by reference to Exhibit 4.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2016, filed on March 1, 2017)
*10.1	Patent License Agreement, dated as of August 3, 2005, by and between Axogen Corporation and the Board of Regents of the University of Texas System (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 6, 2011).
*10.2.1	Amended and Restated Standard Exclusive License Agreement with Sublicensing Terms, dated as of February 21, 2006, by and between Axogen Corporation and the University of Florida Research Foundation, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on October 6, 2011).
10.2.2	Second Amendment to the Amended and Restated Standard Exclusive License Agreement No. A5140, effective as of July 5, 2016, by and between Axogen Corporation and the University of Florida Research Foundation, Inc. (incorporated by reference to Exhibit 10.2.1 to the Company's Current Report on Form 8-K filed on July 11, 2016).
*10.3	Sid Martin Biotechnology Development Institute Incubator License Agreement, dated as of September 26, 2006, by and between Axogen, Inc. and the University of Florida Research Foundation, Inc. (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on October 6, 2011).
*10.4.1	Amended and Restated Nerve Tissue Processing Agreement, dated as of February 27, 2008, by and between Axogen Corporation and LifeNet Health (incorporated by reference to Exhibit 10.4.1 to the Company's Current Report on Form 8-K filed on October 6, 2011).
*10.4.2	Second Amendment to Amended and Restated Nerve Tissue Processing Agreement, dated as of August 9, 2011, by and between Axogen Corporation and LifeNet Health (incorporated by reference to Exhibit 10.4.2 to the Company's Current Report on Form 8-K filed on October 6, 2011).
*10.4.3	Third Amendment to Amended and Restated Nerve Tissue Processing Agreement, dated as of March 12, 2012, by and between Axogen Corporation and LifeNet Health (incorporated by reference to Exhibit 10.4.3 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011, filed on March 15, 2012).
*10.4.4	Fourth Amendment to Amended and Restated Nerve Tissue Processing Agreement, dated as of September 8, 2014, by and between Axogen Corporation and LifeNet Health (incorporated by reference to Exhibit 10.4.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, filed on November 13, 2014).

Exhibit Number	Description
*10.5.1	Distribution Agreement, dated as of August 27, 2008, by and between Axogen, Inc. and Cook Biotech Incorporated (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed on October 6, 2011).
10.5.2	Amendment No. 1 to Distribution Agreement, dated as of February 24, 2012, by and between Axogen, Inc. and Cook Biotech Incorporated (incorporated by reference to Exhibit 10.5.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011, filed on March 15, 2012).
10.5.3	Amendment No. 2 to Distribution Agreement, dated as of February 26, 2018, by and between Axogen, Inc. and Cook Biotech Incorporated (incorporated by reference to Exhibit 10.5.3 to the Company's Annual Report on Form 10-K for the year ended December 31, 2016, filed on March 1, 2017).
10.6.1	Lease dated as of February 6, 2007, by and between Axogen Corporation and WIGSHAW, LLC (incorporated by reference to Exhibit 10.10 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, filed on November 14, 2011).
10.6.2	Second Amendment to Lease, dated as of February 27, 2013 to lease dated as of February 6, 2007, by and between Axogen Corporation and SNH Medical Office Properties Trust (incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012, filed on March 12, 2013).
10.6.3	Third Amendment to Lease, dated November 12, 2013 to lease dated as of February 6, 2007, by and between Axogen Corporation and SNH Medical Office Properties Trust (incorporated by reference to Exhibit 10.10.3 to the Company's Annual Report on Form 10-K for the year ended December 31, 2013, filed on March 6, 2014).
10.6.4	Fourth Amendment to Lease, dated as of March 16, 2016, by and between Axogen Corporation and SNH Medical Office Properties Trust (incorporated by reference to Exhibit 10.10.4 to the Company's Current Report on Form 8-K filed on March 18, 2016).
10.6.5	Current Premises Election Notice, dated as of April 10, 2018, by and between Axogen Corporation and SNH Medical Office Properties Trust (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 13, 2018).
10.6.6	Fifth Amendment to Lease, dated as of November 30, 2020, by and between AxoGen Corporation and SNH Medical Office Properties Trust (incorporated by reference to Exhibit 10.9.5 to the Company's Current Report on Form 8-K, filed on December 4, 2020).
10.6.7	Letter Agreement effective September 20, 2018 by between Axogen Corporation and SNH Medical Office Properties Trust (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 21, 2018).
**10.7	Axogen, Inc. 2010 Stock Incentive Plan, as amended and restated as of March 23, 2016 (incorporated by reference to Appendix A to the Company's Proxy Statement filed on April 8, 2016).
**10.8.1	Form of Employee Incentive Stock Option Agreement (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K filed on September 26, 2007).
**10.8.2	Amended Form of Employee Incentive Stock Option Agreement pursuant to the Axogen, Inc. 2010 Stock Incentive Plan, as amended and restated as of March 23, 2016 (incorporated by reference to Exhibit 10.10.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2016, filed on March 1, 2017).

Exhibit Number	Description
**10.9.1	Executive Employment Agreement, effective as of October 1, 2011, by and between Axogen, Inc. and Gregory Freitag (incorporated by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011, filed on March 15, 2012).
**10.9.2	Amendment No. 1 to Executive Employment Agreement, dated as of May 11, 2014, by and between Axogen, Inc. and Greg Freitag (incorporated by reference to Exhibit 10.16.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, filed on August 4, 2014).
**10.9.3	Amendment No. 2 to Employment Agreement, dated as of August 6, 2015, by and between Gregory G. Freitag and Axogen, Inc. (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed on November 5, 2015).
**10.9.4	Amendment No. 3 to Employment Agreement, dated as of June 1, 2016, by and between Greg Freitag and Axogen, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 31, 2016).
**10.9.5	Amendment No. 4 to Employment Agreement, dated as of October 29, 2018, by and between Greg Freitag and Axogen, Inc. (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed on October 29, 2018).
**10.9.6	Amendment No. 5 to Employment Agreement, dated as of June 1, 2020, by and between Greg Freitag and Axogen, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on June 1, 2020).
10.10.1	Commercial Lease, dated April 21, 2015, by and between Axogen Corporation and Ja-Cole, L.P. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 22, 2015).
10.10.2	Addendum to Commercial Lease, dated April 21, 2015 by and between Axogen Corporation and Ja-Cole, L.P. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on April 22, 2015).
10.10.3	Commercial Lease Amendment 2, dated as of October 25, 2016, by and between Axogen Corporation and Ja-Cole L.P. (incorporated by reference to Exhibit 10.2.1 to the Company's Current Report on Form 8-K filed on October 31, 2016).
10.10.4	Commercial Lease Amendment 3, dated November 21, 2018 by and between Ja-Cole L.P. and Axogen Corporation (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 26, 2018).
10.10.5	Commercial Lease Amendment 4, dated March 12, 2019, by and between Ja-Cole L.P. and Axogen Corporation (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, filed on May 8, 2019).
10.11.1	License and Services Agreement, dated as of August 6, 2015, by and between Axogen Corporation and Community Blood Center (d/b/a Community Tissue Services) (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed on November 5, 2015).

Exhibit Number	Description
10.11.2	Fourth Amendment to License and Services Agreement, dated as of February 22, 2019, by and between Axogen Corporation and Community Blood Center (d/b/a Community Tissue Services). (incorporated by reference to Exhibit 10.13.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2018, filed on February 26, 2019)
10.13	Securities Purchase Agreement, dated as of August 26, 2015, between Axogen, Inc. and Essex Woodlands Fund IX, L.P. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed on November 5, 2015).
10.14	Development, License & Option Agreement, dated as of November 3, 2014, by and between Axogen Corporation and Sensory Management Services LLC (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed on November 5, 2015).
**10.15	Executive Employment Agreement, dated as of March 11, 2016, by and between Axogen Corporation and Kevin Leach (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 14, 2016).
10.16	Form of Non-Incentive Stock Option Agreement pursuant to the Axogen, Inc. 2010 Stock Incentive Plan, as amended and restated as of March 23, 2016 (incorporated by reference to Exhibit 10.22 to the Company's annual report on Form 10-K for the year ended December 31, 2016, filed on March 1, 2017).
*10.17	Form of Performance Stock Unit Award Agreement pursuant to the Axogen, Inc. 2010 Stock Incentive Plan, as amended and restated as of May 26, 2016 (incorporated by reference to Exhibit 10.23 to the Company's annual report on Form 10-K for the year ended December 31, 2016, filed on March 1, 2017).
**10.18	Retention Stock Unit Award Agreement, dated December 29, 2016, by and between Axogen, Inc. and Karen Zaderej, pursuant to Axogen, Inc. 2010 Stock Incentive Plan, as amended and restated as of March 23, 2016 (incorporated by reference to Exhibit 10.24 to the Company's annual report on Form 10-K for the year ended December 31, 2016, filed on March 1, 2017).
10.19	Lease, dated as of January 23, 2017, by and between Axogen Corporation and SNH Medical Office Properties Trust (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 26, 2017).
**10.20	Form of 2018 Performance Stock Unit Award Agreement pursuant to the Axogen, Inc. 2010 Stock Incentive Plan, as amended and restated as of March 23, 2016 (incorporated by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K for the year ended December 31, 2017, filed on March 1, 2018).
**10.21	Form of Restricted Stock Unit Award Agreement pursuant to the Axogen, Inc. 2010 Stock Incentive Plan, as amended and restated as of March 23, 2016 (incorporated by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K for the year ended December 31, 2016, filed on March 1, 2017).
10.22	Current Premises Election Notice, dated as of April 10, 2018, by and between Axogen Corporation and SNH Medical Office Properties Trust (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 13, 2018).
10.23	Agreement For Purchase and Sale of Real Property, dated as of June 8, 2018 by and between ARC CRVANOH001, LLC and Axogen Corporation, (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 12, 2018).

Exhibit Number	Description
10.24	Letter Agreement effective September 20, 2018 by between Axogen Corporation and SNH Medical Office Properties Trust (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 21, 2018).
10.25	Office Lease dated September 20, 2018 by and between Axogen, Inc., Axogen Corporation and Heights Union, LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on September 21, 2018).
**10.26	Form of Incentive Stock Option Agreement pursuant to the Axogen, Inc. 2010 Stock Incentive Plan, as amended and restated as of October 29, 2018 (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on October 29, 2018).
**10.27	Form of Restricted Stock Unit Award Agreement pursuant to the Axogen, Inc. 2010 Stock Incentive Plan, as amended and restated as of October 29, 2018 (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on October 29, 2018).
10.28	Axogen, Inc. 2017 Employee Stock Purchase Plan (incorporated by reference to Appendix B to theCompany's Proxy Statement filed on April 7, 2017).
10.29	Lease, dated November 19, 2018 by and between SNH Medical Office Properties Trust and Axogen Corporation (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 26, 2018).
10.30.1	Lease, dated November 19, 2018 by and between SNH Medical Office Properties Trust and Axogen Corporation (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on November 26, 2018).
10.30.2	First Amendment to Lease dated as of November 19, 2018 by and between SNH Medical Office Properties Trust and Axogen Corporation (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on November 26, 2018).
**10.31	Separation Agreement and General Release, dated January 15, 2019, between Axogen Corporation and Jon Gingrich (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 16, 2019).
**10.32	Separation Agreement and General Release, dated January 18, 2019, between Axogen Corporation and Shawn McCarrey (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 18, 2019).
**10.33	Form of Non-Qualified Stock Option Inducement Award Agreement to be granted by Axogen, Inc. to Eric Sandberg on January 22, 2019 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on January 22, 2019).
**10.34	Form of Performance Stock Unit Award Agreement pursuant to the Axogen, Inc. 2010 Stock Incentive Plan, as amended and restated as of April 5, 2017 (incorporated by reference to Exhibit 10.47 to the Company's Annual Report on Form 10-K for the year ended December 31, 2018, filed on February 26, 2019).
10.35	Standard Form of Agreement Between Owner and Design-Builder, dated as of July 9, 2019, by and between Axogen Corporation and CRB Builders, L.L.C. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on July 9, 2019).

Exhibit Number	Description
**10.36	Axogen Inc. 2019 Long-Term Incentive Plan and forms of award notices and agreements thereunder (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, filed on November 6, 2019).
***10.37	Nerve End Cap Supply Agreement, dated June 27, 2017, by and between Cook Biotech Incorporated and Axogen Corporation (incorporated by reference to Exhibit 10.51 to the Company's Annual Report on Form 10-K, filed on February 24, 2020).
10.38	Term Loan Agreement, dated June 30, 2020, among Axogen, Inc., Axogen Corporation, AxoGen Processing Corporation, TPC Investments II LP and Argo SA LLC. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on July 1, 2020).
10.39	Security Agreement, dated June 30, 2020, among Axogen, Inc., Axogen Corporation, AxoGen Processing Corporation, and Argo SA LLC. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on July 1, 2020).
10.4	Revenue Participation Agreement, dated June 30, 2020, between Axogen, Inc. and Argo SA LLC. (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed on July 1, 2020).
10.41	Option Agreement, dated June 30, 2020, between Axogen, Inc. and TPC Investments II LP. (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K, filed on July 1, 2020).
**10.42	Amended and Restated Employment Agreement, dated November 1, 2020, by and between Axogen Corporation and Karen Zaderej (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on October 29, 2020).
**10.43	Amended and Restated Employment Agreement, dated November 1, 2020, by and between Axogen Corporation and Peter Mariani (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on October 29, 2020).
**10.44	Amended and Restated Employment Agreement, dated November 1, 2020, by and between Axogen Corporation and Eric Sandberg (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed on October 29, 2020).
**10.45	Amended and Restated Employment Agreement, dated November 1, 2020, by and between Axogen Corporation and Maria Martinez (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K, filed on October 29, 2020).
**10.46	Amended and Restated Employment Agreement, dated November 1, 2020, by and between Axogen Corporation and Isabelle Billet (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K, filed on October 29, 2020).
**10.47	Amended and Restated Employment Agreement, dated November 1, 2020, by and between Axogen Corporation and Bradley Ottinger (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K, filed on October 29, 2020).
**10.48	Second Amended and Restated Employment Agreement, dated January 4, 2021, by and between Axogen Corporation and Angelo Scopelianos (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on January 6, 2021).

Exhibit Number	Description
**10.49	Commercial Lease, dated October 1, 2020, by and between Axogen Corporation and Ja-Cole, L.P (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, filed on October 30, 2020.
21.1	Subsidiaries of the Registrant.
23.1	Consent of Deloitte & Touche, LLP.
++24.1	Power of Attorney.
31.1	Certification of Principal Executive Officer.
31.2	Certification of Principal Financial Officer.
+++32.1	Chief Executive Officer and Chief Financial Officer Certifications pursuant to 18 U.S.C. 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.
101	Inline XBRL Document Set for the consolidated financial statements and accompanying notes in Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K.
+101.INS	XBRL Instance Document – The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
+101.SCH	Inline XBRL Taxonomy Extension Schema Document.
+101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
+101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
+101.LAB	Inline XBRL Extension Labels Linkbase.
+101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Inline XBRL for the cover page of this Annual Report on Form 10-K, included in the Exhibit 101 Inline XBRL Document Set.

*	Confidential treatment has been granted for portions of this Exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934 as amended. The confidential portions have been deleted and filed separately with the United States Securities and Exchange Commission.
**	Management contract or compensatory plan or arrangement.
***	Confidential treatment has been requested as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.
+	Filed herewith.
++	Included on signature page.
+++	Furnished herewith.

ITEM 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AXOGEN, INC

/s/ Karen Zaderej
Karen Zaderej
Chief Executive Officer
March 1, 2021

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Karen Zaderej (with full power to act alone), as his or her true and lawful attorney-in-fact and agent, with full powers of substitution and re-substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to the Annual Report on Form 10-K of Axogen, Inc., and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or their substitute or substitutes, lawfully do or cause to be done by virtue hereof.

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

/s/ Karen Zaderej Karen Zaderej, Chief Executive Officer, President and Chairman of the Board (Principal Executive Officer)	March 1, 2021
/s/ Peter Mariani Peter Mariani, Chief Financial Officer (Principal Financial Officer) (Principal Accounting Officer)	March 1, 2021
/s/ Gregory G. Freitag Gregory G. Freitag Director	March 1, 2021
/s/ Dr. Mark Gold Mark Gold, M.D. Director	March 1, 2021
/s/ Guido J. Neels Guido J. Neels Director	March 1, 2021
/s/ Paul G. Thomas Paul G. Thomas Director	March 1, 2021
/s/ Amy Wendell Amy Wendell Director	March 1, 2021
/s/ Quentin S. Blackford Quentin S. Blackford Director	March 1, 2021
/s/ Alan M. Levine Alan M. Levine Director	March 1, 2021

SUBSIDIARIES OF AXOGEN, INC.

As of December 31, 2020, Axogen Inc. had three sole subsidiaries:

1. Axogen Corporation, a Delaware corporation;
2. Axogen Europe GmbH, an Austrian corporation; and
3. Axogen Processing Corporation, a Delaware corporation.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-220770 and 333-224713 on Form S-3 and Registration Statement Nos. 333-173539, 333-177980, 333-201238, 333-211660, 333-218290, 333-230418, 333-233416, and 333-222019 on Form S-8 of our report dated February XX, 2021, relating to the financial statements and financial statement schedule of Axogen, Inc., and the effectiveness of Axogen, Inc.'s internal control over financial reporting appearing in this Annual Report on Form 10-K for the year ended December 31, 2020.

/s/ DELOITTE & TOUCHE LLP

Miami, Florida
March 1, 2021

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Karen Zaderej, certify that:

1. I have reviewed this annual report on Form 10-K of Axogen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have;

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) a)All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) b)Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 1, 2021

/s/ Karen Zaderej

Karen Zaderej
Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Peter Mariani, certify that:

1. I have reviewed this annual report on Form 10-K of Axogen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have;

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 1, 2021

/s/ Peter Mariani

Peter Mariani
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES -OXLEY ACT OF 2002

In connection with the Annual Report of Axogen, Inc. (the "Company") on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission (the "Report"), I, Karen Zaderej, Chief Executive Officer and Peter Mariani, Chief Financial Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Karen Zaderej

Karen Zaderej
Chief Executive Officer
March 1, 2021

/s/ Peter Mariani

Peter Mariani
Chief Financial Officer
March 1, 2021